DGP-WG/05-Flimsy12
21/4/05

DANGEROUS GOODS PANEL (DGP)

MEETING OF THE WORKING GROUP OF THE WHOLE

Montreal, 18 to 22 April 2005

Agenda Item 2: Development of recommendations for amendments to the *Technical Instructions* for incorporation in the 2007/2008 edition
2.2: Part 2 — Classification

DIVISION 6.2 - ADDENDUM TO THE 2005-2006 TECHNICAL INSTRUCTIONS

(Presented by J. Abouchaar)

1. BACKGROUND

1.1 During the course of WG/05, the Panel considered changes to the provisions applicable to Division 6.2 - Infectious substances contained in WP/3, WP/41 and WP/51 to reflect the changes agreed by the UN Subcommittee for inclusion into the 14th revised edition of the Model Regulations. WP/41 and WP/51 proposed amendments or additions to the UN changes. The Panel supported the proposals contained in these working papers. In the normal course of events, these amendments would become effective with the 2007-2008 edition of the ICAO Technical Instructions.

1.2 Following consideration of these working papers, the Panel then discussed development of a guidance document on the provisions applicable to Division 6.2 based on that contained in IP/3. There has been a fundamental shift with respect to the classification of infectious substances with effect from the 2005-2006 edition of the Technical Instructions. These changes have generated a significant number of questions from shippers and others involved in the transport of infectious substances. For this reason it was believed that there would be a benefit if ICAO were to make a guidance document available that expanded on the regulatory text.

1.3 The discussions on the content of IP/3 quickly identified that there were differences of opinion, even within the Panel, on the application of what constituted material that could be considered as 'not regulated' within the scope of the existing Technical Instructions provisions.

1.4 The text that the Panel have agreed for inclusion into the 2007-2008 Technical Instructions clarifies the classification of infectious substances into category A, category B and those considered as exempt material. In discussion on IP/3, the Panel came to the conclusion that for the guidance document to be effective and to ensure a consistent position for industry, there was a need for the new provisions on

'exempt human specimens' and 'exempt animal specimens' to become part of the Technical Instructions immediately by way of an addendum to the 2005-2006 edition.

1.5 The benefit of adopting these new provisions in an addendum to the 2005-2006 edition of the Technical Instructions is that it would remove the ambiguity that currently exists with respect to what must be classified as UN 3373 and be packed according to PI 650 and what substances may meet the definition of exempt specimens. This would remove the difficulty that the health system is currently facing in moving routine specimens.

2. PROPOSAL

2.1 That an addendum to the 2005-2006 Technical Instructions be issued that reflects the decisions taken at WG/05 as follows:

In Part 2, Chapter 6, amend paragraph 6.3.1.3 to read:

> 6.3.1.3 Cultures are the result of a process by which pathogens are intentionally propagated. This definition does not include human or animal patient specimens as defined below in 6.3.1.4.

In Part 2, Chapter 6, amend paragraph 6.3.1.4 to read:

> 6.3.1.4 Patient specimens are ~~human or animal materials~~, 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, disease treatment and prevention.

In Part 2, Chapter 6, add the following new paragraph 6.3.2.3 and renumber existing paragraph 6.3.2.3 to become 6.3.2.3.1:

> 6.3.2.3 ***Exemptions***

In Part 2, Chapter 6, amend paragraph 6.3.2.3 to read 6.3.2.3.1:

> 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.

In Part 2, Chapter 6, add the following new paragraph 6.3.2.3.2 to read:

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

In Part 2, Chapter 6, add the following new paragraph 6.3.2.3.3 to read:

> 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.

In Part 2, Chapter 6, add the following new paragraph 6.3.2.3.4 to read:

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.

In Part 2, Chapter 6, renumber paragraph 6.3.2.4 to read 6.3.2.3.5:

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.

In Part 2, Chapter 6, delete paragraph 6.3.2.5:

~~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 that have been treated so that the pathogens have been neutralized or deactivated so that they no longer pose a health risk.~~

In Part 2, Chapter 6, delete paragraph 6.3.2.6:

~~6.3.2.6 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~~.

In Part 2, Chapter 6, add the following new paragraph 6.3.2.3.6 to read:

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 minimal likelihood that pathogens are present, an element of professional judgment is required to determine if a substance is exempt under this paragraph. That judgment 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 the blood or urine tests to monitor cholesterol levels, blood glucose levels, hormone levels, or prostate 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.

In Part 2, Chapter 6, add the following new paragraph 6.3.6 to read:

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 shall 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, 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 the competent authority.

In Part 2, Chapter 6, add the following new paragraph 6.3.7 to read:

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.

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