DANGEROUS GOODS PANEL

Frankfurt, 16 to 20 September 2002

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

TRANSPORT OF INFECTIOUS SUBSTANCES

(Presented by the Secretary)

1. At the recent meeting of the UN Sub-Committee, proposed amendments to the provisions for Division 6.2 substances were adopted; these are shown in WPs 12, 13 and 14. Attached is an *edited* form of the working paper which provided the basis for the amendments (ST/SG/AC.10/C.3/2002/16).

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APPENDIX A

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. **(See WP/12, Chapter 6, 6.3)**

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. **(See WP/13, Chapter 3, A138)**

   (b) to UN 3373:

   YYY. **(See WP/13, Chapter 3, A139)**

Proposal Number 5

1. In Chapter 4.1, the following changes to P620 are proposed **(See WP/14, Chapter 8)**

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 **(See WP/14, Chapter 8)**

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.

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