COMMITTEE OF EXPERTS ON THE TRANSPORT OF DANGEROUS GOODS AND ON THE GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS

Sub-Committee of Experts on the Transport of Dangerous Goods

Twenty-fifth session
Geneva, 5-14 July 2004
Item 6 of the provisional agenda

LISTING CLASSIFICATION AND PACKAGING

Infectious substances

Guidance Note from the Joint Aviation Authorities (JAA) Dangerous Goods Study Group

Transmitted by the expert from the United Kingdom

For information purposes the expert from the United Kingdom would like to draw the attention of the Sub-Committee to the attached guidance note produced by the Joint Aviation Authorities (JAA) Dangerous Goods Study Group on the infectious substances requirements in the 2005-6 ICAO Technical Instructions.

ANNEX

CONSIGNMENT OF INFECTIOUS SUBSTANCES BY AIR FROM 1 JANUARY 2005
An Interpretation/Guidance Document developed by the
Joint Aviation Authorities (JAA) Dangerous Goods Study Group

1. Introduction

The 2005-2006 edition of the International Civil Aviation Organization's Technical Instructions for the Safe Transport of Dangerous Goods by Air contains new requirements for the transport of infectious substances, *ie* substances which are known or reasonably expected to contain pathogens which are defined as micro-organisms (including bacteria, viruses, rickettsiae, parasites, fungi), plasmids and other agents such as prions, which can cause disease in humans or animals.

This document provides interpretation for use by regulators, shippers and operators etc within JAA states and is endorsed by the World Health Organization.

2. Current situation

The current references to risk for determining if a substance is to be transported as an infectious substance or diagnostic specimen is based upon:

- Assignment to a "risk group", based upon the hazard posed in a laboratory environment,
- The purpose for sending the sample,
- The perceived risk as opposed to scientific or empirical evidence.

The result is a regime which imposes a set of controls that are disproportionate to the risk during transport, and as a consequence places an unnecessary burden on the provision of healthcare, diagnostic analysis and the swift treatment of new and emerging diseases.

3. The new requirements

From January 1st 2005 risk groups will no longer be used. Instead Infectious substances will be placed into one of two categories based upon a scientific assessment of their risk during transport.

Categories are defined as:

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 disease to humans or animals.

- Any other infectious substance when shipped as a culture (laboratory stocks) ie *the result of a process by which pathogens are amplified or propagated in order to generate high concentrations, thereby increasing the risk of infection when exposure to them occurs. This refers to cultures prepared for the intentional generation of pathogens and does not include cultures intended for diagnostic and clinical purposes. Cultures prepared for the intentional generation of pathogens may not be transported as diagnostic specimens.*

Substances assigned to category A must be shipped in accordance with the Technical Instructions under UN2814 or UN2900 as appropriate. An indicative list of substances assigned to Category A can be found in Appendix A. The list is not exhaustive. Infectious substances, including those containing new or emerging pathogens, which do not appear in the list but which meet the same criteria must be transported as a Category A infectious substance. In addition, if there is doubt as to whether or not a pathogen falls within this category it must be transported as a Category A infectious substance.

Category B: An infectious substance that does not meet the criteria for inclusion in category A, unless shipped in a cultured (laboratory stocks) form.

Although the method of classification has been changed, UN3373 "Diagnostic specimens" or "Clinical specimens" has been retained but redefined, and the Technical Instructions (ICAO) now requires such substances to be assigned to category B. UN3373 is defined in ICAO in **Special Provision A141** as applying to human or animal material including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluids, and body parts being transported for purposes such as research, diagnosis, investigational activities, disease treatment or prevention.

Blood or blood components which have been collected for the purpose of transfusion or for the preparation of blood products to be used for transfusion or transplantation and any tissues or organs intended for use in transplantation are not subject to these Instructions, since people offering blood for transfusion undergo verbal assessment and screening.

Only substances meeting the following criteria are not subject to the provisions applicable to division 6.2 of the Technical Instructions::

- Substances in a form that any pathogens present have been neutralised or inactivated such that they no longer pose a health risk; or
- Substances known not to contain infectious substances or taken from pathogen free sources; or
- Micro-organisms that are non-pathogenic for humans or animals; or
- Substances from non-human or non-animal sources for which there is a low probability that infectious substances are present, or are present in concentrations encountered naturally and not considered to pose a significant risk e.g. foodstuffs, water samples.

