

WorldOrganisationOrganisationmondialefor Animalde la santéHealthanimale

Organización Mundial de Sanidad Animal

PROCEDURE FOR THE APPLICATION FOR THE PUBLICATION OF A SELF-DECLARATION OF ANIMAL HEALTH STATUS¹

June 2023

CONTEXT

WOAH has developed Standard Operating Procedures (SOPs) to assist Members with the process relating to the official recognition of a specific animal health status or for the endorsement of an official control programme. These SOPs currently apply to six WOAH-listed terrestrial animal diseases, namely: African horse sickness, bovine spongiform encephalopathy, classical swine fever, contagious bovine pleuropneumonia, foot and mouth disease and peste des petits ruminants.

However, Delegates also can self-declare their country, a zone, or a compartment within their territory, free from any disease. Should Delegates request it, WOAH offers to publish the self-declaration(s) on its website. However, WOAH will not publish self-declarations of animal health status related to those diseases for which a specific procedure for official recognition of animal health status is in place.

Standard Operating Procedure on the publication of the self-declaration of animal health status of Members

| Description/ Scope: | This procedure describes the process for the preparation, screening and publication of self-declarations of freedom from any disease (other than those diseases for which WOAH has put in place a specific procedure for official recognition of animal health status). The procedure is composed of four parts: Part A: Submission of a self-declaration by a Member, Part B: Screening and publication by WOAH of a self-declaration submitted by a Member Part C: Loss of self-declared animal health status Part D: Recovery of self-declared animal health status |
|---------------------|---|
| Related documents: | Self-Declaration Publication Process – Guidelines (included in this document) Article 1.6.3. of the <i>Terrestrial Animal Health Code</i> . Article 1.4.4. of the <i>Aquatic Animal Health Code</i> Annex II. Template for self-declarations of terrestrial animal health status Annex III. Template for self-declarations of aquatic animal health status |
| List of acronyms: | Codes: Terrestrial Animal Health Code and Aquatic Animal Health CodeSD: Status Department (in consultation with other relevant WOAHDepartments when necessary)WAHIAD: WOAH World Animal Health Information and AnalysisDepartmentWAHIS: World Animal Health Information SystemDG: Director GeneralDDG: Deputy Director GeneralEDFZ : Equine Disease Free Zone |

¹ For the purpose of this document, animal health status includes both <u>aquatic</u> and <u>terrestrial</u> animal health status as defined in the respective *Codes*.

| A - SUBMISSION OF SELF-DECLARATIONS BY MEMBERS (Section A of Guidelines) | | | | |
|--|---|-------------------------------|--|-----------------------|
| Step | Time Reference | Responsible person | Action | Reference Document |
| A-1. | | Delegate | Sends the self-declaration to WOAH in one of the three official languages. | § A Guidelines |
| | B - SCREENIN | NG AND PUBLIC | ATION OF A SELF-DECLARATION SUBMITTED BY A MEMBER (Section B of Guidelines) | R |
| Step | Time Reference | Responsible person | Action | Reference Document |
| B-1. | Within 24hrs after reception (working hours) | SD | Acknowledges receipt to the Delegate. | § B Guidelines |
| B-2. | 24hrs after sending the documents | Delegate | If no acknowledgement email has been received, sends an email/letter to WOAH verifying the reception of the self-declaration. | § B Guidelines |
| В-З. | Within 2 weeks after acknowledgem ent of receipt ² | SD | Reviews the self-declaration: If information is missing, see step B-4; If the self-declaration is complete, see step B-5. | § B Guidelines |
| B-4. | | SD | Sends an email to the Delegate or contact point (appointed by the Delegate) requesting additional information, clarification and/or an update of the information in WAHIS within a specific deadline. - If no information is received, see step B-4.2. | § B Guidelines |
| B- 4.1. | Before the allocated time | Delegate/ contact point | Provides WOAH with the necessary information and/or amended document and/or information in WAHIS | § B Guidelines |
| B- 4.2. | | SD | Sends a reminder to the Delegate or the contact point to submit the requested information. If no feedback is received by the deadline set in the second reminder, the process of publication of the self-declaration will be discontinued with no further notice. | |
| B-5. | Upon receipt of a complete self- declaration or additional documents | SD | Compiles and reviews information and comments. If additional information is needed, see step B-4. If not, provides an edited version of the self- declaration to the Delegate or contact point for final validation within an allocated time. | § B Guidelines |

