Annexes II-VI of Commission Decision 2009/177/EC 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
1. Identification of the programme	
1.1. Declaring Member State	Finland
1.2. Competent authority (address, fax, e-mail)	Finnish Food Safety Authority Evira Mustialankatu 3, FIN- 00790 Helsinki FINLAND
1.3. Reference of this document	Evira/1739/0512/2011
1.4. Date sent to the Commission	March 17th 2011
2. Type of communication	
2.1. x Declaration of disease-free status : Uusikaupunki-Pyhäranta-Rauma coastal compartment 2.2. □ Submission of application for disease-free-status	
3. National legislation[1]	The aquatic animal health rules are based on the Act on Animal Diseases (55/1980, several amendments). It covers both farmed and wild fish, all species. The most important legislative measures, which are all based on the abovementioned Act, are: - The Statute on Animal Diseases (601/1980) - The Statute on Animal Transports (1363/1994) - The Decision on Animal Diseases to be Combated and Disease Notification (1346/1995) - The Statute to combat VHS in the Uusikaupunki, Pyhäranta and Rauma restriction zone (452/2003) - The Decision of the register of farms of the aquatic animals (212/1996) - The Statute to combat animal diseases in fish, crustaceans and molluscs (470/2008)
4. Diseases	
4.1. Fish	x VHS □ IHN

[1] National legislation in force applicable to the declaration of and application for disease-free status.

	□ ISA □ KHV
4.2. Molluscs	□ infection with *Marteilia refringens* □ infection with *Bonamia ostreae*
4.3. Crustaceans	□ White spot disease

5. Grounds for disease free-status	
5.1. □ No susceptibles[2]	
5.2. □ Pathogen not viable[3]	
5.3. □ Historic free-status[4]	
5.4. x Targeted surveillance[5]	Fish to be sampled for VHS were selected twice per year when the water temperature was below 14°C. At minimum 30 fishes (in various age, and from various ponds and tanks) were collected for sampling. If weak, abnormally behaving or freshly dead (not decomposed) fish were present, primarily such fish were selected. Samples of fish were sent to Evira, the reference laboratory for VHS in Finland. Samples of fish were examined in accordance with the diagnostic methods specified in Commission Decision (2001/183/EC) of 22 February 2001 laying down the sampling plans and diagnostic methods for the detection and confirmation of certain fish diseases and repealing Decision 92/532/EEC. Due to yeast contamination in BF-2 and EPC cell lines in December 2011 in Evira national reference laboratory, it was not possible to follow all parts of diagnostics methods included in the Commission Decision/manual including prolonged freezing period and freezing/thawing . The sensitivity of tests might have been lowered due to the freezing/thawing process but Evira is convinced that the test results are reliable because IPNV was isolated twice from samples frozen at –80 °C and thawed twice. The EU reference laboratory in Denmark was contacted and according to them IPNV does not tolerate the freezing as well as VHSV and the sensitivity for this examination is lowered more for IPNV than it is for VHSV and IHNV in the same circumstances

2 Applicable if none of the species susceptible to the disease(s) in question is present in the Member State, zone or compartment, and where relevant in its water source.

3 Applicable if the pathogen is known not to be able to survive in the Member State, zone or compartment, and where relevant in its water source. Provide the scientific information supporting the inability of the pathogen to survive in the Member State, zone or compartment.

4 Applicable if susceptible species are present, but where there has not been any observed occurrence of the disease for at least a period of 10 years before the date of declaration of 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 of 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.

5 Applicable if targeted surveillance complying with Community requirements has been in place for at least a period of two years without the detection of the disease agent on farm, or in mollusc farming areas that rears any of the susceptible species.
Where there are parts of the Member State, zone or compartment in which the number of farms or mollusc farming areas is limited, but in which there are wild populations of susceptible species, information on the targeted surveillance in those wild populations shall be given.

