



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

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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.

Self-declaration SOP

Standard Operating Procedure for the self-declaration of freedom from diseases of Members

Description/ Scope:	<p>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).</p> <p>The procedure is composed by four parts:</p> <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 free status- Part D: Recovery of self-declared free status
Related documents:	<p>Self-Declaration Process - Guidelines Chapter 1.6 of the <i>Terrestrial Animal Health Code</i>.</p>
List of acronyms:	<p><i>Codes: Terrestrial Animal Health Code and Aquatic Animal Health Code</i> DSD: Disease Status Department WAHIAD: World Animal Health Information and Analysis Department WAHIS: World Animal Health Information System DG: Director General</p>

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.	§ 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 acknowledgement 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.	§ 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-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.		DG	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, in the three official languages.	§ 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, including the translated versions of the self-declaration in the 2 other languages.	§ B.2 Guidelines

C - LOSS OF A SELF-DECLARED FREE 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) to the OIE via an immediate notification in WAHIS.	§ C Guidelines
C-2.		DSD and WAHIAD	Liaise to share information and confirm or deny the impact of the reported outbreak on the self-declared status. <ul style="list-style-type: none"> - If additional information is needed, see step C-3; - If not, see step C-4. 	§ C Guidelines
C-3.		DSD	Contacts the Delegate concerned and requests the necessary additional information within the allocated deadline.	§ C Guidelines
C-3.1	Within the allocated deadline	Delegate	Provides the OIE with the necessary information.	§ C Guidelines
C-4.		DSD	<ul style="list-style-type: none"> - If the reported outbreak does not impact the self-declared status, see step C-5; - If the reported outbreak affects the self-declared status, see step C-6. 	§ C Guidelines
C-5.		DSD	Confirms maintenance of the self-declared status to the Delegate (end of procedure).	§ C Guidelines
C-6.		DSD	Informs the Delegate that the self-declared status if affected and that the dedicated OIE website has been/will be updated.	§ C Guidelines
C-7.		DSD	Publishes a notice on the OIE website including a link to the relevant immediate notification in WAHIS.	§ C Guidelines

D - RECOVERY OF SELF-DECLARED FREE STATUS (section D of Guidelines)

Step	Time Reference	Responsible person	Action	Reference Document
D-1.		Delegate	When the Member Country wishes to publish a recovered self-declared status, it sends a new self-declaration; when the information on the conditions for recovering the self-declared free status are met, see steps B-1 to B-13.	§ D Guidelines

Guidelines for self-declaration of freedom from a diseases

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 status and any bilateral agreement with a potential trade partner. Any self-declaration for freedom for a country, a zone or a compartment should provide documented information on compliance with the relevant chapter of the OIE *Codes*.

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 objective of the declaration, first declaration of freedom or recovery of the self-declared free status.
 - 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 infectious hypodermal and haematopoietic necrosis virus);
 - Reference to the relevant chapters and articles of the *Terrestrial Code* or the *Aquatic Code*;
 - Whether the self-declaration of freedom relates to the whole country, to one or more zones or to a compartment and to a first declaration of freedom or a recovery of the self-declared free status;
 - 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 notifiable to the Competent Authority at national level:

Reference to the regulatory system in place relevant to the specific disease should be made.

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

The self-declaration should be clear as to 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 control measures described should comply with the historical and current control measures reported by the Member Country to WAHIS.

- Surveillance and 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., substantiating the self-declared freedom. Results of the surveillance activities should be provided.

- 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 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.

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 how risks are accounted for within surveillance programmes.

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 *Glossary* of 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 Country without delay.
- d. The self-declaration should be duly signed by the OIE Delegate of the Member Country.

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 cannot be sent as part of a follow-up or final report in WAHIS.

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, based on compliance with this 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 Country should provide any clarification or additional information within the allocated time frame. Once all the information is available, the Disease Status Department will send an edited version of the self-declaration document to the Delegate or nominated contact point for validation.

The Member Country 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.

NOTE: if the Disease Status Department officer in charge of the self-declaration is proficient in the language used to prepare the documents of the self-declaration, the self-declaration will be assessed in that language. The same language will be used to communicate with the OIE Delegate concerned.

2. Publication on the OIE website

The final version of the self-declaration document as validated by the Member Country, is reviewed by the OIE 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 as well as the translated versions of the self-declaration.

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

A disease outbreak in a Member Country, a zone or a compartment having a self-declared free status for that disease should be notified to the OIE through an immediate notification in the World Animal Health Information System (WAHIS). The OIE World Animal Health Information and Analysis Department and the Status Department liaise on a daily basis to identify all immediate notifications that may impact a self-declaration of disease freedom.

Any loss of self-declared free status is communicated to the Member Country and reflected on the OIE website, including via a link to WAHIS’s immediate notification.

D. Recovery of the self-declared free status

The Delegate of the concerned Member Country wishing to reclaim a disease free status for a suspended self-declared status should submit a new self-declaration document to the OIE (self-declaration@oie.int) demonstrating that the country, zone or compartment has recovered the self-declared free status in compliance with the relevant provisions of the *Terrestrial or Aquatic Codes*, following the steps for a first self-declaration.

Annex I: 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 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: