General requirements and procedures related to the publication of self-declaration for aquatic listed diseases

Action Plan Development for AQMENET Implementation

Workshop on enhancing aquatic animal health and biosecurity

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World Organisation for Animal Health
Organisation mondiale de la santé animale
Organización Mundial de Sanidad Animal

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Kingdom of Saudi Arabia المملكة العربية السعودية

Why self-declare an animal health status ?

Demonstrate **transparency** in animal disease situation

Increase **visibility** of disease freedom

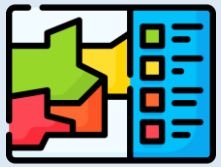
Promote **good animal health practices**

Demonstrate the quality of **Veterinary Services**

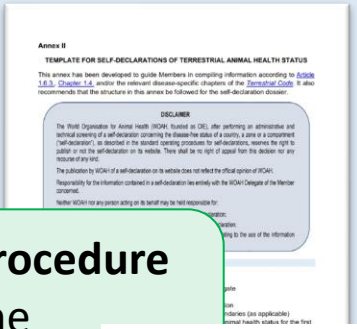
Demonstrate continuous **compliance** with **WOAH international standards**

The procedure

Applicable **for Country, Zone or Compartment (Chapter 4.2)**



No fixed schedule, submit at any time of the year !



Documented **compliance** with the provisions of **Article 1.4.4.** and with **disease-specific articles** of the *Aquatic Code*

Following the **Standard Operating Procedure (SOP) and template (Annex III)** on the publication of self-declarations

For Aquatic **Listed** diseases

A self-declaration of disease freedom is entirely **under the Delegate's responsibility**

www.woah.org/self-declaration

World Organisation for Animal Health

The procedure

1. Acknowledgement of receipt within 24 hours

2. Review of the self-declaration

3. Self-declaration **complete**

OR

3. Request of **additional information** and compilation of the information

4. DDG's review

Reception of a self-declaration

Publication on WOAH official webpage

Pathways for Freedom

Pathway	Primary surveillance evidence to claim disease freedom	Secondary evidence to claim freedom (if required)	Applicable level of application
1. Absence of susceptible species 	Surveys, historical data, import records, environmental information	None	Country, zone
2. Historical freedom 	Passive surveillance	Targeted surveillance (in populations where passive surveillance is not appropriate)	Country, zone
3. Targeted surveillance 	Targeted surveillance	Passive surveillance (in appropriate populations)	Country, zone, compartment
4. Returning to freedom 	Targeted surveillance	Passive surveillance (in appropriate populations)	Country, zone, compartment

Further details on the pathways for freedom are provided in **Chapter 1.4.** of the *Aquatic Code*

Not all pathways are available for every disease; they are disease-specific.

Example, Chapter 10.3 : Infection With Gyrodactylus Salaris

Article.10.3.4

Requirements for self-declaration of freedom from infection with *G. salaris*

A Member Country may make a self-declaration of freedom from infection with *G. salaris* for the entire country, a *zone* or a *compartment* in accordance with the provisions of Articles 10.3.5. to 10.3.8., as relevant. The self-declaration of freedom must be made in accordance with other relevant requirements of the *Aquatic Code* including that the Member Country meet the following conditions:

1. complies with the provisions of Chapter 3.1.; and
2. uses appropriate methods of *diagnosis*, as recommended in the *Aquatic Manual*; and
3. meets all requirements of Chapter 1.4. that are relevant to the self-declaration of freedom.

"Quality Of Aquatic Animal Health Services"

"Aquatic Animal Disease Surveillance"

Example, Chapter 10.3 : Infection With Gyrodactylus Salaris

Article.10.3.5

Country free from infection with *G. salaris*

1. none of the *susceptible species* referred to in Article 10.3.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six months;

OR

2. pathway 2 (historical freedom) is [under study];

OR

3. *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last three years without detection of *G. salaris*, and *basic biosecurity conditions* have been continuously met and have been in place for at least two years prior to commencement of *targeted surveillance*;

means a minimum set of conditions, as described in Article 1.4.6., required to ensure biosecurity for a specific disease, in a country, zone or compartment.

Example, Chapter 10.3 : Infection With Gyrodactylus Salaris

4. it previously made a self-declaration of freedom from infection with *G. salaris* and subsequently lost its free status due to the detection of *G. salaris* but the following conditions have been met:

   a. on detection of *G. salaris*, the affected area was declared an infected *zone* and a *protection zone* was established; and

   b. infected populations within the infected *zone* have been killed and disposed of by means that minimise the likelihood of further transmission of *G. salaris*, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c. previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with *G. salaris*; and

   d. *targeted surveillance*, as described in Chapter 1.4., has been in place for:

      i. at least the last three years in wild and farmed *susceptible species* without detection of *G. salaris*; or

      ii. at least the last one year without detection of *G. salaris* if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

Loss of Self-declared animal health status

Occurrence/recurrence of the disease

Notification to WAHIS

Liaison between WAHIS or Member and Status Department

Outbreak does not impact the self-declaration

No further action, the self-declaration remains accessible online

Outbreak impacts the self-declaration

Communication with Member

WOAH website updated, the self-declaration is not accessible anymore online

24h

24 h

Update of Self-declared status of animal health status

Standard Operating Procedures or *Aquatic Code* chapter updates

WOAH assesses the impact of changes on freedom requirements

WOAH reviews self-declarations

Updates do not impact the self-declaration

No further action, the self-declaration remains accessible online

Updates impact the self-declaration

Communication with Member: request for updated self-declaration

WOAH website updated

Submission of a self-declaration

- Challenges
  - Events not closed in WAHIS 
  - Time requirements not included 
  - Surveillance data not provided or insufficient 
  - Submission to another Department → self-declaration@woah.org
  - Poor-quality Maps 

Submission of a self-declaration

- **Strengths**
  - Clarity of structure, following the template (annex III of the SOP)

  - Hyperlinks to pieces of legislation/documents that substantiate statements

  - Test results presentation

Thank you!

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Pathway 1 – Absence of susceptible species

Unless otherwise specified in the relevant *disease*-specific chapter of the *Aquatic Code*, a self-declaration of freedom from a specific *disease* may be made for a country or *zone* without applying *targeted surveillance* if there are no *susceptible species* (as listed in Article X.X.2. of the relevant *disease*-specific chapter of the *Aquatic Code*) present in that country or *zone*.

Basic biosecurity conditions should be in place for a period of time prior to a *self-declaration of freedom from disease*.

This pathway relies on confidence that *susceptible species* are in fact absent from a country or *zone*. To be confident that *susceptible species* are absent there should be:

1. sound knowledge of the range of *susceptible species* of a *pathogenic agent*; and

2. sufficient knowledge, of the local *aquatic animal* fauna (including wild populations) demonstrated by the following forms of evidence:

   a. reports which provide evidence regarding the absence of the *susceptible species* in the country or *zone* from structured surveys (e.g. of fisheries and aquatic fauna surveys, historical fisheries data);

   b. documentation from the relevant *Competent Authority* showing that those *susceptible species* have not been imported into the country or *zone*;

   c. provision of documentation which sets out scientific evidence indicating that the likelihood of the presence of *susceptible species* in the country or *zone* is negligible (e.g. data on physiological requirements, oceanographic information, biodiversity databases).

This pathway cannot be used for *diseases* where there is uncertainty regarding the full range of *susceptible species* (e.g. *diseases* with a broad host range), or where the *pathogenic agent* may not be obligate (e.g. able to survive indefinitely outside the host). In these *cases*, the pathway will be absent from the relevant *disease*-specific chapter of the *Aquatic Code*, and alternative pathways to demonstrate freedom should be utilised.

The pathway is intended primarily to be used by a *Competent Authority* wishing to establish freedom ahead of farming a new species.