 $^{^{2}}$ This period may be longer for reviews of self-declarations of EDFZ or involving multiple diseases.

| B-6. | Within the set deadline | Delegate/ contact point | Reviews the edited version and: If there are comments on the self- declaration, sends them to SD. See step B-7; If not, see step B-8. | § B Guidelines |
|-----------|----------------------------|-------------------------------|--|---------------------|
| B-7. | | SD | Compiles comments. See step B-5. | § B Guidelines |
| B-8. | Within the set deadline | Delegate/ contact point | Validates and sends back to SD the edited version of the self-declaration. | § B Guidelines |
| B-9. | | DDG | Reviews the edited self-declaration prior to the publication and: If the self-declaration is not acceptable for publication despite the clarification and additional information provided by the Delegate, see step B-10 If the self-declaration is acceptable for publication, see step B-11. | § B Guidelines |
| В- 10. | | DG | Sends a letter notifying the Delegate that the self- declaration will not be published and indicating the gaps to be filled for any future self-declaration (end of the procedure). | § B.2 Guidelines |
| В- 11. | | SD | Translates and finalises the version validated by the Delegate | § B.2 Guidelines |
| В- 12. | | SD | Publishes the self-declaration on the website. | § B.2 Guidelines |
| B- 13. | | SD | Sends an email to the Delegate/contact point confirming the publication of the self-declaration on the website while mentioning that the translated versions will become available upon finalisation. | § B.2 Guidelines |

| | C - LOSS OF A SELF-DECLARED ANIMAL HEALTH STATUS (section C of Guidelines) | | | |
|------|--|-----------------------|---|-----------------------|
| Step | Time Reference | Responsible person | Action | Reference Document |
| C-1. | Within 24h of the outbreak(s) | Delegate | Notifies the outbreak(s) via an immediate notification in WAHIS. | § C Guidelines |
| C-2. | | SD | Analyses the impact of the reported outbreak on the self-declared animal health status: If the reported outbreak does not impact the self-declaration, it remains unchanged on the website (end of the procedure); If the reported outbreak affects the self- declaration, see steps C-3 and C-4. | § C Guidelines |
| C-3. | | SD | Updates the website. | § C Guidelines |
| C-4. | | SD | Informs the Delegate that the self-declaration is affected (e.g., deactivation) and that the dedicated website has been updated. | § C Guidelines |

| D – SELF-DECLARATION OF THE RECOVERY OF AN ANIMAL HEALTH STATUS (section D of Guidelines) | | | | |
|---|----------------|-----------------------|--|-----------------------|
| Step | Time Reference | Responsible person | Action | Reference Document |
| D-1. | | Delegate | When the Member wishes to publish a recovered self-declared animal health status, the Delegate sends a new self-declaration; when the conditions for recovering the self-declared animal health status are met, see steps B-1 to B-13. | § D Guidelines |

Guidelines for the publication of a self-declaration of animal health status

A. Submission of a self-declaration by a Member

1. Introduction

When planning to self-declare a country, a zone or a compartment free from a particular disease, the Delegate should refer to the provisions of the disease-specific chapter of the *Terrestrial Animal Health Code* (*Terrestrial Code*) or the *Aquatic Animal Health Code* (*Aquatic Code*). In the absence of specific requirements for freedom from a particular disease, compliance with the relevant horizontal chapters of the applicable *Code* should be used. For its publication, the self-declaration should therefore provide the relevant documented evidence according to the provisions of the relevant chapters of the *Code* to support the claimed animal health status.

2. Self-declaration structure

2.1 Content

Each self-declaration document should contain the following.

