

Annex to: Species which may act as vectors or reservoirs of diseases covered by the Animal Health Law: Listed pathogens of molluscs. doi:10.2903/j.efsa.2023.8173

© European Food Safety Authority, 2023

## **Annex A – Protocol for the assessment of Vectors or Reservoirs for Mollusc Diseases (M-2022-00138)**

### **Problem formulation**

#### **Background as provided by the requestor**

In accordance with Article 8 of Regulation (EU) 2016/429 (AHL), the disease-specific rules for listed diseases provided in the AHL, and the rules adopted pursuant to that Regulation, apply to listed species. In compliance with that Article, the Commission shall establish a list of animal species or groups of species, which pose a considerable risk for the spread of specific listed diseases based on the capability of those animals to carry those specific diseases. Animal species or groups of animal species shall only be added to the list if they pose a considerable risk for the spread of a specific listed disease because they are vectors or reservoirs for that disease, or scientific evidence indicates that such role is likely.

The list of vector species, which is set out in the fourth column of the table in the Annex to Implementing Regulation (EU) 2018/1882, was carried forward from the list, which was previously set out in Commission Regulation (EU) 1251/2008. The Commission now requires scientific advice to inform an amendment to that list, to ensure that only species, which comply with Article 8 of the AHL are listed. This amendment may involve species, which are currently set out in the fourth column of the Annex to Implementing Regulation (EU) 2018/1882 being removed and/or new species being added to that list.

It should be noted that vector species of aquatic animals are not listed in the OIE Aquatic Code<sup>1</sup> or in the OIE Aquatic Manual<sup>2</sup>. In the disease specific chapters of the OIE Aquatic Manual however, as well as listing susceptible species, other species which have shown incomplete evidence of susceptibility are listed, as are species in which PCR positive results have been reported, but where an active infection has not been demonstrated. In 2020, the EU Reference Laboratories (EURLs) for fish, crustaceans and molluscs, with the assistance of experts, reviewed those non-susceptible species, which are listed in the OIE Manual, in an effort to determine whether or not, they could be considered to be vectors of specific listed diseases. The reports which have been prepared by the EURLs and which have been furnished to the Commission, may be of assistance to the risk assessor in providing the scientific advice, which is currently sought. The three reports (concerning fish, molluscs and crustaceans) accompany this letter. It should, however, be noted that these reports also contain information concerning susceptible species to the listed diseases, which is not pertinent to this request for a scientific opinion.

In addition, for those species and groups of species referred to above, which should be listed in accordance with Article 8 of the AHL, scientific advice is also required, concerning the conditions under which these species should be regarded as vectors or reservoirs for the purposes of movements.

The conditions under which these species should be regarded as vectors are set out in Annex I to Commission Delegated Regulation (EU) 2020/990<sup>3</sup> and in Annex XXX to

---

<sup>1</sup> OIE Aquatic Animal Health Code, 2021, 23<sup>rd</sup> Edition.

<sup>2</sup> OIE Aquatic Manual, 2021, 8<sup>th</sup> Edition.

<sup>3</sup> Commission Delegated Regulation (EU) 2020/990 of 28 April 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council, as regards animal health and certification requirements for movements within the Union of aquatic animals and products of animal origin from aquatic animals (OJ L 221, 28 April 2020, p.42).

Commission Delegated Regulation (EU) 2020/692<sup>4</sup> It should be noted that the conditions set out in Annex I to Commission Delegated Regulation (EU) 2020/990 are not identical to the conditions set out in Annex XXX to Commission Delegated Regulation (EU) 2020/692, and both sets of conditions are different to those which were previously set out in columns 3 and 4 of Annex I to Commission Regulation (EC) 1251/2008.

### ToR as provided by the requestor

In view of the above, the Commission asks EFSA for a scientific opinion on the listing of vector species of aquatic animals in accordance with Article 8 of Regulation (EU) 2016/429, as follows:

1. For each of the aquatic diseases listed in Annex II to the AHL, an assessment concerning which species or groups of species of aquatic animals pose a considerable risk for their spread based on the fact that:
  - (i) they are vector species or reservoirs for that disease, or
  - (ii) scientific evidence indicates that such role is likely.For each of the species or groups of species, which are assessed to be vector species or reservoirs of the listed diseases, or where scientific evidence indicates that such role is likely, they should be aquatic animals which are **not already listed as susceptible to the listed disease.**
2. For each of the species or groups of species, which are assessed to fulfil the requirements for listing by virtue of being a vector or reservoir of a listed disease, or where scientific evidence indicates such a role is likely, an assessment of the suitability of the conditions under which they should be regarded as vectors or reservoirs for the purposes of movements.

These conditions are set out in Annex I to Commission Delegated Regulation (EU) 2020/990 and in Annex XXX to Commission Delegated Regulation (EU) 2020/692, however, alternative conditions should be proposed, if the conditions which are set out in those Regulations, are assessed to be unsuitable.

### Scope of the request in terms of population, exposure and outcome of interest

#### Diseases of concern

According to the background and the terms of reference provided by the EC, the request concerns the diseases of aquatic animals listed in Annex II of AHL, in total 13.

---

<sup>4</sup> Commission Delegated Regulation (EU) 2020/692 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin (OJ L 174, 3.6.2020, p.379).

Table 1: Diseases of mollusc species of concern for the purposes of this Assessment

<b>Molluscs (5 diseases)</b>		
Infection with	<i>Mikrocytos</i>	<i>mackini</i>
Infection with	<i>Bonamia</i>	<i>exitiosa</i>
Infection with	<i>Marteilia</i>	<i>refringens</i>
Infection with	<i>Perkinsus</i>	<i>marinus</i>
Infection with	<i>Bonamia</i>	<i>ostreae</i>

### Population of concern

According to the background and the terms of reference provided by the EC, the population of concern for this assessment constitutes the **mollusc species** that can pose a **considerable risk of spread** of the diseases because of their role as **vectors** or **reservoirs** for each disease.

According to the EU legislation point (3) of article 4 of AHL "**molluscs** mean animals of all life stages, including eggs, sperm and gametes of the following species: aquatic molluscs belonging to the phylum Mollusca;

For the purposes of this assessment as **mollusc species** are considered those described in point (3) of article 4 of AHL mentioned above, amphibians although included in the definition provided for mollusc species by WOAHA are out of the scope of this assessment. Other species that may act as vectors but not included in the above a, b, and c, will be out of the scope of this assessment.

Molluscs both from aquaculture and wildlife are considered in the assessment.

### Translation of ToR into assessment questions and sub-questions

The two ToR were broken down into three assessment elements included in the request. These were translated into assessment questions (Table 2). In a next step, the assessment questions were broken down into sub-questions.

#### Assessment elements included in ToR 1:

To assess the mollusc **species** or **groups of species** of the population of concern (as described above) for their ability to be **vectors** or **reservoirs** for each disease in accordance with Article 8 of Regulation (EU) 2016/429 and based on scientific evidence:

- a) mollusc **species** or **group of species** listed already as **Vector species** in the current EU regulation (EU Reg 2018/1882),
- b) mollusc **species** or **groups of species** other than those described in point (a) above and they have not been already listed as susceptible (listed species in column 3 of Annex to Reg 2018/1882), for which there is scientific evidence that indicates that they can act as vectors or reservoirs.

#### Assessment elements included in ToR 2:

- a) to assess the **suitability of the conditions** described in current EU Legislation (Annex I to Commission Delegated Regulation (EU) 2020/990 and in Annex XXX to Commission

Delegated Regulation (EU) 2020/692), **under which the mollusc species resulted from ToR1 should be regarded as vectors or reservoirs for the purposes of movements.**

b) propose alternative suitable conditions in case those in point (a) are assessed to be unsuitable

*Questions, Sub-questions, related data needed and methods to collect it*

## **ToR 1**

### **What is the definition of vectors for mollusc diseases?**

Since there is no definition on vectors in the EU legislation, the WG will evaluate the already existing definition in Aquatic Animal Code of WOA and based on available scientific evidence and expert opinion, a suitable definition for the term "**vector**" for mollusc diseases will be derived and agreed by the working group.

### **What are the criteria according to which an mollusc species or a group of species can be classified as vector for a specific mollusc disease?**

The WG will work on the criteria and the parameters according to which a species or group of species can be classified as vector or not, for specific diseases. These criteria/parameters will be provided to the contractor to conduct the literature review and update the scientific evidence per each disease and vector.

### **What is the definition of reservoirs for mollusc diseases?**

Since there is no definition on reservoirs in EU legislation and WOA Aquatic Animal Code, the WG based on available scientific evidence and expert opinion will agree on a suitable definition for the term "**reservoir**" for mollusc diseases.

### **What are the criteria according to which a mollusc species or a group of species can be classified as reservoir for a specific mollusc disease?**

The WG will work on the criteria and the parameters according to which a species or group of species can be classified as reservoir or not, for specific diseases. These criteria/parameters will be provided to the contractor to conduct the literature review and update the scientific evidence per each disease and reservoir.