6. General information		
	6.1. Competent authority[6]	The chain of command regarding animal disease control is staged at three levels: national, provincial and municipal. The Unit for Animal Health and Welfare of the Ministry of Agriculture and Forestry is the central competent authority. The Unit has three objectives: • Strategic leadership • Effective input/output at the international level • Development of new legislation Day-to-day responsibilities are delegated to Evira. Within Evira, the Animal Health and Welfare Unit has, in the area of animal health responsibility for: • Prevention of animal diseases • Organisation and implementation of animal health controls • Contingency planning • Control of animal diseases • Training and delivery of information on animal health • Compilation of statistics and other executive tasks The Research Department of Evira together with its three regional laboratories (Seinäjoki, Kuopio and Oulu) provides laboratory services. All laboratory investigations for VHS are carried out at Evira, the national reference laboratory. The provincial veterinary officers are responsible for controls within their territories. Municipal veterinary officers are responsible for carrying out animal health controls at holdings. Municipal Veterinary Officers report directly to the provincial veterinary officers on animal health matters. All veterinarians whether official or private, must inform the provincial veterinary officers if a notifiable animal disease is suspected. In addition, the animal and holding must be placed under restrictions pending investigation. Most notifiable diseases like VHS must be reported immediately to the provincial veterinary officer or Evira.
	6.2. Organisation, supervision of all stakeholders involved in the programme	Evira has coordinated the program and supervised provincial veterinary officer in charge. Provincial veterinary officer has ordered municipal veterinarians to carry out the clinical inspections and samplings in the farms

Describe diagnostic methods and sampling schemes. When OIE or EU standards are applied, reference must be made to them. If not, describe them. Name the laboratories involved in the programme (National reference laboratory or designated laboratories).

[6] A description shall be provided of the structure, competencies, duties and powers of the competent authority involved.

	to achieve disease free status [7]	in question. The samples have been analysed in Evira.
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	Aquaculture farms in Uusikaupunki-Pyhäranta-Rauma –area are mostly net cage farms in brackish water, but there are also 2 brackish water ponds/enclosures. Ten of the farming sites produce big (> 1 kg) rainbow trout for consumption. One farm produces sturgeon and whitefish for consumption. There are no brood fish at the farms. There are 3 processing plants in the restriction zone where the fish are eviscerated before leaving the area. Processing plants are connected to the municipal sewage water system. Rantamaan lohi owns a storage pond (Meri-Ihamo) and two net cage farming sites (Sasinklopit, Planeetti) which operate as one epidemiological unit. Sites Sasinklopit and Planeetti are used in summer months when the water temperature is mostly over 14°C. Fish are kept in storage pond in spring , late autumn and winter, and the samples have been taken from there. Mannerlohi owns 7 farming sites and farms only rainbow trout for food consumption. Pullonkari is a land based pond which use brackish water. Hulmakari is a winter storage place. The others are net cage farms in brackish water. Most of the farms are empty every winter for 4 to 6 months or at least fallowed for a shorter period annually. VHS-virus was detected in October 2008 in Pyhäsalmi net cage. The farm was emptied soon after detection and the infection has not been found ever since. Salmisen kalankasvattamo produces mainly sturgeon, but also some whitefish in land based ponds which use brackish water.
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)?	The notification of VHS as an easily spreading animal disease has been compulsory since 1980, (Act on Animal diseases 55/1980).