- a. an **introduction** including
 - The formal request that WOAH publishes the self-declaration;
 - The exact denomination of the disease(s) for which freedom is self-declared (*e.g.*, high pathogenicity avian influenza; infection with rabies virus or dog-mediated rabies; infection with infectious hypodermal and haematopoietic necrosis virus);
 - Reference to the relevant chapters and articles of the *Terrestrial Code* or the *Aquatic Code*;
 - The scope of the self-declaration in terms of:

 \circ first declaration or recovery of an animal health status;

- (i) For terrestrial animal diseases, if it is the first declaration of animal health status, whether or not the self-declaration is based on historical freedom from the disease according to Article 1.4.6.
- (ii) For aquatic animal diseases, indicate the pathway for demonstrating freedom from disease (Article 1.4.3.)
- geographical boundaries (i.e., the whole country, one or more zones, one or more compartments);
- \circ the species and target subpopulation, when relevant;
- The starting date of the declaration of freedom;
- A statement that the Delegate takes responsibility for the self-declaration (Annex I).
- b. the following **documented information** supporting compliance with the requirements of the *Terrestrial* and *Aquatic Codes;* in the absence of specific requirements for freedom from that particular disease, compliance with the relevant horizontal chapters of the *Codes* should be considered.
 - b.1. Terrestrial animal diseases (for more guidance, please refer to Annex II):
 - Evidence that the disease is notifiable in the entire country;

It should be clearly referred to national legislations, regulations and Veterinary Authority directives in place for the concerned disease.

- <u>History of absence or eradication of the disease in the country, zone</u> <u>or compartment:</u>

A summary of the disease history, including a description of the susceptible animal population in the country and the date of last occurrence of the disease in the country, zone, or compartment, should be given. Maps should be provided, whenever possible.

When relevant, a description of the measures that led to the control and eradication of the disease in the country, zone or compartment should be provided.

The information provided in the self-declaration and through WAHIS (e.g., date and number of cases/outbreaks reported, control measures, etc.) should be consistent.

It should be specified if a vaccine was ever used to eradicate the disease in the country, zone, or compartment and the last vaccination date.

Surveillance, including an early warning system for all relevant species in the country, zone or compartment:

Sound evidence should be provided that surveillance complies with the provisions of the relevant articles of disease-specific chapters of the *Terrestrial Code* (for WOAH-listed diseases) or Chapter 1.4. (for non-listed diseases), substantiating the self-declared animal health status. Surveillance, including an early warning system, should be clearly described and supported by data.

A self-declaration based on historical freedom must also follow the provisions stated in the relevant disease-specific chapter. In their absence, the self-declaration should provide evidence that the surveillance programme is in accordance with Article 1.4.6. of the *Terrestrial Code.* If there has been no formal application of pathogen-specific surveillance, the self-declaration must be justified by demonstrating compliance with the relevant provisions of Article 1.4.6. paragraph 2, including that the pathogenic agent is likely to produce identifiable clinical or pathological signs in susceptible animals.

In the case of self-declaration for recovery of an animal health status, evidence should be provided on compliance with the provisions of relevant articles on recovery of status and any additional surveillance or control measures implemented to control and eradicate the outbreak.

- <u>Measures implemented to maintain freedom in the country, zone or</u> <u>compartment:</u>

Evidence should be provided that the requirements for maintaining freedom are being met in accordance with the relevant disease-specific chapters (for listed diseases). For example, the measures in place to prevent the (re)-introduction of the disease in the country, zone or compartment should be described.

- b.2. Aquatic animal diseases (for more guidance, please refer to Annex III):
 - <u>Procedure to claim freedom from aquatic animal diseases:</u>

The procedure by which freedom is being declared (in accordance with Article 1.4.3. of the *Aquatic Code*) should be identified.

Evidence that basic biosecurity conditions have been and are being met should be provided as per definitions of the disease and the early detection system should be described (in accordance with Article 1.4.6. of the *Aquatic Code*).

Surveillance evidence supporting the animal health status in accordance with the requirements of the relevant pathway and that complies with Article 1.4.10. or the provisions of the relevant articles X.X.4. - X.X.7.of disease-specific chapters of the *Aquatic Code* and Manual (for WOAH-listed diseases) should be provided.

If the self-declaration is for a country or zone where multiple countries border shared water bodies, all countries sharing the water bodies should either submit a self-declaration of freedom or cooperate for a single self-declaration of freedom.

