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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-first session, 1-10 July 2002, agenda item 7)

TRANSPORT OF INFECTIOUS SUBSTANCES

Revision of Division 6.2 provisions

Transmitted by the expert from Canada on behalf of the Division 6.2 Informal Working Group

Background

1. At the twentieth session of the Sub-Committee of Experts on the Transport of Dangerous Goods, it was agreed (ST/SG/AC.10/C.3/40) that an informal working group meeting would be held in Paris from 11 to 13 March 2002 to consider the requirements in the Model Regulations for transporting infectious substances.

2. The informal working group meeting was attended by representatives of Canada, the Czech Republic, France, Germany, Italy, Norway, the United Kingdom, the United States, the Basel Convention Secretariat, the World Health Organization (WHO), the American Biological Safety Association (ABSA), the Dangerous Goods Advisory Council (DGAC, also known as HMAC), the European Biosafety Association (EBSA), the International Air Transport Association (IATA) and the International Express Carriers Conference (IECC).

3. The working group meeting was chaired by Dr. Sergio Benassai, Italy.

4. The recommendations resulting from this working group meeting are presented below for consideration and adoption by the Sub-Committee.

Proposal number 1

In the 12th revised edition of the Model Regulations, replace section 2.6.3, Division 6.2 – Infectious Substances, of Chapter 2.6 with the following text.

2.6.3 Division 6.2 - Infectious substances

2.6.3.1 *Definitions*

For the purposes of these Regulations:

2.6.3.1.1 *Infectious substances* are substances which are known or are reasonably expected to contain pathogens. Pathogens 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.

2.6.3.1.2 *Biological products* are those products derived from living organisms which are manufactured and distributed in accordance with the requirements of national governmental authorities, which may have special licensing requirements, and are used either for prevention, treatment, or diagnosis of disease in humans or animals, or for development, experimental or investigational purposes related thereto. They include, but are not limited to, finished or unfinished products such as vaccines.

2.6.3.1.3 *Cultures* are the result of a process by which pathogens may be amplified or propagated to generate high concentrations not normally found in nature, thereby increasing the risk of infection when exposure to them occurs.

2.6.3.1.4 *Genetically modified micro-organisms and organisms* are micro-organisms and organisms in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally.

2.6.3.1.5 *Medical or clinical wastes* are wastes derived from the medical treatment of animals or humans or from bio-research.

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 or UN 3373, as appropriate. Infectious substances are divided into the following categories.

2.6.3.2.2 The criteria for each category are as follows:

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 humans or animals. Indicative examples of substances that meet these criteria are given in the table to this paragraph.

***NOTE** : An exposure occurs when an infectious substance is released outside of the protective packaging, resulting in physical contact with humans or animals.*

(a) Infectious substances meeting these criteria shall be assigned to UN 2814 or UN 2900. Infectious substances which cause disease in humans or both in humans and animals shall be assigned to UN 2814. Infectious substances which cause disease only in animals shall be assigned to UN 2900.

(b) Assignment to UN 2814 or UN 2900 should be based on the known medical history and symptoms of the source human or animal, endemic local conditions, or professional judgement concerning individual circumstances of the source human or animal.

NOTE 1*: The proper shipping name for UN 2814 is INFECTIOUS SUBSTANCE, AFFECTING HUMANS. The proper shipping name for UN 2900 is INFECTIOUS SUBSTANCE, AFFECTING ANIMALS ONLY.*

NOTE 2**: The following table is not exhaustive. Infectious substances, including new or emerging pathogens, which do not appear in the table but which meet the same criteria should be assigned to Category A. In addition, if there is doubt as to whether or not a substance meets the criteria it shall be included in Category A.*

NOTE 3: *In the following table, the micro-organisms written in italics are bacteria, mycoplasmas, rickettsia or fungi.*

INDICATIVE EXAMPLES OF INFECTIOUS SUBSTANCES INCLUDED IN CATEGORY A IN ANY FORM UNLESS OTHERWISE INDICATED (2.6.3.2.2.(a))	
UN Number and Proper Shipping Name	Micro-organism
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)

INDICATIVE EXAMPLES OF INFECTIOUS SUBSTANCES INCLUDED IN CATEGORY A IN ANY FORM UNLESS OTHERWISE INDICATED (Continued) (2.6.3.2.2.(a))	
UN Number and Proper Shipping Name	Micro-organism
UN 2814 Infectious substances affecting humans	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)