### **Do the aquatic animal species already listed as *Vector species* in the current EU regulation (EU Reg 2018/1882) fulfil the criteria to be classified as vectors or reservoirs?**

The aquatic animal species or group of species already listed as *Vector species* in the current EU regulation (EU Reg 2018/1882) will be assessed at first place. Updated information for all the criteria/parameters per *Vector species* will be provided and assessed. The WG will review the evidence and elaborate the final assessment.

### **Are there mollusc species other than those already listed as *Vector species* in the current EU regulation (EU Reg 2018/1882) that fulfil the criteria to be classified as vectors or reservoirs and they have not been already listed as susceptible (listed species in column 3 of Annex to Reg 2018/1882)?**

Evidence in the literature for other mollusc species fulfilling the criteria to be classified as vectors or reservoirs for each specific disease will be searched for and reviewed.

## **ToR 2**

**Which are the suitable conditions under which the mollusc species resulted from ToR1 should be regarded as vectors or reservoirs for the purposes of movements?**

The WG will develop a list of conditions under which the mollusc species resulted from ToR1 should be regarded as vectors or reservoirs for the purposes of movements.

**Are the conditions described in EU Regulations suitable to consider the mollusc species as vectors or reservoirs for the purposes of movements?**

The WG will assess the conditions already existing in the EU legislation to consider the mollusc species as vectors or reservoirs of each specific disease for the purposes of movements.

Table 2 Interpretation of assessment elements included in the ToRs

ToR	Assessment element	Questions	Data/information needed	Data collection methods/sources	Assessment Methods	
1	a	To assess the mollusc <b>species</b> or <b>groups of species</b> of the population of concern (as described above) to their ability to be <b>vectors</b> or <b>reservoirs</b> for each disease in accordance with Article 8 of Regulation (EU) 2016/429 and based on scientific evidence.	1) What is the definition of <b>vectors</b> for mollusc diseases?	<ul style="list-style-type: none"> <li>- Definition of vectors</li> <li>- List of the diseases to be considered</li> </ul>	<ul style="list-style-type: none"> <li>- EU Legislative documents</li> <li>- WOAHA Aquatic Animal Code and Manual</li> <li>- Literature</li> <li>- WG experts' knowledge</li> </ul>	Narrative description The WG will provide the definition
			2) What are the criteria according to which an mollusc species or a group of species can be classified as <b>vector</b> for a specific mollusc disease?	<ul style="list-style-type: none"> <li>- Criteria/parameters to be used for the classification of mollusc species as vectors for certain disease</li> <li>- Scientific evidence on the criteria/parameters</li> </ul>	WG will define the criteria/parameters to be used for the classification of vectors	Narrative description of the criteria/parameters provided by the WG
			3) What is the definition of <b>reservoirs</b> for mollusc diseases?	<ul style="list-style-type: none"> <li>- Definition of reservoirs</li> <li>- List of the diseases to be considered</li> </ul>	<ul style="list-style-type: none"> <li>- EU Legislative documents</li> <li>- WOAHA Aquatic Animal Code and Manual</li> <li>- Literature</li> <li>- WG experts' knowledge</li> </ul>	Narrative description The WG will provide the definition
			4) What are the criteria according to which an mollusc species or a group of species can be classified as <b>reservoir</b> for a	<ul style="list-style-type: none"> <li>- Criteria/parameters to be used for the classification of mollusc species as reservoirs for certain disease.</li> <li>- Scientific evidence on the criteria/parameters</li> </ul>	<ul style="list-style-type: none"> <li>- WG will define the criteria/parameters to be used for the classification of reservoirs</li> </ul>	Narrative description of the criteria/parameters provided by the WG

