

8TH MEETING, RINDERPEST JOINT ADVISORY COMMITTEE
OIE Headquarters, Paris, 4-5 November 2015

Day 1 (9:00 – 18:00)

1. Welcoming and Introduction

The Chair opened the meeting by thanking the Committee members for their participation and for the work they would undertake over the next day and a half. He also recognized the good work of the previous OIE Secretariat – Drs Keith Hamilton and David Visser - for their efforts in support of the JAC. With that he welcomed the incoming OIE Secretariat team of Ms Tianna Brand and Dr Kazutoshi Matsuo and provided the opportunity for them both to introduce themselves to the Committee.

The Director General, OIE and the Deputy Directors General welcomed the Committee. Dr Bernard Vallat, Director General, expressed his thanks to the JAC for their work, which is important to the OIE and the FAO in the decision making process for post-eradication activities. He emphasized some key challenges facing the Committee; namely, convincing all countries to get rid of their rinderpest infected materials; how best to organize preparedness if an outbreak occurs; and the establishment and management of regional vaccine banks. The Committee members thanked Dr Vallat for his support of the JAC and wished him every success in the future. The meeting was also addressed by Drs Monique Eloit, and Brian Evans. Dr Evans noted that after discussions with FAO, both organizations have reaffirmed their commitment to the JAC seeing its work as important for ensuring rinderpest freedom. The organizations will revisit the mandate of JAC to ensure there is alignment of technical requirements with appropriate expertise.

The names of the attendees to the Rinderpest Joint Advisory Committee (JAC) meeting are found in Appendix 1.

2. Adoption of the agenda

Adopted as is.

3. Update on FAO activities.

Agenda items 3 and 4 were presented together by the Rinderpest FAO Co-Secretariat. The main outcome of the FAO Regional Meeting for African “Maintaining Global Freedom from Rinderpest”,

5-6 August 2015 has been close liaison with the African nations that have agreed to destroy or sequester their stocks of rinderpest virus containing materials (RVCM): Ethiopia, Kenya, Nigeria, Senegal and Sudan. Arrangements are being made for transfers of RVCM to PANVAC while the final approval for the destruction and sequestration of RVCM are being sought in other countries. The outcomes of the meeting can be found at the following link:

http://www.fao.org/ag/againfo/programmes/en/empres/news_130815.html .

Committee members, noting that AU-IBAR was instrumental in laying the groundwork for convincing African countries to relinquish their current holdings of RVCM, which has helped the bilateral discussions with the FAO, also noted that there was not the same regional coordination in the Asian nations but that there is on-going bilateral discussions with individual nations.

FAO reported that advocacy efforts to raise awareness about rinderpest are being undertaken through revising the FAO website and in developing specific communications products/tools for animal health professionals. The FAO Co-Secretariat is also trying to develop methodologies to communicate effectively with the laypeople such as the farmer or farm staff – in the surveillance and detection of rinderpest. The feedback from JAC was to include messaging on rinderpest in the FMD and PPR eradication campaigns.

With respect to the Regional meeting held in August, clarification was sought from JAC on the intentions to destroy the virus being held in the countries that participated (noting that South Africa did not attend the meeting). The FAO Co-Secretariat noted that all the countries that attended had agreed that they should destroy or sequester all of their RVCM holdings including the sequestration at PANVAC of all stocks of vaccine. So far, Botswana has transferred its first shipment vaccine seed stock to AU-PANVAC in August 2015 to be followed by another shipment in November 2015.

