

Seventh Meeting

FAO-OIE Rinderpest Joint Advisory Committee

FAO Headquarters, Rome, Italy

8-9 April 2015

1. Opening

The Director of Animal Production and Health Division of FAO welcomed the Committee and thanked them for their commitment to taking forward their assigned tasks. In addition to maintaining global freedom from rinderpest, he acknowledged that the Committee could be used as a model to contribute to the global PPR control and eradication campaign. He highlighted that the leadership of the Chairman had been a key factor in achieving consensus and cooperation. His comments were echoed by the Chief Veterinary Officer (CVO) of FAO who also highlighted that the Committee should provide recommendations on safe manipulation of rinderpest virus containing material (notably for vaccine manufacture and diagnostics) in addition to approval of holding facilities. The CVO also identified a number of gaps including vaccine production, early detection, and hazard analysis. The Chair welcomed the comments and thanked the Committee members for their cooperation, noting the high quality of their work.

The OIE representative highlighted that the OIE was also grateful for the work that the Committee had done in meeting their core objectives. He explained that the Committee's recommendations on approval of applicant rinderpest holding facilities would be taken forward to the OIE General Session in May 2015 where OIE Member Countries would make a final decision for the OIE on which facilities to approve.

2. Review minutes of the previous meeting and adoption of the agenda

The minutes of the sixth meeting had been agreed by the Committee following an electronic exchange. The agenda for the seventh meeting was agreed and the OIE representative was identified as rapporteur.

Action items from the previous (sixth) meeting were reviewed. The Committee requested that OIE and FAO provide an update on progress with the confidentiality agreement for sharing data between FAO and OIE.

3. Review of applications for rinderpest holding facilities

The Committee had previously reviewed paper applications for rinderpest holding facilities and recommended site inspections to these facilities. The decision on whether to recommend each facility for approval as a rinderpest holding facility was made by the Committee based on their evaluation of the

site inspection report against the adopted mandate for rinderpest holding facilities (see annex). These recommendations would be taken forward by the FAO and OIE to the OIE General Session where successful adoption would be decided by passing of a Resolution by the World Assembly of OIE Delegates.

Ethiopia

Pan African Veterinary Vaccine Centre of the African Union (AU-PANVAC) had applied to be approved as a rinderpest holding facility for categories A and B.

The Committee reviewed the report of the site inspection to *AU-PANVAC* noting its recommendations for corrective actions.

The Committee agreed with the conclusion of the site inspection report, that *AU-PANVAC* should be approved as a rinderpest holding facility for category B. The facility was recommended for approval for Category A noting corrective actions that must be addressed within 12 months. It was also noted that PANVAC must not manipulate or handle rinderpest virus containing material until the corrective actions had been verified. The Committee also recommended that Standard Operating Procedures and training on those procedures should be put in place immediately.

Japan

Applications for rinderpest holding facilities had been received from two institutes in Japan – one in *Kodaira* (for category A) and one in *Tsukuba* (for category B).

High Containment Facilities of Exotic Diseases Research Station, National Institute of Animal Health (Kodaira facility)

The Committee reviewed the site inspection report for *Kodaira facility* and recommended that it should be approved as a rinderpest holding facility for category A.

The Committee expressed concerns about inoculation of live animals with historical strains of rinderpest virus and reiterated that facilities should not manipulate rinderpest virus containing material without prior permission of FAO and OIE.

Building for Safety Evaluation Research, Production Center for Biologicals; Building for Biologics, Research and Development (storage), National Institute of Animal Health (Tsukuba facility)

The Committee recommended that *Tsukuba facility* should be approved as a rinderpest holding facility for category B.

The Committee also noted that approval for manufacture of rinderpest vaccine would require a separate application because manufacture is considered to be a manipulation of rinderpest virus containing material. Such approval would be based on risk assessment for the whole manufacturing process, including transport of material between facilities.

United States of America

The OIE and FAO had received an application for rinderpest holding facility category A from USDA-APHIS, Foreign Animal Disease Diagnostic Laboratory (FADDL).

