



## Suspension\_SOP

### Standard Operating Procedures on suspension, recovery or withdrawal of officially recognised disease status and withdrawal of the endorsement of official control programmes of Members

<b>Description/ Scope:</b>	<p>This procedure describes the process for i) the suspension, recovery or withdrawal of official disease status and ii) the withdrawal of the endorsement of an official control programme.</p> <p>The scope includes the process for approval of a containment zone following a suspension due to an outbreak.</p> <p>This procedure may occur following the occurrence of an outbreak or for other reasons such as non-submission of the annual reconfirmation as well as non-compliance with the requirements laid out in the relevant chapters of the <i>Terrestrial Animal Health Code (Terrestrial Code)</i>.</p> <p>The subprocess for the suspension, recovery or withdrawal of a disease status or endorsed official control programme fits in the overall Official Status Recognition Process.</p>
<b>Related documents</b>	<p>Guidelines for suspension, Recovery or Withdrawal<sup>1</sup> (Annexed)</p> <p>Resolution No.15 of the 2020 Adapted Procedure</p> <p>Resolution No.16 of the 2020 Adapted Procedure</p>
<b>Related processes</b>	<p>Official Status Recognition Process</p> <ul style="list-style-type: none"><li>- Procedure (Application_SOP)</li><li>- Guidelines (Application_Guidelines)</li></ul> <p>Expert Mission Deployment</p> <ul style="list-style-type: none"><li>- Procedure (Mission_SOP)</li><li>- Guidelines (Mission_Guidelines)</li></ul> <p>Reconfirmation of a Status or Programme</p> <ul style="list-style-type: none"><li>- Procedure (Reconfirmation_SOP)</li><li>- Guidelines (Reconfirmation_Guidelines)</li></ul>
<b>List of acronyms:</b>	<p>AHG: <i>Ad hoc</i> Group</p> <p>DDG: Deputy Director General, Standards and Science</p> <p>DG: Director General</p> <p>DSD: Disease Status Department</p> <p>SCAD: Scientific Commission for Animal Diseases</p> <p><i>Terrestrial Code: Terrestrial Animal Health Code</i></p>

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<sup>1</sup> For the purpose of clarity, this will be referred to as « Suspension Guidelines »

Step	Time Reference	Responsible person	Action	Reference Document
1.	Following an outbreak / non-submission of the annual reconfirmation / non-compliance with <i>Terrestrial Code</i> requirements	DSD / SCAD	<p>Assess the situation:</p> <ul style="list-style-type: none"> <li>- In the case of obvious non-compliance with the requirements for freedom or status<sup>2</sup> (occurrence of an outbreak in a disease-free zone or country; or non-submission of an annual reconfirmation in due course), see step 4;</li> <li>- In the case of a possible non-compliance with the requirements of the <i>Terrestrial Code</i> (e.g. doubts with the annual reconfirmation), see step 2.</li> </ul>	
2.		DG	Sends letter to the Member's Delegate requesting necessary clarifications within a set deadline.	
2.1	Within the required deadline	Delegate	Provides requested information.	§ B.2 Suspension Guidelines
2.2		DSD	<p>Compiles and analyses the provided information and:</p> <ul style="list-style-type: none"> <li>- If further information is required, see step 2;</li> <li>- If not, forwards it to SCAD.</li> </ul>	
2.3		SCAD	<p>Reviews the gathered information and:</p> <ul style="list-style-type: none"> <li>- If further information is required, see step 2;</li> <li>- If not, see step 2.4.</li> </ul>	
2.4		SCAD	<ul style="list-style-type: none"> <li>- If a specific expert opinion is necessary, requests recommendation from relevant <i>ad hoc</i> Group experts and see step 2.5;</li> <li>- If not, see step 2.7.</li> </ul>	
2.5		DSD	Contacts the identified expert(s).	
2.6		Expert(s)	Provide(s) recommendation on the suspension or withdrawal.	
2.7		SCAD	<ul style="list-style-type: none"> <li>- If a mission is necessary, see mission subprocess (Mission_SOP);</li> <li>- If not, decides on the outcome of the maintenance of an officially recognised disease status or endorsement of an official control programme.</li> </ul>	
2.8		SCAD	<p>Reports its assessment to the OIE and:</p> <ul style="list-style-type: none"> <li>- If the evaluation outcome is positive, see step 3;</li> <li>- If the evaluation outcome is negative, see step 4.</li> </ul>	