Pathway 2 – Historical freedom

Unless otherwise specified in the relevant *disease*-specific chapter of the *Aquatic Code*, a *self-declaration of freedom from disease* may be made for a country or *zone* on the basis of historical freedom. The primary evidence for historical freedom is *passive surveillance* information generated by a country"s *early detection system*. For this pathway to be utilised, the following conditions should be met:

1. the country or *zone* has *basic biosecurity conditions* in place, including an *early detection system*, that is sufficiently sensitive to detect the *disease* should it occur, and the requirements for *basic biosecurity conditions* of Article 1.4.6., *early detection system* of Article 1.4.7. and *passive surveillance* of Article 1.4.8. are met;

2. the *disease* has not been reported in the country or *zone* (including in wild *aquatic animal* populations) for the minimum period specified in the relevant *disease*-specific chapter of the *Aquatic Code*.

Requirements for passive *surveillance*

A *Competent Authority* making a *self-declaration of freedom from disease* on the basis of historical freedom will need to provide an explanation of how the criteria (i.e. for *basic biosecurity conditions*) presented for this pathway have been met. Specifically, a *Competent Authority* needs to provide evidence that its *early detection system* meets the conditions described in Article 1.4.7. and the requirements for *passive surveillance* in Article 1.4.8. The *early detection system* needs to represent all the *susceptible species* populations in the country or *zone*. If a *Competent Authority* cannot demonstrate that the required characteristics are fulfilled, due to a country"s circumstances (e.g. nature of the *early detection system*, environmental conditions, nature of the *aquaculture*), this pathway is not considered valid. Instead, an alternative pathway that utilises *targeted surveillance* data will be required, or the *passive surveillance* information will need to be supplemented with *targeted surveillance* data (see below).

Need for targeted *surveillance*

If the requirements for *passive surveillance* specified in points 1 and 2 above would not be met for some defined populations of *susceptible species* (e.g. for wild populations), *targeted surveillance* may be used to provide additional evidence of freedom for those populations. Pathway 2 should only be utilised as the basis of a *self-declaration of freedom from disease*, if it is based primarily on *passive surveillance* information to demonstrate historical freedom; alternatively, pathway 3, as described in Article 1.4.13., should be used.

Pathway 3 – Targeted surveillance

As specified in the relevant *disease*-specific chapter of the *Aquatic Code*, a *self-declaration of freedom from disease* may be made for a country, a *zone* or a *compartment* where the primary evidence for freedom is *targeted surveillance* data. For this pathway to be utilised, the following conditions should be met:

1. prior to the commencement of *targeted surveillance*, *basic biosecurity conditions* have been in place for a default minimum period as specified in the relevant *disease*-specific chapter of the *Aquatic Code*;

2. the *disease* has not been reported in the country, *zone* or *compartment*, despite *targeted surveillance* that has been conducted for a period as specified in the relevant *disease*-specific chapter of the *Aquatic Code*, and in accordance with the requirements below.

Requirements for targeted *surveillance*

For many *diseases*, there will be significant temporal variability in the *prevalence* and intensity of *infection* (and therefore likelihood of detection by *targeted surveillance*). For example, the likelihood of detection may be greatest for a particular life stage, or during periods of the year when *pathogenic agent* replication and transmission are at their highest.

Environmental variability from one year to another may also result in differences in *prevalence* and intensity between years that could affect likelihood of detection. Surveys should therefore be designed to account for such variability and sample populations in a manner to maximise the likelihood of detecting a *disease* should it occur. This may require targeting temporal windows such that sampling can only take place during limited periods within a single year. Based on an assessment of potential pathways of introduction of the *diseases*, high *risk* regions or *aquaculture establishments* should be identified and preferentially included in the *surveillance* programmes. For example, establishments near ports or processing facilities may have higher likelihood of exposure to introduced *pathogenic agents*.

To maximise the likelihood of *pathogenic agent* detection, surveys should select species and life stages most likely to be infected and take place at times of the year when temperature and season offer the best opportunity for detection. At least two surveys per year (for at least two consecutive years – the default minimum period) need to be conducted three or more months apart to declare freedom unless *disease*-specific evidence supports an alternative strategy. In situations where seasonal conditions do not permit a gap of at least three months between surveys, the maximum possible time gap should be allowed to elapse between one survey and the next.