INDICATIVE EXAMPLES OF INFECTIOUS SUBSTANCES INCLUDED IN CATEGORY A IN ANY FORM UNLESS OTHERWISE INDICATED (End) (2.6.3.2.2.(a))	
UN Number and Proper Shipping Name	Micro-organism
UN 2900 Infectious substances affecting animals only	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

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

2.6.3.2.3 Substances which do not contain infectious substances or substances which are unlikely to cause disease in humans or animals are not subject to these Regulations unless they meet the criteria for inclusion in another class.

2.6.3.2.4 Blood which has been collected for the purpose of blood transfusion or for the preparation of blood products, blood products, 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.

2.6.3.3 ***Biological products***

2.6.3.3.1 For the purposes of these Regulations, biological products are divided into the following groups:

(a) those known or reasonably believed to contain infectious substances and which meet the criteria for inclusion in Category A or Category B. Substances in this group shall be assigned to UN 2814, UN 2900 or UN 3373, as appropriate.

(b) those which are manufactured and packaged in accordance with the requirements of national governmental health authorities and transported for the purposes of final packaging or distribution, and use for personal health care by medical professionals or individuals. Substances in this group are not subject to these Regulations.

***NOTE**: Some licensed biological products may present a biohazard only in certain parts of the world. In that case, competent authorities may require these biological products to be in compliance with local requirements for infectious substances or may impose other restrictions.*

2.6.3.4 Genetically modified micro-organisms and organisms

2.6.3.4.1 Genetically modified micro-organisms which meet the definition of an infectious substance shall be classified in Division 6.2 and assigned to UN 2814, UN 2900 or UN 3373.

2.6.3.4.2 Genetically modified organisms, which are known or suspected to be dangerous to humans, animals or the environment, shall be transported in accordance with conditions specified by the competent authorities.

2.6.3.4.3 Animals which contain or which are contaminated with genetically modified micro-organisms which meet the definition of infectious substances shall be transported in accordance with conditions specified by the competent authorities.

2.6.3.4.4 Except when authorized for unconditional use by the governments of the countries of origin, transit and destination, genetically modified micro-organisms which do not meet the definition of infectious substances but which are capable of altering animals, plants or microbiological substances in a way not normally the result of natural reproduction shall be classified in Class 9 and assigned to UN 3245.

2.6.3.5 Medical or clinical wastes

2.6.3.5.1 Medical or clinical wastes containing Category A infectious substances or 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.

2.6.3.5.2 Medical or clinical wastes which are reasonably believed to have a low probability of containing infectious substances shall be assigned to UN 3291.

***NOTE**: The proper shipping name for UN 3291 is CLINICAL WASTE, UNSPECIFIED, N.O.S. or (BIO) MEDICAL WASTE, N.O.S. or REGULATED MEDICAL WASTE, N.O.S.*

2.6.3.5.3 Decontaminated medical or clinical wastes which previously contained infectious substances are not subject to these Regulations unless they meet the criteria for inclusion in another class.

Justification

1. In the last biennium, and in this biennium, a number of problems with the current requirements in the Model Regulations for transporting infectious substances have been brought to the attention of the Sub-Committee. These problems include the lack of clarity of the current text, the lack of guidance for competent authorities, consignors and carriers in determining what is and what is not included in Division 6.2 and the classification procedure which, based on the WHO risk group definitions and criteria, resulted in inconsistent classification from country to country.

2. In Proposal Number 1, definitions for *infectious substances*, *biological products*, *cultures*, *genetically modified micro-organisms and organisms*, and *medical or clinical wastes* are provided at the beginning of section 2.6.3 and are separated from any requirements or exemptions attached to them.

The definition of *infectious substances* is basically the same as in the 12th revised edition as are the definitions for *biological products*, *genetically modified micro-organisms and organisms*, and *medical or clinical wastes*. A new definition for *cultures* was added and the definition of *diagnostic specimens* was deleted.

Notes 1 and 2 following the definition of *infectious substances* in the 12th revised edition have been incorporated into the text: *Note 1* is now regulatory text in 2.6.3.2.3 and *Note 2* is in the regulatory text for Category A at 2.6.3.2.2.1.

3. In Proposal Number 1, to address the problems with classification and to provide more guidance for users, this paper proposes deleting 2.6.3.2 of the 12th edition, including the reference to risk groups, and replacing it with a new 2.6.3.2 which divides infectious substances into categories.

Category A is the high risk category – assigned to UN 2814 or UN 2900, as appropriate - and with it is a table that contains an indicative list of examples of substances that fit the criteria for inclusion in this category. There are new notes to provide guidance for users including a note that explains exposure and a note (Note 2) that clearly states that the table is not exhaustive and that infectious substances, including new and emerging pathogens, not included in the table but that meet the criteria for Category A should be assigned to that category as should any substance if there is doubt as to whether or not it meets the Category A criteria.

Category B includes infectious substances that do not meet the criteria for inclusion in Category A and these are assigned to UN 3373.

4. In Proposal Number 1, 2.6.3.2.3, 2.6.3.2.4 and 2.6.3.2.5 retain the notions in the 12th edition that

- substances that do not contain infectious substances or substances that are unlikely to cause in humans or animals are not subject to the Model Regulations unless they meet the criteria for inclusion in another class,
- blood for transfusion, blood products and tissues and organs for transplant are not subject to the Model Regulations,
- 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 the Model Regulations and examples include water samples, living persons, foodstuffs and substances that have been treated so that the pathogens are neutralized or deactivated.

5. In Proposal Number 1, only minor editorial changes have been made to the sections in the 12th edition dealing with biological products, genetically modified micro-organisms and organisms, and medical or clinical wastes.

Proposal Number 2

1. In Chapter 3.2, Dangerous Goods List, UN 2814 and UN 2900, add special provision XXX. The text of the proposed new special provision is in Proposal Number 4.

Justification

This special provision is intended to provide for those instances when there is an outbreak or a disease investigation and the substance is not known. In this case, it is impossible to show an accurate technical name on a shipping document or a package.

Proposal Number 3

1. In Chapter 3.2, Dangerous Goods List, UN 3373 change the shipping name associated with UN 3373 to "DIAGNOSTIC SPECIMENS or CLINICAL SPECIMENS"

2. In Chapter 3.2, Dangerous Goods List**,** UN 3373**,** add special provision number YYY to UN 3373. The text of the proposed new special provision is in Proposal Number 4.

Justification

1. At the working group meeting there was considerable discussion about the continued use of UN 3373. It was finally decided to propose that the shipping name be changed to include clinical specimens and that a special provision be added to provide guidance to competent authorities, consignors and carriers as to what substances would be described by UN 3373 and transported under that UN number.

2. It was felt that UN 3373 and the associated shipping name were known by most consignors and carriers and that deletion and use of a new UN number and shipping name would not be helpful. Consequently, it was agreed that the changes mentioned above would provide the required direction for consignors and carriers, as well as competent authorities, and that a new special provision would enhance the clarity of the text.

Proposal Number 4

1. In Chapter 3.3, Special Provisions Applicable to Certain Articles or Substances, add the following special provisions as indicated:

   (a) to UN 2814 and UN 2900:

   "XXX. When there is an outbreak of a disease or a disease investigation is being conducted and the pathogen causing the disease is unknown, the technical name required by special provision 274 need not be shown on the transport document, on the outer packaging or on the document inside the outer packaging if the substance is assigned to UN 2814 or UN 2900 as appropriate and the words "Outbreak/Disease Investigation" are shown, in parentheses, following the proper shipping name on the transport document, on the outer packaging and on the document inside the outer packaging."

   (b) to UN 3373:

   "YYY. 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. Infectious substances packed and marked in accordance with Part 1 of Packing Instruction P650 are not subject to any other requirements in these Regulations."

Proposal Number 5

1. In Chapter 4.1, the following changes to P620 are proposed:

P620	**PACKING INSTRUCTION**	**P620**

This instruction applies to UN Nos. 2814 and 2900.

The following packagings are authorized provided the special packing provisions of **4.1.8** are met:

Packagings meeting the requirements of Chapter 6.3 and approved accordingly consisting of:

(a) Inner packagings comprising:

(i) watertight primary receptacle(s);

(ii) a watertight secondary packaging;

(iii) other than for solid infectious substances, an absorbent material in sufficient quantity to absorb the entire contents placed between the primary receptacle(s) and the secondary packaging; if multiple fragile primary receptacles are placed in a single secondary packaging, they shall be **either** individually wrapped **or separated** so as to prevent contact between them;

(b) A **rigid** outer packaging of adequate strength for its capacity, mass and intended use. The smallest external dimension shall be at least 100 mm.

Additional requirements:

1. Inner packagings containing infectious substances shall not be consolidated with inner packagings containing unrelated types of goods. Complete packages may be overpacked in accordance with the provisions of 1.2.1 and 5.1.2: such an overpack may contain dry ice.

2. Other than for exceptional consignments, e.g. whole organs which require special packaging, the following additional requirements shall apply:

(a) Substances consigned at ambient temperatures or at a higher temperature. Primary receptacles shall be of glass, metal or plastics. Positive means of ensuring a leakproof seal shall be provided, e.g. a heat seal, a skirted stopper or a metal crimp seal. If screw caps are used, they shall be secured by positive means, e.g., tape, parrafin sealing tape or manufactured locking closure;

(b) Substances consigned refrigerated or frozen. Ice, dry ice or other refrigerant shall be placed around the secondary packaging(s) or alternatively in an overpack with one or more complete packages marked in accordance with 6.3.1.1. Interior supports shall be provided to secure secondary packaging(s) or packages in position after the ice or dry ice has dissipated. If ice is used, the outer packaging or overpack shall be leakproof. If dry ice is used, the outer packaging or overpack shall permit the release of carbon dioxide gas. The primary receptacle and the secondary packaging shall maintain their integrity at the temperature of the refrigerant used;

(c) Substances consigned in liquid nitrogen. Plastics primary receptacles capable of withstanding very low temperature shall be used. The secondary packaging shall also be capable of withstanding very low temperatures, and in most cases will need to be fitted over the primary receptacle individually. Provisions for the consignment of liquid nitrogen shall also be fulfilled. The primary receptacle and the secondary packaging shall maintain their integrity at the temperature of the liquid nitrogen.

(d) Lyophilized substances may also be transported in primary receptacles that are flame-sealed glass ampoules or rubber-stoppered glass vials fitted with metal seals;

3. Whatever the intended temperature of the consignment, the primary receptacle or the secondary packaging shall be capable of withstanding without leakage an internal pressure producing a pressure differential of not less than 95 kPa and temperatures in the range -40 ºC to +55 ºC.

Justification

1. The change in (a)(iii), 6th line, is proposed to make P620 consistent with P650.

2. It was the belief of the working group that "rigid" needed to be added to (b) to ensure the quality of the outer packaging.

3. The change under Additional Requirements, section 2, regarding lyophilized substances is proposed to ensure clarity in packaging for these substances. It is the understanding of the working group that the packaging requirements in 2(b) apply and that lyophilized substances **may also** be transported in primary receptacles … etc.

Proposal Number 6

1. Replace P650 in the 12th edition with the following:

P 650	**PACKING INSTRUCTION**	**P650**
This packing instruction applies to UN 3373		

Part 1: Provisions for primary receptacles that do not exceed 500 mL or 500 g

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,

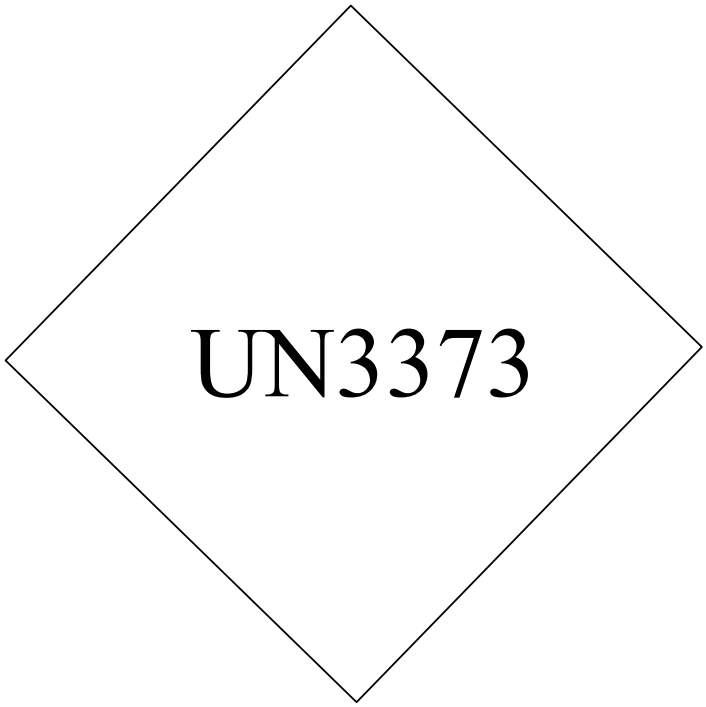
(b) a secondary packaging, and

(c) an outer packaging.

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.

P 650	PACKING INSTRUCTION (cont'd)	P650

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.



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 except that the height of the drop shall not be less than 1.2 m.

Liquid substances

1. The primary receptacle(s) shall be leakproof and shall not contain more than 500 mL of the liquid substance.

2. The secondary packaging shall be leakproof.

3. 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.

4. 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.

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

6. The outer packaging shall not contain more than 4 litres of the liquid substance.

P 650	PACKING INSTRUCTION (cont'd)	P650

Solid substances

1. The primary receptacle(s) shall be sift proof and shall not contain more than 500 g of the solid substance.

2. The secondary packaging shall be siftproof.

3. 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.

4. The outer packaging shall not contain more than 4 kg of the solid substance.

Dry ice and liquid nitrogen

(a) When UN 1845, Carbon Dioxide, Solid, (dry ice) is used as a refrigerant, the packaging shall be designed and constructed to permit the release of the gaseous carbon dioxide to prevent the build up of pressure that could rupture the packaging.

(b) Substances consigned in liquid nitrogen or dry ice shall be packed in primary receptacles that are capable of withstanding very low temperatures. The secondary packaging shall also be capable of withstanding very low temperatures and, in most cases, will need to be fitted over the primary receptacle individually.

Infectious substances in Category B which are packed and marked in accordance with Part 1 of this packing instruction are not subject to any other requirement in these Regulations.

P 650	PACKING INSTRUCTION (cont'd)	P650

Part 2: Provisions for primary receptacles that exceed 500 mL or 500 g (liquid and solid) or outer packagings that exceed 4 L or 4 kg.

1. When the primary receptacle(s) contain substances in excess of 500 mL or 500 g, the following packagings shall be used and shall meet the general provisions of 4.1.1 and 4.1.3 and the requirements of Chapter 6.1 at the packing group II performance level.

2. The packaging shall consist of three components:

(a) a primary receptacle,

(b) a secondary packaging, and

(c) a rigid outer packaging.

3. For liquids

(a) the primary receptacle and the secondary packaging shall be watertight,

(b) an absorbent material shall be placed between the primary receptacle(s) and the secondary packaging in a quantity sufficient to absorb the entire liquid content of the primary receptacle(s),

(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) The primary receptacle or the secondary packaging shall be capable of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 95 kPa (0.95 bar).

4. For solids, the primary receptacle and the secondary packaging shall be siftproof.

5. The outer packaging shall be strong enough for its capacity, mass and intended use and the smallest external dimension shall be at least 100 mm.

Infectious substances in Category B which are packed in accordance with Part 2 of this packing instruction are subject to all the other requirements in these Regulations. The UN number and proper shipping name are UN 3373, DIAGNOSTIC SPECIMENS or CLINICAL SPECIMENS. The label for Division 6.2 is required.

Justification

1. Some editorial changes have been made to P650 but there are two major changes: the change of marking from "DIAGNOSTIC SPECIMEN" to the UN number UN 3373 in a diamond shape; and the addition of Part 2 to handle substances in a quantity greater than 500 mL or 500 g or 4 L/4kg since such quantities are required for some medical tests and research.

2. The working group felt that there should be some guidance as to the packaging to use for quantities greater than 500 mL/500g/4 L/4kg. However, the working group also felt that such quantities should be subjected to the other requirements of the Model Regulations and there is a note to that effect at the end of Part 2 of the proposed P650.

Proposal Number 7

1. Change the Alphabetical Index of Substances and Articles to reflect the change in shipping name for UN 3373. That is, DIAGNOSTIC SPECIMENS or CLINICAL SPECIMENS.
