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**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, 29 November-3 December 2004  
Item 2 of the provisional agenda

TEXTS ADOPTED BY THE SUB-COMMITTEE AT ITS TWENTY-THIRD, TWENTY-FOURTH  
AND TWENTY-FIFTH SESSIONS AND RELATED PROPOSALS

Infectious substances

Transmitted by the experts from Canada, the Netherlands and South Africa

**Background**

1. At the twenty-fifth session of the Sub-Committee, a number of changes to the Model Regulations were adopted regarding infectious substances. Specifically, the changes to section 2.6.3.2.3 proposed by the World Health Organization (WHO) in UN/SCETDG/25/INF. 79, resulted in the deletion of section 2.6.3.2.5 (see ST/SG/AC.10/C.3/50/Add.1 , page 4).
2. Section 2.6.3.2.5 in the 13th edition of the Model Regulations currently reads:  
  
"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 Regulations. Examples are: foodstuffs, water samples, living persons and substances which have been treated so that the pathogens have been neutralized or deactivated."
3. The changes from the July meeting have resulted in section 2.6.3.2.5 being divided into two sections:

"2.6.3.2.3.3 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 Regulations unless they meet the criteria for inclusion in another class.

2.6.3.2.3.4 Environmental samples (including food and water samples) which are not considered to pose a significant risk of infection are not subject to these Regulations unless they meet the criteria for inclusion in another class."

4. These changes have removed an extremely important exemption from the Model Regulations, namely, the exemption for substances for which there is a low probability that infectious substances are present. This exemption has existed in the Model Regulations for some years and is intended to cover substances transported for routine screening tests or diagnosis for other than the presence of pathogens (see for example, 2.6.3.1.3(b) of the 10th and 11th editions of the Model Regulations, in Annex 1 attached to this paper). It is an important exemption for national healthcare systems and, indeed, for global healthcare.
5. Routine screening tests include, but are not limited to,
  - the blood or urine tests that a doctor may order as part of a medical check-up to monitor cholesterol levels, blood glucose levels, hormone levels, prostate specific antibodies (PSA);
  - those required to monitor organ functions such as heart, liver or kidney function for millions of people who have non-infectious diseases;
  - therapeutical drug monitoring;
  - those conducted for insurance or employment purposes and are intended to determine the presence of drugs or alcohol;
  - pregnancy tests.
6. Tests for diagnosis other than for the presence of pathogens include, but are not limited to, biopsies to detect cancer, antibody titre testing (tests done to determine the presence of antibodies as a result of being exposed to a disease in the past – the pathogen is no longer in the host but the antibodies that reacted against it remain).
7. It must be noted that millions of routine screening tests and tests for diagnosis other than for the presence of pathogens are transported everyday in countries around the world. They pose a negligible risk in transport - not a low risk like Category B infectious substances but a negligible risk - because the probability that they contain a Category A or Category B infectious substance is extremely low.
8. The only reason that any of these tests would be considered to be regulated is if one applies the concept of universal precautions. Like the risk group classification criteria, universal precautions were devised for laboratories and hospitals where healthcare professionals are in direct contact with samples and must manipulate the samples. Consequently, in a lab and a hospital all samples are considered to be potentially infectious and are handled by technicians, nurses, doctors, etc., in that manner. However, the laboratory and hospital environment is totally different from the transport environment. In the laboratory and hospital environment personnel have to open tubes containing blood or other human or animal material, remove the blood or other material to manipulate it or prepare it for testing. These activities are not performed in the transport

environment. As stated in WHO's "Transport of Infectious Substances, Background to the amendments adopted in the 13th revision of the United Nations Model Regulations guiding the transport of infectious substances",

