International Civil Aviation Organization

DGP/20-WP/13
11/8/05

WORKING PAPER

DANGEROUS GOODS PANEL (DGP)

TWENTIETH MEETING

Montréal, 24 October to 04 November 2005

Agenda Item 2: Development of recommendations for amendments to the Technical Instructions for the Safe Transport of Dangerous Goods by Air (Doc 9284) for incorporation in the 2007-2008 Edition

INFECTIOUS SUBSTANCES

(Presented by the Secretary)

1. INTRODUCTION

1.1 Since DGP/19, two addenda to the Technical Instructions relating to infectious substances have been issued. During the discussion of the proposed second addendum, concern was expressed by the Air Navigation Commission at the issuance of a second addendum; it was agreed that members be asked to ensure coordination be undertaken between State authorities and medical experts when considering any future amendments to the Instructions.

1.2 At DGP-WG/05, additional amendments to Packing Instruction 650 were agreed. A consolidated text of the amendments to Part 2, Chapter 6 and Part 4, Chapter 8, Packing Instruction 650 are presented in the appendix to this working paper. Amendments agreed to at WG/05 which were not included in an addendum are shown as changes.

2. PROPOSAL

a) *delete* the second sentence to the Note following 6.3.2.2.2 as follows:

Note.— The proper shipping name of UN 3373 is ***Diagnostic specimens*** *or* ***Clinical specimens*** *or* ***Biological substances, Category B.*** ~~*From 1 January 2007, the use of the shipping names* ***Diagnostic specimens*** *and* ***Clinical specimens*** *will no longer be permitted.*~~

b) *amend* the last sentence of Packing Instruction 650, paragraph 4 to read:

4) For transport, the mark illustrated below must be displayed on the external surface of the outer packaging on a background of a contrasting colour and must be clearly visible and legible. The mark must be in the form of a square set at an angle of 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", "Clinical specimen" or~~ "Biological substance, Category B" in letters at least 6 mm high must be marked on the outer package adjacent to the diamond-shaped mark.

— — — — — — — —

APPENDIX

CONSOLIDATED AMENDMENTS TO PART 2, CHAPTER 6 AND PART 4, CHAPTER 8, PACKING INSTRUCTION 650

Part 2

Chapter 6

CLASS 6 — TOXIC AND INFECTIOUS SUBSTANCES

. . .

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 to contain, 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* are the result of a process by which pathogens are intentionally propagated. This definition does not include patient specimens as defined in 6.3.1.4.

6.3.1.4 Patient specimens are those 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, and disease treatment and prevention.

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

6.3.2.1 Infectious substances must be classified in Division 6.2 and assigned to UN 2814, UN 2900, UN 3291 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 in otherwise healthy humans or animals. Indicative examples of substances that meet these criteria are given in Table 2-10.

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 in both 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 (Table 2-10) is not exhaustive. Infectious substances, including new or emerging pathogens, which do not appear in Table 2-10 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 Table 2-10, the micro-organisms written in italics are bacteria, mycoplasma, rickettsiae or fungi.

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.

Note.— The proper shipping name of UN 3373 is ***Diagnostic specimens*** *or* ***Clinical specimens*** *or* ***Biological substances, Category B.*** *From 1 January 2007, the use of the shipping names* ***Diagnostic specimens*** *and* ***Clinical specimens*** *will no longer be permitted.*

6.3.2.3 *Exemptions*

6.3.2.3.1 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.

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

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

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

6.3.2.3.5 Dried blood spots, collected by applying a drop of blood onto absorbent material, or faecal occult blood screening tests and blood or blood components that 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.

6.3.2.3.6 Patient specimens for which there is minimal likelihood that pathogens are present are not subject to these Instructions 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 must meet the following conditions:

a) The packaging must 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 100 mm × 100 mm;

b) For liquids, absorbent material in sufficient quantity to absorb the entire contents must 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 the cushioning material;

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

Note.— In determining whether a patient specimen has a minimum likelihood that pathogens are present, an element of professional judgment is required to determine if a substance is exempt under this paragraph. 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 paragraph include blood or urine tests to monitor cholesterol levels, blood glucose levels, hormone levels, or prostate specific antibodies (PSA); tests required to monitor organ function such as heart, liver or kidney function for humans or animals with non-infectious diseases, or therapeutic drug monitoring; tests conducted for insurance or employment purposes and are intended to determine the presence of drugs or alcohol; pregnancy tests; biopsies to detect cancer; and antibody detection in humans or animals.

6.3.6 Infected animals

6.3.6.1 A live animal that has been intentionally infected and is known or suspected to contain an infectious substance must not be transported by air unless the infectious substance contained cannot be

consigned by any other means. Infected animals may only be transported under terms and conditions approved by the appropriate national authority.

6.3.6.2 Unless an infectious substance cannot be consigned by any other means, live animals must not be used to consign such a substance.

6.3.6.3 Animal carcasses affected by pathogens of Category A or which would be assigned to Category A in cultures only, must be assigned to UN 2814 or UN 2900 as appropriate. Other animal carcasses affected by pathogens included in Category B must be transported in accordance with provisions determined by the competent authority.

6.3.7 Patient specimens

Patient specimens must be assigned to UN 2814, UN 2900 or UN 3373 as appropriate except if they comply with 6.3.2.3.

6.3.8 Biological products

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.

6.3.9 Genetically modified micro-organisms and organisms

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

6.3.10 Medical or clinical wastes

6.3.10.1 Medical or clinical wastes containing Category A infectious substances must be assigned to UN 2814 or UN 2900 as appropriate. Medical or clinical wastes containing infectious substances in Catogory B must be assigned to UN 3291.

6.3.10.2 Medical or clinical wastes that 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.***

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

Table 2-10. 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) *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 Hantavirus causing haemorrhagic fever with renal syndrome Hendra virus Hepatitis B virus (cultures only) Herpes B virus (cultures only) Highly pathogenic avian influenza virus (cultures only) Human immunodeficiency virus (cultures only) Japanese Encephalitis virus (cultures only) Junin virus Kyasanur Forest disease virus

UN Number and Proper Shipping Name	***Micro-organism***
	Lassa virus Machupo virus Marburg virus Monkeypox virus *Mycobacterium tuberculosis (cultures only)* Nipah virus Omsk hemorrhagic fever virus *Poliovirus (cultures only)* Rabies virus *(cultures only)* *Rickettsia prowazekii (cultures only)* *Rickettsia rickettsii* (cultures only) Rift Valley fever virus *(cultures only)* *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 *(cultures only)* *West Nile virus (cultures only)* *Yellow fever virus (cultures only)* *Yersinia pestis* (cultures only)
UN 2900 **Infectious substances affecting animals only**	African swine fever virus *(cultures only)* Avian paramyxovirus Type 1 – Velogenic newcastle disease virus *(cultures only)* Classical swine fever virus *(cultures only)* Foot and mouth disease virus *(cultures only)* Goatpox virus *(cultures only)* Lumpy skin disease virus *(cultures only)* *Mycoplasma mycoides* – Contagious bovine pleuropneumonia *(cultures only)* Peste des petits ruminants virus *(cultures only)* Rinderpest virus *(cultures only)* Sheep-pox virus *(cultures only)* Swine vesicular disease virus *(cultures only)* Vesicular stomatitis virus *(cultures only)*

. . .

Part 4

Chapter 8

CLASS 6 — TOXIC AND INFECTIOUS SUBSTANCES

. . .

650	PACKING INSTRUCTION 650

. . .

10) When packages are placed in an overpack, the package markings required by this packing instruction must either be clearly visible or the markings must be reproduced on the outside of the overpack and the overpack must be marked with the word "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 name and address of the shipper and of the consignee must be provided on each package;

~~a~~b) 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~~c) classification must be in accordance with 2;6.3.2;

~~c~~d) the incident reporting requirements in 7;4.4 must be met; and

de) the inspection for damage or leakage requirements in 7;3.1.3 and 7;3.1.4;

~~e~~f) passengers and crew members are prohibited from transporting infectious substances either as, or in, carry-on baggage or checked baggage or on their person.

Note.— When the shipper or consignee is also the 'person responsible' as referred to in b) above, the name and address need be marked only once in order to satisfy the name and address marking provisions in both a) and b), above.

. . .

— END —