- Measures implemented to maintain freedom:

Evidence that the requirements for maintaining freedom are being met in accordance with Article 1.4.15. and Article X.X.8. of the relevant disease-specific chapters (for listed diseases) should be provided.

- c. the contact details (name, email address and phone numbers) of technical staff involved in the preparation of the self-declaration document who will be the contact point, so that any questions arising when screening the document may be referred to the Member without delay;
- d. The self-declaration should be duly signed by the Delegate of the Member.

2.2 Format of the self-declaration

2.2.1 Size

Any self-declaration should be limited to a document of no more than 7 pages (excluding disclaimer, tables, figures and annexes) per disease in A4 format, single-spaced using Calibri font size 10pt. References to more detailed information supporting the self-declaration are encouraged, for instance, to publications in the scientific literature or other information on the Competent Authority's website. Relevant appendices may be attached to the core document and should be clearly cross-referenced.

Members can also submit for publication a self-declaration of an EDFZ, following the <u>guidelines to support countries in the establishment of an EDFZ and the publication of their self-declaration</u>.

It is recommended that a self-declaration of an EDFZ submitted to WOAH be composed of the following:

- an executive summary following the template provided in the guidelines (5 pages maximum);

- an EDFZ dossier following the template, provided above including appendices as appropriate and annexed to the executive summary (45 pages maximum)

2.2.2 Language

The documents and appendices should be prepared in one of the WOAH official languages (English, French or Spanish).

2.2.3 File compatibility

The self-declaration should be provided in Word format for revision, editing and translation purposes. Tables and graphs should be editable and provided in the original files. Maps and other images should be provided with a resolution of at least 300 dpi.

2.2.4 Submission format

The documents should be supplied in electronic format to the Status Department (using the following email address: <u>self-declaration@woah.org</u>).

Note: Self-declaration of an animal health status cannot be published in WAHIS via a follow-up or final report.

B. Screening and publication of a self-declaration submitted by a Member

1. Review by the Status Department

Within 24 hours from receipt of the self-declaration document, the Status Department acknowledges receipt. Members that have not received any acknowledgment of receipt within 24 hours should verify with WOAH if the self-declaration has been received.

Within two weeks³ following the acknowledgement of receipt, the Status Department (in consultation with other relevant WOAH Departments when necessary) conducts an analysis of the self-declaration document:

- an administrative screening that entails checking that the structure of the selfdeclaration dossier is in accordance with the SOP;
- a technical screening based on the information available in WAHIS and the relevant requirements of the *Terrestrial* or *Aquatic Codes*. The Status Department does not assess compliance with the requirements of the relevant *Code* chapters but rather ensures that the self-declaration document includes the information consistent with

³ This period may be longer for reviews of self-declarations of EDFZ or involving multiple diseases.

the requirement described in the relevant *Code* and needed for any stakeholder to evaluate this compliance.

If gaps in the information are identified, the Status Department may need to contact the country by emailing the Delegate or the nominated contact point to request additional information and clarification to be provided before a set deadline.

The Member should provide any clarification or additional information within the allocated timeframe. Once all the information is available, the Status Department will send an edited version of the self-declaration document to the Delegate or nominated contact point for validation.

The Status Department will send up to two reminders to the Delegate or the contact point to submit the requested information within an allocated timeframe. If no feedback is received by the deadline set in the second reminder, WOAH will consider the publication process of the self-declaration discontinued.

The Member must validate or provide comments on the final version of the selfdeclaration to WOAH before the indicated deadline in order to proceed with the steps for publication on the website.

2. Publication on the website

The final version of the self-declaration document is reviewed by the Deputy Director General prior to its publication on the website. Self-declaration documents are then translated into other official languages and uploaded on the relevant webpage. Delegates or contact points are sent a confirmation of the publication of the relevant selfdeclaration requested.

Considering that translation of self-declarations may take time to be finalised, once the document has been validated by the concerned Member and reviewed by the Deputy Director General, if the translations are not ready, the self-declaration will be immediately published in the language used for the version that has been validated.

