**USA COMMENTS**

CHAPTER 1.4.  
  
**AQUATIC ANIMAL DISEASE SURVEILLANCE**

Article 1.4.1.

**Purpose**

This chapter provides guidance on the *surveillance* approaches to be used by a *Competent Authority* to make a *self-declaration of freedom from disease* or to confirm the occurrence of a *listed disease* or an *emerging disease*.

Article 1.4.2.

**Introduction and scope**

This chapter supports the *Competent Authority* to meet the requirements for *self-declaration of freedom from disease* at the level of a country, *zone* or *compartment*, and for maintenance of freedom, that are presented in each *disease*-specific chapter. It also provides the *Competent Authority* with guidance to meet the requirements of *notification* of a *listed* *disease* or an *emerging disease* in accordance with Chapter 1.1.

This chapter is not intended to provide detailed technical guidance on *surveillance* design or analysis. The *Competent Authority* is encouraged to consult published literature and seek appropriate expertise to design and analyse *surveillance* programmes that meet the requirements of the *Aquatic Code*.

1) The general requirements of a *surveillance* system necessary to support a *self-declaration of freedom from* *disease* are specified in Article 1.4.5. to Article 1.4.8. .

2) The criteria that have been used to set the periods specified in each *disease*-specific chapter for *basic* *biosecurity conditions* to be in place, or for *targeted surveillance* that should be undertaken, prior to claiming freedom, are included in Article 1.4.9. and 1.4.10.

3) The requirements for each of the four pathways for claiming freedom, and for maintaining freedom, are introduced in Article 1.4.3 and described in detail in Article 1.4.11. to Article 1.4.15.

4) Guidance on the design of surveys to demonstrate freedom from *disease*, and for combining multiple sources of *surveillance* information are provided in Article 1.4.16. and Article 1.4.17., respectively.

5) Article 1.4.18. provides guidance on diagnostic confirmation of *listed* *diseases* or an *emerging disease*.

The *Competent Authority* should refer to the relevant *disease*-specific chapter of the *Aquatic Manual* for recommendations on sample collection and appropriate diagnostic methods for *surveillance* and diagnosis of *listed diseases*. The relevant *disease*-specific chapter of the *Aquatic Manual* should also be consulted for the necessary information on epidemiology and diagnostic performance of assays required for *surveillance* programme design.

**Rationale:** Clarification is needed to specify that former article introduces this information, but additional detail is found in later.

Article 1.4.3.

**Pathways for demonstrating freedom from disease**

The *Competent Authority* may use one of four pathways to make a *self-declaration of freedom from* *disease*. Each pathway outlines the *aquatic animal* health circumstances and requirements that should be met for a self-declarationto be made. Any one of these four pathways may be utilised; however, the *Competent Authority* should provide evidence that all relevant requirements to demonstrate *disease* freedom have been met as described in this chapter and the relevant *disease*-specific chapter of the *Aquatic Code*. The four pathways are:

1. Absence of susceptible species

This pathway may be utilised if, as described in Article 1.4.11., it can be demonstrated that no *susceptible species* are present.

2. Historical freedom

This pathway may be utilised if, as described in Article 1.4.12., there is evidence of historical absence of a *disease* that is supported primarily by *passive surveillance* ~~data~~ information generated by a country’s *early detection system*. This pathway demands the demonstration of awareness, competence, and readiness of the fish health infrastructure for disease detection and investigation. It does not require empirical assessment but rather relies on belief in a functional system and a long-running absence of confirmed findings. Reliant on the observation of concerning visual (or other sensory) signals or production measures, this pathway only applies to pathogens, hosts, and environments conducive to clinical expression.

**Rationale:** Change needed to reflect that passive surveillance might provide qualitative information OR empirical data.

Additional language added to this section to clarify that this pathway represents general knowledge (better described as information, rather than data which implies something empirical) generated through the awareness, readiness, and competence of the fish health infrastructure. A strong system (combined with a pathogen that manifests clinically) should, given enough time, detect disease if it was present. Through time, this infrastructure affords belief in disease absence. The surveillance pathway, in contrast, relies on empirical data and their assessment, which would allow the claim to progress more rapidly (e.g., 2 years versus 10). The embedded 10 year requirement presumes that this type of system affords 30% confidence per year. In other words, the expectation that strong infrastructure provides 30% confidence is built into this route and does not require separate assessment. If a country believes its infrastructure (and passive surveillance) provides more than 30% confidence per year, it could switch to pathway 3 (surveillance) and achieve freedom in a shorter time frame (e.g., through empirical assessment of passive and/or active surveillance DATA).

3. Surveillance

This pathway may be utilised if the requirements of pathway 1 (absence of *susceptible species*) or pathway 2 (historical freedom) cannot be met, or if a shorter pathway is desired. The pathway primarily uses targeted *surveillance* data, but other sources of evidence may be utilised as described in Article 1.4.13. Passive surveillance data may also be used in this pathway. A key difference between the surveillance and the historical freedom pathways is that the former ~~latter~~ typically generates qualitative, and the latter quantitative (and thus the potential for more rapid), ~~and the former qualitative,~~ assessments.

**Rationale:** Additional language needed to allow for a shorter pathway because if one is generating empirical data, or an SSe can be otherwise calculated (e.g., based on predictive factors or models), then the actual confidence derived from passive (+/- active) surveillance could be calculated. If shown to be 95% this would afford a more rapid claim than the same data without formal assessment.

This addition is needed as mentioned above for historical freedom because if one is generating empirical data, or an SSe can be otherwise calculated (e.g., based on predictive factors or models), the actual confidence derived from passive (+/- active) surveillance could be calculated. If shown to be 95% this would afford a more rapid claim than the same data without formal assessment. Note that the 10-year requirement for the historical freedom pathway presumes ~30% confidence per year (as stated below).

4. Returning to freedom

This pathway may be utilised, as described in Article 1.4.14., in circumstances where a self-declaration had been made, but free status was subsequently lost due to detection of the *disease*.