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

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)?[8]	An early detection system for fish diseases, including VHS in farmed and wild animals and ornamental animals, has been in place since 1980. (a) A broad awareness of fish diseases is gained by communications and lecturing. National seminar on fish health for fish farmers and other stake holders is organised by Evira each year. A lecture / demonstration in the Helsinki University, Faculty of Veterinary Medicine and Faculty of Biosciences is also organised each year. Furthermore, Evira writes articles of fish diseases in farming press. (b) Veterinarians are trained in recognising fish diseases on the average every 3rd year. Last time Evira organised 7 training days for veterinarians in 2008. Some veterinarians also attend to national fish health seminar held annually. The fish diseases section in the operations manual related to contingency planning for provincial veterinarians was completed in 2011. (c) Evira is the national reference laboratory for VHS
6.6. Source of aquaculture animals of species susceptible to the disease in question entering in the Member State, zone or compartments for farming.	Aquaculture animals in the area in question originate only from approved farms located in continental Finland which is declared VHS free. All stocks entering the compartment must have a health certificate.
6.7. Guidelines on good hygiene practice[9]	The Act on Animal Diseases (55/1980, amendment 408/2008) requires that almost all operating fish farming companies have to apply for health authorisation from Finnish Food Safety Authority (Evira). Exceptions are small scale farms that do not supply living fish. The application must include a description of the health control system of the company and each of its farms. By being authorised you are required, as the business owner or operator, to meet the minimum record keeping and biosecurity standards. Turbin-project (Biosecurity to control biorisks in aquaculture) was launched aiming to help aquaculture companies to record procedures in aquaculture management. As a tool for fish farmers a free computer program "Merta" was developed for farm data recording (fish movements (traceability) mortality, medicine record book etc).The project was run by Evira and the Finnish Game and Fisheries Research Institute and funded through European Fishery Fund (EFF).
7. Area covered	

[8] The early detection systems shall in particular ensure the rapid recognition of any clinical signs consistent with the suspicion of a disease, emerging disease, or unexplained mortality in farms or mollusc farming areas, and in the wild, and the rapid communication of the event to the competent authority with the aim to activating diagnostic investigation with minimum delay. The early detection system shall include at least the following:
(a) broad awareness, among the personnel employed in aquaculture businesses or involved in the processing of aquaculture animals, of any signs consistent with the presence of a disease, and training of veterinarians of aquatic animals health specialists in detecting and reporting unusual disease occurrence;
(b) veterinarians or aquatic animal health specialists trained in recognising and reporting suspicious disease occurrence;
(c) access by the competent authority to laboratories with the facilities for diagnosing and differentiating listed and emerging diseases.

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

7.1. □ Member State	
7.2. □ Zone (entire water catchment area)[10]	
7.3. □ Zone (part of water catchment area)[11] Identify and describe the artificial or natural barrier that delimits the zone and justify its capability to prevent the upward migration of aquatic animals from the lower stretches of the water catchment area.	
7.4. □ Zone (more than one water catchment area)[12]	

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

11 Part of a water catchment area from the source(s) to a natural or artificial barrier that prevents the upward migration of aquatic animals from the lower stretches of the water catchment area.

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

7.5. □	Compartment independent of the surrounding health status[13]		
	Identify and describe for each farm the water supply[14]	□ Well, borehole or spring □ Water treatment plant inactivating the relevant pathogen[15]	
	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. x	Compartment dependent on the surrounding health status[16] Uusikaupunki-Pyhäranta-Rauma coastal compartment comprises a coastal area (45x60 km) situated in the Gulf of Bothnia in the south-western Finland (see the maps). This coastal compartment covers the fish farms in the municipalities of Uusikaupunki, Pyhäranta and Rauma and some minor water sources (no farms) draining to that area. There are 3 operating fish farming companies with 11 farming sites. Many of the sites are used only in summer/early autumn. Finnish inland waters received VHS-free status in autumn 2005 and coastal waters in spring 2007. The area surrounding this compartment is VHS free (EC /177/2009)		
	One epidemiological unit due to geographical localisation and distance from other farms/farming areas[17]		
□	All farms comprising the compartment fall within a common biosecurity system.[18]		
□	Any additional requirements[19]		

[13] Compartments comprising one or more farms or mollusc farming areas where the health status regarding a specific disease is independent of the health status regarding that disease of surrounding natural waters.

[14] A compartment which is independent of the health status of surrounding waters, shall be supplied with water:
(a) through a water treatment plant inactivating the relevant pathogen in order to reduce the risk of the introduction of the disease to an acceptable level; or
(b) directly from a well, a borehole or a spring. Where such water supply is situated outside the premises of the farm, the water shall be supplied directly to the farm, and be channelled through a pipe.

