

Fifth Meeting

FAO-OIE Rinderpest Joint Advisory Committee

FAO Headquarters, Rome, Italy

25-26 February 2014

1. Opening

The Chairman welcomed the Committee members and thanked them for the continuing support to rinderpest post eradication activities and the work accomplished since the previous meeting.

Remarks made by FAO representatives:

Dr Berhe Tekola (Director, Animal Production and Health Division), Dr Juan Lubroth (Chief, Animal Health Service) and Dr Eran Raizman (newly appointed head of Emergency and Prevention System for transboundary animal diseases [EMPRES]) welcomed the Committee, congratulated the Chairman and the JAC for their proficient and effective actions and contributions, and made some opening remarks. FAO highlighted the likelihood and the concern about the potential increase in the number of applications for rinderpest holding facilities. FAO emphasized that the priorities for future work should include completing all elements of the international preparedness plan and that regions and other role-players including Member Nations, stakeholders and politicians should be better engaged in post rinderpest eradication activities.

Remarks by the Committee:

The Chairman highlighted some of the achievements to date and re-emphasized the importance of FAO-OIE rinderpest holding facilities, post-Rinderpest research and development activities and the existence of an international preparedness plan that also includes vaccine strategic reserves.

The committee suggested that FAO and OIE may promote a mechanism for Member Nations to give up rinderpest virus stocks, perhaps, by emphasizing the risk of storing the virus and to set high requirements for storing the virus. In the case of smallpox, it took many years for the WHO to reduce the number of repositories to only two locations with the experience of accidental virus release from one of the laboratories (UK in 1978) that accelerated the sequestration process.

2. Review meeting agenda and action items from the previous meeting

The Committee adopted the agenda as it was proposed by the Chairman (Annex 1).

The minutes of the previous meeting had been adopted by email exchanges and had been made available on the FAO's and the OIE's websites.

Updates were provided on the action items from the previous meeting:

- The Committee submitted to OIE a text and a justification to amend the current Guidelines for Rinderpest Virus Sequestration regarding storing vaccine seed material and manufactured vaccine outside of BSL3 a facility. The text was agreed upon by the OIE Biological Standards Commission and would be considered in future guidance, including the mandate for rinderpest holding facilities. The Committee noted that there were some recognized risks when transferring vaccine seed material and manufactured vaccines from a high biocontainment level (if currently stored there) to a biosafety level 2 facility. To minimize this risk, a risk assessment should be conducted and appropriate mitigations should be considered.
- The Committee suggested that FAO and OIE should conduct an international table-top exercise to identify gaps and further develop an international preparedness plan. This activity is of the utmost importance and a basic concept document should be developed by FAO and OIE. When recourses allow, this basic concept could be developed into a comprehensive plan.
- With regard to the legal endorsement of FAO-OIE rinderpest holding facilities, FAO had prepared an instrument for legal approval of the facilities and exchanged the latest draft with OIE. Three documents prepared include: terms and conditions with the defined mandate, declaration of interest, and a designation letter. These documents are in their final stage of approval.

Action 1: The Committee will draft procedures to enable safe transfer of rinderpest vaccine seed material and manufactured vaccine outside of biocontainment for storage in a biosafety level 2 facility.

Action 2: FAO to contact AU-PANVAC, Japan, India, and China to prepare a list of all vaccine strain stocks kept in their facilities with detailed history. The OIE will give the FAO access to the data from OIE Member Country reports on remaining stocks of rinderpest virus (RPV) containing material once the data are validated and endorsed by the OIE Member Countries during the next OIE General Session in May 2014.

3. Terms and Conditions for FAO and OIE rinderpest holding facilities

FAO presented the document of the terms and conditions to the Committee that was approved by FAO legal Counsel (Annex 2). This document is meant to be used as a legal instrument for rinderpest holding facilities, regarding the clauses set forward by FAO and OIE; and the mandate defining their responsibilities to the international community; and technical requirements and actions needed to support safe storage and destruction of remaining stocks of RPV-containing material. The Committee suggested changes to this document to clearly distinguish and exclude vaccine seed material and manufactured vaccine from RPV-containing materials.

