



The Transportation of Dangerous Goods— More Changes for Infectious Substances in the Model Regulations

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Introduction

What's going on with the shipping of infectious substances? It seems like they are in a state of continual flux if you look at recent information out from ICAO/IATA, US DOT, Transport Canada, etc.

Unfortunately, I can't tell you what every federal and modal (mode of transport) regulator is going to do, but I can tell you what went on during the recent biennium at the meetings at the UN Sub-Committee of Experts on the Transport of Dangerous Goods, and what the revised 14th UN Model Regulations will be.

Who Is This Group and Why Are They Involved in Dangerous Goods Regulations?

You're probably asking why anyone should care what the UN does in this area since they cannot issue enforceable regulations. You may be thinking that their activity doesn't have any impact on what we really have to do in the shipping arena—but does it? Based on the recent addendum to the 2005-2006 ICAO Technical Instructions for the transport of dangerous goods on Division 6.2 Infectious Substances, I would suggest that it already has.

The UN Sub-Committee of Experts on the Transport of Dangerous Goods develops "model regulations" that each country and regulators for each mode of transport uses to develop consistency in the global transport of dangerous goods. The Sub-Committee is made up of delegations of "Experts" from 30 different countries such as, the US, Canada,

UK, Australia, Germany, Japan, France, etc., who vote on the issues before the group. There are a number of other groups who serve as Advisors and Observers to the Experts. These include 15 International organizations such as WHO, Universal Postal Union, and ICAO; 21 other countries, like Switzerland, Ireland and Greece; and, 44 other organizations such as ABSA, EBSA, IATA, IFALPA (International Pilots), DGAC, Compressed Gas Association, World Nuclear Transport Institute, International Union of Railways, ISO, WTCC, etc.

The Sub-Committee meets 2 times per year for a week, and then updates the model regulations every other year. So there are essentially 4 meetings per biennium that lead to the formation and/or revision of the model regulations.

Primer on UN Transportation Terminology

This UN Sub-Committee issues regulations on all hazardous goods. These items include hazardous chemicals, biohazards, radiologic hazards, explosives, fireworks, batteries, aerosol cans, etc. They must also consider the particular issues with the modes of transport involved, i.e., air, water, rail, and road.

Infectious substances are included in Division 6.2 under Class 6, Toxic and Infectious Substances. Most of the materials that we are concerned with fall into that area except for genetically modified organisms (GMOs) "that can alter animals, plants or microbiological substances in a way not normally the result of natural reproduction." Those GMOs fall

into Class 9, Miscellaneous Dangerous Substances and Articles.

UN numbers are assigned to each dangerous material and are generally required to be included on all packages. The significant ones from the biohazard standpoint are:

UN 2814 – Infectious substances affecting humans

UN 2900 – Infectious substances affecting animals

UN 3291 – Medical or clinical wastes

UN 3245 – GMOs that can alter organisms

UN 3373 – Diagnostic or clinical specimens (2003);
Biological substance, Category B (2005)

In addition, the Model Regulations include specific packing instructions for dangerous goods. These are:

P620* – Infectious substances 2814 and 2900

P621 – Medical wastes 3291

P650 – Clinical specimens/Biological substances,
Category B 3373

P904 – GMOs that alter organisms 3245

*No, this isn't a typographical error. UN packing instruction for infectious substances is 620 and IATA's is 602.

What Happened During the Last Biennium

The latest biennium concluded in December, 2004. The new Model Regulations, the 14th revised edition, was published earlier this year. While the changes in the area of infectious substances were not as sweeping as the previous edition, there were a couple significant issues, namely, in the area of cultures and low risk clinical materials. A copy of the changes to the 13th Edition that were put together by Linda Hume-Sastre, the Expert from Transport Canada who spearheaded much of the changes in this area, are included at the end of this summary.

