

# Declaration of a compartment 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, Fish Health and Welfare Section, 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>14.08.2017</b>
<b>2. Type of communication</b>	
2.1. <input checked="" type="checkbox"/> Declaration of disease-free status	
2.2. Submission of application for disease-free-status	
<b>3. National legislation<sup>1</sup></b>	<p><b>Acts:</b> The Food Act of 19 December 2003 No. 124</p> <p><b>Regulations:</b></p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• Regulations 17 June 2008 No. 823 on the establishment and expansion of aquaculture establishments, pet shops etc.</li> <li>• Regulations 17 June 2008 No. 822 on operation of Aquaculture Establishments (Aquaculture Operation Regulations).</li> <li>• Regulations 27 October 2007 No. 1254 on animal by-products not intended for human consumption.</li> </ul>
<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>	
5.3. <input type="checkbox"/> Historic free-status <sup>4</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.

<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~~

5.4. x Targeted surveillance <sup>5</sup>	<p>The brood stock site has 30897 Havsundet has been surveyed and samples are tested for ISA virus since 2010, when salmon first time was put to this location. After the introduction of salmon on the site in April 2015 there has been no movement of new fish into the site. To come in position to achieve ISA free status the brood stock farm has been under targeted surveillance since April 2015. Targeted surveillance and sampling program complying with the requirements in order to achieve ISA free status started immediately and has continuously been followed up until landing of the brood fish.</p> <p>The compartment meets the requirements in Annex V, to be considered free from ISA based on targeted surveillance for more than two years without detection of disease agent in fish from the site. To establish zones and compartments with ISA-free status the Norwegian Food Safety Authority carry out at least two inspections annually and take/arrange necessary samples to be analysed in accordance with Commission implementing decision (EU) 2015/1554 of September 11<sup>th</sup> 2015.</p> <p>Compartment 30897 Havsundet has been committed to surveillance and sampling for two years. The sampling has been risk based with samples taken from fish with changed behaviour, visible disorders or newly dead fish.</p> <p>Please refer to Annex 3a, 3b and 3b2 for sampling overview, screening results and analysis certificates, respectively.</p> <p>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. Each zone/compartment would be placed under extended surveillance for two years, involving two official inspections annually, samples from at least 150 fish annually, risk based surveillance and sampling.</p>
<b>6. General information</b>	
6.1. Competent authority <sup>6</sup>	<p>The Competent Authority organizing and surveying health control for aquaculture industry in Norway is the Norwegian Food Safety Authority (NFSA). The NFSA has two administrative levels, the head office and five regional offices. The Norwegian Food Safety Authorities 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 business.</p> <p>Approval of establishment of aquaculture farms in Norway has been compulsory since 1985. The national legislation (regulation of 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 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 programme to achieve disease free status <sup>7</sup>	<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>

~~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).

<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.

	<p>The sampling has been performed by veterinarians and fish health biologists in connection with monthly inspections and additional controls in case of elevated death rates or observed changed behaviour of the fish. The sampling is risk based depending on gross pathology. The laboratory analysis is dominated by PCR, accompanied by histology if necessary for diagnosis.</p> <p>More than 150 samples each year have been analysed in accredited and designated laboratory Patogen Analyse AS, by most sensitive PCR technique (in accordance with the OIE standards) exclusively with negative results.</p> <p>In addition to the surveillance programme all fresh water and all brood stock farms (sea sites and land based) in Norway are obliged to be subject to a minimum of twelve health inspections by veterinarians or fish health biologists annually.</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 30897 Havsundet is situated in Bjugn municipality, Sør-Trøndelag County. It consists of one brood stock sea site, which meets the requirements in Annex V, to be considered free from ISA based on targeted surveillance and sampling for more than two years (2015, 2016 and 2017) without detection of disease agent (ISAV) in fish from the site.</p> <p>The site 30897 Havsundet is located in the sea area outside the island Tarva and is the only aquaculture site within the demarcation of the compartment. See attached description with coordinates in 8.1 and Annex 2 for maps.</p> <p>The compartment 30897 Havsundet is a sea site with fish from smolt stage for the production of salmon brood stock to deliver to the land base about two years later when maturing process has come to an appropriate point and last sorting at the sea site will be finished.</p> <p>Only smolt from ISA free freshwater site is allowed to enter the compartment 30897 Havsundet. The only species kept in the compartment is Atlantic Salmon.</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>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 salmon anaemia (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 (National Reference Laboratory) in accordance with 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/compartment and to prevent spread of disease to other aquatic animals. Each zone/compartment that has been suspended from ISA-free areas based on trade or disease outbreaks, would be placed under extended surveillance for two years, involving at least two official inspections annually, samples from at least 150 fish annually, risk based surveillance and sampling in two prolonged periods.</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>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</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).</p>

