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**PANDA**

Permanent network to strengthen expertise on infectious diseases of aquaculture species and scientific advice to EU policy

Coordination Action

Scientific support to policies

**Work Package 2**

**Risk analysis of exotic, emerging and re-emerging disease hazards**

**Annex 3: OIE and Directive 2006/88/EC disease listing criteria**

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## Annex 3 - OIE and Directive 2006/88/EC disease listing criteria

### 3.1 OIE disease listing criteria

(Chapter 1.1.2., OIE International Aquatic Animal Health Code, 10th edn, 2007; [http://www.oie.int/eng/normes/fcode/en\\_chapitre\\_1.2.2.htm](http://www.oie.int/eng/normes/fcode/en_chapitre_1.2.2.htm); OIE, 2007).

#### i) Article 1.2.2.1. Criteria for listing an aquatic animal disease

Diseases proposed for listing must meet all of the relevant parameters set for each of the criteria, namely A. Consequences, B. Spread and C. Diagnosis. Therefore, to be listed, a *disease* must have the following characteristics: 1 or 2 or 3; and 4 or 5; and 6; and 7; and 8.

| No.                    | Criteria (A–C) | Parameters that support a listing   | Explanatory notes  |
|------------------------|----------------|---|--|
| <b>A. Consequences</b> |                |   |  |
| 1.                     |                | The disease has been shown to cause significant production losses at a national or multinational (zonal or regional) level.   | There is a general pattern that the disease will lead to losses in susceptible <sup>1</sup> species, and that morbidity or mortality are related primarily to the agent and not management or environmental factors. (Morbidity includes, for example, loss of production due to spawning failure.) The direct economic impact of the disease is linked to its morbidity, mortality and effect on product quality. |
| 2.                     | Or             | The disease has been shown to or is scientific evidence indicates that it is likely to negatively affect wild aquatic animal populations that are an asset worth protecting for economic or ecological reasons. | Wild aquatic animal populations can be populations that are commercially harvested (wild fisheries) and hence are an economic asset. However, the asset could be ecological or environmental in nature, for example, if the population consists of an endangered species of aquatic animal or an aquatic animal potentially endangered by the disease.   |
| 3.                     | Or             | The agent is of public health concern.  |  |
| <b>And</b>             |                |   |  |
| <b>B. Spread</b>       |                |   |  |
| 4.                     |                | Infectious aetiology of the disease is proven.  |  |

<sup>1</sup> 'susceptible' is not restricted to 'susceptible to clinical disease' but includes 'susceptible to covert infections'

| No.                               | Criteria (A–C) | Parameters that support a listing   | Explanatory notes  |
|-----------------------------------|----------------|---|--|
| 5.                                | Or             | An infectious agent is strongly associated with the disease, but the aetiology is not yet known.  | Infectious diseases of unknown aetiology can have equally high-risk implications as those diseases where the infectious aetiology is proven. Whilst disease occurrence data are gathered, research should be conducted to elucidate the aetiology of the disease and the results be made available within a reasonable period of time.   |
| 6.                                | And            | Potential for international spread, including via live animals, their products and inanimate objects.   | International trade in aquatic animal species susceptible to the disease exists or is likely to develop and, under international trading practices, the entry and establishment of the disease is a likely risk.   |
| 7.                                | And            | Several countries or countries with zones may be declared free of the disease based on the general surveillance principles outlined in Chapter 1.1.4 of the Aquatic Manual. | Free countries/zones could still be protected. Listing of diseases that are ubiquitous or extremely widespread would render notification unfeasible. However, individual countries that run a control programme on such a disease can propose its listing provided they have undertaken a scientific evaluation to support their request. Examples may be the protection of broodstock from widespread diseases, or the protection of the last remaining free zones from a widespread disease. |
| <b>And</b><br><b>C. Diagnosis</b> |                |   |  |
| 8.                                |                | A repeatable and robust means of detection/diagnosis exists.  | A diagnostic test should be widely available and preferably has undergone a formal standardisation and validation process using routine field samples (see OIE Manual of Diagnostic Tests for Aquatic Animals) or a robust case definition is available to clearly identify cases and allow them to be distinguished from other pathologies.   |

**ii) Article 1.2.2.2. Criteria for listing an emerging aquatic animal disease**

A newly recognised disease or a known disease behaving differently may be proposed for listing if it meets the criteria 1 or 2, and 3 or 4. Such proposals should be accompanied by a case definition for the disease under consideration.

| No. | Parameters that support a listing  | Explanatory notes  |
|-----|--|--|
| 1.  | Infectious aetiology of the disease is proven.   |  |
| Or  |  |  |
| 2.  | An infectious agent is strongly associated with the disease, but the aetiology is not yet known. | Infectious diseases of unknown aetiology can have equally high-risk implications as those diseases where the infectious aetiology is proven. Whilst disease occurrence data are gathered, research should be conducted to elucidate the aetiology of the disease and the results be made available within a reasonable period of time. |
| And |  |  |
| 3.  | The agent is of public health concern.   |  |
|     |  |  |
| 4.  | Significant spread in naive populations of wild or cultured aquatic animals.                     | The disease has exhibited significant morbidity, mortality or production losses at a zone, compartment or country level. 'Naive' means animals previously unexposed either to a new disease or a new form of a known disease.  |

### **3.2 Directive EC/2006/88 disease listing and notification criteria**

#### **Annex IV: Disease listing (Anon, 2006)**

##### **PART I**

##### **Criteria for listing diseases**

- A.** Exotic diseases shall meet the following criteria laid down in point 1 and 2 or 3.
1. The disease is exotic to the Community, as the disease is not established in Community aquaculture, and the pathogen is not known to be present in Community waters.
  2. It has potential for significant economic impact if introduced into the Community, either by production losses in Community aquaculture or by restricting the potential for trade in aquaculture animals and products thereof.
  3. It has potential for detrimental environmental impact if introduced into the Community, to wild aquatic animal populations of species, which are an asset worth protecting by Community or international provisions.
- B.** Non-exotic diseases shall meet the following criteria laid down in point 1, 4, 5, 6, 7, and 2 or 3.
1. Several Member States, or regions in several Member States, are free of the disease.
  2. It has potential for significant economic impact if introduced into a Member State that is free of the disease, either by production losses, and annual costs associated with the disease and its control exceeding 5% of the value of the production of the susceptible aquaculture animal species production in the region, or by restricting the possibilities for international trade in aquaculture animals and products thereof.
  3. The disease has shown, where it occurs, to have a detrimental environmental impact if introduced into a Member State free of the disease, to wild aquatic animal populations of species that is an asset worth protecting under Community law or international provisions.
  4. The disease is difficult to control and contain at farm or mollusc farming area level without stringent control measures and trade restrictions.
  5. The disease may be controlled at Member State level, experience having shown that zones or compartments free of the disease may be established and maintained, and that this maintenance is cost-beneficial.
  6. During placing on the market of aquaculture animals, there is a risk that the disease will establish itself in a previously uninfected area.

7. Reliable and simple tests for infected animals are available. The tests must be specific and sensitive and the testing method harmonised at Community level.