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► **B**

**COMMISSION DECISION**

**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**

*(notified under document number C(2008) 6264)*

**(Text with EEA relevance)**

(2009/177/EC)

(OJ L 63, 7.3.2009, p. 15)

Amended by:

		Official Journal		
		No	page	date
► <b><u>M1</u></b>	Commission Decision 2009/975/EU of 14 December 2009	L 336	31	18.12.2009
► <b><u>M2</u></b>	Commission Decision 2010/171/EU of 22 March 2010	L 75	28	23.3.2010
► <b><u>M3</u></b>	Commission Implementing Decision 2012/753/EU of 4 December 2012	L 334	48	6.12.2012
► <b><u>M4</u></b>	Commission Implementing Decision 2013/706/EU of 29 November 2013	L 322	42	3.12.2013
► <b><u>M5</u></b>	Commission Implementing Decision (EU) 2015/1310 of 28 July 2015	L 200	17	30.7.2015
► <b><u>M6</u></b>	Commission Implementing Decision (EU) 2018/998 of 12 July 2018	L 178	9	16.7.2018
► <b><u>M7</u></b>	Commission Implementing Decision (EU) 2020/1179 of 6 August 2020	L 259	29	10.8.2020
► <b><u>M8</u></b>	Commission Implementing Decision (EU) 2020/2110 of 16 December 2020	L 427	10	17.12.2020

**▼B****COMMISSION DECISION****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***(notified under document number C(2008) 6264)***(Text with EEA relevance)****(2009/177/EC)**

## SECTION 1

**SUBMISSION OF SURVEILLANCE PROGRAMMES AND DISEASE-FREE STATUS DECLARATIONS FOR APPROVAL***Article 1***Conditions for submission of surveillance programmes for approval**

1. Surveillance programmes shall only be submitted for approval, as provided in the first subparagraph of Article 44(1) of Directive 2006/88/EC, if they cover:

- (a) the whole territory of a Member State;
- (b) compartments or groups thereof, comprising more than 75 % of the coastal area of the Member State concerned as regards diseases which only affect salt water species;
- (c) zones and compartments, or groups thereof, comprising more than 75 % of the continental area of the Member State concerned as regards diseases which only affect fresh water species;
- (d) zones and compartments, or groups thereof, comprising more than 75 % of the continental area and coastal area of the Member State concerned as regards diseases which affect both fresh water and salt water species; or
- (e) zones and compartments, which consist of water catchment areas shared with another Member State or third country.

2. For the purpose of this Decision, a compartment or group of compartments of a coastal area shall be considered to cover more than 75 % of the coastal area of a Member State when it covers more than 75 % of the coastline, measured along the baseline of the coast.

*Article 2***Conditions for the submission of disease-free status declarations for approval**

Disease-free status declarations shall only be submitted for approval, as provided for in Article 50(3) of Directive 2006/88/EC, if the declaration complies with one of the conditions set out in Article 1(1) of this Decision.

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## SECTION 2

**LISTS OF MEMBER STATES, ZONES AND COMPARTMENTS  
SUBJECT TO APPROVED SURVEILLANCE AND ERADICATION  
PROGRAMMES AND DISEASE-FREE AREAS***Article 3***Member States, zones and compartments subject to approved  
surveillance programmes**

Member States, zones and compartments subject to a surveillance programme approved in accordance with the first subparagraph of Article 44(1) of Directive 2006/88/EC are listed in the second and fourth column of the table in Part A of Annex I to this Decision as regards the diseases specified in that table.

*Article 4***Member States, zones and compartments subject to approved  
eradication programmes**

Member States, zones and compartments subject to an eradication programme approved in accordance with the first subparagraph of Article 44(2) of Directive 2006/88/EC are listed in the second and fourth column of the table in Part B of Annex I to this Decision as regards the diseases specified in that table.