JAC Members expressed their concerns that priority should be given to destroy virulent virus over the destruction of vaccine stocks. The Committee noted that there has been only one transfer event for vaccine and want to see virulent field strains preferably destroyed, but if the laboratories want to sequester strains they considered this to be a reasonable alternative. The FAO Co-Secretariat reported that they have been working through the proper government channel to obtain consent at the Ministerial level to remove both vaccine and virulent virus from the laboratories and this approach usually results in delays to move forward as intended. During the Sharm el Sheikh Meeting, countries holding virus indicated that they will either destroy or sequester at AU-PANVAC all of their stocks of RVCM. This includes all virulent material as well as vaccine seed stocks and vaccine itself. However, although the momentum is slow it is in the right direction especially given that a number of other countries now wish to engage in the process of destruction and sequestration. The Committee predicted that further momentum will be gained with an international preparedness plan.

The Rinderpest Secretariat maintains that the approach is still: 1. to destroy all stocks; or 2.

transfer to Rinderpest Holding Facilities (RHF) for sequestration; or 3. transfer to other FAO-OIE RHF's able to carry out full sequencing of RVCM under approved projects, followed by the destruction of the material.

Another meeting with all other countries that have holdings of RVCM is planned for 20-22 January 2016 to persuade them to follow the implementation of post-eradication activities. In addition, a specific JAC meeting is planned in February/March 2016 in conjunction with a consultation meeting with subject matter experts to discuss in more detail the issues surrounding the establishment and maintenance of appropriate banks of rinderpest vaccine as a component of the international preparedness plan.

Continuing the discussion from the Regional Meeting in Sharm el Sheikh, one reason for some countries wanting to retain live virus is for its possible use in diagnostic tests. The countries wanted to know what the future is for diagnostics for rinderpest and were assured that the FAO and OIE were working towards the introduction of non-infectious diagnostic tests. Another reason preventing the sequestration of some vaccine stocks has been the commercial requirement to account for the costs of its production.

The FAO Co-Secretariat stated that considerable effort was being expended to push for destruction and sequestration at regional meetings. It was agreed by the Committee and the Secretariats that FAO and OIE Reference Laboratories for Rinderpest and Rinderpest Holding Facilities should also advocate for the destruction and/or sequestration of RVCM. For example, both The Pirbright Institute and CIRAD have close working relationships with some of the laboratories that are being encouraged to give up their stocks of RVCM and could help them to finalise their decisions. The FAO Co-Secretariat is awaiting confirmation from the governments to coordinate missions to destroy and to help select the virus for sequencing by Pirbright or for sequestration at AU-PANVAC.

FAO Co-Secretariat also reported that the computer simulation of rinderpest emergence and the impact of mitigation measures is continuing and that the main developer of the model will visit FAO in November to accelerate the work.

5. Research proposals: evaluation and recommendations by JAC

5.1 Applications for sequence and destroy projects

5.1.1 CIRAD proposal - presented by Dr David Ulaeto

(Dr Geneviève Libeau left the room to avoid any conflict of interest)

Overall, the JAC recommended that the FAO and the OIE approve the proposal. However, the proposal required clarification over the mode of transfer of material from the BSL3 to BSL2 for sequence analysis. The Committee noted that the proposal included a thorough risk assessment and mitigation procedures.

The Committee provided a general recommendation for all research proposals as

follows: if samples were not suitable for partial or full genomic sequence, they should not be further handled and grown in cell culture for amplification. The material should instead be stored safely for possible later sequencing using new technology as it becomes available.

As a side note to the discussion, the OIE secretariat announced that CIRAD had very recently informed them that they were ready to accept on-site inspection for approval as an FAO-OIE rinderpest holding facility; which the Committee welcomed.

5.1.2 Pirbright proposal – presented by Dr Geneviève Libeau

(Dr David Ulaeto left the room to avoid any conflict of interest)

Overall, the JAC recommends that the FAO and the OIE approve the proposal.

However, they noted that, like the CIRAD proposal, there is no need to grow the virus for amplification if there is insufficient RNA in samples. With changes in technologies it is recommended to store the sample for possible future use.

The relatedness of certain motifs to virus pathogenicity has not been fully studied for rinderpest virus; however some data is available for PPR virus, so the full genomic data provided out of the three projects might be useful for developing criteria for such correlation.