The definition of "culture" was changed because it was felt that it could be confused with certain types of clinical specimens, like throat swabs. So now it reads: "Cultures are the result of a process by which pathogens are intentionally propagated. This definition does not include human or animal patient specimens as defined in 2.6.3.1.4."

A definition of patient specimens was added: "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."

Many of you are probably wondering how this wording came about. Keep in mind the wording is developed so that it will be understandable and be able to withstand translation into many languages. Also, there is not a lot of time to devote to semantics, since there are lots of significant issues on the docket. Lastly, almost every issue involves some level of compromise, so if it's going to move the motion forward, it becomes much more palatable.

There were some changes made to the lists of indicative example of Category A organisms. The Hantavirus on the list was changed from the one that causes "hantavirus pulmonary syndrome" to the one "causing hemorrhagic fever with renal syndrome." Rabies, Rift Valley Fever virus and Venezuelan Equine Encephalitis virus were amended to apply to "cultures only," as were all of the organisms listed in the indicative list of animal pathogens, UN 2900. African horse sickness virus and Bluetongue virus were deleted from the list for UN 2900.

A significant change was made to eliminate the requirement for all cultures of Category B infectious agents to be labelled and shipped as UN 2814 or UN 2900, the same as the Category A agents. This was brought about by the Worldwide Federation of Culture Collections (WFCC), in conjunction with all the worldwide microbiological societies writing in to show their support for this issue. ABSA spoke up in support of this issue during the discussion preceding the vote.

There were some changes made to the materials exempted. In addition to materials that do not contain infectious organisms and blood for transfusion, the following items were added:

- Substances containing microorganisms that are non-pathogenic to humans or animals.
- Substances where the pathogens present have been neutralized or inactivated so that they no longer pose a health risk.
- Environmental samples (including food and water samples) which are not considered to pose a significant risk of infection.
- Dried blood spots or fecal occult blood screening tests.

- Human or animal specimens for which there is a minimal likelihood that pathogens are present, except they must be triple packed.

The most contentious issue was the latter. Canada again submitted a proposed change to exempt low risk materials, such as standard screening tests from normal populations. Maureen Best presented information to support the Canadian position. There was opposition to this from others. This included WHO and the Expert from the UK who argued that every specimen poses a risk. One cannot dispute that the materials could contain an infectious agent and appropriate precautions need to be used when manipulating these materials in a laboratory situation. However these materials pose an extremely low risk in transport. There have been no reported incidents of infection associated with these materials in transport conditions; there have been limited, if any exposures reported when the material has been suitably triple packed. The US DOT has not and cannot, under their mandates regulate these materials because they do not pose a level of risk that requires their inclusion in the “dangerous goods” category.

There are drawbacks to requiring all clinical samples to be shipped as UN 3373 under Packing Instruction 650. Namely, that the materials technically become Dangerous Goods. As such, there are restrictions as to which carriers can accept these materials and generally additional surcharges that are assessed for transporting these materials. Fortunately, a compromise was reached that addressed the concerns of potential exposure by requiring a triple packaging which will prevent any leakage and is marked with the words: “exempt human specimen” or “exempt animal specimen.”

At this point, everyone hopes that the issue of infectious substances will be stable for a while, but one never knows.

Changes to the UN Model Regulations, 14th Edition

**As Written by Linda Hume-Sastre,
Transport Canada**

[Note: Deletions are crossed through and new wording is underlined in this version so that it could be printed in black and white.]

2.6.3 Division 6.2—Infectious Substances

2.6.3.1 Definitions

2.6.3.1.1—Infectious substances are substances which are known or are reasonably expected to contain pathogens. Pathogens are defined as micro-organisms (including bacteria, viruses, rickettsiae, parasites, fungi), and other agents such as prions, which can cause disease in humans or animals.

2.6.3.1.2—Biological products are those products derived from living organisms which are manufactured and distributed in accordance with the requirements of appropriate national 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.

