

Declaration of a compartment free of Infectious Salmon Anaemia (ISA) in Norway.

<i>Requirements/information needed</i>	<i>Information/further explanation and justification</i>
1. Identification of the program	
1.1. Declaring Member State	Norway
1.2. Competent authority (address, fax, e-mail)	The Norwegian Food Safety Authority, Head office, Section for fish health and fish welfare, Felles postmottak, postboks 383, 2381 Brumunddal. postmottak@matilsynet.no
1.3. Reference of this document	Council Directive 2006/88/EC, Article 50, Annex V
1.4. Data sent to the Commission	
2. Type of communication	
2.1. <input checked="" type="checkbox"/> Declaration of disease-free status	
2.2. Submission of application for disease-free-status	
3. National legislation¹	<p>Acts: The Food Act of 19 December 2003 No. 124</p> <p>Regulations:</p> <ul style="list-style-type: none"> • Regulations 17 June 2008 No. 819 on the placing on the market of aquaculture animals and product thereof, prevention and control of infectious diseases in aquatic animals. • Regulations 17 June 2008 No. 823 on the establishment and expansion of aquaculture establishments, pet shops etc. • Regulations 17 June 2008 No. 822 on operation of Aquaculture Establishments (Aquaculture Operation Regulations). • Regulations of 27 October 2007 No. 1254 on animal by-products not intended for human consumption.
4. Diseases	
4.1. Fish	<input type="checkbox"/> VHS <input type="checkbox"/> IHN <input checked="" type="checkbox"/> ISA <input type="checkbox"/> KHV
4.2. Molluscs	<input type="checkbox"/> infection with <i>Marteilia refringens</i> <input type="checkbox"/> infection with <i>Bonamia ostreae</i>
4.3. Crustaceans	White spot disease
5. Grounds for disease free-status	
5.1. <input type="checkbox"/> No susceptibles ²	
5.2. <input type="checkbox"/> Pathogen not viable ³	

¹ National legislation in force applicable to the declaration of and application for disease-free status.

² Applicable if none of the species susceptible to the disease(s) in question is present in the Member State, zone or compartment, and where relevant in its water source.

³ Applicable if the pathogen is known not to be able to survive in the Member State, zone or compartment, and where relevant in its water source. Provide the scientific information supporting the inability of the pathogen to survive in the Member State, zone or compartment.

5.3. <input type="checkbox"/> Historic free-status ⁴	
5.4. <input checked="" type="checkbox"/> Targeted surveillance ⁵	<p>Compartment details</p> <p>The compartment comprises of one farm, Bolaks department Nystølen, site No. 12110, located next to Lygrepollen in Fusa Municipality, Hordaland County.</p> <p>Nystølen meets the requirements in Annex V, part II, part II of directive 2006/88/EC to be considered free of ISA based on targeted surveillance for more than six years without detection of disease agent in fish from the farms.</p> <p>Attachment: map with coordinates for the compartment in the sea (Annex V)</p> <p>Description of the surveillance program</p> <p>The farm obtained historic free status for ISA in 2009.</p> <p>A surveillance program for maintaining the disease free status has been in place for the past nine years without detection of the disease agent. To maintain the ISA free status of site Nystølen a minimum of 30 analyses has been performed annually on moribund or dead fish (risk based sampling).</p> <p>The sampling has been performed by veterinarians or aqua medicine biologists (animal health professional) in FoMAS- Fiskehelse and Miljø AS. The analyses have been done at two accredited laboratories for ISA- virus analysis (in accordance with the OIE-standards); Patogen Analyse AS and Pharmaq Analytic AS (former Havbruksinstituttet AS). Results of all test results from 2009-2015 are attached in Annex I and II.</p> <p>In addition to the surveillance program all brood stock farms in Norway are obliged to be subject to a minimum of twelve health inspections by veterinarians or aqua medicine biologists (animal health professional) annually.</p> <p>Additional information</p> <p>The farm in the new compartment was previously a part of a bigger compartment which lost its ISA-free status due to an outbreak on a sea site in the compartment. Epizootic investigations by the Norwegian Food Safety Authority (the NFSA) in cooperation with National Veterinary Institute, that were initiated immediately after the suspicion were notified has assured us that the outbreak is limited to the sea site. Nystølen (site No. 12110) was followed at the time of the outbreak. The site has a secure water source and</p>

⁴ Applicable if susceptible species are present, but where there has not been any observed occurrence of the disease for at least a period of 10 years before the date of declaration of application for the disease-free status, despite conditions that are conducive to its clinical expression, and if it complies *mutatis mutandis* with the requirements laid down in Part 1.1. of Annex V to Directive 2006/88/EC. This ground for disease free status must be declared of or applied for by 1 November 2008. Provide detailed information on the compliance with Part 1.1. of Annex V to Directive 2006/88/EC.

