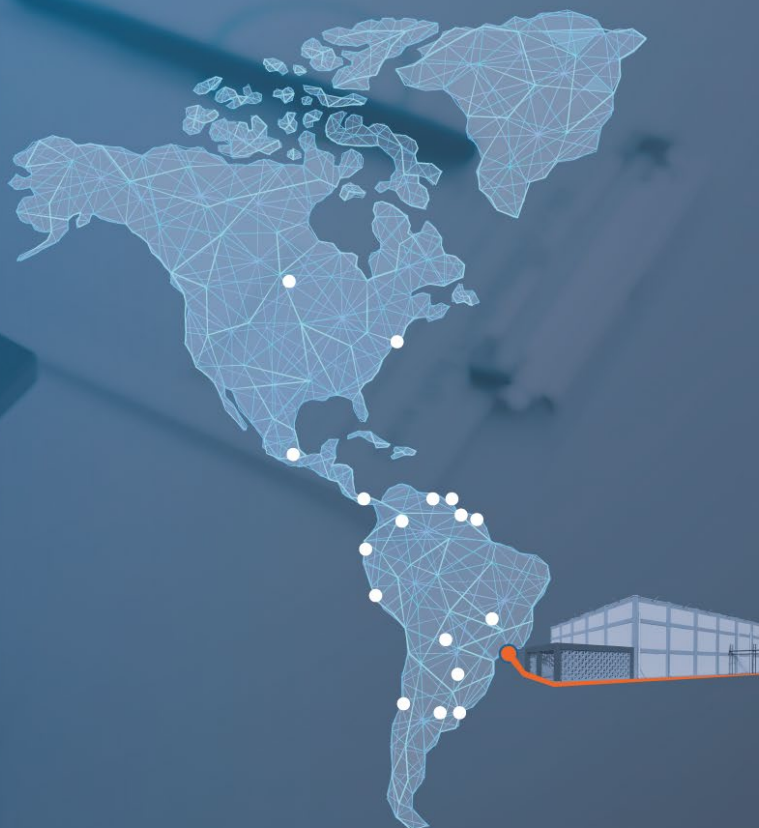


**Pan American Center for Foot-and-Mouth Disease and Veterinary
Public Health**

PANAFTOSA/VPH – PAHO/WHO

Guidelines for the international transport of biological materials.



OPS



Organización
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de la Salud



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Región de las Américas

PANAFTOSA

Centro Panamericano de Fiebre Aftosa
y Salud Pública Veterinaria





1.0 Objectives

The objective of this procedure is to guide the transport of samples suspected of vesicular diseases to the WOAH Reference Laboratory of PANAFTOSA–PAHO/WHO, located in Brazil.

2.0 Applications

According to IATA standards (IATA Dangerous Goods Regulations Manual), samples suspected of containing infectious microorganisms capable of causing disease in humans or animals must be transported as Biological Substance, **Category B (UN 3373)**, which are considered to present a **significant public health risk**.

Substances in this category may pose a relevant risk to public health and sanitary safety, and, therefore, for their entry into Brazil, must comply with the Sanitary Regulation for the Importation of Materials of Animal Origin and Agents of Veterinary Interest Intended for Research or Diagnosis, established by Interministerial Normative Instruction No. 32 of August 16, 2013 (INI 32/2013), Chapter III.

3.0 Responsibility

As described in item 5.1.

4.0 Definitions

4.1 Abbreviations

DSA: Agricultural Defense Secretariat

DSI: Simplified Import Document

IATA: International Air Transport Association

INI: Interministerial Normative Instruction

LPCO: Licenses, Permits, Certificates, and Other Documents

MAPA: Ministry of Agriculture and Livestock

UN: United Nations

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5.0 Procedures

5.1 Documentation required for the transport of UN 3373 samples destined for Brazil

The table below summarizes the documents required for the transport of biological samples intended for diagnostic purposes.

