DANGEROUS GOODS PANEL (DGP)

MEETING OF THE WORKING GROUP OF THE WHOLE

Montreal, 18 to 22 April 2005

Agenda Item 5: Discussion of miscellaneous dangerous goods issues

GUIDANCE DOCUMENT FOR THE TRANSPORT OF INFECTIOUS SUBSTANCES

(Presented by G A Leach)

1. BACKGROUND

1.1 A guidance document addressing the transport by all modes of infectious substances has recently been produced in the United Kingdom by the Department for Transport, Maritime and Coastguard Agency and the Civil Aviation Authority. The document provides advice across industry and addresses the changes in the 2005 Regulations as well as anticipated changes for 2007. It also highlights those areas where there are differences between the air and other modes.

1.2 A copy of this document is attached for the information of the Working Group.

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TRANSPORT OF INFECTIOUS SUBSTANCES

A GUIDANCE DOCUMENT PRODUCED BY THE DEPARTMENT FOR TRANSPORT, THE CIVIL AVIATION AUTHORITY AND THE MARITIME AND COASTGUARD AGENCY.

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1. INTRODUCTION -The Purpose of this document

1.1 New requirements are being introduced in all modes of transport for the transport of infectious substances, i.e. 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. These requirements are based on the UN Model Regulations for the Transport of Dangerous Goods, the latest revision of this non-mandatory set of regulations coming into effect from 1 January 2005.

1.2 This document provides guidance for regulators, consignors/shippers and operators etc and has been produced with the assistance of the Dangerous Goods European Aviation Liaison Group and the World Health Organization.

1.3 Applicability

	Domestic	International
Air (ICAO)[1]	1 January 2005	1 January 2005
Road and rail (ADR and RID)[2]	1 July 2005*	1 July 2005
Sea (IMDG)[3]	1 January 2006*	1 January 2006*

*These regulations may be used now.

Note: Category A infectious substances are subject to security provisions for high consequence dangerous goods.

1. Air: ICAO Technical Instructions for the Safe Transport of Dangerous Goods by Air
2. Road European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR)
2. Rail Regulations concerning the International Carriage of Dangerous Goods by Rail (RID)
3. Sea: International Maritime Dangerous Goods Code(IMDG)

2. THE OLD SYSTEM

(*Note: for UK domestic road and rail the old system based on the requirements in RID/ADR 2003 can continue to be used until the issue of new domestic regulations during the summer of 2005 based on RID/ADR 2005. However HSE have issued authorisation No7 which allows consignors to anticipate the new classifications for 6.2 in 2005 RID/ADR provided all the relevant new provisions are complied with*)

For sea the requirements of Amendment 31 of the IMDG code can be used until December 31st 2005.

2.1 Prior to the current changes in legislation, classification of infectious substances was based upon:

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

2.2 Although based on the best information available at the time the result was a regime which imposed a set of controls that could be seen as disproportionate to the risk during transport, and as a consequence placed an unnecessary burden on the provision of healthcare, diagnostic analysis and the swift treatment of new and emerging diseases.

3. THE NEW REQUIREMENTS--- Classification

3. With the appearance of the 13th edition of the Model Regulations in 2003 risk groups disappeared. Instead infectious substances were placed into one of two categories A& B based upon a scientific assessment of their risk during transport. There is no direct relationship between the old style Risk Groups and Category A&B. These requirements are now in the various modal requirements from 1st January 2005.

3.2 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;

and for all modes of transport other than air:

- when consigned as a culture (laboratory stocks) i.e. 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.

Note the air mode has anticipated the classification requirements for 2007 now, see ICAO addendum Doc 9284- AN/905 attached.

Substances assigned to category A must be consigned/shipped as either 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 any doubt as to whether or not a pathogen falls within this category, it must be transported as a Category A infectious substance. Clinical wastes containing Category A infectious substances shall be assigned to UN 2814 or UN 2900 as appropriate.

Category B:

An infectious substance that does not meet the criteria for inclusion in Category A.

Substances assigned to Category B must be consigned/shipped as UN 3373. Although the method of classification has changed, the Proper Shipping Name and UN number UN3373 “Diagnostic Specimens” or “Clinical Specimens” has been retained but redefined, and such substances are now assigned to Category B. For the purpose of guidance, UN3373 could be deemed to include patient specimens of human or animal material including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluid swabs, and body parts being transported for purposes such as research, diagnosis, investigational activities, disease treatment or prevention.

4.EXCEPTIONS- Where these regulations do not apply

The new requirements do not apply to the following:

I. 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;

II. Substances in a form that any pathogens present have been neutralised or inactivated such that they no longer pose a health risk;

III. Substances known not to contain infectious substances or taken from pathogen free sources;

IV. Micro-organisms that are non-pathogenic for humans or animals;

V. 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.

VI. Dried blood spots, collected by applying a drop of blood onto absorbent material, are not specifically mentioned in the transport requirements. However, expert medical advice in the United Kingdom is that such items are not realistically capable of posing a risk to health, safety, property or the environment and consequently, unless they are known or reasonably believed to contain infectious substances of Category A, need not be classified as UN3373.

VII. Substances which do not contain infectious substances or substances which are unlikely to cause disease in humans or animals (unless they meet the criteria for inclusion in another class of dangerous goods).

NOTE: UK competent authorities do not accept the interpretation behind Exception VII. By definition, such an exception can only apply to substances which are known not to contain (for example following testing or action taken to neutralise or inactivate any pathogens present). Expert medical advice in the United Kingdom is that it is not always possible to determine which human or animal samples contain pathogens to some degree and consequently it cannot be assumed that, for example, a blood sample taken for the purposes of cholesterol level testing, will necessarily be exempt from the requirements.

It is therefore strongly recommended that unless it is known or reasonably believed to contain infectious substances of Category A, **all** human or animal material should be regarded as

UN3373; failure to do so may result in the inadvertent consignment of category B infectious substances when not in compliance with modal regulations, for which legal penalties may result.

Further information in respect of classification can be found in **Appendices B and C**.

5. THE NEW REQUIREMENTS. Packaging

Packing instruction P650

13TH UN edition into 2005 RID/ADR/UK DOMESTIC FROM SUMMER 2005 but can be used now.

IMDG CODE 1st JANUARY 2006 but can be used now

NOTE: HIGHLIGHTED TEXT REFERS TO AIR TRANSPORT:

P650 PACKING INSTRUCTION **P650**	
This packing instruction applies to UN 3373.	
(1) The packaging shall 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 shall be constructed and closed to prevent any loss of contents that might be caused under normal conditions of transport by vibration or by changes in temperature, humidity or pressure.	
(2) The packaging shall consist of three components: (a) a primary receptacle, (b) a secondary packaging, and (c) an outer packaging	The outer packaging must be rigid
Note: From 2007 it is likely that the secondary or the outer packaging must be rigid	
(3) Primary receptacles shall 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 shall be secured in outer packagings with suitable cushioning material. Any leakage of the contents shall not compromise the integrity of the cushioning material or of the outer packaging.	
(4) For transport, the mark illustrated below shall be displayed on the external surface of the outer packaging on a background of a contrasting colour and shall be clearly visible and legible. The width of the line shall be at least 2 mm; the letters and numbers shall be at least 6 mm high.	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 45° (diamond-shaped) with each side having a length of at least 50 mm,** the width of the line must be at least 2 mm, and the letters and numbers must be at least 6 mm high. The proper shipping name “Diagnostic specimen” or “Clinical specimen” in letters at least 6 mm high must be marked on the outer package adjacent to the diamond-shaped mark.

