

## 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	ESPAÑA
1.2. Competent authority (address, fax, e-mail)	Consejería de Agricultura, Agua y Desarrollo Rural DG Agricultura y Ganadería Servicio de Sanidad Animal. C/ Pintor Matías Montero, 4 – 45001 Toledo <a href="mailto:sanidadanimal@jccm.es">sanidadanimal@jccm.es</a>
1.3. Reference of this document	CLM 2021/1
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 checked="" type="checkbox"/> Submission of application for disease-free-status	
<b>3. National legislation<sup>1</sup></b>	Real Decreto 1614/2008, de 3 de octubre, que es la trasposición de la Directiva 2006/88/CE por la que se establecen los requisitos zoonosanitarios de los animales acuáticos y de los productos de la acuicultura, así como la prevención y el control de determinadas enfermedades de los animales acuáticos.  Dicho RD establece en el artículo 47 los requisitos para la declaración de zonas o compartimentos libres de enfermedades.
<b>4. Diseases</b>	
4.1. Fish	<input checked="" type="checkbox"/> VHS <input checked="" 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

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

<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 checked="" type="checkbox"/> Targeted surveillance <sup>5</sup>	<p><b>Se solicita la calificación como libre de enfermedad (Categoría I) frente a NHI y SHV de la zona comprendida entre el nacimiento del río Mundo y la presa de El Pontarrón localizada en la provincia de ALBACETE (CASTILLA-LA MANCHA - ESPAÑA).</b></p> <p>Dado que en la zona se cumplen los requisitos establecidos en la parte II del Anexo V de la Directiva 2006/88/CEE, se ha procedido a aplicar la Parte I del Anexo I de la Decisión de Ejecución (UE) 2015/1554 de la Comisión por la que se establecen disposiciones de aplicación de la Directiva 2006/88/CE en lo que respecta a los requisitos de vigilancia y métodos de diagnóstico.</p> <p>Esta zona está calificada como Categoría II y se ha aplicado un programa de vigilancia aprobado por la Comisión con inspecciones sanitarias y muestreo durante un periodo mínimo de dos años consecutivos conforme al Cuadro 1.A de la mencionada Decisión y aplicando los métodos de diagnóstico del punto II.2, a fin de confirmar la ausencia de SHV y NHI</p> <p style="text-align: center;"><b><u>(Ver anexo de información adicional).</u></b></p>

<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 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.

<sup>5</sup> Applicable if targeted surveillance complying with Community requirements has been in place for at least a period of two years without the detection of the disease agent on farm, or in mollusc farming areas that rears any of the susceptible species.

Where there are parts of the Member State, zone or compartment in which the number of farms or mollusc farming areas is limited, but in which there are wild populations of susceptible species, information on the targeted surveillance in those wild populations shall be given.

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

<b>6. General information</b>	
6.1. Competent authority <sup>6</sup>	Consejería de Agricultura, Agua y Desarrollo Rural de la Comunidad Autónoma de CASTILLA-LA MANCHA DG Agricultura y Ganadería
6.2. Organisation, supervision of all stakeholders involved in the programme to achieve disease free status <sup>7</sup>	DG Agricultura y Ganadería Servicio de Sanidad Animal. Delegación Provincial de Agricultura, Agua y Desarrollo Rural de Albacete Oficina Comarcal Agraria de Alcaraz
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	Se pretende la declaración como libre de enfermedad de la zona comprendida entre el nacimiento del río Mundo y la presa de El Pontarrón que ejercería de barrera.  En la zona, existe una única piscifactoría autorizada relacionada epidemiológicamente con las aguas de este río. Es la Piscifactoría Río Mundo S.L.U., autorizada con el código ES020670000068.  La finalidad de la piscifactoría es la producción de ovas embrionadas de Trucha arco iris ( <i>Oncorhynchus mykiss</i> ) además de la cría y engorde de las mismas para su posterior venta tanto para consumo humano como para engorde en otras piscifactorías.  <b><u>(Ver anexo de información adicional)</u></b>
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)?	Desde 1994 en que se publica el RD 1882/1994, de 16 de septiembre, por el que se establecen las condiciones de sanidad animal aplicables a la puesta en el mercado de animales y productos de la acuicultura, y que incorpora al ordenamiento jurídico español la Directiva 91/67/CEE del Consejo.

