

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 programme	
1.1. Declaring Member State	Norway
1.2. Competent authority (address, fax, e-mail)	The Norwegian Food Safety Authority, Head office, Fish health and Welfare Section, 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	28.08.2018
2. Type of communication	
2.1. <input checked="" type="checkbox"/> Declaration of disease-free status	
2.2. <input type="checkbox"/> 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"> • Regulation 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. • Regulation 17 June 2008 No. 823 on the establishment and expansion of aquaculture establishments, pet shops etc. • Regulation 17 June 2008 No. 822 on operation of Aquaculture Establishments (Aquaculture Operation Regulation). • Regulation 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	<input type="checkbox"/> 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	
5.3. <input type="checkbox"/> Historic free-status ⁴	

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 watersource.

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.

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.~~

5.4. X Targeted surveillance ⁵	<p>Description of the surveillance programme.</p> <p>18000 Rimstad is a continental compartment whose health status is independent of the surrounding natural waters in accordance with point 3 of Part II of Annex V to Directive 2006/88/EC. The site Rimstad is designed for and used only for holding maturing broodfish (8-16 kg fish) before stripping and subsequent egg incubation.</p> <p>18000 Rimstad has been a part of the established ISA-free compartment 4.15 in Gjemnes, Nesset, Tingvoll and Sunndal municipalities. The Rimstad compartment comprising sea and land sites was granted ISA-free status on historical grounds. ISA was confirmed at 18000 Rimstad July 13th 2017. It was verified through virus genome sequencing that the ISA-virus infection at Rimstad was a direct consequence of the transfer of sub-clinically infected fish from the sea site 12904 Merraberget in the period from May 25th 2017 to June 1th 2017. Infection at Merraberget was confirmed by July 10th based on routine surveillance sampling.</p> <p>The application for reestablishment of ISA-free status at Rimstad is based on emptying, total cleaning and disinfection of all facilities, followed by fallowing. The site was emptied for fish by July 17th 2017, thoroughly cleaned and disinfected, and the sanitation program was ended at September 21th 2017. The site was restocked with brood fish from ISA free compartment 12917 Sjølseng (land-based production) on February 19th 2018, representing a fallowing period of 21 weeks and 4 days. The abovementioned measures meet the requirements in Commission implementing decision (EU) 2015/1554, Annex I, part 3, point I.2.2.2.</p> <p>A total of 2747 brood fish were transferred from ISA-free compartment 12917 Sjølseng to restock 18000 Rimstad. 2721 of the transferred fish were killed by the point of stripping and sampled at Rimstad. 26 fish were sorted out and disposed of before the operator decided to start the screening. The 26 individuals not tested were not stripped. Please refer to Annex 3b for documented heart and kidney samples from 2721 individuals. None of the samples were pooled, which constitutes a total number of 5442 samples, all negative with respect to ISAV.</p> <p>The samples were analyzed by the official laboratory Patogen (designated and accredited), using tissues and test methods in accordance with EC 2015/1554 Annex I, Part 3, points II.1 and II.2, and Annex II, Part 3. Please refer to Annex 3a and 3b for sampling overview and analysis certificates, respectively.</p>
6. General information	
6.1. Competent authority ⁶	<p>The competent authority organizing and surveying health control for aquaculture industry in Norway is the Norwegian Food Safety Authority (NFSA).</p> <p>The NFSA has two administrative levels, the head office and five regional offices. The Norwegian Food Safety Authority has about 1300 employees. The 32 local offices carry out practically all of the active inspections. Having offices throughout the country means that the NFSA is close to both consumers and the relevant businesses.</p> <p>Approval of establishments of aquaculture farms in Norway has been compulsory since 1985. The national legislation (regulation 17 June 2008 NO 819) concerning the placing on the market and imports of aquaculture animals for farming or restocking in Norway is in accordance with the requirements of Directive 2006/88/EC.</p> <p>For more information about the NFSA please read the presentation in Annex 1.</p>
6.2. Organisation, supervision of all stakeholders involved in the	<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>

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 programme (National reference

- laboratory or designated laboratories).
- ⁶ A description shall be provided of the structure, competencies, duties and powers of the competent authority