Note:- dried blood spots, collected by applying a drop of blood onto absorbent material, are not specifically mentioned in the Technical Instructions. However, according to World Health Organization advice, dried blood spots, need not be classified as UN3373.

Packing requirements

Substances assigned to Category A, UN 2814 and UN2900 are subject to all applicable provisions of the Technical Instructions, including Packing instruction 602 and consequently (apart from the indicative list of assigned substances at Appendix A) it is impractical to reproduce these in this document.

Substances assigned to Category B, UN3373 must be prepared in accordance with Packing Instruction 650, which is reproduced below:

P650	**Packing Instruction**	**P650**

This packing instruction applies to UN 3373

(1) The packaging must be of good quality, strong enough to withstand the shocks and loadings normally encountered during transport, including transhipment between transport units and between transport units and warehouses as well as any removal from a pallet or overpack for subsequent manual or mechanical handling. Packagings must be constructed and closed to prevent any loss of content that might be caused under normal conditions of transport by vibration or by changes in temperature, humidity or pressure.

(2) The packaging must consist of three components:
- (a) a primary receptacle,
- (b) a secondary packaging, and
- (c) a rigid outer packaging.

(3) Primary receptacles must be packed in secondary packagings in such a way that, under normal conditions of transport, they cannot break, be punctured or leak their contents into the secondary packaging. Secondary packagings must be secured in outer packagings with suitable cushioning material. Any leakage of the contents must not compromise the integrity of the cushioning material or of the outer packaging.

(4) For transport, the mark illustrated below must be displayed on the external surface of the outer packaging on a background of a contrasting colour and must be clearly visible and legible. The mark must be in the form of a square set at an angle of 45º (diamond-shaped) with each side have a length of at least 50 mm, the width of the line shall be at least 2 mm and the letters and numbers shall be at least 6 mm high. The proper shipping name "Diagnostic specimen" or "Clinical specimen" in letters at least 6mm high must be marked on the outer package adjacent to the diamond-shaped mark.

5) At least one surface of the outer packaging must have a minimum dimension of 100 mm x 100mm.

(6) The completed package must be capable of successfully passing the drop test in 6;6.2. as specified in 6;6.1.5 of the Instructions except that the height of the drop must not be less than 1.2m.

P650	Packing Instruction (cont'd)	P650

(7) For liquid substances

(a) The primary receptacle(s) must be leakproof and must not contain more than 1 litre.

(b) The secondary packaging must be leakproof.

(c) If multiple fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent contact between them.

(d) Absorbent material must be placed between the primary receptacle(s) and the secondary packaging. The absorbent material must be in quantity sufficient to absorb the entire contents of the primary receptacle(s) so that any release of the liquid substances will not compromise the integrity of the cushioning material or of the outer packaging.

(e) The primary receptacle or the secondary packaging must be capable of withstanding, without leakage, an internal pressure of 95 kPa (0.95 bar).

(f) The outer package must not contain more than 4 litres. This quantity excludes ice, dry ice, or liquid nitrogen when used to keep specimens cold.

(8) For solid substances:

(a) The primary receptacle(s) must be siftproof and must not exceed the outer packaging mass limit.

(b) The secondary packaging must be siftproof.

(c) If multiple fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent contact between them.

(d) Except for packages containing body parts, organs or whole bodies, the outer package must not contain more than 4 kg. This quantity excludes ice, dry ice or liquid nitrogen when used to keep specimens cold.

(e) If there is any doubt as to whether or not residual liquid may be present in the primary receptacle during transport then a packaging suitable for liquids, including absorbent materials, must be used.

(9) Refrigerated or frozen specimens: ice, dry ice and liquid nitrogen

(a) When dry ice or liquid nitrogen is used to keep specimens cold, all applicable requirements of these Regulations shall be met. When used, ice or dry ice shall be placed outside the secondary packagings or in the outside packaging or an overpack. Interior supports shall be provided to secure the secondary packagings in the original position after the ice or dry ice has dissipated. If ice is used, the outside packaging or overpack shall be leakproof. If Carbon dioxide, solid (dry ice) is used, the packaging shall be designed and constructed to permit the release of carbon dioxide gas to prevent a build-up of pressure that could rupture the packagings.