4. OIE Resolution:

The OIE presented a draft Resolution entitled 'Procedure for the Designation of Facilities Holding RPV-containing Material to Maintain Global Freedom from Rinderpest' to be adopted by its membership at the 82nd OIE General Session. The Committee

supported the spirit and content of the resolution and suggested to consider making a clearer reference to the joint involvement of FAO and OIE in this process. The Committee proposed that a similar document could be presented at the forthcoming FAO committee on Agriculture (COAG) in October 2014.

5. Review FAO-OIE rinderpest holding facility applications:

Following deliberation, the Committee requested that the Secretariat should liaise in advance with applicants to ensure the application dossier is complete when it is presented to the Committee. This would allow sufficient time for assessment before review and discussion at the next Committee meeting. Since the fourth Committee meeting FAO and the OIE had received applications for review from: African Union-Pan African Veterinary Vaccine Centre (AU-PANVAC, Ethiopia), UK, Japan and USA for becoming FAO-OIE rinderpest holding facilities. FAO-OIE was asked to proceed with urgency (in close liaison with JAC).

AU-PANVAC (Ethiopia): this application is for:

1. storing and manipulating RPV containing material for confirmatory diagnosis;
2. rinderpest vaccine quality control (except for potency and efficacy testing) or maintaining vaccine seed virus; and
3. storing of packaged or manufactured stockpiles of rinderpest vaccines.

The Committee assessed the information that had been provided in the PANVAC dossier against objective criteria requested in the application form.

Approval was requested for the three categories mentioned above; this would include BSL2 and BSL 3 facilities. The Committee concluded that the information provided in this dossier was complete, and was satisfied that the application could move to the next stage of evaluation (a site inspection).

Pirbright Institute (UK): this application is for:

1. storing and manipulating RPV containing material for confirmatory diagnosis; and
2. storing, manipulating or using live rinderpest virus for scientifically legitimate experimental research purposes.

The Committee acknowledged the supplementary documentation provided in the application. However, information about a national disease contingency plan was not provided by the applicant. Other information in the questionnaire was evaluated against the criteria and the Committee requested further clarification on two points.

The Committee recommended that the application could only move to the next stage of evaluation (a site inspection) after the applicant had satisfactorily addressed the requested points of clarification and provided some explanation about a national disease contingency plan. The Committee indicated that it would agree to review the additional information by email exchange.

Foreign Animal Disease Diagnostic Laboratory, USDA (USA): this application is for:

1. storing and manipulating RPV containing material for confirmatory diagnosis, with future intention of becoming a holding facility for storing, manipulating or using live rinderpest virus for scientifically legitimate experimental research purposes.

The Committee appreciated the supplemental documentation, and acknowledged that a national disease contingency plan specifically referring to rinderpest was provided; this encouraged the Committee. A thorough review of the information allowed the Committee to conclude that all aspects of the criteria in the dossier were addressed sufficiently to move forward in the approval process.

The Committee recommended that the application move to the next stage of the process (a site inspection).

High Containment Facility of Exotic Diseases Research State, National Institute of Health (Japan): this application is for:

1. storing, manipulating or using live rinderpest virus for scientifically legitimate experimental research purposes.
2. The Committee indicated that several items in the dossier would need to be clarified, partly because some of the supporting documentation was not available in English. The Secretariat was requested to officially communicate the preliminary outcome of the application with the applicant and to request further information. The Committee recommended that the application could only move to the next stage of evaluation (a site inspection) after the applicant had satisfactorily addressed the requested points of clarification. The Committee indicated that it would agree to review the additional information by email exchange.

National Institute of Animal Health: Building for Safety Evaluation Research, Production Center for Biologicals, and Building for Biologics Research and Development (Japan): this application is for:

1. rinderpest vaccine quality control (except for potency and efficacy testing) or maintaining vaccine seed virus; and
2. maintaining and storing packaged or manufactured stockpiles of rinderpest vaccine.

