**USA COMMENTS IN RED FONT**

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 and maintain 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 ~~are~~ 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.

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* (excluding species with incomplete or no evidence of susceptibility) are present in wild and farmed populations in the country or zone.

**RATIONALE:** Edits provided for clarification. Additionally, the USA is recommending that compartment be added to this pathway in Table 1.1 below. If accepted, it should be added here as well.

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*. *Targeted surveillance* data may also be used in this pathway, where appropriate.

**GENERAL COMMENT:** Throughout the document “passive surveillance data” is changed to “passive surveillance information”. This seems to be a change made to be more inclusive of input types, but it is unclear if there is any meaningful difference in what will be accepted as evidence of passive surveillance results. If there is qualitative information that is going to be allowed for passive surveillance of disease, that should be specified into Articles 1.4.8 “requirements for passive surveillance”, Article 1.4.12, and Article 1.4.16.

3. Targeted Surveillance

This pathway may be utilised if the requirements of pathway 1 (absence of *susceptible species*) or pathway 2 (historical freedom) cannot be met. The pathway primarily uses ~~targeted~~ *targeted* *surveillance* data, but other sources of evidence may be utilised as described in Article 1.4.13. *Passive surveillance* ~~information~~ may also ~~be used in~~ contribute evidence to this pathway, where appropriate.

**RATIONALE:** Terms covered in the OIE Glossary are italicized. Removal of “information” is suggested because it is not necessary. Other editorial clarifications.

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~~ ~~s~~Secondary evidence to claim freedom (if required)** | **Applicable level of application** |
| 1. Absence of susceptible species
 | *~~Active surveillance~~Surveys, historical data, import records, environmental information* | None | Country, *zone,* compartment**RATIONALE:** This pathway is more demonstrable for compartments than country/zone. It is very difficult to prove the absence of a species in an open population. |
| 1. Historical freedom
 | *Passive* *surveillance* | *Targeted surveillance* (in populations where *passive* *surveillance* is not appropriate) | Country, *zone* |
| 1. Targeted *su*rveillance
 | *Targeted surveillance* | *Passive* *surveillance* (in appropriate populations) | Country, *zone*, *compartment* |
| 1. Returning to freedom
 | *Targeted surveillance* | *Passive* *surveillance* (in appropriate populations) | Country, *zone*, *compartment* |

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~~should inform the OIE of the claimed status for a country, *zone* or *compartment* 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~~available on the OIE website) 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 or return to *disease* freedom;

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

**RATIONALE:** Editorial suggestion to distinguish from the term used for disease confirmation by a laboratory.

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~~will be published only after all the information provided has been received and administrative and technical screening has been performed by the OIE, with a satisfactory outcome. Publication does not however, 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. The notification of an outbreak in a country, *zone* or *compartment* for which a self-declaration of freedom has been made, will result in an update of the OIE website concerning the original declaration. 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 biosecurity and *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.;

**RATIONALE:** Editorial

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 and expertise to investigate and report *disease* events to the *Competent Authority*;

6) the *Competent Authority* has access to appropriate diagnostic capability (from a laboratory with a quality management system that meets requirements of Chapter 1.1.1. of the *Aquatic Manual*) to confirm or exclude cases of *listed diseases* and *emerging diseases* in accordance with Article 1.4.18.

Article 1.4.6.

**Basic biosecurity conditions**

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

**RATIONALE:** Clarification.

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

~~2~~1) an *early detection system* (as described in Article 1.4.7.);

~~3~~2) 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 aself-declaration of freedom froma specific *disease* for a country, *zone* or *compartment,* the C*ompetent Authority* should describe how all of the requirements for ~~the~~ *basic biosecurity conditions* relevant to its declaration, ~~and ensure all requirements for~~ *~~basic biosecurity conditions~~* ~~described in this chapter~~ are continuously met.

Article 1.4.7.

