



Food and Agriculture Organization
of the United Nations



WORLD ORGANISATION FOR ANIMAL HEALTH
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Ninth Meeting

FAO-OIE Rinderpest Joint Advisory Committee

FAO Headquarters, Rome, Italy

Ethiopia Room (C285/9)

20-21 April 2016

1. Opening

The Director of Animal Production and Health Division of FAO, Berhe G. Tekola, welcomed the Committee and thanked them for their commitment to taking forward their assigned tasks. He acknowledged that the current term of the FAO-OIE Rinderpest Joint Advisory Committee (JAC) is coming to an end and he thanked all the members for their contribution during the last 4 years and requested, during this session, to set the objectives for the next 3 years which will help FAO and OIE to select the members for the next term of the JAC.

The chairman, Junaidu Maina, thanked the Director and, speaking for all members of the Committee, stated that the experience of working in the JAC had been very pleasant, and he expressed his appreciation to FAO and OIE for inviting them.

The Head of EMPRES, Eran Raizman, welcomed the JAC on behalf of Juan Lubroth, Chief, Animal Health Service, FAO. He stressed the importance of the post-eradication work on rinderpest, stating “the last incident of cattle with rinderpest-like signs was yesterday, and there will be another tomorrow”. Therefore we must make sure that rinderpest is still recognized and can still be diagnosed in the laboratory if it should reoccur. He noted that the way rinderpest has been eradicated will hopefully be repeated with peste des petits ruminants (PPR) over the next 20 years. The JAC has been very instrumental in the post-eradication work on rinderpest and he took the opportunity to thank them for this effort.

OIE Representative, Tianna Brand, also thanked again the members of the JAC for their contributions in the past and hoped to have a productive meeting.

2. Introduction by the chair and adoption of the agenda

The Chair, J. Maina, welcomed everyone. The agenda was reviewed and adopted, with the change that, as the Rinderpest Holding Facility (RHF) application from Iran was not complete and therefore not ready for review, it could not be considered by the JAC at this stage. A time slot was requested by Beverly Schmitt and allocated to discuss the chapter on rinderpest in the OIE Manual for Diagnostic Tests and Vaccines for Terrestrial Animals.



3. Report of last meeting and action items

The action items from the report of last meeting were reviewed.

- OIE to inform laboratories on the decision on research proposals: Completed
- JAC to provide a cautionary statement on the risks of publishing the sequence data in the public domain: Completed in December 2015.
- OIE and FAO to write to the heads of the laboratories that will carry out the three research projects to ensure that they coordinate and collaborate for the best coverage of temporal and geographical isolates. This was covered in discussions at the first meeting of these laboratories, which took place during the international meeting “Maintaining Global Freedom from Rinderpest” held in Rome in January 2016.
- Rinderpest Secretariat to send a letter to the Pirbright Institute on acknowledgement of the results from the PPR protection study. This letter was not sent, but acknowledgement of FAO and OIE approval was included when the study was published (Journal of Virology, May 2016).
- JAC to review the annual report form for RHF. The finished report form has been sent out, and 4 out of 5 RHF have replied.
- JAC to review the Standard Operational Procedure (SOP) for receipt of Rinderpest Virus Containing Material (RVCM). This was not done, but David Ulaeto assured that he would send his comments directly after the meeting, allowing this to be finalised.
- JAC to review the RHF application form to be finalized. This has been done and the new form is in use.
- FAO to finalize the discussion paper on rinderpest vaccine. This is done, and the paper was presented during the technical consultation before the 9th JAC meeting.
- FAO to explore support from AU to ensure that AU-PANVAC is meeting the biosafety standards for storing RVCM. Samia Metwally reported that it had not been possible to secure funding; AU-IBAR said they did not have funding to support AU-PANVAC; an approach to the Defense Threat Reduction Agency (DTRA) was initially successful, but the funding was later withdrawn. There had been some biosafety training in Ethiopia including AU-PANVAC but that was not directed toward working in Bio-Security Level (BSL) 3 facilities (**ongoing action for FAO**).
- Rinderpest Secretariat to address the issue of data sharing from Foreign Animal Disease Diagnostic Laboratory at Plum Island (FADDL). This issue has been discussed in the USA, the data have been shared with FAO. B. Schmitt reports that sharing it with the other RHF is most likely not a problem but she shall check and officially answer to the secretariat (**Action B. Schmitt**).
- Rinderpest Secretariat to send the revised rinderpest chapter of the OIE Manual to JAC for their comments and suggestions as it becomes available. The draft OIE manual rinderpest chapter has been circulated at 8th JAC meeting for evaluation (**continuous action for OIE**).
- JAC to draft a concept note on the principle of making available diagnostic tests containing non-infectious material to be considered by the OIE Biological Standards Commission. It was agreed that the OIE Terrestrial Animal Health Code would include the use of non-infectious material, therefore the concept note is not necessary anymore.
- Rinderpest Secretariat to come up with a process and common structure for both organizations for declaring an emergency, to activate the vaccine bank and a general response. These matters were part of the technical consultation and it has been suggested to form two FAO-OIE *ad hoc*



groups to draft both the international preparedness plan as well as a vaccine reserve operational manual. These documents will include the process for declaration of the emergency response and the roles of the international and regional organizations.