The review of this application delivered a similar outcome as the previous application from Japan as some information was not clearly explained and the Committee requested the Secretariat to facilitate the additional information needed for further review.

The Committee recommended that the application could only move to the next stage of evaluation (a site inspection) after the applicant had satisfactorily

addressed the requested points of clarification. The Committee indicated that it would agree to review the additional information by email exchange.

Action 3: The Secretariat to request additional information from the facilities that did not fully complete their application for a second round of review by the committee.

Action 4: The secretariat to plan and organize the site inspection for the holding facilities that are ready to move to the next step in the process for evaluation as a suitable candidate for designation as a rinderpest holding facility.

6. Review research proposal submitted by Pirbright Institute

The Committee reviewed a re-submitted research proposal from The Pirbright Institute (UK) entitled '*Sequencing and destruction of historical rinderpest virus isolates*' against the criteria approved by FAO and OIE (Annex 3). The first submission of this proposal was reviewed by the committee during their fourth meeting, (September 2013) where the committee requested further scientific justification and background. The further information provided by the applicant was then fully discussed. The Committee emphasized that the outcome of this research should facilitate the destruction of rinderpest virus for a safer world. Additionally, it was noted that the list of viruses to be sequenced should be comprehensive. The Committee approved the proposal and recommended to request six-month progress reports from the principal investigator.

Action 5: The Committee will provide feedback to the OIE and FAO on their decision to recommend that the project should be approved.

7. Update on progress with PPR vaccine research project

The Committee was informed that the first stage of the project 'Testing the potential for protecting cattle against rinderpest using attenuated PPR virus vaccine' commenced in late 2013; it was, however, mentioned that there was no significant progress made.

8. International preparedness and response

Drs. Ian Douglas (ID) and Ed Arza (EA) (Crisis Management Centre-Animal Health, FAO) joined the meeting to discuss the urgency in disseminating the template for a national contingency plan to countries and the need to complete all elements of the international contingency plan which contributed to the template.

During this discussion, it was acknowledged that a response to a reoccurrence of rinderpest would need to engage a whole range of stakeholders beyond OIE and FAO. Depending on the nature of a reoccurrence, significant resources may also need to be mobilized for the response and consideration should be given to a strategy for mobilizing these resources at the international level.

It was suggested that a policy document should be developed by OIE and FAO describing which actors would be involved in the international response to a reoccurrence of rinderpest. This should engage other international and regional agencies and donors.

It was suggested that it might be more appropriate to call this policy paper a preparedness agreement rather than international contingency plan and that the availability of vaccine stocks should be included in the preparedness agreement. The secretariat shared some guidelines with the Committee to be used in the development of an international preparedness plan.

The Chairman stressed the importance of having an International plan available, so that countries can be assured of emergency preparedness when they surrender their RPV-containing material.

Action 6: FAO to prepare a preparedness plan/discussion paper before the next meeting.

9. OIE Database

The OIE informed the Committee about the preliminary information received in the secure electronic rinderpest reporting system developed by the OIE, and the comprehensive response from member countries in that 87% of member states completed the annual questionnaire for 2013 with reports from only 24 countries outstanding. This being a first time official questionnaire, some countries experienced difficulties in accessing the web-based system for different reasons, some of these countries were provided with a paper copy of the questionnaire to be completed. The data will be collated into a final report to be presented to Member Countries at the OIE General Session in May 2014. By doing this, the full data set will be validated and endorsed by the World Assembly of Delegates in a transparent way. It was also mentioned that three countries requested assistance with sequestration of RPV-containing material, and the detail of these requests will be shared with FAO once the complete information is received. The Committee recognized the cooperation between the FAO and the OIE joint secretariat and expressed its appreciation.

10. Preparation for site visits for holding facilities

Composition of the team for site inspection was proposed to include the following attributes:

- Advisor with experience in WHO inspection of smallpox collaborating centers, to provide guidance and advice based on WHO prior experience
- Biosafety expert (technical expertise with expertise in database inventory)
- Biosecurity expert with biocontainment engineering expertise
- Diagnostician/laboratory expert
- Representative from FAO or OIE (team leader)

The Committee suggested that a committee member be included as an observer. This needs to be approved by FAO and OIE management. It was also proposed that the team should not exceed five individuals.

