Organisation Mondiale de la Santé Animale | World Organisation for Animal Health | Organización Mundial de Sanidad Animal

Application_SOP

Standard Operating Procedure for official recognition of disease status and for the endorsement of national official control programmes of Member Countries

Description/ Scope: This procedure describes the process for the preparation, assessment and approval of dossiers for the official recognition of disease status and for the endorsement of national official control programmes of Member Countries.

Related documents:
Guidelines for the Official Status Recognition Process[1] (Annexed)
Resolution No. 15 adopted at the 83rd General Session
Resolution No. 16 adopted at the 83rd General Session

Related processes:
Expert Mission Deployment
- Procedure (Mission_SOP)
- Guidelines (Mission_Guidelines)

Reconfirmation of a Status or Programme
- Procedure (Reconfirmation_SOP)
- Guidelines (Reconfirmation_Guidelines)

Suspension, Recovery and Withdrawal
- Procedure (Suspension_SOP)
- Guidelines (Suspension_Guidelines)

List of acronyms:
AHG: *ad hoc* Group
Assembly: World Assembly of Delegates
DDG: Deputy Director General, Standards and Science
DG: Director General
DSD: Disease Status Department
GS : General Session
SCAD: Scientific Commission for Animal Diseases
Terrestrial Code: Terrestrial Animal Health Code

Step	Time Reference	Responsible person	Action	Reference Document
1.	After the GS	DG	Sends letter to Delegates confirming SCAD and AHGs dates and deadlines for dossiers submission.	
2.	2 months before the relevant AHG	Delegate	Sends dossier to OIE.	§ A Application_ Guidelines
3.	Less than 7 days after reception	DSD	Sends email acknowledging reception to Delegate.	
4.	7 days after sending the dossier	Delegate	If no acknowledgement email has been received, sends letter to OIE requesting acknowledgement.	§ B Application_ Guidelines
5.		DSD	Checks deadline compliance and: - If dossier was sent less than 2 months before the relevant AHG, see step 6; - If dossier was sent respecting the 2 months deadline, see step 7.	

[1] For the purpose of clarity, this will be referred to as « Application Guidelines »

6.		DG	Sends letter notifying Delegate that the dossier will be assessed at the following year's AHG meeting and that an updated dossier should be provided **(end of procedure)**. See step 1 for updated dossier.	
7.		DSD	Checks budgetary compliance and: - If dossier is not compliant with fee payment, see step 8; - If dossier is compliant with fee payment, see step 9.	
8.		DG	Sends letter notifying Delegate that the dossier will be assessed at the following year's AHG if proof of payment is provided with the updated dossier **(end of procedure)**. See step 1 for updated dossier.	
9.		DSD	Sends documents provided in French or Spanish for translation in English.	
10.		DSD	Checks administrative and technical compliance, and: - If dossier is not fully compliant with the questionnaires and/or the SOPs and information is missing, see step 11; - If dossier is fully compliant with the questionnaires and the SOPs, see step 12.	
11.	Within 3 weeks of reception	DG	Sends letter to the Delegate,: - Confirming the dates of the meetings of the AHG and of SCAD where the dossier will be evaluated; - Requesting the necessary additional information within a specific deadline.	
11.1	Within the allocated time	Delegate	Provides the OIE with the necessary information and/or amended dossier.	§ B.1 Application_ Guidelines
12.	Within 3 weeks of reception	DG	Sends letter to the Delegate acknowledging receipt of the dossier and confirming that it will be presented to the AHG and specifies the dates of the AHG and Scientific Commission meetings during which the dossier will be assessed.	
13.		Delegate	- If they wish to send a representative for the meeting of the SCAD (February of the following year), see step 14; - If they do not wish to send a representative, see step 15.	
14.	By 31 December	Delegate	Sends letter to the DG requesting participation of a representative.	§ D.3 Application_ Guidelines
14.1		DSD	Provides SCAD with requests received for representation of the applicant country at the meeting.	
14.2		DG / SCAD	Reviews request and : - If request is not accepted, see step 14.3; - If request is accepted, see step 14.4.	
14.3		DG	Sends letter to Delegate denying their request with justification, see step 15.	
14.4		DG	Sends letter to Delegate confirming the possibility to meet with the SCAD and requesting the contact detail of the relevant technical delegation.	
14.5		Delegate	Sends contact detail of technical delegation.	