WOAH will publish a self-declaration document if it complies with section A "Submission of self-declarations by Members" of this procedure. If a self-declaration does not comply despite the clarification and additional information provided by the Delegate, it will not be published. The Delegate will receive an official letter signed by the Director General indicating the gaps to be filled for any future self-declaration.

Status Department will periodically verify published self-declaration to ensure that they are accurate and compliant with the current versions of the Codes. If non-compliance is identified, the Status Department may contact the country to request an updated self-declaration.

Members having a self-declaration that will be impacted by an update of the relevant Code chapter(s)/the adoption of provisions relevant to disease freedom at the General Assembly of Members will be informed that their self-declaration should be updated to remain in accordance with the current Code provisions. If an updated self-declaration is not sent to WOAH within the given deadline (determined according to the importance/impact of the updates), the self-declaration of animal health status will be deactivated.

C. Loss of the self-declared animal health status

An outbreak in a country, a zone, or a compartment with a self-declared animal health status should be notified to WOAH through an immediate notification in WAHIS. The World Animal Health Information and Analysis Department and the Status Department liaise on a daily basis to identify all notifications that may impact a self-declaration of animal health status published by WOAH.

Any loss of self-declared animal health status is communicated to the Member and reflected on the website.

D. Self-declaration of the recovery of animal health status

The Delegate of the concerned Member wishing to reclaim a lost animal health status should submit a new self-declaration document in electronic format to WOAH using the following email address: <u>self-declaration@woah.org</u> providing the documented evidence that the country, zone or compartment has recovered the self-declared animal health status in compliance with the relevant provisions of the *Terrestrial* or *Aquatic Codes*, following the steps for a first self-declaration.

Statement to be included in the self-declaration document.

I, the undersigned,

.....

Delegate of.....

to the World Organisation for Animal Health (WOAH), takes responsibility for the self-declaration of freedom from

......(disease)

DISCLAIMER

WOAH, after performing an administrative and technical screening of a self-declaration concerning the animal health status of a country, a zone or compartment ("self-declaration"), as described in the standard operating procedures for self-declarations, reserves the right to publish or not the self-declaration on its website. There shall be no right of appeal from this decision or any recourse of any kind.

The publication by WOAH of self-declaration on its website does not reflect the official opinion of WOAH. Responsibility for the information contained in a self-declaration lies entirely with the Delegate of the Member concerned.

Neither WOAH nor any person acting on its behalf may be held responsible for the following:

- (i) Any errors, inaccuracies or omissions in the content of a self-declaration,
- (ii) The use which may be made of the information contained in a self-declaration;
- (iii) Any direct or indirect consequences of any nature arising from or relating to the use of the information contained in a self-declaration.

Drawn up on/...../...../

Signature of the Delegate:

TEMPLATE FOR SELF-DECLARATIONS OF TERRESTRIAL ANIMAL HEALTH STATUS

This annex has been developed to guide Members compile information according to <u>Article</u> <u>1.6.3.</u>, <u>Chapter 1.4.</u> and/or the relevant disease-specific chapters of the <u>Terrestrial Code</u>. It also recommends a structure to be followed for the self-declaration dossier.

DISCLAIMER

The World Organisation for Animal Health (WOAH, founded as OIE), after performing an administrative and technical screening of a self-declaration concerning the disease-free status of a country, a zone or a compartment ("self-declaration"), as described in the standard operating procedures for self-declarations, reserves the right to publish or not the self-declaration on its website. There shall be no right of appeal from this decision nor any recourse of any kind.

The publication by WOAH of a self-declaration on its website does not reflect the official opinion of WOAH.

Responsibility for the information contained in a self-declaration lies entirely with the WOAH Delegate of the Member concerned.

Neither WOAH nor any person acting on its behalf may be held responsible for:

- (i) any errors, inaccuracies or omissions in the content of a self-declaration;
- (ii) the use which may be made of the information contained in a self-declaration;
- (iii) any direct or indirect consequences of any nature arising from or relating to the use of the information contained in a self-declaration.

