Department
for Environment
Food & Rural Affairs

Report of an audit to evaluate the aquatic animal health controls for the production and export of live Salmonidae and their germinal products for aquaculture purposes from Norway to Great Britain

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Contents

Executive summary

This report sets out the findings and conclusions of the audit conducted by the Department for Environment, Food and Rural Affairs (Defra) in Norway between 24 and 28 March 2025. The audit assessed the official aquatic animal health controls relating to the production of live Salmonidae and their germinal products (ova and gametes) for aquaculture purposes.

Great Britain (England, Scotland and Wales) has historically imported Atlantic salmon ova from Norway since 2003. However, imports stopped in 2022 due to the loss of disease-free status for highly polymorphic region deleted infectious salmon anaemia virus (ISA HPR-deleted). In October 2024, the Norwegian Food Safety Authority (NFSA) submitted a request to permit the resumption of trade. An audit was undertaken to verify the delivery of official controls related to aquatic animal disease.

The audit, led by Defra's UK Office for Sanitary and Phytosanitary Trade Assurance, was carried out by 3 officials from Defra and Scottish Government's Marine Directorate. The audit team visited the central and regional competent authorities, 2 official laboratories, one salmonid aquaculture broodstock establishment, one hatchery and post smolt establishment, and one on-growing establishment.

The competent authority has effective systems to ensure compliance of aquaculture salmonid production establishments and businesses with Great Britain's legislative requirements and the requirements set out in the British model health certificates. However, aquatic animal health controls should be included in the internal audit programme of the Norwegian competent authority.

The process and standards to approve a compartment as disease-free for listed diseases are comparable to those of Great Britain, and follow the requirements of the European Animal Health Law, Regulation (EU) 2016/429 of the European Parliament and of the Council. The NFSA has adequate processes to ensure that the testing required by Great Britain has been implemented. Samples are tested using suitable laboratory methodologies.

The robustness of the compartment approval process should be strengthened by issuing a written protocol for NFSA staff. This will ensure that all aquaculture establishments applying for, and maintaining, disease-free compartment status, are assessed comprehensively and consistently against the legislative requirements. This will provide Great Britain with assurances that individual aquaculture establishments meet the relevant export certification requirements.

Surveillance is conducted in line with legislative requirements. However, the competent authority should conduct simulation exercises to ensure that there is a high level of disease awareness, and preparedness for a disease outbreak.

The report makes recommendations to the Norwegian competent authorities in relation to observations and findings made by the audit team during its visit to Norway. The recommendations concern: internal auditing, disease preparedness and the documented procedures for implementing official controls in compartments.

The report concludes that the official control and certification systems are robust, they are supported by an adequate legal framework and there are sufficient competent authority resources to implement the legislative requirements effectively. Addressing the recommendations made in this report will further strengthen certain areas of official aquatic animal disease controls.

1. Introduction

The Department for Environment, Food and Rural Affairs (Defra) undertook an audit mission to Norway between 24 and 28 March 2025. The audit, led by Defra's UK Office for Sanitary and Phytosanitary Trade Assurance, was carried out by 3 officials from Defra and the Scottish Government's Marine Directorate. The audit team was accompanied by 4 representatives of the Norwegian Food Safety Authority (NFSA, also known as Mattilsynet), the central competent authority of Norway, for the duration of the audit.

The audit team assessed the official controls for salmonid aquaculture. The official controls for the approval and supervision of establishments including surveillance, approval of disease-free compartments, and the diagnostic capability and capacity of official laboratories for aquatic animal diseases were assessed.

The opening meeting took place on 24 March 2025, with representatives of the central and regional competent authorities at the NFSA office in Bergen. Additional information was provided to the audit team at the opening meeting and throughout the audit to supplement the material provided by the NFSA in their response to the pre-audit questionnaire.

The closing meeting was held remotely on 2 April 2025, during which the audit team presented a high-level summary of main findings and recommendations. Representatives of the competent authority acknowledged the findings.

1.1 Background

Great Britain has imported Atlantic salmon ova from Norway since 2003 and rainbow trout ova from 2006 to 2017. In 2022, the import of salmon ova into Great Britain stopped due to the loss of disease-free status from ISA HPR-deleted.

In May 2019, the Norwegian competent authority implemented a voluntary suspension on issuing certificates for compartments declared free from ISA HPR-deleted following shortcomings identified by the European Free Trade Association (EFTA) Surveillance Authority during their audit of the official control system. Following a review of the compartment approval and maintenance process, the suspension was lifted from 3 compartments in March 2020, but exports to Great Britain were minimal. Since February 2022, there have been no imports from Norway, and at the time of the audit in March 2025, there were no compartments declared by the NFSA as free from ISA HPR-deleted in operation.

In October 2024, the NFSA requested the resumption of trade from an aquaculture establishment undergoing the process to be recognised as a compartment free from ISA HPR-deleted, in accordance with European Union (EU) legislation and under the supervision of the NFSA. A provisional declaration of freedom from ISA HPR-deleted for

the compartment was published on the NFSA website in May 2025 and will take effect 60 days after the publication date as per the relevant EU regulation if no objections are raised.

1.2 Objective, scope and legal basis

1.2.1 Objective

The audit objective was to evaluate the aquatic animal health controls for the production and export certification of live Salmonidae and their germinal products for aquaculture purposes to Great Britain. The assessment included a desktop element using information received from the Norwegian central competent authority and an in-country verification audit.

1.2.2 Scope

The scope of the audit included the evaluation of the structure, official control systems and processes of the competent authority of Norway governing the production, processing and export of live salmonids and their germinal products for aquaculture production. The audit focused on:

- competent authority systems, structure, and governance in place to ensure effective official controls for aquatic animal health and implementation of relevant legislation
- compliance with Great Britain's aquatic animal health regulations for live aquaculture salmonid production
- internal audits undertaken on the Norwegian competent authority, or the delegated bodies, responsible for delivery of official controls on aquatic animal health, including investigations and corrective actions taken following non-compliance
- official control systems in place covering production, dispatch, segregation (from processing and domestic production), and distribution chains, for salmonids to be exported to Great Britain for aquaculture purposes
- authorisation, approval, and monitoring of Salmonidae aquaculture establishments including those intending to export to Great Britain
- processes for approval, listing and monitoring of disease-free compartments and/or zones including biosecurity measures, movement controls and traceability
- disease freedom and disease outbreak notification processes
- national disease surveillance, disease investigation procedures, contingency plans, control, and eradication procedures
- vaccination programmes and protocols for susceptible species within disease free compartments and or zones for aquatic animal diseases attested for on Great Britain's model health certificates, including processes for segregation for domestic and international trading partners
- export health certification procedures
- import control procedures
- aquatic animal disease laboratory testing and facilities including capability, capacity, accreditation, designation, regulatory oversight and co-ordination with the competent authority.