ToR	Assessment element	Questions	Data/information needed	Data collection methods/sources	Assessment Methods
		specific aquatic disease?			
		5) Do the mollusc species already listed as <b>Vector species</b> in the current EU regulation (EU Reg 2018/1882) fulfil the criteria to be classified as vectors or reservoirs?	<ul style="list-style-type: none"> <li>- List of mollusc species listed as vectors in the current EU regulation (EU Reg 2018/1882)</li> <li>- Matrix tables per disease: <i>Vector species</i> in the current EU regulation x criteria for vectors and reservoirs</li> </ul>	<ul style="list-style-type: none"> <li>- Literature review (peer-reviewed and grey literature) conducted by the contractor</li> <li>- The matrix tables per disease will be provided by the contractor</li> </ul>	<ul style="list-style-type: none"> <li>- Narrative description on the results from literature review provided by the contractor</li> <li>- Assessment conducted by the WG</li> </ul>
		6) Are there mollusc species other than those already listed as <b>Vector species</b> in the current EU regulation (EU Reg 2018/1882) that fulfil the criteria to be classified as vectors or reservoirs and they have not been already listed as <b>susceptible</b> (listed species in column 3 of Annex to Reg 2018/1882)?	<ul style="list-style-type: none"> <li>- List of mollusc species listed as vectors in the current EU regulation (EU Reg 2018/1882)</li> <li>- List of mollusc species other than those already listed as <b>Vector species</b> in the current EU regulation (EU Reg 2018/1882) and they have not been already listed as <b>susceptible</b> (listed species in column 3 of Annex to Reg 2018/1882).</li> <li>- Criteria/parameters to be used for the classification of mollusc species as vectors of reservoirs for certain disease.</li> <li>- Matrix tables per disease: Vector or reservoir species not listed in the current EU regulation as vectors or susceptible species x criteria for vectors and reservoirs</li> </ul>	<ul style="list-style-type: none"> <li>- Literature review (peer-reviewed and grey literature)</li> <li>- The matrix tables per disease will be provided by the contractors</li> </ul>	<ul style="list-style-type: none"> <li>- Narrative description on the results from literature review provided by the contractor</li> <li>- Assessment by the WG</li> </ul>

ToR		Assessment element	Questions	Data/information needed	Data collection methods/sources	Assessment Methods
2	a	To assess the suitability of the <b>conditions</b> described in current EU Legislation, under which the mollusc species resulted from ToR1 should be regarded as vectors or reservoirs for the purposes of movements.	7) Are the conditions described in EU Regulations suitable to consider the mollusc species as vectors or reservoirs, for the purposes of movements?	<ul style="list-style-type: none"> <li>- List of the conditions as described in EU Regulations</li> <li>- Description of the conditions as described in EU Regulations</li> <li>- Criteria/parameters for the conditions as described in EU Regulations-</li> <li>- Scientific evidence</li> </ul>	<ul style="list-style-type: none"> <li>- Literature review (peer-reviewed and grey literature)</li> <li>- WG will define the criteria/parameters to be used for the conditions as described in the EU regulations</li> </ul> <p>The scientific evidence for the criteria/parameters will be provided by the contractors</p>	<ul style="list-style-type: none"> <li>- Narrative description on the results of the literature review provided by the contractor</li> <li>- Assessment by the WG</li> </ul>
2	b	To propose alternative suitable conditions in case those in point (a) are assessed to be unsuitable	8) Which are the suitable conditions under which the mollusc species resulted from ToR1 should be regarded as vectors or reservoirs for the purposes of movements?	<ul style="list-style-type: none"> <li>- Description of the conditions not included in EU Regulations</li> <li>- Criteria/parameters for the conditions not included in EU Regulations</li> <li>- Scientific evidence</li> </ul>	<p>Literature review (peer-reviewed and grey literature)</p> <ul style="list-style-type: none"> <li>- WG will define the criteria/parameters to be used for the conditions not included in the EU regulations</li> </ul>	<ul style="list-style-type: none"> <li>- Narrative description of the literature review provided by the contractor</li> <li>- Assessment by the WG</li> </ul>



ToR		Assessment element	Questions	Data/information needed	Data collection methods/sources	Assessment Methods
					The scientific evidence for the criteria/parameters will be provided by the contractors	

**Annex 1: List with the susceptible species and vectors per disease**

Diseases of concern listed species for each disease and listed vectors for each disease according to the Annex to Implementing Regulation 2018/1882 as amended by Implementing Regulation (EU) 2022/925.

<b>Listed disease</b>	<b>Listed species/group of species or Susceptible species in WOA Aquatic Animal Diseases Code</b>	<b>Listed Vectors</b>
<b>Epizootic haematopoietic necrosis</b>	Ameiurus melas, Bidyanus bidyanus, Esox lucius, Galaxias olidus, Gambusia affinis, Gambusia holbrooki, Macquaria australasica, Melanotaenia fluviatilis, Oncorhynchus mykiss, Perca fluviatilis, Sander lucioperca	Aristichthys nobilis, Carassius auratus, Carassius carassius, Cyprinus carpio, Hypophthalmichthys molitrix, Leuciscus spp., Rutilus rutilus, Scardinius erythrophthalmus, Tinca tinca

