Food and Agriculture Organization of the United Nations

WORLD ORGANISATION FOR ANIMAL HEALTH
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Receiving of Rinderpest Materials

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Section

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1. Purpose

The purpose of this document is to define how rinderpest virus (RPV) and material likely or suspected to contain RPV (Rinderpest Virus Containing Material or RVCM) must be received at an FAO/OIE approved institution. It is the responsibility of both staff and management to ensure that the RVCM is received securely under conditions that minimize the risk of accidental release of RPV. For the purpose of this document RVCM shall mean rinderpest virus or any material reasonably expected to contain rinderpest virus.

2. Background

RPV is a negative-sense RNA genome virus of the morbillivirus family. It is the causative agent of rinderpest, a fatal disease of cattle capable of devastating epidemic spread. The incubation period ranges from 5 – 11 days and the disease is characterized by pyrexia, nasal and ocular discharges and necrosis and erosion of the nasal and oral mucosae. Animals develop diarrhoea, and death generally occurs between 7 and 12 days after onset of symptoms. RPV has poor environmental stability and is sensitive to inactivation by heat, desiccation and exposure to sunlight. The last confirmed case of rinderpest was in Kenya in 2001, and the world was declared free from rinderpest by the OIE and by FAO in 2011. Interruption of the chain of virus transmission was achieved by a global eradication programme coordinated by the UN Food and Agriculture Organization (FAO). The vaccine used against rinderpest is a live attenuated strain of RPV, and, despite its safe prolonged and widespread use, the possibility of reversion to virulence means that it must be handled under the same regulatory constraints as virulent strains in the post-eradication era.

The cost and effort of eradication, and the global emergency and severe consequences that are likely to accompany a re-emergence or release dictate that the containment procedures for handling, packaging and shipping RVCM must be enhanced in the post-eradication era. RVCM excluding vaccine virus must now be handled and held in BSL3 conditions. RVCM that comprises vaccine stocks or vaccine seeds or other RVCM maintained solely for vaccine production can be held in secure facilities lower than BSL3.

Vaccine stocks must be maintained until all RPV has been destroyed or gathered into internationally regulated repositories. However, the possibility of cross-contamination of vaccine stocks or seed-stocks with virulent virus dictate that vaccine and non-vaccine RVCM should be stored, handled and shipped separately.

RPV is non-infectious for humans and poses no direct hazard to human health. Containment and handling regulations are to prevent the accidental transport and introduction of the virus to susceptible animals.

RPV is classified by the UN as Dangerous Goods. It is a category A material: “An infectious substance which is transported in a form that, when exposure to it occurs, is

capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals".

RPV is assigned to United Nations number UN2900 and for packaging and shipping purposes should be described and labeled as "INFECTIOUS SUBSTANCE AFFECTING ANIMALS ONLY"

Carriage of RVCM by hand in airplanes, or in diplomatic pouches is not permitted under international regulations.

RVCM must not be shipped in a consolidated package with any non-RVCM material. In addition the vaccine strain of RPV may not be shipped in a consolidated package with any non-vaccine RVCM

3. Training

Training is the responsibility of the receiving institution. Persons involved in the receipt of RVCM must be appropriately trained to deal with an accidental release occurring prior to the RVCM entering the secure laboratory and/or, for non-vaccine material, the Biosafety Level 3 (BSL3) laboratory. Persons entering the BSL3 laboratory must be appropriately trained to handle risk group 3 pathogens.

4. Packaging

All RVCM arriving at the institution must be shipped in triple layer packaging.

The primary container, which will hold the RVCM, must be a sealed, watertight leak-proof vessel such as an ampoule. It should preferably be made from polypropylene, with a polypropylene screw-cap with an internal o-ring seal. The primary container must have been surface decontaminated prior to packaging within the secondary container. Vaccine or vaccine seed RPV will probably be in freeze-dried form either in stoppered vials or heat sealed glass ampoules and should be treated as above for wet frozen RVCM.

The secondary container must be a robust sealed, watertight, leak-proof vessel, supplied as part of a commercial shipping container that meets UN, IATA (International Air Transport Association) and ICAO (International Civil Aviation Organization) requirements for shipping category-A dangerous goods. More than one primary container may be packaged in the same secondary container, as long as all primary containers contain RVCM, and vaccine and non-vaccine RVCM are not included in the same package. Sufficient absorbent material must be included in the secondary package to cushion the primary container(s) and to absorb all fluid in case of leakage.

The outer container must be a commercial shipping container that meets UN, IATA and ICAO requirements for shipping category-A dangerous goods. The secondary container

is placed in the outer container with appropriate cushioning material, an itemized inventory of the package and a material safety data sheet (MSDS) for RPV.

The packaging must meet United Nations class 6.2 specifications and the outer packaging must bear the United Nations packaging specification marking (Figure 1). When the above instructions are followed the package will comply with UN Packing Instruction P620.

5. Pre-agreement for shipping

The receiving institution must have the status of Rinderpest Holding Facility (OIE Resolution No. 23, 2014), and valid transfer documentation, to receive RCVM. Prior to shipping any RVCM permission from the Chief Executive or Director of the receiving institution must have been obtained. The Chief Executive/Director or his nominee will name staff members to receive a specific shipment of RVCM.