Over the period of *targeted surveillance*, the combined number of *aquaculture* establishments and *aquatic animals* sampled should be sufficient to generate at least 95% confidence that the *pathogenic agent* would be detected if present at or above the design *prevalence* in the country, *zone* or *compartment*. Design *prevalence* at the animal and higher levels of aggregation (i.e. pond, *aquaculture establishment*, village, etc.) should be set to a maximum of 2% (a higher design *prevalence* can only be used if justified by epidemiological evidence as described in Article 1.4.16.). Surveys should be designed in accordance with the recommendations provided in Article 1.4.16.

Other sources of data

This pathway to *disease* freedom should be based primarily on the results of *targeted surveillance*. However, the submission may also include an analysis of the *passive surveillance* information to provide supplemental evidence. This evidence may be used for defined populations of *susceptible species* where *passive surveillance* is demonstrated to be sufficiently sensitive (as described in Article 1.4.8.).

Pathway 4 – Returning to freedom

As specified in the relevant *disease*-specific chapter of the *Aquatic Code*, a *self-declaration of freedom from disease* may be made for a country, a *zone* or a *compartment* for which a self-declaration had previously been made, but subsequently lost due to an *outbreak* of the *disease*.

For a country or a *zone*, the default minimum period of *surveillance* to regain freedom is consistent with the requirements for pathway 3. However, a self-declaration of freedom can be made sooner if the relevant *Competent Authority* can demonstrate that the approach would provide an appropriate standard of evidence for the circumstances of the *outbreak* and the *disease*.

Compartments are able to return to freedom relatively rapidly; however, a minimum period of time is required as specified in each *disease*-specific chapter of the *Aquatic Code* to demonstrate that eradication has been successful and to ensure the reviewed *basic biosecurity conditions* are effective.

For a country, *zone* or *compartment*, a self-declaration utilising this pathway should provide information on the process employed to review and update *basic biosecurity conditions*. This information should also address the outcomes of the review and any relevant *sanitary measures* implemented to strengthen *basic biosecurity conditions*.

1. Infected *zone* and protection *zone*

Infected *zones* and protection *zones* should be established through exposure contact tracing from known infected *aquaculture establishments* (e.g. by following movements of *aquatic animals* or equipment to and from infected establishments) to identify all known infected establishments. Once contact tracing is complete and no new *cases* are being reported or detected through tracing, the boundaries of infected *zones* and protection *zones* can be finalised. The geographic extent of an *infected zone* should be based on the spatial distributions of infected and non-infected establishments within a region (e.g. river, estuary or bay). The *zone* should be defined to encompass geographically clustered infected populations.

The geographic extent of a *protection zone* needs to provide a very high level of confidence that measures implemented within the *zone* will prevent spread from the *zone* and should be based on the epidemiology of the transmissible *pathogenic agent*, the potential for exposure of neighbouring *aquaculture establishments*, the type of *aquaculture* production systems (e.g. open or closed systems), the influence of wild populations, and the local hydrology. In the marine environment, local hydrology (including tidal excursion), the distribution of suitable habitats for *susceptible species* and the movement of wild *susceptible species* or *vectors* should be considered. In the freshwater environment, the boundaries of the *protection zone* should be informed by the distance downstream that viable *pathogenic agent* is likely to spread on currents. If susceptible wild populations or *vectors* are present, their migratory patterns and ranges should be used.

Once infected *zones* and protection *zones* have been established, and no new *cases* have been detected for a period equal to or greater than the incubation period of the *pathogenic agent* (but no shorter than one month), the region outside of the infected *zones* and protection *zones* can be declared a *disease free zone*. Re-establishing *disease* freedom in the infected *zones* and protection *zones* requires *targeted surveillance*.

