

# **Sixth Meeting**

## **FAO-OIE Rinderpest Joint Advisory Committee**

OIE Headquarters, Paris, France

12-13 November 2014

### **1. Opening**

The Chairman welcomed the Committee members, thanked them for their commitment, and for their contributions to post rinderpest activities since June 2012; he also welcomed two observers to the meeting, one from FAO and one from the OIE.

The OIE representative:

On behalf of the Director General of the OIE, Dr Dietrich Rassow (Veterinary advisor to the Scientific and Technical Department) welcomed the Committee and remarked on the advanced collaboration of committee members in dealing with challenges in post eradication activities. He mentioned that the issue of rinderpest vaccines and virus stored in laboratories elicited attention during the recent OIE General Session and acknowledged that the Committee had focused on their core tasks, which the OIE appreciated. He finished by wishing them a productive meeting.

FAO representative:

The FAO co-secretariat welcomed the Committee members on behalf of the FAO. It was noted that the Committee is near reaching their first three-year term and their contribution to the task put forward has been valuable. FAO understands the big challenge put before the Committee in advising both organizations particularly in approving rinderpest holding facilities and research proposals. FAO would like the Committee to come up with the work plan and setup the priorities for the next three-year term.

Remarks by the Committee:

The Chairman highlighted the progress which had been made, noting that since the previous meeting, the OIE and FAO had reached the point of inspecting rinderpest holding facilities (the final step in the approval process). The Committee had produced technical documents and guidelines as well as having advised FAO and the OIE on key rinderpest matters. The importance of completing the site inspections before April 2015 was reiterated, and the joint secretariat's support and the progress made in facilitating site inspections with expert teams and institute managers was also acknowledged.

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

The provisional agenda was discussed and rearranged to ensure a better flow of activities; the amended agenda was proposed by the Chairman and the Committee adopted the agenda (Annex 1).

The report of the previous meeting had been adopted by email exchange and had been made available on the FAO and the OIE websites.

Previous minutes were adopted, and the action items discussed. Notable actions which had taken place included:

- The Committee drafted a procedure to enable safe transfer of rinderpest vaccine seed material and manufactured vaccines outside of the biocontainment for storage in a biosafety level two (BSL2) laboratory. The document needed some refinement since more information had become available.
- The OIE had requested permission from their Member Countries to share data with FAO from the first official rinderpest report (2013). Only four Member Countries had not responded to the request; OIE would follow-up with them. The information from consenting countries would be shared with the FAO once the proposed confidentiality agreement between the two organisations had been finalised and signed
- All outstanding issues from rinderpest holding facility applications reviewed at the previous meeting had been resolved by email exchange between the applicant facilities, the Secretariat, and the Committee.

## **3. Site inspections**

The Committee had developed a checklist for site inspections of applicant rinderpest holding facilities and discussed how to improve the format so that it could be used in the evaluation process by both the applicant facility and the inspection team. The Committee recommended including the following additional material in the pre-inspection documents - a questions and answers document for the inspection team, a confidentiality agreement, and the mandate for rinderpest holding facilities. The Committee suggested that the secretariat provide the inspection team with complete documentation in advance of the inspection and follow up with a conference call to ensure that all members are well informed about the process and objectives of the mission, their responsibilities and to respond to any questions they may have.

The Committee reviewed the format of the report and agreed on its outline. It was also recommended that the report reflect a qualitative assessment by consensus.

It was agreed that the inspection team should share the findings of the evaluation with facility management at the conclusion of the inspection, discuss nonconformities and then agree on a deadline for any corrective actions. The committee agreed that

open publication of inspection findings, including the Executive Summary, should be by agreement between FAO, OIE, and the facility.

The secretariat presented an update on the preliminary timeframe for inspections; visits to AU-PANVAC, Ethiopia and two facilities in Japan were scheduled for January 2015, a USA facility in February 2015 and a United Kingdom facility in March 2015. The Committee wished to be kept informed about progress in finalising the site inspections and on the composition of expert teams. The Committee also offered to assist FAO and the OIE with additional support or advice for the inspections if it was needed.

**Action 1:** The Committee would finalise the checklist for site inspections by email and the secretariat would make it available to the facility and inspection team in preparation for the first inspections in January 2015.