14.6		DG	When relevant, sends official invitation letter to the technical delegation.	
14.7		DSD/ Technical delegation	Finalise the appointment.	
15.	60 - 30 days before the AHG	DSD	Compiles comprehensive working document per country, including country dossiers and supporting information and prepares the relevant AHG meeting.	§ C. Application_ Guidelines.
16.		DSD	- If the *ad hoc* Group member has not provided the confidentiality agreement and declaration of interest, see step 17; - If the *ad hoc* Group member has provided the confidentiality agreement and declaration of interest, see step 18.	
17.		DSD	Requests confidentiality agreement and/or declaration of interest.	
17.1		AHG member	Fills out, signs and sends confidentiality agreement and/or declaration of interest.	
17.2		DSD	Analyses potential conflicts of interest and stores confidentiality agreement and declaration of interest.	
18.	30 days before the AHG meeting	DSD	Sends working documents, Terms of Reference and agenda to the AHG.	
19.		AHG	Receives and reviews working documents, and: - If complementary information is required, see step 20; - If not, see step 21.	
20.	7 days before the AHG meeting	AHG	Prepares a list of questions for the Member Country, to address lacking information in the dossier. Sends the list of questions to the DSD.	
20.1		DSD	Screens the questions to ensure they comply with *Terrestrial Code* requirements. Sends the questions to the relevant Delegate or contact point (appointed by the Delegate) with a specific deadline.	
20.2	Before the indicated deadline	Delegate/Contact point	Compiles the complementary information requested and sends it to the DSD. Sends information to the DSD.	§ C.4 Application_ Guidelines
20.3		DSD	Forwards information to the AHG.	
21.	AHG meeting	AHG	Meets and reviews dossiers collectively based on *Terrestrial Code* requirements.	
22.		AHG	- If complementary information is required, drafts the questions and see step 23; - If not, see step 24.	
23.		DSD	Sends questions to the Member Country contact point with a clear deadline.	
23.1	Within the allocated time frame	Contact point	Provides requested information.	§ C.4 Application_ Guidelines
24.		AHG	Reaches decision and provides either a positive or negative outcome for each dossier, with possible recommendation of an in-country mission.	

25.		AHG / DSD	Draft full report of the AHG's discussions and recommendations.	
26.		DDG	Reviews and endorses the report. Transmits the report to the DG for information highlighting potential sensitive issues.	
27.		SCAD Secretariat / DSD	Forwards AHG report to the SCAD.	
28.	SCAD February meeting	SCAD	Meets and assesses the applications, reviews the report of the AHG on the detailed evaluation of each dossier, and considers the feedback of the SCAD representative who attended the AHG meeting; and: - If complementary information is required, see step 29; - If not, see step 30.	
29.		DSD	According to the necessary information, contacts the Member Country contact point and/or the relevant *ad hoc* Group.	
29.1	Within the allocated time frame	Contact point and/or *ad hoc* Group	Provides requested information.	§ D.3 of Application_ Guidelines
30.		SCAD	- If mission is requested to reach an informed position, see mission sub procedure (Mission_SOP); - If no mission is requested, see step 31.	
31.		SCAD	Decides on the outcome of the assessment of each Member Country request.	
32.		SCAD Secretariat/ DSD	Prepares draft SCAD full report and forwards it to the DDG.	
33.		DDG	Reviews the report and for each dossier: - If the evaluation outcome is negative, see step 34; - If the evaluation outcome is positive, see step 35; - If a mission is pending prior to the final decision, see step 36. Forwards the report to the DG for information.	
34.		DG	Sends detailed report and letter to the Delegate of the applicant Member Country explaining the reason for the negative outcome of the evaluation and the detailed report of the assessment.	
34.1		DSD	Does not include the Member Country in the list of countries/ zones that will be proposed by SCAD to the Assembly for official status recognitions and endorsement of their national programmes..	
34.2		SCAD Secretariat	Uploads amended AHG and SCAD reports (without mention of the countries with non-successful applications) on the OIE website.	
34.3		Delegate	Takes note of refusal and information gaps to be addressed in a future application; see step 36.	§ E Application_ Guidelines
35.		DG	Sends letter to the Delegate of the applicant Member Country indicating the positive outcome of the evaluation, with possible recommendations.	

35.1		DSD	Includes the applicant Member Country in the list of countries/zones that will be proposed by SCAD to the Assembly for official status recognitions and endorsement of their national programmes.	
35.2		Delegate	Takes note of recommendations. Awaits the list of countries/zones that will be proposed for official status recognition or endorsement of their national official programmes.	§ E Application_ Guidelines
36.	60 days before the GS	DG	Sends the letter to all Delegates with two lists detailing i) the countries/zones that will be proposed by SCAD for official status recognitions and endorsement of their national programmes, and ii) the countries/zones whose already recognised official status /endorsed programme will be proposed for maintenance. When a mission is pending prior to the final decision: - If the Member Country wishes to keep its application confidential, it is not included in this year's list; - If the Member Country agrees to appear temporarily pending the mission's outcome, it is included in this year's list. When a mission is pending and programmed after the GS, the Member Country is not included in this year's list.	
37.		Member Country	Receives the lists and: - If a Member Country has further questions about the lists, see step 38; - If not, see step 39.	§ E.2 Application_ Guidelines
38.		Requesting Member Country	Sends request for information directly to the concerned Member Country.	
38.1	10 days after receiving request for information	Interrogated Member Country	Responds directly to requesting Member Country.	
39.		Member Country	- If a Member Country has comments about the list, see step 40; - If not, see step 41.	
40.		Member Country	Provides potential comments to the DG.	
40.1		DG	Forwards comments to SCAD president.	
40.2		DSD / SCAD president	Compile and further explore comments.	
41.		OIE HQ	Prepares Draft Resolutions.	
42.	Before the May meeting Council	OIE HQ	Prepares Certificates for newly recognised status or newly endorsed official control programmes.	
43.	May meeting of the Council	President of the OIE	Reviews and signs the Certificates.	
44.	At the GS	Assembly	Discusses and votes Resolutions.	§ E.3 Application_ Guidelines
45.	At the GS	DG / OIE President	Give the certificates to the relevant Member Countries.	

46.	Within 10 days after the GS	DSD	Updates on-line maps and lists.

Application_Guidelines

Guidelines for official recognition of disease status and for the endorsement of national official control programmes of Member Countries

A. Application by Member Countries

1. Application structure

1.1 CONTENT

Each dossier should contain:

- A **letter signed** by the OIE Delegate requesting the evaluation of the dossier.
- A **one-page executive summary** stating clearly :
    - What the Member Country is applying for :
        - official status recognition or endorsement of a national official control programme;
        - in the case of an official status recognition:
            - whether the dossier relates to the whole country or to one or more zones;
            - for which status it is applying:
                - i.e. in the case of BSE risk status, a Member Country without a recognised risk status should indicate whether it is applying for "negligible risk" or "controlled risk" categories of for both risk categories (in this case, the OIE evaluates the dossier for both);
                - i.e. in the case of FMD free status, a Member Country should indicate whether it is applying for recognition of a "free status without vaccination" or a "free status with vaccination";
        - the territory included in the application (with specific indication regarding the possible non-contiguous territories);
    - How it has addressed the various requirements set out in the *Terrestrial Animal Health Code (Terrestrial Code*);
    - What information is provided in the dossier.
- A **core document**, with possible relevant **appendices**, based on the model of the relevant questionnaire for that particular disease or control programme published in Chapter 1.6. of the *Terrestrial Code*:
    - If the applicant Member Country wishes to receive official recognition for a specific disease status based on historical freedom, the application should also detail how the requirements of Article 1.4.6. point 1. a) of the *Terrestrial Code* are met;
    - When a Member Country applies for zoning, geo-referenced maps must be submitted and must correspond to the zones as designated by the Delegate at the time of submission of the dossier;
    - Relevant appendices may be attached to the core document where they should be clearly cross-referenced.
- 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 before or during the meeting of the relevant *ad hoc* Group or during the meeting of the Scientific Commission for Animal Diseases (hereafter Scientific Commission) could be referred to the Member Country without delay.
- A **proof of payment of application fees** (see 2. Financial obligations).

A checklist for applications is available in Annex 1 of these Guidelines.

1.2 SIZE

Any dossier – whether for official recognition of disease status or for the endorsement of national official control programmes - 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.

1.3 LANGUAGE

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).

1.4 FILE COMPATIBILITY

The maps should be provided using the shapefile format and be compatible with the mapping software (ArcGIS™) currently used by the OIE. Used projection system should be indicated.

1.5 TRANSMISSION FORMAT

The dossier must be supplied in electronic format to the Director General of the OIE (as email file attachments using the following email address: disease.status@oie.int or in CD-ROM).

1.6 DEADLINE FOR SUBMISSION

Dossiers must be sent 2 months before the date of the meeting of the relevant *ad hoc* Group that will review the dossier. Dates are available on the OIE Delegate website and provided in a letter from the OIE Director General in June each year.

2. Financial obligations

2.1 FEE AMOUNTS

In accordance with Resolution No. 16 adopted at the 83rd General Session, financial obligations are as follows (in Euros):

	OIE Member Countries (*except least developed countries*)			**Least developed countries (Members) based on the current official UN list**		
	AHS, CSF and BSE	**CBPP/FMD**	**PPR**	**AHS, CSF and BSE**	**CBPP/FMD**	**PPR**
First time application[1]						
Entire country	9,000	7,000	5,000	4,500	3,500	2,500
One or more zone(s) at the same time	9,000	7,000	5,000	4,500	3,500	2,500
Endorsement of a national official control programme	N/A	2,000	2,000	N/A	1,000	1,000
Additional applications for the same disease/programme						
New additional zone(s)	4,500	3,500	2,500	2,250	1,750	1,250
Change in category (same disease[2]*)*	4,500	3,500	2,500	2,250	1,750	1,250
Re-application for status (if the previous application was rejected)	4,500	3,500	2,500	2,250	1,750	1,250
Endorsement of national official control programme (if the previous application was rejected)	N/A	500	500	N/A	250	250

NB: The costs of possible country missions are not included in the above amounts. *N/A: not applicable*

1. For official recognition of disease status (including historical freedom) or for endorsement of national official control programme

2. E.g. BSE - from "controlled risk" to "negligible risk" status
FMD - from "FMD free where vaccination is practiced" to "FMD free where vaccination is not practiced"

Resolution No. 16 adopted at the 83rd General Session confirms that Member Countries that are included at the moment of their application in the list of the Least Developed Countries published by the United Nations, will only acquit 50% of the amount due by the other countries.

2.2 BANK ORDER

The OIE bank account details are available on request, as well as attached to the letter mentioned in Step 1. of this procedure.

The bank order should clearly indicate the name of the applicant country, the disease for which status or endorsement of a national official control programme is requested (e.g. "[COUNTRY] - [disease status/programme]").

2.3 REIMBURSEMENT

Once an assessment of the dossier has started, application fees cannot be reimbursed under any circumstances.

B. Pre-screening by the Disease Status Department

1. Procedure for pre-screening by the Disease Status Department

Upon receipt of the dossier:

- The OIE Headquarters (Disease Status Department) acknowledges within one week receipt to the Delegate of the applicant Member Country. Applicant Member Countries that have not received any acknowledgement of receipt within one week should verify with the OIE if the dossier has been received.
- The OIE Headquarters (Disease Status Department) conducts a preliminary screening of the dossier, both administrative (cf. criteria presented in Annex 2.a) and technical (cf. relevant *Terrestrial Code* chapters in Annex 2.b*)*. If an information gap is identified, the OIE Headquarters may need the submission of an amended dossier or additional information to complete the dossier to be provided to the experts. Delegates will receive acknowledgment of receipt for all complementary information provided.
- The OIE DG sends aletter, confirming the meeting dates of the relevant *ad hoc* Groups and the Scientific Commission at which the dossier is likely to be evaluated and, when relevant, requesting the submission, before a set deadline, of an amended dossier or additional information as identified by the Disease Status Department.
- Applicant Member Countries should provide the amended dossier or additional information within the allocated time frame.

2. Additional information analysed by the Disease Status Department

Complementary information is systematically considered, such as the information available in WAHIS (last occurrence of the disease, control or preventive measures implemented…), as well as national Performance of Veterinary Services (PVS) Evaluation, Evaluation Follow-up and Gap Analysis Reports (hereafter PVS reports).

The consideration of PVS reports is based on the identification and prioritisation of relevant OIE PVS tool critical competencies (hereafter CCs). Relevant information on each identified CC is collected from available PVS reports and analysed in parallel with the status application and may lead to requests for clarification to the Member Country.

However, not all PVS reports are considered:

- All reports older than 5 years are considered out-dated and therefore excluded from the evaluation.
- The use of confidential reports is contingent on the approval of the applicant Member Countries, to whom the request is made. The OIE PVS reports for which the Member Country has not agreed to their release are not considered.

In case of information gaps, requests for information or clarification are added to the official letter sent by the OIE DG confirming the meeting dates of the relevant *ad hoc* Groups and the Scientific Commission at which the dossier is likely to be evaluated (see section B.1.).

C. Evaluation by the Ad Hoc Group

The following guidelines are applicable to each *ad hoc* Group constituted for the official recognition of the disease status, BSE risk status and endorsement of national official control programmes, hereinafter *ad hoc* Groups.

1. Purpose and scope

Ad hoc Groups for official recognition of disease status or endorsement of national official control programmes are convened at the initiative of the OIE DG to support the work of the Scientific Commission. They are tasked with assessing the dossiers submitted by Member Countries willing to be recognised as having an official disease status or to have its official control programme endorsed by the OIE.

The general Terms of Reference and internal rules for *ad hoc* Groups are described in the OIE Basic texts, but the DG has the mandate to define through the Terms of Reference the purpose, duration and means of execution of the mission of the Group and to select appropriate experts. The DG informs all Delegates of the composition of the *ad hoc* Groups.

The DG is responsible for making available to the Group all the necessary facilities, including translations and documentation required for producing reports of its meetings. The Group reports to the DG, who transmits the report to the Scientific Commission.

2. Selection of the experts of the Ad Hoc Group

2.1 COMPOSITION OF THE *AD HOC* GROUP

Each *ad hoc* Group shall include a chairperson, a rapporteur and at least two additional members – in practise at least five experts will be invited to ensure that the *ad hoc* Group can be conducted in case of a last minute cancellation. Based on their expertise in the relevant disease and their availability, a representative of the Scientific Commission generally attends the meeting of the *ad hoc* Group.

2.2 QUALIFICATIONS OF THE MEMBERS

Experts are selected on the basis of an assessment taking into consideration specific criteria including, but not limited to,

- national or international expertise in the relevant disease;
- holistic understanding of the health-disease process, animal diseases control and international trade in animals and their products/by-products;
- deep understanding of the OIE principles and standards;
- ability to work in English (working language of *ad hoc* Groups);
- understanding/awareness of the provisions of the *Terrestrial Code* as well as other relevant OIE standards;
- availability and willingness to spend time prior to the meeting on the evaluation of the dossiers (important preparation work for the status recognition) and after the meeting to finalise the assessment of the dossiers and the report, where needed;
- ability to interact within a group, respect other opinions and determine a common approach;
- contribution at previous *ad hoc* Group meeting(s) (preparedness, ability and willingness to express opinion, to interact with other experts, listening skills).

The composition of the *ad hoc* Group will also take into consideration criteria such as:

- diversity and balanced combination of different areas of expertise (laboratory, field, epidemiology, policy) within an *ad hoc* Group;
- geographical balance, as much as possible;
- gender balance whenever possible;
- working knowledge/understanding of French or Spanish can be an asset.

2.3 POOL OF SPECIALISTS

The experts for the official recognition of disease status are selected from three different pools of specialists:

- experts of OIE Reference Centres, and in particular of the OIE Reference Laboratories for the concerned disease;
- the candidates for the election for the Specialist Commissions that were pre-selected by the OIE Evaluation Committee but not elected by the World Assembly of Delegates;
- other experts that have the above mentioned qualifications for official status recognition.

In addition, the Disease Status Department will consider suggestions to feed this pool received from:

- members of the Scientific Commission and other Specialist Commissions;
- experts (of the OIE Reference Centres, of the concerned *ad hoc* Group, of another *ad hoc* Group, any other OIE expert);
- OIE Staff (HQ, Regional and Sub-Regional Representations), identified during missions/conferences/workshops/meetings;
- previous members of Specialist Commissions;
- Delegates (either following OIE request, or directly suggested by the Delegate);
- experts from other international or regional organisations with which the OIE may or may not have cooperative agreements.

The *ad hoc* Group composition is reconsidered every year based on the internal OIE HQ evaluation of the performance of the *ad hoc* Group and each member in the previous year(s), as well as on the expert's willingness and availability for participating in future *ad hoc* Groups. Despite no formal limitation of the numbers of mandate (cf. *ad hoc* Group Terms of Reference and Internal Rules), the relevance of recurring participation will be taken into consideration.

2.4 INFORMAL CONTACT

The Status Department contacts the experts recently proposed to ascertain their interest and availability to participate in the *ad hoc* Group meeting, as well as to request their Curriculum Vitae (CV) and the relevant scientific publications reflecting his/her expertise in the area.

After assessment of the CV against the above-mentioned criteria, the Status Department informs the experts on the decision taken include them or not in the pool of OIE specialists.

2.5 LIST OF EXPERTS SUBMITTED FOR APPROVAL OF THE DG

Following this informal verification of interest and availability, and before each cycle, the Status Department proposes to the DG a list of experts for consideration, including information such as their countries/regions of origin, their areas of expertise, their experiences in OIE *ad hoc* Groups, and whether they belong to OIE Reference Centres.

The list for approval of the Director General includes alternative experts who may be convened in case of unavailability of an expert initially invited. Experts are selected early on, ideally before the General Session, and no later than mid-June.

2.6 FINALISATION OF THE GROUP

The Status Department is responsible for issuing invitations to selected experts for signature by the Deputy Director General. Invitations are sent with a copy to the Regional/Sub-Regional Representations and to the OIE Delegate for the country of origin of the expert.

To effectively take part in the work of an *ad hoc* Group, selected members are requested to comply with OIE requirements and procedures on confidentiality and on the management of conflicts of interest. To this end, each member of an *ad hoc* Group must fill in, sign and send back to the Disease Status Department a statement covering potential conflicts of interest and confidentiality undertaking prior to being sent any working documents. The confidentiality agreement is valid for the entire breadth of activities in which the expert participates, both in terms of variety and time.

For future reference, the list of experts presented to the DG, the CV of expert(s) proposed for the first time, the terms of reference of the Group and the official invitations are electronically archived.

2.7 EVALUATION OF EXPERTS

After each *ad hoc* Group meeting, the Status Department assesses the performance of the participating experts to determine whether they should be invited again in another meeting (cf. Criteria above). This assessment may also take into consideration the opinion of the SCAD on the quality of the evaluation of the dossiers.

3. Process for the evaluation of dossiers

3.1 TYPE OF MEETING

Unless otherwise requested by the OIE Headquarters or the Scientific Commission, dossiers are discussed and evaluated by the relevant *ad hoc* Group:

- by electronic means (electronic correspondence or teleconference), when two or less dossiers have been sent for consideration by the *ad hoc* Group;
- in a physical meeting, when more than two dossiers have been sent for consideration by the *ad hoc* Group or when required by the complexity of the dossiers.

3.2 CONFIDENTIALITY AND CONFLICT OF INTEREST

Members of *ad hoc* Groups are required to respect the legitimate confidentiality of information with which they may be entrusted in the performance of their functions.

The Chairperson of each *ad hoc* Group and the OIE Secretariat ensure that any members with conflicting interests in relation to a particular dossier do not take part in the deliberation and decision-making. Any total or partial withdrawal of a member of the *ad hoc* Group from the evaluation of a dossier is duly recorded in the report of the meeting.

3.3 EVALUATION CRITERIA

Members of the *ad hoc* Group apply evaluation criteria strictly following the provisions of the Terrestrial Code as presented in Annex 2.b.

4. Interaction with the applicant Member Country

4.1 CONTACT POINT AVAILABILITY

During the evaluation of a submitted dossier, the *ad hoc* Group may determine that interaction with the applicant Member Country is necessary, for which the contact point should remain available on stand-by for telecommunication (phone, fax or email). Contact between Member Countries and the *ad hoc* Group is managed through the Disease Status Department.

4.2 INTERACTION FORMAT

As a more cost and time-effective means of consultation, exchanges will be made by email or teleconference.

- When requests for complementary information are made during the screening of dossiers prior to the *ad hoc* Group meeting, the applicant Member Country should provide written answers to the questions asked before the indicated deadline.
- When the request is made during the *ad hoc* Group meeting for immediate clarification, the applicant Member Country should respond within a 24h deadline.
- If it is not possible to meet the deadline, the applicant Member Country should indicate when the additional information requested would be submitted to the OIE Headquarters.

All correspondence that has taken place between an applicant Member Country and the OIE Headquarters is duly documented in the report by the OIE Headquarters.

5. Additional sources of information

5.1 USE OF PVS REPORTS

As the participants of the *ad hoc* Groups are bound by the OIE rules on confidentiality of information, relevant outcomes of the reports of national Performance of Veterinary Services (PVS) evaluation, evaluation follow up and Gap analysis (hereafter PVS reports) may be made available to the *ad hoc* Groups upon request during the meetings, following the process described in paragraph 2 of section B.

5.2 USE OF SANITARY INFORMATION REPORTS

Relevant reporting of sanitary information to the OIE is made available to the *ad hoc* Group, which will take into account in its evaluation of a dossier:

- The submission of sanitary information by the Member Country to the OIE, such as the regular submission of six-monthly and annual reports and the existence of immediate notifications;
- The information provided in these reports and whether they are compliant with the status request received (including information such as the date and location of the latest outbreaks or the control measures in place over the past years and their relevance to the situation).

5.3 OTHER INFORMATION

The participants of the *ad hoc* Groups may take into account any other information available in the public domain that is considered pertinent to the evaluation of dossiers, as described in paragraph 4.3 of section D.

6. Report of the Ad Hoc Group

After its meeting, the *ad hoc* Group produces a report, which contains its recommendations for the outcomes of the evaluation of dossiers from applicant Member Countries. Any minority opinion is recorded. The report is transmitted to the Scientific Commission before its meeting.

Amended *ad hoc* Group reports would be Annexed to the report of the Scientific Commission, where the identity of the Member Countries whose application has not been favourably recommended is kept confidential.

D. Evaluation by the Scientific Commission for Animal Diseases

1. Composition of the Scientific Commission

The OIE Scientific Commission is composed of six specialists in animal disease control elected by the Assembly every three years and bound by the OIE rules on confidentiality of information and management of conflict of interests. Their mandate is described in the OIE Basic Texts.

The process for the selection of the experts of the Scientific Commission is further detailed in the Procedure for Selection of Experts for Nomination for Election to the Specialist Commissions, available on the OIE website.

2. Process for the evaluation of dossiers

2.1 RELATIONS WITH *AD HOC* GROUPS

When conducting an evaluation of a Member Country's application, the Scientific Commission considers the reports of the *ad hoc* Groups, including their analysis of dossiers, as well as other findings and recommendations. However, the Scientific Commission is not bound by the views of *ad hoc* Groups and may elect to take decisions without consultation of an *ad hoc* Group.

To address questions that may arise from the Scientific Commission, the Chairpersons of relevant *ad hoc* Groups are requested to remain contactable by phone or by email during the meeting of the Scientific Commission.

2.2 EVALUATION CRITERIA

Members of the Scientific Commission apply evaluation criteria strictly following the provisions of the Terrestrial Code.

3. Interaction with the applicant Member Country

3.1 CONTACT POINT AVAILABILITY

Technical staff from the applicant Member Country involved in the preparation of the dossier whose contact details have been provided to the OIE Headquarters before the meeting must remain contactable by phone or by email during the meeting of the Scientific Commission.

3.2 INTERACTION FORMAT

As a more cost and time-effective means of consultation, exchanges by email or teleconference are given preference over face-to-face meetings.

However, if an applicant Member Country wishes to dispatch technical experts (no more than two) to meet with the Scientific Commission during its February meeting at the OIE Headquarters, they may do so at their own cost. Such visits should be requested to the OIE Headquarters as early as possible before the meeting of the Scientific Commission, and before 31 December at the latest. Upon receipt of such a request the Scientific Commission and its Secretariat will evaluate whether:

- the recommendations made by the ad hoc Group suggest that the information presented thus far will not allow for the Scientific Commission to reach a decision on the requested disease status or national official control programme;
- the Member Country has already applied in the past with negative outcome and remaining gaps in the current dossier were identified by the ad hoc Group;
- critical information mentioned in the application was pending finalisation at the time of the ad hoc Group meeting;
- in any of the above cases, it is reasonable to expect that additional information that could be presented by the experts would have a material bearing on the decision to be made by the Scientific Commission; and
- sufficient time would be available during the meeting to receive country experts.

3.3 TRACEABILITY OF COMMUNICATION

In accordance with the Basic Texts of the OIE, all formal correspondence between the Scientific Commission and outside individuals or bodies shall be issued through the OIE Headquarters. All correspondence that has taken place between an applicant Member Country and the OIE Headquarters is duly documented by the OIE Headquarters

4. Additional sources of information

4.1 USE OF PVS REPORTS

As the participants of the Scientific Commission are bound by the OIE rules on confidentiality of information, relevant outcomes of the OIE PVS reports may be made available to the Scientific Commission upon request during the meetings following the process described in paragraph 2 of section B.

4.2 USE OF SANITARY INFORMATION REPORTS

Relevant reporting of sanitary information to the OIE is made available to the Scientific Commission, which will take into account in its evaluation of a dossier:

- The submission of sanitary information by the Member Country to the OIE, such as the regular submission of six-monthly and annual reports and the existence of immediate notifications;
- The information provided in these reports and whether they are compliant with the status request received (including information such as the date and location of the latest outbreaks or the control measures in place over the past years and their relevance to the situation).

4.3 OTHER INFORMATION

The Scientific Commission may take into account any other information available in the public domain that is considered pertinent to the evaluation of dossiers.

The OIE expects the Member Country to take a full and transparent approach to disclosure of information that could have a bearing on the outcome of the evaluation. This includes information that may not be in the public domain arising from internal or external control processes, such as audit reports. Full and transparent disclosure of such information, supported by information on how any deficiencies or weaknesses are being or will be addressed, provides a stronger degree of assurance and confidence than non-disclosure.

5. Expert mission

In accordance with Resolution No. 15 adopted at the 83rd General Session and other relevant Resolutions previously adopted, the Scientific Commission may request the Director General to deploy an expert mission to an applicant Member Country to verify and complement the facts contained in its dossier before a decision or recommendation is made by the Scientific Commission on the application of the Member Country.

More information is available in the Standard Operating Procedure for the deployment of expert missions to Member Countries (Mission_SOP) and related Guidelines.

E. Official recognition and endorsement by the Assembly

1. Communication on the outcome of the evaluations

1.1 CONFIDENTIALITY ON REJECTED APPLICATIONS

The identity of the Member Countries whose application has not been accepted is kept confidential and not revealed in the report of the Scientific Commission.

1.2 COMMUNICATION TO APPLICANT MEMBER COUNTRIES

Each applicant Member Country whose dossier has been evaluated by the Scientific Commission receives a specific letter from the Director General of the OIE, informing the Member Country of:

- the outcome of the evaluation,
    - in the case of a positive outcome, reference is made to the *ad hoc* Group report Annexed to the Scientific Commission's report;
    - in the case of a negative outcome, the detailed assessment of the *ad hoc* Group is enclosed;
- as relevant, in particular in the case of a negative outcome, existing information gaps or specific areas that should be addressed in the future, based on the evaluations by the *ad hoc* Group and the Scientific Commission.

The letters from the Director General of the OIE are not released in the public domain.

1.3 COMMUNICATION TO OTHER MEMBER COUNTRIES

Prior to each General Session, the Director General of the OIE circulates, to all Delegates for comments within a 60-day period, a list of the Member Countries for which the Scientific Commission has recommended to recognise an official disease status or to endorse a national official control programme at the forthcoming General Session, in accordance with Resolution No. 15 adopted at the 83rd General Session, and other relevant Resolutions previously adopted.

The Disease Status Department also makes available amended reports (respecting the confidentiality of non-approved applications) of the *ad hoc* Groups and Scientific Commission on the OIE website.

2. Member Countries' comments on the outcome of the evaluations

During the 60-day commenting period, any Member Country may request clarification on an applicant Member Country's inclusion on the list by referring to the applicant Member Country concerned, which is requested to provide information to the Member Country soliciting information, with copy to the OIE Headquarters (disease.status@oie.int).

In making application for official recognition of a specific disease status or for the endorsement of a national official control programme, a Member Country is also committing to provide the whole or part of its dossier to another Member Country should it be requested during the 60-day comment period prior to the General Session. It is expected that the Member Country will comply with any request received for its dossier within maximum 10 days of receiving such a request.

Comments and concerns raised by Member Countries to the OIE are addressed by the Disease Status Department in consultation with the Scientific Commission and, where necessary, with the relevant *ad hoc* Group. They may be further clarified by the President of the Scientific Commission at the General Session.

3. Adoption of a Resolution by the Assembly

The Assembly, on the basis of the recommendations of the Scientific Commission and comments that might have been received from OIE Member Countries, officially recognises and approves by adoption of a relevant Resolution, the disease status, as well as the endorsement of national official control

programmes of Member Countries. The President of the Scientific Commission, when requested, provides additional clarification to any comments and concerns raised by Member Countries at the General Session. Any new official disease status and endorsed national official control programme recommended by the Scientific Commission comes into force after adoption of the Resolutions by the Assembly (usually the last day of the General Session).

OIE Member Countries with newly recognised official disease status or with newly endorsed national official control programme receive a certificate to that effect during the General Session.

The Disease Status Department updates, on its website, the Lists of Member Countries and zones having an officially recognised disease status or endorsed national official control programme as well as the relevant maps.

ANNEX 1

Official Status Recognition Application Dossier or for the endorsement of official control programme

Checklist

Dead-line to submit the application:	
Dossier following the template Questionnaire of Article 1.6. of the *Terrestrial Code*	☐
Dossier answering all questions under each section of the template Questionnaire of Article 1.6. of the *Terrestrial Code*	☐
Cover letter signed by the Delegate	☐
One-page executive summary	☐
Scope of the application clearly described (e.g. country, zone, historical freedom, category of BSE risk status) in the cover letter and executive summary	☐
Indications whether non-contiguous territories are included or not in the application in the cover letter, executive summary	☐
Information on the included non-contiguous territories in the dossier itself	☐
Core document's language: English or French or Spanish	☐
Core document : maximum 50 pages A4 format, single-spaced, Times New Roman 10pt (without the appendices)	☐
Appendices: in one of the OIE languages and adequately cross-referenced in the core document	☐
Contact person or staff details (name, phone/fax numbers and email address)	☐
Proof of payment	☐
If zoning approach, shapefile provided	☐
For endorsement of official control programme: control plan attached or included into the core document	☐
After submission of the application, Acknowledgement of receipt from the OIE	☐

ANNEX 2.a

Prescreening Checklist

Year:	**Disease:**
Country:	**Requested category:**
Date of application:	**Date of immediate acknowledgment:**
ID database :	**Date of official acknowledgment:**

Check points	y/n/n.a.	Actions required	Follow-up	Deadline	Comments
Executive summary					
Core dossier					
Number of pages of the core dossier					
Translation needed					
If translation, Word version requested					
Translation requested					
Access to the appendices					
Contact point(s) provided					
Shapefile (zoning) provided					
Inclusion of non-contiguous territories					
Occurrence of territorial disputes					
Proof of payment provided					
Commitment of payment provided					
Electronic format					
Hard copy					
Check points	**Score**	**Actions required**	**Follow-up**		**Comments**
Structure (score)*					
Content (score)*					
Check points(for official control programme only)	**y/n/n.a.**	**Actions required**	**Follow-up**		**Comments**
Plan included					
Indicators included					
Timeline included					

Performance of Veterinary Services (PVS)	y/n/n.a.	Actions required	Follow-up		Comments
PVS Evaluation					
PVS Gap analysis					
PVS follow-up					
Other PVS					
WAHIS	**y/n/n.a.**	**Actions required**	**Follow-up**		**Comments**
WAHIS up to date					
WAHIS specific information on the control measures					
Archiving	**y/n/n.a.**	**Actions required**	**Follow-up**		**Comments**
Archiving					
Comments					
Managed by[*]: **Experts assigned to the dossier:**					

* Compliance of dossiers with structure and requirements of the Terrestrial Code:

Score 1: Poor (major non-compliance);

Score 2: Average (general compliance but some requirements not fulfilled);

Score 3: Satisfactory

ANNEX 3

Technical criteria for dossier assessment – Relevant Chapters and Articles of the Terrestrial Code and Manual of the OIE

A. GENERAL REQUIREMENTS

Official recognition of disease status or endorsement of official control programme requires compliance with the requirements of the OIE *Terrestrial Animal Health Code (Terrestrial Code),* as well as with those of the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual)*.