⁵ Applicable if targeted surveillance complying with Community requirements has been in place for at least a period of two years without the detection of the disease agent on farm, or in mollusc farming areas that rears any of the susceptible species.

Where there are parts of the Member State, zone or compartment in which the number of farms or mollusc farming areas is limited, but in which there are wild populations of susceptible species, information on the targeted surveillance in those wild populations shall be given.

Describe diagnostic methods and sampling schemes. When OIE or EU standards are applied, reference must be made to them. If not, describe them. Name the laboratories involved in the program (National reference laboratory or designated laboratories).

	<p>efficient biosecurity measures in place to rule out the possibility of any transmission of ISAV from the sea site to the freshwater site. It does not use sea water in the production and are completely separated from the infected site.</p> <p>As a result of the epizootic investigations following the outbreak, the surveillance program that the farm was subject to in order to achieve disease free status in the past and testing to maintain free status according to Directive 2006/88, the NFSA hereby, in agreement with Bolaks AS, declare a new compartment consisting of one fresh water sites in accordance with Article 50 of Council Directive 2006/88/EC.</p>
6. General information	
6.1. Competent authority ⁶	<p>The Norwegian Food Safety Authority (NFSA)</p> <p>For more information about the NFSA please read the presentation in Annex III.</p>
6.2. Organisation, supervision of all stakeholders involved in the program to achieve disease free status ⁷	<p>The NFSA supervise all farms, aquatic animal health services and laboratories involved in the surveillance program and coordinate the measures taken to fulfil the requirements to achieve disease free status.</p> <p>The sampling has been performed by veterinarians and aqua medicine biologists (animal health professional) in FoMAS- Fiskehelse and Miljø AS. The analyses have been done at two accredited laboratories for ISA- virus analysis (in accordance with the OIE-standards); Patogen Analyse AS and Pharmaq Analytic AS (former Havbruksinstituttet AS).</p> <p>In addition to the surveillance program all brood stock farms in Norway are obliged to be subject to a minimum of twelve health inspections by veterinarians or aqua medicine biologists (animal health professional) annually.</p>
6.3. An overview of the structure of the aquaculture industry in the area in question (disease-free Member State, zone or compartment) including types of production and species kept	<p>Lygrepollen is a sea area in Fusa municipality, Hordaland County. Nystølen, site No. 12110, is located on dry land, next to Lygrepollen.</p> <p>Nystølen are separated from aquaculture production in Lygrepollen by physical and hygienic barriers. Nystølen uses entirely fresh water from a source without other aquaculture activity as described in pt. 7.5. Furthermore Nystølen are located two meters above maximum tide level, and the production facilities are designed to protect the stock from external contaminants, i.e. predators, animals, birds etc. Nystølen also has biosecurity measures to avoid transmission of infectious diseases with personnel or equipment and through transport. The hygienic routines for Nystølen are manifested in Bolaks Animal & Welfare Plan with annually revisions.</p> <p>Well boats with closed valves are used to restock the brood stock facilities at Nystølen. Atlantic salmon from other ISA free compartments will be transferred directly from the boat into the freshwater tanks inside the compartment.</p> <p>After spawning and incubation of the eggs, Nystølen is emptied, cleaned, disinfected and fallowed, normally in the period from February to May.</p> <p>Maps and picture of the farm are attached in Annex IV - VI to the declaration.</p>
6.4. The notification to the competent authority of the suspicion and confirmation of the disease(s) in question has been compulsory since when (date)?	<p>An early detection system and compulsory notification system for all listed diseases, including exotic diseases, has existed since 1990 (cf. Act of 22 June 1990 No. 44).</p> <p>According to the legislation The competent authority must be notified in case of suspicion and confirmation of the disease in question. All suspicions and diagnoses of ISA are handled according to the approved scheme for the withdrawal of all fish in</p>

⁶ A description shall be provided of the structure, competencies, duties and powers of the competent authority involved.