**Early detection system**

The *early detection system* of the *Competent Authority* ~~underpins~~ is important both as supporting evidence for disease freedom claims and as assurance that a change in status could be aptly discovered. ~~to anycollects~~ *~~passive surveillance~~* ~~data information utilised by a~~ *~~Competent Authority~~* ~~to make a~~ *~~self-declaration of freedom from disease~~*~~.~~

**RATIONALE:** The current wording is confusing. An objective should follow “is important to”. Additionally, the objective of early detection is to support ongoing faith in freedom claims and afford an opportunity for effective intervention should an introduction occur.

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

1) broad awareness, ~~e.g.~~ among observers (e.g. the personnel ~~employed at~~ of *aquaculture establishments,* ~~or involved in processing~~ processors, transportation services) 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 (from a laboratory with a quality management system that meets requirements of Chapter 1.1.1. of the *Aquatic Manual*) to confirm or exclude cases of *listed* *diseases* and the capacity and expertise to investigate *emerging* *diseases* as described in Article 1.4.18.;

5) *veterinarians,* ~~and~~ *aquatic animal health professionals* and others with an occupational role with aquatic animals have a legal obligation to report suspicion~~s~~ of listed or emerging *diseases* occurrence to the *Competent Authority*.

6) enhances awareness of the status of susceptible populations through time;

**RATIONALE:** The additional requirement is proposed to emphasize that early detection systems need to address the element of time to justify the use of the term ‘early’. In addition, early detections systems may include producer-led observation of population health, continuous surveillance outside of official sampling plans, and include testing modalities that detect both known and emerging pathogens. Trained aquatic animal professionals will make observations related to diseases that are clinically expressed and record the appearance (e.g., body condition, lesions), behavior (e.g., intensity of feeding), and morbidity/mortality of the populations. A system for managing these data and reporting problems shall be put in place.

The sensitivity of an *early detection system* is the likelihood that the *disease* will be detected in a timely manner if present. Of fundamental importance is *disease* reporting by farmers, *aquatic animal health professionals* and *veterinarians* and others to initiate the necessary steps of *passive surveillance* or investigation. Specifically, the *Competent Authority* should be able to demonstrate that efforts have been made to make ~~farmers~~ relevant observers (e.g. farmers and fishers) aware of signs of *listed diseases* and *emerging diseases*, and secondly the obligation of farmers, *aquatic animal health professionals* and others with an occupational role with aquatic animals 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 functioning of the *early detection system* is best illustrated through examples of investigations in response to reported suspicion of *disease*. ~~Ideally, t~~The sensitivity of an *early detection system* (i.e. the likelihood of *pathogenic agent* detection following introduction) ~~should~~can be quantified, for example, by use of a scenario tree model; however, in most circumstances a qualitative assessment will be sufficient.

**RATIONALE:** Revision is proposed because without this clarification the sensitivity of an *early detection system* only addresses detection capability rather than ‘early’ detection capability. “…or investigation” is proposed because not all early detection systems will be done by passive surveillance. Propose deleting “diagnostic” because assays used during surveillance for pathogens in subclinically infected animals were excluded as previously written. Revision is needed because without this clarification the sensitivity measure will only address detection capability, rather than ‘early’ detection capability.

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:

a) 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;

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 investigation and where appropriate, reporting to the~~ *~~Competent Authority~~*~~;~~

**RATIONALE:** Removal is needed because the language is redundant with Items 1 and 5 in Article 1.4.7. We recommend removing the language here (after ensuring all detail is included above) and focus on what is unique to this section.

