

GUIDANCE NOTES
FOR THE TRANSPORT OF
CLASS 6.2 (INFECTIOUS SUBSTANCES)
DANGEROUS GOODS

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Competent Authorities Sub-Committee

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FOREWORD

These Guidance Notes on the Transport of Class 6.2 (Infectious Substances) Dangerous Goods are based on the 10th revised edition of the UN Recommendations on the Transport of Dangerous Goods. This Document is intended to provide users of the 6th edition of the Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG Code) with GUIDANCE INFORMATION on the assignment and packaging of infectious substances for land transport within Australia.

It is important to note that the transport of infectious substances (UN 2900, UN 2814) is prohibited except under the required conditions of the appropriate Commonwealth, State or Territory authority. For the legislative requirements governing the transport of infectious substances readers need to refer to the applicable Commonwealth, State or Territory legislation. Your local Dangerous Goods Competent Authority can provide assistance in this regard.

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1 Definitions

For the purposes of these Guidance Notes:

- 1.1** *Regulations* are those road transport regulations enacted by States and Territories to give effect to the 6th edition of the Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG Code)
- 1.2** *Infectious substances* are those substances known or reasonably expected to contain pathogens.
- (a) Pathogens are defined as micro-organisms (including bacteria, viruses, rickettsiae, parasites, fungi) or recombinant micro-organisms (hybrid or mutant), that are known or reasonably expected to cause infectious disease in animals or humans.
 - (b) However, they are not subject to the Regulations and ADG Code if they are unlikely to cause human or animal disease.
 - (c) Infectious substances are subject to the Regulations and ADG Code if they are capable of spreading disease when exposure to them occurs.
- 1.3** *Biological products* are those products derived from living organisms, that are manufactured and distributed in accordance with the requirements of appropriate Commonwealth, State or Territory 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 and diagnostic products.

For the purposes of the Regulations and ADG Code, biological products are divided into the following groups:

- (a) those which contain pathogens in risk group 1; those which contain pathogens under such 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 purposes of the Regulations and ADG Code;
- (b) those manufactured and packaged in accordance with the requirements of Australian health 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 the Regulations and ADG Code applicable to Class 6.2;
- (c) those known or reasonably expected to contain pathogens in risk groups 2, 3, or 4 and which do not meet the criteria of 1.3 (b) above. Substances in this group should be classified in Class 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 case competent authorities may require these biological products to comply with the requirements for infectious substances or may impose other restrictions.

- 1.4** *Diagnostic specimens* are any human or animal material including, but not limited to, excreta, secretions, blood and its components, tissue and tissue fluids being transported for diagnostic or investigation purposes, but excluding live infected animals.

For the purposes of the Regulations and ADG Code, 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 those where a relatively low probability exists that pathogens of risk group 4 are present. Such substances should be classified in Class 6.2 under UN 2814 or UN 2900, as appropriate. Specimens transported for the purpose 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 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.
- 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. They are divided into the following categories:
- (a) genetically modified micro-organisms which meet the definition of an infectious substance given above should be classified in Class 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, should be transported in accordance with conditions specified by the appropriate Commonwealth, State or Territory regulatory authority;
 - (c) animals which contain or are contaminated with genetically modified micro-organisms and organisms that meet the definition of an infectious substance should be transported in accordance with conditions specified by the appropriate Commonwealth, State or Territory regulatory authority;
 - (d) except when authorised for unconditional use by the appropriate regulatory authority 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 should be classified in Class 9 and assigned to UN 3245.

- 1.6** *Wastes (transported under UN 3291)* are wastes derived from the medical treatment of animals or humans or from bio-research where there is a relatively low probability that infectious substances are present. Waste infectious substances which can be specified should be assigned to UN 2814 or to UN 2900. Decontaminated wastes which previously contained infectious substances are considered non-dangerous unless the criteria of another class are met.

2 *Classification of infectious substances and assignment to risk groups*

- 2.1** Infectious substances should be classified in Class 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 Organisation (WHO) and published in the WHO "Laboratory Biosafety Manual, second edition (1993)". A risk group is characterised 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.
- 2.2** 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 effective 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 purposes of the Regulations or ADG Code.

3 Biological products, diagnostic specimens and clinical or (bio)medical waste

3.1 Biological products known to contain, or thought likely to contain, any infectious substances should meet the requirements for infectious substances. Biological products referred to in 1.3 (a) and (b) are not subject to the requirements applicable to Class 6.2.

3.2 Diagnostic specimens known to contain, or thought likely to contain, any infectious substances should meet the requirements of the Regulations applicable to infectious substances. Diagnostic specimens referred to in 1.4 (b) need not meet the provisions 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 is in accordance with 3.4.