1.2.3 Legal basis and legal references

This audit was conducted under the general provisions of the following regulations:

- Regulation[1] 2017/625 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection, and its Implementing Regulations
- Regulation 1251/2008/EC 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
- Regulation 2015/1554/EU laying down rules for the application of Directive 2006/88/EC regards requirement for surveillance and diagnostic methods
- Regulation 2009/177/EC as regards surveillance and eradication programmes and disease-free status of EU Member States, zones and compartments
- Statutory Instrument 2009 No 436 The Aquatic Animal Health (England and Wales) Regulations 2009
- Scottish Statutory Instrument 2009 No 85 The Aquatic Animal Health (Scotland) Regulations 2009.

A full list of Regulations relevant to the audit referred to in this report is included in Annex I.

1.2.4 Itinerary

Competent Authority

- opening meeting with NFSA central staff at the Regional Office, Bergen
- meeting with regional NFSA Regional Office staff, Ålesund

Laboratories

- National Reference Laboratory (NRL) – Norwegian Veterinary Institute (Veterinærinstituttet), Bergen
- one private designated laboratory

Aquaculture business operators

- Salmonid aquaculture brood stock establishment: one establishment in Møre og Romsdal
- Salmonid aquaculture hatchery and post smolt establishment: one establishment in Møre og Romsdal
- Salmonid aquaculture on-growing establishment: one establishment in Møre og Romsdal.

[1] *References to European Union legislations are references to those as assimilated in UK law*

2. Audit findings

2.1 Norwegian competent authority

2.1.1 Organisation and structure

The NFSA is responsible for the implementation of controls relating to animal health and welfare, food safety, and is the first responder for aquatic animal disease outbreaks. The Norwegian Veterinary Institute (NVI) serves as the NRL.

The NFSA is governed by 3 ministries; the Ministry of Agriculture and Food, the Ministry of Trade, Industry and Fisheries, and the Ministry of Health and Welfare. The administrative responsibility for NFSA lies with the Ministry of Agriculture and Food.

At the time of the audit, the NFSA was undergoing a restructuring process, expected to be completed by May 2025. Within the new structure, there are 4 supervisory divisions which include an Aquaculture Division. This Division is responsible for the implementation of aquatic animal health controls and is split into 4 departments; North, South, Technical Assistance, and Audit, Method and Analysis. Each department comprises multiple teams, which together service the entire territory of Norway.

During the audit, the UK team saw evidence of the NFSA implementation of aquatic animal health processes and procedures. Randomly selected case records and operational procedures were examined. Aquaculture Division staff provided evidence that demonstrated how controls are efficiently implemented in relation to aquatic animal health. More information on the departments and teams within the Aquaculture Division is provided in Figure 1.

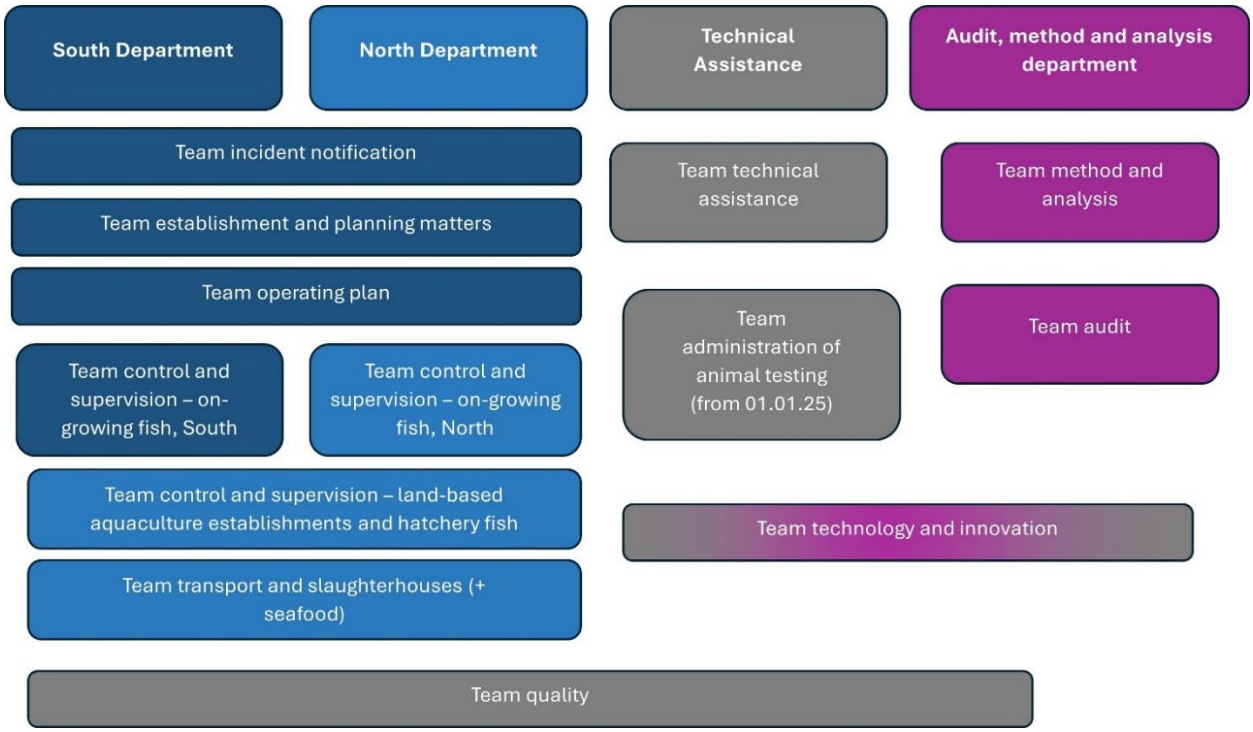

Figure 1. Departments and teams within the Aquaculture Division (source: NFSA)

2.1.2 Capacity and capability

The NFSA employs approximately 75 staff, including veterinarians and fish health biologists, in the Aquaculture Division. There are 23 staff located at central level that support the Aquaculture Division by providing guidance and developing regulation. Official controls for aquatic animal health are delivered through the inspection teams in the North and South departments, who operate across 70 NFSA offices situated along the coast.

