



Organisation
Mondiale
de la Santé
Animale

World
Organisation
for Animal
Health

Organización
Mundial
de Sanidad
Animal

Standard Operating Procedures
for official recognition of disease status
or risk status of bovine spongiform encephalopathy
and for the endorsement of national official control programmes
of Member Countries

1. Scope and Background

At the request of OIE Member Countries, the OIE has developed Standard Operating Procedures (SOP) to assist Member Countries wishing to apply for the official recognition of a specific disease status or risk status for bovine spongiform encephalopathy (BSE) or for the endorsement of a national official control programme. The SOP are based on the relevant provisions of the *Terrestrial Animal Health Code* (hereafter *Terrestrial Code*) and the relevant Resolutions adopted by the OIE World Assembly of Delegates (hereafter World Assembly) and serve as a single document of reference to facilitate the understanding of the OIE Delegates on the applicable procedures. The SOP currently apply to the official recognition of disease status for African horse sickness (AHS), classical swine fever (CSF), contagious bovine pleuropneumonia (CBPP), foot and mouth disease (FMD), peste des petits ruminants (PPR) and for BSE risk status as provided for in Chapter 1.6. of the *Terrestrial Code*. As regards rinderpest, further recognition of disease status is not taking place following the global eradication of the disease in 2011. These SOP also apply to the endorsement of a national official control programme for CBPP, FMD and PPR by the OIE in accordance with the provisions laid out in Chapters 11.7., 8.7. and 14.7. as well as in Chapter 1.6. of the *Terrestrial Code*.

The OIE Scientific Commission for Animal Diseases (hereafter Scientific Commission) is composed of six specialists in animal disease control elected by the World Assembly every three years. Since 1994, the Scientific Commission has been responsible to undertake, on behalf of the World Assembly, the assessment of applications by OIE Member Countries in accordance with the relevant provisions of the *Terrestrial Code*. The assessment by the Scientific Commission is usually preceded by an assessment and recommendation by a relevant *ad hoc* Group composed of world specialists for each particular disease. The meetings of *ad hoc* Groups are convened by the Director General of the OIE and their reports are provided to the Director General, who forwards them to the Scientific Commission for consideration. These reports assist the Scientific Commission in making informed decisions and in formulating recommendations for adoption by the World Assembly at the General Session in May every year, or in certain specific situations to take final decisions (see Point 9).

2. Submission of an application

An OIE Member Country wishing to submit an application (dossier) for official recognition of its disease status or its BSE risk status or for endorsement of its national official control programme should take careful note of the OIE calendar of meetings. To this end, a letter is sent by the Director General after each General Session to inform the Delegates of Member Countries of the dates of the scheduled *ad hoc* Group meetings dedicated to official recognition of disease status or BSE risk status and endorsement of national official control programmes. The OIE work programme cycle runs from May to May, of which the General Sessions of the World Assembly are the starting and ending points. The meetings of the *ad hoc* Groups responsible for the official recognition of disease status, BSE risk status

or for the endorsement of a national official control programme are usually held between the first (August/September) and the second (February) meeting of the Scientific Commission in this cycle. Depending on the number of dossiers received, one or more meetings of the relevant *ad hoc* Group could be scheduled between two General Sessions.

Applications should be submitted 45 days before the date scheduled for the relevant *ad hoc* Group meeting. The 45-day period gives the OIE sufficient time to screen, translate into English when necessary, and process the dossiers for *ad hoc* Group evaluation. Deadlines must be strictly observed to allow also a full evaluation of the dossiers by the members of the relevant *ad hoc* Group prior to its meeting. Applications received after the deadline are examined in the following cycle of meetings of the *ad hoc* Groups and the Scientific Commission, after the General Session in May, unless they are received in time for evaluation on the occasion of a second meeting of the *ad hoc* Group if scheduled within the one-year cycle.