3.3 Waste clinical or (bio)medical substances should meet all the requirements for infectious substances except the packaging requirements of 3.4 and Division 3.7 of the ADG Code.

Such waste should be transported in rigid, leakproof packagings or IBCs in accordance with the provisions of Chapter 3 of the ADG Code or Supplement 2 to the ADG Code (Specifications for intermediate bulk containers for the transport of dangerous goods) for solids, at the Packing Group II performance level, 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 should be carried in rigid packagings or IBCs in accordance with the provisions of Chapter 3 of the ADG Code or Supplement 2 to the ADG Code at the Packing Group II performance level for liquids.

Packagings or IBCs intended to contain sharp objects such as broken glass and needles should be resistant to puncture and retain liquids under the performance test conditions in Chapter 3 of the ADG Code or Supplement 2 to the ADG Code.

3.4 The packaging should include the following essential elements:

- (a) An inner packaging comprising:
 - (i) watertight primary receptacle(s);
 - (ii) a watertight secondary packaging;
 - (iii) 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 should be individually wrapped so as to prevent contact between them.
- (b) An outer packaging of adequate strength for its capacity, mass and intended use, and with a minimum external dimension of 100 mm.

4 Requirements for the construction and testing of packagings for Class 6.2 substances

- 4.1 A packaging that meets the requirements of this section and of 4.2 may, after decision by the Competent Authority, be marked with:
- (a) the United Nations packaging symbol;
 - (b) the code designating the type of packaging according to the requirements of Division 3.4 of the ADG Code;
 - (c) the text CLASS 6.2;
 - (d) the last two digits of the year of manufacture of the packaging;
 - (e) the state authorising the allocation of the mark, indicated by the distinguishing sign for motor vehicles in international traffic;
 - (f) the name of the manufacturer or other identification of the packaging specified by the competent authority;
 - (g) for packagings meeting the requirements of 4.2.9, the letter "U" should be inserted immediately following the marking required in (b) above.

4.1.2 Example of marking:



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as in 4.1 (a), (b), (c) and (d)
as in 4.1 (e), (f)

4.2 Test requirements for packagings

4.2.1 Other than for packagings for live animals and organisms, samples of each packaging should be prepared for testing as described in 4.2.2 and then subjected to the tests in 4.2.4 to 4.2.6. If the nature of the packaging makes it necessary, equivalent preparation and tests are permitted, provided that these may be demonstrated to be at least as effective.

4.2.2 Samples of each packaging should be prepared as for transport except that a liquid or solid infectious substance should be replaced by water or, where conditioning at -18°C is specified, by water/antifreeze. Each primary receptacle should be filled to 98% capacity.

4.2.3 Tests required

Material of					Tests required				
outer packaging			inner packaging		Refer to 4.2.5				Refer to 4.2.6
Fibre-board	Plastics	Other	Plastics	Other	(a)	(b)	(c)	(d)	
x			x			x	x	When dry Ice is Used	x
x				x		x			x
	x		x				x		x
	x		x				x		x
		x		x	x				x

4.2.4 Packagings prepared as for transport should be subjected to the tests in 4.2.3, which - for test purposes - categorises packagings according to their material characteristics. For outer packagings, the headings in the table relate to fibreboard or similar materials whose performance may be rapidly affected by moisture; plastics which may embrittle at low temperature; and other materials such as metal whose performance is not affected by moisture or temperature. If a primary receptacle and a secondary packaging of an inner packaging are made of different materials, the material of the primary receptacle determines the appropriate test. In instances where a primary receptacle is made of two materials, the material most liable to damage determines the appropriate test.

4.2.5

(a) Samples should be subjected to free-fall drops on to a rigid, non-resilient, flat, horizontal surface from a height of 9 m. Where the samples are in the shape of a box, five should be dropped in sequence:

- (i) flat on to the base,
- (ii) flat on to the top,
- (iii) flat on to the longest side,
- (iv) flat on to the shortest side,
- (v) on to a corner.

Where the samples are in the shape of a drum, three should be dropped in sequence:

- (vi) diagonally on to the top chime, with the centre of gravity directly above the point of impact,
- (vii) diagonally on to the base chime,
- (viii) flat on to the side.

Following the appropriate drop sequence, there may be no leakage from the primary receptacle(s) which should remain protected by absorbent material in the secondary packaging.

Note: *While the sample should be released in the required orientation, it is accepted that for aerodynamic reasons the impact may not take place in that orientation.*

- (b) The sample should be subjected to a water spray that simulates exposure to rainfall of approximately 5 cm per hour for at least one hour. It should then be subjected to the test described in (a).
- (c) The sample should be conditioned in an atmosphere of -18°C or less for a period of at least 24 hours and within 15 minutes of removal from that atmosphere be subjected to the test described in (a). Where the sample contains dry ice, the conditioning period may be reduced to 4 hours.
- (d) Where the packaging is intended to contain dry ice, a test additional to that specified in (a) or (b) or (c) should be carried out. One sample should be stored so that all the dry ice dissipates and then be subjected to the test described in (a).

