

Reconfirmation_SOP

Standard Operating Procedure on the reconfirmation of officially recognised disease status and of the endorsement of official control programmes of Members

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| Description/ Scope: | <p>This procedure describes the process for the submission of annual reconfirmations for the maintenance of official disease status or endorsed official control programmes.</p> <p>The subprocess for the reconfirmation of a status or of an endorsed control programme fits in the overall Official Status Recognition Process.</p> |
| Related documents | <p>Reconfirmation of a Status or Programme - Guidelines¹ (annexed)</p> <p>Resolution No. 15 of the 2020 Adapted Procedure</p> <p>Resolution No. 16 of the 2020 Adapted Procedure</p> |
| Related process | <p>Official Status Recognition Process</p> <ul style="list-style-type: none"> - Procedure (Application_SOP) - Application_Guidelines <p>Expert Mission Deployment</p> <ul style="list-style-type: none"> - Procedure (Mission_SOP) - Mission_Guidelines <p>Suspension, Recovery and Withdrawal</p> <ul style="list-style-type: none"> - Procedure (Suspension_SOP) - Suspension_Guidelines |
| List of acronyms: | <p>AHG: <i>Ad hoc</i> Group</p> <p>DDG: Deputy Director General, Standards and Science</p> <p>DG: Director General</p> <p>DSD: Disease Status Department</p> <p>SCAD: Scientific Commission for Animal Diseases</p> |

| Step | Time Reference | Responsible person | Action | Reference Document |
|------|----------------------|--------------------|--|---------------------------------|
| 1. | September | SCAD | Selects 10% of official status reconfirmations and all the official control programmes for a comprehensive review at its forthcoming February meeting. | |
| 2. | October | DG | Sends reminder letters for Delegates of Members with an officially recognised status or endorsed control programme. | |
| 3. | October | Delegate | <ul style="list-style-type: none"> - If the letter states that they were preselected for a comprehensive review, see step 4; - If not, see step 5. | § C.2 Reconfirmation Guidelines |
| 4. | October/ November | Delegate | Responds to DG acknowledging receipt and providing the details of a contact person. | |

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

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| 5. | November | Delegate | Submits reconfirmation online, including supportive information as per requested in the <i>Terrestrial Code</i> . | § A.2 Reconfirmation Guidelines |
| 6. | | DSD | Checks administrative and technical compliance: <ul style="list-style-type: none"> - If reconfirmation is not fully compliant and information is missing, see step 7; - If reconfirmation is fully compliant, see step 8. | |
| 7. | | DSD | Send emails to Delegates requesting the necessary additional information within a set deadline. | |
| 7.1 | Within the specified deadline | Delegate | Provides the OIE with the necessary information. | § C.1 Reconfirmation Guidelines |
| 7.2 | | DSD | Checks the provided additional information <ul style="list-style-type: none"> - If the information provided allows the assessment of the annual reconfirmation, see step 8; - On the contrary, see step 7. | |
| 8. | | DSD | Verifies the type of reconfirmation: <ul style="list-style-type: none"> - If it concerns a selected annual reconfirmation (official control programme or selected status), see step 10; - In any other case, see step 9. | |
| 9. | | DSD | <ul style="list-style-type: none"> - If there are any indications that the Member may not continuously comply with the requirements for maintenance of the disease status, see step 10; - If the assessment confirms compliance with the requirements for maintenance of the disease status, see step 11. | |
| 10. | | DSD | Forwards the Member's reconfirmation dossier to the SCAD for review with the reasons for requesting the SCAD's revision. | |
| 11. | | DSD | Drafts a report on all reconfirmations assessed by the Department for the SCAD, specifying whether the reconfirmation has been positively assessed or whether SCAD must review the application in depth. | |
| 11.1 | | DSD | Validates in the on-line system the positively assessed reconfirmations. | |
| 11.2 | | Delegate | Receives automatic message upon validation. | § D.1 Reconfirmation Guidelines |
| 12. | | SCAD | Reviews the report on reconfirmations assessed by the DSD (in step 11). Comprehensively reviews all official control programme reconfirmations, preselected disease status reconfirmations and reconfirmations highlighted by the DSD (in step 10). | |