11. Roadmap

Due to time constraints, the work plan describing activities to be carried out by FAO, the OIE and the Committee will be updated and shared with the Committee at a later time.

12. Next meeting

The next meeting of the rinderpest joint advisory committee will take place at OIE Headquarters in Paris during the week of 11-12 November 2014.

AGENDA**5th Meeting, Rinderpest Joint Advisory Committee**

25-26 February 2014

FAO HQs, Rome, Italy

India Room A327

Day 1 Tuesday, 25 February, 2014		
09:00-10:30	Welcoming remarks – FAO and OIE	Juan Lubroth / OIE
	Introduction by Chair	Junaidu Maina
	Review minutes and action items from the last meeting	all
	<ul style="list-style-type: none"> • Terms and Conditions for FAO and OIE rinderpest holding facilities • OIE Resolutions 	Samia Metwally Dawid Visser
10:30-11:00	Coffee break	
11:00-12:00	Review Rinderpest holding facility applications: 1. PANVAC (Ethiopia) application and next steps	All
12:00- 13:30	Lunch	
13:30- 15:00	2. Plum Island Animal Disease Center (USA) application and next steps	All
15:00-15:15	Coffee break	
15:15-16:45	3. Pirbright Institute (UK) application and next steps	All
16:45- 17:45	International preparedness and response	All- Ian Douglas & Ed Arza (FAO)
7:30-	Dinner	
Day 2 Wednesday, 26 February, 2014		
9:00- 9:15	Summary of the first day	Junaidu /Gerrit Viljoen
9:15-10:45	4. Japan application and next steps	All
10:45-11:00	Coffee break	
11:00- 12:00	Review research proposal submitted by Pirbright Institute	All
12:00- 13:00	Lunch	
13:00 – 13:30	<ul style="list-style-type: none"> • Update on the PPR vaccine project • Update on OIE database 	Dawid Visser
13:30-13:45	Preparation for site visits for holding facilities	All
13:45-14:15	Update of roadmap	Samia Metwally
14:15-14:45	Action items	All
14:45-15:00	Meeting wrap-up and dates of next meeting	Junaidu/Gerrit

Working documents:

1. Meeting agenda
 2. Report of 4th joint advisory committee meeting
 3. Terms and conditions for FAO-OIE rinderpest holding facility
 4. Rinderpest holding facility applications and supplements: PANVAC, US, Japan and UK
 5. Research proposal from Pirbright Institute
 6. Terms and conditions of rinderpest holding facility
 7. International preparedness and response
-

List of Participants

Dr Gordon Abraham
Virology & Biosecurity specialist
Gordon Abraham, B.Sc., PhD.
8 St Georges Court
Highton, Vic. 3216
AUSTRALIA

Dr Geneviève Libeau
In charge of FAO Reference Centre for Morbilliviruses in Ruminants
CIRAD-Département Systèmes Biologiques UPR "Contrôle des Maladies Animales
Exotiques et Emergentes"
Groupe Virologie
TA A-15/G (bureau G204)
Campus International de Baillarguet
34398 Montpellier cedex 5
FRANCE

Dr Junaidu Maina
Contingency Plan Specialist
J M Global Associates Ltd
13 Khartoum Street Wuse Zone 5
Post Office Box 8867
Abuja
NIGERIA
Post code 900281

Dr Samia Metwally (Secretariat)
Animal Health Officer/Virologist
FAO Secretariat
Food and Agriculture Organization
Viale delle Terme di Caracalla
00153 Rome
ITALY

Dr Beverly Schmitt
Director
Diagnostic Virology Laboratory
National Veterinary Services Laboratories
Ames, Iowa, 50010
UNITED STATES OF AMERICA

Dr David Ulaeto FSB
Principal Scientist
Department Biomedical Sciences
Dstl Porton Down
Salisbury SP4 0JQ
UNITED KINGDOM