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 (or proxy or sentinel populations) should:

 OR

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

~~ii) be epidemiologically linked to farmed populations, such that if the~~ *~~disease~~* ~~were to occur in wild~~ *~~aquatic animal~~* ~~populations would occur and it would be observed and reported in adjacent 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,~~**~~veterinarians~~* ~~and~~~~others)~~~~recognizing signs of~~ *~~disease~~* ~~that are suspicious of a~~ *~~listed disease~~*  ~~reporting suspicion of~~ *~~disease~~* ~~or unexplained increased mortality and reporting them to the~~ *~~Competent Authority~~*~~. For wild populations, the requirements of point 4 a) 1 d) i) above are unlikely to be may not be met under most circumstances and, therefore,~~ *~~passive~~**~~surveillance~~* ~~will be insufficiently sensitive. If a~~ *~~Competent Authority~~* ~~utilises~~ *~~passive surveillance~~* ~~data information 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 will result in detection of the~~ *~~disease~~* ~~should it occur.~~

**RATIONALE:** Revision is to clarify that the observation applies to the wild populations as well as any proxy or sentinel populations (e.g., hatchery fish receiving water from streams where a disease is present in wild fish). Everything is now organized under 1 d).

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.).

 **RATIONALE:** Revision is needed because if ‘survey’ is meant to denote testing in the sentence, then this would be active surveillance, not passive.

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, at least seasonallyduring at least a period of the year; and~~

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

**RATIONALE:** Removal of this section is needed because the information is already covered in item 1)a) above.

5) Evidence from published literature will generally be sufficient to demonstrate the environmental conditions in ~~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*.

6) *Passive surveillance* only contributes to the *early detection system* if observations and investigations that lead to suspicion of *listed diseases* or *emerging diseases* are rapidly reported, to allow ~~by~~ the *Competent Authority* ~~follow reports of~~ *~~disease~~*to undertake their own investigation.

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~~ the specific *pathogenic agent* would not 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. number of *aquaculture establishments* and *aquatic animals* needed to demonstrate freedom).

2) Each disease-specific chapter of the *Aquatic Code* includes minimum periods that *basic biosecurity conditions* should be in place prior to a *self-declaration of freedom from* *disease*.These periods ~~are determined~~~~based on the factors described below.~~ reference a default minimum period or a longer period if determinednecessarybased on the factors described below:

a) For pathway 1, the default minimum period ~~that~~ of *basic biosecurity conditions* required ~~should be in place~~prior to a self-declaration, for all *listed diseases, ~~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~~listed disease* based on its epidemiology (e.g. agent stability in the environment, presence of resistant life stages, *vectors*), and ~~is~~ a period longer than the default minimum may be specified in the relevant disease-specific chapter of the *Aquatic Code*.

b) For pathway 2, the default minimum period ~~that~~of *basic biosecurity conditions* required ~~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~~ longer than ten years, as appropriate. An evaluation of the following factors will determine whether a period longer than ten years is recommended in the disease-specific chapters.~~required~~:

 **RATIONALE:** It is important to clarify that these are criteria for disease-specific chapter determinations. They are not intended for country-specific evaluation. Further, if this point is clearly articulated, there is no reason to limit default adjustments to those that will lengthen the period. If criteria are met, and a shorter period is supported for a particiular disease, and member countries agree with recommended changes to the disease-specific chapter, why not allow a shortened duration?

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)~~

**RATIONALE:** All of these listed factors (i-vi) are intended to inform the likelihood of annual detection and this clause is already stated in 2)b) above.

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.

c) For pathway 3, the default minimum period ~~that~~ of *basic biosecurity conditions* ~~should be in place~~ required 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~~ may ~~affect~~ limit the ~~expected transmission, and thus~~ increase in *prevalence* and intensity of *infection* in the *susceptible species* following introduction of the *disease*. In these instances, 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 longer than one year, as appropriate. An evaluation of the following factors will determine whether a period longer than one year is required:

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* in the country or *zone* should be considered in the design of each survey

(i.e. included in the sampling frame). Populations with higher likelihood of *infection* can be preferentially sampled. Article 3.1. of the relevant disease*-*specific chapter of the *Aquatic Manual* should be used to inform sampling at ~~the~~ ~~farm~~ all levels.~~should be included in the scope of each survey.~~ If sampling is clustered in time, t~~T~~here should be a gap of at least three months between surveys. If sampling is clustered in time, there should be a gap of at least three months between surveys. If sampling is more continuous, results may be aggregated for twice annual analysis, so long as assumptions are clear (e.g., that the system is relatively stable across the sampling window) and/or sampling is determined to be sufficient to address introduction risk over time, AND the design is otherwise sound (e.g., sampling appropriately targets the pathogens of concern and avoids non-conducive environments). If ~~and, if~~ there are breaks in production, the surveys should also ideally span two production cycles.