The applicant Member Country must comply with all the relevant requirements specified in the *Terrestrial Code* for the requested category of official disease status or BSE risk status or for the endorsement of national official control programmes and submit all the required information by using the relevant questionnaire for that particular disease or control programme. It is essential for the applicant Member Country to use the model of the relevant questionnaire published in Chapter 1.6. of the *Terrestrial Code*. In the case of a dossier for official recognition of disease status or BSE risk status, the applicant Member Country should specify, whether the dossier relates to the whole country or to one or more zones and for which status (with or without vaccination) or category(ies) of risk 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 both “negligible risk” and “controlled risk” categories (in this case, the OIE evaluates the dossier for both) or only for one of these risk categories.

A Member Country wishing to receive official recognition for a specific disease status based on historical freedom should submit a dossier detailing how the requirements of Article 1.4.6. point 1. a) of the *Terrestrial Code* are met while following the template of the questionnaire outlined in Chapter 1.6. of the *Terrestrial Code* for the relevant disease status.

Any dossier - for official recognition of disease status or BSE risk 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. Relevant appendices may be attached to the core document. Each dossier should be prefaced with a one-page executive summary stating clearly what the Member Country is applying for, how it has addressed the various requirements set out in the *Terrestrial Code* and describing what information is provided in the dossier. The core document with the executive summary as well as appendices – which should be clearly cross-referenced in the core document – must be prepared in one of the official languages of the OIE (English, French or Spanish). 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. In addition, the digital format of the maps (e.g. shapefile) should be compatible with the mapping software (ArcView) currently used by the OIE.

The dossier must be duly signed by the Delegate of the applicant Member Country and be supplied in electronic format to the Director General of the OIE (in CD-ROM or as email file attachments using the following single email address: disease.status@oie.int) and, in case this is not possible, in hardcopy.

The contact details (name, phone/fax numbers and email address) of technical staff involved in the preparation of the dossier must be notified to the OIE Headquarters (disease.status@oie.int) so that any questions arising before or during the meeting of the relevant *ad hoc* Group or during the meeting of the Scientific Commission could be referred to the Member Country without delay.

To complete the application, a proof of payment of application fees must be sent to the OIE Headquarters (see details at Point 11).

3. Preliminary screening of application

Upon receipt of the dossier, the OIE Headquarters (Scientific and Technical Department) acknowledges receipt to the Delegate of the applicant Member Country and confirms the meeting dates of the relevant *ad hoc* Groups and the Scientific Commission at which the dossier is likely to be evaluated.

The OIE Headquarters (Scientific and Technical Department) conducts a preliminary screening of the dossier. If an information gap is identified, the OIE Headquarters may request the submission of an amended dossier or additional information before the set deadline.

4. Evaluation by the *ad hoc* Group

In general, the dossiers are discussed and evaluated by the relevant *ad hoc* Group at its physical meeting held at the OIE Headquarters; however in exceptional cases, the Scientific Commission or the Director General may request the *ad hoc* Group to conduct an evaluation by correspondence or teleconference.

The Director General of the OIE appoints, in consultation with the Scientific Commission, from among internationally recognised experts selected in priority from OIE Reference Laboratories (the list of which is submitted annually to the vote of the World Assembly), the members and supplementary members of each *ad hoc* Group responsible for formulating recommendations to the Scientific Commission on the requests from Member Countries asking for the official recognition of a disease status or a BSE risk status or for the endorsement of a national official control programme. Only those experts having committed, in writing, to the Terms of Reference and conditions for their participation in the *ad hoc* Group, are called upon to constitute an *ad hoc* Group.

The members of the *ad hoc* Groups are requested to comply with OIE requirements and procedures on confidentiality and on management of conflict of interest. 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.

As the participants of the *ad hoc* Groups are bound by the OIE rules on confidentiality of information, OIE PVS* reports may be made available to the *ad hoc* Groups upon request during the meetings. The OIE PVS reports provide complementary information to the *ad hoc* Groups and facilitate the analysis by the experts of the disease status or BSE risk status and the situation of Veterinary Services in the Member Country in question. However, the OIE PVS reports that are considered to be obsolete or those for which the Member Country has not agreed to its release to designated partners of the OIE are not made available to the *ad hoc* Groups. The *ad hoc* Groups may take into account any other information

* The OIE *PVS Tool* is designed to assist Veterinary Services to establish their current level of performance, to identify gaps and weaknesses in their ability to comply with OIE Standards on quality of Veterinary Services, to form a shared vision with stakeholders (including the private sector) and to establish priorities and carry out strategic initiatives.

available in the public domain that is considered pertinent for the evaluation of dossiers.

During the evaluation of a submitted dossier, the *ad hoc* Group may determine that interaction with the applicant Member Country is necessary. Such communication is ensured primarily through telecommunication (phone, fax or email). The applicant Member Country should then provide written answers to the questions asked before the deadline indicated (or within 24 hours if the question was asked for immediate clarification during the *ad hoc* Group meeting). 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 by the OIE Headquarters.

The applicant Member Country is not required to visit the OIE Headquarters, but should remain available on stand-by for telecommunication. A physical meeting between the *ad hoc* Group and representatives of the applicant Member Country may be considered on a case by case basis, after consultation with the Director General of the OIE (travel and accommodation costs are to be paid by the applicant Member Country).

5. Evaluation by the Scientific Commission

The Terms of Reference, Internal Rules, Qualification and election procedures of members of the Scientific Commission are found in the Basic Texts of the OIE. The members of the Scientific Commission are elected or re-elected every three years by the World Assembly and are bound by the OIE rules on confidentiality of information and on management of conflict of interests. The Scientific Commission requests *ad hoc* Groups to conduct evaluations of dossiers and provide their opinion and recommendations to the Scientific Commission. 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.

When conducting an evaluation of a Member Country application, the Scientific Commission considers the reports of the *ad hoc* Groups, including their analysis of dossiers, as well as other findings and recommendations. OIE PVS reports may be made available to the Scientific Commission upon request unless considered to be out-dated or those for which the Member Country has not agreed to its release to designated OIE partners. The Scientific Commission may take into account any other information available in the public domain that is considered pertinent to the evaluation of dossiers.

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. This should also be the case for the 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.

If an applicant Member Country wishes to dispatch experts (no more than two) to meet with the Scientific Commission during its meeting at the OIE Headquarters, they may do so at their own cost. Such visits should be notified to the OIE Headquarters at least 14 days before the meeting of the Scientific Commission. Upon receipt of such request, the Scientific Commission evaluates whether sufficient time would be available during the meeting to receive country experts and whether this would contribute to the evaluation of the requested disease status or BSE risk status or endorsement of a national official control programme. As a more cost- and time-effective means of consultation, exchanges by email or teleconference are given preference.

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 office of the Director General of the OIE. All correspondence that has taken place between an applicant Member Country and the OIE

Headquarters is duly documented by the OIE Headquarters.

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 the facts contained in its dossier before a decision or recommendation is made by the Scientific Commission on the application of the Member Country (see Point 10).

6. Communication on the outcome of the evaluation with the applicant and other Member Countries

After its meeting, the Scientific Commission produces a report, which contains the outcomes of the evaluation of dossiers from applicant Member Countries. 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. In parallel, 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, with a summary of the evaluation including reasons for a positive or negative outcome. In the case of a negative outcome, the letter could also indicate 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. This letter from the Director General of the OIE is not released in the public domain.

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 BSE risk status or to endorse a national official control programme, in accordance with Resolution No. 15 adopted at the 83rd General Session, and other relevant Resolutions previously adopted.

During the 60-day commenting period, questions raised by Member Countries are addressed by the OIE Headquarters in consultation with the Scientific Commission and, where necessary, with the relevant *ad hoc* Group. It is recommended that the questions are first referred to the applicant Member Country concerned, which is requested to provide clarification to the Member Country soliciting information, with copy to the OIE Headquarters.

In making application for official recognition of a specific disease status or risk status for BSE 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.

7. Official recognition and endorsement by the World Assembly

The World 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, new or, if that is the case, continuing disease status, BSE risk status as well as national official control programmes of Member Countries. The President of the Scientific Commission, when requested, provides additional clarification to the questions raised by Member Countries at the General Session. Any new official disease status, BSE risk status and endorsed national official control programme recommended by the Scientific Commission comes into force only after adoption of the Resolutions by the World Assembly (usually the last day of the General Session).

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

Shortly after the General Session, the OIE Headquarters implements the Resolutions adopted by the World Assembly and updates, on its website, the Lists of Member Countries having an officially recognised disease status or BSE risk status or endorsed national official control programme.