<p>programme to achieve disease free status ⁷</p>	<p>To maintain zones and compartments with ISA-free status the Norwegian Food Safety Authority carry out at least one inspection annually and take/arrange for necessary samples to be analysed according to Commission implementing decision (EU) 2015/1554 of September 11th 2015.</p> <p>In addition to the surveillance programme all fresh water and 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 National Reference Laboratory (NRL) is the Norwegian Veterinary Institute. For details on the early detection system and diagnostic methods see section 6.5.</p> <p>All sampling and supervision of the health situation in the compartment 18000 Rimstad is carried out by veterinarian or aqua medicine biologist. All analyses are performed by laboratory accredited and designated for ISA-virus analysis (in accordance with OIE-standards), usually Patogen AS.</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>6.3. 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>	<p>Compartment details</p> <p>The broodstock compartment 18000 Rimstad is the land base for AquaGen, department Tingvoll, located in Tingvoll municipality, Møre og Romsdal County.</p> <p>The compartment consists of a closed farm unit not dependent of animal health status of the surrounding waters as it is the only aquaculture activity in the water catchment area. The site is solely based on use of freshwater in its total production. The inlet water is filtered (10µm) before UV-disinfection.</p> <p>The purpose of the broodstock plant 18000 Rimstad is to produce eyed salmon and rainbow trout eggs to serve AquaGen customers nationally and internationally. The species kept on the site is Atlantic salmon and Rainbow trout.</p> <p>The compartment 1800 Rimstad consists of two separate departments: a) tanks for keeping the maturing brood fish and the adjacent stripping facilities and b) egg incubation department. These two units are distinctly separated for practical and biosafety reasons. Both departments only use freshwater in its production.</p>
<p>6.4. The notification to the competent authority of the suspicion and confirmation of the</p>	<p>According to the legislation The competent authority must be notified in case of suspicion and confirmation of the disease in question. Notification has been compulsory since 1990. All suspicions and diagnoses of ISA are handled according to the approved scheme for the withdrawal of all fish in Norwegian farms infected with infectious</p>

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

<p>disease(s) in question has been compulsory since when (date)?</p>	<p>salmon anaemia (ISA) (cf. EFTA Surveillance Authority' Decision No 394/06/COL of 13 December 2006).</p> <p>Monitoring is carried out by Norwegian Food Safety Authority and by fish health services as described in 5.4 and 6.2. 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>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 (NRL) 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 compartment and to prevent spread of the disease to other sites.</p> <p>Sampling will be performed by Norwegian Food Safety Authority in connection with inspections and by veterinarian and aqua medicine biologists performing the monthly inspections in the compartment.</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>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). Basic biosecurity measures have been in place continuously since 1990. The implementation of trade and import conditions to prevent introduction of the diseases into Norway is effective.</p> <p>To maintain zones and compartments with ISA-free status the Norwegian Food Safety Authority carry out at least one inspection annually and take/arrange for necessary samples to be analysed according to Commission implementing decision (EU) 2015/1554 of September 11th 2015. All fresh water and brood stock farms in Norway are obliged to be subject to a minimum of 12 health inspections by veterinarians or aqua medicine biologists (animal health professional) annually.</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 Regulation 17 June 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>

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>(ii) The competence must be documented through practical and theoretical training.</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) 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, c) Real volume, d) 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, e) Mortalities f) Relevant parameters for water quality and water quality measures
<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>Only brood fish from sites with ISA-free status will be allowed to enter the compartment 18000 Rimstad. The species in the compartment will be Atlantic salmon and Rainbow trout. Only full cycle landbased broodfish from ISA-free compartments will be transferred and stripped at Rimstad for the first two years of production.</p>
<p>6.7. Guidelines on good hygiene practice⁹</p>	<p>Regulation 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> <ul style="list-style-type: none"> - Regulation 17 June 2008 No. 822 Regulations relating to Operation of Aquaculture Establishments (Aquaculture Operation Regulation) - Regulation 27 October 2007 No. 1254 on animal by-products not intended for human consumption. <p>AquaGen compartment 18000 Rimstad has strict procedure for handling of dead fish. All dead fish is obliged to autopsy by qualified person (veterinarian, aqua medicine biologist or other educated and trained person on the plant). In case of suspected disease appropriate sampling and diagnostic investigation will be performed immediately. Official authorities will be informed with no delay.</p>
<p>7. Area covered</p>	
<p>7.1. Member State</p>	
<p>7.2. <input type="checkbox"/> Zone (entire water catchment area)¹⁰</p>	