<sup>2</sup> Not including BSE risk status

3.		DG	Sends letter to the Member confirming the maintenance of the status or of the endorsement of the official control programme and requesting follow-up reports when necessary.	
3.1		Delegate	Takes note of the maintenance of the officially recognised disease status or endorsement of an official control programme, and provides follow-up reports as relevant <b>(end of procedure)</b> .	
4.		DG	Prepares letter for the Member notifying and explaining the reason for the status suspension or endorsement withdrawal, and the options proposed by SCAD if involved in the assessment.	
4.1		DSD	Publishes suspension notice or withdrawal of the endorsed programme on the OIE website. Updates maps and lists on the OIE website.	
5.		Delegate	Takes note of the status suspension or endorsement withdrawal and: <ul style="list-style-type: none"> <li>- In the case of an endorsed official control programme, see step 6;</li> <li>- In the case of a disease status see step 7.</li> </ul>	
6.		Delegate	<ul style="list-style-type: none"> <li>- If the Member wishes to apply again for the endorsement of its official control programme, see the Application_SOP;</li> <li>- If not, takes note of the withdrawal of the endorsement <b>(end of procedure)</b>.</li> </ul>	§ A.1 Suspension Guidelines
7.		Delegate	<ul style="list-style-type: none"> <li>- If the Member wishes to apply for the recovery of its status or for the establishment of a containment zone, see step 8;</li> <li>- If the Member does not apply to recover its status within 2 or 3 years<sup>3</sup> following the suspension or for the establishment of a containment zone, see step 21.</li> </ul>	§ A.2 Suspension Guidelines
8.	Within 2 or 3 years of the suspension <sup>3</sup>	Delegate	Submits an application to the OIE for the establishment of a containment zone and/or for the recovery of a suspended status or for the status recovery of a previously established containment zone.	§ B.1 Suspension Guidelines
9.		DSD	Screens dossier and: <ul style="list-style-type: none"> <li>- If further information is necessary, see step 10;</li> <li>- If information is satisfactory see step 11.</li> </ul>	
10.		DSD	Contacts and requests the Delegate or Contact point to provide clarification or additional information within a set deadline.	
10.1		Delegate / Contact point	Provide the requested information within the set deadline.	
11.		DSD	Forwards dossier to the President of the SCAD.	

<sup>3</sup> A period of 3 years applies only in the case of AHS status.

12.		President of SCAD	Decides on the procedure to follow for the assessment (electronic consultation, physical meeting, involvement of specific experts...). Shares the dossier with SCAD Members and coordinates the assessment.
13.		SCAD	Examines dossier and: - If information is required, see step 14; - If not, see step 15.
14.		DSD	Requests information to the Member Delegate or Contact point within a set deadline.
14.1	Within the set deadline	Delegate/ Contact point	Provides requested information.
14.2		DSD	Shares information with SCAD.
15.		SCAD	- If specific technical expertise is required to assess the dossier, see step 16; - If not, see step 17.
16.		DSD	Requests recommendation from relevant expert(s).
16.1		Expert(s)	Provide(s) recommendation on the dossier to SCAD.
17.		SCAD	- If a mission is necessary, see Mission subprocess (Mission_SOP); - If not, concludes on the outcome of the establishment of a containment zone and/or of the maintenance of a previously recognised disease status.  Notifies DSD of outcome.
18.		DSD	- If the evaluation outcome is positive, see step 19; - If the evaluation outcome is negative, see step 20.
19.		DG	Sends letter confirming the establishment of a containment zone and/or reinstatement of the status.
19.1		Delegate	Receives notification of reinstatement of the disease status and/or of the establishment of a containment zone; see step 23.
20.		DG	Sends letter notifying that the application for recovery/containment zone has not been endorsed and that therefore the disease status remains suspended, explaining the reason for the negative outcome of the evaluation.
20.1		Delegate	Takes note of the negative outcome of the assessment and that therefore the disease status remains suspended.

20.2	Within a 2 or 3 year <sup>3</sup> deadline of the initial suspension	Delegate	<ul style="list-style-type: none"> <li>- If the Member wishes to reapply for the recovery of its status, see step 8;</li> <li>- If the deadline has passed and the Member did not apply for recovery or was unsuccessful in its application(s), see step 21.</li> </ul>
21.	2 or 3 years <sup>3</sup> after the initial suspension	DG	Sends letter to the Delegate of the Member notifying the withdrawal of the disease status.
22.		Delegate	Takes note that the disease is withdrawn.
23.		DSD	Updates maps and lists on the OIE website.

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<sup>3</sup> A period of 3 years applies only in the case of AHS status.



## Suspension\_Guidelines

### Guidelines on suspension, recovery or withdrawal of officially recognised disease status and withdrawal of the endorsement of official control programmes of Members

#### A. Suspension or withdrawal of an official status and withdrawal of the endorsement of an official control programme

##### 1. Official control programme

The endorsement of an official control programme may be **withdrawn** following:

- the non-submission of the annual reconfirmation, normally due in November each year, by January of the following year;
- the negative assessment of the annual reconfirmation by the Scientific Commission for Animal Diseases (Scientific Commission);
- the non-compliance of the Member with the requirements laid out in the relevant chapters of the *Terrestrial Animal Health Code (Terrestrial Code)*.