<sup>6</sup> A description shall be provided of the structure, competencies, duties and powers of the competent authority involved.

<sup>7</sup> A description shall be provided of the competent authority in charge of the supervision and coordination of the programme and the different operators involved.

<p>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></p>	<p>Desde la entrada en vigor del RD 1882/1994, actualmente derogado por el RD 1614/2008 de 3 de octubre relativo a los requisitos zoonosológicos de los animales y los productos de la acuicultura, así como la prevención y control de determinadas enfermedades de los animales acuáticos.</p> <p style="text-align: center;"><b><u>(Ver anexo de información adicional).</u></b></p>
<p>6.6. Source of aquaculture animals of species susceptible to the disease in question entering in the Member State, zone or compartments for farming.</p>	<p>Todos los especímenes de Trucha arco iris que se introducen en la zona proceden de zonas calificadas como categoría I frente a SHV y NHI.</p> <p>Los orígenes de los peces de la piscifactoría Rio Mundo S.L. son tres explotaciones calificadas como categoría I. No ha habido más entradas de peces practicándose hasta el momento la autoreposición.</p>
<p>6.7. Guidelines on good hygiene practice<sup>9</sup></p>	<p>La explotación aplica Guía de Buenas Prácticas de Higiene como herramienta para facilitar y unificar el desarrollo de los protocolos de actuación que se realizan en ella.</p> <p>Se ha obtenido la certificación de calidad GLOBALG.A.P que abarca la certificación de todo el proceso de producción, desde la entrada de especímenes en la explotación hasta que se transforma en un producto no procesado.</p> <p>GLOBAL G.A.P. proporciona las normas y el marco para la certificación independiente y por tercera parte, de los procesos de producción primaria, basados en la Guía ISO/IEC/65 que asegura que sólo se certifiquen aquellos que alcanzan un determinado nivel de cumplimiento de las Buenas Prácticas Agrícolas (G.A.P.)</p>

<sup>8</sup> The early detection systems shall in particular ensure the rapid recognition of any clinical signs consistent with the suspicion of a disease, emerging disease, or unexplained mortality in farms or mollusc farming areas, and in the wild, and the rapid communication of the event to the competent authority with the aim to activating diagnostic investigation with minimum delay. The early detection system shall include at least the following:

- (a) broad awareness, among the personnel employed in aquaculture businesses or involved in the processing of aquaculture animals, of any signs consistent with the presence of a disease, and training of veterinarians of aquatic animals health specialists in detecting and reporting unusual disease occurrence;
- (b) veterinarians or aquatic animal health specialists trained in recognising and reporting suspicious disease occurrence;
- (c) access by the competent authority to laboratories with the facilities for diagnosing and differentiating listed and emerging diseases.

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

<b>7. Area covered</b>	
7.1. <input type="checkbox"/> Member State	
7.2. <input type="checkbox"/> Zone (entire water catchment area) <sup>10</sup>	
7.3. <input checked="" 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.	Río Mundo desde su nacimiento hasta la presa del Pontarrón (barrera lo suficientemente importante para impedir la migración de animales acuáticos de las partes inferiores de la zona a calificar).  <b><u>(Ver anexo de información adicional)</u></b>
7.4. <input type="checkbox"/> Zone (more than one water catchment area) <sup>12</sup>	

<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.

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		
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>		

<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.