**RATIONALE:** This section is also referring to the country or zone (in addition to the farm), hence, the word “all”. The current wording that precludes sampling distributed over time is problematic in a number of ways. First, an acceptable survey duration is not specifically defined and should be left to the Competent Authority to establish based on the epidemiology, demographics, and constraints of the system under evaluation, consistent with other sections of the Code. Surveys collecting large volumes of samples over broad populations/geographies (e.g., for a country or zone), would quickly overwhelm veterinary, resource (vessels, for example), and laboratory capacities if the presumption is they need to be conducted in a single day or even single week. The overly prescriptive requirement for a gap of 3 months between samplings may have unintended consequences in the varied and temporally unique production settings of the aquatic sector. This requirement for discrete, 3-month spaced out surveys, may not adequately represent all life stages, seasonal stressors, optimum periods of pathogen persistence/replication, or production challenges and processes. In many cases, more distributed sampling will improve temporal coverage and the ability to detect episodic presentations. Countries should have the flexibility needed to design surveys that are optimized to a particular setting, as indicated Article 1.4.2’s introductory text (initial lines of the second paragraph), but the hard delineation of a 3-month gap is inconsistent with this sentiment.  Note, again because the term is not defined, if survey duration is interpreted to be *longer* than a day or a week (e.g., up to 3-9 months if a 3-month gap is the only fixed requirement), the argument that the statistical analyses required to adequately account for introduction risk are too complex also applies to the existing wording. Consequently, we request that the Code language is relaxed to allow flexibility for different approaches that best suit the context, epidemiology, and capacities of the unique member countries, so long as the assumptions are clear (e.g., that the system is relatively stable across the sampling window) and/or sampling is determined to be sufficient to address introduction risk over time, AND the design is otherwise sound (e.g., sampling appropriately targets the pathogens of concern and avoids non-conducive environments). The option for temporally distributed sampling could improve survey representativeness and feasibility, address unique aquatic species production and country characteristics, and pose limited risk to interpretation of the resultant surveillance data

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* and as specified in the relevant disease-specific chapter). However, at least one ~~round of testing~~survey in the compartment is required to demonstrate that eradication has been successful and to ~~test~~ensure the reviewed *basic biosecurity conditions* are effective in accordance with the aquatic code for a specific pathogen.

**RATIONALE:** Revision is needed because one survey seems to be the bare minimum. A single survey will miss a lingering infection approximately 5% of the time (95% confidence) – and more if the survey is conducted too soon after the last possible transmission (because prevalence could be under the detection threshold). The added language emphasizes that the epidemiology of a particular pathogen may necessitate more than one survey as outlined in the aquatic code.

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* or *compartment* 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* or *compartment*.

**RATIONALE:** Addition of “compartment” is proposed because species compositions could be definitive, and the constituent species are often well studied. Country/zone claims would be very tenuous in comparison. For example, most wild species won’t have been assessed for susceptibility, and it would be tough to demonstrate species absence in these huge systems.

*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) demonstrated by the following forms of evidence:~~.~~

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

~~1~~a) 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~~b) documentation from the relevant *Competent Authority* showing that those *susceptible species* have not been imported into the country or *zone*;

~~3~~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 will only apply in limited situations. It 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.

**RATIONALE:** Revision is needed because there is uncertainty with most pathogens. The OIE Code does not provide a listing (or criteria) for non-susceptibility. Therefore, the absence of a species on the list of susceptible species could simply mean data are lacking (which is likely the case for many non-commercial, wild, species). This pathway seems most applicable to compartments (e.g., koi farms should not have to test for ISAV) and is only very rarely applicable to countries or zones.

