UN/SCETDG/20/INF.22

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
(Twentieth session, 3-12 December 2001, agenda item 6)

Transport of Infectious Substances

Transmitted by the Expert from Canada

Background

1. At the 21st Session of the Committee of Experts on the Transport of Dangerous Goods (December 2000), Canada proposed (ST/SG/AC.10/2000/32) that a review of the requirements in the Model Regulations for the transport of infectious substances be undertaken in the next biennium.

2. The Committee agreed to add this review to the work plan and, at the same time, tasked Canada with coordinating the work (ST/SG/AC.10/27).

3. At the 19th Session of the Sub-Committee of Experts on the Transport of Dangerous Goods held from 2 to 6 July 2001, the Expert from Canada provided the Sub-Committee with a brief outline of the problems and recommendations most often mentioned in discussions held since December 2000 (UN/SCETDG/19/INF.11).

4. On 6 September 2001, in a continuing effort to promote consultation and transparency and inclusivity in the review process, the Expert from Canada invited delegations to participate in an informal meeting in Lyon, France (11 and 12 October 2001) to discuss the existing requirements in the Model Regulations and the results of a meeting of the World Health Organization held 8-10 October in Lyon. At the same time, a draft re-write of section 2.6.3, intended to provoke thought and discussion, was circulated to delegations. Unfortunately, most experts had other commitments and could not participate.

Ideas for Consideration

1. In the Appendix to this INF PAPER is a draft of section 2.6.3. No decision or action is being requested beyond that the Sub-Committee consider the information and ideas put forward in this paper and in the Appendix and provide comments to the Expert from Canada at the earliest convenience.

   Note that those items in square brackets in the Appendix deserve special consideration.

2. The text in the Appendix suggests a re-organization of the existing text in section 2.6.3. The suggested re-organization in the Appendix

   (a) separates definitions from regulatory requirements so that under the heading "Definitions" (2.6.3.1) the terms infectious substances, [biological materials], biological products, [(bio) medical or clinical] wastes and genetically modified micro-organisms and organisms are defined but, unlike the current text, the definitions do not contain regulatory requirements;

   (b) moves classification criteria immediately after definitions; and

   (c) retains the current text, with some editorial changes, of biological products, genetically modified micro-organisms and organisms and [(bio) medical or clinical] wastes.

3. Definitions (2.6.3.1)

   - The text in the Appendix suggests a change to the definition of infectious substances to clarify the definition. It should be noted here that the WHO has suggested that the name of Class 6.2 be changed from Infectious Substances to Biohazardous Substances.

4. Classification of Infectious Substances (2.6.3.2)

   - There has been considerable discussion about whether or not risk groups should be deleted from the Model Regulations. In the draft document, the term "category" is used. Whether these "categories" are called categories, risk groups or, as has been suggested, transport risk groups, or something else has to be considered. The suggested draft in the Appendix does not include a reference to the WHO "Laboratory Biosafety Manual" and if the term "risk group" is retained it would not be linked to laboratory containment and handling procedures, which are quite different from transport conditions.

   - From the discussions held since December 2000 a clearer picture of what needs to be regulated has begun to emerge. There seems to be a tendency to divide substances that can be included in Division 6.2 into two categories:

     - Catgegory A: These are substances that cause serious or fatal disease, are easily transmitted directly or indirectly and for which there are no treatment or preventive measures.

In the Appendix, these substances are assigned to UN2814 or UN2900 and all the requirements in the Model Regulations, including P620, apply. In other words, there is no change in requirements from the current Model Regulations for such substances.

Sample Lists. An example of the substances that would meet the criteria for inclusion in Category A – UN2814 or UN2900 – are included in tables following section 2.6.3.2.2 in the draft.

These sample lists were developed by WHO, at the WHO meeting in Lyon, 8-10 October, and WHO has undertaken to provide notes on the criteria used during that meeting to develop these lists.

These lists include the substances on the select agents list of the Centre for Disease Control in Atlanta and the substances on List A of the Office international des epzooties (substances affecting animals), and are included for guidance purposes only for those who classify, for consignors, carriers, and competent authorities. They are not exhaustive. Whether such lists are needed or whether the lists should be included in the Model Regulations has to be considered.

. Category B: These are infectious substances that can cause disease in humans or animals but that do not meet the criteria for inclusion in Category A. In other words, they can cause disease but they are not readily transmitted directly or indirectly and there are effective treatment and/or preventive measures for them.

These substances would be assigned to UN3373 and, if they are packed and marked in accordance with P650, no other regulatory requirements would apply. In addition, the shipping name for UN3373 would be changed from Diagnostic Specimens to **[**Biological Materials**]**. There have been suggestions that the term [Biological Materials] is not appropriate because it could be confused with biological products. In addition, concerns have been raised that Category B would capture substances that are classified in RG 3 and 2 under the current scheme and that these substances pose too much risk to be transported without full regulation.

The mark would be the Caduceus (medical symbol), suggested by WHO, inside a [diamond]. The symbol would be black and the background white. There have been suggestions that the Caduceus should be in a triangle, square, rectangle, circle, oval or on its own and not placed within any shape. There has also been a suggestion that the Caduceus is not an appropriate symbol, because it indicates healing and medicine (health) and this is not the message that should be conveyed about infectious substances, and that the existing label for Class 6.2 should be used.

- In P650 it is intended that Category B substances, if the quantity of the substance in the primary receptacles exceeds 500 mL or 500 g, would be subject to full regulation including package testing at the packing group II level and the display of the Class 6.2 label.

5. Substances that are unlikely to cause disease or substances that are believed not to contain an infectious substance would not be subject to the Model Regulations. Included are, for example, blood collected for transfusion or for the preparation of blood products, tissues and organs for transplant and water samples for analysis (see the note following 2.6.3.3.1). The existing exemption in the Model Regulations is continued for these substances.

6. The current concept for exception from regulatory requirements for UN 3373 (2.6.3.3) is retained but with the introduction of a mark, namely the Caduceus inside a [diamond]. The Caduceus would be black and would be on a white background or other contrasting colour. The Caduceus replaces the words "Diagnostic Specimen".

7. The current requirements for biological products (see 2.6.3.4), genetically modified micro-organisms and organisms (see 2.6.3.5) and [(bio) medical or clinical] wastes (see 2.6.3.6) are retained.

8. P904 (assigned to genetically modified micro-organisms, Class 9), includes suggested modifications to link it to combination packagings and to include provisions for dry ice and liquid nitrogen when they are used as refrigerants but these modifications need to be reviewed and, indeed, the entire packing instruction may need to be reviewed. Genetically modified micro-organisms are currently under discussion by the parties to the Biodiversity Convention and, consequently, no change has been made to the existing reguirements in the Model Regulations.

9. P650 is revised to include the Caduceus mark and provisions for dry ice and liquid nitrogen when they are used as refrigerants. As well, there is a suggestion in the revised P650 to include provisions for quantities that exceed 500 mL or 500 g.

10. There may be a need to consider a packaging instruction for body parts and comments and suggestions are invited. At this time, according to section 4.1.3.7, the competent authority determines the packaging. However, as noted above, P650 includes suggestions for provisions for quantities that exceed 500 mL or 500 g. It may be necessary to review carefully this particular suggestion for P650.

    As far as organs for transplant are concerned, the medical community has historically packaged these precious commodities in such a simple and effective way that it would seem a difficult task to develop a packaging that would meet the existing standards and the need to do so is questionable.

11. The views of the Sub-Committee are requested on whether the exemption from the regulations for [Biological Materials] that are packed and marked in accordance with P650 be placed in the text of section 2.6.3 or in the packing instruction as is currently the case for UN3373.

12. There are no changes proposed for the requirements for waste but it is recognized that the requirements of P621 highlight distribution problems associated with the rigid packaging required. However, it is also recognized that the Expert from the United Kingdom has a bulk packaging proposal for medical waste before the Sub-Committee that merits consideration.

13. There are some consequential amendments that the Sub-Committee is invited to comment on:

(a) Consider changing paragraph 2.6.1(b) to be consistent with the definition of infectious substances.

(b) Consider deleting SP 274 (the requirement for a technical name) from UN2814 and UN2900. The transport document contains details about the substances and it is questionable that a technical name enhances safety when the shipping name, class and UN number provide emergency response personnel with all the information they need to effect emergency response procedures. A technical name may mean a great deal to a microbiologist but likely means very little to an emergency responder especially since the technical name would not change emergency response procedures. It is important to note that in North America, for example, a large percentage of fire departments, first responders, are volunteer departments and a technical name in this instance does not help them.

(c) In section 4.1.8.5. consider changing “diagnostic specimens” to [biological materials].

(d) Consider deleting section 5.4.1.5.6.

The address of the consignee is already required in section 5.4.1.3 to appear on the transport document.

The rest of the section requires the name of a "responsible" person and "his" telephone number. This is only required for infectious substances. The requirement does not specify what qualifications the "responsible" person should have (e.g., a microbiologist? a nurse?) or what the person should be able to do (e.g., provide advice? but what kind of advice?), or when the person should be available (e.g., 24 hours?).

(e) Consider deleting section 5.5.1.2. The Sub-Committee has already been advised that airlines do not comply with paragraph (d) for security reasons. Given recent events it seems even more advisable to consider security in this instance. The rest of the section is comprised of general statements the contents of which are second nature to those involved in healthcare or medical research. If the Sub-Committee does not wish to delete the entire section then paragraph (d) could be deleted and the rest of the section changed to be advisory, that is, replace "shall" with "should". Finally, a note could be added to either Chapter 5.5 or 5.4 to the effect that box number 10 in the sample transport document does not need to be complied with.

(f) Consider changing the proper shipping name of UN3373 to **[**Biological Materials**]**.

Conclusion

1. The Sub-Committee is invited to consider the ideas in this INF PAPER and in the Appendix at the earliest convenience of the Experts and provide the Expert from Canada with comments, suggestions and ideas.

2. There are two opportunities to have an informal intersessional meeting on infectious substances:

   - in Paris in March 2002 either before or after IATA's meeting (scheduled to be held the week of 11 March) at which members of the ICAO DGP may also be present;

   - in Antwerp 2002 either before or after the HMAC/PIRA conference (scheduled to be held 4 and 5 April).

   At this time, the Expert from Canada is planning to attend the IATA meeting in Paris and the HMAC/PIRA meeting in Antwerp. Those Experts who may be available to attend such an informal intersessional meeting are invited to indicate to the Expert from Canada which of the two opportunities would be the most convenient or if an informal intersessional meeting should be held in both Paris and Antwerp**.**

APPENDIX

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 **that are** known **to contain** or **that are** reasonably **believed** to contain **viable** micro-organisms that **can** cause disease in human**s** or animal**s**.

2.6.3.1.2 *Biological products* are those products derived from living organisms, that 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 and diagnostic products.

2.6.3.1.3 ***[Biological materials]*** **are any human or animal materials including but not limited to excreta, secreta, blood and its components, tissue and tissue fluids [but excluding live infected animals].**

2.6.3.1.4 **[(*Bio) Medical or Clinical]*** *wastes* are wastes derived from bio-research or the medical treatment of animals or humans.

2.6.3.1.5 *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.

2.6.3.2 ***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 UN3373, as appropriate. Infectious substances are divided into [categories].

2.6.3.2.2 The criteria for each [category] according to the level of risk are as follows:

(a) **[Category]** A: infectious substances that cause serious or fatal disease in humans or animals and that can be readily transmitted, directly or indirectly, and for which effective treatment and preventive measures are not usually available.

Infectious substances meeting these criteria shall be assigned to UN2814 or UN2900. Infectious substances that cause disease both in humans and in animals shall be assigned to UN2814. Infectious substances that cause disease only in animals shall be assigned to UN2900.

When samples taken from a human or animal are to be transported, assignment to UN2814 or UN2900 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 UN2814 is INFECTIOUS SUBSTANCE, AFFECTING HUMANS. The proper shipping name for UN2900 is INFECTIOUS SUBSTANCE, AFFECTING ANIMALS*.

***Note 2**: Indicative examples of substances that meet these criteria are given in the following tables. The tables are not exhaustive and are provided for guidance purposes only. Substances that do not appear in the tables but that exhibit similar characteristics should be assigned to UN2814 or UN2900. In addition, if there is doubt as to whether or not a substance meets the criteria for inclusion in [Category] A, it should be assigned to UN2814 or UN2900.*

Note: Viruses affecting animals only are indicated with an asterisk

Viruses

*African horse sickness virus******	*Machupo virus*
*African swine fever virus******	*Marburg virus*
Avian paramyxovirus Type 1(Newcastle virus)	*Monkeypox virus*
*Bluetongue virus******	*Nipah virus*
Classical swine fever	*Omsk Hemorrhagic fever virus*
Crimean-Congo hemorrhagic Fever virus	*Peste des petits ruminants virus******
Eastern equine encephalitis	*Poliovirus*
Ebola virus	*Rabies virus*
Flexa virus	*Rift Valley Fever*
Foot and mouth virus	*Rinderpest virus******
Guanarito virus	*Russian spring-summer encephalitis*
Hanta virus (Pulmonary Syndrome)	*Sabia*
Hendra virus	*Sheep and Goat pox virus******
Herpes B virus	*Swine vesicular disease virus*
High pathogenic avian influenza virus	*Tick-borne encephalitis virus*
Junin virus	*Variola virus*
Kyasanur Forest disease virus	*Venezuelan equine encephalitis virus*
Lassa virus	*Vesicular stomatitis virus*
*Lumpy Skin Disease virus******	*Yellow Fever virus*

Bacteria, Rickettsia and Fungi

Bacteria
Bacillus anthracis
Brucella abortus, melitensis, suis
Burkholderia mallei, pseudomallei
Clostridium botulinum
Francisella tularensis
Mycobacterium tuberculosis, Multi drug resistant
Shigella dysenteriae type 1
Verotoxigenic E coli
Yersenia pestis
Mycoplasma
Contagious bovine pleuropneumonia
Rickettsia
Coxiella burnetii
Rickettsia prowazekii
Rickettsia rickettsii
Fungi
Coccidioides immitis

(b) [Category] B: infectious substances that do not meet the criteria for inclusion in [Category] A, that can cause disease in humans or animals but that are not readily transmitted directly or indirectly and for which effective treatment and preventive measures are readily available. Infectious substances meeting these criteria are [Biological materials] and shall be assigned to UN3373.

Note: The proper shipping name for UN3373 is [BIOLOGICAL MATERIALS].

2.6.3.2.3 Substances that are unlikely to cause disease in humans or animals or that are known not to contain or that are believed not to contain infectious substances included in [Category] A or [Category] B are not subject to these Model Regulations.

NOTE: *Blood that has been collected for the purpose of blood transfusion or for the preparation of blood products,blood products, any tissues or organs intended for use in transplants and water samples for analysis are examples of substances addressed in this section.*

2.6.3.3 [*Biological Materials*]

2.6.3.3.1 [Biological materials] are infectious substances that meet the criteria for inclusion in [Category] B. These substances shall be assigned to UN3373. [Biological materials that are packed and marked in accordance with P650 are not subject to these Model Regulations].

2.6.3.4 *Biological Products*

2.6.3.4.1 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 that meet the criteria **for inclusion in Category A or B**. Substances in his group shall be assigned to UN2814, UN 2900 **or UN3373**, as appropriate.

(b) those that contain **substances** that are unlikely to cause disease in humans or animals **or that are reasonably believed not to contain infectious substances or that 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 Model Regulations**.

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

2.6.3.5 *Genetically Modified Micro-organisms and Organisms*

2.6.3.5.1 Genetically modified **micro-organisms** that meet the definition of an infectious substance shall be classified in Division 6.2 and assigned to UN 2814, UN 2900 **or UN3373**.

2.6.3.5.2 Genetically modified **organisms**, that 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.

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

2.6.3.5.4 Except when authorized for unconditional use by the Governments of the countries of origin, transit and destination, genetically modified micro-organisms that 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 UN3245.

2.6.3.6 [(Bio) Medical or *Clinical] Wastes*

2.6.3.6.1 [(Bio) Medical or Clinical] wastes that are reasonably believed to have a low probability of containing infectious substances shall be assigned to UN3291.

Note: The proper shipping name for UN3291 is CLINICAL WASTE, UNSPECIFIED, N.O.S. or (BIO) MEDICAL WASTE, N.O.S. or REGULATED MEDICAL WASTE, N.S.O.

2.6.3.6.2 [(Bio) Medical or Clinical] wastes containing infectious substances shall be assigned to UN2814, UN2900 **or UN3373**.

2.6.3.6.3 Decontaminated **[(bio) medical or clinical]** wastes that previously contained infectious substances are not subject to **these Model Regulations** .

P650 REVISED PACKING INSTRUCTION P650

This packing instruction applies to UN3373

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

Biological materials shall be packed in good quality packagings which shall be strong enough to withstand the shocks and loadings normaly encountered durng transport including trans-shipment 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.

The packaging shall consist of three components: a primary receptacle, a secondary packaging and an outer packaging.

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.**

For transport, the mark illustrated below shall be displayed clearly and durably on each outer packaging. The symbol is black and the background is white.

The completed package shall be capable of sucessfully 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

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

The secondary packaging shall be leakproof.

If several fragile primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated to prevent contact between them.

Absorbent material shall be placed between the primary receptacle(s) and the secondary packaging. The absorbent material shall be in a **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.

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).

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

Solid Substances

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

The secondary packaging shall be **siftproof**.

If several fragile primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated to prevent contact between them.

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

Dry Ice and Liquid Nitrogen

When UN1845, Carbon Dioxide (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.

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.

[Biological Materials that are packed and marked in accordance with this packing instruction are not subject to any other requirements in these Model Regulations.]

Provisions for primary receptacles that exceed 500 mL or 500 g

When the primary receptacle(s) contain liquid substances and exceed 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.

The packaging shall consist of three components: a primary receptacle, a secondary packaging and an outer packaging.

The primary receptacle and the secondary packaging shall be watertight.

An absorbent material shall be placed between the primary receptacle(s) and the secondary packaging in a quantity sufficient to absorb the entire contents of the primary receptacle(s).

If several fragile primary receptacles are placed in a single secondary packaging, they shall be individually wrapped or separated to prevent contact between them.

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).

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.

Dry Ice and Liquid Nitrogen

When UN1845, Carbon Dioxide (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.

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.

P904 **REVISED**	PACKING INSTRUCTION	P904

This packing instruction applies to UN3245

The following packagings are authorized provided the general provisions of 4.1.1 and 4.1.3 are met:

(1) **Combination packagings** according to P001 or P002 conforming to the packing group III performance level.

(2) Outer packagings, which need not conform to the packaging test requirements of Part 6, but conforming to the following:

(a) an inner packaging comprising

(i) a watertight primary receptacle(s);

(ii) a watertight secondary packaging which is leakproof;

(iii) absorbent material **placed** between the primary receptacle(s) and the secondary packaging. The absorbent material shall be in a **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;

(iv) if several **fragile** primary receptacles are placed in a single secondary packaging they shall be individually wrapped **or separated** to prevent contact between them.

(b) an outer packaging shall be strong enough for its capacity, mass and intended use and the smalles external dimension shall be at least 100 mm.

Dry Ice and Liquid Nitrogen

When UN1845, Carbon Dioxide (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.

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.