

[Addendum] Protection Zone_SOP

Standard Operating Procedure on the establishment of a protection zone in a country or zone having an officially recognised animal health status

<p>Description/ Scope:</p>	<p>This procedure describes the process for the application and approval of a protection zone in a country or zone having an officially recognised animal health status.</p> <p>This procedure may be used to preserve the animal health status of an animal population in a free country or a free zone by in accordance with Chapter 4.4. and other disease-specific chapters of the <i>Terrestrial Animal Health Code (Terrestrial Code)</i>.</p> <p>If the animal health status of the protection zone changes due to the occurrence of a case or non-compliance with the relevant requirements of the <i>Terrestrial Code</i>, the Suspension_SOP should be consulted.</p> <p>The subprocess for the establishment of a protection zone fits in the overall Official Status Recognition Process.</p>
<p>Related documents</p>	<p>Guidelines for application of a protection zone¹ (Annexed) Resolutions Nos 15 and 16 of the 2020 Adapted Procedure Resolutions Nos 22 and 23 adopted at the 88th General Session</p>
<p>Related processes</p>	<p>Official Status Recognition Process</p> <ul style="list-style-type: none"> - Procedure (Application_SOP) - Guidelines (Application_Guidelines) <p>Expert Mission Deployment</p> <ul style="list-style-type: none"> - Procedure (Mission_SOP) - Guidelines (Mission_Guidelines) <p>Reconfirmation of a Status or Programme</p> <ul style="list-style-type: none"> - Procedure (Reconfirmation_SOP) - Guidelines (Reconfirmation_Guidelines) <p>Suspension, Recovery and Withdrawal</p> <ul style="list-style-type: none"> - Procedure (Suspension_SOP) - Guidelines (Suspension_Guidelines)
<p>List of acronyms:</p>	<p>AHG: <i>Ad hoc</i> Group DDG: Deputy Director General, Standards and Science DG: Director General SD: Status Department SCAD: Scientific Commission for Animal Diseases <i>Terrestrial Code: Terrestrial Animal Health Code</i></p>

¹ For the purpose of clarity, this will be referred to as « Protection Zone Guidelines »

Step	Time Reference	Responsible person	Action	Reference Document
1.		Delegate	Submits an application to the OIE for the establishment of a protection zone within a country or zone having an officially recognised animal health status.	§ A.1 Protection Zone Guidelines
2.		SD	Screens dossier and: <ul style="list-style-type: none"> - If further information is necessary, see step 3; - If information is satisfactory, see step 4. 	
3.		SD	Contacts and requests the Delegate or Contact point to provide clarification or additional information within a set deadline.	
3.1	Within the set deadline	Delegate / Contact point	Provide the requested information.	
4.		SD	Forwards dossier to the President of the SCAD.	
5.		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.	
6.		SCAD	Examines dossier and: <ul style="list-style-type: none"> - If information is required, see step 7; - If not, see step 8. 	
7.		SD	Requests information to the Member Delegate or Contact point within a set deadline.	
7.1	Within the set deadline	Delegate/ Contact point	Provides requested information.	
7.2		SD	Shares information with SCAD.	
8.		SCAD	<ul style="list-style-type: none"> - If specific technical expertise is required to assess the dossier, see step 9; - If not, see step 10. 	
9.		SD	Requests recommendation from relevant expert(s).	
9.1		Expert(s)	Provide(s) recommendation on the dossier to SCAD.	
10.		SCAD	<ul style="list-style-type: none"> - If a mission/virtual interview is necessary, see Mission subprocess (Mission_SOP); - If not, concludes on the outcome of the establishment of a protection zone. Notifies SD of outcome.	
11.		SD	<ul style="list-style-type: none"> - If the evaluation outcome is positive, see step 12; - If the evaluation outcome is negative, see step 13. 	