All staff can access the latest NFSA guidance, training material and instructions through a bespoke online learning platform (Læringsportalen). Newly recruited members undergo a 12-month formal training programme, with 3 assessments during this period. In addition to electronic learning material, all new members of staff build their experience by undertaking aquaculture establishment visits with experienced colleagues. During the audit, the NFSA provided satisfactory evidence of the training programme and its delivery.

NFSA are supported in their work through multiple online databases and portals that include systems for case management, export health certificate management and stakeholder communication (see Annex II for a summary of Norwegian databases and portals).

2.1.3 Internal audits

NFSA internal audits are carried out by a dedicated team situated at central level. The team reports directly to the Chief Executive Officer of the NFSA, and the reports are published on the NFSA website. Non-compliances identified during the audit are followed up by the NFSA regional team who is responsible for identifying the root cause, and ensuring adequate corrective action is taken.

The UK team noted that no internal audit covering the aquatic animal health area has been conducted in the last 10 years. The NFSA also confirmed there are no plans for audits in this work area in the foreseeable future. Internal audits are essential to providing assurance that legal requirements are complied with at all levels of the competent authority, as per the requirements of the Official Controls Regulation 2017/625.

Recommendation 1: The NFSA to ensure internal audits are conducted focusing on the implementation of aquatic animal health controls in accordance with Article 6 of the Official Controls Regulation 2017/625.

2.2 Official controls of aquaculture establishments

2.2.1 Salmonidae aquaculture industry overview

Norway is the largest producer of farmed Atlantic salmon globally and in 2024 over 1,545,000 tonnes of Atlantic salmon were harvested. Rainbow trout is another major farmed species with over 95,000 tonnes harvested in 2024.

In 2024, there were 132 salmon hatchery establishments and 827 salmon seawater establishments in operation. There were 18 rainbow trout hatchery establishments, 81

rainbow trout seawater establishments, and a further 64 other salmonid species production establishments (mix of freshwater and seawater).

In addition to inspections and surveillance conducted by the NFSA, the Salmonidae aquaculture production industry contracts the services of fish health personnel for regular health checks. Fish health personnel are veterinarians or fish health biologists employed either directly by the aquaculture business operator or through private fish health services.

2.2.2 Approval and monitoring of aquaculture establishments

All aquaculture establishments in Norway are approved by the NFSA under EU legislation, Regulation (EU) 2016/429 of the European Parliament and of the Council known as the Animal Health Law (AHL), and Commission Delegated Regulation (EU) 2020/689.

All businesses must hold an aquaculture licence to operate an aquaculture establishment. The licence details the location, permitted species and production stages, maximum biomass limit or capacity, and purpose of the licence. Information about the licence is held in the Aquaculture Register.

Details of aquaculture establishments are made publicly available on the online platform called BarentsWatch. BarentsWatch provides various services and information for maritime activities, including aquaculture in Norway. The website includes a map of aquaculture establishments and summary data such as species held on the establishment, sea lice numbers and treatments, whether an establishment is in a listed disease surveillance or protection zone, and results from listed disease testing carried out by the NVI.

Aquaculture business operators must maintain records, in line with Article 186 of the AHL, including stock numbers, movements, mortality and results of health testing. There are further record keeping requirements detailed in national legislation, the Regulations on the Operation of Aquaculture Facilities (Aquaculture Operations Regulations) (FOR-2008-06-17-822). These include equipment checks and reports from environmental surveys and water quality assessment. The business operator must maintain a contingency plan to deal with fish health and welfare in emergency situations. Norwegian legislation also requires aquaculture establishment staff to undertake training in fish welfare.

The NFSA carries out regular inspections and, as part of the enforcement process, issue a written notice for any non-compliances identified during the official inspection. No aquaculture establishments have had their approval suspended or withdrawn at the time of the audit. A process is in place to be followed when major non-compliances are detected, where the NFSA carries out an assessment to determine the appropriate action to take.

Penalties may be applied for certain types of non-compliances such as inability to control sea lice numbers, or non-reporting of increased unexplained mortality. Business operators may be subject to financial penalties, prohibitions, or have the maximum biomass limit of the aquaculture establishment reduced.

2.2.3 Approval of compartments

As part of the compartment approval process, business operators must submit a formal application to the NFSA. The NFSA official inspectors assess whether the aquaculture establishment can meet the legislative biosecurity requirements before starting a 2-year surveillance and sampling period. Vaccination for the relevant diseases is prohibited in disease-free compartments, and only movements of animals from a source of equal or higher health status are permitted. Compartments must be supplied with either, water through a water treatment plant that inactivates the relevant disease agent, or directly from a well, borehole or spring.

The audit team examined the approval procedure for an aquaculture establishment holding Atlantic salmon which is undergoing the process to be recognised as an ISA HPR-deleted disease-free compartment. Non-compliances observed during the NFSA inspections were appropriately followed up with the business operator and satisfactorily resolved. The non-compliances identified did not impact biosecurity.

A 2-year inspection and testing regime for ISA HPR-deleted was implemented in April 2023, following the requirements of Section 2, Chapter 2, Part II, Annex VI of Commission Delegated Regulation (EU) 2020/689. The NFSA conducted 6 inspections per year and 75 fish were sampled twice per year. ISA HPR-deleted was not detected in the samples examined. The operator of the compartment conducted additional surveillance for ISA HPR-deleted. All broodfish were examined and sampled at stripping. The samples were processed by a designated private laboratory (see section 2.5.2 for details), and all results were negative.