Note: From 2007 the terms “Diagnostic specimen” or “Clinical specimen” will be replaced by “**BIOLOGICAL SUBSTANCE, CATEGORY B**” and this name will have to appear on all packages for all modes of transport. ICAO being the only organisation requiring names on these packages has agreed this new name can be used immediately as an alternative.

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



(5) The completed package shall be capable of successfully passing the drop test in 6.3.2.5 as specified in 6.3.2.3 and 6.3.2.4 of these Regulations except that the height of the drop shall not be less than 1.2 m.

(6) For liquid substances

(a) The primary receptacle(s) shall be leakproof;

And must not contain more than 1 l

(b) The secondary packaging shall be leakproof;

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

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

(e) The primary receptacle or the secondary packaging shall 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.

(7) For solid substances

(a) The primary receptacle(s) shall be siftproof;

And must not exceed the outer packaging mass limit

(b) The secondary packaging shall be siftproof;

(c) If multiple fragile primary receptacles are placed in a single secondary packaging, they shall 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.**

(8) 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 outer 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 and shall be marked "Carbon dioxide, solid" or "Dry ice".

(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 which could result if refrigeration were lost.

(9) 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 Regulations.

	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.
	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: a) the proper shipping name, UN number and the name, address and telephone number of a person responsible must be provided on a written document (such as an air waybill) or on the package; b) classification must be in accordance with 2;6.3.2 of the ICAO TIs; c) the incident reporting requirements in 7;4.4 of the ICAO TIs must be met; d) the inspection for damage or leakage requirements in 7;3.1.3 and 7;3.1.4 of the ICAO TIs; e) 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 to the consignor or to the person who prepares the package (e.g. patient) by packaging manufacturers and subsequent distributors 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.
Note: Air provision 13 is likely to be applied by all modes from 2007	

Note: Category A substances must be transported in accordance with Packing Instruction 620 (P602 air)

6. AIR 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.

7. EMERGENCY RESPONSE PROCEDURES (CATEGORY A AND B)

The following information is primarily of use by operators in the event that a package containing infectious substances (of either Category A or B) is involved in an incident resulting in spillage.

7.1 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.

7.2 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.*

UN2814 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 (replaced by Hantavirus causing hemorrhagic fever with renal syndrome for air transport and likely to be applied for all modes from 2007
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 (***NOTE: 'cultures only' likely to be added from 2007)***
Rabies virus (for air transport)
*Rickettsia prowazekii (*cultures only*)*
Rickettsia rickettsii (cultures only)
Rift Valley fever virus ***(NOTE: 'cultures only' likely to be added from 2007)***
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 ***(NOTE: 'cultures only' likely to be added from 2007***
West Nile virus (cultures only)
Yellow fever virus (cultures only)
Yersinia pestis (cultures only)

UN2900 Infectious substances affecting animals

African horse sickness virus ***(NOTE: likely to be deleted from 2007)***
African swine fever virus ***(NOTE: 'cultures only' likely to be added from 2007)***
Avian paramyxovirus Type 1 – ***(Velogenic likely to be added from 2007)*** Newcastle disease virus ***(NOTE: 'cultures only' likely to be added from 2007)***
Bluetongue virus ***(NOTE: likely to be deleted from 2007)***
Classical swine fever virus ***(NOTE: 'cultures only' likely to be added from 2007)***
Foot and mouth disease virus ***(NOTE: 'cultures only' likely to be added from 2007)***
Goatpox virus ***(NOTE: 'cultures only' likely to be added from 2007)***
Lumpy skin disease virus***(NOTE: 'cultures only' likely to be added from 2007)***
Mycoplasma mycoides - Contagious bovine pleuropneumonia ***(NOTE: 'cultures only' likely to be added from 2007)***
Peste des petits ruminants virus ***(NOTE: 'cultures only' likely to be added from 2007)***
Rinderpest virus ***(NOTE: 'cultures only' likely to be added from 2007)***
Sheep-pox virus ***(NOTE: 'cultures only' likely to be added from 2007)***
Swine vesicular disease virus ***(NOTE: 'cultures only' likely to be added from 2007)***
Vesicular stomatitis virus ***(NOTE: 'cultures only' likely to be added from 2007)***

APPENDIX B

Scenarios involving the transport of infectious substances

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

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

   UK Guidance: UN2814 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 transport. Consequently they 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..