5.1.3 Plum Island proposal – presented by Dr Gerrit Viljoen

(Dr Beverly Schmitt left room to avoid any conflict of interest)

This proposal refers to maintaining minimal stocks of the well characterized viruses, however, the objective of the proposals are to sequence and destroy. Therefore the Committee recommended that the FAO and the OIE proceed with approval on the condition that destruction of virus must take place after sequencing. Treating one proposal differently than the others sets a precedent “for sequence and retain” which is not the intention of the proposals.

Action: OIE Secretariat to inform the laboratories of the results of deliberations as well as inform the OIE World Fund to commence contract negotiations.

Previous JAC meetings discussed the issue of ownership of viruses for those countries transferring material to a rinderpest holding facility (RHF). The same issue will apply to the genetic sequence data from RVCM exchanged from one country to another. The Committee’s previous advice was that the receiving institute does not own the material and this will be the same with the genetic data derived from such a virus.

The other significant issue was that of how the data should be stored and accessed. The Committee strongly felt that the sequence data should be put into the public domain so that, essentially, everyone owns it. This has been the experience with smallpox virus

sequencing data and several other viruses. Restricting access to the sequence data by not putting it in the public domain was considered to be counterproductive by the JAC. There is already a number of rinderpest viruses characterized and in the public domain and holding back this information will not prevent a determined attempt to recreate the virus. The Committee felt that the donating country and receiving laboratory should undertake discussions on this. There are examples of material transfer agreements (such as the one used in OFFLU) that can be adapted as needed. The Committee also recommended that there should be coordination between laboratories on the selection of virus strains to be fully sequenced in order to avoid duplication of effort. The proposed research projects on sequencing and destruction are entirely consistent with the JAC's long-term position that the most secure method for reducing the risk posed by rinderpest viruses continues to be their total destruction.

Action: JAC to provide a cautionary statement on the risks of publishing the sequence data in the public domain.

Action: The OIE and FAO 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.

5.2 Development and deployment of non-infectious diagnostic test (PIADC) – presented by Dr Samia Metwally.

The Committee recommended that the proposal be approved but suggested to include additional primers to increase the sensitivity of the test in detection of three rinderpest lineages. The diagnostic should have a multiplex approach with different gene sites. The Committee also noted that even though this proposal did not include the manipulation of virus or virus containing material, it was appreciated that it came forward for discussion and review.

5.3 Maintaining diagnostic capability for rinderpest virus (Pirbright) – Presented by Tianna Brand.

The Committee recommended that the proposal be approved, but like that of PIADC, this proposal takes a multiplex approach. If there is to be validation with live virus the laboratory needs to come back to the OIE and the FAO with a proposal for review by the JAC and if it is their intention to validate every two years with virus they will need to come back each time for approval by the FAO and the OIE.

6. Final report on approved research project "Testing the potential for protecting cattle against rinderpest using attenuated peste des petits ruminants virus vaccines".(Pirbright) – Dr Paul Rossiter.

In view of earlier studies the Committee felt that the results were not unexpected though the experiment had been worth doing because of the significant potential benefits. The Committee did not recommend any further work on this subject despite the intriguing data and new scientific questions posed. The OIE and the FAO should follow up with Pirbright on its intentions to publish this data and ensure acknowledgement in the publication of the roles of OIE, FAO, and JAC including the reasons why the research was undertaken and the approval process for the use of rinderpest virus. The Committee wished to be informed of all publications on rinderpest in the post-eradication era.

Action: Letter from Rinderpest Secretariats to Pirbright

7. Review of action items from previous meeting (7th JAC 8-9 April 2015)

7.1 Format of annual report for approved rinderpest holding facilities:

In May 2015, the JAC was to provide their comments; however, the revised form was presented at the 8th JAC under item 7.1

Action: The JAC will review and the Secretariat should expect comments from the Committee by December 2015.