The endorsement of a revised official control programme will then be feasible through the procedure for application (Application\_SOP), with reduced fees (cf. Annex 1).

##### 2. Official disease status

###### 2.1 SOURCES OF SUSPENSION AND WITHDRAWAL

The official status of a given Member may be **suspended** following:

- the occurrence of an outbreak,
- the non-submission of the annual reconfirmation by January of the following year,
- the negative assessment of the annual reconfirmation by the Scientific Commission,
- the non-compliance of the Member with the requirements laid out in the relevant chapters of the *Terrestrial Code*.

As the official bovine spongiform encephalopathy (BSE) risk status of a country or zone is determined on the basis of an overall assessment of risks, the occurrence of a new BSE case does not automatically lead to the suspension of the official BSE risk status, except if the new case reveals a change in the epidemiological situation indicating failure of the BSE risk mitigating measures in place or non-compliance with the applicable requirements outlined in the *Terrestrial Code*.

Members may recover their official status within 2 years, or 3 years in the case of AHS status, by proving they have managed to comply with the relevant requirements of the *Terrestrial Code* for recovery of status. When the status has not been recovered or an application for recovery has not been submitted within 2 years (or 3 years in the case of AHS status) of suspension, the official status is **withdrawn** and Members must then reapply following the procedure for the application for status recognition, with reduced fees (cf. Annex 1).

###### 2.2 COMMUNICATION ON SUSPENSIONS

Any suspension of official status is officially conveyed by an official letter from the Director General of the OIE to the Delegate of the Member concerned and is simultaneously announced through the publication of a notice on the OIE website. The suspension takes effect at the date when the Member

was not compliant anymore with the requirements of the *Terrestrial Code*, even if the information was provided to the OIE with delay.

### 3. Authority for withdrawal or suspension

In the case of obvious non-compliance with the requirements for a given status or endorsed official control programme (e.g. occurrence of an outbreak, non-submission of the annual reconfirmation by the end of January of the following year), the relevant status or endorsement may be respectively suspended or withdrawn directly by the OIE Director General, without the involvement of the Scientific Commission.

When information received by the OIE suggests potential non-compliance of a Member with the requirements laid out in the relevant chapters of the *Terrestrial Code* (e.g. through the reconfirmation process), the Scientific Commission will be requested to provide its assessment of the situation and its decision on the maintenance of an endorsed official control programme or suspension of a disease status.

## B. Recovery of a previously recognised official status

### 1. Submission of an application for recovery of status

#### 1.1 APPLICATION CONTENT

Further to a suspension, a Member wishing to recover its previously recognised official status has to submit an application to the OIE which should contain:

- A **one-page executive summary** stating clearly:
  - What the Member is applying for;
  - How it has addressed the various requirements set out in the *Terrestrial Code*;
  - What information is provided in the dossier.
- A **core document**, with possible relevant cross-referenced **appendices**, based on the model of the relevant questionnaire for that particular disease published in Chapters 1.7. to 1.12. of the *Terrestrial Code* with specific reference to its last paragraph under the Section on 'Recovery of status'.
- The **contact details** (name, phone/fax numbers and email address) of technical staff involved in the preparation of the dossier so that any questions arising during the assessment of the application could be referred to the Member without delay.

The application must be duly signed by the Delegate of the applicant Member.

#### 1.2 APPLICATION FORMAT

Applications must be limited to a core document of no more than 50 pages in A4 format, single-spaced using Times New Roman font size 10pt. Page numbers must be displayed.

The core document with the executive summary as well as appendices must be prepared in one of the official languages of the OIE (English, French or Spanish).

The application must be supplied in electronic format to the Director General of the OIE (as email file attachments or provision of link from which documents can be downloaded using the following email address: [disease.status@oie.int](mailto:disease.status@oie.int)). In case this is not possible, the dossier may be supplied in hardcopy.

### 2. Evaluation of the application

The Scientific Commission has been given the mandate to proceed with such recovery without further consultation of the OIE World Assembly of Delegates (hereafter the Assembly), in accordance with Resolution No. 15 of the 2020 Adapted Procedure and other relevant Resolutions previously adopted.

## 2.1 EVALUATION BY THE DISEASE STATUS DEPARTMENT

Following the same process as for evaluation of first time-applications, the Disease Status Department performs a first screening of the application before transmission to the Scientific Commission, in order to identify gaps in the information provided and, where necessary, contact the Member for clarifications (cf. section B of Application\_Guidelines).