⁷ A description shall be provided of the competent authority in charge of the supervision and coordination of the program and the different operators involved.

	<p>Norwegian farms infected with infectious salmon anemia (ISA) (cf. The EFTA Surveillance Authority' Decision No 226/04/COL of 9 September 2004).</p> <p>In the case of suspicion of fish being infected with ISA, an official investigation to confirm or rule out the presence of the disease will be carried out as quickly as possible, involving at least one inspection and one sampling of about 10 fish. ISA diagnostics are done at The Norwegian Veterinary Institute according to the methods outlined by the OIE. If ISA is confirmed the Norwegian Food Safety Authority will impose the control measures which are needed to eradicate the disease from the zone/compartments and to prevent spread of disease to other aquatic animals. Each zone/compartments that has been suspended from ISA-free areas based on trade or disease outbreaks, would be placed under extended surveillance involving at least one official inspection annually, samples from at least 2 x 30 fish, risk based surveillance and sampling.</p> <p>Monitoring is carried out by Norwegian Food Safety Authority and by fish health services as described in 5.4..In the event of suspicion or confirmation of ISA within ISA-free areas, trade with susceptible species and vector species to other areas with a higher health status for ISA will immediately be suspended in accordance with Article 53 of Directive 2006/88/EC and the ISA-free status will be withdrawn.</p> <p>The Norwegian Food Safety Authority is responsible for the control and supervision of the actions taken in case of a disease outbreak and will supervise the cleaning, disinfection and fallowing of the facility, risk-based surveillance and regular inspections.</p>
<p>6.5. Early detection system in place throughout the Member States, enabling the competent authority to undertake effective disease investigation and reporting since when (date)?⁸</p>	<p>Approval of establishments of aquaculture farms has been compulsory in Norway since 1985. The national legislation (Regulations of 17 June 2008 No. 819) on the placing on the market and imports of aquaculture animals for farming or restocking, is in the accordance with the requirements of Directive 2006/88/EC.</p> <p>Basic biosecurity measures have been in place continuously since 1990 in the Norwegian legislation. The implementation of requirements for the placing on the market and import to prevent introduction of the disease into Norway is effective.</p> <p>An early detection system for all listed diseases, including exotic diseases, has existed since 1990 (cf. Act of 22 June 1990 No. 44).</p> <p>To maintain zones/compartments with ISA-free status Norwegian Food Safety Authority carry out at least one inspection annually and take/arrange to have taken samples from 30 fish.</p> <p>There is a broad awareness among the personnel employed in aquaculture businesses or involved in the processing of aquaculture animals of any signs consistent with the presence of a disease, as they are obliged to keep daily records of the health status and to have the following competence:</p> <p>(i) Anyone participating in aquaculture activities covered by Regulations 17 June</p>

⁸ The early detection systems shall in particular ensure the rapid recognition of any clinical signs consistent with the suspicion of a disease, emerging disease, or unexplained mortality in farms or mollusc farming areas, and in the wild, and the rapid communication of the event to the competent authority with the aim to activating diagnostic investigation with minimum delay. The early detection system shall include at least the following:

- (a) broad awareness, among the personnel employed in aquaculture businesses or involved in the processing of aquaculture animals, of any signs consistent with the presence of a disease, and training of veterinarians of aquatic animals health specialists in detecting and reporting unusual disease occurrence;
- (b) veterinarians or aquatic animal health specialists trained in recognising and reporting suspicious disease occurrence;
- (c) access by the competent authority to laboratories with the facilities for diagnosing and differentiating listed and emerging diseases.

	<p>2008 No. 819 is obliged to have the necessary professional knowledge to perform those activities. The person responsible for the daily operation of aquaculture establishments must be educated in aquaculture business including knowledge about management, animal health and welfare.</p> <p>(ii) The competence must be documented through practical and theoretical training.</p> <p>All brood stock farms in Norway are obliged to be subject to a minimum of twelve health inspections by veterinarians or aqua medicine biologists (animal health professional) annually.</p> <p>The NFSA has full access to laboratories with the facilities for diagnosing and differentiating all listed diseases.</p> <p>At a minimum an operating journal at the production level must contain updated information on;</p> <ul style="list-style-type: none"> a) Stocking of fish: date, species, number of fish, cohort and origination, b) Slaughtered quantity: date, species, number of fish, slaughter weight and slaughter condition, c) Removal of live fish: date, species and quantity. If fish are removed a journal entry shall be made of the aquaculture establishment to which the fish have been moved, d) Real volume, e) Health and welfare status of the fish: number of health checks, number of autopsied fish, sampling, examinations, diagnosis, injuries, treatments and known or probable causes of injuries and production diseases, f) mortalities g) Relevant parameters for water quality and water quality measures, h) Attacks by predators, algae or jellyfish and other measures taken. <p>These data must monthly be reported electronically to the Competent Authority every month.</p>
<p>6.6. Source of aquaculture animals of species susceptible to the disease in question entering in the Member State, zone or compartments for farming.</p>	<p>The entering of species susceptible to ISA into the ISA-free compartment is only allowed from other ISA-free Member States, zones or compartments. All consignments must be accompanied by a health certificate from the place of origin declaring the source to be disease free of ISA.</p> <p>The origin of the restocked fish at Nystølen is a farm in an ISA free compartment in Rogaland County.</p>
<p>6.7. Guidelines on good hygiene practice⁹</p>	<p>Regulations 17 June 2008 No. 819 relating to the placing on the market of aquaculture animals and products thereof, prevention and control of infectious diseases in aquatic animals, give guidelines on hygiene practices for handling of fish with suspected or diagnosed animal disease and on the fish farmers own supervision, including good hygiene practices in farms.</p> <p>Handling of dead fish is done in accordance with;</p>

⁹ A description shall be provided in accordance with Article 9 of Directive 2006/88/EC

	<ul style="list-style-type: none"> - Regulations 17 June 2008 No. 822 Regulations relating to Operation of Aquaculture Establishments (Aquaculture Operation Regulations) - Regulations of 27 October 2007 No. 1254 on animal by-products not intended for human consumption. 	
7. Area covered		
7.1. Member State		
7.2. <input type="checkbox"/> Zone (entire water catchment area) ¹⁰		
7.3. <input type="checkbox"/> Zone (part of water catchment area) ¹¹ Identify and describe the artificial or natural barrier that delimits the zone and justify its capability to prevent the upward migration of aquatic animals from the lower stretches of the water catchment area.		
7.4. <input type="checkbox"/> Zone (more than one water catchment area) ¹²		
7.5. <input checked="" type="checkbox"/> Compartment independent of the surrounding health status ¹³		
Identify and describe for each farm the water supply ¹⁴	Well, borehole or spring Water treatment plant inactivating the relevant pathogen ¹⁵	The fresh water supply to Nystølen comes from lake Håvikvatnet through a 2 km long pipeline. Håvikvatnet is located 1 km from the fjord, 57 meter above sea level. The pipeline runs directly into the water treatment system of Nystølen. The water treatment system inactivates the ISA-virus in addition to other disease agents. There is no use of seawater on the plant. Two barriers in the creek from the lake prevent anadromous fish from migrating to the lake.
Identify and describe for each farm natural or artificial barriers and justify its capability to prevent that aquatic animals enter each farm in a compartment from the surrounding watercourses.		Nystølen is located on an area of land at Lygrepollen, close to sea, two meters above sea level. See picture in Annex IV. In addition, the tanks are 1.8 meters high and covered with tarpaulin. In total, there are over three meters from sea level to the top of the tanks. Wave height in Lygrepollen are never exceeds 50 cm. The water inlet and outlet are designed

¹⁰ An entire water catchment area from its sources to its estuary.

¹¹ Part of a water catchment area from the source(s) to a natural or artificial barrier that prevents the upward migration of aquatic animals from the lower stretches of the water catchment area.

¹² More than one water catchment area, including their estuaries, due to the epidemiological link between the catchment areas through the estuary.

¹³ Compartments comprising one or more farms or mollusc farming areas where the health status regarding a specific disease is independent of the health status regarding that disease of surrounding natural waters.

¹⁴ A compartment which is independent of the health status of surrounding waters, shall be supplied with water:

(a) through a water treatment plant inactivating the relevant pathogen in order to reduce the risk of the introduction of the disease to an acceptable level; or

(b) directly from a well, a borehole or a spring. Where such water supply is situated outside the premises of the farm, the water shall be supplied directly to the farm, and be channelled through a pipe.

¹⁵ Provide technical information to demonstrate that the relevant pathogen is inactivated in order to reduce the risk of the introduction of the disease to an acceptable level.

		to function as a barrier to prevent aquatic animals from entering the farm from the surrounding water sources.
Identify and describe for each farm the protection against flooding and infiltration of water from the surrounding		See above.
7.6. Compartment dependent on the surrounding health status ¹⁶		
One epidemiological unit due to geographical localization and distance from other farms/farming areas ¹⁷		
All farms comprising the compartment fall within a common biosecurity system. Describe the common biosecurity system. ¹⁸		
<input type="checkbox"/> Any additional requirements ¹⁹		
8. Geographical demarcation ²⁰		
8.1. Farms or mollusc farming areas covered (registration numbers and geographical situation)		Bolaks AS, Nystølen, site No. 12110. Maps and picture attached in Annex IV and VI.
8.2. <input type="checkbox"/> Non-free buffer zone ²¹	Geographical demarcation ²⁶	
	Farms or mollusc farming areas covered (registration numbers, geographical situation and health status ²²)	
	Type of health surveillance	
8.3. <input type="checkbox"/> Non-free zones or compartments ²³	Geographical demarcation ²⁶	
	Farms or mollusc farming areas covered (registration numbers geographical situation and health status ²²)	
8.4. <input type="checkbox"/> Extension of disease-free zone to other Member States ²⁴	Geographical demarcation ²⁶	

¹⁶ Compartments comprising one or more farms or mollusc farming areas where the health status regarding a specific disease is dependent on the health status of surrounding natural waters regarding that disease.

¹⁷ A description shall be provided of the geographical localisation and the distance from other farms/farming areas that makes it possible to consider the compartment as one epidemiological unit.

¹⁸ A description shall be provided of the common biosecurity system.

¹⁹ Each farm or mollusc farming area in a compartment which is dependent on the health status of surrounding waters shall be subject to additional measures imposed by the competent authority, when considered necessary to prevent the introduction of diseases. Such measures may include the establishment of a buffer zone around the compartment in which a monitoring program is carried out, and the establishment of additional protection against the intrusion of possible pathogen carriers or vectors.

²⁰ The geographical demarcation shall be clearly described and identified on a map, which must be attached as an Annex to the declaration/application. Any substantial modification in the geographical demarcation of the zone or compartment to be declared free must be subjected to a new application.

²¹ In connection with a zone or a compartment dependent on the health status of surrounding waters, a buffer zone in which a monitoring programme is carried out shall be established, as appropriate. The demarcation of the buffer zones shall be such that it protects the disease-free zone from passive introduction of the disease. (Part II.1.5 of Annex V to Directive 2006/88/EC).

²² Health status in accordance with Part A of Annex III to Directive 2006/88/EC.

²³ Relevant in cases of declaration of disease-free Member States, where minor areas of the Member State are not considered disease-free.

²⁴ Where a zone extends to more than one Member State, it may not be declared a disease-free zone unless the conditions set out in points 1.3, 1.4, and 1.5 of Part II of Annex V to Directive 2006/88/EC apply to all areas of that zone. In that case both Member States concerned shall apply for approval for the part of the zone situated in their territory.

8.5. <input type="checkbox"/> Existing disease-free zones/compartments in the vicinity.	Geographical demarcation ²⁶	
	Farms or mollusc farming areas covered (registration numbers and geographical situation)	
9. Farms or mollusc farming areas which commence or recommence their activities²⁵		
9.1. New farm		
9.2 Recommencing farm	Health history of farm known to Competent authority	
	<input type="checkbox"/> Not subject to animal health measures in respect of listed diseases	
	<input type="checkbox"/> Farm cleaned, disinfected and, as necessary, fallowed	

²⁵

In accordance with Part II.4 of Annex V to Directive 2006/88/EC