   Culture of a clinical specimen taken from a cow in a herd known to be affected by BOVINE TUBERCULOSIS.

   UK Guidance: UN3373.

   Reason: Pathogens assigned to Category B may be responsible for causing disease in humans or animals, but the conditions in transport are such that the likelihood of the disease being contracted from a sample in transport 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 consigned/shipped under UN2814 or UN2900 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).

UK Guidance: UN3373

Reason: In this example it is assumed that the sample has not been inactivated or neutralised. Consequently, unless it can be categorically stated that no pathogens are present or those that are present do not pose a health risk, it is suggested that to avoid an inadvertent breach of regulations, UN3373 should be assigned.

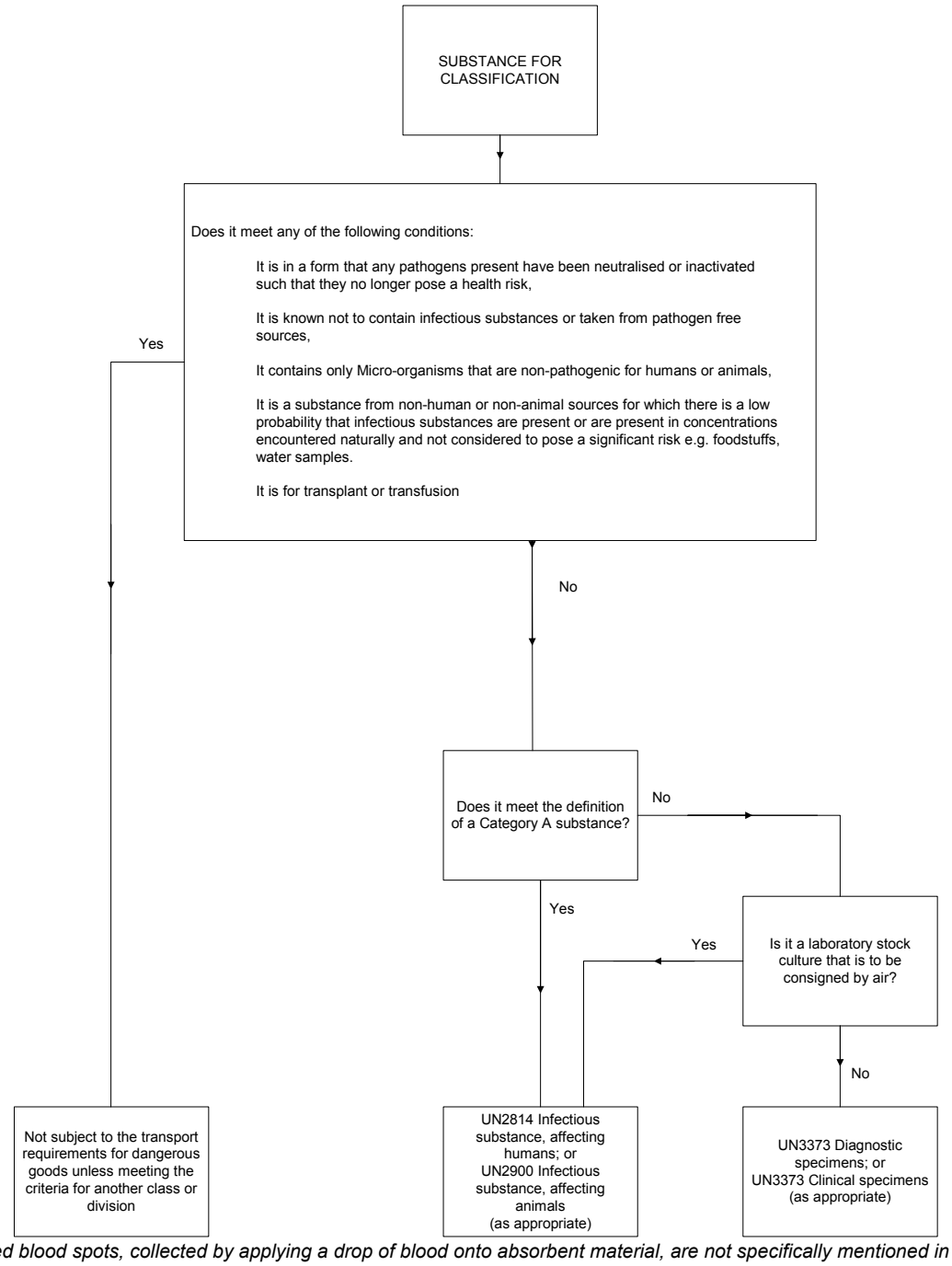
5. Specimen containing a Category A or B infectious substance, treated so as to inactivate or neutralise the pathogens such that they no longer pose a health risk.