EXPORTER'S RESPONSIBILITY (Requesting Laboratory)	IMPORTER'S RESPONSIBILITY (PANAFTOSA)
Required documents (UN 3373)	Required documents/actions (UN 3373)
• Send an official letter to the Director of PANAFTOSA, together with the test request containing the sample data. Optionally, an email may be sent in advance to the team to expedite the process; however, this does not replace the mandatory submission of the official letter and the test request (Annex 1 – test request template). • Proforma invoice (Commercial Invoice): must contain a detailed description of the samples, a symbolic value of USD 10.00 (for customs purposes only), indication of the country of origin, the Mercosur Common Nomenclature (NCM) number, and must mandatorily include the following statement: "Material for laboratory use only – No commercial value." • Certificate of Origin (sample provenance) • International Veterinary Certificate (IVC) or International Zoosanitary Certificate (IZC) – Must follow the model established in Annex III of Interministerial Normative Instruction No. 32, of August 16, 2013 (INI 32/2013). • Donation letter for the shipped materials: must provide a detailed record of all samples included in the shipment.	• Application for authorization to import live animals, animal reproductive material, microorganisms, products of animal origin, or biological material of animal origin not intended for human or animal consumption, to obtain authorization for the entry of samples into Brazil, accompanied by the following documents: • Laboratory protocol or flowchart specifying the use and final destination of the imported material, as well as the protocol for inactivation, destruction, and disposal of the imported material and its residues. These protocols must be signed by the responsible professional and may use the following methods: incineration, autoclaving, or another method approved by the Agricultural Defense Secretariat – DSA/MAPA; • Declaration of use and purpose, stating that the goods will not be used for consumption or for inoculation in animals, will be intended exclusively for in vitro use, and will be inactivated and destroyed before disposal, without prejudice to the other requirements presented in the Normative Instruction;



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| <ul style="list-style-type: none">• Content declaration (or packing list): on the official letterhead of the originating laboratory institution, describing the type of material, type of preservative, and inactivating agent (if any).• Air Waybill (AWB): will be issued by the airline at the time of flight booking. The classification UN3373 must be included. We recommend shipping the material via a commercial airline (for example, Copa Airlines) to Tom Jobim International Airport – Galeão (GIG) in Rio de Janeiro.• The exporter must include the import authorization, duly issued by the competent authority of the importing country, in the clearance dossier.• Preparation of the documents and shipment dispatch must be carried out by a qualified professional. These professionals must be properly trained to classify the material, prepare the shipment, prepare all required documentation, and carry out the export process in accordance with the regulations in force in both the country of origin and the country of destination. | <ul style="list-style-type: none">• Declaration of responsibility regarding the safety, conservation, use, and destruction of the material to be imported, endorsed by the person responsible at the recipient institution. The term of responsibility must also be accompanied by a protocol for inactivation, destruction, and disposal;• Following the issuance of a favorable technical assessment, the Ministry of Agriculture and Livestock (MAPA) will proceed with the notification, through the SISBIN system, to the Brazilian Intelligence Agency (ABIN) and to the security forces, via COMBioLAB. It should be noted that ABIN will act exclusively in the follow-up and monitoring of the process, with no executive role, and that the continuation of the institutional procedures will be the responsibility of the competent authorities.• Forward the import authorization issued by DSA/MAPA to the exporter.• LPCO request (licenses, permits, certificates, and other documents): include all documentation in the LPCO within Siscomex.• Attach the DSI (Simplified Import Declaration) to the dossier and request authorization from the Brazilian Federal Revenue Service after the material arrives in Brazilian territory. |
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Notes:

- A) All documents must be issued on the official letterhead of the institution responsible for the shipment and must include the signature and job title of the responsible technical officer. In cases

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of **simulated sample shipment exercises**, all documents must clearly display a visible watermark indicating “**Simulated**” to identify them as simulation documents.