Table 1.1. A summary of the four pathways for *self-declaration of freedom from* *disease*, including the types of primary and secondary *surveillance* information, and the applicable level of application for either a country, *zone* or *compartment*.

|  |  |  |  |
| --- | --- | --- | --- |
| **Pathway** | **Primary surveillance evidence to claim disease freedom** | **Proposed secondary evidence to claim freedom (if required)** | **Applicable level of application** |
| 1. Absence of susceptible species | *~~Active surveillance~~* Ecological surveys (wild) and industry review (farmed) to demonstrate host species absence | None | Country, *zone, compartment* |
| 1. Historical freedom | *Passive* *surveillance,* qualitative | *Targeted surveillance* (in populations where *passive* *surveillance* is not appropriate) | Country, *zone* |
| 1. Surveillance | *Targeted surveillance*, quantitative | *Passive* *surveillance* (in appropriate populations). Additional forms of evidence (e.g., expert opinion, introduction risk, risk factors) may also be considered. | Country, *zone*, *compartment* |
| 1. Returning to freedom | *Targeted surveillance*, quantitative | *Passive* *surveillance* (in appropriate populations). Additional forms of evidence may also be considered. | Country, *zone*, *compartment* |

**Rationale:** Active surveillance used elsewhere in the OIE implies a focus on a pathogen. This change in wording is needed to clarify that the “evidence” is focusing on the presence/absence of the host, not the pathogen. Pathway 1, column 4: Compartment should be added here because the absence of susceptible species is a clear reason to preclude testing for that pathogen at the compartment level. Other changes reflect the revised emphasis described in the main text.

Article 1.4.4.

**Publication by the OIE of a self-declaration of freedom from disease by a Member Country**

A Member Country may make a *self-declaration of freedom from disease* in a country, *zone* or *compartment*. The Member Country may inform the OIE of the claimed status and the OIE may publish the self-declaration.

A Member Country requesting the publication of a self-declaration should follow the Standard Operating Procedure (under development) for submission and provide documented information on its compliance with the relevant chapters of the *Aquatic Code.* This information should include, but is not limited to the following:

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

2) information to confirm that the general requirements of *biosecurity* and *surveillance* systems have been met;

3) details of the *surveillance* design and assumptions;

4) the *surveillance* analysis and results;

5) the measures implemented to maintain freedom.

The *self-declaration of freedom from disease* may be published only after all the information provided has been received and administrative and technical screening has been performed by the OIE. Publication does not imply endorsement of the claim of freedom by the OIE and does not reflect the official opinion of the OIE. Responsibility for the accuracy of the information contained in a self-declaration lies entirely with the OIE Delegate of the Member Country concerned.

Except when otherwise provided for in the *disease*-specific chapter, an *outbreak* in a Member Country, a *zone* or a *compartment* having a self-declared free status results in the loss of the self-declared free status. A Member Country wishing to reclaim a lost free status should submit a new self-declaration following the procedure described in this chapter.

Article 1.4.5.

**Biosecurity and surveillance system requirements**

The following *surveillance* system requirements should be met for any *self-declaration of freedom* *from disease* in the given compartment, zone or country:

1) the quality of *Aquatic Animal Health Services* can be substantiated to meet the requirements of Chapter 3.1.:

2) *basic biosecurity conditions* as described in Article 1.4.6. are in place;

3) an *early detection system* as described in Article 1.4.7. is in place;

4) there has been no vaccination of *susceptible aquatic animals* for the specific *disease* for at least the period that *basic biosecurity conditions* have been applied prior to self-declaration;

5) the *Aquatic Animal Health Services* have sufficient capacity to investigate and report *disease* events to the *Competent Authority*;

6) the *Competent Authority* has access to appropriate diagnostic capability to confirm or exclude cases of *listed diseases* and *emerging diseases* in accordance with Article 1.4.18.

**Rationale:** This change clarifies the scope of the subitems. As an example, if the focus is compartment, as long as vaccination is not used in the compartment, its use elsewhere in the country should not impact compartment status (presuming other biosecurity measures also apply).

Article 1.4.6.

**Basic biosecurity conditions**

*Basic biosecurity conditions* include requirements for preventing the introduction and spread of a specific *disease* and for detection of the *disease* should it occur. The requirements for *basic biosecurity conditions* include:

1) a compulsory requirement for *notification* of a specific *disease*, or suspicion of the *disease*, to the *Competent Authority*;

2) an *early detection system* (as described in Article 1.4.7.);

3) measures to prevent the introduction of the *pathogenic agent* into a country, *zone* or *compartment*, or the spread within or from *infected zones* and *protection zones*, in accordance with the relevant *disease*-specific chapter.

In making a *self-declaration of freedom from disease* for a country, *zone* or *compartment,* the C*ompetent Authority* should describe the *basic biosecurity conditions* relevant to its declaration, and ensure all requirements for *basic biosecurity conditions* described in this chapter are met.

Article 1.4.7.

**Early detection system**

The *early detection system* of the *Competent Authority* underpins any *passive surveillance* ~~data~~ information utilised by a *Competent Authority* to make a *self-declaration of freedom from disease*.

**Rationale:** (as mentioned in comment for Article 1.4.3.) This change is needed to reflect that passive surveillance might provide qualitative information OR empirical data.

A *self-declaration of freedom from disease* needs to document that the *early detection system* fulfils each of the five characteristics below:

1) broad awareness, e.g. among the personnel employed at *aquaculture establishments* or involved in processing, of the characteristic signs of *listed diseases* and *emerging diseases*;

2) *veterinarians* and *aquatic animal health professionals* are trained in recognising and reporting suspicion of *disease* occurrence;

3) the *Aquatic Animal Health Services* have capacity to undertake rapid and effective *disease* investigation based on a national chain of command;

4) the *Aquatic Animal Health Services* have access to sufficient diagnostic capability to confirm or exclude cases of *listed* *diseases* and the capability to investigate *emerging* *diseases* as described in Article 1.4.18.;

**Rationale:** Add “the capability to investigate” because the ability to perform diagnostic testing is not a requiment for emerging diseases.

5) *veterinarians* and *aquatic animal health professionals* have a legal obligation to report suspicions of *disease* occurrence to the *Competent Authority*.