UK Guidance : Not subject to the transport requirements for dangerous goods, unless meeting the criteria for another class or division.

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



Note:- dried blood spots, collected by applying a drop of blood onto absorbent material, are not specifically mentioned in the transport requirements. However, expert medical advice in the United Kingdom is that these items need not be classified as UN3373 unless they are known or reasonably believed to contain infectious substances of category A. In addition expert medical opinion in the United Kingdom is that faecal occult blood tests using the guaiac smear method are not realistically capable of posing a risk to health, safety, property or the environment during transport.

APPENDIX D

Package Testing Requirements

a) Samples must be subjected to free-fall drops onto a rigid, non-resilient, flat, horizontal surface from a height of (1.2 metres). Where the samples are in the shape of a box, five must be dropped in sequence:

1) flat onto the base;

2) flat onto the top;

3) flat onto the longest side;

4) flat onto the shortest side;

5) onto a corner.

Where the samples are in the shape of a drum, three must be dropped in sequence:

6) diagonally onto the top chime, with the centre of gravity directly above the point of impact;

7) diagonally onto the base chime;

8) flat onto the side.

Following the appropriate drop sequence, there must be no leakage from the primary receptacle(s), which must remain protected by absorbent material in the secondary packaging.

Note.— While the sample must be released in the required orientation, it is accepted that for aerodynamic reasons the impact may not take place in that orientation.

b) If the test sample includes an outer packaging constructed of fibreboard, the sample must be subjected to a water spray that simulates exposure to rainfall of approximately 5 cm per hour for at least one hour. It must then be subjected to the test described in a) above.

c) If the test sample includes an inner or outer packaging constructed of plastic, the sample must be conditioned in an atmosphere of –18°C or less for a period of at least 24 hours and within 15 minutes of removal from that atmosphere be subjected to the test described in a) above. Where the sample contains dry ice, the conditioning period may be reduced to 4 hours.

d) Where the packaging is intended to contain dry ice, a test additional to that specified in a) or b) or c) must be carried out. One sample must be stored so that all the dry ice dissipates and then be subjected to the test described in a).

8. CHANGES LIKELY FROM 2007 (AS A RESULT OF THE 26TH SESSION OF THE UN SUB-COMMITTEE OF EXPERTS ON THE TRANSPORT OF DANGEROUS GOODS)

NOTE: CHANGES ARE SHOWN AS HIGHLIGHTED OR STRIKETHROUGH

As stated previously, the new provisions for the transport of Division 6.2 were agreed at the December 2004 session of the UN Sub- Committee of Experts on the Transport of Dangerous Goods. Below are the changes to the UN text that are likely to be adopted in the modes in 2007 and then into domestic regulations. **Note: Some of these have already been adopted by the air mode see ICAO addendum Doc 9284-AN/905 attached**.