(b) The primary receptacle and the secondary packaging shall maintain their integrity at the temperature of the refrigerant used as well as the temperatures and the pressures that could result if refrigeration were lost.

(10) When packages are placed in an overpack, the package markings required by this packing instruction must either be clearly visible or be reproduced on the outside of the overpack.

P650	Packing Instruction (cont'd)	P650

(11) Infectious substances assigned to UN 3373 which are packed and marked in accordance with this packing instruction are not subject to any other requirement in these Instructions except for the following:

(i) the proper shipping name, UN number and the name, address and telephone number of a responsible person must be provided on a written document (such as an air waybill) or on the package;
(ii) classification must be done in accordance with 2;6.3.2;
(iii) the incident reporting requirements in 7;4.4 must be met;
(iv) the inspection for damage or leakage requirements in 7;3.1.3 an 7;3.1.4; and
(v) passengers and crew members are prohibited from transporting infectious substances either as or in carry-on baggage or checked baggage or on their person.

(12) Clear instructions on filling and closing such packages must be provided by packaging manufacturers and subsequent distributors to the consignor or to the person who prepares the package (e.g. patient) to enable the package to be correctly prepared for transport.

(13) Other dangerous goods must not be packed in the same packaging as Division 6.2 Infectious Substances unless they are necessary for maintaining the viability, stabilizing or preventing degradation or neutralizing the hazards of the infectious substances A quantity of 30 ml or less of dangerous goods included in Classes 3, 8 or 9 may be packed in each primary receptacle containing infectious substances. When these small quantities of dangerous goods are packed with infectious substances in accordance with this packing instruction no other requirements in these Instructions need be met.

4. Passenger provisions:

Infectious substances in category A or B are not permitted for transport in carry-on or checked baggage and must not be carried on the person.

5. Emergency response procedures (Category A and B)

Mitigation procedures:

- Isolate spill or leak area immediately in all directions.
- Keep unauthorized personnel away.
- Obtain identity of substance involved if possible and report the spill to the appropriate authorities.
- Do not touch or walk through spilled material.
- Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.
- Be particularly careful to avoid contact with broken glass or sharp objects that may cause cuts or abrasions that could significantly increase the risk of exposure.
- Damaged packages containing solid CO2 as a refrigerant may produce water or frost from condensation of air. Do not touch this liquid as it could be contaminated by the contents of the package.
- Liquid nitrogen may be present and can cause severe burns.
- Absorb spilled materials with earth, sand or other non-combustible material while avoiding direct contact.
- Cover damaged package or spilled material with damp towel or rag and keep wet with liquid bleach or other disinfectant. Liquid bleach will generally effectively inactivate the released substance.

CLEAN-UP OR DISPOSAL SHOULD ONLY BE EFFECTED BY A COMPETENT PERSON.

First Aid:

- Move exposed person(s) to a safe isolated area.

CAUTION: Exposed person(s) may be a source of contamination.

- Call emergency medical services.
- Remove and isolate contaminated clothing and shoes.
- In case of contact with substance, immediately flush skin or eyes with running water
- for at least 20 minutes.
- Effects of exposure (inhalation, ingestion or skin contact) to substance may be
- delayed.
- For further assistance, contact the appropriate public health authority.
- Ensure that medical personnel are aware of the substances involved, and take
- precautions to protect themselves.

APPENDIX A

INDICATIVE EXAMPLES OF INFECTIOUS SUBSTANCES ASSIGNED TO CATEGORY A IN ANY FORM UNLESS OTHERWISE INDICATED

NOTE 1**:** *The following list is not exhaustive. Infectious substances, including those containing new or emerging pathogens, which do not appear in the following list but which meet the same criteria must be transported as a Category A infectious substance. In addition, if there is doubt as to whether or not a pathogen falls within this category it must be transported as a Category A infectious substance.*

NOTE 2: *In the following table, the micro-organisms indicated in italics are bacteria, mycoplasmas, rickettsiae or fungi.*