#### **4. Review FAO-OIE rinderpest holding facility application for CIRAD (France)**

The Committee had received a completed application for rinderpest holding facility status from CIRAD (France) in advance of the meeting.

This application was for a category (A) facility:

***Rinderpest virus holding facilities for storing rinderpest virus containing material, excluding vaccine stocks***

During the review of the application, the committee member from CIRAD recused herself from the discussion.

Upon review of the application, the Committee acknowledged the completeness of the dossier and further discussed information about the contingency plan, the Laboratory Information Management System (LIMS) and validity of the current accreditation license of biocontainment to ensure compliance with the requirements in the application form. The Committee concluded that the information was acceptable, with further written clarification on one point in the application form (verbal clarification had been provided in the meeting), and recommended that the dossier move forward in the application process (a site inspection of the facility).

#### **5. Updates on the official Member Country rinderpest reports to OIE**

##### **5.1 Results of Member Countries official reports to the OIE**

The OIE presented an update on the first official OIE rinderpest report (2013). It was highlighted that, as of November 2014, 94% of OIE Member Countries had responded by completing the electronic rinderpest questionnaire, and only 11 countries had not responded. Most importantly, 23 countries reported to still hold some form of rinderpest virus-containing material including manufactured vaccine stocks. All the results had been individually verified with countries to ensure

accuracy. It was noted that fewer facilities had reported to hold rinderpest virus in the OIE survey (2013) when compared with a previous survey conducted by FAO and the Royal Veterinary College (UK) in 2011, which might suggest that some of the rinderpest virus stocks had been destroyed. It was also acknowledged that there may be under-reporting in some countries whose veterinary services may not be aware of stocks stored in unknown localities in their country.

## **5.2 Research projects**

On the approved rinderpest research projects, the Committee was informed that OIE had secured funding for the two projects which had previously been approved. The peste des petits ruminants (PPR) vaccine research project **“Testing the potential for protecting cattle against rinderpest using attenuated PPR virus vaccine”** was due to start in April 2015 once the animal facility in the new Pirbright Institute was up and running. The second proposal for *sequencing and destruction of rinderpest virus* by Pirbright Institute (UK) had been approved at the Committee meeting in February 2014. OIE had since received donor support for sequence and destruction of rinderpest virus and would put out a call for proposals to facilities which may be eligible for funding. However any manipulation of rinderpest virus must first be approved by FAO and OIE, with advice from the Committee.

## **5.3. Resolution passed at OIE General Session**

The Committee was informed about the adoption of OIE Resolution 23 at the 82<sup>nd</sup> OIE General Session in May 2014. This resolution on the **“Procedure for the Designation of Facilities Holding Rinderpest Virus Containing Material to maintain Global Freedom from Rinderpest”** endorsed the legal mandate describing the requirements of the two categories of Rinderpest Holding Facility:

- A) Rinderpest Holding Facility for storing rinderpest virus containing material, excluding vaccine stocks
- B) Rinderpest Vaccine Holding Facility for storing only manufactured vaccines, vaccine stocks and material solely for their production

## **6. Updates on virus sequestration and FAO projects**

### **6.1 Virus sequestration**

The Committee was informed on progress made on transfer of rinderpest vaccine seed stocks from Botswana Vaccine Institute (BVI) to PANVAC for safe storage (sequestering). FAO has been working closely with the two institutes to facilitate the process, agreement on the procedures and the material transfer agreement (MTA). The Committee has been kept informed and advised on the number of samples to be stored. BVI voluntarily destroyed the majority of their stocks and

provided documentation to FAO as proof of destruction; this was kept as a record and was shared with the Committee and the OIE. BVI and PANVAC have agreed on the number of the vaccine virus stocks to be transferred and would ship the materials in two separate shipments to ensure its safe arrival. FAO would support the cost of shipment once the MTA was finalized and would publish a press release on this initiative.

Additionally, a Scopus literature search was conducted by FAO to hone down on the possible whereabouts of rinderpest virus kept outside of government entities. The search retrieved a total of 941 documents pertaining to rinderpest virus and approximately 40 institutions were affiliated with the research in question. Twenty two institutions in 12 countries were found to be affiliated with publications using rinderpest virus and 15 institutions were excluded from the collated list as they were already known to possess rinderpest virus containing material or had confirmed the destruction of their stock. The list of these institutions will be included on the advocacy of virus destruction and sequestration.

