

Organisation mondiale de la santé animale Organización Mundial de Sanidad Animal

Suspension_SOP

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

Description/Scope:

This procedure describes the process for i) the suspension, recovery or withdrawal of official animal health status and ii) the withdrawal of the endorsement of an official control programme.

The scope includes the process for approval of a containment zone following a suspension due to an outbreak.

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 *Terrestrial Animal Health Code (Terrestrial Code)*.

The subprocess for the suspension, recovery or withdrawal of an animal health status or endorsed official control programme fits in the overall Official Status Recognition Process.

Related documents

Guidelines for suspension, Recovery or Withdrawal¹ (Annexed)

Resolution No.15 of the 2020 Adapted Procedure Resolution No.16 of the 2020 Adapted Procedure Resolution No. 20 of the 90th General Session

Related processes

Official Status Recognition Process

- Procedure (Application_SOP)
- Guidelines (Application_Guidelines)

Expert Mission Deployment

- Procedure (Mission_SOP)
- Guidelines (Mission_Guidelines)

Reconfirmation of a Status or Programme

- Procedure (Reconfirmation_SOP)
- Guidelines (Reconfirmation_Guidelines)

List of acronyms:

AHG: Ad hoc Group

DDG: Deputy Director General, Standards and Science

DG: Director General SD: Status Department

SCAD: Scientific Commission for Animal Diseases Terrestrial Code: Terrestrial Animal Health Code WAHIS: World Animal Health Information System

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 $^{^{\}mathrm{1}}$ 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 Terrestrial Code requirements	SD / SCAD	Assess the situation: In the case of obvious non-compliance with the requirements for freedom or status (occurrence of an outbreak in a disease-free zone or country; or non-submission of an annual reconfirmation in due course), see step 4; In the case of possible non-compliance with the requirements of the <i>Terrestrial Code</i> (e.g., doubts about the annual reconfirmation), see step 2. In the case of an indigenous case of classical BSE in an animal born after the date from which the risk of BSE agents being recycled within the cattle population has been negligible, see step 2.	
2.		DG	Sends letter to the Member's Delegate requesting necessary clarifications within a set deadline (within 90 days of confirming ² an indigenous case of classical BSE)	
2.1	Within the required deadline	Delegate	Provides requested information.	§ B.2 Suspension Guidelines
2.2		SD	Compiles and analyses the provided information and: - If further information is required, see step 2; - If not, forwards it to SCAD. - For BSE: If no documentation is provided before the set deadline, see step 4.	
2.3		SCAD	Reviews the gathered information and: - If further information is required, see step 2; - If not, see step 2.4.	
2.4		SCAD	 If a specific expert opinion is necessary, requests recommendation from relevant ad hoc Group experts and see step 2.5; If not, see step 2.7. 	
2.5		SD	Contacts the identified expert(s).	
2.6		Expert(s)	Provide(s) recommendation on the suspension or withdrawal.	
2.7		SCAD	 If a mission is necessary, see mission subprocess (Mission_SOP); If not, decides on the outcome of the maintenance of an officially recognised animal health status or endorsement of an official control programme. 	

² 90 days start to count from the confirmation date included in the Immediate Notification sent to WAHIS

		Reports its assessment to WOAH and:				
2.8	SCAD	If the evaluation outcome is positive, see step 3;If the evaluation outcome is negative, see step 4.				
3.	DG	Sends a 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 animal health status or endorsement of an official control programme and provides follow-up reports as relevant (end of the procedure).				
4.	DG	Prepares a letter for the Member notifying and explaining the reason for the status suspension ³ or endorsement withdrawal and the options proposed by SCAD if involved in the assessment.				
4.1	SD	Publishes suspension notice or withdrawal of the endorsed programme on the website. Updates maps and lists on the website.				
5.	Delegate	Takes note of the status suspension or endorsement withdrawal and: - In the case of an endorsed official control programme, see step 6; - In the case of an animal health status, see step 7.				
6.	Delegate	 If the Member wishes to apply again for the endorsement of its official control programme, see the Application_SOP; If not, takes note of the withdrawal of the endorsement (end of the procedure). 	§ A.1 Suspension Guidelines			
7.	Delegate	 If the Member wishes to apply for the recovery of its status or for the establishment of a containment zone⁴, see step 8; If the Member does not apply to recover its status within 2 or 3 years⁵ following the suspension or for the establishment of a containment zone, see step 21. 	§ A.2 Suspension Guidelines			
Within 2 or 3 8. years of the suspension ³	Delegate	Submits an application to WOAH 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			

 $^{^3}$ BSE: Suspension date is the date of confirmation of the indigenous case of classical BSE included in the Immediate Notification sent to WAHIS .