Following completion of the official 2-year inspection and testing regime, the NFSA has assessed the aquaculture establishment as meeting the requirements for compartments which are independent of the health status of surrounding natural waters as laid out in Article 79 of Commission Delegated Regulation (EU) 2020/689. A provisional declaration of freedom from ISA HPR-deleted for this compartment was published on the NFSA website in May 2025. Additional sampling for ISA HPR-deleted has been conducted to ensure the aquaculture establishment meets Great Britain's model health certificate requirements.

The approval process implemented for the compartment visited was satisfactory and followed the requirements of Commission Delegated Regulation (EU) 2020/689. However, written standard operational procedures (SOPs) for official controls for compartmentalisation did not include instructions for the initial approval and maintenance of disease-free status. The procedures referred only to approval withdrawal and were based on outdated legislation, Council Directive (EC) 2006/88.

Compartment approval, monitoring and withdrawal procedures should be based on AHL requirements and included in the written SOPs. This will support officials in ensuring official controls related to compartments are clear and implemented consistently.

Recommendation 2: The NFSA to ensure the standard operating procedures for official controls at compartment level are based on the AHL requirements and include instructions on approval, monitoring and withdrawal of approval.

2.2.4 Official inspections

Risk-based inspection programme

The NFSA inspections are carried out at a risk-based frequency based on 2 criteria: the possibility of direct spread of pathogens via water, and the movement of aquaculture animals as per Chapter 2, Part I of Annex VI of Commission Delegated Regulation (EU) 2020/689. The NFSA noted they may use mortality levels during the previous production period as an additional criterion.

Official inspectors complete a digital form (Riskovurdering) for each aquaculture establishment to determine the risk categorisation. Broodstock facilities are always categorised as high risk. The inspection frequency is determined by the risk category:

- high risk are inspected once per year
- medium risk are inspected once every 2 years
- low risk are inspected once every 3 years

An increased inspection frequency is applied to compartments approved as free from ISA HPR-deleted:

- high risk are inspected twice per year
- medium risk are inspected once per year
- low risk are inspected once every 2 years

The profiles of the aquaculture establishments are stored in an online database known as SILD which provides official inspectors quick access to a range of information including:

- risk-based surveillance category
- business operator
- location
- species
- production type
- mortality data

This data is used by the NFSA in prioritising inspections at aquaculture establishments where there may be issues such as increased mortality.

Official inspectors use a dedicated case management system, MATS, to record inspections and details of any samples taken during the inspection. Each case is allocated a unique number. MATS holds inspection templates and is linked to the latest regulations, business register, and register of aquaculture.

Official inspectors follow the inspection checklist (Kravpunkliste) specific to the aquaculture establishment type which provides the mandatory inspection and testing requirements along with best practice recommendations.

Aquaculture establishment business operators are legally required to supply documentation and records such as:

- mortality data
- copies of reports of fish health inspections and sampling conducted by fish health personnel
- water testing reports

The information above is usually supplied in advance of the inspection and the official inspector examines all facilities on the aquaculture establishment. In addition, the official inspector can remove abnormally behaving or moribund fish for examination and autopsy. Dead fish are also collected and examined, with diagnostic samples taken where appropriate in accordance with the requirements laid out in Commission Delegated Regulation (EU) 2020/689. Samples are sent to the NVI for testing. At the end of the inspection, the establishment personnel receive a verbal summary of the inspection findings.

Details of the inspection, including sample information and photographic evidence, are recorded onto the MATS system by the official inspector, using a dedicated form (Tilsynskvittering). The resulting inspection report is recorded onto MATS and submitted to the Quality Team of the Aquaculture Division for review. This is followed by approval by the team leader before it is issued to the business operator.

Any non-compliances identified during the inspection are detailed in the report, along with a completion date for corrective action. The business operator must submit evidence to demonstrate that corrective action has been taken, and the case remains open until the NFSA are satisfied that the non-compliance has been resolved. Where written guidance has been provided by the NFSA, they confirm that this has been implemented during the next routine inspection.

Once the inspection has been completed and all outstanding actions resolved, the case is closed, and the case history is stored in MATS. All associated correspondence is saved in Elements, a separate archive system linked to MATS.

Other inspections

In addition to the risk-based inspection programme, the NFSA conducts further visits to aquaculture establishments. These are grouped into 3 categories:

- unannounced inspections which focus on individual aquaculture establishments, selected randomly or based on intelligence
- inspection campaigns (known as “sprints”) which target a geographical area and focus on specific areas of concern, such as sea lice
- business audits which focus on large industrial aquaculture producers with multiple establishments and aim to verify systemic compliance with legal criteria across multiple establishments under the same management.

2.3 Disease preparedness and surveillance

2.3.1 Current disease status

The NFSA lists salmonid diseases into multiple categories as per the relevant requirements in the AHL and national legislation. The categories include all relevant notifiable diseases in Great Britain.

Epizootic haematopoietic necrosis (EHN)

EHN has never been detected in Norway, and it is free from the disease. Vaccination for EHN is prohibited.

Infectious haematopoietic necrosis (IHN)

The whole territory of Norway, apart from a buffer zone in the north, has disease-free status for IHN, in accordance with EFTA Surveillance Authority Decision No 032/21/COL. Vaccination is prohibited in disease-free areas and in areas or compartments undergoing surveillance to achieve disease-free status.

Viral haemorrhagic septicaemia (VHS)

The whole territory of Norway, apart from a buffer zone in the north, has disease-free status for VHS in accordance with EFTA Surveillance Authority Decision No 032/21/COL. Vaccination is prohibited in disease-free areas and in areas or compartments undergoing surveillance to achieve disease-free status.

ISA HPR-deleted

ISA HPR-deleted is the pathogenic form of ISA. ISA HPR-deleted is endemic in natural seawater in Norway and there are no disease-free areas. Vaccination is permitted in areas that are not disease-free, and business operators may choose to vaccinate fish prior to transfer to sea. Vaccination is prohibited in disease free compartments.

***Gyrodactylus salaris* (Gs)**

The whole territory of Norway is free from Gs except for water catchment areas undergoing eradication (EFTA Surveillance Authority Delegated Decision No 203/21/COL). Gs is present in 6 rivers in the Drammen infection region. Treatment of 5 rivers in the Driva infection region was completed in 2024 and the NFSA is awaiting confirmation of eradication. Vaccination is prohibited.