## **6.2 Rinderpest vaccine**

To collect the most up-to-date information on rinderpest vaccine, FAO distributed inquiries to 16 of the former vaccine producers to provide the following:

- type of vaccine traditionally produced in the facility;
- the name of vaccine strain(s) used for production;
- whether the vaccine is produced in GMP/GLP facility;
- capacity and scale of production in regards to the number of doses;
- list of vaccine seed strains and an approximate number of vaccine doses currently stored in the facility.

The results showed that eight of the 16 contacted vaccine companies responded to the inquiry. Three of the eight respondents are GMP/GLP-certified. Two of the eight companies acknowledged holding vaccine stock and three acknowledged possession of vaccine seed stock. The production capacity ranged from 60,000 to 4 million doses on a monthly basis.

## **6.3 FAO projects**

FAO was able to secure funding to support rinderpest virus destruction and sequestration; communication and advocacy to maintain vigilance and increase awareness; and disease surveillance for rumour tracking at national, regional and global levels.

## **7. International Preparedness and Response plan**

In response of the Committee's request for the development of an international preparedness and response plan, Dr Ian Douglas (Crisis Management Centre-Animal

Health, FAO) presented a white paper. The proposed basic framework is called; ***an international preparedness plan for an outbreak of rinderpest***. (Annex 3)

The Committee had previously recommended producing a plan of global mitigation and the steps to be taken in the event of a rinderpest virus leak to the environment and susceptible animal populations in the post-eradication era. The Committee now considered this to be a matter of urgency and was in a position to produce a concept note to support this plan and to participate in the entire process. The process should take into account the existing OIE Terrestrial Animal Health Code (2014), Chapter: 8.14 for an individual country to detect, respond and control the disease and to include the contribution of FAO in the global preparedness for a reoccurrence of rinderpest.

**Action 3.** The Committee would draft a concept note before the end of 2014 to engage with FAO in developing a preparedness and response plan

## **8. Committee achievements and work plan for 2015**

The Committee discussed their achievements since June 2012 in support of post rinderpest eradication activities. It was agreed that a comprehensive document should be compiled to reflect achievements since the appointment of this Committee in June 2012.

The rinderpest roadmap document was updated indicating a list of tasks completed, ongoing and planned for near future. This roadmap document had been used to set milestones and measure accomplishment by FAO, OIE and JAC towards rinderpest post eradication initiatives.

**Action 4.** The joint Secretariat to compile evidence from previous reports to prepare a complete list to share by email communication

## **9. Next Meeting**

It was proposed that the next meeting of the rinderpest Joint Advisory Committee meeting be tentatively scheduled 17-18 March 2015 in Rome.



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## 6<sup>TH</sup> MEETING, RINDERPEST JOINT ADVISORY COMMITTEE Paris, 12-13 November 2014

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### Agenda

1. **09h00:** Welcoming and Introduction
2. Review of previous meeting minutes (already adopted)
  - 2.1. Action items from last meeting
  - 2.2. Adoption of agenda
3. Site inspections:
  - 3.1. Finalise checklist for site inspections
  - 3.2. Q & A's to inform expert teams
  - 3.3. Format of report for site inspections
  - 3.4. Inspections of facilities in Japan, Ethiopia, UK and US
4. Review CIRAD application for Rinderpest Holding Facility
5. Updates on:
  - 5.1. Results of official Member Country reports to OIE
  - 5.2. Research projects
  - 5.3. OIE Resolution passed at General Session
6. Updates by FAO on:
  - 6.1. Virus sequestration Vaccine issues
  - 6.2. FAO projects
7. International Preparedness and Response plan
8. JAC achievements and work plan for 2015-16
9. **13h00:** Meeting summary
  - 9.1. Dates for next meeting

## **Working documents:**

1. Meeting agenda
2. Report of 5<sup>th</sup> joint advisory committee meeting
3. Application for rinderpest holding facility
4. Q & A – Rinderpest inspections
5. Checklist for site inspections
6. An International preparedness plan for an outbreak of rinderpest
7. Operational guidance for site inspections to approve FAO-OIE Rinderpest Holding Facilities