Chapter 1.4- 1.4.1 In the table for Division 6.2 insert (UN Nos UN 2814 and 2900)" after "Category A".

2.6.3.1.3 Cultures (~~laboratory stocks~~) are the result of a process by which pathogens are ~~amplified or~~ intentionally propagated. This definition does not include human or animal patent specimens as defined in 2.6.3.1.4. ~~in order to generate high concentrations thereby increasing the risk of infection when exposure to them occurs. This definition refers to cultures prepared for the intentional generation of pathogens and does not include cultures intended for diagnostic and clinical.~~

2.6.3.1.4 Patient specimens are human or animal materials collected directly from humans or animals, including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluid swabs, and body parts being transported for purposes such as research, diagnosis, investigational activities, disease treatment and prevention.

2.6.3.2 Classification of Infectious substances

2.6.3.2.1 Infectious substances shall be classified in Division 6.2 and assigned to UN 2814, UN 2900, UN 3291 or UN 3373 as appropriate.

2 6.3.2.2.1 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~~ in otherwise healthy humans or animals. Indicative examples of substances that meet these criteria are given in the table in this paragraph.

Add a new note below Note 3 to read as follows;

NOTE [X] Animal carcasses affected by pathogens which would be assigned to Category A either as pathogens or in cultures only, shall be assigned to UN 2814 or UN 2900 as appropriate.
Other animal carcasses affected by pathogens included in category B shall be transported in accordance with provisions determined by competent authority.

CHANGES TO THE SUBSTANCES LISTED IN THE TABLES SEE APPENDIX A OF THIS DOCUMENT

2.6.3.2.2 Category B: An infectious substance which does not meet the criteria for inclusion in Category A. Infectious substances in Category B shall be assigned to UN 3373 ~~except that cultures as defined in 2.6.3.1.3 shall be assigned to UN 2814 or UN 2900 as appropriate~~.

NOTE: The proper shipping name for UN 3373 is BIOLOGICAL SUBSTANCE, CATEGORY B" ~~"DIAGNOSTIC or CLINICAL SPECIMENS~~"

2.6.3.2.3 *Exemptions*

2.6.3.2.3. 1 Substances etc. (Note: the only change to this paragraph is the number)

2.6.3.2.3.2 Substances containing micro organisms which are non- pathogenic to humans or animals are not subject to these Regulations unless they meet the criteria for inclusion in another class.

2.6.3.2.3.3 Substances in a form that any present pathogens have been neutralized inactivated such that they no longer pose a health risk are not subject to these Regulations unless they meet the criteria for inclusion in another class.

2.6.3.2.3.4 Environmental samples (including food and water samples) which are not considered to pose a significant risk of infection are not subject to these Regulations unless they meet the criteria for inclusion in another class.

2.6.3.2.5 Dried blood spots, collected by applying a drop of blood onto absorbent material, or faecal occult blood screening tests and blood or blood components which have been collected for the purpose of transfusion or for the preparation of blood products to be used for trans fusion or transplantation and any tissues or organs intended for use in transplants are not subject to these Regulations.

~~2.6.3.2.5 Substances for which there is a low probability that infectious substances are present, or where the concentration is at a level naturally encountered are not subject to these~~

~~regulations. Examples are foodstuffs, water samples, living persons and substances which have been treated so that the pathogens have been neutralized or deactivated~~.