I. Introduction

Provide a general overview of the self-declaration, including:

- Formal request to publish the self-declaration by the Delegate
- Specific disease for which the self-declaration is for
- Susceptible species and, if relevant, the target subpopulation
- General description of country, zone, or compartment boundaries (as applicable)
- Statement indicating whether the Member is claiming an animal health status for the first time, whether it is based on historical grounds or not, or for recovering a previously lost animal health status
- Reference to relevant *Terrestrial Code* article(s)
- The start date of validity of the self-declaration
- Reference to a statement that the Delegate takes responsibility for the self-declaration (Annex I, Disclaimer)

II. Evidence that the disease is notifiable in the entire country

This information should include:

• List of all relevant veterinary legislation, regulations and Veterinary Authority directives related to notification and reporting of concerned disease. Add web links when available.

- When historical freedom is claimed based on point 2b. of Article 1.4.6. of the *Terrestrial Code,* provide information on for how long the disease has been notifiable.
- Structure and role of the Veterinary Services in the prevention and control of the concerned disease.

III. History of absence or eradication of the disease in the country, zone(s), or compartment(s)

This information should include:

- A summary of the disease history with an emphasis on recent years, including a description of the susceptible animal population and the date of the last occurrence of the disease;
- Map(s) showing the temporal and spatial distribution of outbreaks (when available);
- The date of the last case or eradication;
- A description of the measures leading to the control and eradication of the disease (e.g., stamping-out policy, movement control, zoning, etc.);
- Whether vaccines were used to eradicate the disease and when the last vaccination was carried out;
 - If vaccination is still utilised, it should clearly specify how it aligns with provisions of the *Terrestrial Code* and the *Terrestrial Manual*, and how this is accounted for in surveillance programme.

IV. Surveillance, including an early warning system for all relevant species in the country, zone(s), or compartment(s)

- Early warning system and the date since which it has been in place for all relevant species;
 - This information could include those listed in <u>Article 1.4.5.</u> of the *Terrestrial Code*:
 - that the Veterinary Services has current knowledge of and authority over all target populations; (e.g., demographics, distribution, production types, etc.);
 - laboratory capability to diagnose and differentiate relevant diseases;
 - training and awareness programmes for relevant stakeholders (veterinarians, veterinary paraprofessionals, owners/keepers, staff involved in handling animals at farms, in transport, at slaughterhouses/abattoirs) potentially involved in detecting and reporting the disease;
 - a legal obligation to report suspected cases or cases of notifiable diseases or emerging diseases to the Veterinary Authority, including the description of findings;
 - epidemiological investigations of suspected cases by the Veterinary Services to confirm cases and carry out all necessary further actions.
- Surveillance in place substantiating the self-declared animal health status and how it complies with the relevant articles of the disease-specific chapter(s) of the *Terrestrial Code* (for WOAH-listed diseases) or with Chapter 1.4. (including for non-listed diseases).
 - Type and scope of surveillance conducted, including information on the target population and frequency;
 - The number of samples tested for the disease, type of sample, testing methods and results (including differential diagnosis) for the period specified in the disease-specific chapter;
 - Description of the interpretation of laboratory results in the context of the epidemiological situation.

- When historical freedom is claimed, provide evidence that the surveillance programme is in accordance with <u>Article 1.4.6.</u> point 2 of the *Terrestrial Code*.
- In case of a self-declaration for recovery of an animal health status, provide evidence of compliance with the relevant article(s) on recovery of status and any additional surveillance or control measures implemented to control and eradicate the outbreak.

V. Measures implemented to maintain freedom in the country, zone(s) or compartment(s)

Evidence should be provided that the requirements for maintaining freedom are met following the relevant disease-specific chapter(s) (for listed diseases).

- For example, the measures in place to prevent the (re)-introduction of the disease in the country, zone(s), or compartment(s), such as:
 - physical/geographical barriers;
 - movement control and imports requirements;
 - coordination with other countries;
 - biosecurity measures in place;
- Any other requirements specified in the relevant disease-specific chapter(s)

VI. Other consideration

A brief description of any other relevant considerations or information that has not been covered in the sections above within the self-declaration.

VII. Conclusion

Include a brief conclusion and reference to relevant *Terrestrial Code* chapters/articles.