*Article 5***Disease-free Member States, zones and compartments**

Member States declared disease-free in accordance with Article 49(1) of Directive 2006/88/EC, and zones and compartments declared disease-free in accordance of Article 50(3) of that Directive, are listed in the second and fourth column of the table in Part C of Annex I to this Decision as regards the diseases specified in that table.

## SECTION 3

**MODEL FORMS FOR SUBMISSIONS OF DECLARATIONS AND  
APPLICATIONS***Article 6***Model forms for surveillance programmes**

1. Submissions for the approval of surveillance programmes, as provided for in the first subparagraph of Article 44(1) of Directive 2006/88/EC, shall be in conformity with the model forms set out in Annexes II and III to this Decision.

2. Submissions for declarations of surveillance programmes, provided for in the fourth subparagraph of Article 44(1) of Directive 2006/88/EC, shall be in conformity with the model form set out in Annex II to this Decision.

**▼B***Article 7***Model form for eradication programmes**

Submissions for the approval of eradication programmes, as provided for in the first subparagraph of Article 44(2) of Directive 2006/88/EC, shall be in conformity with the model form set out in Annex V to Decision 2008/425/EC.

*Article 8***Model forms for the submission for disease-free status**

1. Submissions of documentation for the approval of disease-free status, as provided for in Article 49(1) and Article 50(3) of Directive 2006/88/EC, shall be in conformity with the model forms set out in Annexes IV and V to this Decision.
2. Submissions of declarations of disease-free status of zones or compartments, as provided for in Article 50(2) of Directive 2006/88/EC, shall be in conformity with the model forms set out in Annexes IV and V to this Decision.
3. By way of derogation from paragraphs 1 and 2, when disease-free status is to be achieved in accordance with Articles 49(1)(a), (b) or point 1 of Part I of Annex V to Directive 2006/88/EC, Member States shall not be required to submit the model forms set out in Annex V to this Decision.

## SECTION 4

**OBLIGATIONS FOR REPORTS AND INTERNET-BASED INFORMATION***Article 9***Reporting**

By 30 April each year at the latest, Member States shall submit a report to the Commission on:

- (a) surveillance programmes approved in accordance with the first subparagraph of Article 44(1) of Directive 2006/88/EC;
- (b) eradication programmes not subject to Community funding and approved in accordance with the first subparagraph of Article 44(2) of that Directive.

The report shall be in conformity with the model form set out in Annex VI to this Decision.

*Article 10***Internet-based information pages**

1. Member States shall establish and keep up-to-date Internet-based information pages in order to make:
  - (a) declarations of surveillance programmes submitted to the Standing Committee on the Food Chain and Animal Health (the Committee), in accordance with the fourth subparagraph of Article 44(1) and Article 50(2) of Directive 2006/88/EC, accessible to the Commission and the other Member States;

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- (b) declarations of disease-free status submitted to the Committee, in accordance with Article 50(2) of that Directive, accessible to the Commission and the other Member States;
  - (c) publicly available the list of zones or compartments declared subject to an approved surveillance programme or disease-free, in accordance with Article 50(2) of that Directive.
2. When Member States publish on the Internet-based information pages the declarations referred to in points (a) and (b) of paragraph 1, they shall immediately notify the Commission thereof.
  3. Member States shall communicate to the Commission the Internet addresses of the Internet-based information pages provided for in paragraph 1.

## SECTION 5

## TRANSITIONAL PROVISIONS

*Article 11***Transitional provisions as regards disease-free areas**

1. Continental zones recognised as approved with regard to viral haemorrhagic septicaemia (VHS) and infectious haematopoietic necrosis (IHN) by Decision 2002/308/EC and listed in Annex I thereto shall be regarded as zones complying with the requirements for disease-free zones set out in Annex V to Directive 2006/88/EC.
2. Fish farms recognised as approved with regard to VHS and IHN by Decision 2002/308/EC and listed in Annex II thereto shall be regarded as compartments complying with the requirements for disease-free compartments set out in Annex V to Directive 2006/88/EC.
3. Continental zones and fish farms referred to in paragraphs 1 and 2 of this Article shall be included in the list of zones and compartments established in accordance with Article 10(1)(c).
4. By way of derogation from Article 50(2) of Directive 2006/88/EC, Member States shall not be required to submit declarations to the Committee, as regards the continental zones and fish farms referred to in paragraphs 1 and 2 of this Article.