8. Annual re-confirmation

In accordance with Resolution No. 15 adopted at the 83rd General Session and other relevant Resolutions previously adopted, Member Countries having an officially recognised disease status or BSE risk status should reconfirm every year, during the month of November, that their status has remained unchanged by submitting relevant data specified in the applicable Article in the *Terrestrial Code* for the recognised status category. Member Countries having an officially endorsed control programme should inform the OIE during the month of November on the progress on the implementation of the control programme, in accordance with Resolutions No. 15 adopted at the 83rd General Session. The forms for annual reconfirmations of recognised disease status or BSE risk status and of endorsed national official control programmes are available on the OIE website.

As announced at the 83rd General Session, a web-based tool has been developed to facilitate the procedure for the annual reconfirmation procedure for the OIE and its Member Countries. An official letter from the Director General will be sent to all Delegates providing a specific ID and password with a link to the secured on-line system. Once logged in Delegates will find the relevant annual reconfirmation forms that they should submit to the OIE, for maintenance of their countries' recognised official status or endorsed national official control programme. The paper formats of all annual reconfirmation forms will be kept available on the Delegates' website as well as the OIE website (<http://www.oie.int/en/animal-health-in-the-world/official-disease-status/>).

As regards rinderpest, in view of the global eradication of the disease, the World Assembly at the 79th General Session in 2011 decided to suspend the duty of Member Countries to send annual reconfirmation to the OIE for this disease.

9. Suspension and reinstatement (recovery) of official status

Any suspension or recovery of official status is officially conveyed by a letter from the Director General of the OIE to the Delegate concerned and is simultaneously announced through the publication of a notice on the OIE website. As the official BSE risk status of a country or zone is determined on the

basis of an overall assessment of risks, the occurrence of a new BSE case does not automatically lead to a re-assessment of the official BSE risk status, except in the event of a change in the epidemiological situation indicating failure of the BSE risk mitigating measures in place or non-compliance with the applicable requirements outlined in the *Terrestrial Code*.

The official status of a given Member Country may be suspended for other reasons than disease outbreaks such as non-submission of the form and data for annual status reconfirmation as well as non-compliance with the requirements laid out in the relevant chapters of the *Terrestrial Code*.

Further to a suspension, a Member Country wishing to recover its previously recognised official status or to establish a *containment zone* has to submit an application to the OIE. The Scientific Commission has been given the mandate to proceed with such recognition without further consultation of the World Assembly, in accordance with Resolution No. 15 adopted at the 83rd General Session and other relevant Resolutions previously adopted. The Scientific Commission decides, either at its regular meeting or by correspondence amongst its members, on the process to follow in undertaking the evaluation of the application. The process of evaluation may or may not involve an assessment by the relevant *ad hoc* Group (either by correspondence or at a physical meeting) taking into account factors such as the nature and quality of the data related to the outbreak, control measures or changes in the zoning approach.

When the Scientific Commission has decided that the Member Country or zone has complied with the relevant provisions of the *Terrestrial Code* on the recovery of an official status, or has complied with the requirements of the *Terrestrial Code* for the establishment of a *containment zone*, the OIE informs the Delegate of the applicant Member Country 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 endorse the application, a statement on the reasons for non-endorsement is communicated by a letter from the Director General of the OIE to the applicant Member Country. This letter of the Director General of the OIE is not released in the public domain.

10. Expert mission to Member Countries

In accordance with Resolution No. 15 adopted at the 83rd General Session and other relevant Resolutions previously adopted, the Scientific Commission may decide to request the Director General to deploy an expert mission to Member Countries as part of the evaluation of the Member Country dossier (including for recovery of status or evaluation of a national official control programme), or as a monitoring mechanism to assess the maintenance of an allocated disease status, an allocated BSE risk status or an endorsed national official control programme. Member Countries chosen are requested to fully cooperate with the OIE Headquarters and the mission experts, allow access to fields/facilities as necessary, and provide all information requested.

The travel and accommodation costs of the expert mission are to be defrayed by the Member Country concerned. The experts do not receive an honorarium.