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| 13. | | SCAD | For each reconfirmation: - If information is required, see step 14; - If not, see step 15. | |
| 14. | | DSD | Requests information from the Member contact point. | |
| 14.1 | Within the required deadline | Delegate / point of contact | Provides requested information. | § C.3 Reconfirmation Guidelines |
| 15. | | SCAD | For each reconfirmation: - If a specific expert opinion is required, see step 16; - If not, see step 17. | |
| 16. | | DSD | Requests recommendation from relevant expert(s). | |
| 16.1 | | Expert(s) | Provide(s) recommendation on the reconfirmation. | |
| 17. | | SCAD | For each reconfirmation: - If a mission is necessary, see mission subprocess (Mission_SOP) - If not, decides on the outcome of the maintenance of the officially recognised disease status or endorsement of the official control programme. | |
| 18. | | SCAD | Annexes a report dedicated to annual reconfirmations to its February meeting report. | |
| 19. | | DSD | For each reconfirmation: - If the evaluation outcome is positive, and the reconfirmation had already been validated on line by DSD (in step 11.1), see step 36 of Application_SOP; - If the evaluation outcome is positive, and the reconfirmation had not been yet validated on line by DSD, see step 20; - If the evaluation outcome is negative, see Suspension, Recovery and Withdrawal subprocess | |
| 20. | | DSD | Validates annual reconfirmations endorsed by SCAD through the online system. | |
| 20.1 | | Delegate | Receives automatic message upon validation; and see step 36 of Application_SOP. | § D.1 Reconfirmation Guidelines |



Reconfirmation_Guidelines

Guidelines on the reconfirmation of officially recognised disease status and of the endorsement of official control programmes of Members

A. Scope for annual reconfirmations

1. Officially recognised disease status

As stated in the provisions of the *Terrestrial Animal Health Code (Terrestrial Code)*, annual reconfirmation is mandatory for Members with an officially recognised disease status in order to maintain their official recognition.

When a Member fails to maintain compliance with the requirements of the *Terrestrial Code* for a disease for which its status had been officially recognised, its previously recognised official status can be suspended (cf. Suspension_SOP).

2. Official control programmes

Members having an officially endorsed control programme must inform the OIE on an annual basis of the progress on the implementation of the official control programme.

When a Member fails to maintain compliance with the requirements of the *Terrestrial Code* related to a Member having an endorsed official control programme, the endorsement of the programme can be withdrawn (cf. Suspension_SOP).

In accordance with Resolution No. 15 of the 2020 Adapted Procedure, Members with an endorsed official control programme and for which the entire territory had been further recognised as having an officially recognised free status for that disease are only requested to provide the annual reconfirmation for the official disease status.

B. Submission of an annual reconfirmation

1. Timeline

Whether for the reconfirmation of an officially recognised disease status or endorsed programme, Members must submit their annual reconfirmation before 30 November of the corresponding year. Members that have not completed their annual reconfirmation by 31 January of the following year would have their officially recognised disease status automatically suspended and the endorsement of their official control programme automatically withdrawn.

An official letter from the Director General is sent, in October of each year, to remind all OIE Delegates of Members having at least one officially recognised status or having an officially endorsed control programme about their duties with regard to annual reconfirmation.

2. Available channels/methods

Members may submit their annual reconfirmations through:

- The **on-line secured system** developed by the OIE to facilitate the submission and follow-up of all annual reconfirmations:

- The system is accessible in the three official working languages of the OIE (English, French and Spanish) via the following link:
<http://www.oie.int/annual-reconfirmation>.
Only the Delegate's username and password allow access to the on-line system (same as the access for the OIE World Animal Health Information System, WAHIS); the personal username and password of the OIE focal points for animal disease notification (provided by the Delegate to allow the focal point's access to WAHIS) do not allow access to the on-line annual reconfirmation system.
- Once logged in, the Delegates are directed to the relevant annual reconfirmation forms that they can complete and submit on-line with uploaded supportive documents and information, as appropriate.
- While it is strongly encouraged that Members submit their annual reconfirmations through the on-line system, the **traditional forms** are available on the OIE website and the OIE Delegates' website.
If used, the annual reconfirmation forms must be duly signed by the OIE Delegate and be supplied in electronic format to the Director General of the OIE as email file attachments to the following email address (disease.status@oie.int) or in hardcopy.

Irrespective of the chosen channel, supportive documents should be provided, as stated in the relevant *Terrestrial Code* chapters and annual reconfirmation forms. The reference to the relevant articles of the *Terrestrial Code* stating the information to be provided for retention on the OIE List of Members or zones having an officially recognised disease status or an endorsed official control programme is provided in Annex 1.