2.3.2 Disease preparedness

NFSA provided evidence of having contingency plans in place for:

- EHN, IHN, VHS and ISA HPR-deleted in ISA HPR-deleted free compartments
- ISA HPR-deleted (except in disease free compartments)
- Gs
- emerging diseases

The audit team reviewed the ISA HPR-deleted contingency plan, noting that the plan met the requirements laid out in the AHL, and is comparable to the Great Britain contingency plan.

The audit team observed that no national simulation exercises for listed salmonid diseases have been conducted by the NFSA. In accordance with Article 45 of Regulation (EU) 2016/429, the exercises should test the contingency plans for the relevant diseases to ensure there is a high level of disease awareness, preparedness and ability to launch a rapid response.

Recommendation 3: The NFSA to ensure simulation exercises for listed salmonid diseases are carried out in accordance with the requirements of Article 45 of the Regulation (EU) 2016/429.

2.3.3 Surveillance and sampling

Official surveillance for listed diseases is carried out at aquaculture establishments by NFSA staff during routine inspections. If there is an increase in mortality, or signs of disease are observed during the inspection, a diagnostic investigation must be initiated and sampling carried out. Targeted surveillance, where specific samples are tested to demonstrate maintenance of disease freedom, is only required for specific listed diseases.

Sampling procedures conducted by official inspectors are in accordance with Commission Delegated Regulation (EU) 2020/689, or with the relevant World Organisation for Animal Health (WOAH) standards, as appropriate for the pathogen.

Passive surveillance measures supplement the official control inspections. Detection or suspicion of any listed disease must be reported by either the operator or any relevant person to the NFSA. The NFSA will conduct an immediate investigation and take diagnostic samples as appropriate.

In the event of abnormal mortality, other signs of disease, or significantly reduced production rate of unknown cause, but no immediate suspicion of the presence of a listed disease, operators must ensure that fish health personnel assess the health situation and carry out relevant examinations and sampling to determine the cause. If the circumstances persist and the causal factors are not identified, a second assessment must be carried out within 14 days of the initial assessment. Operators must notify the NFSA as soon as practical if the causal factors are still unidentified after the second assessment has been carried out, so that the NFSA can investigate. If the presence of a listed disease is suspected at any time during the 14-day period, the NFSA must be notified immediately.

In addition to the official control inspections, the statutory requirements mandate that a specified number of health checks per year, dependent on the type of aquaculture establishment and population size, are conducted by fish health personnel. This provides an additional level of surveillance.

EHN

Passive surveillance measures, in conjunction with the risk-based inspections conducted by the NFSA for listed diseases, monitor for EHN. If the presence of EHN is suspected, individual testing is performed using polymerase chain reaction (PCR), histopathology and cell culture.

IHN and VHS

Routine risk-based inspections are conducted by the NFSA as per the requirements of Commission Delegated Regulation (EU) 2020/689 to monitor for IHN and VHS. If either disease is suspected during the inspection, testing of individual fish is performed using PCR, histopathology and cell culture. In the event of a positive result, further verification would be conducted by the EU reference laboratory (EURL) at DTU Aqua in Denmark.

Further to the AHL requirements described above, the NFSA carries out a national targeted surveillance programme for IHN and VHS, with up to 650 samples tested using PCR per year. This includes samples taken at freshwater aquaculture establishments holding trout, and from wild caught pink salmon. Additional diagnostic samples from Atlantic salmon, rainbow trout, and cleaner fish submitted to the NVI by fish health personnel provide further assurance of IHN and VHS disease-free status.

ISA HPR-deleted

Samples from individual fish are collected by the NFSA when the presence of ISA HPR-deleted is suspected, either due to observations of clinical signs during the inspection or notification of suspicion from the business operator or fish health personnel.

Ten fish are sampled if clinical signs are present and 30 fish if clinical signs are absent at the time of the inspection. Confirmation of ISA HPR-deleted requires 2 distinct detection methods to both return positive results: Reverse Transcription quantitative Polymerase Chain Reaction (RT-qPCR) plus either histopathology/immunohistochemistry or virus isolation. Additionally, all positive results are genome sequenced.

Following confirmation of the presence of ISA HPR-deleted, monthly screening for ISA HPR-deleted is carried out at aquaculture establishments within protection zones by the NFSA, and in surveillance zones by fish health personnel. A minimum of 10 fish are sampled individually and tested using RT-qPCR. Samples taken by official inspectors are always sent to the NVI. Those taken by fish health personnel are sent either to the NVI or to a designated private laboratory.

The NFSA recently concluded a multi-year surveillance programme to map the presence of non-pathogenic ISA HPR0 in hatcheries. The findings are being used to inform the development of a new ISA surveillance plan. The NFSA intends to implement a new surveillance and control plan, alongside the AHL requirements for ISA HPR-deleted, by early 2026, with the aim of reducing the incidence of ISA HPR-deleted in the country.

Gs

Targeted surveillance is carried out to demonstrate absence of Gs in aquaculture and wild populations, and to detect and track any spread of the parasite. Official inspectors take fin

samples to test for Gs every second year in aquaculture hatcheries holding salmon or rainbow trout. Annual sampling of aquaculture establishments holding susceptible species must be completed by the business operator as required by domestic legislation. Samples taken by the official inspectors and fish health personnel are sent to the NVI for testing.

Surveillance sampling for Gs is carried out in rivers. Whole juvenile fish are removed for examination from approximately 70 rivers annually, along with water samples for environmental DNA (eDNA). These samples are collected by the NVI or specialist contractors and sent to the NVI for examination.

Preliminary diagnosis of Gs is by morphology, with confirmation by PCR and DNA sequencing as per the WOAH diagnostic manual.

The risk-based inspections conducted by the NFSA, along with inspections carried out by fish health personnel, provide sufficient assurance that effective systems are in place to maintain freedom and detect listed diseases.

2.4 Listed disease response

2.4.1 Notification of disease suspicion

The requirements of the AHL for disease control and eradication are implemented in Norway through domestic legislation. There is a duty on business operators or any relevant person to notify the NFSA immediately if there is suspicion of the presence of a listed aquatic animal disease.

