

PROCEDURE FOR THE APPLICATION FOR THE PUBLICATION BY THE OIE OF A SELF DECLARATION OF DISEASE FREEDOM

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CONTEXT

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

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

Standard Operating Procedure on the publication of the self-declaration of freedom from diseases 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 the OIE has put in place a specific procedure for official recognition of disease status). The procedure is composed by four parts: <ul style="list-style-type: none"> - Part A: Submission of a self-declaration by a Member, - Part B: Screening and publication by the OIE of a self-declaration submitted by a Member - Part C: Loss of self-declared disease freedom - Part D: Recovery of self-declared disease freedom
Related documents:	Self-Declaration Publication Process – Guidelines (included in this document) Chapter 1.6 of the <i>Terrestrial Animal Health Code</i> .
List of acronyms:	<i>Codes: Terrestrial Animal Health Code and Aquatic Animal Health Code</i> DSD: OIE Disease Status Department WAHIAD: OIE World Animal Health Information and Analysis Department WAHIS: OIE World Animal Health Information System DG: Director General of the OIE DDG: Deputy Director General of the OIE

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 the OIE in one of the three official OIE languages.	§ A Guidelines

**B - SCREENING AND PUBLICATION OF A SELF-DECLARATION SUBMITTED BY A MEMBER
(Section B of Guidelines)**

Step	Time Reference	Responsible person	Action	Reference Document
B-1.	Within 24hrs after reception (working hours)	DSD	Acknowledges receipt to the Delegate.	§ B Guidelines
B-2.	24hrs after sending the documents	Delegate	If no acknowledgment email has been received, sends email/letter to OIE ensuring reception of the self-declaration.	§ B Guidelines
B-3.	Within 2 weeks after acknowledgment of receipt	DSD	Reviews the self-declaration: <ul style="list-style-type: none"> - If information is missing, see step B-4; - If the self-declaration is complete, see step B-5. 	§ B Guidelines
B-4.		DSD	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. <ul style="list-style-type: none"> - If no information received, see step B-4.2. 	§ B Guidelines
B-4.1.	Before the allocated time	Delegate/ contact point	Provides the OIE with the necessary information and/or amended document and/or information in WAHIS	§ B Guidelines
B-4.2.		DSD	Sends reminder to the Delegate or the contact point to submit the requested information. If no feedback received by the deadline set in the second reminder, the process of publication of the self-declaration will be discontinued.	
B-5.	Upon receipt of a complete self-declaration or additional documents	DSD	Compiles and reviews information and comments and provides an edited version of the self-declaration. Sends the edited version of the self-declaration to the Delegate or contact point, for final validation within an allocated time.	§ B Guidelines
B-6.	Within the set deadline	Delegate/ contact point	Reviews the edited version and: <ul style="list-style-type: none"> - If there are comments on the self-declaration, sends them to DSD, see step B-7; - If not, see step B-8. 	§ B Guidelines

B-7.		DSD	Compiles comments, see step B-5.	§ B Guidelines
B-8.	Within the set deadline	Delegate/ contact point	Validates and sends back to DSD the edited version of the self-declaration.	§ B Guidelines
B-9.		DDG	Reviews the edited self-declaration prior to the publication and: <ul style="list-style-type: none"> - 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
B-10.		DG	Sends 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 procedure).	§ B.2 Guidelines
B-11.		DSD	Translates and finalises the version validated by the Delegate	§ B.2 Guidelines
B-12.		DSD	Publishes the self-declaration on the OIE website.	§ B.2 Guidelines
B-13.		DSD	Sends an email to the Delegate / contact point confirming the publication of the self-declaration on the OIE website while mentioning that the translated versions will become available upon finalisation.	§ B.2 Guidelines

C - LOSS OF A SELF-DECLARED DISEASE FREEDOM (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) to the OIE via an immediate notification in WAHIS.	§ C Guidelines
C-2.		DSD	Analyses the impact of the reported outbreak on the self-declared disease freedom: <ul style="list-style-type: none"> - If the reported outbreak does not impact the self-declaration, it remains unchanged on the OIE website (end of procedure); - If the reported outbreak affects the self-declaration, see steps C-3 and C-4. 	§ C Guidelines

C-3.		DSD	Updates the OIE website including a link to the relevant immediate notification in WAHIS.	§ C Guidelines
C-4.		DSD	Informs the Delegate that the self-declaration is affected and that the dedicated OIE website has been updated.	§ C Guidelines

D – SELF-DECLARATION OF THE RECOVERY OF DISEASE FREEDOM (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 disease freedom, it sends a new self-declaration; when the information on the conditions for recovering the self-declared disease freedom are met, see steps B-1 to B-13.	§ D Guidelines

Guidelines for the publication of a self-declaration of freedom from a disease

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 OIE Delegate should refer to the provisions of 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 *Codes* should be applied. For its publication, the self-declaration should therefore provide the relevant documented evidence of compliance with the provisions of the relevant chapters of the *Codes*, in order to support the claimed disease freedom and any bilateral agreement with a potential trade partner.