11. Financial obligations

The fees to be paid by Member Countries applying for the official recognition or re-instatement of disease status for AHS, CBPP, CSF, FMD, PPR, for BSE risk status, as well as for endorsement of a national official control programme for CBPP, FMD or PPR are reproduced in Annex 1 of the present document, in accordance with Resolution No. 16 adopted at the 83rd General Session. The fees to be paid by Member Countries applying for historical freedom are the same as those listed in Annex 1 for each relevant disease. The bank account details are included in Annex 2. 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]”).

As already mentioned in Point 2, a proof of payment of application fees must be sent to the OIE Headquarters at the same time as the submission of the dossier. Once the proof of payment of application fees has been received by the OIE Headquarters and an assessment of the dossier has started, application fees cannot be reimbursed under any circumstances.

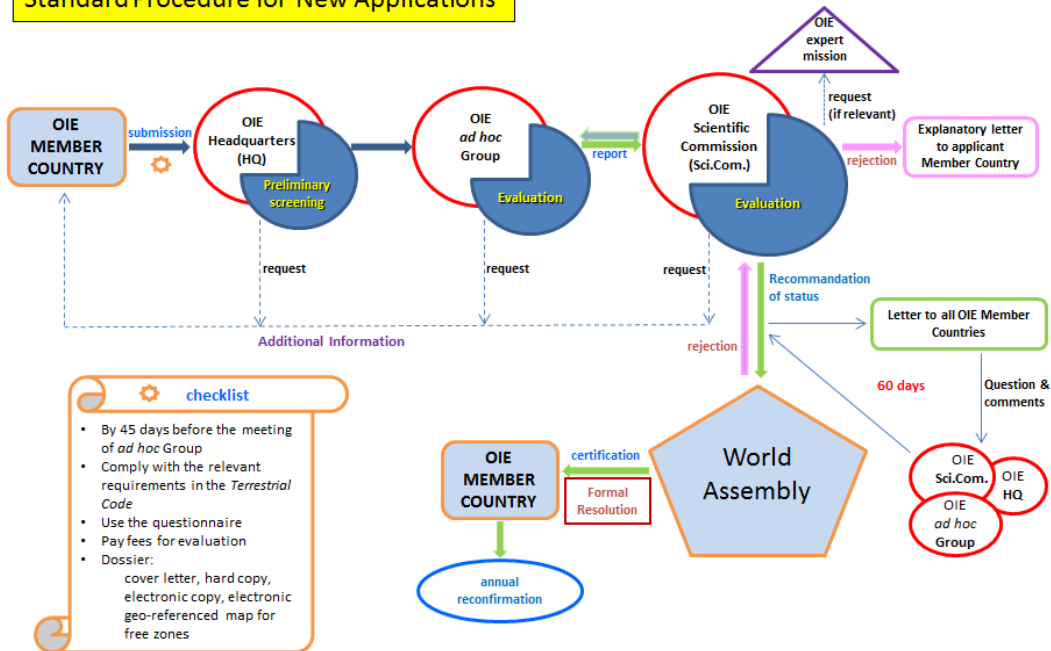
Resolution No. 16 adopted at the 83rd General Session confirms that Member Countries that are included at the moment of their application in the list of the Least Developed Countries published by the United Nations, will only acquit 50% of the amount due by the other countries.

12. Other

The present SOP and Annexes are subject to review by the Director General of the OIE and the Scientific Commission on an on-going basis and are subject to modification, taking into account new Resolutions and amendments to the *Terrestrial Code* adopted by the World Assembly, among others.