2. Requirements for *targeted surveillance* in a country or *zone*

2. Requirements for *targeted surveillance* in a country or *zone*

Once all infected populations have been depopulated and affected *aquaculture establishments* have been disinfected, as described in Chapter 4.4., and synchronously fallowed as described in Chapter 4.7., for a period determined by the biophysical properties of the *pathogenic agent* (i.e. survival in the environment), a *surveillance* programme within the protection *zones* and infected *zones* should commence. The programme should include both farmed and wild populations of *susceptible species* in the protection *zones* and infected *zones*. A *risk*-based approach to the design of the survey is recommended (as described in Article 1.4.6.). The following *aquaculture establishments* or populations should be preferentially selected for sampling:

a. establishments which have been restocked following depopulation;

b. establishments and wild populations at greatest *risk* of exposure to *infection* during the *outbreak*, i.e. in close hydrographical proximity to infected establishments or with other epidemiological contacts such as sharing equipment or movements of *aquatic animals*;

c. wild populations of *susceptible species* downstream or in the immediate vicinity of previously infected establishments.

It is recommended that at least two negative surveys are conducted prior to reclaiming freedom. The second survey should start at least three months after completion of the first survey. Surveys should take place during optimum seasons, temperatures, and priority life stages to optimise *pathogenic agent* detection. If there are breaks in production, the surveys should also ideally span two production cycles. The number of *aquaculture establishments* and the samples taken per establishment in each survey should be sufficient to demonstrate with 95% confidence that the *pathogenic agent* would be detected if present above a *prevalence* of 2% (a higher design *prevalence* can be used if justified by epidemiological evidence). If *disease* is detected in wild populations of *susceptible species* and eradication is not possible, the country or *zone* remains infected.

3. Requirements for *targeted surveillance* in a *compartment*

Once the infected populations have been depopulated and affected *aquaculture establishments* disinfected, as described in Chapter 4.4. and fallowed as described in Chapter 4.7., for a period determined by the biophysical properties of the *pathogenic agent* (i.e. survival in the environment), the *compartment* can be restocked. A single survey is required following restocking to demonstrate that eradication has been successful. The survey should be undertaken at least sixth months, or at the maximum length of time allowed by the production cycle of species, after the *aquaculture establishment* has been restocked to ensure that the reviewed *basic biosecurity conditions* are effective. The survey should take place during optimum seasons, temperatures, and priority life stages to optimise *pathogenic agent* detection. The number of holding *units* (e.g. ponds, tanks) and the animals per holding *unit* sampled should be sufficient to demonstrate with 95% confidence that the *pathogenic agent* would be detected above a *prevalence* of 2% (a higher design *prevalence* can be used if justified by epidemiological evidence).

Maintenance of disease free status

A country, *zone* or *compartment* that is declared free may maintain its free status provided that the *biosecurity* and *surveillance* requirements described in Article 1.4.5. are continuously maintained and the following requirements are met, as relevant:

1. For a country or *zone* with shared water bodies extending across the *territory* of other countries, free status can only be maintained if the requirements to maintain freedom are in place across all epidemiologically linked shared water bodies.

2. A country, *zone* or *compartment* declared free may maintain its free status without *targeted surveillance* provided that the requirements for *passive surveillance* in Article 1.4.8. are met for the entire country, *zone* or *compartment*, and in the *case* of:

   a. a declared free *zone*, the *zone* occurs within the *territory* of a country declared free;

   b. a declared free *compartment*, the *compartment* occurs within the *territory* of a country declared free.

3. If the conditions of point 2 are not met, ongoing *targeted surveillance* for the *pathogenic agent*, as described in Article 1.4.16., is required at a level determined by a *Competent Authority*, to generate an annual 95% confidence of detection, taking into account the likelihood of *infection*.

4. *Competent Authorities* should ensure prompt investigation of any health events or other information that may raise suspicion of the occurrence of a *listed disease* from which a country, *zone* or *compartment* has been declared free. The investigation should be undertaken in accordance with Article 1.4.18. and the requirements of Chapters 1.1. and 5.1. should be met at all times.

(What should be included in the self-declaration ?)

The scope of the declaration, i.e. the specific *disease*, the level of freedom (country, *zone* or *compartment*) and the pathway utilised to claim or return to *disease* freedom;

information to verify that *basic biosecurity conditions* and the requirements of *surveillance* systems have been met;

details of the *surveillance* design and assumptions

the *surveillance* analysis and results

the measures implemented to maintain freedom