- Rinderpest-Secretariat to look at the OIE resolutions governing RVCM and the mandate of the RHF, to align them with possible changes to the mandates or new resolution. The Category B RHF has a duty to perform regular quality controls (QC), but cannot do this without approval from FAO and OIE. It was proposed that "With prior approval of FAO and OIE" should be added to the line on quality control in the mandate for RHF Category B section, and the mandate to be updated in the OIE next year Resolution. **Action: Secretariat to alter mandate for Category B RHF and OIE to make a change to the resolution.**
- FAO to follow up with AU-PANVAC and AU-IBAR on the requirements for QC testing. Not possible as AU-PANVAC doesn't have an approved BSL3 facility (**ongoing action FAO**).
- Rinderpest Secretariat to follow up with Japan to start discussions on stockpiling vaccine. This has been done, and Japan is considering maintaining older stocks of vaccine (over its 2-year shelf life), as they have proven to maintain viability for at least 10 years.

4. Application by China for Rinderpest Holding Facility

China submitted a Rinderpest Holding Facility application for Categories A and B. The Committee reviewed the application and noted that proposed Category A facility has yet to be certified as a BSL3 facility; currently this facility has not been completed. Therefore, the BSL3 certification is not ready for evaluation. The Committee, however, suggested that the FAO-OIE Secretariat remains engaged with the applicant and to notify the Secretariat when the facility is certified to conduct the inspection. Overall, the Committee deemed the application for Category A to be sound and when they are ready for inspection there should be attention paid to procedures in the bio-safety manual to ensure they are followed.

With respect to the proposed Category B application, further clarification is being sought on how the vaccines are currently being stored in relation to other RVCM that are held in the facility. The applicant will be provided with advice on storage of vaccines at a lower level than BSL3; however, the Committee also strongly recommended that China should avoid transferring or moving their vaccine viruses into a BSL3 facility, as contemporary international standards do not allow their removal for vaccine manufacture.

The Committee concluded and advised that the evaluation of the facility under Category B could be undertaken.

Action: FAO – OIE to write to China conveying the JAC's findings, and asking for information on the storage of the viruses and separation of vaccine and wild-type strains.

Action: FAO-OIE to clarify in the available documentation that storing vaccine master seeds and seed stocks may be maintained at lower than BSL3 under the oversight and regulation of FAO and OIE.

Action: OIE to make a clear change to the definitions by means of an updated resolution in 2017.



Conclusion: The facility can be inspected for Category B (Category A is excluded as it is not an official BSL3 facility) (**Action FAO – OIE to inform China**).

5. Diagnostic assays in the post-eradication era of rinderpest

With OIE Resolution No. 18 (GS79, 2011) forbidding the manipulation of RVCM, the application and use of diagnostics recognized in the OIE Manual is hindered unless permission is sought from OIE and FAO. Furthermore, such permission would usually only be granted to RHF.

In this regard, the experts from the Rinderpest Reference Laboratories at the Pirbright Institute and CIRAD have been engaged to draft a table for the OIE Manual of the various diagnostics and their fitness for different purposes. The Committee suggested that the Manual should indicate that the RT-PCR test should be validated with plasmids only (preferably synthetic DNA, not coming from BSL3 facilities), and that only negative controls are used for the whole process. When non-infectious RNA controls become available the RT-PCR can be properly quality controlled as required by normal diagnostic procedures. Currently, confirmation of rinderpest virus should be done at Pirbright (currently the only RHF with approval to QC the RT-PCR assay and the project for the full-length sequence of the virus).

Action: G. Libeau and M. Baron to update the table of diagnostics in the rinderpest chapter of the Manual.

6. Application by Japan to manufacture vaccine in its Category B Vaccine RHF

The Committee agreed to recommend that this application should be considered by FAO and OIE for approval. The JAC added a recommendation that Japan maintains the expired production lots that currently exist in considering that efficacy of these vaccines beyond their 2-year shelf life would contribute significantly to the establishment of a global rinderpest vaccine reserve. They should include those batches in the QC currently applied to new production batches.

Action: FAO – OIE will inform Japan on the results of the deliberations, and request them to maintain nationally expired batches of vaccine in order to build up a regional vaccine reserve.