*Article 12***Transitional provisions as regards approved programmes**

1. By way of derogation from Article 44 of Directive 2006/88/EC, Member States shall not be required to submit surveillance and eradication programmes which were approved for the purpose of obtaining approved zone status with regard to:
  - (a) VHS and IHN by Decision 2003/634/EC;
  - (b) bonamiosis and marteiliosis by Decision 94/722/EC.

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2. By 30 April 2009 at the latest, the Member States concerned shall submit to the Commission a report on the programmes referred to in paragraph 1, which shall contain at least:

- (a) information on the geographical demarcation of the programmes;
- (b) the information required under Annex VI for the previous four years of implementation of the programmes.

SECTION 6

**FINAL PROVISIONS**

*Article 13*

**Repeal**

Decisions 2002/300/EC and 2002/308/EC are repealed with effect from 1 August 2009.

*Article 14*

**Application**

This Decision shall apply from 1 November 2008.

*Article 15*

**Addressees**

This Decision is addressed to the Member States.

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## ANNEX I

▼ **M2**

## PART A

## Member States, zones and compartments subject to approved surveillance programmes

Disease	Member State	ISO Code	Geographical demarcation of the area under a surveillance programme (Member State, zones or compartments)
▼ <b>M7</b> Viral haemorrhagic septicaemia (VHS)	Estonia	EE	Whole territory
	Finland	FI	The Province of Åland
Infectious haematopoietic necrosis (IHN)	Estonia	EE	Whole territory except the compartment comprising the fish farm Neli Elementi OÜ (approval No 05/VV/KK01)
▼ <b>M2</b> Koi herpes virus (KHV) disease	► <b>M4</b> ——— ◀	► <b>M4</b> — ◀	► <b>M4</b> ————— ◀
	Hungary	HU	Whole territory
Infectious salmon anaemia (ISA)			
Infection with <i>Marteilia refringens</i>			
Infection with <i>Bonamia ostreae</i>			
White spot disease			

▼ **M3**

## PART B

## Member States, zones and compartments subject to approved eradication programmes

Disease	Member State	ISO code	Geographical demarcation of the area under an eradication programme (Member State, zones or compartments)
Viral haemorrhagic septicaemia (VHS)	► <b>M4</b> ——— ◀	► <b>M4</b> — ◀	► <b>M4</b> ————— ◀
▼ <b>M7</b> _____			
Infectious haematopoietic necrosis (IHN)	Estonia	EE	The compartment comprising the fish farm Neli Elementi OÜ (approval No 05/VV/KK01)
▼ <b>M3</b> Koi herpes virus (KHV) disease	Germany	DE	Land Saxony
	Infection with <i>Marteilia refringens</i>		
	Infection with <i>Bonamia ostreae</i>		
	White spot disease		

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## PART C

Member States <sup>(1)</sup> zones and compartments declared disease-free

Disease	Member State	ISO Code	Geographical demarcation of the disease-free area (Member State, zones or compartments)
Viral haemorrhagic septicaemia (VHS)	Denmark	DK	Whole continental territory
	Ireland	IE	Whole territory
	Cyprus	CY	All continental areas within its territory
	Finland	FI	All continental and coastal areas within its territory, except the Province of Åland
	Sweden	SE	Whole territory
	United Kingdom (Northern Ireland)	UK(NI)	Northern Ireland
Infectious haematopoietic necrosis (IHN)	Denmark	DK	Whole territory
	Ireland	IE	Whole territory
	Cyprus	CY	All continental areas within its territory
	Finland	FI	Whole territory, except the coastal compartment in Ii, Kuivaniemi, and the following water catchment areas: 14.72 Virmasvesi, 14.73 Nilakka, 4.74 Saarijärvi area and 4.41 Pielinen area
	Sweden	SE	Whole territory
	United Kingdom (Northern Ireland)	UK(NI)	Northern Ireland
Koi herpes virus (KHV) disease	Ireland	IE	Whole territory
	United Kingdom (Northern Ireland)	UK(NI)	Northern Ireland
Infectious salmon anaemia (ISA)	Belgium	BE	Whole territory
	Bulgaria	BG	Whole territory
	Czech Republic	CZ	Whole territory
	Denmark	DK	Whole territory
	Germany	DE	Whole territory
	Estonia	EE	Whole territory
	Ireland	IE	Whole territory
	Greece	EL	Whole territory