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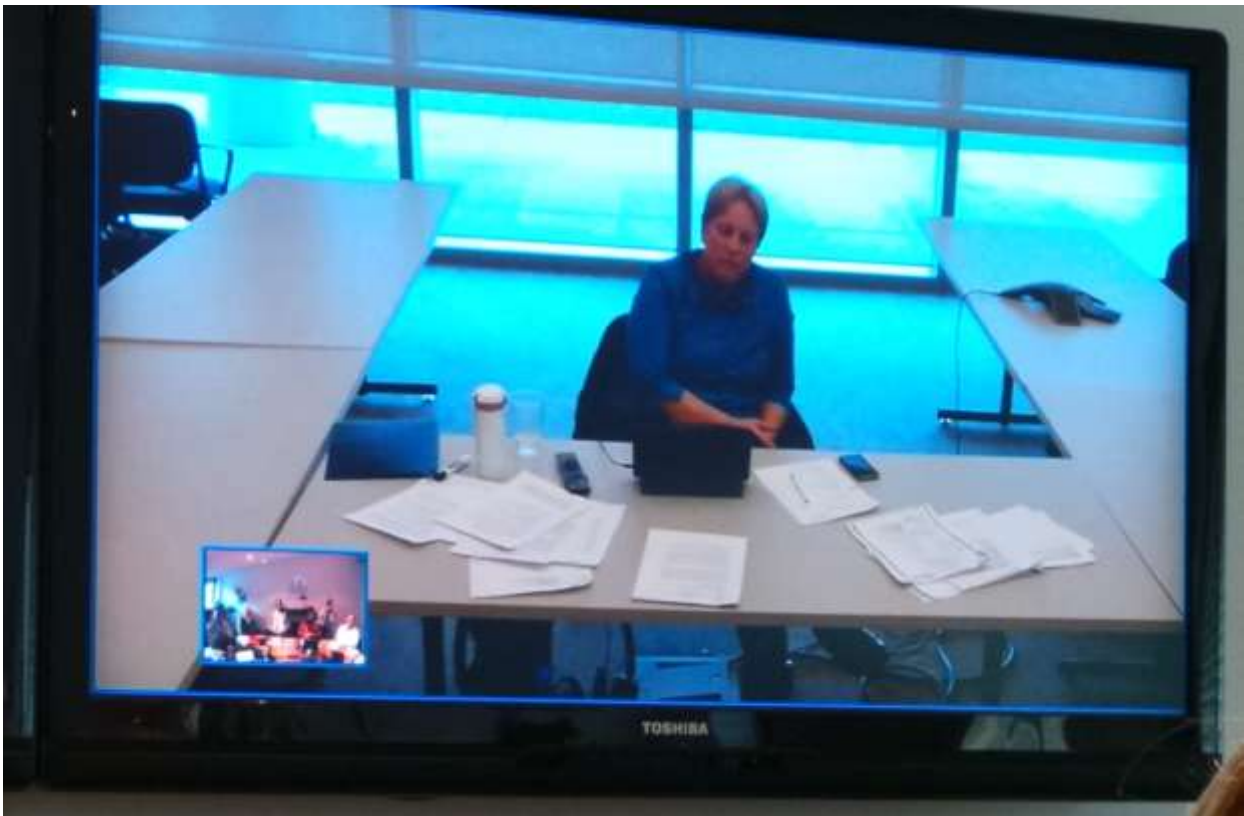
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RESOLUTION No. 23

**Procedure for the Designation of Facilities Holding Rinderpest Virus Containing Material to Maintain Global Freedom from Rinderpest**

ACKNOWLEDGING the declaration of global freedom from rinderpest in May 2011 and the commitment made by Member Countries to maintaining this status,

CONSIDERING OIE Resolution No.18 (2011) requesting the Director General of the OIE to approve facilities in which rinderpest virus-containing material can be held, and to conduct regular site visits to those facilities to verify whether their biosafety/biosecurity conditions are adequate,