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 freedom**

**RATIONALE:** Editorial.

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:

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~~* ~~datainformation (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~~*~~. If a combination of~~ *~~surveillance~~* ~~data sources is to be used (e.g.~~ *~~passive surveillance~~* ~~and~~ *~~targeted surveillance~~*~~), the level of confidence should also be set at 95% that the~~ *~~disease~~* ~~is absent. The data sources for~~ *~~passive surveillance~~* ~~are described in Article 1.4.8. of this chapter.~~

**RATIONALE:** This paragraph should be removed since the evidence for this pathway is qualitative only.

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)~~ and the requirements for passive surveillance in Article 1.4.8. The *early detection system* needs to ~~cover~~ represent 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~~information will need to be supplemented with *targeted surveillance* data (see below).

**RATIONALE:** Editorial change to emphasize that the Early Detection Systems should be representative of the populations (e.g., various life stages present) of susceptible species in the country or zone.

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. ~~However, for this~~ This pathway should only ~~pathway to~~ be utilised as the basis of a *self-declaration of freedom from* *disease*, if it is ~~it should be~~ based primarily on *passive surveillance* ~~data~~ information to demonstrate historical freedom; alternatively, pathway 3, as described in Article 1.4.13., should be used.

Article 1.4.13.

**Pathway 3 – Targeted 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)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 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 three or more months apart to declare freedom unless disease-specific evidence supports an alternative strategy. The number of *aquaculture establishments* and *aquatic animals* sampled should be sufficient to generate ~~an overall~~ at least 95% confidence ~~or greater~~ that the *pathogenic agent* would be detected if present at or above ~~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 set to a maximum of 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:** The surveillance sensitivity (confidence) calculates the probability of detecting a pathogen if present.

~~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~~ *targeted* *surveillance*, however, the submission may also include an analysis of the *passive surveillance* ~~data~~information to provide supplemental evidence. In some cases, the confidence provided through passive surveillance could act as primary evidence, with targeted surveillance reserved to cover gaps in observation. However, to be used in this pathway, the confidence derived through passive surveillance should be evaluated quantitatively. Methods for quantification of all evidence used, both passive and active, should be documented and peer-reviewed. This evidence may be used for defined populations of *susceptible species* where the *~~sensitivity~~* ~~of~~ *passive surveillance* is demonstrated to be sufficiently sensitive (as described in Article 1.4.8. ).

**RATIONALE:** Member countries should have the flexibility to ascertain the health status based on highly functioning passive surveillance systems, given the full assessment of the sensitivity of those systems.

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~~ demonstrate that eradication has been successful and to ensure the reviewed *basic biosecurity conditions* are effective~~, 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 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* 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 productions 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 ~~determined~~ 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.

**RATIONALE:** Editorial comment to make the point that the boundary of the protection zones is informed vs. determined by the distance downstream that viable pathogenic agent is likely to spread on currents. Informed indicates that there other factors that are important too. Determined means the boundaries are solely determined by the distance downstream that viable pathogenic agent is likely to spread on currents. For example, the next sentence states that vectors may also influence the boundary.

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~~ the pathogen has been eradicated or otherwise contained, and affected *aquaculture establishments* have been disinfected, as described in Chapter 4.~~3~~4., and synchronously fallowed as described in Chapter 4.~~6~~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* 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:

**RATIONALE:** Revision is needed because the goal is eradication of the pathogen, which will not always require depopulation.

1. establishments which ~~were depopulated (following restocking)~~ have been restocked following ~~depopulation;~~ pathogen eradication;

**RATIONALE:** Revision is needed because depopulation is not the only strategy to eliminate the pathogen.

b) establishments and wild populations at greatest *risk* of exposure to *infection* during the *outbreak*, i.e. in close ~~geographic~~ 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* ~~is not present above~~ would be detected if present at 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.

**RATIONALE:** The surveillance sensitivity (confidence) calculates the probability we would detect a pathogen if present.