- B) Before shipping the material, the issued documentation must be reviewed together with the PANAFTOSA laboratory technical team to avoid potential discrepancies that could result in customs delays. **The material should only be dispatched after confirmation from the PANAFTOSA reference laboratory technical team.**
- C) Place the official letter addressed to the Director of PANAFTOSA, together with Annex III of IN No. 32/2013, duly signed (with an original handwritten signature), and the packing certificate (if available), inside an envelope affixed to the lid of the outer packaging (cardboard box), so that customs officers may access the documents without the need to open the box. All other documents must be placed inside the secondary packaging (canister) or on top of the polystyrene box (Styrofoam).

5.2 Packaging

Samples classified as UN3373 must be packed in triple packaging for transport, as described in IATA Packing Instruction 650. This packaging must consist of three components, supplemented by a polystyrene box:

- Primary receptacles (plastic tubes and vials containing the sample);
- Secondary receptacle – leakproof (a leakproof bag, plastic box, or rigid container (canister) that protects the primary receptacle, and is placed inside the polystyrene box, which acts as thermal insulation and helps maintain a stable temperature);
- Rigid outer packaging (a cardboard box that provides the final protection for the entire package).



- The primary receptacle must be leakproof and contain no more than 1 liter each. The total volume per package must not exceed 4 liters / 4 kg, excluding gel packs, dry ice, or liquid nitrogen. The primary receptacles must be placed inside durable secondary packaging to protect them against leakage. In addition, absorbent material must be placed between the primary and secondary receptacles in an amount sufficient to absorb the entire contents in the event of breakage or leakage. Primary receptacles must be individually wrapped or separated to prevent contact between them.
- The secondary packaging (canister) must be leakproof and properly secured so that it remains immobile inside the polystyrene box (foam box), which maintains the appropriate temperature. This polystyrene box must then be placed inside the rigid outer packaging (cardboard box).
- The label (Figure 1) must be in the shape of a square set at an angle of 45° (diamond-shaped), with each side measuring at least 50 mm in length. The line width must be at least 2 mm, and the letters and numbers must be at least 6 mm high.
- The UN3373 label (Figure 1) must be affixed to the outer packaging on a contrasting background and placed on the side of the box, ensuring that it is clearly visible and legible.

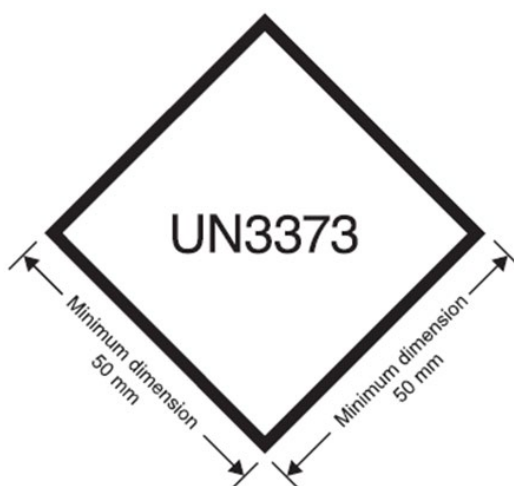




Figure 1 – UN3373 Label.
Image source: IATA, 2024.

- The proper shipping name (Biological substances, Category B) must be marked on the outer packaging, next to the diamond-shaped mark (Figure 1 – UN3373 label), in letters at least 6 mm high.
- The minimum dimensions of the outer packaging are 100 mm × 100 mm on at least one surface of the box.
- Preferably, packaging supplied by manufacturers authorized to produce containers classified as UN3373 should be used, ensuring that all required safety tests have been performed. Such packaging must, for example, withstand without leakage an internal pressure of 95 kPa under temperatures ranging from -40 °C to +55 °C, in addition to successfully passing the drop test specified in the corresponding packaging instruction.

5.3 Labels

Labels must be visibly placed on the outer packaging and include (Figure 2):

- Proper shipping name and UN number (Biological substance, Category B – UN3373);
- Shipper's and consignee's labels, with full names and addresses;
- The name and contact number of a responsible person must be indicated on the air waybill or on the packaging;
- "Net quantity" label: indicates the volume of the liquid content or the weight, i.e., of the product being transported, excluding the weight of the ice;
- "This side up" labels on opposite sides of the packaging;
- Transport temperature.