TEMPLATE FOR SELF-DECLARATIONS OF AQUATIC ANIMAL HEALTH STATUS

This annex has been developed to guide Members compile information according to <u>Chapter</u> <u>1.4.</u> and/or relevant disease-specific chapters of the <u>Aquatic Code</u>. It also recommends a structure to be followed for the self-declaration dossier.

DISCLAIMER

The World Organisation for Animal Health (WOAH, founded as OIE), after performing an administrative and technical screening of a self-declaration concerning the disease-free status of a country, a zone or a compartment ("self-declaration"), as described in the standard operating procedures for self-declarations, reserves the right to publish or not the self-declaration on its website. There shall be no right of appeal from this decision nor any recourse of any kind.

The publication by WOAH of a self-declaration on its website does not reflect the official opinion of WOAH.

Responsibility for the information contained in a self-declaration lies entirely with the WOAH Delegate of the Member concerned.

Neither WOAH nor any person acting on its behalf may be held responsible for:

- (i) any errors, inaccuracies or omissions in the content of a self-declaration;
- (ii) the use which may be made of the information contained in a self-declaration;
- (iii) any direct or indirect consequences of any nature arising from or relating to the use of the information contained in a self-declaration.

| Section | Contents | |
|---|--|--|
| | General information (Complete for all declarations) | |
| Scope of the declaration/ Introduction | Include a general overview on the self-declaration including: Formal request to publish the self-declaration by the Delegate Specific disease for which the self-declaration is for⁴ Details on the responsible authority for aquatic animal health and position in the general organisation of the Aquatic Animal Health Services General description of country, zone or compartment boundaries (as applicable) Statement indicating whether the Member is claiming an animal health status for the first time, whether it is based on historical grounds or not, or for recovering a previously lost animal health status Pathway for self-declaration of freedom (Article 1.4.3.) Reference to relevant <i>Aquatic Code</i> article(s) Start date of validity of the self-declaration Reference to a statement that the Delegate takes responsibility for the self-declaration (Annex I, Disclaimer) | |

⁴ For ISAV, include information on both HPR -deleted and HPRO throughout the self-declaration

| Section | Contents | |
|---|--|--|
| | General information (Complete for all declarations) | |
| Aquatic animal health situation within the country/zone/compartment | Include a description of the: Geographic description of the country/zone/compartment (including maps) including identification of shared waters (if applicable) Relevant susceptible species (Articles X.X.2.) in farmed and wild aquatic animal populations in the country/zone/compartment Overview of production/wild fishery in the country/zone/compartment Trade of susceptible species in and out of the country/zone/compartment History of detections within the country/zone/compartment (if relevant) If the self-declaration is for pathway 4, include a description of the outbreak, measures implemented and eradication strategy | |
| Basic biosecurity conditions (Article 1.4.6.) ⁵ | Pathways 1-3: Early detection system (Article 1.4.7.) Article 1.4.7. point 1. Description of measures the Competent Authority has put in place to a observers to recognise and report the disease of concern Article 1.4.7. point 2. Description of the training in place for veterinarians and aquatic anim health professionals to recognise and report the disease of concern Article 1.4.7. point 3. Description of the disease investigation and response that would be implemented by the Competent Authority in the event of a suspect ca Article 1.4.7. point 4. Description of the laboratory system and how the laboratory or laborat used to test samples as part of the surveillance programme meets the requirements of Chapter 1.1.1. of the <i>Aquatic Manual</i> Description of diagnostic methods used for surveillance (if applicable, based on pathway), presumptive diagnosis and confirmation of the disease-specific chapter of the <i>Aquatic Manual</i> | |
| | Article 1.4.7. point 5. Cite the legal authority for obligation to report and provide links to legislation which applies in the country/zone/compartment The criteria for suspicion and for confirmation of the disease in question, and the criteria for mandatory reporting to the Competent Authority Pathways 1-3: Measures for preventing introduction of the disease (Article 1.4.6.) Description of the measures in place to prevent the introduction of the disease into the country/zone/compartment through import and/or domestic movements Pathway 4: Failure of basic biosecurity conditions Description of the disease investigation which was carried out to determine the source of disease introduction Details of any modification of basic biosecurity conditions and/or additional mitigation measures which were put in place after eradication of the disease to ensure that the country/zone/compartment may re-gain and maintain disease-freedom | |