3. Requirements for targeted surveillancein a compartment

Once the ~~infected populations have been depopulated~~ pathogen is eliminated and affected *aquaculture establishments* disinfected, ~~and fallowed~~ as described in Chapter 4.~~3~~4. and fallowed as described in Chapter 4.~~6~~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 6 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~~; 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~~ would be detected at a *prevalence* of 2% (a higher design *prevalence* can be used if justified by epidemiological evidence).

**RATIONALE:** Depopulation is not the only strategy to eliminate the pathogen. Revision is needed to clarify the intent of this statement. The surveillance sensitivity (confidence) calculates the probability we would detect a pathogen if present.

Article 1.4.15.

**Maintenance of disease free status**

A country, [*zone*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_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*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_surveillance_specifique) provided that the requirements for *passive surveillance* in Article 1.4.8. are met for the entire country, [*zone*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_zone) or *compartment*, and in the case of:

a) a declared free [*zone*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_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 the *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.

~~For maintenance of~~ *~~disease~~* ~~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. and to maintain *disease* freedom~~)~~. Surveys may be required to supplement *passive* *surveillance* ~~data~~information 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 declared 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 within the selected population of ~~all~~ *susceptible species* to the *disease* in a country, *zone* or *compartment,* to which the *surveillance* results apply. ~~Exotic~~ D*~~d~~isease* 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.

**RATIONALE:** Editorial

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~~*, exposure a single-stage survey can be used.

**RATIONALE:** Differing degrees of susceptibility to infection will determine where to focus sampling efforts (e.g., on one species versus another in the same pond). However, differing degrees of exposure potential will determine whether clustering might occur and whether a multi-stage survey is required.

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*. Similarly, wild aquatic animal populations are not evenly distributed within a zone. 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~~first-stage sampling 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~~ above 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 equal to or 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.

**RATIONALE:** Disease is defined as infection present at or above the design prevalence.

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-specific *~~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 on 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 or that can remain sub-clinical 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*, feed, fomites, *vectors* and ~~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*.

e) animal-level characteristics that indicate greater likelihood of infection (or susceptibility) than the general population, for example morbidity, mortality, lifestage, or recent stressors.

**RATIONALE:** Additional common factors for risk-based sampling should be added to this section.

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~~ 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 pathogenic agent would be detected if present at a *prevalence* ~~is~~ of 2% or lower, which reflects the fact that false negative results can occur. Incorrectly concluding that a population is free ca

n be reduced by increasing the sample size and using more than one assay but cannot be completely eliminated.

**RATIONALE:** Editorial suggestion for consistency with previous comments.

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) or discrete populations or stocks of wild susceptible species, and the second stage may be ponds or individual animals within the establishment (or village) or ~~defined stocks~~ individual animals within a defined wild population stock. At each level, design levels need to be set and sample sizes calculated.

**RATIONALE:** Clarifications regarding the design of multi-stage structured surveys.

8. Discounting

Where disease freedom has not been declared at the country level, ~~conditions are not conducive to clinical expression of~~ *~~disease~~* ~~in a population,~~ ongoing *surveillance* in declared free compartments and zones is required. Where conditions are not conducive to clinical expression, targeted surveillance may be 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.

**RATIONALE:** Proposed edits for consistency throughout the document because elsewhere it states that targeted surveillance must be ongoing for zones/compartments in a country not declared free.

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~~ information 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~~*~~.~~

**RATIONALE:** Proposed deletion because there are various approaches to surveillance sensitivity estimation and combination, a scenario tree is just one approach. The requirement (of a scientifically valid approach) is covered in item 1.

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~~ different standard of evidence for *disease* confirmation within its *territory* for known endemic *diseases*.

**RATIONALE:** Clarification as to what is meant by “lower” standard as it is not clear if this means more or less laxity in the standard of evidence is required.

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 Member Country does not have access to a laboratory with ~~does not have~~ the capability to undertake the necessary diagnostic tests and which meets the requirements of Chapter 1.1.1. of the *Aquatic Manual*~~,~~ 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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