The sensitivity of an *early detection system* is the likelihood that the *disease* will be detected if present. Of fundamental importance is *disease* reporting by farmers to initiate the necessary steps of *passive surveillance*. Specifically, the *Competent Authority* should be able to demonstrate that efforts have been made to make farmers aware of signs of *listed diseases* and *emerging diseases*, and secondly the obligation of farmers, *aquatic animal health professionals* and others to report suspicion. The underpinning legal instruments should be cited.

The capacity of the *Aquatic Animal Health Services* to respond to suspicion of a *listed diseas*e can be evidenced by response plans, and a descriptive chain of command that will result in an official declaration that the *pathogenic agent* has been detected. Standard operating procedures for diagnostic assays for *listed diseases* and accreditation to internationally recognised laboratory standards can demonstrate the capacity of the *Aquatic Animal Health Services* to detect *listed diseases*. In addition, the effective function of the *early detection system* is best illustrated through examples of investigations in response to reported suspicion of *disease*. Qualitative assessment of the sufficiency of *early disease reporting* should involve the documentation of all system components. If possible, the sensitivity of an *early detection system* (i.e. the likelihood of *pathogenic agent* detection following introduction) could be quantified, for example, by use of a scenario tree model. However, this is not a requirement of the historical freedom pathway and lends itself better to the provision of quantitative evidence required in pathway 3 (surveillance).

**Rationale:** Language is needed because if not quantified, then qualitative assessment should include documentation of all early detection system components. Additional language needed here because (as mentioned in earlier comment) the 10-year time frame presumes ~ 30% confidence per year. Calculation of SSe to demonstrate stronger confidence is something a country might want to do to shorten the route to freedom. But this would then fall under pathway 3 (surveillance).

Article 1.4.8.

**Requirements for passive surveillance**

1) In addition to the characteristics of an *early detection system* described in Article 1.4.7., the conditions described in this article should be met for *passive surveillance* ~~data~~information to be utilised for a *self-declaration of freedom from* *disease.* The conditions, which apply to each defined *study population* of *susceptible species* of a specific *disease*, are that:

**Rationale:** (as mentioned in comments above) This change is needed to reflect that passive surveillance might provide qualitative information OR empirical data.

1. conditions (biotic and abiotic) are conducive to clinical expression of the *infection*, such that if the *pathogenic agent* were present within the population of *susceptible species*, it would produce clinical signs of the *disease* at least seasonally.

**Rationale:** Additional clarification needed because if surveillance is focused on the appropriate seasons (with conducive environments) this could be sufficient for retrospective demonstration of freedom.

b) there should be sufficient awareness by potential observers of the *study population*, such that observation of clinical signs of the *disease*, which may include increased mortality, would lead to reporting;

c) populations of susceptible farmed *aquatic animals* should be under ~~sufficient~~ observation in all relevant production systems, such that, if clinical signs of the *disease* were to occur, they would be observed;

d) for populations of susceptible wild *aquatic animals*, they should:

i) be under ~~sufficient~~observation, such that if clinical signs of the *disease* were to occur, they would be observed and reported, or

**Rationale:** Remove “sufficient” because it does not provide a qualitative description to how/what type of observation should be conducted, or a measurable description of degree.

ii) be epidemiologically linked to farmed populations, such that the *disease* would occur and be observed and reported in farmed populations if it were to occur in adjacent wild *aquatic animal* populations.

2) *Passive surveillance* depends primarily on observers (e.g. farmers, *aquatic animal health professionals*) reporting suspicion of *disease* and unexplained increased mortality to the *Competent Authority*. For wild populations, the requirements of point 1 4 a) above are unlikely to be met under most circumstances and, therefore, *passive* *surveillance* will be insufficiently sensitive. If a *Competent Authority* utilises *passive surveillance* data for defined populations of wild *aquatic animals*, it should demonstrate that the conditions of this article have been met, and that the *early detection system* provides ~~appropriate~~*sensitivity* for detection of the *disease* should it occur.

**Rationale:** Change needed to clarify the wild populations reference is in 1 a), not 4 a). Remove “appropriate” unless a justification can be provided for the difference between “appropriate sensitivity” vs. “sensitivity.”

3) Awareness of clinical signs of *disease* and the necessary level of observation is best demonstrated through examples of reporting by farmers, *aquatic animal health professionals* and others to the *Competent Authority*. In addition to reporting, information for *passive surveillance* may originate from inspections at processing plants, routine visits by government officials and surveys (e.g. of wild populations), submissions to laboratories, *aquaculture establishment* records (e.g. mortality, medicine use, etc.).

4) *Passive surveillance* is only effective if conditions are conducive to clinical expressions of *disease*, which include:

a) environmental conditions (e.g. water temperatures) being permissive for the development of clinical signs during at least a period of the year; and

b) the representative presence of *susceptible species* in which *infection* results in clinical signs.

**Rationale:** Language added because this surveillance should well-represent (i.e., provide proxy information for) any non-clinical susceptible populations in the compartment, zone, or country in question. This ensures that surveillance coverage is complete.

5) Evidence from published literature will generally be sufficient to demonstrate the environmental conditions under ~~over~~ which clinical signs appear, and in which *infection* of *susceptible species* will result in clinical signs. This information should be supplemented with data on the environmental conditions for the *target populations*.

**Rationale:** Change needed to clarify the clinical signs appear “under” environmental conditions.

6) *Passive surveillance* only contributes to the *early detection system* if investigations by the *Competent Authority* follow reports of *disease*.

Article 1.4.9.

**Required periods for basic biosecurity conditions**

1) Prior to a Member Country making a *self-declaration of freedom from disease*, *basic biosecurity conditions* should be in place for a defined period. *Basic biosecurity conditions* should be applied for sufficient duration prior to a self-declaration*,* so that, by the end of the period, should the *disease* have been introduced before the *basic biosecurity conditions* began:

a) no *pathogenic agent* would remain present in the environment (see pathway 1 – absence of *susceptible species*),

b) the *disease* would manifest clinically and be detected by the country’s *early detection system* (see pathway 2 – historical freedom), and

c) by the time targeted *surveillance* commenced (see pathway 3 – *surveillance*), *infection* levels would have reached the minimum *prevalence* estimate (i.e. the design *prevalence*) used in the survey design to calculate the sample sizes (e.g. of *aquaculture establishments* and *aquatic animals* needed to demonstrate freedom).