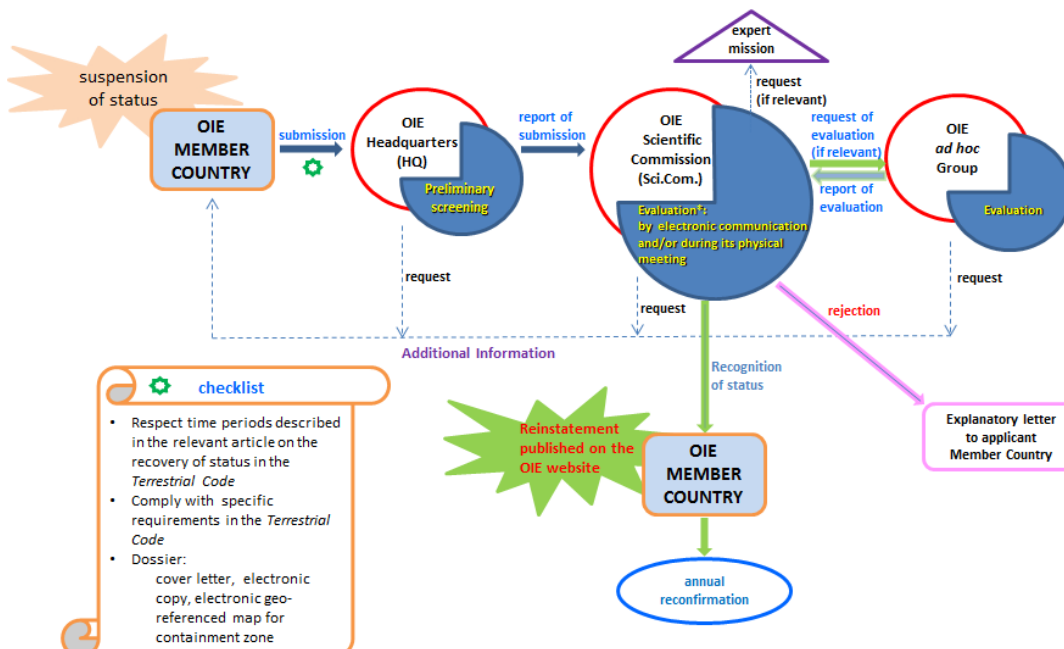
FLOWCHART - 1

Standard Procedure for New Applications



FLOWCHART - 2

Reinstatement of official status (+ application for containment zone)



Annex 1

Title: Financial obligations for official disease status (including historical freedom) or BSE risk status recognition and for endorsement of national official control programmes (in Euros)

Table A) For new applications: when an OIE Member Country applies for recognition of status (including historical freedom) or for endorsement, for the first time

	OIE Member Countries (<i>except least developed countries</i>)			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
<i>Entire country</i>	9,000	7,000	5,000	4,500	3,500	2,500
<i>One or more than one zone(s) at the same time</i>	9,000	7,000	5,000	4,500	3,500	2,500
<i>Endorsement of national official control programme</i>	N/A	2,000	2,000	N/A	1,000	1,000

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

Table B) For additional applications or reinstatement for the same disease

	OIE Member Countries (<i>except least developed countries</i>)			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
<i>New additional zone(s)</i>	4,500	3,500	2,500	2,250	1,750	1,250
<i>Change in category within the same disease*</i>	4,500	3,500	2,500	2,250	1,750	1,250
<i>Re-application for status (if the previous application was rejected)</i>	4,500	3,500	2,500	2,250	1,750	1,250
<i>Reinstatement of the status within the same country or zone(s).</i>	free of charge	free of charge	free of charge	free of charge	free of charge	free of charge
<i>Establishment/lift of a containment zone</i>	free of charge	free of charge	free of charge	free of charge	free of charge	free of charge
<i>Re-endorsement of application for national official control programme (if the previous endorsement was withdrawn due to non-compliance with commitments relating to the initial endorsement)</i>	N/A	1,000	1,000	N/A	500	500
<i>Endorsement of national official control programme (if the previous application was rejected)</i>	N/A	500	500	N/A	250	250

N/A: not applicable

*Examples:

BSE - from "controlled risk" to "negligible risk" status

FMD - from "FMD free where vaccination is practiced" to "FMD free where vaccination is not practiced"

NB: The costs of country missions are not included in the above amounts.

Annex 2

Bank account information

Banque/Bank/Banco:	Crédit industriel et commercial 54 rue de Prony 75017 Paris - France
Code banque/Bank Code/Banco:	N° 30066
Agence/Branch Name/Agencia:	CIC-O-PARIS-PRONY
Code guichet/Branch Code/Sucursal:	N° 10141
Compte/Account/cuenta:	N° 00010308807-38
SWIFT:	CMCIFRPP
IBAN :	FR76 3006 6101 4100 0103 0880 738
Intitulé/Account Name/Nombre de la cuenta:	Office international des épizooties