

# Declaration of zone free of Infectious Salmon Anaemia (ISA) in Norway.

<i>Requirements/information needed</i>	<i>Information/further explanation and justification</i>
<b>1. Identification of the programme</b>	
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. <a href="mailto:postmottak@matilsynet.no">postmottak@matilsynet.no</a>
1.3. Reference of this document	Council Directive 2006/88/EC, Article 50, Annex V
1.4. Data sent to the Commission	<b>4 September 2013</b>
<b>2. Type of communication</b>	
2.1. <input checked="" type="checkbox"/> Declaration of disease-free status	
2.2. <input type="checkbox"/> Submission of application for disease-free-status	
<b>3. National legislation<sup>1</sup></b>	Acts: The food act of 19 December 2003 No. 124 Regulations: Regulations 17 June 2008 No. 819 relating to 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 Regulations on the establishment and expansion of aquaculture establishments, pet shops etc. 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.
<b>4. Diseases</b>	
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
<b>5. Grounds for disease free-status</b>	
5.1. <input type="checkbox"/> No susceptibles <sup>2</sup>	
5.2. <input type="checkbox"/> Pathogen not viable <sup>3</sup>	

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

<sup>2</sup> 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.

<sup>3</sup> 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 <sup>4</sup>	
5.4. <input checked="" type="checkbox"/> Targeted surveillance <sup>5</sup>	<p><b>Zone details</b>  MHN Øyerhamn, located at Varaldsøy within Kvinnherad Municipality, is a site for hatchery reared salmon which meets the requirements in Annex V, Part 2, Point 4.2 of Directive 2006/88/EC to be considered free of ISA.</p> <p><b>History:</b>  Øyerhamn had status as ISA free zone on historical basis until 2009. Øyerhamn lost its ISA free status because of introduction of category III material in November 2009, and was subsequently downgraded to category III by the competent authority. Trade with susceptible species and vector species to other areas with a higher health status for ISA were immediately suspended from the zone in accordance with Article 53 of Directive 2006/88 EC and the ISA free status was withdrawn.</p> <p>We also refer to SANCO/6084/2009-Draft COMMISSION DECISION of Diagnostic Manual for certain aquatic animal diseases C (2009) Part III – Surveillance and diagnostic methods for ISA, Part II, 3. Specific provisions to regain ISA free status: “A continental zone/compartment comprising one single farm with a previously ISA free status, whose health status with regard to that disease is dependent of the surrounding natural waters, and whose free status has been withdrawn, may regain the disease free status immediately after the competent authority has confirmed that the following conditions are complied with:</p> <p>(a) the confirmed infected farm with ISA is emptied, cleansed, disinfected and fallowed; the duration of the fallowing period shall be at least 6 weeks;</p> <p>(b) the confirmed infected farm with ISA has been restocked with fish from ISA free zone/compartments”.</p> <p>The different separate units at Øyerhamn has been emptied, cleansed, disinfected and fallowed for more than 6 weeks. From November 2012 Marine Harvest Øyerhamn incubated category I eggs from Marine Harvest’s broodfish farm Tveitevåg. Only fish from ISA free areas are allowed to enter the Øyerhamn zone.</p> <p>Operations at Øyerhamn are carried out soundly with respect to sanitation and hygiene. Systematic steps are taken to prevent the risk of infections. The farm is inspected by the Norwegian Food Safety Authority. Øyerhamn fulfills the requirements of Directive 2006/88/EC to be considered as an ISA free zone.</p> <p><b>Description of the surveillance programme</b>  The National Reference Laboratory is the Norwegian Veterinary Institute. For details on the early detection system and diagnostics methods see section 6.5.</p> <p>Approval of establishments of aquaculture farms has been compulsory since 1985. The national legislation (Regulations of 17 June 2008 No. 819) concerning the placing on the market and imports of aquaculture animals for farming or restocking in Norway is in the accordance with the requirements of Directive 2006/88/EC. Basic biosecurity measures have been in place continuously since 1990. The implementation of trade and imports conditions to prevent introduction of the disease into Norway is effective. 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</p>

<sup>4</sup> ~~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.~~

<sup>5</sup> 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).

	<p>samples from 30 fish. 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 would be placed under extended surveillance involving two official inspections annually, samples from at least 2 x 150 fish, risk based surveillance and sampling.</p>
<p><b>6. General information</b></p>	
<p>6.1. Competent authority<sup>6</sup></p>	<p>The Norwegian Food Safety Authority has three administrative levels. The head office is located in Oslo. There are eight regional offices and 54 district offices. The Norwegian Food Safety Authority has 1316 employees. The 54 district offices carry out practically all of the active inspections. Having offices throughout the country means that the Norwegian Food Safety Authority is close to both consumers and the relevant businesses.</p> <p>Attached information on the structure and role of the Norwegian Food Safety Authority: Standard Power Point presentation, “This is the Food safety Authority”.</p>
<p>6.2. Organisation, supervision of all stakeholders involved in the programme to achieve disease free status<sup>7</sup></p>	<p>Monitoring is carried out by Norwegian Food Safety Authority. 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. See also section 5.4. The Norwegian Food Safety Authority is responsible for the control and supervision of a possible subsequent recommencement process and will supervise the cleaning, disinfection and following 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><a href="http://www.regjeringen.no/upload/FKD/Diverse/2011/Fakta_Fiskeri_Havbruk_eng-lowres_singlepages.pdf">http://www.regjeringen.no/upload/FKD/Diverse/2011/Fakta_Fiskeri_Havbruk_eng-lowres_singlepages.pdf</a></p>
<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>	<p>The competent authority is notified in case of suspicion and confirmation of the disease(s) 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 salmon anaemia (ISA) (cf. The EFTA Surveillance Authority’ Decision No 226/04/COL of 9 September 2004).</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)?<sup>8</sup></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>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 2008</p>