<p><b>Viral haemorrhagic septicaemia</b></p>	<p><i>Alosa immaculata</i>, <i>Ameiurus nebulosus</i>, <i>Ambloplites rupestris</i>, <i>Ammodytes hexapterus</i>, <i>Aplodinotus grunniens</i>, <i>Centrolabrus exoletus</i>, <i>Clupea harengus</i>, <i>Clupea pallasii pallasii</i>, <i>Coregonus artedii</i>, <i>Coregonus clupeaformis</i>, <i>Coregonus lavaretus</i>, <i>Ctenolabrus rupestris</i>, <i>Cyclopterus lumpus</i>, <i>Cymatogaster aggregata</i>, <i>Dorosoma cepedianum</i>, <i>Danio rerio</i>, <i>Engraulis encrasicolus</i>, <i>Esox lucius</i>, <i>Esox masquinongy</i>, <i>Fundulus heteroclitus</i>, <i>Gadus macrocephalus</i>, <i>Gadus morhua</i>, <i>Gaidropsarus vulgaris</i>, <i>Gasterosteus aculeatus</i>, <i>Labrus bergylta</i>, <i>Labrus mixtus</i>, <i>Lampetra fluviatilis</i>, <i>Lepomis gibbosus</i>, <i>Lepomis macrochirus</i>, <i>Limanda limanda</i>, <i>Merlangius merlangus</i>, <i>Micropterus dolomieu</i>, <i>Micropterus salmoides</i>, <i>Micromesistius poutassou</i>, <i>Morone americana</i>, <i>Morone chrysops</i>, <i>Morone saxatilis</i>, <i>Mullus barbatus</i>, <i>Neogobius melanostomus</i>, <i>Notropis atherinoides</i>, <i>Notropis hudsonius</i>, <i>Oncorhynchus kisutch</i>, <i>Oncorhynchus mykiss</i>, <i>Oncorhynchus mykiss X Oncorhynchus kisutch hybrids</i>, <i>Oncorhynchus tshawytscha</i>, <i>Paralichthys olivaceus</i>, <i>Perca flavescens</i>, <i>Pimephales notatus</i>, <i>Pimephales promelas</i>, <i>Platichthys flesus</i>, <i>Pleuronectes platessa</i>, <i>Pomatoschistus minutus</i>, <i>Pomoxis nigromaculatus</i>, <i>Raja clavata</i>, <i>Salmo marmoratus</i>, <i>Salmo salar</i>, <i>Salmo trutta</i>, <i>Salvelinus namaycush</i>, <i>Sander vitreus</i>, <i>Sardina pilchardus</i>, <i>Sardinops sagax</i>, <i>Scomber japonicus</i>, <i>Scophthalmus maximus</i>, <i>Solea senegalensis</i>, <i>Sprattus sprattus</i>, <i>Symphodus melops</i>, <i>Thaleichthys pacificus</i>, <i>Trachurus mediterraneus</i>, <i>Trisopterus esmarkii</i>, <i>Thymallus thymallus</i>, <i>Uranoscopus scaber</i></p>	<p><i>Acipenser baerii</i>, <i>Acipenser gueldenstaedtii</i>, <i>Acipenser ruthenus</i>, <i>Acipenser stellatus</i>, <i>Acipenser sturio</i>, <i>Ameiurus melas</i>, <i>Argyrosomus regius</i>, <i>Aristichthys nobilis</i>, <i>Carassius auratus</i>, <i>Carassius carassius</i>, <i>Clarias gariepinus</i>, <i>Cyprinus carpio</i>, <i>Dentex dentex</i>, <i>Dicentrarchus labrax</i>, <i>Diplodus puntazzo</i>, <i>Diplodus sargus</i>, <i>Diplodus vulgaris</i>, <i>Epinephelus aeneus</i>, <i>Epinephelus marginatus</i>, <i>Huso huso</i>, <i>Hypophthalmichthys molitrix</i>, <i>Ictalurus punctatus</i>, <i>Ictalurus spp.</i>, <i>Leuciscus spp.</i>, <i>Morone chrysops x</i>, <i>Morone saxatilis</i>, <i>Mugil cephalus</i>, <i>Oreochromis</i>, <i>Pagellus bogaraveo</i>, <i>Pagellus erythrinus</i>, <i>Pagrus major</i>, <i>Pagrus pagrus</i>, <i>Pangasius pangasius</i>, <i>Rutilus rutilus</i>, <i>Salvelinus alpinus</i>, <i>Salvelinus fontinalis</i>, <i>Sander lucioperca</i>, <i>Scardinius erythrophthalmus</i>, <i>Sciaenops ocellatus</i>, <i>Silurus glanis</i>, <i>Soleasenegalensis</i>, <i>Solea solea</i>, <i>Sparus aurata</i>, <i>Thunnus spp.</i>, <i>Thunnus thynnus</i>, <i>Tinca tinca</i>, <i>Umbrina cirrosa</i></p>
--	--	--

