

EN

SANCO/1165/2001 Rev. 6 (PVET/2001/EN/1165R6.doc)



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate E - Food Safety: plant health, animal health and welfare, international questions
E2 - Animal health and welfare, zootechnics

Brussels,
(PVET/2001/EN/1165R6.doc)

WORKING DOCUMENT

APPLICATION FORM, CHECKLIST AND GUIDELINES

for obtaining Community status of approved farm in non-approved zone with regard to viral haemorrhagic septicaemia (VHS) and/or infectious haematopoietic necrosis (IHN)

This document does not necessarily represent the views of the Commission Services

Farm:

Requirements ⁵ , information needed	(To be filled in by the Local Official Service)	(To be filled in by the Central Official Service of the MS)		Observations
	Data and information about the farm, observations	Requirements fulfilled ⁶		
		YES	NO	
1. <u>Geographical data</u>				
2. <u>Plan of the facility</u>				
3. <u>Structure of and production at the farm, species present</u> (details also to be completed in Table 1)				
4. <u>Source of eggs, gametes and/or fish</u> (summary to be completed in Table 2)				
5.1 <u>Water source/inlet</u>				
5.2 <u>Outlet and barriers</u>				
5.3 <u>If deemed necessary, protection against flooding and infiltration</u> (basic data, see p. 2)				
6. <u>Additional measures</u>				

⁵ With reference to requirements of: Directive 91/67/EEC; Decision 2001/183/EC; and Directive 93/53/EEC (as amended) and the guidelines of working document SANCO 2001/1165 R6.

⁶ As relevant, with reference to information needed and recommendations given in the guidelines of working document SANCO 2001/1165 R6 - necessary data available and/or recommendations fulfilled

Farm:

Requirements ⁵ , information needed	(To be filled in by the Local Official Service)	(To be filled in by the Central Official Service of the MS)		
	Data and information about the farm	Requirements fulfilled ⁶		Observations
		YES	NO	
<p>7.1 <u>Existing farm, Model A – Clinical</u> A) <u>status, surveillance, history base, model for approval etc.</u> (Directive 91/67/EEC, Annex C & Annex B.I.B; Decision 2001/183/EC, Part II.2.1.a) (details to be completed in Table 1)</p>				
<p>7.1 <u>Existing farm, Model B – Clinical</u> B) <u>status, surveillance, history base, model for approval etc.</u> (Directive 91/67/EEC, Annex C & Annex B.I.B; Decision 2001/183/EC, Part II.2.1.b) (details to be completed in Table 1)</p>				
<p>7.2 <u>New farms only introducing</u> A) <u>approved stock</u> (Directive 91/67/EEC, Annex C, I.A.6a or II.A.3a) (also Table 2 to be completed)</p>				
<p>7.2 <u>Farms which recommence its</u> B) <u>activities with approved stock following disinfection</u> (Directive 91/67/EEC, Annex C, I.A.6b or II.A.3b) (also Table 2 to be completed)</p>				

Farm:

Requirements ⁵ , information needed	(To be filled in by the Local Official Service)	(To be filled in by the Central Official Service of the MS)		
	Data and information about the farm	Requirements fulfilled ⁶		Observations
		YES	NO	
8. National rules related to approval of the farm (Directive 91/67/EEC, Article 6.1, first indent and Annex C, I.A & II.A); Decision 2001/183/EC, Part I.I.1; I.I.2.1.a; I.I.2.1.b and I.I.2.2; Directive 93/53/EEC, Article 9)				
9. National rules for maintenance of approval; suspension, restoration and withdrawal of approval (Special reference to: Directive 91/67/EEC Article 6.1, second indent and Annex C, I. B & I. C & II. B & II. C; Decision 2001/183/EC, Part I.I.2.3; Directive 93/53/EEC, Article 9)				
10. Miscellaneous				
11. Conclusion by and signature of the Local Official Service	<p> <input type="checkbox"/> The farm fulfils all requirements for approval with regard to VHS* and/or IHN* <input type="checkbox"/> The farm does NOT fulfil the requirements for approval with regard to VHS* and/or IHN* The farm has been under official supervision since * (delete as relevant) Date: Signature: <div style="text-align: right;">Local Official Service</div> </p>			

Table 1* Data on inspections, sampling and analysis carried out on farm:..... *(With reference to point 7.1.A-B)

Date of clinical inspection	Date of sampling	Water temp at inspection /sampling	Fish species present at the sampling	Fish species sampled	Number of fish sampled (total & by species)	Laboratory carrying out the analysis	Results of clinical examination	Results of virological examination for VHS and IHN

