

STANDARD OPERATING PROCEDURE FOR LISTING DECISIONS FOR PATHOGENIC AGENTS OF TERRESTRIAL ANIMALS

The OIE has developed this Standard Operating Procedure (SOP) for the decision to add (or remove) pathogenic agents of terrestrial animals to (or from) the OIE List and to define the roles and responsibilities of Specialist Commissions, subject-matter experts, OIE Headquarters, and Members Countries in this process.

Standard Operating Procedure

Scope:	<p>This procedure describes the process to be followed for assessing a pathogenic agent of terrestrial animals against the criteria in Chapter 1.2. of the <i>Terrestrial Code</i> for decisions regarding inclusion in the OIE List in Chapter 1.3.</p> <p>The procedure has three steps:</p> <ol style="list-style-type: none"> 1: Request for a listing decision; 2: Decision to initiate the process of assessment of a pathogenic agent; 3: Assessment of a pathogenic agent against the criteria for inclusion in the OIE List <u>by</u>: <ol style="list-style-type: none"> 3.1 SCAD or 3.2 subject matter experts via an electronic consultation or 3.3 an ad hoc Group (physical meeting)
Related documents:	<ol style="list-style-type: none"> 1. Template for requesting a listing decision. (Word – PDF) 2. Guidance to the application of the criteria for listing terrestrial animal diseases (Guidelines) 3. Assessment template. 4. Template for reporting assessment results (Summary template). 5. Email template for expert consultation. 6. Chapter 1.2. of the Terrestrial Code. 7. OIE internal procedures for the establishment and management of an <i>ad hoc</i> Group.
List of acronyms:	<p><i>Terrestrial Code: Terrestrial Animal Health Code</i></p> <p>SCAD: Scientific Commission for Animal Diseases TAHSC: Terrestrial Animal Health Standard Commission BSC: Biological Standard Commission DDG: Deputy Director General “International Standards and Science” HQ: Headquarters</p>

1 – REQUEST FOR A LISTING DECISION

Step	Time Reference	Responsible person/entity	Action	Reference Document
1-1.a		Delegate(s), International organisations ¹ , OIE Reference Centres	Sends a request to OIE to assess a pathogenic agent against the criteria for inclusion (or removal) in the OIE List. See 2.1.	Template for requesting a listing decision (Word – PDF)
1-1.b		BSC, SCAD, TAHSC, OIE HQ, OIE Working Groups	Identifies the need for assessing a pathogenic agent against the criteria for inclusion in the OIE List and forwards the request to SCAD Secretariat. See 2.1.	

2 – DECISION TO INITIATE THE PROCESS OF ASSESSMENT OF A PATHOGENIC AGENT

Step	Time Reference	Responsible	Action	Reference Document
2-1		SCAD Secretariat	Acknowledges receipt of the request and presents the request to the DDG.	
2-2		DDG	Taking into consideration Article 1.2.1. of the <i>Terrestrial Code</i> and after consultation with the relevant Specialist Commissions, the DDG decides if the request should be considered. <ul style="list-style-type: none"> - If yes, see 2-3; - If not, see 2-4. 	Guidelines
2-3		DDG	<ul style="list-style-type: none"> i. Sends a letter to the requester noting that the request for an assessment will be considered by the SCAD; and ii. Informs the SCAD, TAHSC and BSC. See 3.1.	
2-4		DDG	<ul style="list-style-type: none"> i. Provides the requester with the rationale for not proceeding with an assessment; and ii. Informs the SCAD, TAHSC and BSC. 	

3.1 – ASSESSMENT OF A PATHOGENIC AGENT AGAINST CRITERIA FOR THE INCLUSION IN THE OIE LIST - PERFORMED BY SCAD

Step	Time Reference	Responsible person/entity	Action	Reference Document
3.1-1	Prior to the SCAD meeting	SCAD Secretariat	Provides the request to SCAD.	
3.1-2	During SCAD meeting	SCAD	Considers the request and agrees to either: <ul style="list-style-type: none"> i. Undertake the assessment (see 3.1-3); or ii. Refer the assessment to subject matter experts via an electronic consultation (see 3.2); or iii. Refer the assessment to an <i>ad hoc</i> Group (see 3.3). 	

¹ International Organisations with whom the OIE has a cooperation agreement

3.1-3	During SCAD meeting	SCAD	Undertakes the assessment; and consults other relevant sources of expertise such as the TAHSC, the BSC, and the Wildlife Working Group, if relevant.	
3.1-4	After SCAD meeting	SCAD	The assessment, including its conclusions, is forwarded to TAHSC and appended to the SCAD report.	Assessment template
3.1-5		TAHSC & SCAD	If the conclusion is to amend Chapter 1.3., the usual process to revise a <i>Code</i> chapter is followed.	

