UN/SCETDG/26/INF.33

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

Twenty-sixth session
Geneva, 29 November-7 December 2004
Item 2 of the provisional agenda

PROVISIONS ADOPTED BY THE SUB-COMMITTEE FOR AMENDMENTS TO THE RECOMMENDATIONS ON THE TRANSPORT OF DANGEROUS GOODS

Infectious substances

Transmitted by the World Health Organization (WHO)

Background:

(1) This INF paper is prepared in response to concerns regarding transport of human and animal biological specimens collected for the purpose of initial diagnosis other than for the presence of human pathogens. These may include routine medical screening tests (i.e. glucose, cholesterol, etc.) and animal surveillance tests. WHO is of the view that damaged packages and potential exposure of transport workers to biological samples are an unacceptable risk whatever the nature or origin of the samples. Therefore, preventive measures are required to minimize breakage or leaking of packages, especially those containing human or animal clinical specimens.

(2) The authors of paper ST/SG/AC.10/C.3/2004/99 suggest that in certain definable circumstances there may be a lower probability that human biological specimens contain human pathogens (e.g. clinical judgment of healthcare professionals, epidemiological information, etc.). The authors acknowledge that while the probability of containing a human pathogen may be reduced in these instances, no certainty exists that this risk is ever zero. Therefore, they suggest that management of "reduced risk" specimens can be achieved through a mandatory minimum level of packaging appropriate to the "reduced risk" involved. WHO supports this concept, and views as necessary a minimum packaging standard to ensure that packages can bear the stresses of transport processing, including shifting and stacking by mechanical sorting machines.

(3) WHO also acknowledges the view expressed in paper UN/SCETDG/26/INF.7 submitted by the World Organization for Animal Health (OIE). This paper argues that samples from animals may be collected from specific groups of animals and for specific reasons that result in these specimens posing a negligible risk to the human population, notably the carriers of these goods. Examples of such reduced risk contexts include:

- Random blood surveillance programmes for disease monitoring, control and eradication;
- Disease free herd testing and export programs;
- Routine mineral and non-infectious clinical tests.

WHO agrees that in certain circumstances animal biological specimens may have a lower probability of containing a human pathogen than human clinical specimens. However, WHO considers exposure of transport workers to biological fluids or tissues from broken sample containers to be an unacceptable safety risk, especially if their nature or origin is not immediately apparent. Therefore, animal specimens should follow the same safety precautions as required for human specimens. WHO therefore promotes the adoption of a universal minimum packaging standard for transport of human or animal specimens.

(4) WHO acknowledges that countries may have national regulations which require carriers to declare if they "will" or "will not" transport dangerous goods. WHO accepts that the smaller carriers often elect not to transport hazardous materials due to resource constraints. WHO recognizes that smaller carriers often serve as the only source of transport for health care specimens to and from isolated communities. These carriers also play a critical role in serving as "feeder carriers" between smaller cities and larger towns. Therefore, WHO supports the concept of an appropriate packaging and transport standard that would facilitate transport by these carriers of specimens for laboratory testing that pose a negligible risk.

(5) WHO feels the current P650 packaging standard can fulfil all of the above described objectives. The P650 packaging standard (including the requirements for a drop test and a pressure test) has been used for the last 10 years. This standard has demonstrated that it is sufficiently robust to handle the physical and mechanical stresses associated with mechanized transport. Therefore, WHO recommends that P650 be used as a mandatory minimum packaging standard. P650 provides sufficient safety precautions for Category B agents, as well as for patient specimens where the risk of containing a human pathogen may be “reduced”. The use of P650 as a mandatory minimum standard also reduces the risk of shippers' errors in their choice of the correct packaging, especially in situations where data on which to base the decision of packaging is limited. It should mitigate the risk of inappropriate choices in an effort to defer cost, administrative requirements, agent identification and/or transport rejections. Moreover, P650 minimizes potential confusion attributable to multiple packaging standards and supports common remediation/clean-up practices for all infectious and potentially infectious materials (UN 2814, UN2900, UN3373 and the proposed "Biomedical Specimens" (see below)). Furthermore, and importantly, with increasing demand, adequate supplies of P650 packages should become available worldwide, and costs thereof should decrease or remain low. However, the UNCETDG is encouraged to carefully look at P650 and make sure that the requirements set out in the packaging instruction, in particular the drop test, the pressure test, and the absorbent material, are necessary.

To facilitate specimen transport by smaller carriers which do not carry dangerous goods, WHO suggests that the text "Biomedical Specimens" be used as a communication marking/label, in substitution of the UN 3373 diamond-shaped label for "Biological Substance(s)-Category B". This new text "Biomedical Specimens” may serve to alert the transport workers that the package contains a human or animal biological specimen and that universal safety precautions are appropriate for damaged or leaky packages. The text also identifies the medical importance of the specimen and the need to expedite shipment to final destination.

(6) In support of this proposal WHO undertakes to continue to develop awareness training through the WHO web site and WHO publications. These materials will be available to the general public, familiarizing the Transport and User community with infectious substance transport requirements and packaging instructions for Category A (UN 2814 & UN 2900), Category B (UN 3373) and Biomedical Specimens (patient specimens that may harbour infectious substances).

Proposal:

The following text would be located in the P650 packaging instruction described under 4.1.4.1.

Proposed text:

This packing instruction applies to (i) UN 3373, (ii) patient specimens (human or animal) transported for laboratory analysis other than for the presence of human pathogens and (iii) for routine screening tests where the probability of the presence of a human pathogen is considered low. For items (ii) and (iii) as indicated above, the package need not meet the requirements for transporting as an infectious substance of Category B, if the conditions described under (4.b) and (9.b) are met.

Paragraph 4 shall become new (4.a).

Insert new (4.b) to read as follows:

> “(4.b) For transport, the text "Biomedical Specimens" shall be displayed within a rectangular-shaped label/marking on the external surface of the outer packaging and shall be clearly visible and legible.”

Paragraph (9) shall become new (9.a).

Insert new (9.b) to read as follows:

> "(9.b) Patient Specimens (human or animal) which are packed in accordance with the P650 packing instruction and marked as "Biomedical Specimens" are not subject to any other requirement in these Regulations."

(7) Justification

WHO feels the above proposal accomplishes the following:

1. This proposal places the safety emphasis on the use of a robust minimum standard packaging (P650) that has been demonstrated to withstand the routine physical and mechanical stresses of automated shipping.

2. This proposal recognizes and defines packaging standards for human and animal patient specimens* where the risk of containing an infectious substance may be negligible or unknown.

***(Note July's adoption of new definition for) Patient specimens** are human or animal materials, 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.

3. This proposal acknowledges that in certain circumstances human and animal specimens may have a low probability of containing infectious material. However because this risk can not be generalized and determined to be zero, the potential risk should be acknowledged and a minimum packaging standard employed.

4. Use of a mandatory minimum standard packaging instruction reduces inappropriate choice by the shipper that may be made in an effort to defer cost, administrative requirements, or specimen identification;

5. This proposal provides a mechanism that allows "non-specialist carriers" of dangerous goods to safely carry human or animal medical specimens that may have a reduced or unknown risk of containing an infectious substance;

6. This proposal allows the development of clear and concise training materials that provide consistent interpretation. These materials will be available to the public, transport and user communities, familiarizing them with the requirements for Category A infectious substances (UN 2814 & UN 2900), Category B infectious substances (UN 3373) and Biomedical Specimens. WHO training material will also make clear that remediation/clean-up procedures are the same for UN 2814, UN2900, UN3373 and Biomedical Specimens.