Operators can notify the NFSA of disease suspicion through the Altinn platform, by email or by phone. The Altinn platform is a dedicated internet portal for businesses and individuals to contact or submit data to government agencies such as the NFSA. Details of the case are immediately disseminated to the appropriate regional team to investigate and implement the required actions. The NFSA updates its official website page detailing the disease-free status in Norway within 24 hours. Outbreaks of certain diseases, including those that are listed, are also published on BarentsWatch.

2.4.2 Investigation and control procedures

Following notification of the suspicion of the presence of a listed aquatic animal disease, the NFSA carry out an investigation during which it takes confirmatory samples. It examines epidemiological links to the aquaculture establishment of origin of the affected population, unless there is clear evidence that it is a geographically local outbreak.

The NFSA uses the MATCIM platform to ensure that all necessary steps are completed when a listed disease is suspected or confirmed on an aquaculture establishment. The platform provides a checklist of actions that must be completed, such as notifying the Chief Veterinary Officer, establishing surveillance and protection zones, and follow-up inspections. Accountability in implementation of actions is ensured by recording within MATCIM who has completed each action and when.

The NFSA implements restrictions and relevant disease control measures upon suspicion of the presence of a listed disease. The size of the protection zone must be at least 5km

radius or one tidal excursion, whichever is larger. The NFSA provide data to determine the appropriate size. Details of the protection and surveillance zones, along with all associated restrictions, are published on Lovdata (the website where legislation and regulation in Norway is published) and on BarentsWatch.

Business operators must obtain official permission before undertaking certain activities such as slaughter and transport of fish, removal of equipment, and movement of boats out of the zones. Applications must be made by the business operator for these activities, and following an assessment, the NFSA grants permission with appropriate biosecurity conditions to prevent the further spread of infection.

Once the affected establishments in the protection and surveillance zones are empty, the NFSA ensures that the required cleaning and disinfection of equipment is carried out, along with completion of minimum fallow periods to meet the requirements of the AHL.

Documents and correspondence, such as notification to the business operator of the results of the confirmatory sampling, or applications and permissions to move equipment, are recorded in MATS.

2.4.3 Eradication programmes

As of March 2025, with the exception of Gs, there are no active eradication programmes in Norway for listed diseases. The NFSA confirmed that if EHN, IHN or VHS were detected in Norway, appropriate eradication measures would be implemented.

The NFSA has an eradication policy in place for Gs at infected aquaculture establishments and river systems. This means that an active eradication programme is in place in specified water catchment areas where Gs has been detected. If Gs is found on an aquaculture establishment, eradication is carried out by culling all host species. In river systems, eradication is achieved by chemical treatment using substances such as rotenone, aluminium sulphate or chlorine.

2.4.4 International notifications

International notification of listed disease occurrences is made via the Animal Disease Information System (ADIS), which links to the World Animal Health Information system (WAHIS). Primary outbreaks are reported within 24 hours, and secondary outbreaks are reported weekly. Direct notification to trading partners only occurs if an agreed obligation exists. Checks are made to recall any consignments in transit if the certification requirements cannot be met, and the relevant export health certificates will be suspended.

2.5 Laboratory services

2.5.1 National reference laboratory

The Norwegian Veterinary Institute (NVI) is designated by the NFSA, fulfilling the function of National Reference Laboratory (NRL) for fish diseases. The NVI carries out all analyses on routine samples taken through official surveillance programmes for fish diseases, as well as samples taken in connection with suspicion and confirmation of listed diseases.

The NVI is composed of 6 regional offices, with the head office in Ås. The NVI is divided into 5 departments, including the Department for Aquatic Animal Health and Welfare. The main diagnostic laboratory for fish is based in Harstad. The Trondheim and Bergen units also deal with wild salmon and wild fish respectively.

The NVI is the WOAH reference laboratory for salmonid alphavirus (SAV) and Gs, and one of 2 WOAH reference laboratories for ISA. In addition, it leads the WOAH Collaborating Centre for Epidemiology and Risk Assessment of Aquatic Animal Diseases in Europe.

The NVI has been ISO/IEC 17025:2017 accredited since 1998 by Norsk Akkreditering, the Norwegian national accreditation body for technical accreditation. The accreditation renewal occurs every 5 years, with the scope of the visit covering several areas including diagnostic tests and their methods. Annual assessments are conducted to ensure continued compliance.

As the NRL for fish and shellfish diseases, the NVI participates in annual interlaboratory proficiency tests (ILPT) provided by the EURL for relevant fish diseases. The most recent proficiency test round was conducted between September to December 2024 and included listed and other relevant fish diseases. Evidence provided to the audit team demonstrated that the NRL achieved an excellent performance score. The laboratory participates in other proficiency tests run by independent accreditation bodies.

The NRL organises regular training sessions for official inspectors covering sampling procedures. Inspectors receive feedback on sample quality and condition, and if sample results are deemed invalid, the NFSA is notified, and resampling is carried out.

2.5.2 Designated private laboratories

In addition to the NRL, there are 4 private laboratories that have been designated by the NFSA, in consultation with the NVI, for specified fish pathogen testing including ISA HPR-deleted and SAV. As part of the designation process, the NFSA carries out an assessment of the testing methods, performance and qualifications of staff in accordance with the Official Controls Regulation 2017/625 and the AHL.

These private laboratories are accredited to ISO/IEC 17025:2017 standards by Norsk Akkreditering. They take part in an annual proficiency test round led by the NRL, with mandatory participation for specific pathogens. The test panel includes ISA HPR0, ISA HPR-deleted, IHN and VHS genotype III.

The audit team reviewed the proficiency test results for 2023 to 2024 and found that all private laboratories are performing to expected standards. All private laboratories identified the agents they are designated for, with genotyping producing expected results.

The latest results from the 2024 to 2025 proficiency test panel were provided and showed a missed detection by one of the private laboratories. An investigation was conducted by the NRL to determine the cause of the missed detection. The follow-up process included reporting the non-compliance to the private laboratory, as well as notifying the NFSA. An investigation into the cause of the non-compliance was carried out by the laboratory and the NRL agreed an action plan. Retests were conducted to confirm if satisfactory results are obtained, following the investigation and subsequent sensitivity checks. This example demonstrated the NRL applies a systematic and efficient follow-up process when non-compliances occur.

The audit team visited a private designated laboratory which demonstrated the relevant processes relating to notification of disease suspicion and sample management were implemented adequately. At the time of the audit, the private laboratories did not take part in any official testing, however they provide an additional level of surveillance.