**3.2 – ASSESSMENT OF A PATHOGENIC AGENT AGAINST CRITERIA FOR THE INCLUSION IN THE OIE LIST
- PERFORMED BY SUBJECT MATTER EXPERTS V/A ELECTRONIC CONSULTATION**

Step	Time Reference	Responsible person/ entity	Action	Reference Document
3.2-1	After SCAD meeting	SCAD Secretariat	Presents the DDG a list of 3-6 experts, selected following the procedure used to identify <i>ad hoc</i> Group members	AHG SOP
3.2-2		SCAD Secretariat	Contacts the identified experts. A minimum of 3 experts would be required for the electronic consultation.	Email template
3.2-3		SCAD Secretariat	Provides experts with the guidance document and an assessment template	Guidelines Assessment template
3.2-4	Within 3 weeks after request is sent	Individual experts	Individual experts conduct an assessment against each of the criteria in Article 1.2.2. and send it to SCAD Secretariat (without sharing the assessment with the other experts).	Guidelines
3.2-5		SCAD Secretariat	Collates individual assessments into a single document	Summary template
3.2-6	Before the next SCAD meeting	SCAD Secretariat	Provides the expert consultation report to the BSC for its opinion regarding the assessment of criterion 3 of Article 1.2.2.	
3.2-7		SCAD Secretariat	Provides the expert consultation report and the BSC opinion to the SCAD.	
3.2-8	During SCAD meeting	SCAD	Discusses the expert consultation report and: <ul style="list-style-type: none"> i. Reaches a conclusion on the assessment, or ii. Requests clarification on some aspects of the assessment. (see 3.3-6) 	
3.2-9	After SCAD meeting	SCAD Secretariat	Once a conclusion is reached, forwards the assessment, including its conclusion, to the TAHSC and appends the assessment to the SCAD report.	
3.2-10		TAHSC & SCAD	If the conclusion is to amend Chapter 1.3., the usual process to revise a <i>Terrestrial Code</i> chapter is followed.	

**3.3 – ASSESSMENT OF A PATHOGENIC AGENT AGAINST CRITERIA FOR THE INCLUSION IN THE OIE LIST
- PERFORMED BY AN *AD HOC* GROUP**

Step	Time Reference	Responsible person/ entity	Action	Reference Document
3.3-1	After SCAD meeting	SCAD Secretariat	Requests that the assessment be undertaken by an <i>ad hoc</i> Group.	
3.3-2		SCAD Secretariat	Follows the procedure for convening an <i>ad hoc</i> Group (physical or electronic).	AHG SOP
3.3-3		SCAD Secretariat	Provides <i>ad hoc</i> Group members with the guidance document and an assessment template	Guidelines Assessment template)
3.3-4	Prior to the <i>ad hoc</i> Group meeting	<i>Ad hoc</i> Group	Individual <i>ad hoc</i> Group members conduct an assessment against each of the criteria in Article 1.2.2. and send it to SCAD Secretariat.	Guidelines
3.3-5	Prior to the <i>ad hoc</i> Group meeting	SCAD Secretariat	Collates individual assessments into a single document	Summary template
3.3-6	During the <i>ad hoc</i> Group meeting	<i>Ad hoc</i> Group	Discusses the individual assessments, agrees on a common position for each criterion and for the overall assessment, which are all documented in the <i>ad hoc</i> Group report.	
3.3-7	Before the next SCAD meeting	SCAD Secretariat	Provides the <i>ad hoc</i> Group report to the BSC for its opinion regarding the assessment of criterion 3 of Article 1.2.2.	
3.3-8		SCAD Secretariat	Provides the <i>ad hoc</i> Group report and the BSC opinion to the SCAD.	
3.3-9	During SCAD meeting	SCAD	Discusses the <i>ad hoc</i> Group report and: iii. Reaches a conclusion on the assessment, or iv. Requests clarification on some aspects of the assessment. (see 3.3-6)	
3.3-10	After SCAD meeting	SCAD Secretariat	Once a conclusion is reached, forwards the assessment, including its conclusion, to TAHSC and appends the <i>ad hoc</i> Group report to the SCAD report.	
3.3-11		TAHSC & SCAD	If the conclusion is to amend Chapter 1.3., the usual process to revise a <i>Terrestrial Code</i> chapter is followed.	