

International shipment of biological and potentially infectious substances - Main requirements

EU / OIE Reference Laboratory for Brucellosis FAO Reference Centre for Brucellosis ANSES – Maisons-Alfort, France





The 4th FAO-APHCA/OIE/DLD
Regional Workshop on Brucellosis Diagnosis and Control in Asia and Pacific Region
- Proficiency Test and Ways Forward for the Region
Chiang Mai, Thailand, 19-21 March, 2014







International Shipment of biological and potentially infectious substances



The 3rd FAO-APHCA/OIE Regional Workshop on Brucellosis Diagnosis and Control with an Emphasis on B. melitensis (in collaboration with DLD) (Sukhothai and Phitsanulok Provinces, Thailand, 21-25 November 2010)

Conclusions and Recommendations

17. That a request to provide the member countries with technical know-how and handling methods on packaging/shipping materials (including specimen containers) for diagnosis to regional or international Reference Laboratories was made and noted for consideration for future support by FAO-APHCA and OIE Asia-Pacific Office.





Why should samples be correctly prepared for transport?

- To prevent any contamination (humans, animals, environment)
- To ensure compliance with international regulations
- To prevent rejection, useless delays, destruction at customs...
- To ensure conservation during shipment (temperature?)

Samples sent should arrive <u>safely</u> and <u>in good conditions</u> to the receiver!

Shipments are costly!

Make sure they are OK!



Biological and potentially infectious substances
CATEGORIZATION

> Shipment

PACKAGING, MARKINGS, LABELS

> International requirements

DOCUMENTS





Biological and potentially infectious substances
CATEGORIZATION





According to the OIE Terrestrial Manual:

Definitions of specimens to be transported

- Infectious substances:
 - Category A
 - Category B
- Cultures
- Patient specimens (human or animal)
- Biological products
- Genetically modified micro-organisms and organisms
- Medical or clinical waste





– Infectious substances:

- Category A
 - 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 diseases in otherwise healthy humans or animals
- Category B
 - An infectious substance which does not meet the criteria for inclusion in Category A

Cultures

- Cultures are the result of a process by which pathogens are intentionally propagated
- Patient specimens (human or animal)
 - Transported for the purpose of research, diagnosis ...Minimal likelihood that pathogens are present!
- Biological products
 - Derived from living organisms, manufactured and distributed in accordance with requirements of appropriate national authorities



- Infectious substances:
 - Category A
 - Category B
- Cultures (Brucella)
- Patient specimens (human or animal)
- Biological products





Biological products: reagents ? Vaccines?
 Others: DNA? Sera?

if known or reasonably believed to contain infectious substances:

Category A or Category B accordingly

If not, they are not concerned by the Dangerous Goods Regulation



Some are considered as biohazard in certain parts of the world only!

Check before!





- Infectious substances:

- Category A
- Category B



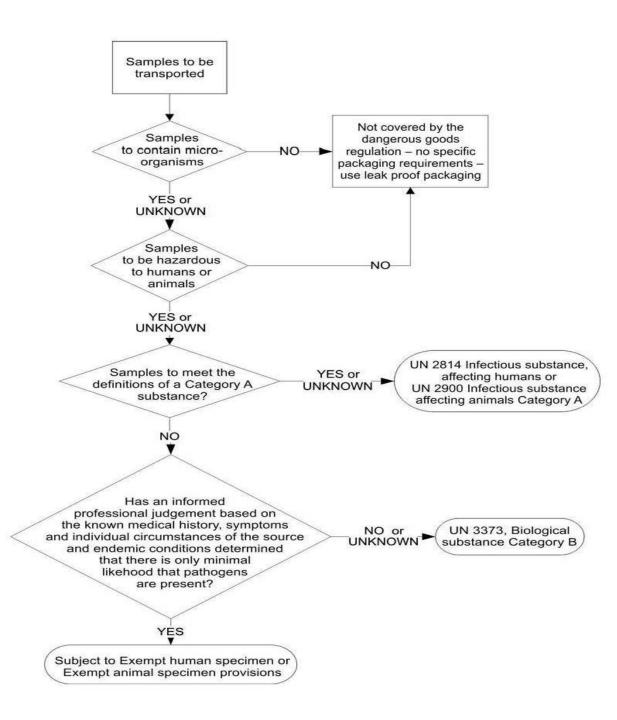


DECISION TREE

OIE Terrestrial Manual (version adopted May 2013)

Brucella examples:

- > serum samples
- > Cultures
- Organs from + animals

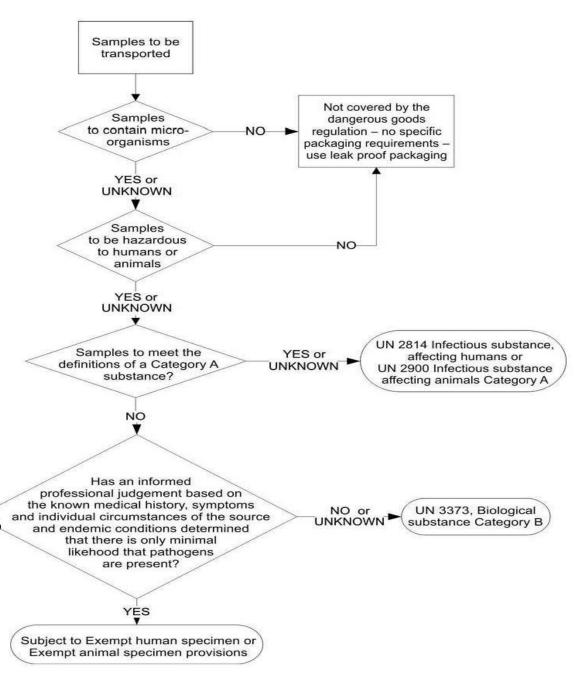


DECISION TREE

OIE Terrestrial Manual (version adopted May 2013)

Brucella examples:

- serum samples no specific requirement
- CulturesCategory A(UN2814/UN2900)
- Organs from + animals and individual circumstances of the source and endemic conditions determined that there is only minimal likehood that pathogens are present?



Category A – Infectious substances Proper shipping names (PSN)



Infectious substance, afffecting humans

UN2900

Infectious substance, affecting animals only







Category B – Infectious substances Proper shipping names (PSN)

UN3373

Biological substance, Category B





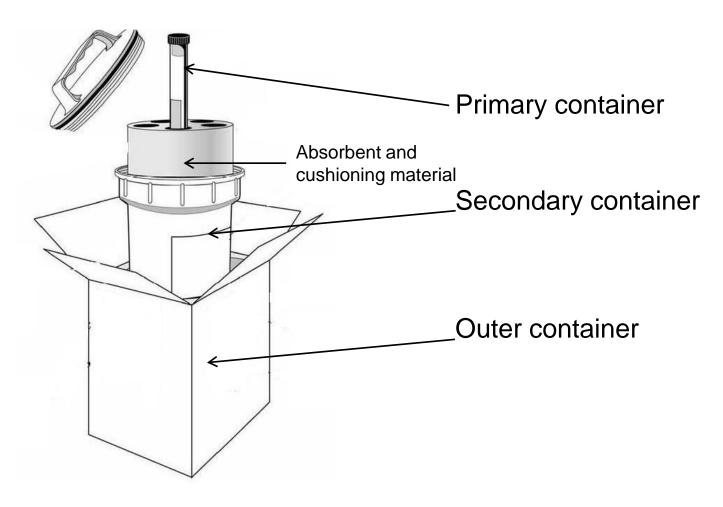
> Shipment

PACKAGING, MARKINGS, LABELS





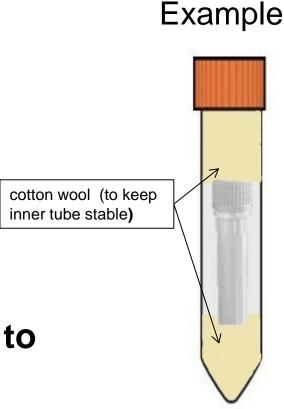
Triple packaging – 3 levels of containment





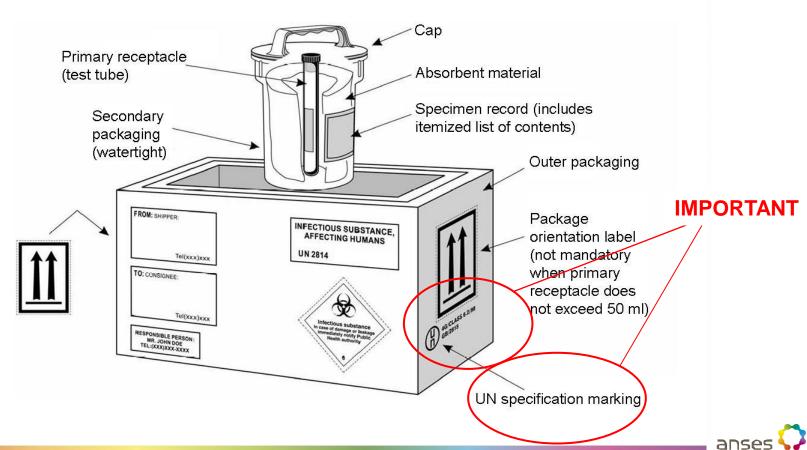
Conditioning the samples in the primary container:

- Avoid use of glass if possible, prefer plastic capped primary containers
- Prevent leaking / breaking (avoid shocks!)
- Use enough absorbent material to contain all liquid if necessary
- Label/identify the sample





Category A – UN 2814/UN 2900 Packing Instructions 620 (PI 620)



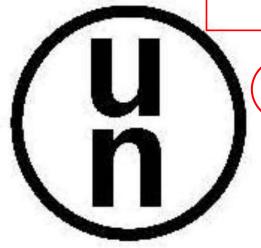


Outer package type: Fiberboard (4G)

Solid plastic box (4H2)

Plastic drum (1H2)

. . .



4G/CLASS 6.2/05 GB/2470





Tests ensuring requirements for Category A (Class 6.2):

Pressure test at 95 kPa

Drop test from 9 m

Puncture test at 7 kg

Stacking test







4G/CLASS 6.2/05

Last two digits of year of manufacture





Code of country authorizing this mark





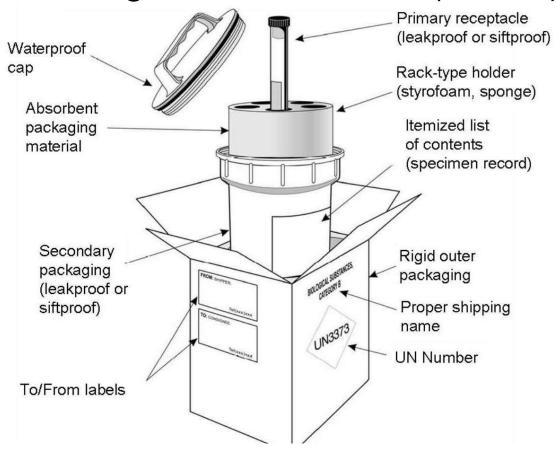
Manufacturer code







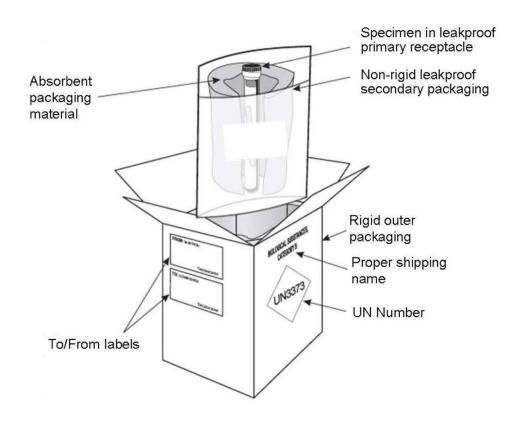
Category B – UN 3373 Packing Instructions 650 (PI 650)







Category B – UN 3373 Packing Instructions 650 (PI 650)







Category A – UN 2814 / UN 2900

MARKINGS

- >Shipper's name and address
- > Receiver's name and address
- ➤ Name and 24 h telephone No. of **responsible person**
- Proper Shipping Name
- >UN Number
- ➤ Net Quantity
- ➤UN Specification markings

LABELS

Infectious substance label





➤Orientation arrows



Cargo Aircraft Only (if cargo aircraft only)





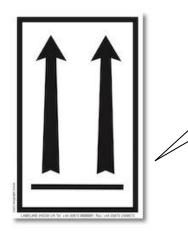
Category A – UN 2814 / UN 2900





And some others that may be necessary





X 2 !!





Category B – UN 3373

MARKINGS

- ➤ Shipper's name and address
- ➤ Receiver's name and address
- ➤ Name and telephone of responsible person

(on the package **or** on the air waybill!)

- ➤ Proper Shipping Name
- >UN Number

LABELS

No labels required (unless shipping with dry ice!)





Category B – UN 3373







SPECIAL REMARKS

– Shipping with Dry-Ice (Carbon Dioxide)
Packages containing Dry Ice are to be properly marked and labelled for all who may come in contact with the package during transport. It should be labelled as follows, knowing that the **net weight** is to be marked



dry ice as coolant

UN1845

Net quantity ____kg



SPECIAL REMARKS

- Flammable liquids (Ethanol)

Quantity and concentration will make us consider it as a Dangerous Good or not! If using Flammable liquids for the preservation of a sample, PLEASE CHECK!