Prior to shipping, the Chief Executive or his nominee must have received an inventory spread sheet from the sender. This inventory spreadsheet must be used to tally the received RVCM.

6. Refrigerants

Preferably, RVCM will be shipped in freeze-dried form which does not require refrigeration. If refrigeration is required the only refrigerant that may be used is frozen carbon dioxide (dry ice). Wet ice and liquid nitrogen must not be used. Where dry ice is used as a refrigerant it must be placed outside the secondary container. Dry ice must not be placed inside the primary or secondary receptacle because they are sealed and expansion of carbon dioxide to the gas phase as it warms presents a risk of explosion in a sealed container. The outer packaging which contains the dry ice must permit the release of carbon dioxide gas to prevent explosions. The above instructions are in accordance with UN Packing Instruction P003.

If dry ice is used to ship infectious substances in Category A, the details shall appear on the shipper's Declaration for Dangerous Goods. In addition, the outermost packaging must carry the hazard label for dry ice.

7. Shipping

All shipping material should be accompanied with the necessary transport documents (i.e. export permit from sending entity, import permit from the receiving entity).The package will be shipped by international courier, and a tracking number must be sent by the sender to the receiving institution's contact person by phone or email immediately after the package has been given to the courier.

The receiving institution's contact person must track the package online at least once daily until the courier has confirmed arrival at its intended destination airport.

8. Receipt

There is a remote possibility of theft of the RVCM from a courier's vehicle during transport from the airport to the institution. In such a scenario it is unlikely that RVCM will have been deliberately targeted, and unlikely also that perpetrators or members of the public will correctly identify the package as containing a serious animal pathogen. Accordingly, additional security for transport between the airport and institution should be considered.

For non-vaccine material, the package must be taken directly to the BSL3 facility at the institution. Once in the BSL3 facility the package must be handled in accordance with instructions in the appropriate SOP[1]. If the outer packaging is undamaged it must be opened and the secondary container inspected for damage. If the secondary container is undamaged it must be removed from the outer packing and placed in the microbiological safety cabinet (MSC), where the secondary container may be opened. After the secondary container has been removed the outer packaging must be placed in the waste stream for the BSL3 laboratory. If the package contained dry ice as a refrigerant, the outer packaging should be retained as a container for the dry ice until it has evaporated, after which the outer packaging must be placed in the waste stream for the BSL3 laboratory.

After opening the secondary container any absorbent wadding material should be carefully removed and placed in a container for solid waste within the MSC, taking care not to transfer primary containers to the solid waste. Primary containers must be checked off against the inventory spreadsheet supplied by the sender. Without opening them, the primary container(s) must be placed in an individual pre-labelled tube with a cap and transferred to the appropriate freezer for storage.

For vaccine material, the package should be taken directly to the approved facility and handled according to the above procedures for non-vaccine material.

9. Damaged Packaging

The outer packaging must be examined for damage by the institution's contact person before it is removed from the courier's office/depot at the airport. If there is penetrating damage to the outer packaging the outer packing must be wiped down with an appropriate disinfectant and the entire package sealed within a clear plastic bag which must then be sealed within a second clear plastic bag. The packaging labels must be clearly visible through the plastic bags. The courier must be informed of the damage before signing for the package, and a note of the damage must be made on the signed receipt. The Chief Executive must be informed of the damage by telephone, and the package transported immediately to the institution.

For all RVCM, the package must be immediately transferred to the appropriate designated laboratory and the entire package, still in the plastic bags, placed in the MSC. The plastic must be removed and the outer packaging opened. The secondary container must be removed and visually inspected for damage. If the secondary container is undamaged, the outer packaging and plastic bags may be removed from the MSC and placed into the waste stream of the BSL3 laboratory without fumigation, and the secondary container then handled as described in section 8.

If the secondary container is damaged, the outer packaging and plastic bags must remain in the MSC while the primary containers are removed from the secondary container and inspected for damage. If the primary containers are undamaged, they may be transferred to freezer storage as described in section 8, and the outer packaging, plastic bags and secondary container transferred to the waste stream without fumigation.

If one or more primary containers are breached, all the primary containers must be wiped with disinfectant without opening and placed in the solid waste receptacle in the MSC in accordance with the appropriate SOP[1]. The MSC must be immediately prepared for fumigation and fumigated in accordance with the appropriate SOP[1]. Staff may leave the laboratory in accordance with the instructions for dealing with a major spill in the appropriate SOP[1], and the Chief Executive must be immediately informed of the incident. The Chief Executive must immediately contact the country's Chief Veterinary Officer (or equivalent), the Chief Veterinary Officer (or equivalent) in the country of origin of the shipment, the OIE[2], the FAO[3], and the courier and inform all of these of the incident and the measures taken to deal with the package.

When the fumigation cycle of the MSC is complete, all the material must be removed to the waste stream in accordance with the appropriate SOP[1].

10. Records

After the primary containers have been tallied with the inventory supplied by the sender, the primary inventory at the institution should be updated to contain the new samples. Receipt of the samples should be formally confirmed to the sender and to the OIE and FAO.

11. Figures

12. References and notes

[1] Handling, Packaging and Shipping of Rinderpest Virus Containing Materials

[2] The Director General,
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