2.6.3.1.3—Cultures (~~laboratory stocks~~) are the result of a process by which pathogens are ~~amplified or~~ intentionally propagated. This definition does not include human or animal patient specimens as defined in 2.6.3.1.4. ~~in order to generate high concentrations thereby increasing the risk of infection when exposure to them occurs. This definition refers to cultures prepared for the intentional generation of pathogens and does not include cultures intended for diagnostic and clinical purposes.~~

2.6.3.1.4—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.

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.

2.6.3.1.6—Medical or clinical wastes are wastes derived from the medical treatment of animals or humans or from bio-research.

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, UN3291 or UN 3373, as appropriate.

2.6.3.2.2 Infectious Substances are Divided into the Following Categories

2.6.3.2.2.1—Category A: An infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease to in otherwise healthy humans or animals. Indicative examples of substances that meet these criteria are given in Table 1 and Table 2.

Note: An exposure occurs when an infectious substance is released outside of the protective packaging, resulting in physical contact with humans or animals.

(a) Infectious substances meeting these criteria which cause disease in humans or both in humans and animals shall be assigned to UN 2814. Infectious substances which cause disease only in animals shall be assigned to UN 2900.

(b) Assignment to UN 2814 or UN 2900 shall be based on the known medical history and symptoms of the source human or animal, endemic local conditions, or professional judgment concerning individual circumstances of the source human or animal.

Note 1: The proper shipping name for UN 2814 is INFECTIOUS SUBSTANCE, AFFECTING HUMANS. The proper shipping name for UN 2900 is INFECTIOUS SUBSTANCE, AFFECTING ANIMALS ONLY.

Note [X]: Animal carcasses affected by pathogens which would be assigned to Category A either as pathogens or in cultures only, shall be assigned to UN2814 or UN2900, as appropriate. Other animal carcasses affected by pathogens included in Category B shall be transported in accordance with provisions determined by the competent authority.

Note 2: Table 1 and Table 2 are not exhaustive. Infectious substances—including new or emerging pathogens—which do not appear in the tables but which meet the same criteria, should be assigned to Category A. In addition, if there is doubt as to

whether or not a substance meets the criteria it shall be included in Category A.

Note 3: In Table 1 and Table 2, the microorganisms written in italics are bacteria, mycoplasmas, rickettsia, or fungi.

2.6.3.2.2.2—**Category B:** An infectious substance which does not meet the criteria for inclusion in Category A. Infectious substances in Category B shall be assigned to UN 3373 except that cultures as defined in 2.6.3.1.3 shall be assigned to UN 2814 or UN 2900 as appropriate.

Note: The proper shipping name for UN 3373 is “BIOLOGICAL SUBSTANCE, CATEGORY B” ~~“DIAGNOSTIC or CLINICAL SPECIMENS”~~.

2.6.3.2.3—Exemptions

2.6.3.2.3.1—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.

2.6.3.2.3.2—Substances containing microorganisms which are non-pathogenic to humans or animals are not subject to these Regulations unless they meet the criteria for inclusion in another class.

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.

2.6.3.2.3.5—Dried blood spots, collected by applying a drop of blood onto absorbent material, or faecal occult blood screening tests and blood or blood components which have been collected for the purpose 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 transplants are not subject to these Regulations.

~~2.6.3.2.4—Blood or blood components which have been collected for the purpose 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 transplants are not subject to these 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.

~~2.6.3.2.6~~ An animal which has been intentionally infected and is known or suspected to contain an infectious substance shall only be transported under terms and conditions approved by the competent authority.

