

**Annexes II-III of Commission Decision 2009/177/EC  
of 31 October 2008  
implementing Council Directive 2006/88/EC as regards surveillance and  
eradication programmes and disease-free status of Member States, zones  
and compartments**

ANNEX II		Model for submission of surveillance programmes for approval and for declarations of surveillance programmes
ANNEX III	Part A	Model for information to be submitted in relation to submissions of surveillance programmes for approval on the epidemiological situation/evolution of the disease in the last four years (one table for each year of implementation)



## ANNEX II

### Model for submission of surveillance programmes for approval and for declarations of surveillance programmes

Requirements/information to be submitted	Information/further explanation and justification
<b>1. Identification of the programme</b>	
1.1. Declaring Member State	Denmark
1.2. Competent authority (address, fax, e-mail)	Danish Veterinary and Food Administration, Stationsparken 31-33, 2600 Glostrup.  Fax: +45 72276501. Phone: +45 72276900. e-mail: tgr@fvst.dk
1.3. Reference of this document	Torben Grubbe
1.4. Date sent to the Commission	30 November 2020
<b>2. Type of communication</b>	
2.1. <input type="checkbox"/> Declaration of surveillance programme	
2.2. <input type="checkbox"/> Application for surveillance programme	
<b>3. National legislation<sup>1</sup></b>	Bekendtgørelse nr. 1451 af 12. december 2019 om overvågning og bekæmpelse af visse smitsomme sygdomme hos akvatiske organismer. Bekendtgørelse nr. 965 af 18. juli 2013 om autorisation og drift af akvakulturbrug, samt om omsætning af akvatiske organismer og produkter heraf. These orders are implementation of Directive 2006/88/EC and the legal base is "Lov om hold af dyr".
<b>4. Diseases</b>	
4.1. Fish	X VHS  <input type="checkbox"/> IHN  <input type="checkbox"/> ISA  <input type="checkbox"/> KHV
4.2. Molluscs	<input type="checkbox"/> <i>Marteilia refringens</i>  <input type="checkbox"/> <i>Bonamia ostreae</i>
4.3. Crustaceans	<input type="checkbox"/> White spot disease

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

<b>5. General information on the programmes</b>	
5.1. Competent authority <sup>2</sup>	<p><b>Danish Veterinary and Food Administration, Glostrup</b></p> <p><b>Team Aquaculture</b>, Danish Veterinary and Food Administration, Veterinary South, Control and Enforcement Office, Vejle.</p> <p>Veterinarians specialized as fish pathologists work in the team. The staff covers the surveillance and monitoring of health and diseases in aquaculture animals in all parts of Denmark.</p> <p>The veterinarians main duties are to carry out health inspections, and sampling for laboratory control of health status of the fish farms. They conduct on annual basis clinical inspection of all fish farms, collect samples of fish for laboratory testing, and provide export certification pertaining to fish diseases. Brood stock farms are inspected twice a year, samples for laboratory tests are taken at each inspection. Between visits, fish farms must keep records of introductions and fish mortalities, which are audited periodically by the veterinarians.</p> <p>Surveillance visits have the following features:</p> <ul style="list-style-type: none"> <li>• Visits are 'unannounced';</li> <li>• The veterinarian inspects each pond/channel, with particular attention to outlet channels, and records findings of abnormal, sick or dead fish;</li> <li>• Sick or dead fish are subjected to post mortem examination at the pond side and samples submitted to the laboratory as appropriate;</li> <li>• Checking of bio-security arrangements (fencing, bird screening and truck loading areas);</li> <li>• Normally, the operator meets with the veterinarian to discuss any significant findings;</li> <li>• Checking of transport vehicles, including records of disinfection, which must be held for each loading of fish.</li> </ul> <p>If the presence of a notifiable disease is suspected, samples are sent to the laboratory (NRL) and official restrictions are placed on the farm.</p>
5.2. Organisation, supervision of all stakeholders involved in the programme <sup>3</sup>	<p><b>Team Aquaculture</b>, Danish Veterinary and Food Administration, Veterinary South, Control and Enforcement Office Vejen are in charge for supervision and coordination for all stakeholders in the programme area.</p>
5.3. An overview of the structure of the	The application goes for marine parts of Denmark. The

<sup>2</sup> A description shall be provided of the structure, competencies, duties and powers of the competent authority involved.