3. Roles and responsibilities

The annual reconfirmation procedure is coordinated by the OIE Headquarters (Disease Status Department). Considering the strong links and the communication channels established with the OIE Members, the OIE Regional and Sub-Regional Representations also play an active role in:

- maintaining awareness among Members in the Region and/or Sub-Region on their obligation to provide the annual reconfirmations of their official disease status and BSE risk status and endorsed official control programme by the 30 November or appointed deadlines for the submission of additional information;
- reminding Members of the timeline and the procedure, and following up on the process until all reconfirmations from the Region/sub-Region are submitted and validated;
- answering any query raised by Members in the Region and/or Sub-Region related to the procedure for the annual reconfirmation and to the requirements described in the relevant *Terrestrial Code* Chapters and Articles, with the support of the Status Department, when relevant;
- informing the Status Department in case of any doubts related to the capacity of a Member to maintain its OIE recognised official status or endorsed control programmes.

An identified contact point within the Disease Status Department is dedicated to each Region and/or Sub-Region as part of the coordination mechanism between OIE Headquarters and Regional and Sub-Regional Representations.

4. Financial obligations

In accordance with Resolution No. 16 of the 2020 Adapted Procedure, fees are not requested for annual reconfirmations.

C. Assessment of the annual reconfirmation

1. Screening by the Disease Status Department

All annual reconfirmations submitted are screened upon receipt by the Disease Status Department according to the requirements stated in the reconfirmation questionnaires, as well as any other information available in the public domain that is considered pertinent to the evaluation of dossiers. If PVS missions have been conducted during the previous year, their reports are also considered as part of the process (Ref. B.2

/Application_SOP). If an information gap is identified, the OIE Headquarters may request the submission of amended documents or additional information by an appointed deadline.

As English is the working language of the Scientific Commission, the relevant documents that are assessed by the Scientific Commission are translated if they have been submitted in Spanish or French.

2. Assessment by the Scientific Commission

2.1 SELECTED ANNUAL RECONFIRMATIONS

2.1.1 OFFICIAL CONTROL PROGRAMMES

All annual reconfirmations of Members having an endorsed official control programme are transmitted every year by the Disease Status Department to the Scientific Commission for Animal Disease (Scientific Commission) for a comprehensive review (except those Members whose entire territory has been further recognised as having an officially recognised free status for that disease, cf. section A.1.2 of these Guidelines).

2.1.2 SELECTED OFFICIAL DISEASE STATUS

In its September meeting each year, the Scientific Commission selects approximately 10% of the annual reconfirmations for disease status that they will comprehensively evaluate at their February meeting, based on the technical and administrative considerations described in Annex 2.

Members are informed that their reconfirmation will be assessed by the Scientific Commission in the letter sent by OIE Headquarters in October, reminding them of the deadline for submission of the annual reconfirmation and asking them to provide the contact details (name, email address and phone number) of a technical person that could be available before or during the February meeting of the Scientific Commission, so that any questions may be referred to the Member without delay.

2.2 OTHER OFFICIAL DISEASE STATUS

A summary report of the assessment of all the other disease status reconfirmations that were not in the preselected 10% is presented to the Scientific Commission by the Disease Status Department.

When the Disease Status Department identifies during its technical screening process an annual reconfirmation which does not provide enough guarantee of continuous compliance with the conditions for maintenance of the disease status, or detects any information deemed of interest for the Scientific Commission, the report specifies the latter or the reasons for the subsisting doubt and includes the information provided in the reconfirmation for a comprehensive review by the Scientific Commission.

3. Interaction with the applicant Member

During the evaluation of a submitted dossier, the Scientific Commission may request complementary information from the Member who should respond within the indicated deadline. If it is not possible to meet the deadline, the applicant Member should indicate when the additional information requested would be submitted to the OIE Headquarters.

All correspondence that has taken place between the Scientific Commission and the OIE Headquarters as well as between the Member and the OIE HQs is duly documented by the OIE Headquarters.

4. Additional information

The Scientific Commission may use any information available in the public domain that is considered pertinent to the evaluation of dossiers; if PVS missions have been conducted during the previous year, their reports are also considered as part of the process (cf. section B.2 of the "Application Guidelines"). When a particular expert opinion is necessary, the Scientific Commission may request the input of a specific expert (e.g. member of the relevant *ad hoc* Group) in the evaluation of Members' status with regard to the concerned disease in the assessment of the annual reconfirmations.

The Scientific Commission may also request the Director General to deploy an expert mission to a Member to monitor the maintenance of the allocated disease status or the progress on the implementation of the official control programme (see section A.3 of Mission_Guidelines).

D. Communication on the outcome of the evaluations

1. Communication to Members having submitted an annual reconfirmation

Following its assessment, the Disease Status Department provisionally validates in the on-line system the annual reconfirmations showing continuous compliance with the conditions for maintenance of the disease status, to be further confirmed by the Scientific Commission. Annual reconfirmations reviewed in depth by the Scientific Commission and for which there is a positive outcome are also validated by the Disease Status Department through the on-line system after the Scientific Commission meeting.