7. Research application from Canada to sequence and destroy its RVCM

The Committee reviewed and debated the contents of the application at length. While the facility where the sequencing and destruction of the material would take place is known for its high containment capacity, the Committee agreed that recommending this work to take place would set a precedent that would be contrary to the principles and policies of the post-eradication activities. The underlying principles and policies, for post-eradication, are to sequester the RVCM in a designated RHF or to destroy the materials. In addition, another option available is to provide the material to a RHF that is contracted with OIE to undertake the sequence and destruction project, i.e. the Pirbright Institute.

The Committee stressed that any manipulation of RVCM should only take place in a RHF and with the approval of OIE and FAO.

The Committee recommended to FAO and OIE not to approve this application.



Action: FAO – OIE will inform Canada of their decision along with the reasons.

Action: For clarity, FAO-OIE to add to the application form for research a statement that only a RHF can apply to undertake the manipulation of RVCM.

8. Report from AU-PANVAC as response to inspection 2015.

AU-PANVAC submitted a report to the FAO-OIE Rinderpest Secretariat on the corrective actions they had taken in response to the inspection of the facility that took place in January 2015. The corrective actions report was reviewed by two bio-security experts, one of whom had been on the original inspection.

Overall, the bio-security experts concluded that there was still more work to be undertaken before the Rinderpest Holding Facility at AU-PANVAC can be certified. The corrective actions taken by AU-PANVAC addressed most but not all non-conformities, noted that the current report and biosafety manual indicated that the required standards were not being fully met, and not all staff were fully familiar with protocols for working at the required BSL3 level.

Conclusion: The JAC took note of the corrective actions that AU-PANVAC has taken to address the recommendations, and concurred with the review findings of January 2015. They concluded that before any manipulation or handling of the RVCM that are currently stored (or will be stored), AU-PANVAC must address all remaining non-conformities. Therefore, JAC recommends that the time for AU-PANVAC to address all remaining non-conformities be extended to December 2016. This must include training by an external consultant with experience in working in a BSL3 shower-out facility, who could also assist in the finalization of AU-PANVAC biosafety and management manuals, and the required BSL3 SOPs.

The Committee, however, stressed that it is essential to have a safe and effective RHF in Africa. Neither FAO nor OIE have a mandate to enable proper functioning of the facility at AU-PANVAC, but can advocate for the AU to allocate resources for AU-PANVAC to meet its obligations.

Action: FAO and OIE to work closely with AU-PANVAC to identify funding sources to address the non-conformities, recognizing that the valuable work of AU-PANVAC in this area will be compromised if the recommendations are not addressed.

9. Reports of OIE and FAO since last meeting.

OIE has received funding from Canada which will, among other activities, support the development communications and advocacy tools related to rinderpest as well as support verification of activities of RHF's. The funding will also support JAC meetings and expert *ad hoc* meetings related to the setting up of a rinderpest strategic vaccine reserve. Furthermore, other donor funding will be used to develop a rinderpest virus tracking system amongst the RHF's and the updating of the Electronic Rinderpest Reporting System for the annual reporting of OIE member countries.

FAO conducted specific activities on advocacy, raising awareness, virus destruction and sequestration and disease surveillance. An international meeting "Maintaining Global Freedom from Rinderpest" was



held in FAO Headquarters in January 2016 (<http://www.fao.org/3/a-bc963e.pdf>). All countries¹ present at this meeting supported the strategy to destroy and sequester RVCM, and stressed that a diagnostic tool that does not rely on infectious material should be made available, and an SOP should be developed for the treatment of serum to inactivate possible viral residue. Furthermore, the participants stressed the need for developing an international rinderpest preparedness plan and vaccine reserve. In the last 6 months, Switzerland declared that it destroyed its RVCM, and Sudan shipped their vaccine stock (24 400 doses) to AU-PANVAC. In the next months, three missions to Africa have been planned for destruction and sequestration of RVCM in Senegal, Kenya and Nigeria. To ensure that any reemergence of rinderpest is detected in an early stage, Senegal, Kenya and Ethiopia are engaged in a project to raise awareness for rinderpest and other transboundary animal diseases. FAO continuously monitors disease reports in media and within the FAO network, none of the over 70 events recorded was caused by rinderpest. FAO organized a disease outbreak investigation workshop for seven French-speaking countries in West and Central Africa².

10. Risk of rinderpest virus spread through serum.

Michael Baron presented current knowledge on the presence of rinderpest virus in serum, which shows that virus cannot be detected in serum of infected animals or in hyperimmune serum. To make the procedure even safer, it is suggested that 2 hours inactivation at 56°C should be enough to remove more than 4 log₁₀ (>2 log₁₀ of virus with 95% confidence) of virus. The JAC agreed that this is an important issue, many laboratories in countries that had rinderpest virus in the past might still have sera from the same period. It is unlikely that they will destroy the material as it is very valuable for future studies, agreeing that sera can be heat-treated is therefore a step forward in risk reduction. Mo Salman suggested that the work be published as a short communication together with the review G enevi eve Libeau has already written for JAC. M. Baron pointed out that the presentation was a summary of already published data, and further publication should therefore be unnecessary.