Dr Gerrit Viljoen
Head
Animal Production and Health Section
Joint FAO/IAEA Programme of Nuclear Techniques in Food and Agriculture
PO Box 100
A-1400 Vienna
AUSTRIA

Mr Dawid Visser (OIE)
OIE Officer
World Organisation for Animal Health (OIE)
12 rue de Prony
75017 Paris
France

**TERMS AND CONDITIONS OF THE DESIGNATION
AS FAO-OIE RINDERPEST HOLDING FACILITY**

1. Introduction

- 1.1. The *{name of institute}*, agrees to be designated by the Food and Agriculture Organization of the United Nations (FAO) and the World Organization for Animal Health (OIE) (the three of them hereinafter referred also as “the Parties”) as a FAO-OIE Rinderpest Holding Facility subject to the terms and conditions contained in this Agreement (also referred to as “letter of designation”).
- 1.2. FAO-OIE Rinderpest Holding Facilities are designated by FAO and OIE on the basis of their specific capacities as certified in their application form, and subject to an independent evaluation.
- 1.3. FAO-OIE Rinderpest Holding Facilities will maintain full independence from FAO and OIE in carrying out their own activities, whilst FAO and OIE will not be responsible nor have liability whatsoever in such respect.
- 1.4. In its capacity as FAO-OIE Rinderpest Holding Facility, the *{name of institute}* shall collaborate only with members of FAO, OIE, the United Nations, any of its Specialized Agencies or the International Atomic Energy Agency.

2. Mandate

- 2.1. *The {name of institute} (hereinafter “the FAO-OIE Rinderpest Holding Facility”) agrees to be designated as category A) Rinderpest Holding Facility for storing rinderpest virus containing material, excluding vaccine stocks; and/or B) Rinderpest Vaccine Holding Facility for storing only manufactured vaccines, vaccine stocks and material solely for their production.*

[For category A:]

- 2.1.1 To safely hold rinderpest virus (hereinafter “RPV”) containing material at an appropriate level of bio-containment and ensure appropriate measures are taken to prevent its accidental or deliberate release.
- 2.1.2 To accept RPV-containing material from FAO and OIE Member Countries for safe storage and/or for destruction.
- 2.1.3 To notify FAO and the OIE before receiving RPV-containing material from other institutes for FAO to assist in shipping if needed and to ensure chain of custody.
- 2.1.4 To provide RPV-containing material to other institutes for the research or vaccine manufacture that has been approved by FAO and the OIE.
- 2.1.5 To retain an up-to-date inventory of RPV-containing material and sequence data (including recording entry and exit of this material into and out of the facility), and to share this information with FAO and the OIE through the designated rinderpest database.

- 2.1.6 To send an annual report to the OIE and FAO.
- 2.1.7 To maintain a system of quality assurance, biosafety and biosecurity.
- 2.1.8 To provide technical advice or training to personnel from other FAO and OIE Member Countries on the destruction, safe shipment of RPV-containing material, and/or decontamination of facilities.
- 2.1.9 To participate in scientific meetings in its capacity as FAO-OIE Rinderpest Holding Facility and using that title.
- 2.1.10 To establish and maintain a network with other rinderpest holding facilities.
- 2.1.11 To seek approval from FAO and the OIE before manipulating RPV-containing materials for the purposes of research or any other purposes, including in private sector institutions, or before shipping RPV-containing materials to other institutes.
- 2.1.12 When FAO and the OIE decide to carry out an audit or site inspection the rinderpest holding facility shall fully cooperate and provide all the relevant reports and information.