REITERATING the importance of reducing the number of existing rinderpest virus stocks through the destruction of virus in a safe manner and/or the transfer of virus stocks to internationally recognised reference institutions,

THE ASSEMBLY

1. REAFFIRMS its commitment to reducing, around the world, the number of institutions holding rinderpest virus-containing material under approved conditions and according to relevant guidelines.
2. URGES the Member Countries to:
  - Approve the Mandate for facilities in which rinderpest virus containing material can be held (hereinafter ‘Rinderpest Holding Facilities’) (Appendix 1) to ensure that they support efforts to maintain global freedom from rinderpest,
  - Agree to approve a required minimum number of Rinderpest Holding Facilities. With approval of each facility being based on information provided by the FAO-OIE rinderpest joint advisory committee’s review of the application, a site inspection (where appropriate), and advice from both the Director General, the Council of the OIE and the FAO Governing body,
  - Ensure that remaining stocks of rinderpest virus containing material are transferred safely to one of the Rinderpest Holding Facilities if they are not destroyed.
3. REQUESTS the Director General:
  - Put in place, jointly with FAO, a system to monitor and evaluate approved Rinderpest Holding Facilities and, when not compliant with the Mandate, to temporally or permanently remove their approved status according to the seriousness of the non-compliance,
  - Put in place, jointly with FAO, a mechanism for tracking stocks of rinderpest virus containing material within and between approved Rinderpest Holding Facilities.

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(Adopted by the World Assembly of Delegates of the OIE on 27 May 2014)

**MANDATE FOR A FACILITY HOLDING  
RINDERPEST VIRUS CONTAINING MATERIAL**

The facilities in which rinderpest virus (RPV)-containing material<sup>1</sup> can be held (hereinafter 'Rinderpest Holding Facilities') should have a mandate which justifies their function and ensures safe storage of this material.

The Rinderpest Holding Facility has a separate mandate and approval mechanism from an OIE Reference Laboratory for rinderpest and an FAO Reference Centre for morbillivirus.

Although the decision to designate a Rinderpest Holding Facility lies with the OIE World Assembly of Delegates, the OIE Delegate must support the application and be fully aware of the Mandate.

The following text describes the Mandates of the two categories of Rinderpest Holding Facility:

- A) Rinderpest Holding Facility for storing rinderpest virus containing material, excluding vaccine stocks
  - B) Rinderpest Vaccine Holding Facility for storing only manufactured vaccines, vaccine stocks and material solely for their production.
- A) Rinderpest virus holding facilities for storing rinderpest virus containing material, excluding vaccine stocks:**
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. To accept RPV-containing material from FAO and OIE Member Countries for safe storage and/or for destruction.
  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.
  4. To provide RPV-containing material to other institutes for the research or vaccine manufacture that has been approved by FAO and the OIE.

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<sup>1</sup> *Rinderpest virus-containing material* means field and laboratory strains of rinderpest virus; vaccine strains of rinderpest virus 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 *rinderpest virus-containing material*. Sub-genomic fragments of morbillivirus nucleic acid that are not capable of being incorporated in a replicating morbillivirus or morbillivirus-like virus are not considered as *rinderpest virus-containing material*.

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.
6. To send an annual report to the OIE and FAO
7. To maintain a system of quality assurance, biosafety and biosecurity.
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.
9. To participate in scientific meetings in its capacity as FAO-OIE Rinderpest Holding Facility and using that title.
10. To establish and maintain a network with other Rinderpest Holding Facilities.
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.
12. When FAO and the OIE carry out an audit or site inspection the rinderpest holding facility shall fully cooperate and provide all the relevant reports and information.

**B) Rinderpest Vaccine Holding Facility for storing only manufactured vaccines, vaccine stocks and material solely for their production:**

1. 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. To validate or destroy stocks of expired vaccines.
3. To regularly test the quality of the vaccines in accordance with the OIE guidelines.
4. To maintain and follow procedures approved by FAO and the OIE for managing vaccine stocks (storing packaged and manufactured vaccine).
5. 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.
6. To accept vaccine virus seeds or stocks from FAO and OIE Member Countries for safe storage and/or for destruction.
7. 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.
8. 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.
9. To send an annual report to the OIE and FAO.
10. To maintain a system of quality assurance, biosafety and biosecurity.
11. When FAO and the OIE carry out an audit or site inspection the rinderpest holding facility shall fully cooperate and provide all the relevant reports and information.