- 4.2.6 Packagings with a gross mass of 7 kg or less should be subjected to the tests described in (a) below and packagings with a gross mass exceeding 7 kg to the tests in (b) below.
- (a) Samples should be placed on a level hard surface. A cylindrical steel rod with a mass of at least 7 kg, a diameter not exceeding 38 mm and the impact end edges a radius not exceeding 6 mm, should be dropped in a vertical free fall from a height of 1 m, measured from the impact end to the impact surface of the sample. One sample should be placed on its base. A second sample should be placed in an orientation perpendicular to that used for the first. In each instance the steel rod should be aimed to impact the primary receptacle. Following each impact, penetration of the secondary packaging is acceptable, provided that there is no leakage from the primary receptacle(s).
 - (b) Samples should be dropped on to the end of a cylindrical steel rod. The rod should be set vertically in a level hard surface. It should have a diameter of 38 mm and the edges of the upper end a radius not exceeding 6 mm. The rod should protrude from the surface a distance at least equal to that between the primary receptacle(s) and the outer surface of the outer packaging with a minimum of 200 mm. One sample should be dropped in a vertical free fall from a height of 1 m, measured from the top of the steel rod. A second sample should be dropped from the same height in an orientation perpendicular to that used for the first. In each instance the packaging should be so orientated that the steel rod would penetrate the primary receptacle(s). Following each impact, penetration of the secondary packaging is acceptable, provided that there is no leakage from the primary receptacle(s).
- 4.2.7 The Competent Authority may permit the selective testing of packagings that differ only in minor respects from a tested type, e.g. smaller sizes of inner packagings or inner packagings of lower net mass; and packagings such as drums, bags and boxes which are produced with small reductions in external dimension(s).
- 4.2.8 Provided an equivalent level of performance is maintained, the following variations in the primary receptacles placed within a secondary packaging are allowed without further testing of the completed package:
- (a) Primary receptacles of equivalent or smaller size as compared to the tested primary receptacles may be used provided:
 - (i) the primary receptacles are of similar design to the tested primary receptacle (e.g. shape: round, rectangular, etc.);
 - (ii) the material of construction of the primary receptacle (glass, plastics, metal, etc.) offers resistance to impact and stacking forces equal to or greater than that of the originally tested primary receptacle;
 - (iii) the primary receptacles have the same or smaller openings and the closure is of similar design (e.g. screw cap, friction lid, etc.);
 - (iv) sufficient additional cushioning material is used to take up void spaces and to prevent significant movement of the primary receptacles; and
 - (v) primary receptacles are oriented within the secondary packaging in the same manner as in the tested package.
 - (b) A lesser number of the tested primary receptacles, or of the alternative types of primary receptacles identified in (a) above, may be used provided sufficient cushioning is added to fill the void space(s) and to prevent significant movement of the primary receptacles.
- 4.2.9 Inner receptacles of any type may be assembled within an intermediate (secondary) packaging and transported without testing in the outer packaging under the following conditions:

- (a) The intermediate/outer packaging combination should have been successfully tested in accordance with 4.2.6 with fragile (e.g., glass) inner receptacles;
- (b) The total combined gross mass of inner receptacles should not exceed one half the gross mass of inner receptacles used for the drop test in (a) above;
- (c) The thickness of cushioning between inner receptacles and between inner receptacles and the outside of the intermediate packaging should not be reduced below the corresponding thicknesses in the originally tested packaging; and if a single inner receptacle was used in the original test, the thickness of cushioning between inner receptacles should not be less than the thickness of cushioning between the outside of the intermediate packaging and the inner receptacle in the original test. When either fewer or smaller inner receptacles are used (as compared to the inner receptacles used in the drop test), sufficient additional cushioning material should be used to take up the void;
- (d) The outer packaging should have successfully passed the stacking test in Division 3.7 of the ADG Code while empty. The total mass of identical packages should be based on the combined mass of inner receptacles used in the drop test in (a) above;
- (e) For inner receptacles containing liquids, an adequate quantity of absorbent material to absorb the entire liquid content of the inner receptacles should be present;
- (f) If the outer packaging is intended to contain inner receptacles for liquids and is not leakproof, or is intended to contain inner receptacles for solids and is not siftproof, a means of containing any liquid or solid contents in the event of leakage should be provided in the form of a leakproof liner, plastics bag or other equally effective means of containment;
- (g) In addition to the markings prescribed in 4.1 (a) to (f), packagings should be marked in accordance with 4.1 (g).