~~2.6.3.2.3.6~~ Human or animal specimens for which there is minimal likelihood that pathogens are present are not subject to these Regulations if the specimen is transported in a packaging that will prevent any leakage and that is marked with the words “Exempt Human Specimen” or “Exempt Animal Specimen”, as appropriate. The packaging should meet the following conditions:

(a) the packaging should consist of three components:

- (i) a leak-proof primary receptacle(s);
- (ii) a leak-proof secondary packaging; and
- (iii) an outer packaging of adequate strength for its capacity, mass and intended use, and with at least one surface having minimum dimensions of 100 mm × 100 mm;

(b) for liquids, absorbent material in sufficient quantity to absorb the entire contents should be 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,

(c) when multiple fragile primary receptacles are placed in a single secondary packaging they should be either individually wrapped or separated to prevent contact between them.

Note: An element of professional judgment is required to determine if a substance is exempt under this section. That judgment should be based on the known medical history, symptoms and individual circumstances of the source, human or animal, and endemic local conditions. Examples of specimens that may be transported under this section include

the blood or urine tests to monitor cholesterol levels, blood glucose levels, hormone levels, or prostate specific antibodies (PSA); those required to monitor organ function such as heart, liver or kidney function for humans or animals with non-infectious diseases, or therapeutic drug monitoring; those conducted for insurance or employment purposes and are intended to determine the presence of drugs or alcohol; pregnancy test; biopsies to detect cancer; and antibody detection in humans or animals.

~~2.6.3.2.3.7~~ Unless an infectious substance cannot be consigned by any other means, live animals shall not be used to consign such a substance. An animal which has been intentionally infected and is known or suspected to contain an infectious substance shall only be transported under terms and conditions approved by the competent authority.

2.6.3.3 Biological Products

~~2.6.3.3.1~~ For the purposes of these Regulations, biological products are divided into the following groups:

(a) those which are manufactured and packaged in accordance with the requirements of appropriate national 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 Regulations.

(b) those which do not fall under paragraph (a) and are known or reasonably believed to contain infectious substances and which meet the criteria for inclusion in Category A or Category B. Substances in this group shall be assigned to UN 2814, UN 2900 or UN 3373, as appropriate.

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

2.6.3.4 Genetically Modified Micro-Organisms and Organisms

~~2.6.3.4.1~~ Genetically modified micro-organisms not meeting the definition of an infectious substance shall be classified according to Chapter 2.9.

2.6.3.5 Medical or Clinical Wastes

2.6.3.5.1—Medical or clinical wastes containing Category A infectious substances ~~or containing Category B infectious substances in cultures~~ shall be assigned to UN 2814 or UN 2900 as appropriate. Medical or clinical wastes containing infectious substances in Category B, ~~other than cultures~~, shall be assigned to UN 3291.

2.6.3.5.2—Medical or clinical wastes which are reasonably believed to have a low probability of containing infectious substances shall be assigned to UN 3291.

Note: The proper shipping name for UN 3291 is CLINICAL WASTE, UNSPECIFIED, N.O.S. or (BIO) MEDICAL WASTE, N.O.S. or REGULATED MEDICAL WASTE, N.O.S.

2.6.3.5.3—Decontaminated medical or clinical wastes which previously contained infectious substances are not subject to these Regulations unless they meet the criteria for inclusion in another class.

Special Provisions

Special Provision 274, requiring the technical name, is deleted from UN 2814 and UN 2900.

Special Provision 318 applies and reads as follows:

“318. For the purposes of documentation, the proper shipping name shall be supplemented with the technical name (see 3.1.2.8). Technical names need not be shown on the package. When the infectious substances to be transported are unknown, but suspected of meeting the criteria for inclusion in Category A and assignment to UN 2814 or UN 2900, the words “suspected category A infectious substance” shall be shown, in parentheses, following the proper shipping name on the transport document but not on the outer packagings.”