Serum, however, is included in the list of RVCM in Chapter 8.15 of OIE *Terrestrial Animal Health Code* and in OIE Resolution No.18/2011. Thus, there is a need to focus the attention of the relevant Specialist Commissions of OIE to revise the Code, the Manual and prepare a draft Resolution with a proposal of the new definition for the OIE Member Countries to consider.

Action: FAO and OIE to prepare an SOP on heat inactivation of serum.

11. Roadmap update.

The roadmap was reviewed and if relevant the status of the tasks were updated.

¹ Bangladesh, Canada, China, Ethiopia, European Union, Iran, Japan, Kazakhstan, Netherlands, Pakistan, Russian Federation, Kingdom of Saudi Arabia, Republic of South Africa, Switzerland, Turkey, UK, USA, Uzbekistan

² Benin, Cameroon, C te d'Ivoire, Guinea, Niger, Senegal and Togo



12. Most important issues for the next JAC term:

1. International preparedness plan
2. Vaccine quality of existing vaccine stocks
3. Expanding vaccine banks
4. Future of rinderpest viruses in RHF
5. Continuing visibility and advocacy
6. Exclusion of sera and other low risk material from the RVCM definition (might also be relevant for PPR)
7. Follow-up of corrective actions at AU-PANVAC

The expertise needed for the next JAC members should fit with the issues mentioned above.

13. Summary of action points mentioned in the Report

- FAO to explore support from AU to ensure that AU-PANVAC is meeting the biosafety standards for storing RVCM, recognizing that the valuable work of AU-PANVAC in this area will be compromised if the recommendations are not fulfilled.
- B. Schmitt will provide final answer on the issue of data sharing from FADDL with other RHF.
- OIE to send revised chapter to the JAC for their comments and suggestions as it comes available.
- FAO should add to the mandate for Category B "With prior approval of FAO and OIE" should be added to the line on quality control.
- OIE to suggest changes to the resolution with regard to QC in RHF Category B.
- FAO and OIE Secretariat should inform China on the current status of their RHF request. Inform them clearly on the changed guidelines for vaccine virus. China should be asked where the RVCM is currently stored; after these answers are given, an inspection can be planned.
- FAO and OIE should define clearly the change in bio-security level for vaccine seeds and stocks, OIE should suggest an update to the current resolution.
- G. Libeau and M. Baron to update the table of diagnostics in the chapter on rinderpest of the Manual.
- FAO-OIE to decide on the approval of vaccine production application and to request from Japan to maintain nationally expired vaccine batches in order to build up a regional vaccine reserve.
- FAO-OIE to add to the application form for research a statement that only a RHF can apply to undertake the manipulation of RVCM.
- FAO-OIE to inform Canada on their research proposal.
- FAO and OIE to prepare an SOP on heat inactivation of low risk material (sera).



14. Agenda

FAO-OIE Rinderpest Joint Advisory Committee

9th Meeting

20th - 21st April 2016

FAO HQs, Rome

Ethiopia Room (C285/9)

DAY 1	Wednesday 20 th April 2016	Speaker/chair
Time	Item	
14:00-14:10	Opening remarks	BG Tekola, E Raizman, T Brand
14:10-14:15	Introduction by Chair and adoption of the agenda	J Maina
14:15-14:45	Report of last meeting and action items	J Maina
14:45-15:45	Applications by China and Iran for Rinderpest holding facility (RHF)	Presented by G Abraham (G Viljoen- Iran)
15:45-16:15	Coffee/Tea	
16:15-16:45	Recommendations to FAO and OIE on RHF application(s)	
16:45-17:00	Application form for vaccine production	All
17:00-17:30	Application by Japan to manufacture vaccine	Presented by B Schmitt
17:30-17:45	Activity by FAO since last meeting	S Metwally
17:45-18:00	Activity by OIE since last meeting	T Brand
18:00-18:15	Break	
18:15-19:00	Research application from Canada	Presented by G Libeau
19:00-19:15	Recommendations to FAO and OIE	
19:15-20:00	Roadmap & JAC membership 2016-2019	FAO
DAY 2	Thursday 21 st April 2016	
09:00-09:20	Summary of technical meeting 19 – 20 April 2016	M Salman and D Ulaeto
09:20-10:15	Feedback on expert meeting: Proposed Actions	All
10:15-10:30	SOP for receipt of material	All
10:30-11:00	Coffee break	
11:00-12:00	Report from PANVAC as response to inspection 2015	Presented by G Abraham
12:00-12:15	Recommendation to FAO and OIE on PANVAC RHF	
12:15-13:00	Safety treatment of serum samples	Presented by M Baron
13:00-14:00	Lunch/Depart	



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