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

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

<sup>8</sup> 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>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>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.</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.	The entering of species susceptible to ISA into Norwegian ISA free compartments 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 for ISA.
6.7. Guidelines on good hygiene practice <sup>9</sup>	<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 in accordance to: Regulations 17 June 2008 No. 822 Regulations relating to Operation of Aquaculture Establishments (Aquaculture Operation Regulations) and Regulations of 27 October 2007 No. 1254 on animal by-products not intended for human consumption.</p>
<b>7. Area covered</b>	
7.1. Member State	
7.2. <input type="checkbox"/> Zone (entire water catchment area) <sup>10</sup>	
7.3. <input checked="" type="checkbox"/> Zone (part of water catchment area) <sup>11</sup> 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>Øyerhamn is Marine Harvest Norway's land site for hatchery reared salmon, where all the broodstock candidate eggs are incubated. The zone include the land based site and the freshwater, Øyerhamnsvatnet, belonging to it. Øyerhamn is based on freshwater and the only water supply is from Øyerhamnsvatnet. The area is defined on map regarding Regine-areas. There are no other aquaculture activities in connection with the water source.</p> <p>There are three different barriers between the sea and the freshwater source:</p> <p>(i) From the sea there is a 20 meter high waterfall that is steep and impossible for fish to pass.</p> <p>(ii) 200 meter from the sea there is a 7 meter high concrete wall.</p>

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

<sup>10</sup> An entire water catchment area from its sources to its estuary.

<sup>11</sup> 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.

		(iii) Where the waterpipe comes out from Øyerhamnsvatnet, there is a 4 meter high concrete wall. The waterpipe is totally closed on its way to the landsite. It is impossible for fish to pass these barriers. The bottom of the lowest placed fish tanks is 2 meter above the sea level. It is not possible for seawater or freshwater from outside the facility to backwash into the facility. The tanks are safe against flooding. The site is split into several separate units where operations are carried out soundly with respect to sanitation and hygiene. Systematic steps are taken to prevent the risk of infections. Only fish from ISA free areas are allowed to enter the Øyerhamn zone.
7.4. <input type="checkbox"/> Zone (more than one water catchment area) <sup>12</sup>		
7.5. <input type="checkbox"/> Compartment independent of the surrounding health status <sup>13</sup>		
Identify and describe for each farm the water supply <sup>14</sup> Described in the enclosed documents.	X Well, borehole or spring X Water treatment plant inactivating the relevant pathogen <sup>15</sup>	
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.		
Identify and describe for each farm the protection against flooding and infiltration of water from the surrounding		
7.6. <input type="checkbox"/> Compartment dependent on the surrounding health status <sup>16</sup>		
One epidemiological unit due to geographical localisation and distance from other farms/farming areas <sup>17</sup>		
All farms comprising the compartment fall within a common biosecurity system. Describe the common biosecurity system. <sup>18</sup>		
<input type="checkbox"/> Any additional requirements <sup>19</sup>		

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

<sup>13</sup> 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.

<sup>14</sup> 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.

<sup>15</sup> 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.

<sup>16</sup> 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.

<sup>17</sup> 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.

<sup>18</sup> A description shall be provided of the common biosecurity system.

<b>8. Geographical demarcation</b> <sup>20</sup>		
8.1. Farms or mollusc farming areas covered (registration numbers and geographical situation)		Marine Harvest site Øyerhamn, site number 12032. Map attached. Regine describes the area of the freshwater Øyerhamnsvatnet with its surrounding watersources, which supplies the land site. Zone Øyerhamn er covered by Regine unit 53.3.
8.2. <input type="checkbox"/> Non-free buffer zone <sup>21</sup>	Geographical demarcation <sup>26</sup>	
	Farms or mollusc farming areas covered (registration numbers, geographical situation and health status <sup>22</sup> )	
	Type of health surveillance	
8.3. <input type="checkbox"/> Non-free zones or compartments <sup>23</sup>	Geographical demarcation <sup>26</sup>	
	Farms or mollusc farming areas covered (registration numbers geographical situation and health status <sup>22</sup> )	
8.4. <input type="checkbox"/> Extension of disease-free zone to other Member States <sup>24</sup>	Geographical demarcation <sup>26</sup>	
8.5. <input type="checkbox"/> Existing disease-free zones/compartments in the vicinity.	Geographical demarcation <sup>26</sup>	
	Farms or mollusc farming areas covered (registration numbers and geographical situation)	
<b>9. Farms or mollusc farming areas which commence or recommence their activities</b> <sup>25</sup>		
9.1. <input type="checkbox"/> New farm		
9.2 x Recommencing farm	x Health history of farm known to Competent authority	Øyerhamn had status as ISA free zone on historical basis until 2009. Øyerhamn lost its ISA free status due to introduction of category III material in November 2009.
	<input type="checkbox"/> Not subject to animal health measures in respect of listed diseases	
	x Farm cleaned, disinfected and, as necessary, fallowed	Øyerhamn has only been subject to precautionary measures in respect of listed diseases. Øyerhamn was emptied, cleansed, disinfected and fallowed for more than 6 weeks prior to recommencing.

<sup>19</sup> 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.

<sup>20</sup> 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.

<sup>21</sup> 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).

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

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

<sup>24</sup> 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.

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



Declaration Øyerhamn-  
Map Norway