2) Each *disease*-specific chapter of the *Aquatic Code* will either include~~s~~ minimum periods that *basic biosecurity conditions* should be in place prior to a *self-declaration of freedom from* *disease* or will reference a default.These periods are determinedbased on the factors described below.

**Rationale:** Language added for clarification of which type of information will be provided in the Code.

a) For pathway 1, the default minimum period that *basic biosecurity conditions* should be in place prior to a *self-declaration of freedom from disease* is six months. It is expected that this period will be sufficient for most *diseases* to ensure that no viable *pathogenic agent* introduced via *aquatic animal* commodities has remained present in the environment, and the *early detection system* was well established and demonstrated to be functioning. The required period that *basic biosecurity conditions* should be in place prior to making a self-declaration*,* using this pathway, is determined for each *pathogenic agent* based on its epidemiology (e.g. agent stability in the environment, presence of resistant life stages, *vectors*), and is specified in the relevant *disease*-specific chapter of the *Aquatic Code*.

b) For pathway 2, the default minimum period that *basic biosecurity conditions* should be in place prior to a self-declaration, for all *listed diseases,* is ten years. This period is the minimum required to achieve 95% likelihood of freedom, if the annual likelihood of detection is approximately 30%. However, if the average annual likelihood of detection by a country’s *early detection system* is considered to be less than 30% in the period preceding declaration (following consideration of the factors below), the minimum period required for *basic biosecurity conditions* defined in the relevant *disease*-specific chapter of the *Aquatic Code* will be set to a period greater than ten years, as appropriate. Similarly, a shorter period may be justified if the annual likelihood of detection can be demonstrated to substantially exceed 30%. An evaluation of the following factors will determine whether a period longer or shorter than ten years is required:

**Rationale:** Addition of “approximately” needed because the equation 1-(1-0.3)^years suggests the minimum period required for a 30% annual likelihood of detection required to achieve 95% confidence is actually 9 years. Additional flexibility to this timeframe is needed here because the default period is relatively arbitrary, so evidence should be allowed to adjust the period in either direction (longer or shorter).

i) the maximum duration of the production cycle for the *susceptible species*;

ii) the life stages at which *aquatic animals* are susceptible;

iii) the variation in predilection to clinical *disease* among *susceptible species*;

iv) the expected severity and duration of clinical signs in the *susceptible species* (and therefore the likelihood of detection);

v) environmental conditions that influence levels of *infection* and clinical expression, including seasonality of the *disease* (period of the year when clinical *disease* occurs, e.g. when water temperatures are permissive);

vi) factors specific to the *pathogenic agent* (e.g. production of spores);

vii) production systems and management practices that would affect observation of clinical signs if they were to occur;

viii) any other relevant factors that may influence presentation of clinical signs and observation of the *disease* should it be present.

1. For pathway 3, the minimum period that *basic biosecurity conditions* should be in place prior to commencement of *targeted surveillance* will generally be one year. It is expected that this period will be sufficient under most circumstances for a *disease* to reach a *prevalence* sufficiently high to be detected by a survey designed in accordance with the recommendations of this chapter. However, different recommendations are provided in the *disease*-specific chapters of the *Aquatic Code* for some *diseases* where the epidemiology of a *disease* and nature of production systems would affect the expected transmission, and thus increase in *prevalence* and intensity of *infection* in the *susceptible species* following introduction of the *disease*. An evaluation of the following factors will determine whether a period longer or shorter than one year is required:

**Rationale:** Additional language included because evidence should be allowed to adjust the period in either direction (longer or shorter).

i) the maximum duration of the production cycle for the *susceptible* *species*;

ii) the life stages at which *aquatic animals* are susceptible;

iii) seasonality of the *disease* (periods of the year when *prevalence* and intensity of *infection* is highest and most conducive to detection);

iv) production systems and management practices that would affect occurrence of *infection*;

v) any other relevant factors that may influence the expected rate of increase in *prevalence* and intensity of *infection* in *susceptible species* following introduction of the *disease*.

d) Pathway 4 is only applicable following the loss of *disease* freedom due to a *disease* *outbreak*. This circumstance implies a failure of *basic biosecurity conditions* to prevent the introduction of the *disease*. The pathway of *disease* introduction should be investigated and *basic biosecurity conditions* should be reviewed and modified as necessary following eradication of the *disease*, and prior to commencement of any *targeted surveillance* that will be utilised as evidence for a subsequent self-declaration.

Article 1.4.10.

**Required periods for targeted surveillance**

Prior to a *Competent Authority* making a *self-declaration of freedom from disease* utilising pathway 3 or pathway 4, *targeted surveillance* should be conducted for a defined period, as described in the relevant *disease*-specific chapter of the *Aquatic Code*. The period of *targeted surveillance* is determined for each *disease*-specific chapter of the *Aquatic Code,* based on the factors described below:

1) the maximum duration of the production cycle for the *susceptible species*;

2) the life stages at which *aquatic animals* are susceptible;

3) seasonality of the *disease* (periods of the year when *prevalence* and intensity of *infection* is highest and most conducive to detection);

4) production systems and management practices that would affect the seasonal occurrence of *infection*.

For a country or *zone*, the minimum default period for which *targeted surveillance* should occur prior to a *self-declaration of freedom from disease* is two years. During the period of *targeted surveillance,* surveys should occur during defined time periods when conditions are optimal for detection of the *pathogenic agent* (e.g. seasons, temperatures, and life stages). All populations of *susceptible species* should be included in the scope of each survey. If sampling is clustered in time (e.g., discrete surveys are conducted twice a year),tThere should be a gap of at least three months between surveys and, if there are breaks in production, the surveys should also ideally span two production cycles. If sampling is relatively continuous (e.g, monthly or seasonally), results may accrue for assessment at 6-month intervals.

**Rationale:** Additional language is needed because a 3-month respite in surveillance only makes sense if sampling is clustered in time. If sampling is relatively continuous, samples should simply be aggregated at 6-month intervals for assessment (as long as they are conducted in conducive temperatures/seasons). Without this additional wording the implication is that is surveys with relatively continuous sampling would need to discard data to achieve a 3-month gap.