Dr Schmitt was excused from the Committee's evaluation of *FADDL's* application owing to a conflict of interest because she is involved in the management of *FADDL*.

Further to review of the site inspection report the Committee recommended that *FADDL* be approved as a rinderpest holding facility for category A.

The Committee noted concerns expressed in the report that *FADDL* may have difficulty sharing rinderpest virus containing material with other international facilities owing to national requirements. One of the terms of reference for a rinderpest holding facility is to share rinderpest virus containing material with other international facilities on request from the OIE and FAO. The Committee recommended that *FADDL* address this issue to ensure compliance with the mandate.

United Kingdom

The Pirbright Institute had applied to become a recognised rinderpest holding facility for category A.

Dr Ulaeto was excused from the Committee's evaluation of the Pirbright Institute because he is seconded to the Pirbright Institute on a part time basis.

Based on the site inspection report and clarification by the laboratory on a number of issues which had previously been raised by the Committee the Pirbright Institute was recommended for approval as a rinderpest holding facility for category A.

4. Other issues arising from the Joint FAO-OIE rinderpest site inspections

During the evaluation of site inspection reports some general issues and actions were noted.

The Committee recommended against any facility performing routine rinderpest challenge or infection studies in animals, and that the OIE should reflect this in the relevant chapter of the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals.

It was noted that, in accordance with the mandate for rinderpest holding facilities, any facility must apply to the FAO and OIE before manipulating or handling rinderpest virus containing material.

Research (including sequencing) and manufacture of rinderpest vaccine in any facility (including approved rinderpest holding facilities) would require prior approval from OIE and FAO following a separate application.

Action item: The Committee should acknowledge the inspection teams for their efforts in conducting the inspection and completing the reports in a timely manner.

5. Format of annual report for approved rinderpest holding facilities

The Committee had discussed that a Rinderpest Holding Facility's annual report should capture information to:

- 1) monitor the inventory and status of remaining stocks of rinderpest virus containing material,
- 2) monitor and assess compliance with the mandate;
- 3) note any significant changes or events which could impact on the ability of the facility to meet the mandate;
- 4) monitor progress with any corrective actions previously identified.

The Committee agreed that the format of the Rinderpest Holding Facility annual report should differ from the country report but it should capture the same data. The report should also be workable for the facilities and not lead to duplication of effort.

Action: The Committee should provide comments to the Secretariat before the end of May 2015 based on the template used for country reporting to the OIE.

6. Revision of application form for approval of rinderpest holding facilities

With experience gained from submission of applications and comments from the site inspection teams, the application form was revised.

7. Revised OIE Standards on safety testing of vaccine

OIE Standards on safety testing of rinderpest vaccine in the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals were undergoing revision to remove the need to undertake challenge testing for rinderpest vaccine quality control. The Committee was in agreement and supported this change.

Action: Any detailed comments on the text in the Chapter should be provided to the Secretariat before 1 August 2015

8. International Contingency Plan

Reviewing progress with international contingency plans, the Committee noted that several elements already exist but these elements should be drawn together in a document. Any gaps in international preparedness should be identified and addressed. The Committee identified that an important element of the international contingency plan was a template for national contingency plans and recognized the value of countries sharing their national plans as models for other countries.

Action: FAO to identify a consultant to develop an international contingency plan, drawing together existing elements and identifying gaps. The international plan would include national, regional and global preparedness for a release of rinderpest virus.

The Committee recognized that there were gaps in the international contingency plan, notably with respect to the availability of diagnostic tests and vaccines. Current diagnostic tests for rinderpest require the use of live virus (as positive control material and for the production of new tests and reagents)

which limits the availability of diagnostic tests because only approved facilities should handle live virus. The Committee recognized the value in making available validated protocols and tests which do not require the use of live virus for controls. This would allow laboratories to maintain diagnostic capability for rinderpest without handling or manipulating live virus.