2.5.3 Sample submission, processing and notification

Samples taken on suspicion of disease, or as part of the surveillance programmes, are sent by the NFSA official inspectors or the fish health personnel by post to the NRL for diagnostic testing. If required, samples are sent in an insulated box with an ice pack to ensure ideal temperature is maintained.

Sample traceability is ensured through use of the EPI sample submission portal of the NVI and the NFSA. This system allocates a unique number to the samples when they are submitted either by the official inspector or fish health personnel. Samples received at the closest branch of the NRL are distributed to the relevant NRL site working with the specific diagnostic methods required. Packing lists are produced for the receiving laboratory to guarantee receipt of all relevant samples.

Once samples arrive at the relevant laboratory, they are allocated another unique ID number by the NRL bespoke Laboratory Management Information System, PGS. This number is linked to an assigned field case number created in MATS. Histology and bacteriology samples are processed at the laboratory in Bergen, with any molecular samples sent to and processed at the laboratory in Ås. Complete traceability of samples is ensured through the association with single cases and the corresponding aquaculture establishment identification number.

Samples taken for routine surveillance, and for suspicion of listed diseases are tested using RT-qPCR. Following confirmatory testing, the NFSA is notified through email to the headquarters and the aquaculture division, which includes a copy of the confirmed results. Private laboratories notify the NFSA of positive ISA HPR-deleted results through the Altinn system on the same day the results are obtained.

During the visit to the NRL site in Bergen, the audit team observed a robust end-to-end sample management process.

2.6 Export health certification and traceability

2.6.1 Export health certification management

The NFSA is responsible for issuing export health certificates (EHCs). NFSA certifying officers sign and issue all EHCs for live fish and germinal products intended for export to trading partners. A dedicated export team within the International Cooperation department in NFSA is responsible for the EHC issuing system. Exports to countries outside of the European Economic Area (EEA) are regulated by Norwegian national legislation.

Clinical health inspections are conducted at exporting aquaculture establishments where required by the importing country's EHC and occur within timescales stated by the certificate.

Model health certificates and detailed guidelines for exporters are available on the NFSA website. The guidelines include information on certificate preparation, model health certificates and relevant health requirements. All issued certificates, either electronic or scanned paper copies, are archived in the dedicated archive system, Elements.

EHC authenticity and traceability are ensured by the unique reference numbers allocated during the export certification process. Systems are in place for the business operators to provide supporting information to the NFSA if required.

2.6.2 Export health certification process for exports to Great Britain

For exports of live aquatic animals to Great Britain, the exporter submits a request to the NFSA central export team, who provides them with a template EHC. The exporter is required to complete the consignment details on the certificate and present this to the NFSA.

Upon receipt of the partially completed EHC, MATS, the case management system, is used to generate a unique EHC number. NFSA then complete the relevant health attestations. As required, the exporter agrees a date of inspection with the NFSA certifying officer. Following an inspection, if no clinical signs of disease are observed and all certification requirements are met, a paper version of the EHC is signed and issued.

2.6.3 EHC quality control

Guidance for certifying officers has recently been updated and, following the NFSA restructure, the central export team is responsible for producing and ensuring quality control of EHCs. This central oversight ensures a standard approach that facilitates the control of quality and consistency within the EHC process.

If non-compliances are detected in EHCs, these are usually rectified by issuing a replacement EHC. Depending on the type of non-compliance, corrective action may be taken. New unique reference numbers are generated if an EHC is replaced whilst the previous EHC is cancelled. Producing and replacing EHC reference numbers is conducted in MATS. This allows for clear identification and traceability of the replacement certificates.

The audit team assessed the system in place for issuing replacement certificates as sufficiently robust to provide the necessary assurance.

2.7 Import control system

Imports of ova to Norway are carried out in accordance with AHL requirements. At the time of the audit, there have been no imports of live salmonids, ova or milt from any third country into Norway. Imports of salmonids originating from the EEA are allowed if the relevant regulations are followed. Salmonid ova are therefore only imported from one disease-free compartment that is authorised by the Icelandic Authorities and meets the requirements of the AHL.

3. Conclusions

The audit team found that the official control, surveillance and certification systems related to aquatic animal health in Norway are supported by an appropriate regulatory framework and are robustly implemented by the NFSA. The NFSA has adequate powers and resources for the implementation of official controls supported by suitable computerised systems, and laboratory facilities. However, aquatic animal health should be included in the internal auditing programme.

The audit team found the implementation of official controls to be satisfactory for the aquatic compartment visited. Systems are in place to ensure maintenance of disease freedom within a compartment with official inspections and as required, additional sampling by NFSA. However, the written operational procedures for official controls at compartment level were found to be incomplete. A comprehensive set of standard operating procedures covering initial approval and ongoing maintenance should be developed and maintained. This will support assessment of future compartment approval requests and ensure consistent implementation of official controls.

The national diagnostic services demonstrated sufficient capacity and capability, due to the robust diagnostic systems provided by both the NRL and the designated laboratories. Disease response procedures are well documented, with satisfactory systems of communication in place for notifying stakeholders and trading partners. Furthermore, the addition of simulation exercises would further strengthen the robustness of the disease response procedures.

The communication procedures implemented by the NFSA provide assurance for export health certification and meets Great Britain's requirements. The centralisation of the certification process, following the NFSA restructure, aims to ensure that quality control is standardised, and support the efficient management of non-compliances.

The official controls for aquatic animal health implemented by the NFSA provide an overall adequate level of assurance that exports to Great Britain can meet the relevant requirements set out in Great Britain health certificates.

The audit team provided recommendations that will require a response from the Norwegian competent authorities. They are set out in the recommendations in the corresponding sections of this report.

4. Recommendations

The Norwegian competent authority is invited to respond to this audit report with an action plan which addresses the recommendations set out in the report and listed below.

Recommendation 1: The NFSA to ensure internal audits are conducted focusing on the implementation of aquatic animal health controls in accordance with Article 6 of the Official Controls Regulation 2017/625.

Recommendation 2: The NFSA to ensure the standard operating procedures for official controls at compartment level are based on the AHL requirements and include instructions on approval, monitoring and withdrawal of approval.