For a country or *zone* to regain freedom in accordance with pathway 4, the required period of *targeted surveillance* specified in the *disease*-specific chapter of the *Aquatic Code* will be consistent with the original self-declaration of freedom.

For *compartments*, the minimum default period that *targeted surveillance* should occur prior to a *self-declaration of freedom from* *disease* is one year. This shorter period for a *compartment* reflects the more clearly defined populations, the *biosecurity* required to maintain its population’s health status and a likely narrower variation in environmental variables. However, a different period (more or less than one year) may be stipulated in the *disease*-specific chapter of the *Aquatic Code* if warranted by the epidemiology of the *disease* and the criteria proposed above. For example, different requirements may be appropriate where *susceptible species* have a three-year production cycle, versus one that has a six-month production cycle; particularly if the *disease* is likely to occur at a very low *prevalence* until near the end of the production cycle.

For *compartments* to regain freedom in accordance with pathway 4,the required period of *targeted surveillance* specified in the *disease*-specific chapter of the *Aquatic Code* may be less than the original declaration of freedom (dependent on the nature of the specific *disease*). However, at least one round of testing is required to demonstrate that eradication has been successful and to test the reviewed *biosecurity* conditions.

Article 1.4.11.

**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, based on active *surveillance*, of the local *aquatic animal* fauna (including wild populations).

The forms of evidence that may be required to demonstrate absence of *susceptible species* include:

1) the absence of reports of the existence of the *susceptible species* in the country or *zone* from structured surveys (e.g. of fisheries and aquatic fauna surveys, historical fisheries data);

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

3) 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 the *Competent Authority* wishing to establish freedom ahead of farming a new species.

Article 1.4.12.

**Pathway 2** – **Historically free**

Unless otherwise specified in the relevant *disease-*specificchapter 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* ~~data~~ information generated by a country’s *early detection system*. For this pathway to be utilised, the following conditions should be met:

**Rationale:** (as mentioned in comments above) This change is needed to reflect that passive surveillance might provide qualitative information OR empirical data.

1) the country has *basic biosecurity conditions* in place, including an *early detection system*, that is sufficiently sensitive to detect the *disease* should it occur, and the conditions 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

The level of confidence provided by *passive surveillance* ~~data~~ information (generated by the *early detection system* of the *Competent Authority*) to demonstrate historical freedom should be set at 95%, equivalent to that of other pathways for which the evidence is provided by *targeted surveillance*. The 10-year time frame presumes that passive surveillance is achieving an annual SSe of approximately 30%. If passive surveillance or a combination of *surveillance* data sources ~~is to be used~~ (e.g. *passive surveillance* and *targeted surveillance*), suggests a higher ~~the~~ level of annual confidence, the time period could be reduced accordingly, or if evidence is very strong, the country, zone, compartment could switch instead to Pathway 3 ~~should also be set at~~which aims to achieve 95% that the *disease* is absent much more rapidly. The data sources for *passive surveillance* are described in Article 1.4.8. of this chapter.

**Rationale:** (as mentioned in comments above) This change is needed to reflect that passive surveillance might provide qualitative information OR empirical data. Text modification because 10 years (and 30% detection capacity) seems relatively arbitrary. Any quantitative assessment that demonstrates a stronger system should allow us to either reduce the 10-year time minimum, or switch to pathway 3 and reach our freedom claim in much shorter duration. Pathway 2 should be qualitative (assuming a yearly default of 30% SSe), and pathway 3 should be quantitative (requiring a demonstration of 95%, based on total evidence, over a shorter term).

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, the *Competent Authority* needs to provide evidence that its *early detection system* meets the conditions as described in Article 1.4.7. ~~(and ideally a quantitative assessment of~~ *~~sensitivity~~* ~~would be included).~~ The  *early detection system* needs to cover all the *susceptible species* populations in the country or *zone*. If the *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* industry), this pathway is not considered valid. Instead, an alternative pathway that utilises *targeted surveillance* data will be required, or the *passive surveillance* data will need to be supplemented with *targeted surveillance* data (see below).

**Rationale:** Remove text because the default historic freedom pathway presumes 30% annual SSe and does not require further assessment.

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) or if a more rapid claim is desired, *targeted surveillance* may be used to provide additional evidence of freedom for those populations. However, for this pathway to be utilised as the basis of a *self-declaration of freedom from* *disease*, it should be based primarily on *passive surveillance* data to demonstrate historical freedom; alternatively, pathway 3, as described in Article 1.4.13., should be used.

**Rationale:** Additional language included because evidence should be allowed to shorten the time period.

Article 1.4.13.

**Pathway 3 – Surveillance**

As specified in the relevant *disease-*specificchapter 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) *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 basic biosecurity conditions

*Targeted surveillance* surveys should only commence following a period of time that *basic biosecurity conditions* have been in place, as specified in the relevant *disease*-specific chapter of the *Aquatic Code*.

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 the rate *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, establishmentsnear 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) need to be conducted. If sampling is clustered in time (e.g., 2 discrete surveys per year), they should be conducted three or more months apart to declare freedom unless *disease*-specific evidence supports an alternative strategy. However, if sampling is relatively continuous through time, samples can be aggregated for assessment at 6 month intervals without requiring a 3 month gap. The number of *aquaculture establishments* and *aquatic animals* sampled should be sufficient to generate an overall 95% confidence or greater that the *pathogenic agent* is at or below the design *prevalence*. Design *prevalence* at the animal and higher levels of aggregation (i.e. pond, *aquaculture* *establishment*, village, etc.) should be 2% or lower (a higher design *prevalence* can only be used if justified by epidemiological evidence). Surveys should be designed in accordance with the recommendations provided in Article 1.4.1.

**Rationale:** Text modification needed per earlier comment under 1.4.10. Additional language is needed because a 3-month respite in surveillance only makes sense if sampling is clustered in time. If sampling is relatively continuous, samples should simply be aggregated at 6-month intervals for assessment (as long as they are conducted in conducive temperatures/seasons). Without this additional wording the implication is that is surveys with relatively continuous sampling would need to discard data to achieve a 3-month gap.