[For category B:]

- 2.1.13. To retain an up-to-date inventory of *vaccine* stocks including current and expired vaccines and any materials solely for vaccine production and to share such information with FAO and the OIE through the designated rinderpest database.
- 2.1.14. To validate or destroy stocks of expired vaccines.
- 2.1.15. To regularly test the quality of the vaccines in accordance with the OIE guidelines.
- 2.1.16. To maintain and follow procedures approved by FAO and the OIE for managing *vaccine* stocks (storing packaged and manufactured vaccine).
- 2.1.17. To contribute, when requested by FAO and the OIE, to the global rinderpest vaccine bank and preparedness strategy, including through the emergency manufacture and preparation of vaccines in accordance with OIE standards.
- 2.1.18. To accept vaccine virus seeds or stocks from FAO and OIE Member Countries for safe storage and/or for destruction.
- 2.1.19. To notify FAO and the OIE before receiving RPV-containing material from other institutes for FAO to assist in shipping if needed and to ensure the chain of custody.

- 2.1.20. To provide vaccine virus seeds or vaccines to other institutes (public or private sector) for the research or vaccine manufacture that has been approved by FAO and the OIE.
- 2.1.21. To send an annual report to the OIE and FAO.
- 2.1.22. To maintain a system of quality assurance, biosafety and biosecurity.
- 2.1.23. When FAO and the OIE decide to carry out an audit or site inspection the rinderpest holding facility shall fully cooperate and provide all the relevant reports and information.

3. Site inspection

If FAO and OIE decide to carry out a site inspection during the period of designation, the FAO-OIE Rinderpest Holding Facility shall fully cooperate and provide all relevant records and information.

4 Reporting

- 4.1 The FAO-OIE Rinderpest Holding Facility shall submit to FAO (GRPP-secretariat@fao.org) and OIE (rinderpest@oie.int) an annual report on the inventory and status of the rinderpest stocks, covering the previous calendar year, by *{the end of January}*.
- 4.2 The first report shall be submitted no later than 12 months after the entrance into effect of this designation.

5 Financial implications for FAO and OIE

This designation does not entail any financial implications on the part of FAO or OIE.

6 Use of the Names, Emblems and other Logos of FAO and OIE

- 6.1 The *{name of institute}* may use the title of “FAO-OIE Rinderpest Holding Facility” in the conduct of official business, including when participating in activities in such capacity. The FAO-OIE Rinderpest Holding Facility may use the name, emblem and other logos of FAO and OIE in its paper documentation and electronic means of communication, in particular on its website, under the conditions set forth below and only during the period when the designation as FAO-OIE Rinderpest Holding Facility remains valid.
- 6.2 The name, emblem and other logos of FAO and OIE are to be used by the FAO-OIE Rinderpest Holding Facility solely for correspondence related to its activities as FAO-OIE Rinderpest Holding Facility.
- 6.3 If the name, emblem and other logos of FAO and OIE are used in the letterhead or the facility’s website, their size should be smaller than the size of those of the institute.
- 6.4 Any document issued by the facility mentioning “FAO-OIE Rinderpest Holding Facility” shall include a reference to this letter of designation by FAO and OIE.

- 6.5 If the language used by the FAO-OIE Rinderpest Holding Facility in its communications is a language other than Arabic, Chinese, English, French, Russian or Spanish, one of the latter should also be included.
- 6.6 All other uses of the name, emblem and other logos of FAO and OIE require the prior written approval of FAO and OIE.

7 Intellectual Property Rights

All intellectual property rights shall normally remain with the originating Party. In the event that the Parties wish to depart from the normal practice, different clauses on intellectual property rights, such as joint property rights or the granting of specific licenses, will be agreed in writing on a case by case basis.

8 Confidentiality

None of the Parties nor their personnel shall communicate to any other person or entity any confidential information made known to it by the other Party in the course of the performance of the work under this letter of designation, nor shall they use this information to private or corporate/industry advantage. This provision shall survive the expiration or termination of the letter of designation.

9 Privileges and Immunities of FAO and OIE

Nothing in this letter of designation or in any document relating thereto, shall be construed as constituting a waiver of the privileges and immunities of the Food and Agriculture Organization of the United Nations (FAO) or of the World Organization for Animal Health (OIE), nor as conferring any of their privileges or immunities to the FAO-OIE Rinderpest Holding Facility, or its personnel.

10 Applicable Law

This letter of designation and any dispute arising there from shall be governed by general principles of law, to the exclusion of any single national system of law.

