COMMITTEE OF EXPERTS ON THE TRANSPORT OF DANGEROUS GOODS
Sub-Committee of Experts on the Transport of Dangerous Goods
(Geneva, 5-16 July 1999, agenda item 5 (f))

MISCELLANEOUS DRAFT AMENDMENTS TO THE MODEL REGULATIONS

Infectious substances

Proposed amendments to section 2.6.3

Transmitted by the World Health Organization (WHO)

Rationale

Infectious health-care wastes

- The classification of infectious substances according to the risk groups in section 2.6.3.2 would not be feasible for health-care wastes. This classification is based on criteria developed by WHO for laboratories and their wastes, but not for wastes from health-care activities. Whereas in laboratories the infectious substances are usually well defined, it is in practice not feasible to segregate wastes from health-care activities into these classes:

  An example: A patient entering a hospital usually produces waste before being diagnosed (diagnostic tests etc.). When the diagnosed, the doctor will know about the disease, but not specifically the nurse treating the patient and producing most of the waste. In a number of cases, the disease will never be diagnosed.

- The current definition of wastes (transported under UN 3291, para. 2.6.3.1.5, "*wastes derived from the medical treatment of animals or humans or from bio-research where there is relatively low probability that infectious substances are present*") may give rise to misinterpretation.

- When waste from health-care activities is considered to have more than a *relatively low probability that infectious substances are present*, the application of packaging instructions 620 seem very cumbersome, not justified and very costly.

  For these reasons, the main changes in the UN document are the following:

- Infectious health-care waste is now not anymore considered as a substance, but as waste. Consequently, the packaging requirements will be less costly/cumbersome (most health-care wastes are now falling under packaging requirements 621, and not anymore under 620). Infectious health-care waste is defined as *discarded materials from health-care activities on humans or animals which have the potential of transmitting infectious agents to humans. These include discarded materials or equipment from the diagnosis, treatment and prevention of disease, assessment of health status or identification purposes, that have been in contact with blood and its derivatives, tissues, tissue fluids or excreta, or wastes from infection isolation wards. Such wastes shall include, but are not limited to, cultures and stocks; tissues; dressings, swabs or other items soaked with blood; syringe needles; scalpels; diapers; blood bags. Incontinence material from nursing homes, home treatment or from specialized health-care establishments which do not routinely treat infectious diseases (e.g. psychiatric clinics) is an exception to this definition and are is not considered as infectious health-care waste.*

- Although some domestic waste may seem similar to infectious health-care waste (such as babies' diapers etc), the probability that infectious health-care waste contains pathogens is much higher than in domestic waste, which justifies special transport requirements.

- Health-care wastes will not anymore be classified according to the specific pathogen they contain.

- Special wastes from research involving known pathogens (e.g. research on HIV, ebola etc.) will still have more restrictive packaging requirements (still transported under 620).

Infectious health-care waste	**Discarded materials from health-care activities on humans or animals which have the potential of transmitting infectious agents to humans. These include discarded materials or equipment from the diagnosis, treatment and prevention of disease, assessment of health status or identification purposes, that have been in contact with blood and its derivatives, tissues, tissue fluids or excreta, or wastes from infection isolation wards. Such wastes shall include, but are not limited to, cultures and stocks; tissues; dressings, swabs or other items soaked with blood; syringe needles; scalpels; diapers; blood bags.** **Incontinence material from nursing homes, home treatment or from specialized health-care establishments which do not routinely treat infectious diseases (e.g. psychiatric clinics) is an exception to this definition and are is not considered as infectious health-care waste.** **Sharps**, whether contaminated or not, should be considered as a subgroup of infectious health-care waste *Includes: Syringe needles, scalpels, infusion sets, knives, blades, broken glass*
Anatomic health-care waste	Consists of recognizable body parts
Pharmaceutical health-care waste	Consisting of/or containing pharmaceuticals *Includes: pharmaceuticals expired, no longer needed; their containers, items contaminated by or containing pharmaceuticals (bottles, boxes)*
Genotoxic health-care waste	Consisting of, or containing substances with genotoxic properties *Includes: cytotoxic and antineoplasic drugs; genotoxic chemicals*
Chemical health-care waste	Consisting of, or containing chemical substances *Includes: laboratory chemicals; film developer; disinfectants expired or no longer needed; solvents, cleaning agents and other*
Health-care wastes with high content of heavy metals	Consists of materials and equipment which include heavy metals and derivatives in their structure. *Include: batteries; broken thermometers; manometeres*
Pressurized containers	*Consists of containers (full or empty) with pressurized liquid, gas or powdered materials* *Includes: gas cylinders and cartridges; aerosol cans*
Radioactive health-care waste	Consisting in, or containing radioactive substances *Includes: unused liquids from radiotherapy or laboratory research; contaminated glassware, packages or absorbent paper; urine and excreta from patients treated or tested with unsealed radionuclides; sealed sources*

Recommendations on the

TRANSPORT OF DANGEROUS GOODS

Model Regulations

United Nations, 1997

2nd draft, 22 June 1999

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 those substances known or reasonably expected to contain pathogens. Pathogens are defined as micro-organisms (including bacteria, viruses, rickettsia, parasites, fungi) or recombinant micro-organisms (hybrid or mutant), that are known or reasonably expected to cause infectious disease in animals or humans.

Note 1: However, they are not subject to the Regulations for this Division if they are unlikely to cause human or animal disease

Note 2: Infectious substances are subject to the Regulations for this Division only if they are capable of spreading disease when exposure to them occurs.

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 not limited to, finished or unfinished products such as vaccines and diagnostic products.

For the purposes of these Regulations, biological products are divided into the following groups:

(a) Those which contain pathogens in risk group 1; those which contain pathogens under the conditions that their ability to produce disease is very low to none; and those known not to contain pathogens. Substances in this Group are not considered infectious substances for the purposes of these Regulations;

(b) Those manufactured and packaged in accordance with the requirements of national governmental health authorities and transported for the purposes of final packaging distribution, and use for personal health care by medical professionals or individuals. Substances in this Group are not subject toe the regulations applicable to Division 6.2.

(c) Those known or reasonably expected to contain pathogens in risk groups 2, 3, or 4 which do not meet the criteria of 2.6.3.1.2(b) above. Substances in this Group shall be classified in Division 6.2 under UN 2814 or UN 2900, as appropriate.

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

2.6.3.1.3 *Diagnostic specimens* are any human or animal material including, but not limited to, excreted secreta, blood and its components, tissue and tissue fluids being transported for diagnostic or investigative 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 in risk groups 2, 3 or 4 and where a relatively low probability exists that pathogens of risk group 4 are present. The 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 present 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 purpose of routine screening tests or initial diagnosis for other than the presence of pathogens fall within this Group;

(c) Those known not to contain pathogens.

2.6.3.1.4 *Genetically modified micro-organisms and organisms in which* are micro-organisms and organisms in genetic material has been purposely altered through genetic engineering in a way that does not occur naturally. They are divided into the following categories:

(a) Genetically modified micro-organisms which meet the definition of an infectious substances given above shall be classified in Division 6.2 and assigned to UN 2814 or to UN 2900.

(b) Genetically modified organisms, which 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;

(c) Animals which contain or are contaminated with genetically modified micro-organisms and organisms that meet the definition of an infectious substance shall be transported in accordance with conditions specified by the competent authorities;

(d) Except when authorized for unconditional use by the Governments of the countries of origin, transit and destination, genetically modified micro-organisms which 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 UN 3245.

2.6.3.1.5 Infectious health-care wastes *(transported under UN 3291, 'Infectious health-care wastes')* are discarded materials from health-care activities on humans or animals which have the potential of transmitting infectious agents to humans. These include discarded materials or equipment from the diagnosis, treatment and prevention of disease, assessment of health status or identification purposes, that have been in contact with blood and its derivatives, tissues, tissue fluids or excreta, or wastes from infection isolation wards. Such wastes shall include, but are not limited to, cultures and stocks; tissues; dressings, swabs or other items soaked with blood; syringe needles; scalpels; diapers; blood bags.

Incontinence material from nursing homes, home treatment or from specialized health-care establishments which do not routinely treat infectious diseases (e.g. psychiatric clinics) is an exception to this definition and are is not considered as infectious health-care waste.

Decontaminated wastes which previously contained infectious substances are considered non-dangerous unless the criteria of another class are met.

2.6.3.1.6 Wastes from bioresearch involving specific, identified microorganisms shall be assigned to UN 2814 or to UN 2900, as appropriate.

2.6.3.2 Classification of infectious substances and assignment to risk groups

2.6.3.2.1 Infectious substances **that are not health-care wastes (as defined under 2.6.3.1.5)** shall be classified in Division 6.2 and assigned to UN 2814 or UN 2900, as appropriate, on the basis of their allocation to one of three risk groups based on criteria developed by the World Health Organization (WHO) and published in the WHO "Laboratory Biosafety Manual, second edition (1993)".

A risk group is characterized by the pathogenicity of the organism, the mode and relative ease of transmission, the degree of risk to both an individual and a community, and the reversibility of the disease through the availability of known and effective preventive agents and treatment.

2.6.3.2.2 The criteria for each risk group according to the level of risk are as follows:

(a) Risk Group 4: a pathogen that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly, and for which effective

treatment and preventive measures are not usually available (i.e., high individual and community risk);

(b) Risk Group 3: a pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another, and for which affective treatment and preventive measures are available (i.e., high individual risk and low community risk);

(c) Risk Group 2: a pathogen that can cause human or animal disease but is unlikely to be a serious hazard, and, while capable of causing serious infection on exposure, for which there are effective treatment and preventive measures available and the risk of spread of infection is limited (i.e., moderate individual risk and low community risk).

Note: Risk Group 1 includes micro-organisms that are unlikely to cause human or animal disease (i.e., no, or very low, individual or community risk). Substances containing only such micro-organisms are not considered infectious substances for the purposes of these Regulations.

2.6.3.3 Biological products, diagnostic specimens, infectious health-care waste and wastes from bioresearch

2.6.3.3.1 Biological products known to contain, or thought likely to contain, any infectious substances shall meet the requirements for infectious substances. Biological products referred to in 2.6.3.1.2 (a) and (b) are not subject to the requirements applicable to Division 6.2.

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 a minimum external dimension of 100 mm.

2.6.3.3.3 Waste from bioresearch involving specific, identified microorganisms or infectious health-care waste shall meet the relevant requirements for infectious substances applicable to the UN number to which they have been assigned.

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PACKING INSTRUCTION (Infectious substances)

The packaging shall, as demonstrated by tests, be capable of passing the design type tests detailed in Chapter 6.3.

A packaging shall include:

(a) Inner packagings comprising:

(i) watertight primary receptacle(s);

(ii) a watertight secondary packaging;

(iii) an absorbent material in sufficient quantity to absorb the entire contents placed between the primary receptacle(s) and the secondary packaging; if multiple primary receptacles are placed in a single secondary packaging, they shall be individually wrapped so as to prevent contact between them;

(b) An outer packaging of adequate strength for its capacity, mass and intended use. The smallest external dimension shall be at least 100 mm.

Inner packagings containing infectious substances shall not be consolidated with inner packagings containing unrelated types of goods. Complete packages may be overpacked in accordance with the provisions of 1.2.1 and 5.1.2: such an overpack may contain dry ice.

Other than for exceptional consignments, e.g. whole organs which require special packaging, infectious substances shall be packed in accordance with the following recommendations.

(a) Lyophilized substances: Primary receptacles shall be flame-sealed glass ampoules or rubber-stoppered glass vials fitted with metal seals

(b) Liquid or solid substances:

(i) Substances consigned at ambient temperatures or at a higher temperature. Primary receptacles shall be of glass, metal or plastics. Positive means of ensuring a leakproof seal shall be provided, e.g. a heat seal, a skirted stopper or a metal crimp seal. If screw caps are used, they shall be reinforced with adhesive tape;

(ii) Substances consigned refrigerated or frozen. Ice or dry ice shall be placed around the secondary packaging(s). Interior supports shall be provided to secure secondary packaging(s) in position after the ice or dry ice has dissipated. If ice is used, the outer packaging shall be leakproof. If dry ice is used, the outer packaging shall permit the release of carbon dioxide gas. The primary receptacle and the secondary packaging shall maintain their integrity at the temperature of the refrigerant used,

(iii) Substances consigned in liquid nitrogen. Plastics primary receptacles capable of withstanding very low temperature shall be used 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. Provisions for the consignment of liquid nitrogen shall also be fulfilled The primary receptacle and the secondary packaging shall maintain their integrity at the temperature of the liquid nitrogen.

Whatever the intended temperature of the consignment, 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 and temperatures in the range -40 °C to +55 °C.

621 PACKING INSTRUCTION (Infectious health-care wastes)

Rigid, leakproof packagings or IBCs in accordance with the requirements of Chapters 6.1 or 6.5 for solids, at the Packing Group II performance level, shall be used provided there is sufficient absorbent material to absorb the entire amount of liquid present and the packaging or IBC is capable of retaining liquids. Packages containing larger quantities of liquid shall be carried in rigid packagings or IBCs in accordance with the requirements of Chapters 6.I or 6.5 at the Packing Group II performance level for liquids. Packagings or IBCs intended to contain sharp objects such as broken glass and needles shall be resistant to puncture and retain liquids under the performance test conditions in Chapters 6.1 or 6.5.

IBC: Intermediate Bulk Container

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