2.6.3.2.6 Human or animal specimens for which there is minimal likelihood that pathogens are present are not subject to these Regulations if the specimen is transported in a packaging which will prevent any leakage and which is marked with the words " Exempt human specimen" or "Exempt animal specimen" as appropriate. The packaging should meet the following conditions:

(a) The packaging should consist of three components:

(i) a leak-proof primary receptacle(s):

(ii) a leak proof secondary packaging: and

(iii) an outer packaging of adequate strength for its capacity, mass and intended use and with at least one surface having minimum dimensions of 100mm × 100mm:

(b) For liquids, absorbent material in sufficient quantity to absorb the entire contents should be placed between the primary receptacle (s) and the secondary packaging so that, during transport, any release or leak of a liquid substance will not reach the outer packaging and will not compromise the integrity of cushioning material;

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

NOTE: *An element of professional judgment is required to determine if a substance is exempt under this section. That judgement should be based on the known medical history, symptoms and individual circumstances of the source, human or animal, and endemic local conditions. Examples of specimens which may be transported under this section include the blood or urine tests to monitor cholesterol levels, blood glucose levels, hormone levels, or prostrate specific antibodies (PSA); those required to monitor organ function such as heart, liver or kidney function for humans or animals with non- infectious diseases, or therapeutic drug monitoring; those conducted for insurance or employment purposes and are intended to determine the presence of drugs or alcohol; pregnancy test. Biopsies to detect cancer; and antibody detection in humans or animals*

2.6.3.2.6 ~~**7**~~ Unless an infectious substance cannot be regulated by any other means, live animals shall not be used to consign such as substance. An animal which has been intentionally infected and is known or suspected to contain an infectious substance shall only be transported under terms and conditions approved by the competent authority.

2.6.3.5 Medical or clinical wastes

2.6.3.5.1 Medical or clinical wastes containing Category A infectious substances ~~or containing Category B infectious substances in cultures~~ shall be assigned to UN 2814 or UN 2900 as

appropriate. Medical or clinical wastes containing infectious substances in Category B, ~~other than cultures~~, shall be assigned to UN 3291.

DANGEROUS GOODS LIST;

CHANGE NAME AND DESCRIPTION FROM DIAGNOSTIC OR CLINICAL SPECIMENS TO BIOLOGICAL SUBSTANCE CATEGORY B . IN THE COLUMNS FOR PORTABLE TANKS INSERT T1 IN COLUMN 10 AND TP1 IN COLUMN 11

SPECIAL PROVISION 319

319 ~~This entry applies 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~~. Substances packed and marked in accordance with packing instruction P650 are not subject to any other requirements in these Regulations.

CHANGES TO PART 4 PACKING INSTRUCTIONS

P650

Amend paragraph 2 to read

(2) The packaging shall consist of at least three components:

(a) A primary receptacle.

(b) A secondary packaging, and

(c) An outer packaging of which either the secondary or the outer packaging shall be rigid.

AMEND PARAGRAPH 4 TO READ

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

A NEW PARAGRAPH 5 TO READ

(5) At least one surface of the outer packaging shall have a minimum dimension of 100mm × 100mm.

OLD PARAGRAPH 5 RENUMBERED 6 AND AMENDED TO READ

(6) the completed package shall be capable of successfully passing the drop test in 6.3.2.5 as specified in 6.3.2.2 to 6.3.2.4 of the Model Regulations ~~except that the~~ at a height of ~~the drop shall not be less than~~ 1.2m. Following the appropriate drop sequence there shall be leakage from the primary receptacle(s) which shall remain protected by absorbent material when required in the secondary packaging.

AMEND PARAGRAPH 8 TO READ

(8) For solid substances;

(a) The primary receptacle(s) shall be siftproof.

(b) The secondary packaging shall be siftproof

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

(d) 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, shall be used.

INSERT A NEW PARAGRAPH 13 TO READ

(13) Other dangerous goods shall 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 30ml or less of dangerous goods included in Classes 3,8 or 9 may be packed in each primary receptacle containing infectious substances in accordance with this packing instruction no other requirements in these Regulations need be met.

AMENDMENTS TO CHAPTER 4.3

Amend the title to read as follows;

Bulk waste goods of Division 6.2 (UN 2900 and UN 2814 (animal carcasses only))
Consequential amendment: Insert " and UN 2814" after "UN 2900" in current sub- paragraphs (a), (b), (c), (d) and (e).

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