For declared *free zones* or *free compartments* in infected countries, and in all cases where conditions are not conducive to clinical expression of the *pathogenic agent*, *targeted surveillance* needs to be continued at a level, determined by the *Competent Authority*, to generate an annual 95% confidence of detection.

Other sources of data

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

Article 1.4.14.

**Pathway 4 – Returning to freedom**

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

Fora *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 freedomcan 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 test the reviewed *biosecurity* conditions, and to undertake sufficient testing to demonstrate that eradication has been successful.

For a country, *zone* or *compartment*, a self-declarationutilising this pathway should provide information on the process employed to review *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* 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 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* should be considered. In the freshwater environment, the boundaries of the *protection zone* should be determined by the distance downstream that viable *pathogenic* *agent* is likely to spread on currents. If susceptible wild populations 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* and *protection zones* requires *targeted surveillance*.

2. Requirements for targeted surveillance ina country or zone

Once all infected populations have been depopulated and affected *aquaculture establishments* have been disinfected, as described in Chapter 4.3., and synchronously fallowed as described in Chapter 4.6., for a period determined by the biophysical properties of the *pathogenic agent* (i.e. survival in the environment), a *surveillance* programme within the *protection* and *infected zones* should commence. The programme should include both farmed and wild populations of *susceptible species* in the *protection* and *infected zones*. A *risk*-based approach to the design of the survey is recommended (refer to Article 1.4.6.). The following *aquaculture establishments* or populations should be preferentially selected for sampling:

a) establishments which were depopulated (following restocking);

b) establishments and wild populations at greatest *risk* of exposure to *infection* during the *outbreak*, i.e. in close geographic 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* is not present above a *prevalence* of 2% (a higher design *prevalence* can be used if justified by epidemiological evidence).

3. Requirements for targeted surveillancein a compartment

Once the infected populations have been depopulated and affected *aquaculture establishments* disinfected~~, and fallowed~~ as described in Chapter 4.3. and fallowed as described in Chapter 4.6., 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 6 months after the *aquaculture establishment* has been restocked to ensure that the reviewed *basic biosecurity conditions* are effective; and 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* is not present above a *prevalence* of 2% (a higher design *prevalence* can be used if justified by epidemiological evidence).

**Rationale:** Revision is needed to clarify the information pertaining to disinfection is in Chapter 4.3 and fallowing is in Chapter 4.6.

Article 1.4.15.

**Maintenance of disease free status**

For maintenance of free status achieved via pathways 2, 3 and 4, the *Competent Authority* should provide evidence that *basic biosecurity conditions* are continuously maintained.

If *targeted surveillance*, that was required for initial demonstration of freedom, is to be discontinued for any identified population, evidence should be provided to demonstrate that conditions remain conducive to clinical expression of *disease*, and that *passive surveillance*, as provided by the country’s *early detection system*, would rapidly detect the *disease* in those populations should it occur.

Any ongoing *targeted surveillance* to maintain freedom should be undertaken at a level necessary to maintain confidence of freedom, and should take into account the likelihood of *infection*.

Article 1.4.16.

**Design of surveys to demonstrate freedom from disease**

Surveys to demonstrate freedom from a specified *disease* (i.e. *targeted surveillance*) are required for pathway 3 as described in Article 1.4.13. to achieve a *disease* free status, and to regain a *disease* free status following detection of the *pathogenic agent* as described in Article 1.4.14.). Surveys may be required to supplement *passive* *surveillance* data generated by the *early detection system* required for pathway 2 as described in Article 1.4.12. In addition, where conditions are not conducive to clinical expression of *disease*, and, therefore, the *early detection system* cannot provide evidence for the maintenance of freedom, ongoing *targeted surveillance* is required.

It is not possible to provide absolute certainty of the absence of *disease*. Surveys can demonstrate freedom from *disease* by generating evidence that a *disease* is not present in a population at or above a predetermined *prevalence* (the design *prevalence*) and to an acceptable level of confidence. Apparent *disease* at any level in the *target population* automatically invalidates any freedom from *disease* claim, unless, on the basis of further testing, positive test results are accepted as false positives. A survey to demonstrate freedom from *disease* should meet the following requirements set out in this article:

1. Population

The population of *epidemiological units* should be clearly defined. *Aquaculture establishments* and holding *units* (e.g. ponds, tanks) within establishments are the most commonly used *epidemiological unit* in surveys to demonstrate *disease* freedom. It is, therefore, important that *Competent Authorities* should keep registries of *aquaculture establishments*, which include geographic location and species held.

The *target population* consists of all individuals of all *susceptible species* to the *disease* in a country, *zone* or *compartment,* to which the *surveillance* results apply. Exotic *disease* introduction may be more likely to occur in some components of the *target population* than others. In these cases, it is advisable to focus *surveillance* efforts on this part of the population.

The design of the survey will depend on the size and structure of the population being studied. If the population is relatively small, and can be considered to be homogenous with regards to *risk* of *infection*, a single-stage survey can be used.

Farmed *aquatic animals* are not individually identified and usually kept in holding *units* (e.g. ponds, tanks) which can lead to clusters of *infection* within *aquaculture establishments*. For these reasons, multi-stage sampling is recommended. In two-stage sampling, at the first stage of sampling, groups of animals (e.g. ponds, *aquaculture establishments* or villages) are selected. At the second stage, animals are selected for testing from each of the selected groups.

In the case of a complex (e.g. multi-level) population structure, multi-stage sampling may be used, and the data analysed accordingly.

2. Dossier of evidence

The sources of evidence should be fully described. A survey should include a description of the sampling strategy used for the selection of units for testing. For complex *surveillance* systems, a full description of the system is required, including consideration of any *biases* that may be inherent in the system. Evidence to support claims of freedom from *disease* can use non-random sources of information, provided that, overall, any *biases* introduced subsequently favour the detection.

3. Statistical methodology

The analysis and interpretation of test results from a survey shall be in accordance with the provisions of this chapter and consider the following factors:

a) the survey design;

b) the diagnostic *sensitivity* and *specificity* of the test or test system;

c) the design *prevalence* (or *prevalences* where a multi-stage design is used).