CHECKLIST AND GUIDELINES¹

for obtaining Community status of approved farm in non-approved zone with regard to viral haemorrhagic septicaemia (VHS) and/or infectious haematopoietic necrosis (IHN)

Requirements ¹ , information needed and recommendations	
1.	<p><u>Geographical data</u></p> <p><i>Information needed:</i> Adequate mapping showing where in the MS the facility is located (down to more detailed maps showing the region, neighbourhood to known towns) and what the surrounding natural waters/catchment areas and farms are, including the status of zones/ farms (approved/programme in place/unknown/infected).</p>
2.	<p><u>Plan of the facility</u></p> <p><i>Information needed:</i> Clear and exact plan of the facility which should be based on the official land register property drawings or aerial photographs which reflect (within a reliable scale) the distribution, number and appearance of the facility's units (including details related to in point 5.1-5.3 - hatchery, ponds, borehole and/or spring, outlet etc.). A corresponding plan, preferably with scale and topographic data (if any) of the immediate neighbourhood, including any other fish farms in the area of concern.</p> <p><i>Recommendation:</i> Photos of the facility of concern, especially focused on the water supply, in- and outlet, barriers, etc.</p>
3.	<p><u>Structure of and production at the farm, species present</u> (Table 1 to be completed)</p> <p><i>Information needed:</i></p> <ul style="list-style-type: none">- <i>brief</i>, general description of the farm, production, species etc.- details on the structure at the time for inspections/sampling

¹ With reference to requirements of: Directive 91/67/EEC; Decision 2001/183/EC; and Directive 93/53/EEC (as amended) - in relation to approval of the farm with regard to VHS and/or IHN; maintenance; suspension; restoration; and withdrawal of the approval; Table 1 and 2, see application form of working document SANCO 2001/1165 R6.

Requirements¹, information needed and recommendations

4. **Source of eggs, gametes and/or fish** (Table 2 to be completed)

Information needed - if not own broodstock:

- status of the source of eggs, gametes and/or fish
- official movement documents on all eggs, gametes and fish introduced during a relevant risk period (see below); the movement documents must be carefully evaluated by the Local and Central Official Services of the MS;
- only a summarising list (table 2) of the main data of the introduced stock and its status is needed in the application to the Commission.

Recommendation: It shall be officially certified that all eggs, gametes and fish introduced to the farm of concern originates from approved farms or zones, at least during the following periods: during the last four years before approval; or during its whole earlier operation period if it is less than four years and a restocking farm; or from its start if a new farm; or during the application of an official programme aiming to achieving approved status.

5.1 **Water source/inlet** - Water must be supplied by a **well, a borehole or a spring**

Where such water supply is situated at a distance from the farm, the water must be supplied directly to the farm, and be channeled through a pipe or, with the agreement of the official service, via an open channel or a natural conduit, provided that this does not constitute a source of infection for the farm and does not allow the introduction of wild fish. The water channel must be under the control of the farm or, in cases where this is not possible, the official service.

Information needed: Description of the water source, fish present including wild species.

5.2 **Outlet** - There must be a **natural or artificial barrier situated downstream which prevents fish from entering the farm***

Information needed: Data on height of barrier/s, size of any mesh, eventual height difference to the downstream, water level etc.

**Clarification:* The barrier shall also prevent fish from downstream reaching in front of the inlet. The barrier can be situated within the farm.

5.3. **Protection against flooding and infiltration** - **If necessary**, the farm must be protected against flooding and infiltration of water. (basic data to be given in point 2)

Recommendation: Protection is needed especially if the farm is located near a larger watercourse, in a flood plain, etc.

Requirements¹, information needed and recommendations

6. Additional measures

The farm may be the subject of **additional measures** imposed by the official service, **when considered necessary to prevent the introduction of diseases**.

Such measures **may include** the establishment of a **buffer zone** around the farm in which a monitoring programme is carried out, and the establishment of **protection against the intrusion of possible pathogen carriers or vectors**.

Information needed: Arrangements in place for protecting the farm from the possibility of contamination from: predators, birds etc. (i.e. is the farm covered by netting or wire?); the general public (do anglers have access?); distances to farm/s of unknown status/infected.

Recommendation: High bio-security level should be maintained. Ponds with susceptible species should be covered – justification if not – or be located at a safe distance from non-approved farms. Uncontrolled public access should be prevented. The site must not be used for angling purposes unless under conditions authorised and supervised by the Local Official Services.