<sup>3</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>aquaculture industry in the area in question including types of production and species kept</p>	<p>area covered is described in the map attached as Annex A.</p> <p>The total number of fish farms in the surveillance programme area is 26 at the start of the programme. They mainly produce rainbow trout for human consumption, but some produce whitefish (<i>Coregonus</i> spp.), brown trout (<i>Salmo trutta</i>), turbot (<i>Scophthalmus maximus</i>) and Atlantic salmon (<i>Salmo salar</i>).</p>
<p>5.4. 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>2 October 1974</p>

<p>5.5. Early detection system in place throughout the Member State, enabling the competent authority to undertake effective disease investigation and reporting since when (date)?<sup>4</sup></p>	<p>2 October 1974</p>
<p>5.6. Source of aquaculture animals of species susceptible to the disease in question entering in the Member State, zone or compartments for farming.</p>	<p>All fish farms in the surveillance programme area are supplied with fish from Danish fish farms in Category I for VHS.</p>
<p>5.7. Guidelines on good hygiene practice<sup>5</sup></p>	<p>As Directive 2006/88 has been implemented the measures outlined in the implemented legislation have to be followed by the stakeholders in relation to prevention and control of disease. This includes that fish farms in the programme zone are only allowed to take in fish, eggs or semen from other farms which are listed in the national register of farm free of VHS or from EU-approved facilities/zones. All fish farms have to be fully covered with net or wires to protect against predating bird thus preventing the introduction infectious agents. Safe handling of dead fish in a way that they not pose any risk of spreading disease.</p>
<p>5.8. Epidemiological situation of the disease in at least the previous four years before the commencement of the programme (<sup>6</sup>)</p>	<p>The last outbreak of VHS in Denmark was confirmed in January 2009 and the whole continental territory of Denmark was approved as VHS-free by the European Union in 2013 (Commission Implementing Decision 2013/7076/EU). All freshwater farms are approved free from VHS (Category I).</p> <p>The saltwater farms has an unknown health status with regard to VHS. These farms has never the less been tested for VHS at least every year. Information is given in the attached Annex III Part A tables for 2016, 2017, 2018 and 2019.</p>

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<sup>4</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.

<sup>5</sup> A description shall be provided in accordance with Article 9 of Directive 2006/88/EC.

<sup>6</sup> Information shall be given using the table laid down in Part A of Annex III. Only applicable to surveillance programmes to be approved by the Commission.

5.9. Description of the submitted programme <sup>(7)</sup>	<p>The main objective of the surveillance programme is to provide the necessary documentation to achieve the status free from VHS in the marine parts of Denmark and thereby the whole country can be declared free from VHS.</p> <p>The surveillance programme will be carried out in accordance with Delegated Regulation (EU) 2020/689 and specifically with the requirements of Section 2. a) i) of Chapter 1 of Part II of Annex VI.</p> <p>The target population is described in 6.7 and area covered is described in 6.1.</p>
5.10. Duration of the programme	1 January 2021 to 31 December 2022.
<b>6. Area covered <sup>(8)</sup></b>	
6.1. <input checked="" type="checkbox"/> Member State	All marine parts. The area covered is described in the map attached as Annex A.
6.2. <input type="checkbox"/> Zone (entire water catchment area) <sup>(9)</sup>	
6.3. <input type="checkbox"/> Zone (part of water catchment area) <sup>(10)</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.	
6.4. <input type="checkbox"/> Zone (more than one water catchment area) <sup>(11)</sup>	

<sup>7</sup> A concise description of the programme shall be given with the main objectives, the main measures, the target population, the areas of implementation and the definition of a positive case.

<sup>8</sup> The area covered shall be clearly identified and described in a map, which must be attached as an Annex to the application.

<sup>9</sup> An entire water catchment area from its sources to its estuary.

<sup>10</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>11</sup> More than one water catchment area, including their estuaries, due to the epidemiological link between the catchment areas through the estuary.

6.5. <input type="checkbox"/> Compartment independent of the surrounding health status <sup>(12)</sup>		
Identify and describe for each farm the water supply <sup>(13)</sup>	<input type="checkbox"/> Well, borehole or spring <input type="checkbox"/> Water treatment plant inactivating the relevant pathogen <sup>(14)</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		
6.6. <input type="checkbox"/> Compartment dependent on the surrounding health status <sup>(15)</sup>		
<input type="checkbox"/> One epidemiological unit due to geographical localisation and distance from other farms/farming areas <sup>(16)</sup>		
<input type="checkbox"/> All farms comprising the compartment fall within a common biosecurity system. <sup>(17)</sup>		
<input type="checkbox"/> Any additional requirements <sup>(18)</sup>		
6.7. Farms or mollusc farming areas covered by the programme (registration numbers and geographical situation)		All marine parts of Denmark.  Data for the farms situated in the surveillance area are found in Annex B.

<sup>12</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>13</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>14</sup> Technical information shall be provided 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>15</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>16</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>17</sup> A description shall be provided of the common biosecurity system.

<sup>18</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.