UN 2814 Infectious substances affecting humans

*Bacillus anthracis (*cultures only*)*
Brucella abortus (cultures only)
Brucella melitensis (cultures only)
Brucella suis (cultures only)
Burkholderia mallei - Pseudomonas mallei – Glanders (cultures only)
Burkholderia pseudomallei – Pseudomonas pseudomallei (cultures only)
Chlamydia psittaci - avian strains (cultures only)
*Clostridium botulinum (*cultures only*)*
Coccidioides immitis (cultures only)
Coxiella burnetii (cultures only)
Crimean-Congo hemorrhagic fever virus
Dengue virus (cultures only)
Eastern equine encephalitis virus (cultures only)
Escherichia coli, verotoxigenic (cultures only)
Ebola virus
Flexal virus
*Francisella tularensis (*cultures only*)*
Guanarito virus
Hantaan virus
Hantaviruses causing hantavirus pulmonary syndrome
Hendra virus
Hepatitis B virus (cultures only)
Herpes B virus (cultures only)
Human immunodeficiency virus (cultures only)
Highly pathogenic avian influenza virus (cultures only)
Japanese Encephalitis virus (cultures only)
Junin virus
Kyasanur Forest disease virus
Lassa virus
Machupo virus
Marburg virus
Monkeypox virus
*Mycobacterium tuberculosis (*cultures only*)*
Nipah virus
Omsk hemorrhagic fever virus
Poliovirus (cultures only)
Rabies virus
*Rickettsia prowazekii (*cultures only*)*
Rickettsia rickettsii (cultures only)

Rift Valley fever virus
Russian spring-summer encephalitis virus (cultures only)
Sabia virus
*Shigella dysenteriae type 1 (*cultures only*)*
Tick-borne encephalitis virus (cultures only)
Variola virus
Venezuelan equine encephalitis virus
West Nile virus (cultures only)
Yellow fever virus (cultures only)
Yersinia pestis (cultures only)

UN 2900 Infectious substances affecting animals

African horse sickness virus
African swine fever virus
Avian paramyxovirus Type 1 - Newcastle disease virus
Bluetongue virus
Classical swine fever virus
Foot and mouth disease virus
Lumpy skin disease virus
Mycoplasma mycoides - Contagious bovine pleuropneumonia
Peste des petits ruminants virus
Rinderpest virus
Sheep-pox virus
Goatpox virus
Swine vesicular disease virus
Vesicular stomatitis virus

APPENDIX B

SCENARIOS INVOLVING THE TRANSPORT OF INFECTIOUS SUBSTANCES

1. A blood sample known or reasonably suspected to contain EBOLA VIRUS
or..

Clinical specimen taken from a cow in a herd known to be affected by FOOT AND MOUTH DISEASE.

Classification: Category A infectious substance, must be shipped under UN 2814 or UN2900 as appropriate.

Reason: Pathogens in category A are responsible for causing serious disease in humans or animals and are capable of posing the greatest risk in air transport, consequently require the most restrictive packaging.

2. A blood sample taken from a patient known or suspected to have a Category B pathogen, such as HEPATITIS B or HIV,
or..

Clinical specimen taken from a cow in a herd known to be affected by BOVINE TUBERCULOSIS.

Classification: Category B infectious substance, must be shipped under UN 3373

Reason: Pathogens assigned to category B may be responsible for causing disease in humans or animals, but the conditions in air transport are such that the likelihood of the disease being contracted from a sample in transit is extremely remote.

3. Laboratory stock culture of a pathogen in category B, E.G INFLUENZA VIRUS, SARS, HIV

Classification: Category A infectious substance, must be shipped under UN 2814 or UN 2900 as appropriate.

Reason: Whilst category B substances in the form they are normally encountered are unlikely to cause infection, the risk is increased when concentrated into a cultured form, such that it is necessary to require additional levels of packaging etc.

4. Specimens other than those known or reasonably suspected to contain a Category A infectious substance e.g. those sent for testing for Cholesterol or HIV (blood), diabetes (urine), bowel cancer (faecal).

Classification: material meets Special Provision A141 and as such must be shipped as UN 3373

Reason: The new requirements apply to all human or animal material because unless a sample is inactivated or neutralized, it cannot be categorically stated that any pathogens present do not pose a health risk.