The Committee agreed that one option to contribute to global preparedness would be to ensure that a number of laboratories could be designated as Regional Leading Laboratories for rinderpest and maintain capability for accurate diagnosis, including taking part in regular proficiency testing.

Action: The Committee should develop a concept note to further elaborate the principle of making available diagnostic tests which do not require live rinderpest virus and will submit this to the OIE Biological Standards Commission. The Committee should also submit their comments on the current chapter on rinderpest in the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals to the Secretariat before 1 August 2015.

9. The preparation of Standard Operating Procedures (SOP) for the receipt and dispatch of rinderpest virus containing material

SOPs for dispatch of rinderpest virus containing material were already prepared. A template SOP for receipt of rinderpest virus containing material had been drafted for AU-PANVAC. The draft document distributed at the Committee meeting would be modified to reflect these existing SOPs and a new draft circulated to Committee members for consideration.

Action: FAO Secretariat. Before next meeting.

10. Update on Joint Advisory Committee road map

The OIE and FAO have not yet finalized a confidentiality agreement for sharing data on the status of remaining stocks of rinderpest virus containing material which has been reported to the OIE. The Committee made a strong recommendation that this issue should be resolved in the interests of international preparedness.

Action: FAO and OIE should resolve this issue.

FAO were engaging disease modelers to estimate the need for vaccines should there be an outbreak of rinderpest. Questions remained including which institutes would have the capability and the willingness to produce vaccine; location of vaccine stocks; management of vaccine stocks; longevity of rinderpest vaccines stored under different conditions; the number of doses that would be required; and the funding required to maintain and mobilize vaccines.

Action: OIE/FAO should prepare a concept note paper on rinderpest vaccine.

11. Date of next meeting

The next meeting would take place at OIE Headquarters in Paris on 7-8 October 2015.

FAO-OIE Rinderpest Joint Advisory Committee

7th Meeting

8-9th April 2015

FAO HQ Rome.

Queen Juliana Room (B324)

Agenda

Day 1.	8th April 2015	
Time	Item	
09:00-09:15	Welcoming remarks; FAO and OIE	Berhe Tekola/Juan Lubroth OIE
09:15-09:30	Introduction by Chair and adoption of the agenda	Junaidu Maina
09:30-09:45	Report of last meeting and action items arising.	Junaidu Maina
Review of the reports of laboratory site inspections		
09:45-10:45	(1) Report on AU-PANVAC Ethiopia	
10:45-11:00	Recommendation to FAO and to OIE on AU-PANVAC application	
11:00-11:15	Coffee/tea break	
11:15 -12:00	(2a) Report on Japan, Kodaira	
12:00-12:45	(2b) Report on Japan, Tsukuba	
12:45-13:00	Recommendations to FAO and to OIE on Japan, Tsukuba and Kodaira applications	
13:00-14:00	Lunch	
14:00-15:00	(3) Report on USA, PIADC	
15:00-15:15.	Recommendation to FAO and to OIE on USA application	
15:15-15:30	Coffee/tea break	
15:30-16:00	(4) Report on UK, Pirbright	
16:00-16:15	Recommendation to FAO and to OIE on UK application	
16:15- 17:00	Other issues arising from the Joint FAO-OIE independent site inspections	
Day 2	9th April	
09:00-09:15	Summary of previous day's discussions	Junaidu Maina
09:15-09:45	Discussion of the format of an annual report by laboratories allowed to hold rinderpest virus	
09:45-10:15	Revision of the form of application for a laboratory to become an approved holding facility for RVCM	
10:15-10:45	Coffee break	
10:45-11:15	Revised OIE standards on safety testing of vaccine	
11:15-11:45	Update on international contingency plan	
12:15-12:30	The preparation of Standard Operating Procedures for the receipt and dispatch of RCVM	Secretariat
12:30-14:00	Lunch	
14:00-14:30	Update on JAC roadmap	Secretariat
14:30-15:00	Action items	Secretariat
15:00-15:30	Coffee/tea break	Secretariat
15:30-16:00	Summarize meeting main issues, set date of next meeting; close meeting..	Chairman

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