Analysis of data for evidence of freedom from *disease* involves estimating the probability (alpha) that the evidence observed (i.e. negative results for *disease* detection from *surveillance*) could have been produced assuming that *infection* is present in the population at or below the minimum specified *prevalence* (the design *prevalence*). The confidence in (or, equivalently, the *sensitivity* of) the survey that produced the evidence is equal to 1–alpha. If the confidence level exceeds a pre-set threshold, the evidence is deemed adequate to demonstrate freedom from *infection*. The required level of confidence (that the survey would detect *infection* if *infection* were present at or above the specified level) should be greater than or equal to 95%.

The power (probability that the survey would report that no *infection* is present if *infection* is truly not present) is by convention set to 80%, but may be adjusted in accordance with the country’s or *zone*’s requirements.

Statistical analysis of *surveillance* data often requires assumptions about population parameters or test characteristics. These are usually based on expert opinion, previous studies on the same or similar populations, and epidemiology of the *disease*.

The values for design *prevalence* used in calculations should be those specified in the relevant *disease* chapter (if present) of the *Aquatic Manual*. If not specified for the particular *disease*, justification for the selection of design *prevalence* values should be provided, and should be based on the following recommendations:

a) At the individual animal level (e.g. *prevalence* of infected animals in a pond, tank or net pen, or cages), the design *prevalence* is based on the epidemiology of the *infection* in the population. It is equal to the minimum expected *prevalence* of *infection* in the *study population*, if the *infection* had become established in that population. A suitable design *prevalence* value at the animal level may be:

i) between 1% and 5% for *infections* that are present in a small part of the population, e.g. are transmitted slowly or have been recently introduced, etc.;

ii) over 5% for highly transmissible and persistent *infections*;

iii) if reliable information, including expert opinion, on the expected *prevalence* in an infected population is not available, a value of 2% should be used for the design *prevalence*.

b) At higher levels (e.g. net pen or cage, pond, *aquaculture establishments*, village, etc.) the design *prevalence* should be based empirical evidence and reflect the expected behaviour of the *infection*. A higher establishment-level design *prevalence* can be used for diseases which spread rapidly between pens or cages, and establishments. *Diseases* which are transient require lower design *prevalences*:

i) a suitable design *prevalence* value for the first level of clustering (e.g. proportion of infected establishments in a *zone*) is normally not greater than 2%. If a higher design *prevalence* is selected, it should be justified.

4. Risk based sampling

*Risk*-based sampling is an approach to identify and sample populations that have the greatest likelihood of *infection*. It can be applied to the design of surveys to demonstrate freedom from *disease* for a country, *zone* or *compartment*. A key advantage of *risk*-based sampling is that it can improve the efficiency of *surveillance* to demonstrate freedom from *disease* compared to random sampling approaches.

*Risk*-based sampling requires the identification of *risk*-factors that are applied to *bias* sample collection to populations of *aquatic animals* considered most likely to be infected if the specific *disease* had been introduced and had established. Where *risk*-based sampling is used for demonstration of freedom, the *risk* factors that underpin survey design, and the evidence or assumptions for their selection, should be documented. Where existing *risk* *assessments* are available, these may be utilised to identify *risk* factors associated with introduction, exposure and establishment. The identification of appropriate *risk* factors may include consideration of:

a) the possible pathways of *disease* introduction (e.g. through imported *aquatic animals*, imported *aquatic animal products*, ship ballast water or biofouling);

b) proximity of susceptible populations to sources of exposure (e.g. to *quarantine* facilities, *aquatic animal* processing facilities, or ports);

c) environmental or husbandry conditions that are permissive for establishment (e.g. temperature, salinity, production system type, habitat type);

d) conditions that are conducive for development of clinical *disease*; including the species or life stages that are most susceptible to clinical *disease*.

5. Test characteristics

All *surveillance* involves performing one or more tests for evidence of the presence of current or past *infection*, ranging from laboratory assays to farmer observations. The performance level of a test is described in terms of its diagnostic *sensitivity* and *specificity*. Imperfect *sensitivity* or *specificity* impact on the interpretation of *surveillance* results, and should be taken into account in the analysis of *surveillance* data. For example, in the case of a test with imperfect diagnostic *specificity*, if the population is free of *disease* or has a very low *prevalence* of *infection*, all or a large proportion of positive tests will be false. Samples that test positive should be confirmed or refuted using a second highly specific test. Where more than one test is used (sometimes called using tests in series or parallel), the *sensitivity* and *specificity* of the test combination should be calculated.

All calculations should take the performance level (*sensitivity* and *specificity*) of any tests used into account. Information on test characteristics provided in the relevant disease-specific chapter of the *Aquatic Manual* should be used unless more appropriate information is available. The estimate of test *sensitivity* when the test was used in apparently healthy *aquatic animals* should be used. Samples should not be pooled before testing, unless approved in the relevant disease-specific chapter of the *Aquatic Manual*. If pooled testing is used, the results of testing should be interpreted using *sensitivity* and *specificity* values that have been determined or estimated for that particular pooled testing procedure, and for the applicable pool sizes being used.

6. Sample size

The number of units to be sampled from a population should be calculated, using a statistically valid technique that takes at least the following factors into account:

a) the *sensitivity* and *specificity* of the diagnostic test,

b) the design *prevalence* (or *prevalences* where a multi-stage design is used),

c) the level of confidence that is desired of the survey results.

Additionally, other factors may be considered in sample size calculations, including (but not limited to):

a) the size of the population (but it is acceptable to assume that the population is infinitely large),

b) the desired power of the survey.

Software for the calculation of sample sizes at varying parameter values are available. ~~Table 1.1~~ Table 1.2 provides examples of sample sizes generated by the software for a type I and type II error of 5% (i.e. 95% confidence and 95% statistical power). However, this does not mean that a type 1 and type 2 error of 0.05 should always be used. For example, using a test with *sensitivity* and *specificity* of 99%, 528 units should be sampled. If nine or less of those units test positive, the population can still be considered free of the *infection* at a design *prevalence* of 2%, provided that all efforts are made to ensure that all presumed false positives are indeed false (i.e. by use of a second highly specific assay). This means that there is a 95% confidence that the *prevalence* is 2% or lower, which reflects the fact that false negative results can occur. Incorrectly concluding that a population is free can be reduce by increasing the sample size and using more than one assay but cannot be completely eliminated.