<sup>(1)</sup> In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, for the purposes of this Annex, references to Member States include the United Kingdom in respect of Northern Ireland.

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Disease	Member State	ISO Code	Geographical demarcation of the disease-free area (Member State, zones or compartments)
	Spain	ES	Whole territory
	France	FR	Whole territory
	Italy	IT	Whole territory
	Cyprus	CY	Whole territory
	Latvia	LV	Whole territory
	Lithuania	LT	Whole territory
	Luxembourg	LU	Whole territory
	Hungary	HU	Whole territory
	Malta	MT	Whole territory
	Netherlands	NL	Whole territory
	Austria	AT	Whole territory
	Poland	PL	Whole territory
	Portugal	PT	Whole territory
	Romania	RO	Whole territory
	Slovenia	SI	Whole territory
	Slovakia	SK	Whole territory
	Finland	FI	Whole territory
	Sweden	SE	Whole territory
	United Kingdom (Northern Ireland)	UK/NI	Northern Ireland
Infection with <i>Marteilia refringens</i>	Ireland	IE	Whole territory
	United Kingdom (Northern Ireland)	UK/NI	Whole coastline of Northern Ireland except Belfast Lough and Dundrum Bay
Infection with <i>Bonamia ostreae</i>	Ireland	IE	The whole coastline of Ireland, except: <ol style="list-style-type: none"> <li>1. Cork Harbour</li> <li>2. Galway Bay</li> <li>3. Ballinakill Harbour</li> <li>4. Clew Bay</li> <li>5. Achill Sound</li> <li>6. Loughmore, Blacksod Bay</li> <li>7. Lough Foyle</li> <li>8. Lough Swilly</li> <li>9. Kilkieran Bay</li> </ol>
	United Kingdom (Northern Ireland)	UK(NI)	Whole coastline of Northern Ireland except Lough Foyle and Strangford Lough
White spot disease			



## 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	
1.2. Competent authority (address, fax, e-mail)	
1.3. Reference of this document	
1.4. Date sent to the Commission	
<b>2. Type of communication</b>	
2.1. <input type="checkbox"/> Declaration for surveillance programme	
2.2. <input type="checkbox"/> Application for surveillance programme	
<b>3. National legislation <sup>(1)</sup></b>	
<b>4. Diseases</b>	
4.1. Fish	<input type="checkbox"/> 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
<b>5. General information on the programmes</b>	
5.1. Competent authority <sup>(2)</sup>	
5.2. Organisation, supervision of all stakeholders involved in the programme <sup>(3)</sup>	
5.3. An overview of the structure of the aquaculture industry in the area in question, including types of production and species kept	
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)?	
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>	

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Requirements/information to be submitted	Information/further explanation and justification
5.6. Source of aquaculture animals of species susceptible to the disease in question entering in the Member State, zone or compartments for farming	
5.7. Guidelines on good hygiene practice <sup>(5)</sup>	
5.8. Epidemiological situation of the disease in at least the previous four years before the commencement of the programme <sup>(6)</sup>	
5.9. Description of the submitted programme <sup>(7)</sup>	
5.10. Duration of the programme	
<b>6. Area covered <sup>(8)</sup></b>	
6.1. <input type="checkbox"/> Member State	
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>	
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 watercourses	
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)	