When an annual reconfirmation is validated in the on-line system a validation message is automatically sent to the Delegate of the relevant Member clarifying that the maintenance of a disease status or of the endorsement of an official control programme will only be sanctioned by the approval of the OIE World Assembly of Delegates at the following General Session.

In the case of a negative outcome after review from the Scientific Commission, a letter from the Director General of the OIE is sent indicating the specific requirement(s) of the *Terrestrial Code* that was (were) not met by the Member and the options on the way forward. Those options may include request of additional information, request of a mission (cf. Mission_SOP), or suspension of the status/withdrawal of the endorsement of the official control programme. A suspended status may be further recovered through the specific procedure for the recovery of an official status (Suspension_SOP).

The outcomes of the assessment of the annual reconfirmations that have been evaluated by the Scientific Commission are published in its meeting report, which is released in the public domain after the outcomes have been communicated to the concerned Members.

2. Communication to Members that have not submitted their annual reconfirmation(s) by the end of January

In the case of a Member that has not submitted their annual reconfirmation(s) by the end of January, the Scientific Commission would not be able to assess their compliance with the requirements of the *Terrestrial Code* for the maintenance of their officially recognised disease status or for the validation of their official control programme. Thus, a letter from the Director General of the OIE is sent indicating the suspension of the status or the withdrawal of the endorsement of the official control programme. A suspended status may be further recovered through the specific procedure for the recovery of an official status (Suspension_SOP).

The Members that have not submitted their annual reconfirmation(s) by the end of January and for which the status has been consequently suspended or the endorsement of their official control programme withdrawn, are named in the meeting report of the Scientific Commission, which is released in the public domain after the outcomes have been communicated to the concerned Members.

3. Communication to other Members

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 Members for which the Scientific Commission has recommended to recognise an official disease status or to endorse an official control programme at the forthcoming General Session, in accordance with Resolution No. 15 of the 2020 Adapted Procedure, and other relevant Resolutions previously adopted. The existing List of Members and zones already having an officially recognised disease status or having an endorsed official control programme and for which the Scientific Commission has recommended to maintain the status or the programme endorsement is also enclosed in this letter to all Delegates for their information and comments.

For more information on the commenting and endorsement process, please refer to the general Guidelines of the official status recognition process (Application_Guidelines).

ANNEX 1

Requirements of the *Terrestrial Code* for the annual reconfirmations

The relevant information to be submitted by Members having an officially recognised disease status, BSE risk status and/or endorsed official control programme through the annual reconfirmation is prescribed in the *Terrestrial Code*, as follows:

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| AHS free country or zone | Article 12.1.2. | NB |
| CBPP free country or zone | Article 11.5.3. | |
| CSF free country or zone | Article 15.2.3. | |
| FMD free country or zone where vaccination is not practiced | Article 8.8.2. | NB |
| FMD free country or zone where vaccination is practiced: | Article 8.8.3. | NB |
| PPR free country or zone: | Article 14.7.3. | NB |
| Negligible BSE risk | Article 11.4.3. | |
| Controlled BSE risk | Article 11.4.4. | |
| Endorsed official control programme for CBPP | Article 11.5.18. | NB |
| Endorsed official control programme for FMD | Article 8.8.39. | NB |
| Endorsed official control programme for PPR | Article 14.7.34. | NB |
| Endorsed official control programme for dog mediated rabies | Article 8.14.11. | NB |

NB: The *Terrestrial Code* requires that Members provide supportive documents to substantiate their annual reconfirmation.

ANNEX 2

Main factors to be considered for selection of annual reconfirmations to be scrutinised

The targeted number of Members to be potentially evaluated represents 10% of Members having an official status for each disease. This 10% includes Members selected based on the following considerations:

- Recent recognition of a disease status for this Member (to ensure the maintenance of measures presented in the application);
- Request for a specific follow-up from the *ad hoc* Group or the Scientific Commission during the initial assessment of the dossier or during the assessment of a previous annual reconfirmation;
- Change in the epidemiology of the disease (increased threat in the region which the maintenance of a high level of surveillance is crucial, occurrence of BSE cases, etc.);
- Members for which the political/economic situation may have impacted the performance of the Veterinary Services;
- Follow-up of the recommendations made during previous missions;
- Feedback from the Regional and Sub-Regional Representations that would justify a close follow-up of the situation;
- Members may also be randomly selected.

NB: Annual reconfirmations of all Members of which the official control programme has been endorsed by the OIE are scrutinised by the Scientific Commission (without selection).