[15] Provide technical information to demonstrate that the relevant pathogen is inactivated in order to reduce the risk of the introduction of the disease to an acceptable level.

[16] Compartments comprising one or more farms or mollusc farming areas where the health status regarding a specific disease is dependent on the health status of surrounding natural waters regarding that disease.

[17] A description shall be provided of the geographical localisation and the distance from other farms/farming areas that makes it possible to consider the compartment as one epidemiological unit.

[18] A description shall be provided of the common biosecurity system.

[19] Each farm or mollusc farming area in a compartment which is dependent on the health status of surrounding waters shall be subject to additional measures imposed by the competent authority, when considered necessary to prevent the introduction of diseases. Such measures may include the establishment of a buffer zone around the compartment in which a monitoring programme is carried out, and the establishment of additional protection against the intrusion of possible pathogen carriers or vectors.

8. Geographical demarcation [20]	
8.1. Farms or mollusc farming areas covered (registration numbers and geographical location)	1) Rantamaan Lohi Ay Processing plant / Meri-Ihamo Reg. number: 139-1 Geographical location: N 6779647 E 3191444 2) Rantamaan Lohi Ay Land-based pond / Meri-Ihamo Reg. number: 139-2 Geographical location: N 6779647 E 3191444 3) Rantamaan Lohi Ay Planeetti Reg number : 139-3 Geographical location N 6780106 E 3187441 4) Rantamaan Lohi Ay Sasi Reg number 139-4 Geographical location: N 6780893 E 3188454 5) Mannerlohi Oy Humalkari Reg number: 112-1 Geographical location: N 6746540 E 3191011 6) Mannerlohi Oy Hylkimys Reg number: 112-2 Geographical location: N 6748946 E 3188323 7) Mannerlohi Oy Pyhäsalmi Reg number: 112-3 Geographical location: N 6774361 E 3191925 8) Mannerlohi Oy Pujo Reg number: 112-4 Geographical location: N 6779755 E 3190177 9) Mannerlohi Oy Huhtakari Reg number: 112-5 Geographical location: N 6779054 E 3192805 10) Mannerlohi Oy Pullonkari Reg number: 112-6 Geographical location: N6770761 E 3186655 11) Mannerlohi Oy Ketteli Reg number: 112-7 Geographical location: N 6776976 E 3194106

[20] The geographical demarcation shall be clearly described and identified on a map, which must be attached as an Annex to the declaration/application. Any substantial modification in the geographical demarcation of the zone or compartment to be declared free must be subjected to a new application.

			12) Mannerlohi Oy processing plant Reg number: 112-8 Geographical location: N 6777493 E 3193025 13) Salmisten kalankasvattamo Tiiraletto / Lintuluoto and processing plant Reg number: 02-039 Geographical location: N 6773089 E 3191469
8.2.	□	Non-free buffer zone[21]	Geographical demarcation[26]	
			Farms or mollusc farming areas covered (registration numbers, geographical location and health status[22])	
			Type of health surveillance	
8.3.	□	Non-free zones or compartments [23]	Geographical demarcation[26]	
			Farms or mollusc farming areas covered (registration numbers geographical location and health status[22])	
8.4.	□	Extension of disease-free zone to other Member States[24]	Geographical demarcation[26]	

21 In connection with a zone or a compartment dependent on the health status of surrounding waters, a buffer zone in which a monitoring programme is carried out shall be established, as appropriate. The demarcation of the buffer zones shall be such that it protects the disease-free zone from passive introduction of the disease. (Part II.1.5 of Annex V to Directive 2006/88/EC).

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

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

24 Where a zone extends to more than one Member State, it may not be declared a disease-free zone unless the conditions set out in points 1.3, 1.4, and 1.5 of Part II of Annex V to Directive 2006/88/EC apply to all areas of that zone. In that case both Member States concerned shall apply for approval for the part of the zone situated in their territory.