7.1 Existing farms (not new or recommencing with approved stock following disinfection): Clinical status, surveillance, history base and model for approval etc.

(Special reference to Annex C & Annex B.I.B of Directive 91/67/EEC and Decision 2001/183/EC).

All fish **must be free for at least four years from any clinical or other sign** of one or both diseases. The farm must be placed under the **supervision of the official services**. **Two health inspections per year for two years** must have been carried out at the times of the year **when the water temperature favours the development of these diseases**. The health inspection must at least consist of:

- an **inspection of fish showing abnormalities**,
- the **taking of samples in accordance with a programme as established by a Commission Decision (Decision 2001/183/EC)** which are to be sent as quickly as possible to an **approved laboratory to be tested** for the pathogens in question. Requirements in **Model A or B of Decision 2001/183/EC shall be fulfilled**. (see below)

Information needed:

Summary of the inspections, sampling and examinations carried out (Model A; B), laboratory and diagnostic methods used etc:

- Information to be **completed in point 7.1.A or 7.1.B**
- Information on details, **Table 1 to be completed!**

Requirements¹, information needed and recommendations

7.1.A **Model A** (Decision 2001/183/EC, Part I.I.2.1.a) (Details to be completed in Table 1)

Following at least two years of absence of any clinical or other sign of VHS and/or IHN, all farms in the zone or any farm in a non-approved zone which are to be approved must be **health inspected twice per year for two years**. During this two-year control period, which precedes achievement of approved status, the absence of clinical or other signs of VHS and/or IHN must have continued and **samples** must be collected for examination in accordance with **Table 1A**. Further, the samples must be selected, prepared and examined as described in **Part I.I–I.IV** and the laboratory examinations must have produced **negative results for VHS and/or IHN.**”

7.1.B **Model B** (Decision 2001/183/EC, Part I.I.2.1.b and III) (Details to be completed in Table 1)

“**Following** an official health inspection programme documenting the **historical freedom** from VHS and/or IHN for at least **four years**, all farms in the zone or any farm in a non-approved zone which are to be approved must be **health inspected twice per year for two years**. During this two-year control period, which precedes achievement of approved status, the absence of clinical or other signs of VHS and/or IHN must have continued and **samples** must be collected for examination in accordance with **Table 1B**. Further, the samples must be selected, prepared and examined as described in **Part I.I–I.IV** and the laboratory examinations must have produced **negative results for VHS and/or IHN**. In order that a health inspection programme might be recognised by the official services for documentation of freedom with regards to VHS and/or IHN, it must fulfil the criteria and guidelines set out in **Part III.**”

Part III of Decision 2001/183/EC: Guidelines and criteria for an official health inspection programme

1. A health inspection programme can only be initiated either after an officially recognised eradication programme for VHSV and/or IHNV including removal of all fish in the farm, cleaning, disinfection and fallowing before restocking with fish from approved farms or on fish farms with no history of VHSV or IHNV infection.
2. The health inspection programme must be based on both clinical inspections and laboratory examinations.
3. The programme must include two annual clinical health inspections according to the guidelines given in Part I.
4. At least at one of the inspections carried out each year, 30 fish tissue and/or ovarian fluid samples shall be collected from each farm. The samples shall be selected, prepared and subjected for laboratory examination according to Part I, II and IV.
5. The health inspection programme shall be conducted for at least 4 years in all farms in the zone or in the farm (in a non-approved zone) to be approved.
6. For the official recognition of the programme, no cases of VHS or IHN shall occur or be detected (no clinical infections or virus isolations).

Requirements¹, information needed and recommendations

7.2.A;B New farms and farms which recommence activities with approved stock following disinfection (Table 2 to be completed)

(Directive 91/67/EEC, Annex C, I.A.6a/b or II.A.3.a/b)

New farms and farms which recommences their activities with fish, eggs or gametes from an approved zone or an approved farm may obtain approval without undergoing the sampling required for the grant of approval if they meet the general requirements laid down - as relevant with regard to water supply; barriers; protection against flooding and infiltration of water and additional preventative measures.

For recommencing farms also the following is required:

- the health history of the farm over the last four years is known to the official service (or over the actual operation period if the farm has been in operation < than four years)
- the farm has not been subject to animal-health measures in respect of VHS and/or IHN and there have been no antecedents of those diseases on the farm,
- prior to the introduction of the fish, eggs, gametes, the farm is cleaned disinfected, and left fallow for a minimum of 15 days under official supervision

Information needed:

- New or recommencing farm?
- Background history
- Source of all stock: initial/future stock;

For restocking farms also:

- Background history, including health status and source of earlier stock
- Date of emptying, cleaning, disinfection, re-stocking; source of new stock; by which authority was/is the farm/procedures supervised?