<b>Infectious haematopoietic necrosis</b>	Esox lucius, Onchorynchus clarkii, Oncorhynchus keta, Oncorhynchus kisutch, Oncorhynchus masou, Oncorhynchus mykiss, Oncorhynchus nerka, Oncorhynchus tshawytscha, Salmo marmoratus, Salvelinus namaycush, Salmo salar, Salmo trutta, Salvelinus alpinus, Salvelinus fontinalis	Acipenser Baerii, Acipenser gueldenstaedtii, Acipenser ruthenus, Acipenser stellatus, Acipenser sturio, Ameiurus melas, Aristichthys nobilis, Astacus astacus, Carassius auratus, Carassius carassius, Clarias gariepinus, Cyprinus carpio, Gadus morhua, Hippoglossus hippoglossus, Hypophthalmichthys molitrix, Huso huso, Ictalurus punctatus, Ictalurus spp., Leuciscus spp., Melanogrammus aeglefinus, Platichthys flesus, Pacifastacus leniusculus, Procambarus clarkii, Pangasius pangasius, Rutilus rutilus, Sander lucioperca, Scardinius erythrophthalmus, Silurus glanis, Tinca tinca
<b>Koi herpes virus disease</b>	All varieties and subspecies of Cyprinus carpio, and Cyprinus carpio hybrids e.g. Cyprinus carpio × Carassius auratus, Cyprinus carpio × Carassius carassius	Carassius auratus, Ctenopharyngodon idella
<b>Infection with HPR-deleted infectious salmon anaemia virus</b>	Oncorhynchus mykiss, Salmo salar, Salmo trutta	
<b>Infection with Mikrocytos mackini</b>	Crassostrea gigas, Crassostrea sikamea, Ostrea edulis	
<b>Infection with Perkinsus marinus</b>	Crassostrea gigas, Crassostrea virginica	Brachyura spp., Cherax destructor, Homarus gammarus, Macrobrachium rosenbergii, Palinurus spp., Penaeus indicus, Penaeus japonicus, Penaeus kerathurus, Penaeus stylirostris, Penaeus vannamei, Portunus puber, Scylla serrata
<b>Infection with Bonamia exitiosa</b>	Crassostrea ariakensis, Crassostrea virginica, Ostrea puelchana, Ostrea angasi, Ostrea chilensis, Ostrea equestris, Ostrea edulis, Ostrea lurida	Crassostrea angulata, Crassostrea gigas, Crassostrea virginica
<b>Infection with Bonamia ostreae</b>	Crassostrea ariakensis, Ostrea chilensis, Ostrea edulis	Cerastoderma edule, Donax trunculus, Mya arenaria, Mercenaria mercenaria, Meretrix lusoria, Pecten maximus, Ruditapes decussatus, Ruditapes philippinarum, Venerupis aurea, Venerupis pullastra, Venus verrucosa

<b>Infection with Marteilia refringens</b>	Ostrea angasi, Ostrea chilensis, Ostrea edulis, Ostrea puelchana	Cerastoderma edule, Donax trunculus, Mya arenaria, Mercenaria mercenaria, Meretrix lusoria, Ruditapes decussatus, Ruditapes philippinarum, Venerupis aurea, Venerupis pullastra, Venus verrucosa
<b>Infection with Taura syndrome virus</b>	Metapenaeus ensis, Penaeus aztecus, Penaeus monodon, Penaeus setiferus, Penaeus stylirostris, Penaeus vannamei	Atrina spp., Buccinum undatum, Brachyura spp., Cherax destructor, Crassostrea angulata, Cerastoderma edule, Crassostrea gigas, Crassostrea virginica, Donax trunculus, Haliotis discus hannai, Haliotis tuberculata, Homarus gammarus, Littorina littorea, Macrobrachium rosenbergii, Mercenaria mercenaria, Meretrix lusoria, Mya arenaria, Mytilus edulis, Mytilus galloprovincialis, Octopus vulgaris, Ostrea edulis, Palinurus spp, Portunus puber, Pecten maximus, Penaeus indicus, Penaeus japonicus, Penaeus kerathurus Ruditapes decussatus, Ruditapes philippinarum, Scylla serrata, Sepia officinalis, Strombus spp., Venerupis aurea, Venerupis pullastra, Venus verrucosa
<b>Infection with yellow head virus</b>	Metapenaeus affinis, Penaeus monodon, Palaemonetes pugio, Penaeus stylirostris, Penaeus vannamei	Atrina spp., Buccinum undatum, Crassostrea angulata, Cerastoderma edule, Crassostrea gigas, Crassostrea virginica, Donax trunculus, Haliotis discus hannai, Haliotis tuberculata, Littorina littorea, Mercenaria mercenaria, Meretrix lusoria, Mya arenaria, Mytilus edulis, Mytilus galloprovincialis, Octopus vulgaris, Ostrea edulis, Pecten maximus, Ruditapes decussatus, Ruditapes philippinarum, Sepia officinalis, Strombus spp., Venerupis aurea, Venerupis pullastra, Venus verrucosa
<b>Infection with white spot syndrome virus</b>	All decapod crustaceans (order Decapoda)	Atrina spp., Buccinum undatum, Crassostrea angulata, Cerastoderma edule, Crassostrea gigas, Crassostrea virginica, Donax trunculus, Haliotis discus hannai, Haliotis tuberculata, Littorina littorea, Mercenaria mercenaria, Meretrix lusoria, Mya arenaria, Mytilus edulis, Mytilus galloprovincialis, Octopus vulgaris, Ostrea edulis, Pecten maximus, Ruditapes decussatus, Ruditapes philippinarum, Sepia officinalis, Strombus spp., Venerupis aurea, Venerupis pullastra, Venus verrucosa