<b>7. Measures of the submitted programme</b>	
7.1. Summary of the measures under the programme	
<p>First year</p> <p><input checked="" type="checkbox"/> Testing</p> <p><input checked="" type="checkbox"/> Harvesting for human consumption or further processing</p> <p><input type="checkbox"/> Immediate</p> <p><input type="checkbox"/> Delayed</p> <p><input type="checkbox"/> Removal and disposal</p> <p><input type="checkbox"/> Immediate</p> <p><input type="checkbox"/> Delayed</p> <p><input type="checkbox"/> Other measures (specify)</p>	<p>Last year</p> <p><input checked="" type="checkbox"/> Testing</p> <p><input checked="" type="checkbox"/> Harvesting for human consumption or further processing</p> <p><input type="checkbox"/> Immediate</p> <p><input type="checkbox"/> Delayed</p> <p><input type="checkbox"/> Removal and disposal</p> <p><input type="checkbox"/> Immediate</p> <p><input type="checkbox"/> Delayed</p> <p><input type="checkbox"/> Other measures (specify)</p>
7.2. Description of the measures of the programme <sup>(19)</sup>	
Target population/species	The target population is described in 6.7.
Used tests and sampling schemes, Laboratories involved in the programme <sup>(20)</sup>	<p>DTU Aqua, the European Union Reference Laboratory (EURL) for Fish and Crustacean Diseases, will perform all tests in the surveillance programme.</p> <p>The sampling will be done in accordance with the requirements of Section 2. a) i) of Chapter 1 of Part II of Annex VI.</p>
Rules on movements of animals	Movement on animals are at present done in accordance with Council Directive 2006/88/EC, implemented in the Danish Order no. 965 of 18 July 2013.
Measures in case of a positive result <sup>(21)</sup>	In case of a positive result the measures of Danish Order no. 1451 of 12 December 2019, which is the implementation of the relevant rules of Council Directive 2006/88/EC, will be put in place.

<sup>19</sup> A comprehensive description needs to be provided unless reference can be made to Community legislation. The national legislation in which the measures are laid down shall be referred to.

<sup>20</sup> Describe diagnostic methods and sampling schemes. When OIE or EU standards are applied, refer to them. If not, describe them. Name the laboratories involved in the programme (national reference laboratory or designated laboratories).

<sup>21</sup> A description is provided of the measures as regards positive animals (immediate or delayed harvesting for human consumption, immediate or delayed removal and disposal, measures to avoid the spread of the pathogen when harvesting, further processing or removal and disposal, a procedure for the disinfection of the infected farms or mollusk farming areas, a procedure for restocking with healthy animals in farms or farming areas which have been depopulated and creation of surveillance zone around the infected farm or farming area, etc.)

Control and supervision on the implementation of the programme and reporting	The control and supervision on the implementation of the programme will be carried out by the Animal Health Division of the Danish Veterinary and Food Administration.
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*ANNEX III*

**PART A**

**Model for information to be submitted in relation to submissions of surveillance programmes for approval on the epidemiological situation/evolution of the disease in the last four years (one table for each year of implementation)**

**1. Data on testing animals**

Member State, zone or compartment<sup>(a)</sup>

Disease: ...VHS..... Year: .....

Farm or mollusc farming area <sup>(b)</sup>	Number of samplings	Number of clinical inspections	Water temperature at sampling/ inspection	Species at sampling	Species sampled	Number of animals sampled (total and by species)	Number of tests	Positive results of laboratorial examination	Positive results of clinical inspections
<b>TOTAL</b>								<b>TOTAL</b>	

(a) Member State, zone or compartment as defined in Point 6 of Annex II.

(b) When the number of farms/mollusc farming areas is limited or no farms/mollusc farming areas are present in whole or parts of the Member State, zone or compartment subject to the submission, and sampling therefore is carried out in wild populations, the geographical situation of the sampling must be given.

2. Data on testing farms or farming areas

Disease: ..... Year: .....

Member State, zone or compartment <sup>(a)</sup>	Total number of farms or mollusc farming areas <sup>(b)</sup>	Total number farms or mollusc farming areas under the programme	Number of farms or mollusc farming areas checked <sup>(c)</sup>	Number of positive farms or mollusc farming areas <sup>(d)</sup>	Number of new positive farms or mollusc farming areas <sup>(e)</sup>	Number of farms or mollusc farming areas depopulated	% positive farms or mollusc farming areas depopulated	Animals removed and disposed of <sup>(f)</sup>	TARGET INDICATORS		
									% farms or mollusc farming areas coverage	% positive farms or mollusc farming areas period farms or mollusc farming areas prevalence	% new positive farms or mollusc farming areas farms or mollusc farming areas incidence
1	2	3	4	5	6	7	8 =	9	10 = (4/3)x100	11 = (5/4)x100	12 = (6/4)x100
<b>Total</b>											

- (a) Member State, zone or compartment as defined in Point 6 of Annex II.
- (b) Total number of farms or mollusc farming areas existing in the Member State, zone or compartment as defined in Point 6 of Annex II.
- (c) Check means to perform a farm/mollusc farming area level test under the programme for the respective disease with the purpose of upgrading the health status of the farm/mollusc farming area. In this column a farm/mollusc farming area must not be counted twice even if has been checked more than once.
- (d) Farms or mollusc farming areas with at least one positive animal during the period independent of the number of times the farms or mollusc farming areas has been checked.
- (e) Farms or mollusc farming areas in which the health status for the past reporting period was, either category I, category II, category III or category IV in accordance with Part A of Annex III to Directive 2006/88/EC but which have had during this period of reference at least one positive animal for the disease in question.  
In the case of programmes submitted before 1 August 2008, farms or mollusc farming areas which were not positive to the disease in question in the previous period and have at least one positive animal in this period.
- (f) Animals x 1000 or total weight of animals removed and disposed of.