*"In contrast to transport workers, laboratory workers carry out extensive manipulations with microorganisms which place them at higher risk of infection (through accidental exposures caused by splashes, cuts, scratches). Moreover, certain laboratory procedures (e.g., vortexing, mixing, centrifuging) can generate aerosols which place the workers performing those operations at increased risk of infection. These conditions do not usually occur in transport. spills or leakage of substances alone do not generate aerosols. The generation of aerosols requires energy to be applied to liquid substances using some type of equipment or device, and therefore, the potential for microorganisms to become airborne during transport is extremely remote. Thus overall, microorganisms in transport do not pose the same level of risk as they do in laboratory situations."*

9. The risk group classification criteria were removed from the Model Regulations because, as stated above, the criteria were devised for labs and hospitals and were not appropriate for transport. Is it logical now to require samples to be classified as infectious substances in Category B when a healthcare professional has no reason to believe or suspect that they contain infectious substances on the basis of another concept devised for labs and hospitals, namely, universal precautions? The authors of this paper maintain that it is not logical and that this requirement not only negates the goal of developing requirements for transport that are based on real risk and not on perceived risk but also does not enhance safety or advance global public health.

10. The authors of this paper see no logic in negating the judgement of healthcare and medical professionals. The Regulations rely on that judgement for determining whether or not a substance is included in Category A (see 2.6.3.2.2.1(b)) but for samples for which there is no reason to believe or suspect contain infectious substances, there is a notion that this judgement is no longer trustworthy.

The authors of this paper have had considerable experience working with their own healthcare and medical professionals and have no difficulty at all in supporting their judgement. It is not up to the transport industry to judge the proficiency of healthcare professionals just as it is not up to healthcare professionals to judge pilots or others within the transport industry.

11. The authors of this paper agree that blood and blood components intended for transfusion should be exempt. It is noted, however, that blood for transfusion or for the preparation of blood products is tested in some countries for the presence of HIV or Hepatitis B or C but not in all countries and that verbal screening in most countries is the primary method of determining if the blood may or may not contain infectious substances. There seems to be little logic in requiring routine screening tests or tests for diagnosis, other than to determine the presence of pathogens, to be considered infectious substances in Category B when healthcare professionals have far more information about the patients in front of them than do blood collection agencies who must rely on the donor's word and who have no real knowledge of the donor's medical history, symptoms or individual circumstances.

12. The authors of this paper question how "no carry" air carriers – those who have declared they do not transport dangerous goods – will be able to provide much needed service in various parts of the world where the "no carry" concept prevails. Routine screening tests and tests for initial diagnosis, other than to determine the presence of pathogens, will not be accepted for transport by "no carry" air carriers under the changes made to the UN Model Regulations in July.

This means that isolated communities that, in many instances, can only be reached by air transport will not have essential healthcare available to them if they are serviced only by "no carry" air carriers. The negligible risk that these samples pose in transport does not justify the denial of healthcare.

However, isolated communities are not the only ones at risk. Millions of routine screening tests and tests for diagnosis, other than to determine the presence of pathogens, are transported between cities and towns by "feeder airlines" who, for the most part, are "no carry" air carriers. What is the rationale for limiting the delivery of healthcare to these communities given the negligible risk posed by these samples?

13. Attached to this paper is Annex 2 entitled, "Science vs Perception". The Annex addresses the real risk that infectious substances pose in transport so that routine screening tests and tests for diagnosis, other than for the presence of pathogens, that is, samples that healthcare and medical professions can reasonably believe have an extremely low probability of containing infectious substances and that pose a negligible risk in transport, can be viewed with some perspective.

### **Proposal**

Re-number the new 2.6.3.2.3.6 as 2.6.3.2.3.7 (see ST/SG/AC.10/C.3/50/Add.1, page 4) and add the following text as 2.6.3.2.3.6:

2.6.3.2.3.6 Specimens transported for the purposes of diagnosis, other than for the presence of infectious substances, or for routine screening tests and for which there is no reason to believe or suspect that an infectious substance is present need not meet the requirements of these Regulations if the following conditions are met:

- (a) the primary receptacle(s) do not contain more than 1L;
- (b) the outer packaging does not contain more than 4L;
- (c) the packaging includes:
  - (i) a leakproof primary receptacle(s);
  - (ii) a leakproof secondary packaging;
  - (iii) a firm outer packaging of adequate strength for its capacity, mass and intended use, and with at least one surface having a minimum dimension of 100 mm x 100 mm; and
  - (iv) absorbent material in sufficient quantity to absorb the entire contents, 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;
- (d) if multiple fragile primary receptacles are placed in a single secondary packaging, they shall be individually wrapped so as to prevent contact between them during handling and transport; and
- (e) the outer packaging is marked with the words "Diagnostic Specimen – Not Regulated".

**Note 1:** *As with determining whether or not a substance is included in Category A (see 2.6.3.2.2.1(b)), an element of professional judgement is required to determine if a substance is exempt under this section. 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 routine screening tests include, but are not limited to, the blood or urine tests to monitor cholesterol levels, blood glucose levels, hormone levels, prostate specific antibodies (PSA); those required to monitor organ function such as heart, liver or kidney function for people who have non-infectious diseases, therapeutic drug monitoring; those conducted for insurance or employment purposes and are intended to determine the presence of drugs or alcohol; pregnancy tests. Tests for diagnosis other than for the presence of pathogens include but are not limited to, biopsies to detect cancer and antibody titre testing.*

**Note 2:** *Consignors must fill and close the package as prepared for transport to ensure that there is no leak during transport. The package must have enough absorbent material in it to absorb all liquid, including wet ice used as a coolant that may melt during transport. Any liquid, whether from the specimen or from melted wet ice, must not reach the outer packaging. If the consignor is a patient, then the healthcare facility dealing with the patient must ensure that the patient understands how to prepare and mark the package for transport.*

### **Justification**

1. The authors of this paper do not believe that routine screening tests and tests for diagnosis, other than for the presence of pathogens, should be subject to the Model Regulations for the reasons given in the Background section above. However, it is recognized that the risk, while negligible, is not zero. It is also recognized that achieving zero risk in transport is not a realistic goal but that managing the negligible risk posed by these samples can be achieved through a minimal level of packaging appropriate to the real risk involved.
2. The issues for carriers are recognized: that a package does not leak during transport and that there is some marking to indicate that the package contains a human or animal sample. The packaging proposed above is a viable tool to manage the negligible risk posed by these samples and will accomplish the goal of containing them in a reasonable type of packaging. The proposed marking will alert carriers to the fact that there is a human or animal sample in the package but that the risk is negligible.

**Annex 1**

**Text from the 10th and 11th editions of the UN Model Regulations**

“2.6.3.1.3 *Diagnostic Specimens* are any human or animal material including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluids, being transported for diagnostic or investigational purposes, but excluding live infected animals.

For the purposes of these Regulations, diagnostic specimens are divided into the following groups:

- (a) Those known or reasonably expected to contain pathogens is risk groups 2, 3 or 4 and those where a relatively low probability exists that pathogens of risk groups 2, 3 or 4 are present. Such substances shall be classified in Division 6.2 under UN 2814 or UN 2900, as appropriate. Specimens transported for the purposes of initial or confirmatory testing for the presence of pathogens fall within this Group;
- (b) Those where a relatively low probability exists that pathogens of risk groups 2 or 3 are present. Specimens transported for the purposes of initial diagnosis for other than the presence of pathogens or specimens transported for routine screening tests fall within this Group;
- (c) Those known not to contain pathogens.

2.6.3.3.2 Diagnostic specimens known to contain, or thought likely to contain, any infectious substances shall meet the requirements of these Regulations applicable to infectious substances. Diagnostic specimens referred to in 2.6.3.1.3(b) need not meet the requirements for infectious substances when the following conditions are met:

- (a) The primary receptacle(s) do not contain more than 100 mL;
- (b) The outer packaging does not contain more than 500 mL;
- (c) The primary receptacle(s) are leakproof; and
- (d) The packaging includes:
  - (i) an inner packaging comprising:
    - watertight primary receptacle(s);
    - a watertight secondary packaging;
    - absorbent material in sufficient quantity to absorb the entire contents placed between the primary receptacle(s) and the secondary packaging; if several primary receptacles are placed in a single secondary packaging they shall be individually wrapped so as to prevent contact between them;
  - (ii) an outer packaging of adequate strength for its capacity, mass and intended use, and with minimum external dimensions of 100 mm.”

## Annex 2

### Science vs Perception<sup>1</sup>

1. When the World Health Organization hosted a meeting Lyon in October, 2001, the scientists invited to that meeting were tasked with evaluating the substances that are known to be transported . They looked at each micro-organism individually and considered
  - . the intrinsic characteristics of each one,
  - . the form that it may be transported in (culture, diagnostic specimen) and whether or not the risk was increased or decreased depending on the form,
  - . the pathogenicity of each substance
  - . the infectious dose needed to cause disease (10 micro-organisms vs 100,000)
  - . the routes of infection:
    - . ingestion (splashes into the mouth, contaminated articles and fingers, eating, drinking),
    - . inoculation (needlesticks, cuts from sharp objects, animal bites and scratches),
    - . dermal (contamination of the skin and mucous membranes from spills and splashes, contaminated surfaces and equipment),
    - . inhalation (aerosols)
  - . the stability of the substance in the environment (fragile virus vs hardy spore)
2. The WHO meeting considered the risks posed during transport. For any substance to pose a risk there has to be damage to the package containing the substance to the extent that the substance is released from the package. This would include the primary receptacle (vial or tube of a blood sample) breaking, the secondary packaging breaking or leaking and the absorbent material around it failing to absorb the contents of the vial or tube so that the liquid would reach the outer packaging.
3. If a substance is released it has to be released in a quantity sufficient to cause infection. For example, if a vial of blood from a person infected with cholera were to break in transport, an employee of a carrier would have to ingest (swallow) 100,000,000 of the micro-organism that causes cholera to be a candidate for infection. The West Nile virus would require 1 micro-organism but this would have to be transmitted by intramuscular injection (for example, a mosquito bite from an infected mosquito).

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<sup>1</sup> *Science vs Perception is based on a presentation given by Maureen Best, Director, Office of Laboratory Security, Health Canada, on 30 March 2004 at the Canadian Infectious Substances Conference hosted by Transport Canada.*

4. Infectious substances each have a specific route of transmission and many routes of exposure or transmission are unlikely in transport. In other words, if an infectious substance can be transmitted only by ingestion then it cannot be transmitted through contact with the skin or through inhalation or through injection (e.g., an inadvertent needlestick).
  5. Intact skin is an effective barrier because very few infectious substances can penetrate intact skin. Immediate hand washing with soap and water or antiseptic hand wipes can eliminate risks to non-intact skin.
  6. Infectious substances in aerosolized form have caused particular concern amongst carriers. However, a liquid sample of human or animal material cannot aerosolize on its own. A considerable force must be generated to create aerosol droplets and this is usually done in a lab through vortexing, mixing or other specific procedures. Normal ventilation in an aircraft or any other means of transport does not generate enough force to create aerosol droplets. In addition, bacteria and viruses cannot evaporate so it is very unlikely that a spill of a liquid substance in a package could generate aerosol droplets.
  7. So, does exposure to an infectious substance mean that infection is imminent? The answer is, "No":
    - . first, the infectious substances must have contact with a susceptible host;
    - . second, gaining entry to that host is not enough to cause infection; the infectious substance must gain entry to the host through the route of infection or transmission that will allow it to cause infection;
    - . third, it has to be in an infectious dose that will cause infection;
    - . fourth, the infectious substance must withstand a host's defense systems which include enzymes in tears and saliva, mucus in the respiratory tract, cilia in the trachea, stomach acids, and phagocytes in blood and tissues; and
    - . fifth, the infectious substance must withstand the protection afforded the host from previous infections and vaccinations and treatment available.
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