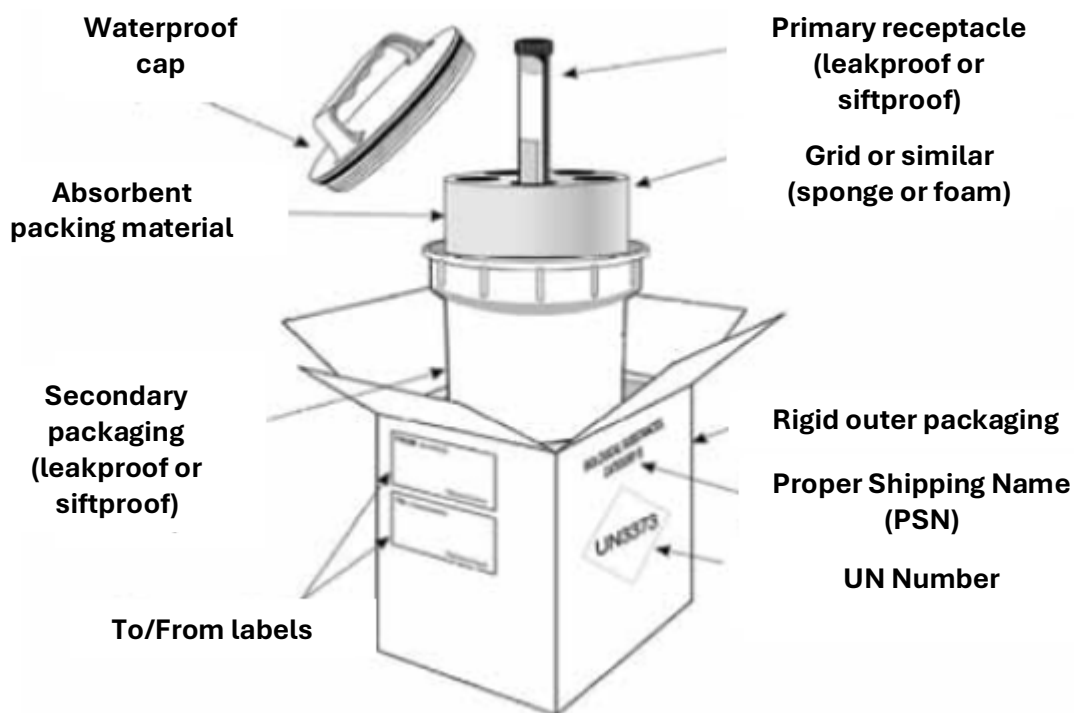


Figure 2 – Schematic representation of UN3373 packaging
Image source: Brazil, 2015



Figure 3 – Schematic representation of UN3373 packaging (validated in accordance with technical requirements). The certified packaging ensures that the batch has passed the required strength tests and complied with the technical requirements (drop test, pressure test, and load resistance – withstanding vibration and variations in temperature and humidity).

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5.4 Additional information

To classify the material, personnel must have basic knowledge to determine when the material should be considered Exempt, UN 3373 – Biological Substance, Category B, or UN 2900 – Infectious Substance, Affecting Animals Only. For this purpose, Table 1 provides guidance on the correct classification:

Table 1 – Classification of Exempt Material, Biological Substance Category B (UN3373), and Infectious Substance Affecting Animals Only (UN2900)