11 Settlement of Disputes

- 11.1 Any dispute between two or more Parties concerning the interpretation and the execution of this letter of designation, or any document or arrangement relating thereto, shall be settled by negotiation between them. If the dispute is not settled by negotiation, it shall, at the request of one of the Parties, be submitted to one conciliator. Should the Parties fail to reach agreement on the name of a sole conciliator, each party shall appoint one conciliator. The conciliation shall be carried out in accordance with the Conciliation Rules of the United Nations Commission on International Trade Law, as at present in force.
- 11.2 Any dispute between the Parties that is unresolved after conciliation shall, at the request of one or more Parties, be settled by arbitration in accordance with the Arbitration Rules of the United Nations Commission on International Trade Law, as at present in force.
- 11.3 The conciliation or the arbitration proceedings shall be conducted in the language in which this letter of designation was drafted.
- 11.4 The Parties may request conciliation during the execution of this letter of designation and anyway not later than twelve months after the expiry or the termination of this letter of designation. The Parties may request arbitration not later than ninety days after the

termination of the conciliation proceedings.

- 11.5 Any arbitration award rendered in accordance with the provisions of this paragraph shall be final and binding on the Parties.

12 Period of Designation

The designation as a FAO-OIE Rinderpest Holding Facility shall come into effect upon acceptance of these terms and conditions. The designation shall remain in effect for a period of three years. The designation may be extended by FAO and OIE beyond such period upon positive review, as described below.

13 Review and Renewal of Designation

- 13.1. Before the end of the three-year period, the collaboration shall be subject to a review between FAO, OIE and the FAO-OIE Rinderpest Holding Facility. The review shall be based on the degree of implementation or compliance with the “Mandate” (paragraph 2). Due consideration shall be given to the annual reports submitted by the FAO-OIE Rinderpest Holding Facility.
- 13.2. Upon positive review, the designation as FAO-OIE Rinderpest Holding Facility may be renewed for a specified period of time.
- 13.3. If interested in a renewal of the designation, the FAO-OIE Rinderpest Holding Facility should contact FAO (GRPP-secretariat@fao.org) and OIE (rinderpest@oie.int) not less than six months before the expiry date of this letter of designation.

14 Termination

- 14.1. This Agreement, and consequently the designation as FAO-OIE Rinderpest Holding Facility, may be terminated by any Party upon thirty days written notice to the other Parties. The Party giving notice shall not be required to provide reasons for termination.
 - 14.2. In the event of termination, the Parties shall agree on measures required for the orderly conclusion of ongoing activities.
-

CRITERIA FOR ASSESSING APPLICATIONS FOR RESEARCH INVOLVING RINDERPEST VIRUS

Background

1. The World Assembly of the OIE Delegates at the 79th General Session (May 2011) and the 37th FAO Conference (June 2011) declared the world free from rinderpest infection. The OIE Resolution No. 18 (Appendix 1) adopted by the World Assembly requested the Director General of the OIE to establish, jointly with FAO, an advisory body that assists both organizations in (i) the approval of facilities for holding rinderpest virus-containing material and of facilities that produce and/or hold rinderpest vaccines, (ii) the approval of requests for research and other manipulations of the rinderpest virus, (iii) reviewing the plans and results of regular site visits of virus repositories, and (iv) planning and implementing other rinderpest-related activities as required ; and to ensure that Member Countries are informed of the status of rinderpest virus sequestration and research involving rinderpest virus. The same Resolution urged Member Countries to destroy, under the supervision of the Veterinary Authority, rinderpest virus-containing materials or assure the storage or use of these materials in a biosecure facility in their country or, where applicable, assure the safe transfer to an approved laboratory in another country in agreement with the Veterinary Authority of the receiving country and complying with the standards of the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* and the Guidelines elaborated by the Joint FAO/OIE Committee on Global Rinderpest Eradication (Appendix 2).
2. In accordance with the above Resolutions, FAO and the OIE established the Joint FAO/OIE Rinderpest Advisory Committee (JAC) in June 2012.
3. Now that rinderpest virus (RPV) infection has been eradicated, herd immunity to RPV is absent and there is potential for rapid spread of infection from an index case. Extensive surveillance has demonstrated no evidence of wildlife reservoirs for RPV and the most likely source for re-introduction of the infection is perceived to be accidental release from a laboratory. The most likely sequence of events leading to such a release would involve laboratory use of rinderpest virus containing materials (RVCM).
4. In accordance with OIE Resolution No. 18 (May 2011)¹ ‘*Declaration of global eradication of rinderpest and implementation of follow-up measures to maintain world freedom from rinderpest*’ Rinderpest virus (RPV) containing material (RVCM) is defined as field and laboratory strains of RPV; vaccine strains of RPV including valid and expired vaccine stocks; tissues, sera and other clinical material from infected or suspect *animals*; and diagnostic material containing or encoding live virus. Recombinant morbilliviruses (segmented or non-segmented) containing unique rinderpest virus nucleic acid or amino acid sequences are considered to be rinderpest virus. Full length genomic material including virus RNA and cDNA copies of virus RNA is considered to be RVCM. Sub-genomic

