DANGEROUS GOODS PANEL

Dubai, 31 March to 4 April 2003

Agenda Item 2 : Development of recommendations for amendments to the Technical Instructions for incorporation in the 2005/2006 edition

CONSOLIDATED AMENDMENTS - DIVISION 6.2

(Presented by the Secretary)

SUMMARY

To facilitate discussion on infectious substances, the proposed amendments for Division 6.2 in Parts 2, 3, 4, 5 and 7 have been consolidated.

Part 2; Chapter 6

CLASS 6 – TOXIC AND INFECTIOUS SUBSTANCES

INTRODUCTORY NOTES

~~*Note 1 – Genetically modified micro-organisms and organisms which do not meet the definition of an infectious substance should be considered for classification in class 9 and assignment to UN 3245.*~~

Note 1. ~~2.~~ – Toxins from plant, animal or bacterial sources which do not contain any infectious substances or toxins that are not contained in substances which are infectious substances should be considered for classification in division 6.1 and assignment to UN 3172.

6.1 DEFINITIONS

Class 6 is divided into two divisions as follows:

a) Division 6.1 – Toxic substances.

Substances liable either to cause death or injury or to harm human health if swallowed, if inhaled or by skin contact.

Note – In these Instructions 'poisonous' has the same meaning as 'toxic'.

b) Division 6.2 — Infectious substances.

Substances know to contain, or reasonably expected to contain, pathogens. Pathogens are defined as micro-organisms (including bacteria, viruses, rickettsia, parasites, fungi) ~~or recombinant micro-organisms (hybrid or mutant), that are known or reasonably expected to cause infectious disease in animals or humans~~ and other agents such as prions, which can cause disease in humans or animals.

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Editorial note: Delete 6.3 and replace with the following new text

6.3 Division 6.2 - Infectious substances

6.3.1 *Definitions*

For the purposes of these Instructions:

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) and other agents such as prions, which can cause disease in humans or animals.

6.3.1.2 *Biological products* are those products derived from living organisms which are manufactured and distributed in accordance with the requirements of appropriate national 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.

6.3.1.3 *Cultures* (laboratory stocks) are 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 definition refers to cultures prepared for the intentional generation of pathogens and does not include cultures intended for diagnostic or clinical purposes.

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.

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

6.3.2 *Classification of infectious substances*

6.3.21 Infectious substances must be classified in Division 6.2 and assigned to UN 2814, UN 2900 or UN 3373 as appropriate..

6.3.2.2 Infectious substances are divided into the following categories.

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 in 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 which cause disease in humans or both in humans and animals must be assigned to UN 2814. Infectious substances which cause disease only in animals must be assigned to UN 2900.

(b) Assignments to UN 2814 or UN 2900 must 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 in not exhaustive. Infectious substances, including new or emerging pathogens, which do not appear in the table but which meet the same criteria must be assigned to Category A. In addition, if there is doubt as to whether or not a substance meets the criteria it must be included in Category A.*

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

INDICATIVE EXAMPLES OF INFECTIOUS SUBSTANCES INCLUDED IN CATEGORY A IN ANY FORM UNLESS OTHERWISE INDICATED (6.3.2.2.1 (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)

INDICATIVE EXAMPLES OF INFECTIOUS SUBSTANCES INCLUDED IN CATEGORY A IN ANY FORM UNLESS OTHERWISE INDICATED (6.3.2.2.1 (a))	
UN Number and Proper Shipping Name	**Micro-organism**
	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
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

6.3.2.2.2 Category B: An infectious substance which does not meet the criteria for inclusion in Category A. Infectious substances in Category B must be assigned to UN 3373 except that cultures as defined in 6.3.1.3 must be assigned to UN 2814 or UN 2900 as appropriate.

Note.- The proper shipping name of UN 3373 is ***Diagnostic specimens*** *or* ***Clinical specimen***s

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 Instructions unless they meet the criteria for inclusion in another class.

6.3.2.4 Blood or blood components which have been collected for the purposes 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.

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

[6.3.2.6 An alive animal which has been intentionally infected and is known or suspected to contain an infectious substance must only be transported under terms and conditions approved by the appropriate national authority.]

6.3.3 Biological products

6.3.3.1 For the purposes of these Instructions, biological products are divided into the following groups:

(a) Those which are manufactured and packaged in accordance with the requirements of appropriate national 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 Instructions.

(b) Those which do not fall under paragraph (a) and are 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 must be assigned to UN 2814, UN 2900 or UN 3373, as appropriate.

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

6.3.4 *Genetically modified micro-organisms and organisms*

6.3.4.1 Genetically modified micro-organisms not meeting the definition of infectious substances must be classified according to Chapter 9.

6.3.5 *Medical or clinical wastes*

6.3.5.1 Medical or clinical wastes containing Category A infectious substances or containing Category B infectious substances in cultures must be assigned to UN 2814 or UN 2900 as appropriate. Medical or clinical wastes containing infectious substances in Catogory B, other than cultures, must be assigned to UN 3291.

6.3.5.2 Medical or clinical wastes which are reasonably believed to have a low probability of containing infectious substances must 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.***

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

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Part 3; Chapter 3

SPECIAL PROVISIONS

A47 Genetically modified micro-organisms and genetically modified organisms, which ~~are not~~ meet the definition of an infectious substance~~s~~ and the criteria for inclusion in Division 6.2 in accordance with 2;6 must be transported as UN 2814, UN 2900 or UN 3373, as appropriate. ~~but which are capable of altering animals, plants or microbiological substances in a way that is not normally the result of natural reproduction, must be transported as UN 3245. Genetically modified micro-organisms which are infectious must be transported as UN 2814 or UN 2900.~~

A136 This entry must not be used for Division 6.1 substances that meet the inhalation toxicity criteria for packing group I described in 2;6.2.2.4.3.

A139 For the purposes of documentation, the proper shipping name must be supplemented with the technical name (see 1.2.7). Technical names need not be shown on the package. When the infectious substances to be transported are unknown, but suspected of meeting the criteria for inclusion in category A and assignment to UN 2814 or UN 2900, the words "suspected category A infectious substance" must be shown, in parentheses, following the proper shipping name on the transport document, but not on the outer packagings.

A140 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 650 are not subject to any other requirements in these Instructions.

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Part 4; Chapter 8

P620	PACKING INSTRUCTION	P620

This instruction applies to UN Nos. 2814 and 2900.

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

Packagings meeting the requirements of Part 6, Chapter 6 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 packaging of adequate strength for its capacity, mass and intended use. The smallest external dimension must be not less than 100 mm.

Additional requirements:

1. Inner packagings containing infectious substances must 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 must apply:

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

(b) *Substances consigned refrigerated or frozen*. Ice, dry ice or other refrigerant must be placed around the secondary packaging(s) or alternatively in an overpack with one or more complete packages marked in accordance with 6;2.2.2. Interior supports must 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 must be leakproof. If dry ice is used, the outer packaging or overpack must permit the release of carbon dioxide gas. The primary receptacle and the secondary packaging must 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 must be used. The secondary packaging must 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 must also be fulfilled. The primary receptacle and the secondary packaging must 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 must 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.

Special packing provisions

1) Shippers of infectious substances must ensure that packages are prepared in such a manner that they arrive at their destination in good condition and present no hazard to persons or animals during transport.

The definition in Part 1, Chapter 3 and the general packing provision of Part 4, Chapter 1, apply to infectious substances packages. [However, liquids must be filled into packagings, which have an appropriate resistance to the internal pressure that may develop under normal conditions of transport.]

An itemized list of contents must be enclosed between the secondary packaging and the outer packaging. When the infectious substances to be transported are unknown, but suspected of meeting the criteria for inclusion in Category A and assignment to UN 2814 or UN 2900, the words “suspected category A infectious substance” must be shown, in parentheses following the proper shipping name on the document inside the outer packaging.

Before an empty packaging is returned to the consignor, or sent elsewhere, it must be thoroughly disinfected or sterilized and any label or marking indicating that it had contained an infectious substance must be removed or obliterated.

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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 contents 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) an 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 width of the line must be at least 2 mm; the letters and numbers must be at least 6 mm high.

(5) 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 1.2 m.

(6) For liquid substances

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

(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

P650	PACKING INSTRUCTION	P650

absorbent material must 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 must be capable of withstanding, without leakage, an internal pressure of 95 kPa (0.95 bar).

(7) For solid substances

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

(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.

(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 Instructions must be met. When used, ice or dry ice must be placed outside the secondary packagings or in the outer packaging or an overpack. Interior supports must 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 must be leakproof. If carbon dioxide, solid (dry ice) is used, the packaging must 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 must be marked "Carbon dioxide, solid" or "Dry ice".

(b) The primary receptacle and the secondary packaging must 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 Instructions.

(10) 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.

Part 5; Chapter 1

GENERAL

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1.2 ADDITIONAL GENERAL REQUIREMENTS FOR INFECTIOUS SUBSTANCES

~~1.2.1 The transport of infectious substances requires coordinated action by the shipper, the operator and the consignee to ensure safe transport and arrival on time and in proper condition. To this end, the following measures must be taken:~~

~~a) Advance arrangements between shipper, operator and consignee. Dispatch of infectious substances must not take place before advance arrangements have been made between shipper, operator or consignee and before the consignee has confirmed with his appropriate national authorities that the substances can legally be imported and that no delay will be incurred in the delivery of the consignment to its destination.~~

~~b) Preparation of dispatch documents. In order to secure transmission without hindrance it is necessary to prepare all dispatch documents, including the transport document (see Chapter 4), in strict accordance with rules governing the acceptance of goods to be dispatched;~~

~~c) Routing. Whatever the mode used, transport must be by the quickest routing. If transhipment is necessary, precautions must be taken to ensure special care, expeditious handling and monitoring of the substances in transit.~~

~~d) Timely notification of all transport data by shipper to consignee. The shipper must notify the consignee in advance of transport details. The most rapid means of communication must be used for this notification.~~

~~1.2.2~~ 1.2.1 Unless an infectious substance cannot be consigned by any other means, ~~L~~ live vertebrate or invertebrate animals must not be used to consign such a substance. ~~infectious substances unless such substances cannot be consigned by any other means.~~ Infected live animals must not be transported by air unless exempted in accordance with Part 1;1.1.2

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Part 7; Chapter 3

INSPECTION AND DECONTAMINATION

3.1 INSPECTION FOR DAMAGE OR LEAKAGE

3.1.1 It is the operator's responsibility to ensure that a package or overpack containing dangerous goods is not loaded onto an aircraft or into a unit load device unless it has been inspected immediately prior to loading and found free from evidence of leakage or damage.

3.1.2 A unit load device must not be loaded aboard an aircraft unless the device has been inspected and found free from any evidence of leakage from or damage to any dangerous goods contained therein.

3.1.3 Packages or overpacks containing dangerous goods must be inspected for signs of damage or leakage upon unloading from the aircraft or unit load device. If evidence of damage or leakage is found, the position where the dangerous goods or unit load device was stowed on the aircraft must be inspected for damage or contamination and any hazardous contamination removed. The special responsibilities of operators regarding infectious substances are detailed in 3.1.4 and 3.1.5.

3.1.4 If any person responsible for the carriage or opening of packages containing infectious substances becomes aware of damage to or leakage from such a package, that person must:

a) avoid handling the package or keep handling to a minimum;

b) inspect adjacent packages for contamination and put aside any that may have been contaminated;

c) inform the appropriate public health authority or veterinary authority, and provide information on any other countries of transit where persons may have been exposed to danger;

d) notify the consignor and/or the consignee.

3.1.5 Compartment of an aircraft which has been used to transport infectious substances must be inspected for release of the substance before re-use. If the infectious substances were released during transport, the compartment must be decontaminated before it is re-used. Decontamination may be achieved by any means which effectively inactivates the released infectious substance.

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