LIMITATIONS

Main limitations for shipping Infectious or potentially infectious substances by air:

- Cat. A Substances (UN2814 / UN2900)
 Maximum 50mL or 50 g per package (passenger plane)
- Cat. B Substances (UN3373)
 Maximum 4 L or 4 kg per package (pass or cargo plane)
- Multiple samples (several primary containers may be placed in the same package (individually wrapped or separated to prevent contact)
- PI620 (the smallest external dimension shall not be less than 10 cm)
- PI650 (at least one surface of the outer packaging must be 10x10 cm minimum)



- Proficiency Test and Ways Forward for the Region

> International requirements

DOCUMENTS



Category A – UN 2814 / UN 2900

- AIR WAYBILL (usually filled out by the transport company) To be signed by the shipper
- DANGEROUS GOODS DECLARATION Should be completed and signed by the shipper (usually transport companies pre-fill the form for the shipper)(several original copies)
- IMPORT / EXPORT PERMITS
 Both, the shipper and the receiver should check on their respective country's requirements
- LIST OF CONTENTS
- > INVOICE (FOR CUSTOMS)





SHIPPER'S DECLARATION FOR DANGEROUS GOODS				(Provide at least two copies to the airline)							
Shipper				Air Waybill No. Page of Shipper's Reference Number (optional)							
Consign	noo										
Two completed and signed copies of this Declaration must be handed to the operator. TRANSPORT DETALS. TRANSPORT DETALS. This stignment in within the limitations proscribed the states non-applicable. PASSENCE GARDO ARCRAFT ONLY AIRCRAFT ONLY AIRCRAFT ONLY AIRCRAFT ONLY				WARNING Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable line, subject to legal penalties. Shipment Type (Motes non-applicable)							
								NON	RADIOACTIVE	RADIOACTIVE	
								ATURE	AND QUANTITY OF		
				UN or ID No.	Proper Shipping N	Doods Identification	Class or Division (Subsidiary NSA)	Pack- ing Group	Quantity and Type of Packing	Packing Instr	Authorization
Additio	nal Handling Informat	lon		Emerger	ncy Response Telepho	one Number:					
I hereity declare that the contents of this consignment are failly and accurately described above by the proper shipping name, and are classified, packaged, marked and labelledglacarded, and are in all respects in proper condition for transport according to applicable interrestional and national governmental regulations. I declare that all of the applicable air transport requirements have been met.					Name/Title of Signatory Place and Date Signature (see warning abore)						





Category A – UN 2814 / UN 2900 IMPORT / EXPORT PERMITS

- Example: France (*Brucella* strains/DNA)
 - > Import
 - 1 import permit required
 - > Export
 - 2 export permits required
 Bio warfare regulations!!



Category B – UN 3373

AIR WAYBILL (usually filled out by the transport company) To be signed by the shipper name and 24h phone number of a responsible person

IMPORT / EXPORT PERMITS

Both, the shipper and the receiver should check on their respective country's requirements

- * Animal origin!!
- > LIST OF CONTENTS
- > INVOICE (FOR CUSTOMS)





Category B – UN 3373 IMPORT / EXPORT PERMITS

Both, the shipper and the receiver should check on their respective country's requirements
* Animal origin!!

- > Example: France
 - > Import
 - import permit required if sample of animal origin



REMINDER

- Shipment of infectious or potentially infectious substances needs to be well organized (shipper/receiver/transport company)
- import/export permits may take a long time
- Door-to-Door transport
 - transport by route is not always allowed
 - unexpected handling/customs fees!
- > Let the other party know when the package is picked up/received by e mail as soon as possible





International Shipping Regulations:

- UN United Nations
- ICAO (International Civil Aviation Organization)
- IATA (International Air transport Association)

DGR-Dangerous Goods Regulations

- IMO (International Marine Organization)
- UPU (Universal Postal Union)



+ Different National Regulations may apply!





FOR MORE INFORMATION

> WHO

http://www.who.int/ihr/publications/who_hse_ihr_2012.12/en/http://www.who.int/ihr/publications/WHO_CDS_CSR_LYO_2004_11/en/http://www.who.int/ihr/publications/WHO_CDS_EPR_2006_6/en/http://www.who.int/csr/delibepidemics/biochemguide/en/http://www.who.int/ihr/i_s_shipping_training/en/

> IATA

http://www.iata.org/whatwedo/cargo/dgr/Pages/index.aspx





ขอบคุณครับ



Thanks for your attention...