¹ http://www.oie.int/fileadmin/Home/eng/Media_Center/docs/pdf/RESO_18_EN.pdf

fragments of morbillivirus nucleic acid that are not capable of being incorporated in a replicating morbillivirus or morbillivirus-like virus are not considered as RVCM.

5. FAO and OIE jointly regulate all use and storage of RVCM, and its use requires prior permission of the two organizations. The only purposes for which use of RVCM can be approved are those which offer clearly defined significant scientific benefits as described below. Although all research using RVCM should be discouraged, this document will serve the JAC as a basis for advising OIE and FAO on evaluation of applications for research involving manipulation of rinderpest virus. The JAC shall have due regard to the justification for the research and to the undertaking that the research, if approved, will be conducted safely and securely without risk to global rinderpest freedom status. The JAC may propose modifications to the proposed research plan and/or attach conditions that are deemed necessary. If the JAC concludes that the proposed research is not justified, or cannot/will not be undertaken with due regard to biosafety and biosecurity, it may recommend approval be withheld.
 6. This document is also shared with FAO/OIE approved repositories for RVCM and interested research facilities proposing essential research.
-

CRITERIA TO CONSIDER WHEN REVIEWING RESEARCH PROPOSALS INVOLVING THE MANIPULATION OF RINDERPEST VIRUS

Consideration of the research proposal should account for benevolent scientific intent and benefits that the proposed research is expected to yield, weighed against the risks that the research may pose for rinderpest reoccurrence (risk-benefit ratio). In general, the following criteria are meant to be used taking into account an overall balance, rather than a single criterion being considered in an absolute manner.

Objectives of the research proposal should meet one or more of the following criteria:

1) Food security

Outputs or impacts of the research aim to protect or improve food security for local and worldwide populations.

2) Sustaining effective and efficient global freedom from rinderpest

Outputs of the research would contribute to effective and efficient safe storage of remaining rinderpest virus stocks; destruction and sequestration of remaining stocks of rinderpest virus; early detection of rinderpest virus infection, and /or cost-effective disease control measures should there be a reoccurrence of rinderpest. Such research may inform global contingency plans.

3) Significant scientific benefits for public health or animal health

Outputs or impacts of the research would provide significant scientific benefits for public health or animal health.

Review of research proposals should account for the following factors:

- The intent of the research meets one or more of the objectives above
- The overall scientific and technical merits of the proposal and methodology are valid and feasible
- Whether the use of RVCN is essential for the research
- The research addresses an issue of significance to the post eradication era which has not adequately been addressed before and is timely to address it now
- Adequate biosecurity and biosafety measures to prevent accidental or deliberate release of RPV would be in place
- Appropriate animal welfare standards are ensured for all animals used in the research
- Potential for malign use of the research outputs has been considered
- Principal investigators' knowledge, capabilities, related experience, past performance and qualifications are relevant to the proposal