<p>authority to undertake effective disease investigation and reporting since when (date)?<sup>8</sup></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>To maintain zones/compartments with ISA-free status Norwegian Food Safety Authority carry out at least two inspections annually and take/arrange to have taken samples from not less than 30 fish in two periods, all together at least 60 fish each year. In situations of increased mortality or changed behaviour of the fish additional samples will be taken and analysed.</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> <ul style="list-style-type: none"> <li>(i) Anyone participating in aquaculture activities covered by Regulations 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.</li> <li>(ii) The competence must be documented through practical and theoretical training.</li> </ul> <p>All on-growing sea sites in Norway are obliged to be subject to a minimum of six health inspections by veterinarians or fish health biologists annually. All brood stock sites in seawater are obliged to a minimum of twelve inspections annually.</p> <p>The NFSA has full access to laboratories with the facilities for diagnosing and differentiating all listed diseases.</p> <p><b>At a minimum an operating journal at the production level must contain updated information on;</b></p> <ul style="list-style-type: none"> <li>a) Stocking of fish: date, species, number of fish, cohort and origination,</li> <li>b) Slaughtered quantity: date, species, number of fish, slaughter weight and slaughter condition,</li> <li>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,</li> <li>d) Real volume,</li> <li>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,</li> <li>f) Mortalities</li> <li>g) Relevant parameters for water quality and water quality measures,</li> <li>h) Attacks by predators, algae or jellyfish and other measures taken.</li> </ul>
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<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 or 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.

	Data including b), c) and f) must be reported to the competent authority every month.	
6.6. Source of aquaculture animals of species susceptible to the disease in question entering in the Member State, zone or compartments for farming.	Only smolt from ISA free Member States, zones or compartments will be allowed to enter the site 30897 Havsundet. The only species introduced and kept in the compartment will be Atlantic salmon. All consignments must be accompanied by a health certificate from the place of origin declaring the source to be disease free of 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 done in accordance with;</p> <ul style="list-style-type: none"> <li>- Regulations 17 June 2008 No. 822 Regulations relating to Operation of Aquaculture Establishments (Aquaculture Operation Regulations)</li> <li>- Regulations 27 October 2007 No. 1254 on animal by-products not intended for human consumption.</li> </ul>	
<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 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.		
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>	Well, borehole or spring 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 checked="" 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>	30897 Havsundet is the only aquaculture site within the demarcation of the compartment, see 8.1 describing the geographical limitation of the compartment and also Annex 2 for maps. The closest site is 12794 Rundklumpen, about 8 km in distance from Havsundet.	

<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.

<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.

<p>All farms comprising the compartment fall within a common biosecurity system. Describe the common biosecurity system.<sup>18</sup></p>	<p>All use of well boats when transporting live fish to and from the compartment has been and will be done according to The Norwegian Food Safety Authority regulations.</p> <p>Operations at 30897 Havsundet are carried out soundly with respect to sanitation and hygiene. Systematic measures are taken to prevent the risk of introduction of pathogens to the site.</p> <p>The compartment 30897 Havsundet 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 in accordance with Marine Harvest internal procedures and the Norwegian Food Safety Authority regulations.</p> <p>The compartment has its own service boats. All external boats have to be cleaned and disinfected before entering the area of the compartment, and must be followed by a certificate showing that cleaning and disinfection has been properly performed.</p> <p>Fish health and welfare parameters such as mortality, appetite, environmental indicators etc. are continuously registered according to the Norwegian legislation.</p> <p>The fish health service conducts at least one health control every month and additional controls in case of increasing mortality, drops in appetite and observed changed behaviour of the fish.</p> <p>Please refer to Annex 3a, 3b and 3b2 for sampling overview, screening results and analysis certificates, respectively.</p>
<p><input type="checkbox"/> Any additional requirements<sup>19</sup></p>	
<p><b>8. Geographical demarcation<sup>20</sup></b></p>	
<p>8.1. Farms or mollusc farming areas covered (registration numbers and geographical situation)</p>	<p>The only farm within the compartment is location 30897 Havsundet owned by Marine Harvest Norway AS.</p> <p>The compartment comprises of a coastal area around Tarva which covers about 5 km from the site in all directions:</p> <ul style="list-style-type: none"> <li>● To the south from Havsundet in Tarvafjorden (coordinate N 63° 45.393' E 9° 28.148').</li> <li>● To the east from Havsundet in Tarvafjorden (coordinate N 63° 47.740' E 9° 32.467').</li> <li>● To the east north-east from Havsundet at the eastside of Været (coordinate N 63° 49.343' E 9° 31.665').</li> <li>● To the north from Havsundet at the north of Været (coordinate N 63° 50.664' E 9° 27.370').</li> <li>● To the west from Havsundet at the west of Karlsøya (coordinate N 63° 46.605' E 9° 21.119').</li> </ul> <p>Please refer to Annex 2 for maps.</p>
	<p>Geographical demarcation<sup>26</sup></p>

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

<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.

8.2. <input type="checkbox"/> Non-free buffer zone <sup>21</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<sup>25</sup></b>		
9.1. <input type="checkbox"/> New farm		
9.2. <input type="checkbox"/> 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	

<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