Special Provision 319 is against UN 3373, Biological Substance, Category B Diagnostic or Clinical Specimens

~~“319. This entry applies to human or animal material including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluids, and body parts being transported for purposes such as research, diagnosis, investigational activities, disease treatment or prevention. Substances packed and marked in accordance with packing instruction P650 are not subject to any other requirements in these Regulations.”~~

4.1.8.3—For UN 281 and UN 2900, an itemized list of contents shall be enclosed between the secondary packaging and the outer packaging. When the infectious substances to be transported are unknown but suspected of meeting the criteria for inclusion in Category A and assignment to UN 2814 or UN 2900, the words “suspected category A infectious substance” shall be shown, in parentheses, following the proper shipping name on the document inside the outer packaging.

7.1.6.2.3 Decontamination of Transport Units

A railway wagon, road vehicle, cargo space of a ship, compartment of an aircraft or other transport unit which has been used to transport infectious substances shall be inspected or release of the substance before re-use. If the infectious substances were released during transport, the transport unit shall be decontaminated before it is re-used. Decontamination may be achieved by any means which effectively inactivates the released infectious substance.

Note: The 14th Edition of the UN Model Regulations on the Transport of Dangerous Goods is available online at: www.unece.org/trans/danger/publi/unrec/rev14/14files_e.html.

Table 1

Indicative examples of infectious substances included in Category A in any form unless otherwise indicated. (2.6.3.2.2.(a))	
UN Number and Proper Shipping Name	Micro-organism
UN 2814 Infectious substances affecting humans	<i>Bacillus anthracis</i> (cultures only) <i>Brucella abortus</i> (cultures only) <i>Brucella melitensis</i> (cultures only) <i>Brucella suis</i> (cultures only) <i>Burkholderia mallei</i> – <i>Pseudomonas mallei</i> –Glanders (cultures only) <i>Burkholderia pseudomallei</i> – <i>Pseudomonas pseudomallei</i> (cultures only) <i>Chlamydia psittaci</i> –avian strains (cultures only) <i>Clostridium botulinum</i> (cultures only) <i>Coccidioides immitis</i> (cultures only) <i>Coxiella burnetii</i> (cultures only) Crimean-Congo hemorrhagic fever virus Dengue virus (cultures only) Eastern equine encephalitis virus (cultures only) <i>Escherichia coli</i> , verotoxigenic (cultures only) Ebola virus Flexal virus <i>Francisella tularensis</i> (cultures only) Guanarito virus Hantaan virus Hantaviruses causing hantavirus pulmonary syndrome Hantaviruses causing <u>hemorrhagic fever with renal</u> hantavirus pulmonary syndrome Hendra virus Hepatitis B virus (cultures only) Herpes B virus (cultures only) Human immunodeficiency virus (cultures only) Highly pathogenic avian influenza virus (cultures only) Japanese Encephalitis virus (cultures only) Junin virus Kysanur Forest disease virus Lassa virus Machupo virus Marburg virus Monkeypox virus <i>Mycobacterium tuberculosis</i> (cultures only) Nipah virus Omsk hemorrhagic fever virus Poliovirus (cultures only) Rabies virus (cultures only) <i>Rickettsia prowazekii</i> (cultures only) <i>Rickettsia rickettsii</i> (cultures only) Rift Valley fever virus (cultures only) Russian spring-summer encephalitis virus (cultures only) Sabia virus <i>Shigella dysenteriae</i> type 1 (cultures only) Tick-borne encephalitis virus (cultures only) Variola virus Venezuelan equine encephalitis virus (cultures only) West Nile virus (cultures only) Yellow fever virus (cultures only) <i>Yersinia pestis</i> (cultures only)

Table 2

Indicative examples of infectious substances included in Category A in any form unless otherwise indicated. (2.6.3.2.2.(a))	
UN Number and Proper Shipping Name	Micro-organism
UN 2900 Infectious substances affecting animals only	African horse sickness virus African swine fever virus (cultures only) Avian paramyxovirus Type 1–Velogenic Newcastle disease virus (cultures only) Bluetongue virus Classical swine fever virus (cultures only) Foot and mouth disease virus (cultures only) Lumpy skin disease virus (cultures only) Mycoplasma mycoides–Contagious bovine pleuropneumonia (cultures only) Peste des petits ruminants virus (cultures only) Rinderpest virus (cultures only) Sheep-pox virus (cultures only) Goatpox virus (cultures only) Swine vesicular disease virus (cultures only) Vesicular stomatitis virus (cultures only)

Table 3

Dangerous Goods List

UN No (1)	Name and description (2)	Class or Division (3)	Sub. risk (4)	PG (5)	SP (6)	LQ (7)	Packaging and IBCs		Portable Tanks	
							PI (8)	PP (9)	T (10)	TP (11)
2814	Infectious Substance Affecting Humans	6.2			318	None	P620			
2900	Infectious Substance Affecting Animals only	6.2			318	None	P620			
3373	Diagnostic or Clinical Specimens Biological Substance, Category B	6.2			319	None	P650		T1	TP1

Table 4
Packaging Instruction

P620	Packing Instruction	P620
This instruction applies to UN Nos. 2814 and 2900.		
The following packagings are authorized provided the special packing provisions of 4.1.8 are met:		
Packagings meeting the requirements of Chapter 6.3 and approved accordingly consisting of: <ol style="list-style-type: none"> (a) Inner packagings comprising: <ol style="list-style-type: none"> (i) watertight primary receptacle(s); (ii) a watertight secondary packaging; (iii) other than for solid infectious substances, an absorbent material in sufficient quantity to absorb the entire contents placed between the primary receptacle(s) and the secondary packaging; if multiple fragile primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated so as to prevent contact between them; (b) A rigid outer packaging of adequate strength for its capacity, mass and intended use. The smallest external dimension shall be not less than 100 mm. 		
Additional requirements: <ol style="list-style-type: none"> 1. 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. 2. Other than for exceptional consignments, e.g., whole organs which require special packaging, the following additional requirements shall apply: <ol style="list-style-type: none"> (a) 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 secured by positive means, e.g., tape, paraffin sealing tape or manufactured locking closure; (b) Substances consigned refrigerated or frozen. Ice, dry ice or other refrigerant shall be placed around the secondary packaging(s) or alternatively in an overpack with one or more complete packages marked in accordance with 6.3.1.1. Interior supports shall be provided to secure secondary packaging(s) or packages in position after the ice or dry ice has dissipated. If ice is used, the outer packaging or overpack shall be leakproof. If dry ice is used, the outer packaging or overpack 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; (c) 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. (d) <u>Lyophilized substances may also be transported in primary receptacles that are flame-sealed glass ampoules or rubber-stoppered glass vials fitted with metal seals;</u> 3. <i>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.</i> 		

