Biological material packaging and sending of rabies samples for diagnosis suspicion

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ANSES - Nancy Laboratory for Rabies and Wildlife

European Union Reference Laboratory for Rabies

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FOREWORD

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INTRODUCTION

The transport of biological materials within a country and between countries for diagnostics, or research purposes, needs special consideration for safety reason. Biological specimens fall under the Dangerous Goods Regulations since they may contain pathogens. Infectious substances must be classified in Class 6.2. Their transport are covered by international, regional or national regulations that are updated on a regular basis. Their transport is strictly controlled and it is a legal and mandatory requirement to comply with the regulations.

Based on the United Nations guideline on transport of dangerous goods (United Nations, 2015), the World Organisation for Animal Health (OIE) and World Health Organization (WHO) guidance document on "Transport of Infectious Substances" summarise the different transport regulations and are regularly updated (OIE, 2018; WHO, 2019). Within European Union, the regulation of transport infectious samples is based on 2008/68/CE directive (EC, 2008). Countries, other international organisations, international treaties and conventions such as the International Air Transport Association (IATA) (IATA, 2021) provide also additional guidance and regulations that should be considered in planning the transportation of biological materials. Other equivalent reagents or equipment could be used as far as it does not affect the results.

1. PURPOSE AND SCOPE

This procedure describes the transport of diagnostic specimens sent to the EURL in the context of animal rabies suspicion.

2. REFERENCE DOCUMENTS

Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods (Text with EEA relevance), (2008).

IATA. (2021). *Dangerous Goods Regulations Manual*. In T. I. A. T. Association (Series Ed.), (pp. 187). Retrieved from https://store.iata.org/IEC_ProductDetails?id=9065-62&_ga=2.246059012.1615191473.1614592232-1439436827.1614592232

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United Nations. (2015). Recommendations on the Transport of Dangerous Goods. In (Vol. Volume 1, pp. 453). Retrieved from https://unece.org/fileadmin/DAM/trans/danger/publi/unrec/rev19/Rev19e_Vol_I.pdf.

WHO. (2019). *Guidance on regulations for the transport of infectious substances 2019–2020*. In W. H. Organization (Ed.), (pp. 56). Retrieved from https://www.who.int/ihr/publications/WHO-WHE-CPI-2019.20/en/

3. DOCUMENT AND REQUIREMENT

The shipment detail must be agreed with the Rabies EURL before sending. A proforma invoice (indicting the nature and number of sample (s), name, address, email and phone of the sender, date and signature) must accompany the shipment.

4. CONDITION OF DISPATCH TO THE LABORATORY

The shipment of samples must adhere to the requirement given in the World Organisation for Animal Health (OIE) manual. Original tissue samples must be sent under category B (UN3373) for rabies diagnosis purpose and under category A (UN2814) if the sample is originated from a culture (in vivo or in vitro) (OIE, 2018). Rabies virus fall indeed under category A definition of dangerous goods only if the virus originate from a laboratory culture.

The shipment of infectious substances remains the responsibility of the sender. The sender's liability is always engaged in the event of an accident during transport of a dangerous substance. Packaging infectious substances must be performed according in accordance with the regulations in force, relating to the packaging of dangerous goods.

Packaging must be proceeded as followed:

- Samples must be packed up in a leak-proof primary container (resistant jar or tube – No glass).

- The primary container must be placed in a secondary leak-proof container with an absorbent material (to absorb liquids in case of leakage).
- The secondary container must be placed in an outer packaging (polystyrene box) with cold source when necessary.
- The polystyrene box must be placed in expedition container made of resistant material.
- Envelope containing address of the EURL for rabies and supporting document must be taped outside the expedition container.
- Each package is marked, labelled according to the regulation. The sender ensures proper coordination between the transporter and the consignee, in order to ensure the safety of the infectious substances transported and their arrival at destination. Specialized carriers for this type of transport take care of the packaging, labelling and regulatory documents. It is advisable to rely on their expertise.
- Sender notified the EURL for Rabies when the package is in route.
- EURL for Rabies will acknowledge the good reception of the sample(s).

In case of transport of frozen samples in dry ice, addition safety and legal measure must be followed: Dry ice is a dangerous good (UN1845) and is subject to specific requirements for instructions, packaging and labelling. Shippers who use dry ice as a refrigerant for shipments should be trained. A package containing dry ice requires the risk label for various dangerous substances and objects. Shippers must properly mark and label the surface of outer packaging containing dry ice. The appropriate documents must indicate the presence of dry ice (for category A this information appears on the dangerous goods declaration. For category B and exempt samples this information appears on the ETA). The very low temperature (-79 ° C) of dry ice can indeed cause severe burns to the skin on direct contact.

5. INSTRUCTIONS REGARDNGS SAMPLES

You will find below the instructions for each sample type that could be sent in the frame of rabies diagnosis:

Matrix	Temperature of transport	Temperature of storage before analysis	Required quantity
Fresh brain sample	Refrigerated	+4°C*	≥ 1 gram
Frozen brain sample	Frozen	-20°C	≥ 1 gram
Frozen brain suspension	Frozen	-20°C	≥ 1 gram

*As samples kept at +4°C may deteriorate over time, samples must be sent as quickly as possible.