8.5. □ Existing disease-free zones/ compartments in the vicinity.	Geographical demarcation[26]	Finland is free from VHS, except the municipalities of Uusikaupunki, Pyhäranta and Rauma and the province of Åland.
	Farms or mollusc farming areas covered (registration numbers and geographical location)	
9. Farms or mollusc farming areas which commence or recommence their activities[25]		
9.1. □ New farm		
9.2. □	□ Health history of farm known to Competent authority	
	□ Not subject to animal health measures in respect of listed diseases	
	□ Farm cleaned, disinfected and, as necessary, fallowed	

[25] 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: RT=rainbow trout, WT=whitefish

Member State, zone or compartment[(a)] Uusikaupunki-Pyhäranta-Rauma coastal compartment

Disease: ……VHS…….. Year: ……2010……..

Farm or mollusc farming area[(b)]	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
Rantamaan Lohi, Meri-Ihamo, Planeetti (02-011), Sasinklopit (02-012)	2	2	< 14 °C	RT	RT	60	6	NO	NO
Mannerlohi, Huhtakari (02-096)	1	2 (2. inspection farm was empty)	< 14 °C	RT	RT	30	3	NO	NO
Mannerlohi, Pullonkari (02-029)	2	2	< 14 °C	RT	RT	60	6	NO	NO
Mannerlohi, Pujo (02-097)	2	2	< 14 °C	RT	RT	60	6	NO	NO
Mannerlohi, Humalkari (02-036)		1 Empty winter storage place					6	NO	NO
Mannerlohi, Hylkimys (02-037)	2	2	< 14 °C	RT	RT	60	6	NO	NO
Mannerlohi, Ketteli (former Esan Kala) (02-050)	2	2	< 14 °C	RT	RT	60	6	NO	NO
Mannerlohi, Pyhäsalmi (02-051)	4	2	< 14 °C	RT	RT	80	8	NO	NO
Salmisten Kalankasvattamo (02-039)	2	2	< 14 °C	WT, sturgeon	WT	60	6	NO	NO

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

(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 application or declaration, and sampling therefore is done in wild populations, the geographical location of the sampling should be given.

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[(a)] Uusikaupunki-Pyhäranta-Rauma coastal compartment

Disease: ……VHS…….. Year: ……2009……..

Farm or mollusc farming area[(b)]	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
Rantamaan Lohi, Meri-Ihamo, Planeetti (02-011), Sasinklopit (02-012)		empty							
Mannerlohi, Huhtakari (02-096)	2	2	< 14 °C	RT	RT	60	6	NO	NO
Mannerlohi, Pullonkari (02-029)	2	2	< 14 °C	RT	RT	60	6	NO	NO
Mannerlohi, Pujo (02-097)	2	2	< 14 °C	RT	RT	60	6	NO	NO
Mannerlohi, Humalkari (02-036)	2	2	< 14 °C	RT	RT	60	6	NO	NO
Mannerlohi, Hylkimys (02-037)	2	2	< 14 °C	RT	RT	60	6	NO	NO
Mannerlohi, Ketteli (former Esan Kala) (02-050)	2	2	< 14 °C	RT	RT	30	6	NO	NO

Mannerlohi, Pyhäsalmi (02-051)	2	2	< 14 °C	RT	RT	60	6	NO	NO
Salmisten Kalankasvattamo (02-039)	2	2	< 14 °C	STURGEON, WF, RT	WF, RT	Total 60 30 WF, 30 RT	6	NO	NO

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

(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 application or declaration, and sampling therefore is done in wild populations, the geographical location of the sampling should be given.

Appendix 1. Uusikaupunki, Pyhäranta, Rauma restriction zone in Finland.

Uudenkaupungin, Pyhärannan ja Rauman kunta sekä
vesistöalueet 82.030, 82.031, 32, 82.0 ja 83.001-83.005
Länsi-Suomen lääni
© Genimap Oy, Lupa L4388/01
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20 km

Appendix 2. Farms in the restriction area