Containment zones are not applicable to BSE
 A period of 3 years applies only in the case of AHS status.

9.		SD	Screens dossier and: - If further information is necessary, see step 10; - If information is satisfactory see step 11.
10.		SD	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.		SD	Forwards dossier to the President of the SCAD.
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.		SD	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		SD	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.		SD	Requests recommendation from the 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 animal health status. Notifies SD of the outcome.
18.		SD	 If the evaluation outcome is positive, see step 19; If the evaluation outcome is negative, see step 20.
19.		DG	Sends a letter confirming the establishment of a containment zone and/or the reinstatement of the status ⁶ .

 $^{^{\}rm 6}$ For BSE, a negligible risk status may be reinstated as controlled risk status.

19.1	Delegate	Receives notification of the reinstatement of the animal health status and/or the establishment of a containment zone; see step 23.
20.	DG	Sends a letter notifying that the application for recovery/containment zone has not been endorsed and that, therefore, the animal health 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 animal health status remains suspended.
Within a 2 or 3 year³ deadline of the initial suspension	Delegate	 If the Member wishes to reapply for the recovery of its status, see step 8; If the deadline has passed and the Member did not apply for recovery or was unsuccessful in its application(s), see step 21.
2 or 3 years ⁷ 21. after the initial suspension	DG	Sends letter to the Delegate of the Member notifying the withdrawal of the animal health status.
22.	Delegate	Takes note that the animal health status is withdrawn.
23.	SD	Updates maps and lists on the website.

 $^{^{\}rm 7}$ A period of 3 years applies only in the case of AHS status.

Suspension_Guidelines

Guidelines on suspension, recovery or withdrawal of officially recognised animal health 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 animal health status

2.1 SOURCES OF SUSPENSION AND WITHDRAWAL

2.1.1 ALL DISEASES WITH AN OFFICIAL STATUS PROCEDURE, EXCEPT BSE

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*.

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).

2.1.2 BSE RISK STATUS

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

- 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*.

The occurrence of an indigenous case of classical BSE, born after the date from which the risk of BSE agents being recycled within the bovine population has been negligible, will lead to the suspension of the official BSE risk status only if:

- documented evidence regarding the outcome of subsequent investigations is not submitted to WOAH within 90 days of confirmation of the indigenous case of classical BSE,
- the documented evidence submitted to WOAH regarding the investigation does not demonstrate that any identified source of infection has been controlled and the risk of BSE agents being recycled within the bovine population has continued to be negligible.

Members may recover their official status within 2 years, by proving they have managed to comply with the relevant requirements of the *Terrestrial Code* for negligible or controlled risk status. When the status has not been recovered, or an application for recovery has not been submitted within 2 years 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 to the Delegate of the Member concerned and is simultaneously announced through the publication of a notice on the website. The suspension takes effect at the date when the Member was no longer compliant with the requirements of the *Terrestrial Code*, even if the information was provided to WOAH 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 Director General, without the involvement of the Scientific Commission.

When the information received by WOAH 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 an animal health 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 WOAH 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 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' or on 'Maintenance of BSE risk status'.

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• 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 (English, French or Spanish).

The application must be supplied in electronic format to the Director General (as email file attachments or provision of a link from which documents can be downloaded using the following email address: disease.status@woah.org. In case this is not possible, the dossier may be supplied in hard copy.

2. Evaluation of the application

The Scientific Commission has been given the mandate to proceed with such recovery without further consultation of the 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 STATUS DEPARTMENT

Following the same process as for the evaluation of first time-applications, the 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 which 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, WOAH informs the Delegate of the applicant Member of this decision by a letter from the Director General. In parallel, the decision is published on the 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 to the applicant Member. The assessment of the Scientific Commission and the letter of the Director General 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 WOAH and evaluated and approved by the Scientific Commission.

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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 WOAH 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 the recovery of animal health status, the Scientific Commission has been given the mandate to proceed with the recognition of a containment zone without further consultation with 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, WOAH informs the Delegate of the applicant Member of this decision by a letter from the Director General. In parallel, the Member or zone recovers its previously recognised animal health status with the exclusion of the containment zone; the decision is published on the website and becomes effective from the date of publication unless specified otherwise.

When the Scientific Commission has decided not to approve the application for the establishment of a containment zone, a statement on the reasons for non-acceptance is communicated by a letter from the Director General to the applicant Member. The assessment of the Scientific Commission and the letter of the Director General 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 WOAH 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 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.

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ANNEX 1

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

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

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