7.2 SOP for the receipt and dispatch of rinderpest virus containing material. This item was presented to the 8th JAC under item 7.2. Comments were received from David Ulaeto before the 8th JAC. Secretariats have adapted it; however, still awaiting comments from other JAC members.

Action: JAC to comment as soon as possible in December 2015.

7.3 Confidentially agreement for sharing data on the status of remaining stocks of rinderpest virus containing materials between OIE and FAO.

The agreement is currently with the FAO legal counsel. The Rinderpest Secretariat will endeavour to have it signed by the end of the year.

7.4 Revision of application form for approval of rinderpest holding facilities:

The Secretariats are expecting applications from other countries in the near future and need to be ready for a meeting in January 2016 with countries that still have not destroyed or sequestered their holdings.

Action: Require comments from the JAC by mid- November.

7.5 Discussion paper on rinderpest vaccine

The FAO Co-Secretariat presented a discussion paper on rinderpest vaccine stockpiles to support international preparedness against rinderpest in the post-eradication era. After

considerable discussion it was agreed that the individual members of the Committee should submit their comments in writing for incorporation within or improvement of the paper. FAO was asked to develop its arguments for the recommended size of the vaccine stockpiles. The possibility of RHF (category B) participating in the vaccine stockpiles should be considered.

Looking at the WHO model for smallpox, where WHO set the standard for vaccines, the JAC suggested strengthening the OIE/FAO position by requiring approval from the organizations for inclusion in vaccine bank and meet the standards in chapter 2.1.15. of the *Terrestrial Manual*.

Action: FAO to finalise the discussion paper.

7 (bis) Other items raised during the meeting:

1. Review of applications for RHF.

AU-PANVAC. The FAO Co-Secretariat provided an update on activities undertaken since the corrective actions have been identified. In particular that the FAO will provide two biosafety officers to go as consultants to assist with the corrective action items related to SOPs. From this discussion, it was identified that the future of AU-PANVAC as a category A RHF needs to be addressed with AU-IBAR, and JAC wants to be informed of the outcomes of the work of the corrective actions.

Action: FAO to explore support from AU to ensure that AU-PANVAC is meeting the biosafety standards for storing RVCM.

PIADC- FADDL. As noted in the previous report, the sharing of information held at the FADDL with other international facilities will be problematic. The Secretariat need to clarify this with the laboratory and will work with Dr Beverly Schmitt to follow up (as is done with CDC and WHO for smallpox) before the next meeting.

Action: Rinderpest Secretariat to follow up.

2. Revised OIE standards on safety testing of vaccine:

This was not an agenda item for the 8th JAC; however the Committee notes that work is going on for the new manual in 2016 and welcomes the opportunity to comment on the chapter as it comes available for comment as part of the standards setting process.

Action: Rinderpest Secretariat to send revised chapter to the JAC for their comments and suggestions as it comes available.

3. International Preparedness Plan:

Although not an agenda item for the 8th JAC, the FAO Co-Secretariat provided an update. FAO is attempting to get a consultant for the preparation of a document; however, it is having some difficulties in finding a donor. In the meantime, FAO is working on the components of the contingency plan e.g. diagnostics, vaccine reserves, etc. The JAC felt that an international preparedness plan that points to how much vaccine is required is a starting point. Regarding quantity of vaccine, JAC cannot comment on the amount of vaccine in the discussion paper because of a lack of background information; figures need to be confirmed by modelling work and supported by the international preparedness plan. The Committee also noted that the vaccine bank should be regional and not country based.

Action: Committee members will draft a concept note on the principle of making available diagnostic tests containing non-infectious material to be considered by the Biological Standards Commission.

Action. Rinderpest Secretariat will come up with a process and common structure for declaring an emergency and a response for both organizations to activate the vaccine bank and general response.