## Annex 2: Parts of Legislation and WOA documents

In the background and the terms of reference provided by the EC there are several terms that play a crucial role on this assessment. For some of them there are already definitions in EU legislation but and/or in WOA Aquatic Code and/or Manual.

### Aquatic Animals

**EU legislation:** point (3) of article 4 of AHL **aquatic animals** means animals of the following species, at all life stages, including eggs, sperm and gametes: (a) fish belonging to the superclass Agnatha and to the classes Chondrichthyes, Sarcopterygii and Actinopterygii; (b) aquatic molluscs belonging to the phylum Mollusca; (c) aquatic crustaceans belonging to the subphylum Crustacea;

**WOAH Aquatic Code** in glossary: **aquatic animals** means all viable life stages (including eggs and gametes) of fish, molluscs, crustaceans and amphibians originating from aquaculture establishments or from the wild.

### Vectors

There is no definition for the term **vector** in the current EU legislation.

WOAH Aquatic Code in glossary: **vector** means any **living organism that has been demonstrated to transmit a pathogenic agent to susceptible species**. Susceptible species are not considered as vectors for a specific pathogenic agent.

### Susceptible species

In EU legislation there is no definition of the term **susceptible species**.

In WOA Aquatic Code (glossary) there is a definition of susceptible species and there are criteria to define species as susceptible to infections. Susceptible species means species of aquatic animals that have been demonstrated as susceptible to infection with a specific pathogenic agent, in accordance with the criteria for listing species as susceptible to infection in [Chapter 1.5 of the WOA Aquatic Code](#).

### Reservoir

There is no definition of the term reservoir in EU Regulations and the WOA Aquatic Animal Code and Manual.

## **Aquatic Animal Health Code CHAPTER 1.5.**

### **Criteria for listing species as susceptible to infection with a specific pathogen**

#### **Article 1.5.1. Purpose**

In each disease-specific chapter, Article X.X.2. lists the aquatic animal species that have been found to be susceptible to infection with the relevant pathogenic agent. The recommendations of each disease-specific chapter apply only to the species listed in Article X.X.2.

The purpose of this chapter is to provide criteria for determining which species are listed as susceptible in Article X.X.2. of each disease-specific chapter in the Aquatic Code.

### **Article 1.5.2. Scope**

Species of aquatic animals are considered susceptible to infection with a pathogenic agent when the presence of a multiplying or developing pathogenic agent has been demonstrated by the occurrence of natural cases or by experimental exposure that mimics natural transmission pathways. Susceptibility includes clinical or non-clinical infection.

The decision to list an individual species as susceptible in a disease-specific chapter should be based on a finding that the evidence is definite in accordance with Article 1.5.3. A taxonomic ranking higher than species is listed when the criteria in Article 1.5.9. are met.

Possible susceptibility of a species is also important information and, in accordance with Article 1.5.8., these species are included in Section 2.2.2. Species with incomplete evidence for susceptibility of the relevant disease-specific chapter of the Aquatic Manual.

### **Article 1.5.3. Approach**

A three-stage approach is outlined in this chapter to assess susceptibility of a species to infection with a specified pathogenic agent and is based on:

- criteria to determine whether the route of transmission is consistent with natural pathways for the infection (as described in Article 1.5.4.);
- criteria to determine whether the pathogenic agent has been adequately identified (as described in Article 1.5.5.);
- criteria to determine whether the evidence indicates that presence of the pathogenic agent constitutes an infection (as described in Article 1.5.6.).