12.		DG	Sends letter confirming the establishment of a protection zone for 24 months and reminding that the Member must apply within 24 months either for the removal of the protection zone or official recognition of the protection zone as a separate zone.	
12.1		Delegate	Receives notification of the establishment of a protection zone; see step 14.	
13.		DG	Sends letter notifying that the application for protection zone has not been endorsed, explaining the reason for the negative outcome of the evaluation.	
13.1		Delegate	Takes note of the negative outcome of the assessment.	
13.2		Delegate	If the Member wishes to reapply for the establishment of a protection zone, see step 1.	
14.		SD	Updates map and publishes a web statement on the OIE website.	
15.	Within 24 months from the date of approval of the protection zone	Delegate	<ul style="list-style-type: none"> - If an outbreak occurs in the protection zone after the approval, refer to Suspension_SOP; - If the Member wishes to remove/lift the protection zone, sends a letter to the OIE; - If the Member wishes to maintain the protection zone, apply for its recognition as a separate zone; see Application_SOP. 	<p>§ B.1 Suspension Guidelines</p> <p>§ A Application Guidelines</p>
16.		SD	Updates map and publishes a web statement on the OIE website.	

Protection Zone_Guidelines

Guidelines on the establishment of a protection zone in a country or zone having an officially recognised animal health status

A. Application for a protection zone

1. Scope of application

Further to an increased risk of disease, a Member wishing to establish a protection zone to preserve the animal health status of an animal population in a free country or a free zone has to submit an application to the OIE in accordance with Chapter 4.4. and relevant disease-specific chapters of the *Terrestrial Code* (more information in Annex 2).

2. Application and evaluation process

2.1 APPLICATION CONTENT

A Member wishing to establish a protection zone 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 Article 4.4.6. and the relevant article of the disease-specific chapter of the *Terrestrial Code*.
- The **contact details** (name, phone 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.

2.2 APPLICATION FORMAT

Applications must be limited to a core document of no more than 20 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). In case this is not possible, the dossier may be supplied in hardcopy.

3. Evaluation of the application

The Scientific Commission has been given the mandate to proceed with the recognition of a protection zone without further consultation of the Assembly, in accordance with Resolution No. 22 of the 88th General Session.

3.1 EVALUATION BY THE STATUS DEPARTMENT

Following the same process as for 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).

3.2 EVALUATION BY THE SCIENTIFIC COMMISSION

The President of the Scientific Commission decides on the process to follow in undertaking the evaluation of the 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. These may take place either by correspondence or at a meeting depending on the calendar of the meetings.

The process of evaluation may also involve an expert mission to/virtual interview with the concerned Member (cf. Mission_SOP).

4. 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 protection 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 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 protection 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.

5. Removal or official recognition of the protection zone

A protection zone may be maintained up to 24 months from the date of its approval by the OIE, and the Member should either apply for the removal of the protection zone or for its official recognition as a separate free zone within 24 months from the date of its approval by the OIE.

When the Member wishes to remove or lift the protection zone, the Delegate has to send a letter to the OIE informing of this decision.

If the Member wishes to maintain the protection zone as a permanent separate zone, the Delegate has to submit an application to the OIE following the procedure for application for official recognition of animal health status (cf. Application_SOP).

If the animal health status of an established protection zone changes due to the occurrence of a case, or vaccination, the Delegate should submit as soon as possible an application in accordance with Article 4.4.7. and relevant disease-specific chapters of the *Terrestrial Code* (cf. Suspension_SOP).

For example, if vaccination is implemented in a protection zone that has been established within a country or zone having an officially recognised 'FMD-free where vaccination is not practised' status, the free status cannot be maintained in the protection zone according to Article 8.8.2. 'FMD free country or zone where vaccination is not practised' of the *Terrestrial Code*. Thus, the official status of the protection zone would be suspended.

B. Financial obligations

In accordance with Resolution No. 23 of the of the 88th General Session, fees are not requested for the establishment of a protection zone. However, in the case of applying for official recognition of the protection zone as a separate free zone, reduced fees will be applied, as presented in Annex 1.

ANNEX 1

Financial obligations related to the establishment of a protection zone within a country or zone having an officially recognised animal health status (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>Establishment/lift of a protection 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>Application for the official recognition of the protection zone as a separate free zone</i>	4,500	3,500	2,500	N/A	2,250	1,750	1,250	N/A
<i>Application for the establishment of a containment zone following an occurrence of a case or other factors (e.g., vaccination) contributing to change of animal health status of the established protection zone</i>	free of charge	free of charge	free of charge	N/A	free of charge	free of charge	free of charge	N/A

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

N/A: not applicable

ANNEX 2

Implementation of Protection Zone (PZ) and transition to Containment Zone (CTZ)