<b>8. Geographical demarcation <sup>20</sup></b>		
8.1. Farms or mollusc farming areas covered (registration numbers and geographical situation)		Explotación ES020670000068 UTM30 X: 551.782 Y: 4.259.798 <b>(Ver anexo de información adicional)</b>
8.2. <input type="checkbox"/> Non-free buffer zone <sup>21</sup>	Geographical demarcation <sup>26</sup>	
	Farms or mollusc farming areas covered (registration numbers, geographical situation and health status <sup>22</sup> )	
	Type of health surveillance	
8.3. <input type="checkbox"/> Non-free zones or compartments <sup>23</sup>	Geographical demarcation <sup>26</sup>	
	Farms or mollusc farming areas covered (registration numbers, geographical situation and health status <sup>22</sup> )	
8.4. <input type="checkbox"/> Extension of disease-free zone to other Member States <sup>24</sup>	Geographical demarcation <sup>26</sup>	

<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.

8.5. <input type="checkbox"/> Existing disease-free zones/ compartments in the vicinity.	Geographical demarcation <sup>26</sup>	
	Farms or mollusc farming areas covered (registration numbers and geographical situation)	
<b>9. Farms or mollusc farming areas which commence or recommence their activities<sup>25</sup></b>		
9.1. <input type="checkbox"/> New farm		
9.2. <input type="checkbox"/> Recommencing farm	<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	

<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>: ZONA RIO MUNDO

Disease: SHV - NHI

Year: 2019

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
ES020670000068	1	2	<14°C	Trucha arco iris	Trucha arco iris	30 reproductores y 50 peces en crecimiento	11	0	0
<b>TOTAL</b>						80	11	0	0

Disease: SHV - NHI

Year: 2020

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
ES020670000068	2	2	<14°C	Trucha arco iris	Trucha arco iris	75 peces en crecimiento 30 reproductores y 50 peces en crecimiento	11 13	0	0
<b>TOTAL</b>						155	24	0	0

Disease: SHV - NHI

Year: 2021

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
ES020670000068	1	1	<14°C	Trucha arco iris	Trucha arco iris	75 peces en crecimiento	12	0	0
<b>TOTAL</b>						75	12	0	0

(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 situation of the sampling should be given.

2. Data on testing farms or farming areas

Disease: SHV - NHI

Year: 2019-2021

Member State, zone or compartment <sup>(a)</sup>	Total number of farms or mollusc farming areas <sup>(b)</sup>	Total number farms or mollusc farming areas under the programme	Number of farms or mollusc farming areas checked <sup>(c)</sup>	Number of positive farms or mollusc farming areas <sup>(d)</sup>	Number of new positive farms or mollusc farming areas <sup>(e)</sup>	Number of farms or mollusc farming areas depopulated	% positive farms or mollusc farming areas depopulated	Animals removed and disposed of <sup>(f)</sup>	TARGET INDICATORS		
									% farms or mollusc farming areas coverage	% positive farms or mollusc farming areas period farms or mollusc farming areas prevalence	% new positive farms or mollusc farming areas farms or mollusc farming areas incidence
1	2	3	4	5	6	7	8 =	9	10 = (4/3)x100	11 = (5/4)x100	12 = (6/4)x100
Zona	1	1	1	0	0	0	0	0	100	0	0
<b>Total</b>											

- (a) Member State, zone or compartment as defined in point 7 of Annex IV.
- (b) Total number of farms or mollusc farming areas existing in the Member State, zone or compartment as defined in point 7 of Annex IV.
- (c) Check means to perform a farm/mollusc farming area level test under the programme to achieve disease-free status for the respective disease with the purpose of upgrading the health status of the farm/mollusc farming area. In this column a farm/mollusc farming area must not be counted twice even if has been checked more than once.
- (d) Farms or mollusc farming areas with at least one positive animal during the period independent of the number of times the farms or mollusc farming areas has been checked.
- (e) Farms or mollusc farming areas in which the health status for the past reporting period was, either category I, category II, category III or category IV in accordance with Part A of Annex III to Directive 2006/88/EC but which have had during this period of reference at least one positive animal for the disease in question.  
In the case of programmes submitted before 1 August 2008, farms or mollusc farming areas which were not positive to the disease in question in the previous period and have at least one positive animal in this period.
- (f) Animals x 1000 or total weight of animals removed and disposed