## 2.2 EVALUATION BY THE SCIENTIFIC COMMISSION

The President of the Scientific Commission decides on the process to follow in undertaking the evaluation of the reinstatement application that could be conducted either at its regular meeting or by correspondence amongst its members. When a particular technical expertise is necessary, the Scientific Commission may request the input of a member of the *ad hoc* Group or a relevant expert based on factors such as the distribution of the outbreaks, the nature and quality of the data related to the outbreak and the control measures taken. These may take place either by correspondence or at a physical meeting depending on the calendar of the meetings.

The process of evaluation may also involve an expert mission to the concerned Member (cf. Mission\_SOP).

## 3. Communication on the outcome

When the Scientific Commission has concluded that the Member or zone has complied with the relevant provisions of the *Terrestrial Code* on the recovery of an official status, the OIE informs the Delegate of the applicant Member of this decision by a letter from the Director General of the OIE. In parallel, the decision is published on the OIE website and becomes effective from the date of publication unless specified otherwise. The assessment of the Scientific Commission is duly documented in its following meeting report.

When the Scientific Commission has decided not to approve the application for recovery, a statement on the reasons for non-acceptance is communicated by a letter from the Director General of the OIE to the applicant Member. The assessment of the Scientific Commission and the letter of the Director General of the OIE are not released in the public domain. The status remains suspended until 2 years, or 3 years in the case of AHS status, have elapsed since the suspension or until a new application for recovery is sent to the OIE and evaluated and approved by the Scientific Commission.

## C. Application for a containment zone

### 1. Scope of application

Further to a suspension, a Member wishing to establish a containment zone, in accordance with Chapter 4.4. of the *Terrestrial Code* has to submit an application to the OIE following the template of the relevant questionnaire of Chapters 1.7. to 1.12. with specific reference to the last paragraph under the Section on 'Recovery of status'.

### 2. Application and evaluation process

The procedure for the establishment of a containment zone is similar to the procedure for the recovery of status described in Section B. of this document.

As for recovery of disease status, the Scientific Commission has been given the mandate to proceed with the recognition of a containment zone without further consultation of the Assembly.



### **3. Communication on the outcome**

When the Scientific Commission has concluded that the Member has complied with the requirements of the *Terrestrial Code* for the establishment of a containment zone, the OIE informs the Delegate of the applicant Member of this decision by a letter from the Director General of the OIE. In parallel, the Member or zone recovers its previously recognised disease status with the exclusion of the containment zone; the decision is published on the OIE website and becomes effective from the date of publication unless specified otherwise.

When the Scientific Commission has decided not to approve the application for establishment of a containment zone, a statement on the reasons for non-acceptance is communicated by a letter from the Director General of the OIE to the applicant Member. The assessment of the Scientific Commission and the letter of the Director General of the OIE are not released in the public domain. The status remains suspended until 2 years, or 3 years in the case of AHS status, have elapsed since the suspension or until a new application for a containment zone or for the recovery of status is sent to the OIE and evaluated and approved by the Scientific Commission.

### **4. Status recovery of the containment zone**

When a Member wishes to recover the disease free status of the containment zone, the Delegate has to follow the procedure for the recovery of status, described in Section B of this document.

### **D. Financial obligations**

In accordance with Resolution No. 16 of the 2020 Adapted Procedure, fees are not requested for suspensions of status, evaluations for a recovery of status, or for the establishment of a containment zone. However, in the case the status or the endorsement of the official control programme is withdrawn, reduced fees will be applied when re-applying for the same status category, as presented in Annex 1.

## ANNEX 1

### Financial obligations related to the reinstatement of official disease status and of the endorsement of official control programmes (in Euros)

	OIE Members (except Least developed countries)				Least developed countries (Members) based on the current official UN list			
	AHS, CSF and BSE	CBPP/FMD	PPR	Dog mediated rabies	AHS, CSF and BSE	CBPP/FMD	PPR	Dog mediated rabies
<i>Reinstatement of the status previously suspended within the same Member or zone(s).</i>	free of charge	free of charge	free of charge	N/A	free of charge	free of charge	free of charge	N/A
<i>Re-application for the recognition of a disease status previously withdrawn</i>	4,500	3,500	2,500	N/A	2,250	1,750	1,250	N/A
<i>Establishment/lift of a containment zone</i>	free of charge	free of charge	free of charge	N/A	free of charge	free of charge	free of charge	N/A
<i>Re-endorsement of application for official control programme (if the previous endorsement was withdrawn due to non-compliance with commitments relating to the initial endorsement)</i>	N/A	1,000	1,000	1,000	N/A	500	500	500

NB: The costs of possible missions to Members are not included in the above amounts.

N/A: not applicable