

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

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LOW PROBABILITY INFECTIOUS SUBSTANCES

Comments on ST/SG/AC.10/C.3/2004/62

Transmitted by the International Air Transport Association (IATA)

One issue that occupied a significant part of the discussion at the IATA Dangerous Goods Board (DGB) 84th meeting, held in Bangkok from 2 – 5 March 2004, was the amendments to the classification of Division 6.2 substances flowing from the 13th edition of the UN Model Regulations as incorporated into the ICAO Technical Instructions and especially the handling and transportation of samples collected from healthy-looking living persons for diagnostic purpose.

The report of the DGB/84 meeting on this issue states:

“59 With respect to the revisions to the classification for Division 6.2 and the amendment permitting substances with a “low probability” of containing infectious substances to be considered as “not regulated” the members present expressed some concern that this would remove any requirement for good standard packaging and could result in more incidents. The meeting requested that the Secretariat develop some wording that would require a minimum standard of packaging for “non-infectious” substances such as diagnostic specimens for cholesterol or diabetes tests.”

Air transport is widely used to ship specimens for routine diagnosis and analysis, particularly in continents or countries with a large land mass such as Africa, Australia, Canada, Russia and the United States where air transport is the only available or practical method of moving these specimens from the point of origin to destination, pathology or other laboratories. As such, the airlines wish to ensure that the specimens are able to move as quickly as possible to destination with the minimum of delays and interference. At the same time the airlines also have to ensure that the specimens do not pose any operational or physical risk while in transport. The best way to achieve this is by requiring that all specimens are packaged, such that they are able to withstand the shocks and loading normally encountered during transport.

Subsequent to DGB/84 there were a number of discussions on the alternatives available to the DGB with regard to appropriate packaging methods for diagnostic specimens. The DGB was faced with three alternatives:

1. Do nothing and allow these substances to be shipped as “Not Regulated”;
2. Develop a new ‘pared down’ P650 packing instruction; or
3. Require these substances to be packed according to P650.

Option 1 was discounted as not achieving the above objective. In considering options 2 and 3, the Secretariat reviewed other guidance material produced by the WHO and the Dangerous Goods European Advisory Group (DGELG).

WHO have produced a document titled *Transport of Infectious Substances, Scientific background to the 13th revised edition of the United Nations Model Regulations regarding the requirements for transporting infectious substances*. A review of this document identified that WHO recommends the use of P650 for any substance other than those known not to contain pathogens; an extract of the relevant text from page 16 of the WHO document is attached as Annex 1.

The IATA Secretariat, on behalf of the Board also undertook discussions with the European Dangerous Goods Liaison Group (DGELG). The DGELG comprises representatives from European aviation authorities as well as European airlines and acts as an advisory group to the Joint Aviation Authorities (JAA). The DGELG too had concerns regarding the transport of substances with a “low probability” of containing infectious substances. The direction taken by the DGELG, after discussion with the WHO, was to require that unless the substances were known not to contain pathogens then they must be treated as UN 3373 and be packed according to P650.

Based on the approach taken by both the WHO and DGELG, the 46th edition of the IATA Dangerous Goods Regulations will align with WHO and DGELG and require that unless substances are known not to contain pathogens, then they must be treated as if infectious substances in Category B are present and be assigned to UN 3373 and packaged according to P650. This position is **only** being taken in the absence of an alternative to P650 however.

It is noted that the provisions adopted by the UN Sub-committee in 2.6.3.2.3 and 2.6.3.2.5 in the 13th edition of the Model Regulations is a significant departure from that that existed in the 12th and previous editions with regard to substances being transported for routine analysis.

The 12th edition, 2.6.3.1.3 of the Model Regulations defined diagnostic specimens as follows:

“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.

Diagnostic specimens **shall** (*emphasis*) be assigned to UN 3373 unless the source patient or animal has or may have a serious human or animal disease which can be readily transmitted from one individual to another, directly or indirectly, and for which effective treatment and preventative measures are not usually available, in which case they shall be assigned to UN 2814 or UN 2900.

NOTE 1: *Blood which has been collected for the purpose of blood transfusion or for the preparation of blood products, and blood products and any tissues or organs intended for use in transplants are not subject to these Regulations.*

NOTE 2: *Assignment to UN 2814 or UN 2900 must be based on known medical history of the patient or animal, endemic local conditions, symptoms of the patient or animal, or professional judgement concerning individual circumstances of the patient or animal.”*

This text left no margin for interpretation and the only substances that could be transported as “not regulated” were those covered by Note 1, which are those basically known not to contain pathogens.

The 11th edition of the Model Regulations defined diagnostic specimens slightly differently, but still applied minimum packaging requirements for those with a “relatively low probability of containing pathogens” as follows:

“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.”

Document ST/SG/AC.10/C.3/2004/62 presented by the Expert from Canada proposes some amendments in Proposal 1 to clarify the requirements of 2.6.2.3.5. If this proposal is accepted, IATA would like to propose that the Sub-Committee consider the addition of the following new paragraph following paragraph 2.6.3.2.6 proposed in ST/SG/AC.10/C.3/2004/62 (*Editorial note: it would be better if the proposed 2.6.3.2.6 is renumbered 2.6.3.2.7 and the following paragraph becomes 2.6.3.2.6*).

2.6.3.2.7 The substances referred to in 2.6.3.2.5 (a) shall meet the following conditions for packaging:

- (a) the packaging shall consist of:
 - a watertight primary receptacle (s) which shall not contain more than 1 litre;
 - a watertight secondary packaging;
 - an outer packaging of adequate strength for its capacity, mass and intended use, with at least one external dimension of 100 mm × 100 mm, and which shall not contain more than 4 litres;
 - absorbent material placed between the primary receptacle and secondary packaging in sufficient quantity to absorb the entire contents of liquid substances;
- (b) if multiple fragile primary receptacles are placed in a single secondary packaging they must be either individually wrapped or separated to prevent contact between them.

Annex 1

WHO Transport of infectious substances

Extract from pages 16 and 17

Exemptions from the Model Regulations

As in the past editions of the Model Regulations, there are some exemptions to the rules.

These exemptions are outlined below.

2.6.3.2.3 Substances which do not contain infectious substances or substances which are unlikely to cause disease in humans or animals are not subject to these Regulations unless they meet the criteria for inclusion in another class.

Microorganisms that are non-pathogenic for humans or animals are not subject to these regulations, nor is e.g. animal serum that is sourced from disease-free herds. However, WHO recommends packaging all samples of human or animal origin according to P650 as a minimum standard.

2.6.3.2.4 Blood or blood components which 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 Regulations.

People offering blood for use in transfusions undergo a verbal screening test that allows healthcare professionals to estimate/evaluate the probability for pathogens to be present in their blood. This verbal screening test is sufficient for accepted blood samples to be exempted from these Model Regulations.

2.6.3.2.5 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 Regulations.

Examples are:

foodstuffs, water samples, living persons and substances which have been treated so that the pathogens have been neutralized or deactivated.

This text refers to environmental isolates from uninfected areas, food samples, or other human or animal-sourced substances that may have been treated in such a way to inactivate any infectious substances that might be present, unless they meet criteria for inclusion in another class. Samples collected from healthy-looking living persons are considered infectious substances of category B to be shipped in P650. WHO recommends that inactivated substances that no longer pose a health risk be shipped according to P650 as a minimum standard.