4. Quality control of vaccines (additional agenda item added during the course of discussions).

The question was raised on whether or not facilities would need to apply to the OIE-FAO to conduct regular routine testing of the quality of stored vaccine. The Committee considered this to be virus manipulation and therefore it requires FAO-OIE approval following an application. This brought the discussion back to AU-PANVAC and its expired vaccine. The Committee recommended that a BSL3 facility needs to be approved before vaccine quality control (QC) testing can be carried out: at BSL2 there is a slight risk of exposure, erring on the side of caution. AU-PANVAC should comply with the conditions attached to its approval as an FAO-OIE RHF Category A to get the BSL3 up and running, once that is done it should titrate the vaccine *in vitro* as soon as possible as part QC.

Action: Rinderpest Secretariat look at the resolutions for the mandate of the rinderpest holding facilities to align with a possible form or changes to resolutions.

Action: FAO to follow up with PANVAC and AU-IBAR on the requirements for QC testing.

Also related to vaccine production for stockpiling, there was more discussion around the FAO-OIE RHF in Japan. It recently produced a new batch of 200K doses and said that tests to possibly extend the shelf-life of existing vaccine could be conducted before it is destroyed.

Action: OIE secretariat will follow up with Japan to start discussions

8. Update rinderpest roadmap:

The roadmap was updated at the 8th JAC.

9. Meeting summary

9.1 Dates for next meeting is tentatively scheduled for 15-16 March 2016



8TH MEETING, RINDERPEST JOINT ADVISORY COMMITTEE
Paris, 4-5 November 2015

Provisional Agenda

Day 1 (9:00 – 18:00)

1. Welcoming and Introduction
2. Adoption of the agenda
3. Outcomes of FAO Regional meeting for Africa ‘maintaining global freedom from rinderpest’ and follow-up
4. Updates on FAO project on virus sequestration and raising awareness
5. Research proposals: evaluation and recommendations
 - 5.1. Applications for sequence and destroy projects
 - 5.1.1. CIRAD proposal
 - 5.1.2. Pirbright proposal
 - 5.1.3. Plum Island proposal
 - 5.2. Development and deployment of non-infectious diagnostic test (PIADC)
 - 5.3. Maintaining diagnostic capability for rinderpest virus (Pirbright)
6. Final report on approved research project ‘Testing the potential for protecting cattle against rinderpest using attenuated peste des petits ruminants virus vaccines’.(Pirbright)

Day 2 (9:00 – 14:00)

7. Review of action items from previous meeting
 - 7.1. Format of annual report for approved rinderpest holding facilities
 - 7.2. SOP for the receipt and dispatch of RPV
 - 7.3. Confidentially agreement for sharing data on the status of remaining stocks of rinderpest virus containing materials between OIE and FAO
 - 7.4. Revised application form for FAO-OIE rinderpest holding facility
 - 7.5. Discussion paper on rinderpest vaccine
8. Update rinderpest roadmap

9. Meeting summary
 - 9.1. Dates for next meeting

Working documents:

1. Meeting agenda
2. Report of 7th JAC Meeting
3. Resolution No. 25 at GS83 (2015) of the OIE
4. Abstract of Chapter 2.1.15. of *Terrestrial Manual*
5. Application dossiers for sequence and destroy research projects – Pirbright, CIRAD, USDA
6. Application dossier from the PIADC “Development and deployment of non-infectious rinderpest diagnostic test for rumor tracking in rinderpest-free era”
7. Application dossier from the Pirbright Institute “Maintaining diagnostic capability for rinderpest virus”.
8. Report of Research project on PPR vaccination against RPV by the Pirbright

9. Format of annual report for approved rinderpest holding facilities
10. SOP for the receipt and dispatch of RPV
11. Confidentially agreement for sharing data on the status of remaining stocks of rinderpest virus containing materials between OIE and FAO
12. Revised application form for FAO-OIE rinderpest holding facility
13. Discussion paper on rinderpest vaccine

Appendix 1 – Attendees to the Joint Advisory Committee meeting

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