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Requirements/information to be submitted	Information/further explanation and justification
<b>7. Measures of the submitted programme</b>	
7.1. Summary of the measures under the programme	
First year <input type="checkbox"/> Testing <input type="checkbox"/> Harvesting for human consumption or further processing <input type="checkbox"/> Immediate <input type="checkbox"/> Delayed <input type="checkbox"/> Removal and disposal <input type="checkbox"/> Immediate <input type="checkbox"/> Delayed <input type="checkbox"/> Other measures (specify)	Last year <input type="checkbox"/> Testing <input type="checkbox"/> Harvesting for human consumption or further processing <input type="checkbox"/> Immediate <input type="checkbox"/> Delayed <input type="checkbox"/> Removal and disposal <input type="checkbox"/> Immediate <input type="checkbox"/> Delayed <input type="checkbox"/> Other measures (specify)
7.2. Description of the measures of the programme <sup>(19)</sup>	
Target population/species	
Used tests and sampling schemes. Laboratories involved in the programme <sup>(20)</sup>	
Rules on movements of animals	
Measures in case of a positive result <sup>(21)</sup>	
Control and supervision on the implementation of the programme and reporting	

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- (<sup>1</sup>) National legislation in force applicable to the surveillance programme.
- (<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 authorities in charge of the supervision and coordination of the programme and the different operators involved.
- (<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 of 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.
- (<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.
- (<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.
- (<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 of surrounding natural waters regarding that disease.
- (<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 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.
- (<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 mollusc 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.).

## 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:..... 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
						Total			Total

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

<sup>(b)</sup> 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.

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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 of 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	$8 = (7/5) \times 100$	9	$10 = (4/3) \times 100$	$11 = (5/4) \times 100$	$12 = (6/4) \times 100$
Total											

<sup>(a)</sup> Member State, zone or compartment as defined in Point 6 of Annex II.  
<sup>(b)</sup> Total number of farms or mollusc farming areas existing in the Member State, zone or compartment as defined in Point 6 of Annex II.  
<sup>(c)</sup> 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 it has been checked more than once.  
<sup>(d)</sup> 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 have been checked.  
<sup>(e)</sup> 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.  
<sup>(f)</sup> Animals × 1 000 or total weight of animals removed and disposed of.

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**PART B**

**Model for information to be submitted in relation to submissions for approval of surveillance programmes on targets (one table for each year of implementation)**

**1. Targets related to testing animals**

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

Disease:..... 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
Total							

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

<sup>(b)</sup> 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.

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2. Targets 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 of farms or mollusc farming areas under the programme	Number of farms or mollusc farming areas expected to be checked <sup>(c)</sup>	Number of expected positive farms or mollusc farming areas <sup>(d)</sup>	Number of expected new positive farms or mollusc farming areas <sup>(e)</sup>	Number of farms or mollusc farming areas expected to be depopulated	% positive farms or mollusc farming areas expected to be depopulated	Target indicators		
								Expected % farms or mollusc farming areas coverage	% positive farms or mollusc farming areas Expected period farms or mollusc farming areas prevalence	% new positive farms or mollusc farming areas Expected farms or mollusc farming areas incidence
1	2	3	4	5	6	7	$8 = (7/5) \times 100$	$9 = (4/3) \times 100$	$10 = (5/4) \times 100$	$11 = (6/4) \times 100$
Total										

<sup>(a)</sup> Member State, zone or compartment as defined in Point 6 of Annex II.  
<sup>(b)</sup> Total number of farms or mollusc farming areas existing in the Member State, zone or compartment as defined in Point 6 of Annex II.  
<sup>(c)</sup> 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 it has been checked more than once.  
<sup>(d)</sup> 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 have been checked.  
<sup>(e)</sup> 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.