8. National rules related to approval of the farm

(Special reference to: Directive 91/67/EEC, Article 6.1, first indent and Annex C, I.A & II.A; Decision 2001/183/EC, Part I.I.1; I.I.2.1.a; I.I.2.1.b and I.I.2.2; Directive 93/53/EEC, Article 9)

National rules ensuring compliance with the conditions set out in the Community legislation for approval for VHS and/or IHN must be in place.

Information needed: National legal base

Requirements¹, information needed and recommendations

9. **National rules for maintenance of approval; suspension, restoration and withdrawal of approval**

(Special reference to: Directive 91/67/EEC Article 6.1, second indent and Annex C, I. B & I. C & II. B & II. C; Decision 2001/183/EC, Part I.I.2.3; Directive 93/53/EEC, Article 9)

National rules ensuring compliance with the conditions set out in the Community legislation for maintenance of approval for VHS and IHN, as well as on suspension, restoration and withdrawal of the approval must be in place.

Information needed: Planned surveillance, legal base.

10. **Miscellaneous**

11. **Conclusion by and signature of the Local Official Service**

TABLE 1A from Decision 2001/183/EC

Inspection and sampling scheme for zones and for farms in non-approved zones for the two year control period which precedes achievement of approved status for VHS and/or IHN

(in accordance with Directive 91/67/EEC, Annex B and C and the provisions set out in Part I of this annex)

	Number of clinical inspections per year (two years):	Number of laboratory examinations per year (two years):	Laboratory examination for presence of virus ¹	
			Number of growing fish (organ material)	Number of broodstock fish (ovarian fluid)
<i>Continental zones and farms</i>				
(a) Farms with broodstock	2	2	120 (first inspection) ² 150 (second inspection)	30 (first inspection) ³ 0 (second inspection)
(b) Farms with broodstock only	2	1	0	150 (first or second inspection)
(c) Farms without broodstock	2	2	150 (first and second inspection)	0
<i>Coastal zones and farms</i>				
(a) Farms with broodstock	2	2	120 (first inspection) 150 (second inspection)	30 (first inspection) ³ 0 (second inspection)
(b) Salmonid farms without broodstock	2	2	30 (first and second inspection) ⁴	0
(c) Non-salmonid farms without broodstock	2	2	150 (first and second inspection)	0

Maximum number of fish per pool: 10

¹ Alternatively, a reduced sample size as listed in Table 1B may be used if requirements as described in the text Part I.I.1, I.I.2.1.b and in Part III are fulfilled.

² Clinical inspections.

³ In exceptional circumstances, if it is impossible to obtain ovarian fluid, organs may be sampled instead.

⁴ The samples have to be collected no sooner than three weeks after transfer of fish from fresh to saltwater.

TABLE 1B from Decision 2001/183/EC

Inspection and sampling scheme for the two year control period which precedes achievement of approved status for VHS and/or IHN in zones and farms in non-approved zones with an officially recognised documented history of freedom from these diseases

(in accordance with Directive 91/67/EEC, annex B and C and the provisions set out in Part I and III of this Annex)

	Number of clinical inspections per year (two years):	Number of laboratory examinations per year (two years):	Laboratory examination for presence of virus	
			Number of growing fish (organ material)	Number of broodstock fish (ovarian fluid)
<i>Continental zones and farms</i>				
(a) Farms with broodstock	2	2	0 (first inspection) ¹ 30 (second inspection)	30 (first inspection) ² 0 (second inspection)
(b) Farms with broodstock only	2	1	0	30 (first or second inspection) ²
(c) Farms without broodstock	2	2	30 (first and second inspection)	0
<i>Coastal zones and farms</i>				
(a) Farms with broodstock	2	2	0 (first inspection) 30 (second inspection)	30 (first inspection) ² 0 (second inspection)
(b) Salmonid farms without broodstock	2	2	30 (first and second inspection) ³	0
(c) Non-salmonid farms without broodstock	2	2	30 (first and second inspection)	0

Maximum number of fish per pool: 10

¹ Clinical inspections.

² In exceptional circumstances, if it is impossible to obtain ovarian fluid, organs may be sampled instead.

³ The samples have to be collected no sooner than three weeks after transfer of fish from fresh to saltwater.