⁵ Evidence should be provided that all requirements to demonstrate disease freedom have been met including when waterbodies are shared with other countries or are under the control of different Competent Authorities.

| Section | Contents |
|---|---|
| Pathway spe | cific information (Provide information based on the pathway chosen) ² |
| Pathway 1 – Absence of Susceptible species (Article 1.4.11.) | Description of how the Competent Authority has established that the susceptible species are absent from the country/zone in aquaculture and wild populations including supporting evidence Reports (fisheries and aquatic fauna surveys, historical fisheries data) Import data Scientific data indicating likelihood of presence (physiological requirements, oceanographic information, biodiversity databases) |
| Pathway 2 – Historical Freedom (Article 1.4.12.) | Description of the passive surveillance in place to support historical freedom (Article 1.4.8.) Evidence that the disease has not been reported in the country or zone in farmed and wild aquatic animal populations which support historical freedom for the minimum period specified in the disease-specific chapter articles X.X.5X.X.7. (10.4.510.4.10. for infection with ISAV) If targeted surveillance is being used to supplement the passive surveillance for specific populations of susceptible species, include a description of the targeted surveillance (as described under Pathway 3). |
| Pathway 3 – Targeted surveillance (Article 1.4.13.) | Description of the survey design and assumptions (including the design prevalence chosen and confidence of detection) (Article 1.4.16.) Details on the targeted surveillance completed in aquaculture and wild populations (where relevant) for self-declarations at the level of country/zone Details on the targeted surveillance completed within different populations for self-declarations at the level of compartment Number of surveys completed per year Number of years over which surveys were completed Maps of sampling locations and/or tables indicating samples collected/sampling location/susceptible species for wild and aquaculture animals Details confirming that surveys have been completed under conditions which are most suitable to clinical expression of disease (accounting for factors included in Section 2.3.1. of the disease specific chapters of the <i>Aquatic Manual</i>) Description of shared waters and of the targeted surveillance implemented by other relevant competent authorities. Surveillance analysis and results Other sources of evidence as described in Article 1.4.13. |

| Contents | | |
|---|--|--|
| Pathway specific information (Provide information based on the pathway chosen) ² | | |
| Article 1.4.14. point 1. Descriptions of the infected and protection zones, contact tracing implemented and boundaries of the zones Article 1.4.14. point 2. (Country or Zone) Description of the depopulation, cleaning/disinfection completed and fallowing of infected populations Description of the surveillance program implemented in the protection and infected zones Details on risk based approach to survey design (Article 1.4.6.) and populations preferentially selected for sampling | | |
| Details confirming that surveys have been completed under conditions which are most suitable to detection of the pathogenic agent Maps of sampling locations and/or tables indicating samples collected/sampling location/susceptible species Surveillance analysis and results Article 1.4.14. point 3. (Compartment) Description of the depopulation, cleaning/disinfection completed and fallowing of infected aquaculture establishment(s) Details on the survey design and assumptions, completed after restocking the compartment as described in Article 1.4.14. Surveillance analysis and results | | |
| | | |

| Section | Contents | | |
|---|---|--|--|
| General information (Complete for all declarations) | | | |
| Measures for maintenance of freedom (Article 1.4.15.) | This section may, depending on the pathway used for the self-declaration, include references to information presented in other sections of the self declaration, additional supporting information or modification of approach specifically for maintenance of disease freedom. | | |
| | Article 1.4.15. point 1. | | |
| | Details on how free status will be maintained in shared waters (if applicable) Article 1.4.15. point 2. | | |
| | • Details of the ongoing passive surveillance (Article 1.4.8.) Article 1.4.15. point 3. | | |
| | • Details on ongoing targeted surveillance (Article 1.4.16.) Article 1.4.15. point 4. | | |
| | Description of the disease investigation and response that would be implemented by the Competent Authority in the event of a suspect case | | |
| Other considerations | A brief description of any other considerations or information considered that has not been covered in the sections above within the self-declaration | | |
| Conclusion | Include a brief conclusion and reference to relevant <i>Aquatic Code</i> chapters/articles. | | |