Recommendation 3: The NFSA to ensure simulation exercises for listed salmonid diseases are carried out in accordance with the requirements of Article 45 of the Regulation (EU) 2016/429.

Abbreviations

ADIS	Animal Disease Information System
AHL	Animal Health Law - Regulation (EU) 2016/429
DEFRA	Department for Environment, Food and Rural Affairs
DTU	Technical University of Denmark
eDNA	Environmental DNA
EC	European Commission
EEA	European Economic Area
EFTA	European Free Trade Association
EHC	Export Health Certificate
EHN	Epizootic haematopoietic necrosis
EU	European Union
Gs	*Gyrodactylus salaris*
ISA HPR-deleted	Highly polymorphic region deleted infectious salmon anaemia virus
ISA HPR0	Non-pathogenic infectious salmon anaemia virus
IHN	Infectious haematopoietic necrosis
ILPT	Inter laboratory proficiency test
ISA	Infectious salmon anaemia
ISO	International Organisation for Standardisation
PCR	Polymerase Chain Reaction
NRL	National Reference Laboratory
NFSA	Norwegian Food Safety Authority (Mattilsynet)
NVI	Norwegian Veterinary Institute (Veterinærinstituttet)
RT-qPCR	Reverse Transcription quantitative Polymerase Chain Reaction
SAV	Salmonid alphavirus (pancreas disease)
VHS	Viral haemorrhagic septicaemia
WAHIS	World Animal Health Information System
WOAH	World Organisation for Animal Health

ANNEX I - Legislation

Relevant Norwegian legislation:

- Regulations on the Operation of Aquaculture Facilities (Aquaculture Operations Regulations) (FOR-2008-06-17-822)
- Regulations Relating to Animal Health (Animal Health Regulations) (FOR-2022-04-06-631)
- Regulations Supplementing the Animal Health Regulations with Provisions on Notification, Reporting, Surveillance, Eradication Programmes and Disease-free Status for Specific Animal Diseases (Animal Health Surveillance Regulations) (FOR-2022-04-06-632)
- The Food Export Regulations (FOR-2020-06-18-1547).

Relevant EFTA legislation:

- EFTA Surveillance Authority Decision No 032/21/COL
- EFTA Surveillance Authority Delegated Decision No 203/21/COL.

Relevant EU legislation:

- Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed laws, rules on animal health and welfare, plant health and plant protection products
- Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law')
- Commission Delegated Regulation (EU) 2020/687 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council, as regards rules for the prevention and control of certain listed diseases
- Commission Delegated Regulation (EU) 2020/689 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases
- Commission Delegated Regulation (EU) 2020/691 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of Council as regards rules for aquaculture establishments and transporters of aquatic animals
- Commission Delegated Regulation (EU) 2020/692 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin
- Commission Implementing Regulation (EU) 2018/1882 of 3 December 2018 on the application of certain disease prevention and control rules to categories of listed diseases and establishing a list of species and groups of species posing a considerable risk for the spread of those listed diseases.

- Commission Implementing Regulation (EU) 2020/2002 of 7 December 2020 laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council with regard to Union notification and Union reporting of listed diseases, to formats and procedures for submission and reporting of Union surveillance programmes and of eradication programmes and for application for recognition of disease-free status, and to the computerised information system
- Commission Implementing Regulation (EU) 2020/2236 of 16 December 2020 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal health certificates for the entry into the Union and movements within the Union of consignments of aquatic animals and of certain products of animal origin from aquatic animals, official certification regarding such certificates and repealing Regulation (EC) No 1251/2008
- Commission Implementing Regulation (EU) 2020/690 of 17 December 2019 laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the listed diseases subject to Union surveillance programmes, the geographical scope of such programmes and the listed diseases for which the disease-free status of compartments may be established
- Commission Implementing Regulation (EU) 2021/404 of 24 March 2021 laying down the lists of third countries, territories or zones thereof from which the entry into the Union of animals, germinal products and products of animal origin is permitted in accordance with Regulation (EU) 2016/429 of the European Parliament and the Council
- Commission Implementing Decision (EU) 2021/260 of 11 February 2021 approving national measures designed to limit the impact of certain diseases of aquatic animals in accordance with Article 226(3) of Regulation (EU) 2016/429 of the European Parliament and of the Council and repealing Commission Decision 2010/221/EU
- Commission Implementing Regulation (EU) 2021/620 of 15 April 2021 laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the approval of the disease-free and non-vaccination status of certain Member States or zones or compartments thereof as regards certain listed diseases and the approval of eradication programmes for those listed disease.

ANNEX II –Norwegian databases and portals

Summary of Norwegian information technology databases and portals

- Altinn - A dedicated internet portal for businesses and individuals to contact or submit data to government agencies such as the NFSA
- Aquaculture register – public register of aquaculture establishment licences. Includes information on the holder of the licence, location, permitted species and production stages, maximum biomass limit or capacity, and purpose of the licence
- BarentsWatch- A public website that provides various services and data for maritime activities, including aquaculture in Norway. Aquaculture data is provided by the NFSA, the NVI and the Directorate of Fisheries. The Directorate of Fisheries is an executive body governed by the Ministry of Trade, Industry and Fisheries. The website includes a map of aquaculture establishments and summary data such as species held on the establishment, sea lice numbers and treatments, whether an establishment is in a listed disease surveillance or protection zone and results from listed disease testing carried out by the NVI
- Læringsportalen - Bespoke online training platform available to the NFSA
- Lovdata - The website which publishes legislation and regulation in Norway. The public have access to all Norwegian laws and other judicial information. Restrictions relating to aquatic animal disease, in the form of designation notices, are also published on this website
- Elements - An archive system for incoming and outgoing correspondence used by the NFSA
- EPI - The sample submission portal of the NVI and the NFSA
- MATCIM - A portal of the log of statutory activities used by the NFSA. It details the actions required to be taken during for example, a disease investigation, noting who has dealt with each action
- MATS - The NFSA case management system and which is also linked to the latest regulations, business register, and register of aquaculture. In addition, it holds inspection templates and generates unique EHC numbers
- PGS - Laboratory integrated management service (LIMS) of the NVI
- SILD - NFSA system for risk ranking of aquaculture establishments. Official inspectors use this system to plan inspections