Table 5
Packaging Instruction

P650	Packaging Instruction	P650
<p>This packing instruction applies to UN 3373</p> <p>(1) The packaging shall be of good quality, strong enough to withstand the shocks and loadings normally encountered during transport, including transshipment 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 content that might be caused under normal conditions of transport by vibration or by changes in temperature, humidity, or pressure.</p> <p>(2) The packaging shall consist of <u>at least</u> three components:</p> <p>(a) a primary receptacle;</p> <p>(b) a secondary packaging; and</p> <p>(c) a rigid outer packaging <u>of which either the secondary or the outer packaging shall be rigid.</u></p> <p>(3) 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.</p> <p>(4) For transport, the mark illustrated below shall be displayed on the external surface of the outer packaging on a background of a contrasting colour and shall be clearly visible and legible. <u>The mark shall be in the form of a square set at an angle of 45° (diamond shaped) with each side having a length of at least 50 mm, the width of the line shall be at least 2 mm and the letters and numbers shall be at least 6 mm high. The proper shipping name “BIOLOGICAL SUBSTANCE, CATEGORY B” in letters at least 6 mm high shall be marked on the outer package adjacent to the diamond-shaped mark.</u></p> <div data-bbox="662 1045 961 1331" data-label="Image"> <p>The image shows a diamond-shaped mark (a square rotated 45 degrees) with a black border. Inside the diamond, the text "UN3373" is printed in a bold, black, sans-serif font, centered horizontally and vertically.</p> </div> <p>(5) <u>At least one surface of the outer packaging shall have a minimum dimension of 100 mm x 100 mm.</u></p> <p>(6) <u>The completed package shall be capable of successfully passing the drop test in 6.3.2.5 as specified in 6.3.2.2 to 6.3.2.4 of the Model Regulations except that the at a height of the drop shall not be less than 1.2m. Following the appropriate drop sequence, there shall be no leakage from the primary receptacle(s) which shall remain protected by absorbent material, when required, in the secondary package.</u></p> <p>(7) For liquid substances</p> <p>(a) The primary receptacle(s) shall be leakproof.</p> <p>(b) The secondary packaging shall be leakproof.</p> <p>(c) If multiple fragile primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated to prevent contact between them.</p> <p>(d) Absorbent material shall be placed between the primary receptacle(s) and the secondary packaging. The absorbent material shall be in quantity sufficient to absorb the entire contents of the primary receptacle(s) so that any release of the liquid substances will not compromise the integrity of the cushioning material or of the outer packaging.</p> <p>(e) The primary receptacle or the secondary packaging shall be capable of withstanding, without leakage, an internal pressure of 95 kPa (0.95 bar).</p>		

Table 5 (continued)
Packaging Instruction

P650	Packing Instruction	P650
(8)	<p>For solid substances:</p> <ul style="list-style-type: none"> (a) The primary receptacle(s) shall be siftproof. (b) The secondary packaging shall be siftproof. (c) If multiple fragile primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated to prevent contact between them. (d) <u>If there is any doubt as to whether or not residual liquid may be present in the primary receptacle during transport then a packaging suitable for liquids, including absorbent materials, shall be used.</u> 	
(9)	<p>Refrigerated or frozen specimens: Ice, Dry ice and liquid nitrogen</p> <ul style="list-style-type: none"> (a) When dry ice or liquid nitrogen is used to keep specimens cold, all applicable requirements of these Regulations shall be met. When used, ice or dry ice shall be placed outside the secondary packagings or in the outside packaging or an overpack. Interior supports shall be provided to secure the secondary packagings in the original position after the ice or dry ice has dissipated. If ice is used, the outside packaging or overpack shall be leakproof. If Carbon dioxide, solid (dry ice) is used, the packaging shall be designed and constructed to permit the release of carbon dioxide gas to prevent a build-up of pressure that could rupture the packagings and shall be marked "Carbon dioxide, solid" or "Dry ice." (b) The primary receptacle and the secondary packaging shall maintain their integrity at the temperature of the refrigerant used as well as the temperatures and the pressures that could result if refrigeration were lost. 	
(10)	<p><u>When packages are placed in an overpack, the package markings required by this packing instruction shall either be clearly visible or be reproduced on the outside of the overpack.</u></p>	
(11)	<p>Infectious substances assigned to UN 3373 which are packed and marked in accordance with this packing instruction are not subject to any other requirement in these Regulations.</p>	
(12)	<p>Clear instructions on filling and closing such packages shall be provided by packaging manufacturers and subsequent distributors to the consignor or to the person who prepares the package (e.g., patient) to enable the package to be correctly prepared for transport.</p>	
(13)	<p><u>Other dangerous goods shall not be packed in the same packaging as Division 6.2 infectious substances unless they are necessary for maintaining the viability, stabilizing or preventing degradation or neutralizing the hazards of the infectious substances. A quantity of 30 ml or less of dangerous goods included in Classes 3, 8, or 9 may be packed in each primary receptacle containing infectious substances. When these small quantities of dangerous goods are packed with infectious substances in accordance with this packing instruction no other requirements in these Regulations need be met.</u></p>	