## **An international preparedness plan for an outbreak of rinderpest**

### **Rationale:**

Prior to global eradication, an outbreak of rinderpest may have been considered to be primarily a concern for the country affected. Given the global free status, an outbreak is now a matter for the globe.

While the “host” country maintains its sovereignty to manage the outbreak, it may now be more dependent than previously on:

- Access to diagnostic capability (both in terms of recognition in the field and laboratory analysis);
- Access to vaccines of adequately quality in sufficient quantity;
- Access to resources that can be directed to eradication, including personnel, funds, equipment and supplies.

While the disease may be recognized in a single country, it may be first seen in multiple countries, and countries at risk may be demanding of the same resources as the infected country(ies). This raises the issue of the allocation of scarce resources.

While one imperative is to store rinderpest virus safely, another is to minimize the number of countries that seek to store it. In order to give up virus stocks, high level decisions are going to be required (likely above that of the Chief Veterinary Officer). The decision-maker is likely wishing to have some assurance that:

- If the worst happens and the disease occurs, this country can depend on the international community to provide a diagnostic service and vaccines that are needed but have been surrendered?
- Can this country be certain that it will be treated in an even-handed manner compared to other countries which may have similar needs?
- What is going to be expected of this country by the international community?
- Who is going to be deciding all of this and what is the decision-making process?

### **Planning:**

A plan achieves a number of related outcomes:

1. It causes a process to occur to create and update the plan that necessarily brings together the stakeholders and obtains commitments;
2. It causes resources to be applied to provide solutions to problems that have not yet occurred;
3. It records the outcomes of the deliberations;

4. It expresses the “who”, “what”, “how”, “why”, “when” of the actions decided upon;
5. It provides clarity to those who are affected by the plan, in advance;
6. It provides a strong guide as to the best approach used.

#### **Options if the worst happens:**

- The host country can be left to address the problem and could appeal to laboratories that hold the vital virus-based supplies.
- The international community including FAO, OIE (advised by JAC), large countries, holding laboratories etc., can come together and consider what might be done. FAO/OIE would likely provide leadership and support but not much vaccine, diagnostic capability or financial resources.
- The international community can react by implementing a plan that it has developed for this very purpose, and that has been agreed at a moment in history and is revisited on a regular basis.

#### **Issues to be addressed by an international plan:**

- Differing levels of preparedness for different levels of risk.
- The plan should address what is to be done before an outbreak (international preparedness plan) as well as what is to be done after an outbreak (international contingency plan).
- Who decides how the country’s prevention, detection and response and recovery efforts are supported?
- If this is to be left to whoever comes forward first, will there be delay while various providers wait for one another to step up?
- Will the international community leave this up to OIE/FAO? What limitations will it place on OIE/FAO?
- Given that FAO/OIE do not hold the scarce resources, how can their decisions be put into effect?
- What items will be kept in an international stockpile (vaccines, cold-chain equipment, cleaning and disinfection etc.)?
- Will some form of representative council decide? How is this represented? Will each holder of the scarce resources be bound by the decisions made?
- How long is it acceptable to deal with the problem? Is depopulation required or can the disease be eradicated using approaches used prior to freedom being declared?
- How will the eradication effort be financed? It would seem un-reasonable to establish a reserve fund that may never be used, but can (some) countries agree on a cost-sharing formula and limits to expenditure in that mode? Can those countries obtain the funds required, at short notice, and outside of the normal budget cycle?
- What if this does not occur for decades? Where will the expertise and resources be obtained from then?

## **Summary:**

- Rinderpest represents a different type of threat now that it has been eradicated.
- The risk of an outbreak in the future (perhaps decades into the future when expertise and experience has evaporated) is greater than zero.
- Some countries may need surety now, to be encouraged to find and surrender or destroy virus stocks.
- This disease is eradicable but costs will be less if it is detected and eradicated without delay.
- Failure to plan now, and to establish an international agreement, might be soundly criticized in the future.
- The establishment of a plan requires work and cannot be undertaken by a single organization/country – long-term (3-5 years) engagement is key.