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

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

<p>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.</p>			
<p>7.4. <input type="checkbox"/> Zone (more than one water catchment area)¹²</p>			
<p>7.5. <input checked="" type="checkbox"/> Compartment independent of the surrounding health status¹³</p> <p>AquaGen compartment 18000 Rimstad is a stripping and incubation station for salmon and rainbow trout brood stock. The compartment includes the land base itself and the freshwater source Stølsvatnet, which is the only water source used in the compartment.</p> <p>The compartment 18000 Rimstad is independent of the surrounding health status as there are no other aquaculture activities in connection with the water source Stølsvatnet. Rimstad only uses freshwater in its total production, both for the keeping of the broodfish in tanks and for the stripping and incubation activity. The inlet water is filtered (10µm) prior to UV disinfection.</p> <p>All transport of broodfish to the land base Rimstad will be done according to The Norwegian Food Safety Authority regulations.</p> <p>The compartment 18000 Rimstad has internal hygienic procedures for the staff, visitors and equipment entering the compartment. If equipment is moved between sites it has to be cleaned and disinfected prior to the movement according to AquaGen internal procedures in accordance with the Norwegian Food Safety Authority regulations.</p> <p>Welfare parameters such as mortality and environmental indicators like temperature, pH, oxygen and CO2 levels are continuously monitored at the site.</p> <p>Every brood fish that dies the last 9 months before stripping and in the stripping period is obliged to autopsy by veterinarian, aqua medicine biologist or by educated, trained person on the plant. The fish health service conducts at least one health control every month and additional controls in case of increased mortality or observed changed behavior of the fish. The sampling is risk based depending on gross pathology. The laboratory analyses are dominated by PCR –analyses.</p> <p>At 18000 Rimstad there are strict hygienic barriers between the department where the broodfish is kept and stripped and the department for incubation of the eggs. Internal procedures are strictly followed in the stripping and fertilizing process. The newly stripped and fertilized eggs are subject to thorough disinfection in iodine solution before incubation. All eyed eggs are disinfected in iodine solution before shipping to customer.</p>			
<p>Identify and describe for each farm the water supply¹⁴</p>	<table border="1"> <tr> <td data-bbox="670 1240 1104 1543"> <p>Well, borehole or spring Water treatment plant inactivating the relevant pathogen¹⁵</p> </td> <td data-bbox="1104 1240 1560 1543"> <p>There is no other aquaculture activity connected to the water source Stølsvatnet. Closed waterpipes from an inlet at 10 meters depth in the water source are leading the water from Stølsvatnet to the site. The inlet water is filtered and treated with UV before release to the fish tanks and the incubators for ovas.</p> </td> </tr> </table>	<p>Well, borehole or spring Water treatment plant inactivating the relevant pathogen¹⁵</p>	<p>There is no other aquaculture activity connected to the water source Stølsvatnet. Closed waterpipes from an inlet at 10 meters depth in the water source are leading the water from Stølsvatnet to the site. The inlet water is filtered and treated with UV before release to the fish tanks and the incubators for ovas.</p>
<p>Well, borehole or spring Water treatment plant inactivating the relevant pathogen¹⁵</p>	<p>There is no other aquaculture activity connected to the water source Stølsvatnet. Closed waterpipes from an inlet at 10 meters depth in the water source are leading the water from Stølsvatnet to the site. The inlet water is filtered and treated with UV before release to the fish tanks and the incubators for ovas.</p>		

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.

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 water sources.	Due to natural barriers in the river leading from Stølvatnet to the sea, no anadromous fish can enter the water source. The water pipes are totally closed on their way to the production site. It is impossible for fish to pass these barriers.
Identify and describe for each farm the protection against flooding and infiltration of water from the surrounding	The water pipes leading the fresh water are totally closed. The bottom of the tanks with the fish is at the lowest 2 meters above sea flood level. There is no possibility that sea water or fresh water from outside can reach the brood stock facility.
7.6. <input type="checkbox"/> Compartment dependent on the surrounding health status¹⁶	
One epidemiological unit due to geographical localisation 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 demarcation²⁰	
8.1. Farms or mollusc farming areas covered (registration numbers and geographical situation)	The compartment is located in Tingvoll municipality, Møre og Romsdal County. The only site within the compartment is the land based brood stock facility 18000 Rimstad, operated by AquaGen. Attached maps show the geographic position including catchment area of the water source, please refer to Annex 2.
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

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 programme 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.

	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	
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 <input checked="" type="checkbox"/> Recommencing farm	Health history of farm known to Competent authority	<p>AquaGen compartment 18000 Rimstad is a single, closed continental farm for the production of eyed salmon and rainbow trout eggs to be shipped to freshwater sites for smolt production.</p> <p>The compartment Rimstad Land had restrictions related to detection of ISA-virus in July 2017. This outbreak was directly related to transfer of fish from a sea site (12904 Merraberget) that was diagnosed with ISA after routine surveillance.</p> <p>All facilities at 18000 Rimstad were cleaned, disinfected and fallowed before intake of new biological material (maturing brood fish and eggs) from ISA free compartment 12917 Sjølseng.</p>
	<input checked="" type="checkbox"/> Not subject to animal health measures in respect of listed diseases.	
	<input checked="" type="checkbox"/> Farm cleaned, disinfected and, as necessary, fallowed	<p>The Rimstad department for keeping the landed brood fish and the department for stripping was emptied, cleaned and disinfected completely by September 21st 2017.</p> <p>The department for incubation of eggs was under construction by the time of emptying, cleaning and disinfection of the facility.</p> <p>Both cleaning, disinfection and fallowing performed on the plant is confirmed by representative from NFSA.</p>

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.

²⁵ In accordance with Part II.4 of Annex V to Directive 2006/88/EC