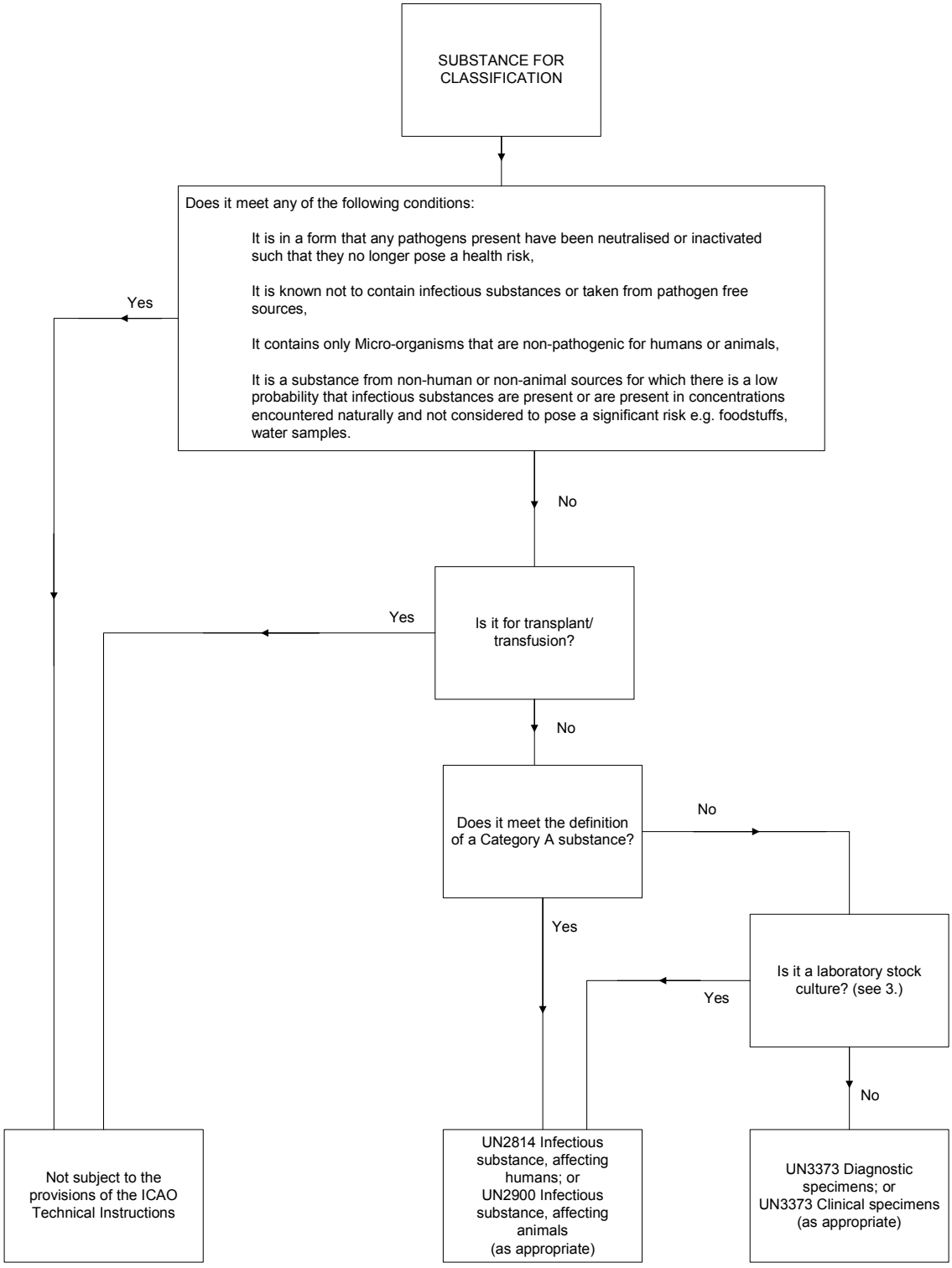
5. Specimen containing a category A or B infectious substance, treated so as to inactivate or neutralise the pathogens such that they no longer pose a health risk.

Classification: Not subject to the 6.2 provisions of the technical instructions

Reason: Any pathogens that may have been present no longer pose a health risk in transport.

APPENDIX C

Flowchart for the classification of infectious substances



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