**Rationale:** Revision needed to clarify this information is in Table 1.2.

In the case in which the values of *sensitivity* and *specificity* are not known (e.g. no information is available in the relevant *disease*-specific chapter of the *Aquatic Manual*), they should not automatically be assumed to be 100%. All positive results should be included and discussed in any report regarding that particular survey, and all efforts should be made to ensure that all presumed false positives are indeed false.

7. Multi-stage structured survey design

In general, a survey to demonstrate freedom at *zone* or *country* level should use a multi-stage design. The first sampling level is often *aquaculture establishments* (or villages), and the second stage may be ponds or individual animals within the establishment (or village). At each level, design levels need to be set and sample sizes calculated.

8. Discounting

Where conditions are not conducive to clinical expression, ongoing *surveillance* is required. Regions and *aquaculture establishments* at high risk of introduction of *pathogenic agent* should be regularly sampled. *Targeted surveillance* required to maintain confidence in *disease* freedom at 95% can be determined based on estimates of the likelihood of introduction of *pathogenic agent* (low due to basic *biosecurity* measures) and the discounting of historic *surveillance*. Methods for using historical *surveillance* data have been developed.

9. Quality assurance

Surveys should include a documented quality assurance system, to ensure that field and other procedures conform to the specified survey design. Acceptable systems may be quite simple, as long as they provide verifiable documentation of procedures and basic checks to detect significant deviations of procedures from those documented in the survey design.

Table 1.2. Sample sizes for different design *prevalences* and test characteristics.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Design prevalence** | **Sensitivity (%)** | **Specificity (%)** | **Sample size** | **Maximum number of  false positive if the  population is free** |
| 2 | 100 | 100 | 149 | 0 |
| 2 | 100 | 99 | 524 | 9 |
| 2 | 100 | 95 | 1,671 | 98 |
| 2 | 99 | 100 | 150 | 0 |
| 2 | 99 | 99 | 528 | 9 |
| 2 | 99 | 95 | 1,707 | 100 |
| 2 | 95 | 100 | 157 | 0 |
| 2 | 95 | 99 | 542 | 9 |
| 2 | 95 | 95 | 1,854 | 108 |
| 2 | 90 | 100 | 165 | 0 |
| 2 | 90 | 99 | 607 | 10 |
| 2 | 90 | 95 | 2,059 | 119 |
| 2 | 80 | 100 | 186 | 0 |
| 2 | 80 | 99 | 750 | 12 |
| 2 | 80 | 95 | 2,599 | 148 |
| 5 | 100 | 100 | 59 | 0 |
| 5 | 100 | 99 | 128 | 3 |
| 5 | 100 | 95 | 330 | 23 |
| 5 | 99 | 100 | 59 | 0 |
| 5 | 99 | 99 | 129 | 3 |
| 5 | 99 | 95 | 331 | 23 |
| 5 | 95 | 100 | 62 | 0 |
| 5 | 95 | 99 | 134 | 3 |
| 5 | 95 | 95 | 351 | 24 |
| 5 | 90 | 100 | 66 | 0 |
| 5 | 90 | 99 | 166 | 4 |
| 5 | 90 | 95 | 398 | 27 |
| 5 | 80 | 100 | 74 | 0 |
| 5 | 80 | 99 | 183 | 4 |
| 5 | 80 | 95 | 486 | 32 |

Article 1.4.17.

**Combining multiple sources of information**

Pathway 1 to achieving *disease* freedom (absence of *susceptible species*) relies on a range of data sources. Pathway 2 to achieving *disease* freedom (historical freedom) will primarily use evidence from *passive* *surveillance,* which may come from multiple sources (as described in Article 1.4.8.). *Passive* *surveillance* data can also be used to provide additional support to case for *disease* freedom, primarily based on *targeted surveillance* (i.e. pathway 3). Estimates of the confidence in each data source may be combined to provide an overall level of confidence of freedom from *disease* for the combined data sources. The methodology used to combine the estimates from multiple data sources:

1) should be scientifically valid and fully documented, including references to published material; and

2) should, where possible, take into account any lack of statistical independence between different data sources.

A scenario tree modelling approach can be used to combine evidence from different sources including *passive* and *targeted surveillance*.

Article 1.4.18.

**Diagnostic confirmation of a listed disease or an emerging disease**

A *Competent Authority* is required to provide *disease* *notifications* as described in Chapter 1.1.

The relevant *disease*-specific chapter of the *Aquatic Manual* provide recommendations for the appropriate diagnostic methods for presumptive and confirmatory diagnostic purposes. The assays recommended for these purposes are presented in Table 4.1 of the relevant *disease*-specific chapter of the *Aquatic Manual*.

The recommended standards of diagnostic evidence to confirm *infection* in either apparently healthy or clinically diseased animals are provided in Section 6 of the relevant *disease*-specific chapter of the *Aquatic Manual*. These case definitions for suspect and confirmed cases have been developed to support decision making in relation to trade and for confirmation of *disease* status at the level of a country, *zone* or *compartment*. A *Competent Authority* may choose to apply a lower standard of evidence for *disease* confirmation within its *territory* for known endemic *diseases*.

If standards of evidence are not met to confirm a suspect case of *disease* in accordance with the case definitions in Section 6 of the relevant *disease*-specific chapter of the *Aquatic Manual*, ongoing investigation is required until sufficient evidence is obtained to either:

1) exclude the presence of a *listed disease* or an *emerging disease*, or;

2) to confirm the presence of a *listed disease* or an *emerging disease*.

If a laboratory does not have the capability to undertake the necessary diagnostic tests, it should seek advice from the relevant OIE Reference Laboratory.

In all circumstances, Member Countries should comply with the requirements described in Chapter 1.1. to provide transparent and timely *notification* to allow Member Countries to take appropriate action to prevent the transboundary spread of important *diseases* of *aquatic animals*.

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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