Exempt Material	UN3373	UN2900
Non-hazardous substance	Biological Substance, Category B	Infectious Substance, Affecting Animals Only
Samples known not to pose any risk to animal health, human health, or the environment. Examples include cell cultures, serum, and inactivated material (viruses or bacteria), among others. Classification by a qualified professional is required.	Samples suspected of containing infectious or potentially infectious microorganisms that may cause disease in humans or animals, but which do not present a high risk of transmission and therefore do not meet the criteria for Category A. Samples suspected of containing infectious microorganisms that do not meet the criteria for Category A.	- Foot-and-mouth disease virus (culture only) - Vesicular stomatitis virus (culture only) - African swine fever virus (culture only) - Avian paramyxovirus type 1 (Velogenic Newcastle disease virus) (culture only) - Classical swine fever virus (culture only) - Lumpy skin disease virus (culture only) <i>Mycoplasma mycoides</i> – Contagious bovine pleuropneumonia (culture only) - Peste des petits ruminants virus (culture only) - Rinderpest virus (culture only) - Sheep pox virus (culture only) - Swine vesicular disease virus (culture only)
		UN2814
		Infectious substance affecting humans <i>Bacillus anthracis</i> (culture only) <i>Brucella abortus</i> (culture only) <i>Brucella melitensis</i> (culture only) <i>Brucella suis</i> (culture only) <i>Burkholderia mallei</i> (<i>Pseudomonas mallei</i>) – glanders (culture only) <i>Burkholderia pseudomallei</i> - <i>Pseudomonas pseudomallei</i> (culture only) <i>Chlamydia psittaci</i> – avian strains (culture only) <i>Clostridium botulinum</i> (culture only) <i>Coccidioides immitis</i> (culture only) <i>Coxiella burnetii</i> (culture only) - Crimean–Congo hemorrhagic fever virus - Dengue virus (culture only) - Eastern equine encephalitis virus (culture only) - Verotoxigenic <i>Escherichia coli</i> (culture only)



- Ebola virus
- Flexal virus
- *Francisella tularensis* (culture only)
- Guanarito virus
- Hantaan virus
- Hantaviruses causing hemorrhagic fever with renal syndrome
- Hendra virus
- Hepatitis B virus (culture only)
- Herpes B virus (culture only)
- Human immunodeficiency virus (culture only)
- Highly pathogenic avian influenza virus (culture only)
- Japanese encephalitis virus (culture only)
- Junin virus
- Kyasanur Forest disease virus
- Lassa virus
- Machupo virus
- Marburg virus
- Monkeypox virus
- *Mycobacterium tuberculosis* (culture only)
- Nipah virus
- Omsk hemorrhagic fever virus
- Poliovirus (culture only)
- Rabies virus (culture only)
- *Rickettsia prowazekii* (culture only)
- *Rickettsia rickettsii* (culture only)
- Rift Valley fever virus (culture only)
- Russian spring-summer encephalitis virus (culture only)
- Sabiá virus
- *Shigella dysenteriae* type 1 (culture only)
- Tick-borne encephalitis virus (culture only)
- Smallpox virus
- Venezuelan equine encephalitis virus (culture only)
- West Nile virus (culture only)
- Yellow fever virus (culture only)
- *Yersinia pestis* (culture only)



6.0 References

- BRASIL. National Health Surveillance Agency. Health Surveillance Manual on the Transport of Human Biological Material for Clinical Diagnostic Purposes. Brasília: ANVISA, 2015. Available in: <https://www.gov.br/anvisa/pt-br/assuntos/sangue/transporte-de-material-biologico/manual-de-transporte-de-material-biologico-humano.pdf>. Accessed on February 5, 2026.
- BRASIL. Ministry of Agriculture, Livestock, and Food Supply; Ministry of Fisheries and Aquaculture. Interministerial Directive No. 32, dated August 16, 2013. Establishes the procedures for the importation of biological materials, samples, and other laboratory materials. Official Gazette of the Union: Section 1, Brasília, DF, p. 5, August 19, 2013.
- International Air Transport Association (IATA). Dangerous Goods Regulations: 2025, 66th edition. Montreal: IATA, 2025.
- World Organization for Animal Health. Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, Chapter 1.1.3 Transport of biological materials. Available at: <https://www.woah.org/en/what-we-do/standards/codes-and-manuals/>, accessed on March 2, 2026.

7.0 Referenced Documents

Not applicable.

8.0 Referenced Files

Not applicable.

9.0 Record Information

Not applicable.

10.0 Attachments

Not applicable.

11.0 Change Control

- The document title has been changed to be more concise.
- Information was added regarding the need to have all documents on hand and the mandatory requirement for shipping confirmation from the PANAFTOSA reference laboratory technical team.

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