## ANNEX IV

## Model for submissions of applications for and declarations of disease-free status

Requirements/information needed	Information/further explanation and justification
<b>1. Identification of the programme</b>	
1.1. Declaring Member State	
1.2. Competent authority (address, fax, e-mail)	
1.3. Reference of this document	
1.4. Date sent to the Commission	
<b>2. Type of communication</b>	
2.1. <input 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>	
<b>4. Diseases</b>	
4.1. Fish	<input type="checkbox"/> VHS <input type="checkbox"/> IHN <input 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
<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>	
5.4. <input type="checkbox"/> Targeted surveillance <sup>(5)</sup>	

▼ **B****6. General information**

6.1. Competent authority <sup>(6)</sup>	
6.2. Organisation, supervision of all stakeholders involved in the programme to achieve disease-free status <sup>(7)</sup>	
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	
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)?	
6.5. Early detection system in place throughout the Member State, enabling the competent authority to undertake effective disease investigation and reporting since when (date)? <sup>(8)</sup>	
6.6. Source of aquaculture animals of species susceptible to the disease in question entering in the Member State, zone or compartments for farming	
6.7. Guidelines on good hygiene practice <sup>(9)</sup>	

**7. Area covered**

7.1. <input type="checkbox"/> 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>	<input type="checkbox"/> Well, borehole or spring <input type="checkbox"/> 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 watercourses	

**▼ B**

7.6. <input type="checkbox"/> Compartment dependent on the surrounding health status <sup>(16)</sup>		
<input type="checkbox"/> One epidemiological unit due to geographical localisation and distance from other farms/farming areas <sup>(17)</sup>		
<input type="checkbox"/> All farms comprising the compartment fall within a common biosecurity system <sup>(18)</sup>		
<input type="checkbox"/> Any additional requirements <sup>(19)</sup>		
<b>8. Geographical demarcation <sup>(20)</sup></b>		
8.1. Farms or mollusc farming areas covered (registration numbers and geographical situation)		
8.2. <input type="checkbox"/> Non-free buffer zone <sup>(21)</sup>	Geographical demarcation <sup>(19)</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>(19)</sup>	
	Farms or mollusc farming areas covered (registration numbers, geographical situation and health status <sup>(15)</sup> )	
8.4. <input type="checkbox"/> Extension of disease-free zone to other Member States <sup>(24)</sup>	Geographical demarcation <sup>(19)</sup>	
8.5. <input type="checkbox"/> Existing disease-free zones/ compartments in the vicinity	Geographical demarcation <sup>(19)</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	<input type="checkbox"/> 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	

## ▼B

- (<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 or 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 I.1 of Annex V to Directive 2006/88/EC. This ground for disease-free status must be declared or applied for by 1 November 2008. Provide detailed information on the compliance with Part I.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 rear 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.
- (<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 of 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.
- (<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.
- (<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.
- (<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.

ANNEX V

**Model for information to be submitted in relation to submissions of applications for and declarations of disease-free status (one table for each year of implementation)**

**1. Data on testing animals**

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

Disease:..... 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
Total								Total	

<sup>(a)</sup> Member State, zone or compartment as defined in point 7 of Annex IV.

<sup>(b)</sup> 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 application or declaration, and sampling therefore is done in wild populations, the geographical situation of the sampling should be given.



ANNEX VI

MODEL REPORT

1. Report related to testing of animals

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

Disease:..... 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
Total								Total	

<sup>(a)</sup> Member State, zone or compartment as defined in point 6 of Annex II.

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

▼B

2. Report 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 of 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	$8 = (7/5) \times 100$	9	$10 = (4/3) \times 100$	$11 = (5/4) \times 100$	$12 = (6/4) \times 100$
Total											

<sup>(a)</sup> Member State, zone or compartment as defined in point 6 of Annex II.  
<sup>(b)</sup> Total number of farms or mollusc farming areas existing in the Member State, zone or compartment as defined in point 6 of Annex II.  
<sup>(c)</sup> 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 it has been checked more than once.  
<sup>(d)</sup> 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 have been checked.  
<sup>(e)</sup> 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.  
<sup>(f)</sup> Animals × 1 000 or total weight of animals removed and disposed of.