### **Article 1.5.4. Stage 1: criteria to determine whether the route of transmission is consistent with natural pathways for the infection**

The evidence should be classified as transmission through:

1. natural occurrence: includes situations where infection has occurred without experimental intervention e.g. infection in wild or farmed populations; or
2. non-invasive experimental procedures: includes cohabitation with infected hosts, infection by immersion or ingestion; or
3. invasive experimental procedures: includes injection, exposure to unnaturally high loads of pathogenic agent, or exposure to stressors (e.g. temperature) not encountered in the host's natural or culture environment.

Consideration needs to be given to whether experimental procedures (e.g. injection, infective load) mimic natural pathways for disease transmission. Consideration should also be given to environmental factors as these may affect host resistance or transmission of the pathogenic agent.

### **Article 1.5.5. Stage 2: criteria to determine whether the pathogenic agent has been adequately identified**

The pathogenic agent should be identified and confirmed in accordance with the methods described in Section 4 (diagnostic methods) of the relevant disease-specific chapter in the Aquatic Manual, or other methods that have been demonstrated to be equivalent.

### **Article 1.5.6. Stage 3: criteria to determine whether the evidence indicates that presence of the pathogenic agent constitutes an infection**

A combination of the following criteria should be used to determine infection (see Article 1.5.7.):

- A. the pathogenic agent is multiplying in the host, or developing stages of the pathogenic agent are present in or on the host;

- B. viable pathogenic agent is isolated from the proposed susceptible species, or infectivity is demonstrated by way of transmission to naive individuals;
- C. clinical or pathological changes are associated with the infection;
- D. the specific location of the pathogenic agent corresponds with the expected target tissues.

The type of evidence to demonstrate infection will depend on the pathogenic agent and potential host species under consideration.

#### **Article 1.5.7. Outcomes of the assessment**

The decision to list a species as susceptible should be based on a finding of definite evidence. Evidence should be provided for the following:

1. transmission has been obtained naturally or by experimental procedures that mimic natural pathways for the infection in accordance with Article 1.5.4.;

AND

2. the identity of the pathogenic agent has been confirmed in accordance with Article 1.5.5.;

AND

3. there is evidence of infection with the pathogenic agent in the suspect host species in accordance with criteria A to D in Article 1.5.6. Evidence to support criterion A alone is sufficient to determine infection. In the absence of evidence to meet criterion A, satisfying at least two of criteria B, C or D would be required to determine infection.

#### **Article 1.5.8.: Species for which there is incomplete evidence for susceptibility**

The decision to list a species as susceptible in Article 1.5.2. of each disease-specific chapter should be based on a finding that the evidence is definite.

However, after application of Article 1.5.7., if there is incomplete evidence to demonstrate susceptibility of a species but partial information is available, these species will be included in Section 2.2.2. Species with incomplete evidence for susceptibility of the relevant disease-specific chapter in the Aquatic Manual.

If there is incomplete evidence to demonstrate susceptibility of a species, the Competent Authority should, prior to the implementation of any import health measures for the species, undertake a risk assessment for the pathogenic agent under consideration, in accordance with the recommendations in Chapter 2.1.

#### **Article 1.5.9. Listing susceptible species at a taxonomic ranking of Genus or higher**

Some pathogenic agents have low host species specificity and can infect numerous species across multiple taxa. These pathogenic agents are eligible for assessment using this article if they have at least one susceptible species in each of three or more taxa at the ranking of Family. The outcome of applying this article may be that susceptible species are listed in Article X.X.2. of each disease-specific chapter at a ranking of Genus or higher.

**1.** For pathogenic agents that have a low host species specificity, a decision to conclude susceptibility of species at a taxonomic ranking of Genus or higher should only be made where:

- a. after application of Article 1.5.7., more than one species within the taxonomic ranking has been found to be susceptible;

AND

- b. no species within the taxonomic ranking has been found to be non-susceptible to infection;

AND

- a. the taxonomic ranking is at the lowest level supported by evidence of points (a) and (b).

**2.** Evidence of non-susceptibility of a species to infection includes:



- a. absence of infection in a species exposed to the pathogenic agent in natural settings where the pathogenic agent is known to be present and has caused infection in co-located susceptible species;
- OR
- b. absence of infection in a species exposed to the pathogenic agent through appropriately designed experimental procedures.

### **Annex 3 Outline of scientific opinion**

- Background as provided by the requestor
- Terms of Reference
- Interpretation of the Terms of Reference
- Data and methods
- Assessment
  - Vectors
  - Reservoirs
  - Conditions
- Conclusions and Recommendations
- References
- Annexes