This implies compliance with the relevant horizontal sections and chapters. During the evaluation for status recognition or endorsement of official control programme, particular attention is given to compliance with:

- **Chapter 1.1.** Notification of diseases, infections and infestations, and provision of epidemiological information
- **Chapter 1.4.** Animal health surveillance (1.4.6. Point 1 should be consulted for applications based on historical freedom from the relevant disease)
- **Chapter 1.6.** Procedures for self-declaration and for official recognition by the OIE
- **Chapters 3.1.** Veterinary services and **3.2.** Evaluation of Veterinary services
- **Chapter 4.3.** Zoning and Compartmentalisation

B. DISEASE SPECIFIC REQUIREMENTS:

1. Foot and mouth disease (FMD)

Compliance with questionnaires in Articles 1.6.6. (status) and 1.6.11. (programme) of the *Terrestrial Code*

Compliance with Chapter 2.1.8. of the *Terrestrial Manual* and Chapter 8.8. of the *Terrestrial Code*, including surveillance and trade recommendations. Particular attention is given to compliance with the requirements in the following articles:

TOPIC	RELEVANT ARTICLES OF THE TERRESTRIAL CODE
FMD free country or zone where vaccination is not practiced	Article 8.8.2.
FMD free country or zone where vaccination is practiced	Article 8.8.3.
Containment zone within a FMD free country or zone	Article 8.8.6.
Recovery of status	Article 8.8.7.
Endorsement of official control programme for FMD	Article 8.8.39.

2. Bovine Spongiform Encephalopathy (BSE)

Compliance with questionnaire in Article 1.6.5. of the *Terrestrial Code.*

Compliance with Chapter 2.4.5. of the *Terrestrial Manual* and Chapter 11.4. of the *Terrestrial Code*, including trade recommendations. Particular attention is given to compliance with the requirements in the following articles:

TOPIC	RELEVANT ARTICLES OF THE TERRESTRIAL CODE
BSE risk status (country, zone or compartment)	Article 11.4.2.
Negligible BSE risk	Article 11.4.3.
Controlled BSE risk	Article 11.4.4.
Surveillance	Articles 11.4.20.–11.4.22.

3. Contagious bovine pleuropneumonia (infection with Mycoplasma mycoides subs. Mycoides SC)

Compliance with questionnaires in Articles 1.6.7. (status) and 1.6.13. (programme) of the *Terrestrial Code.*

Compliance with Chapter 2.4.8. of the *Terrestrial Manual* and Chapter 11.7. of the *Terrestrial Code*, including surveillance and trade recommendations. Particular attention is given to compliance with the requirements in the following articles:

TOPIC	RELEVANT ARTICLES OF THE TERRESTRIAL CODE
CBPP free country or zone	Article 11.7.3.
Endorsement of official control programme for CBPP	Article 11.7.18.

4. Peste des petits ruminants (PPR)

Compliance with questionnaires in Articles 1.6.9. (status) and 1.6.12. (programme) of the *Terrestrial Code.*

Compliance with Chapter 2.7.10. of the *Terrestrial Manual* and Chapter 14.7. of the *Terrestrial Code*, including surveillance and trade recommendations. Particular attention is given to compliance with the requirements in the following articles:

TOPIC	RELEVANT ARTICLES OF THE TERRESTRIAL CODE
PPR free country or zone	Articles 14.7.3.
Containment zone within a PPR free country or zone	Article 14.7.6.
Recovery of status	Article 14.7.7.
Endorsement of official control programme for PPR	Article 14.7.34.

5. African horse sickness (AHS)

Compliance with questionnaire in Article 1.6.9. of the *Terrestrial Code.*

Compliance with Chapter 2.5.1. of the *Terrestrial Manual* and Chapter 14.7. of the *Terrestrial Code*, including surveillance and trade recommendations. Particular attention is given to compliance with the requirements in the following articles:

TOPIC	RELEVANT ARTICLES OF THE TERRESTRIAL CODE
AHS free country or zone	Article 12.1.2.
Containment zone within a AHS free country or zone	Article 12.1.4.
Recovery of status	Article 12.1.5.

6. Classical Swine fever (CSF)

Compliance with questionnaire in Article 1.6.10. of the *Terrestrial Code.*

Compliance with Chapter 2.8.3. of the *Terrestrial Manual* and Chapter 15.2. of the *Terrestrial Code*, including surveillance and trade recommendations. Particular attention is given to compliance with the requirements in the following articles:

TOPIC	RELEVANT ARTICLES OF THE TERRESTRIAL CODE
CSF free country or zone	Articles 15.2.2.–15.2.3.
Containment zone within a CSF free country or zone	Article 15.2.5.
Recovery of status	Article 15.2.6.