2. Self-declaration structure

2.1 Content

Each self-declaration document should contain the following.

- a. an **introduction** including
 - The formal request that the OIE publishes the self-declaration;

- The exact denomination of the disease(s) for which freedom is self-declared (e.g. highly pathogenic avian influenza or avian influenza in poultry; 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:
 - o first declaration of freedom (whether or not it is on the basis of historical freedom from the disease according to Article 1.4.6.) or recovery of the self-declared disease freedom;
 - o geographical boundaries (i.e., the whole country, one or more zones or a compartment);
 - o 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:

- Evidence that the disease is a notifiable disease in the entire country;

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

- History of absence or eradication of the disease in the country, zone or compartment:

The self-declaration should clearly state whether the country is claiming freedom for the first time or the recovery of freedom. A summary of the disease history, including a description of the susceptible animal population in the country, 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 having led to the control and eradication of the disease in the country, zone and 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, when relevant, if a vaccine was ever used in the country, zone or compartment to eradicate the disease for which freedom is declared and when the last vaccination was carried out.

If vaccination is still applied, it should be clearly specified under what circumstances, how these align with provisions of the *Terrestrial Code* and *the Terrestrial Manual*, and how risks are accounted for within surveillance programmes.

- *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 OIE listed diseases), or with Chapter 1.4. (including for non-listed diseases), substantiating the self-declared freedom. 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, or 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 through 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 case of self-declaration for recovery of disease freedom, evidence should be provided on the compliance with the provisions of relevant articles on recovery of disease freedom as well as any additional surveillance or control measures that have been implemented to control and eradicate the outbreak.

- *Measures implemented to maintain freedom in the country, zone or compartment:*

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:

- *Pathways to claim freedom from aquatic animal diseases:*

The pathway by which freedom is being declared (in accordance with Article 1.4.6. 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 early warning system and import requirements in the *Aquatic Code*.

Surveillance evidence supporting freedom in accordance with the requirements of the relevant pathway and that complies with the provisions of the relevant articles of disease specific chapters of the *Aquatic Code* and Manual (for OIE listed diseases) or with Chapter 1.4. of the *Aquatic Code* (for non-listed diseases), should be provided.

- Measures implemented to maintain freedom:

Evidence that the requirements for maintaining freedom are being met in accordance with Article 1.4.7. and relevant disease-specific chapters (for listed diseases), should be provided.

- c. the contact details (name, email address and phone/fax 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 OIE 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 5 pages per disease in A4 format, single-spaced using Times New Roman font size 10pt. Relevant appendices may be attached to the core document and should be clearly cross-referenced. References to more detailed information in support of the self-declaration are encouraged, for instance to publications in scientific literature or other information on the Competent Authority's website.

2.2.2 Language

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

2.2.3 File compatibility

For revision, editing and translation purposes, the self-declaration should be provided in Word format. 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 Transmission format

The documents should be supplied in electronic format to the OIE Disease Status Department (using the following email address: self-declaration@oie.int).

Note: Self-declaration of freedom in accordance to the *Codes* 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 Disease Status Department

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

Within two weeks following the acknowledgment of receipt, the Disease Status Department conducts an analysis of the self-declaration document:

- an administrative screening that entails checking that the structure of the self-declaration dossier is in accordance with the SOP;
- a technical screening based on the information available in WAHIS and on the relevant requirements of the OIE *Terrestrial or Aquatic Codes*. The Disease 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 requirement described in the *Codes*, and needed for any stakeholder to evaluate this compliance.

If gaps in the information are identified, the Disease Status Department may need to contact the country by sending an email to the Delegate or to 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, the OIE will consider that the process of publication of the self-declaration is discontinued.

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

2. Publication on the OIE website

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

Considering that translation of self-declaration may take time to be finalised, once the document has been validated by the concerned Member and reviewed by the OIE 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.

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

The publication of the self-declaration will also be announced in the OIE Bulletin for information of all OIE Members.

C. Loss of the self-declared disease freedom

An outbreak in a country, a zone or a compartment having a self-declared disease freedom should be notified to the OIE through an immediate notification in the WAHIS. The OIE 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 disease freedom.

Any loss of self-declared disease freedom is communicated to the Member and reflected on the OIE website, including via a link to the WAHIS notification.

D. Self-declaration of the recovery of disease freedom

The Delegate of the concerned Member wishing to reclaim a lost disease freedom should submit a new self-declaration document to the OIE (self-declaration@oie.int) providing the documented evidence that the country, zone or compartment has recovered the self-declared disease freedom 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 (OIE), takes responsibility for the self-declaration of freedom from

.....
..... (disease)

DISCLAIMER

The OIE, after performing an administrative and technical screening of a self-declaration concerning the disease-free 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 the OIE of self-declaration on its website does not reflect the official opinion of the OIE. Responsibility for the information contained in a self-declaration lies entirely with the OIE Delegate of the Member concerned.

Neither the OIE 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.

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

Signature of the Delegate: