DANGEROUS GOODS PANEL (DGP)

MEETING OF THE WORKING GROUP OF THE WHOLE

Abu Dhabi, 4 to 8 October 2004

Agenda Item 2: Development of recommendations for amendments to the *Technical Instructions* for incorporation in the 2007/2008 edition
2.5: Part 5 — Shipper's Responsibilities

PROPOSED AMENDMENT TO DIVISION 6.2

(Presented by the Secretary)

1. INTRODUCTION

1.1 Changes to Division 6.2 were agreed at the recent UNSCOE meeting (July 2004); it is likely they will be adopted by the UNCOE in December this year for incorporation in the 2007-2008 edition of the Technical Instructions. A proposal to incorporate these amendments by means of an addendum to the 2005-2006 edition of the Technical Instruction was circulated to panel members by email (13 August 2004).

1.2 The working group is asked to review the proposed changes and to instruct the Secretariat which changes should be brought to the attention of the Air Navigation Commission.

2. LIST OF ATTACHMENTS

- Appendix A - **Request from Robert McGuire, US Associate Administrator for Hazardous Material Safety**
- Appendix B - **Proposed Amendments to 2005-2006 Text**
- Appendix C - **Comments from Olivier Kervella, UN/ECE Secretariat**
- Appendix D - **Comments from World Organization of Animal Health (OIE)**
- Appendix E - **Comments from J. Code**

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APPENDIX A

Request from Robert McGuire
Associate Administrator for Hazardous Material Safety

I am writing to request that an addendum be issued to the 2005-2006 ICAO Technical Instructions (TI) to take into account amendments recently adopted by the United Nations Sub-Committee of Experts on the Transport of Dangerous Goods (UNSCETDG). The amendments pertain to the requirements for the transport of infectious substances. In particular we are requesting amendments

- to P650 to authorize the use of the new proper shipping name for category B infectious substances, Biological Substance, Category B;

- to the indicative list of category A infectious substances;

- to amend the definition of cultures and add a definition for patient specimens; and

- to include consequential amendments to the Category B sections where the reference to cultures has been deleted including paragraphs 2.6.3.2.2.2 and 2.6.3.5.1.

The proposed amendments are provided as an Annex to this letter.

We believe that it is necessary to adopt these amendments in the 2005-2006 ICAO TI because the use of the new proper shipping name and amendment of the definitions will reduce potential confusion in both the healthcare and aviation industries. Implementation delays may lead to non-acceptance of packages due to confusion associated with the historical use of the term "diagnostic specimen". Confusion on whether the specimen is or is not infectious, may lead to rejection of packages containing patient specimens due to concerns about whether or not the shipment needs to meet the requirements of the Technical Instructions. Requiring all Category B cultures to be transported as Category A imposes an unnecessary burden on healthcare systems since Category B cultures pose a low risk in transport. This may have significant affects on patient care and public health.

The amendments to the indicative list are necessary because the World Health Organization (WHO) and the World Organization for Animal Health (OIE) have identified substances on the list that do not meet the definition of Category A substances. These organizations have endorsed the amendments adopted by the UNSCETDG. The transport of the infectious substances as Category A substances when they do not meet the criteria for inclusion in Category A will result in unnecessarily greater costs to health care agencies.

The amendments proposed to be incorporated in the addendum to the 2005-2006 TI were agreed to and supported by the major international health organizations including WHO, OIE, the Centers for Disease Control, Health Canada and the World Federation for Culture Collections (WFCC). These amendments are extremely important for continuing and maintaining international and national disease surveillance and control programs.

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Annex 1 - Amendments that should be addressed in the addendum

(**1) Revised proper shipping name for UN 3373 (Category B Infectious Substances)**. The new proper shipping name "**Biological Substance, Category B**" should be added to the authorized shipping names "Diagnostic Specimen or Clinical Specimen" for Category B infectious substances in P650 and Table 3-1 of the Technical Instructions. The additional PSN should also be added to the Note in 2;6.3.1.2. It is intended that this name will replace the names "Diagnostic Specimen or Clinical Specimen" in the 2007-2008 TI so that there will only be one proper shipping name in the future. Providing an option now gives carriers and shippers a transition period.

Item-1: Adverse Actions if not implemented in 2005:
This change was adopted to reduce the confusion associated with the old definition of "diagnostic specimens" which in some instances was considered to be non-infectious and therefore not regulated. The proper shipping name is required to be marked adjacent to the UN 3373 diamond marking (i.e. serves as hazard communication) on packages and must be indicated on a written document (such as an air waybill) or on the package. Implementation delays may lead to non-acceptance of packages due to confusion associated with the historical use of the term "diagnostic specimen". Confusion as to whether the specimen is or is not infectious, may lead to rejection of shipments due to concerns about appropriate packaging and with respect to operators that are designated or not designated to transport dangerous goods and whether they carry these infectious substances. This could have serious affects on patient care and public healthcare systems

(**2) The indicative list of Category A substances in 2;6.3.2.2.1 should be amended.** WHO and OIE recommended several changes to the Category A list.
Category A list:
(2.a) Replace "Hantaviruses causing hantavirus pulmonary syndrome" with "Hantavirus causing hemorragic fever with renal syndrome";
(2.b) Add "(cultures only)" after Rabies virus, Rift Valley fever virus and Venezuelan equine encephalitis virus;
(2.c) Insert "Velogenic" before Newcastle disease virus;
(2.d) Add "(cultures only)" after all animal microorganisms on the Category A list;
(2.e) Delete African horse sickness virus & Bluetongue virus from the Category A list.

Item-2: Adverse Actions if not implemented in 2005:
Implementation delays are likely to have adverse consequences on long standing domestic and international disease surveillance programs due to the increase cost associated with having to declare and ship routine surveillance specimens in P620 packaging. This also improperly promotes the idea that these specimens pose a significant public health risk as defined by the definition for Category-A infectious substances. Once ingrained, attempting to change this public perception, may prove difficult at a later date. Increased public fears may also lead to non-acceptance of shipments, which could have significant affects on patient care and public health improvement efforts

(3) Revise the definition of cultures and add a definition for patient specimens in 2;6.3.1.3, and amend the definition of Category B infectious substances in 2;6.3.2.2.2 and the text in 2.6.3.5.1.

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 below in 2.6.3.1.4.".

Patient specimens: 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.".

Category B infectious substances definition: Amend the definition of Category B infectious substances in 2;6.3.2.2.2 by deleting the words "except that cultures as defined in 6.3.1.3 must be assigned to UN 2814 or UN 2900 as appropriate."

Consequential amendment in paragraph 2;6.3.5.1: Delete "or containing Category B infectious substances in cultures" in the first sentence and ", other than in cultures, " in the last sentence.

Item-3: Adverse Actions if not implemented in 2005:
Implementation delays are likely to have adverse consequences on patient care and long standing disease surveillance programs, due to the increase cost associated with having to declare and ship a less hazardous Category-B infectious substance in P620 packaging. This improperly promotes the idea that these specimens pose a significant public health risk as defined by the definition for Category-A infectious substances. Once ingrained, attempting to change this public perception may prove difficult at a later date. Increased public fears may also lead to non-acceptance of packages, which will have devastating affect on patient care and public health prevention efforts. The new definitions provide clarification and resolve confusion associated with the term "Culture" when used by the research community vs. the medical community. Requiring Category B cultures to be transported as Category A imposes an unnecessary burden on healthcare systems since Category B cultures pose a low risk in transport just as these substances pose a low risk in transport when they are transported in a form other than a culture. Immediate implementation of this amendment will assist the shipper in making appropriate packaging decisions and enhance regulatory compliance.

(4) Amend the definition of Category A infectious substances in 2;6.3.2.2.1
The definition is a critical factor that is used to determine the appropriate classification of infectious substances. The amendment provides clarification with respect to the substances that are assigned to Category A and Category B.

The words "in otherwise healthy" were added after "fatal disease" and the word "to" was deleted before "humans" so that the text now reads "...life threatening or fatal disease in otherwise healthy humans or animals."

Item-4: Adverse Actions if not implemented in 2005: This amendment will clarify what is intended to be transported as a Category A infectious substance. It will prevent unnecessary confusion and should be implemented as soon as possible.

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APPENDIX B

Proposed Amendments to 2005-2006 Text

Chapter 6
CLASS 6 — TOXIC AND INFECTIOUS SUBSTANCES

INTRODUCTORY NOTES

... *Note.— Toxins from plant, animal or bacterial sources which do not contain any infectious substances or toxins that are not contained in substances which are infectious substances should be considered for classification in Division 6.1 and assignment to UN 3172.*

6.1 DEFINITIONS

Class 6 is divided into two divisions as follows:

a) Division 6.1 — Toxic substances.

Substances liable either to cause death or injury or to harm human health if swallowed, if inhaled or by skin contact.

Note.— In these Instructions "poisonous" has the same meaning as "toxic".

... b) Division 6.2 — Infectious substances.

Substances known to contain, or 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.

6.2 TOXIC SUBSTANCES

6.2.1 Definitions

For the purposes of these Instructions:

... 6.2.1.1 *LD_{50} (median lethal dose) for acute oral toxicity* is the statistically derived single dose of a substance that can be expected to cause death within 14 days in 50 per cent of young adult albino rats when administered by the oral route. The LD_{50} value is expressed in terms of mass of test substance per mass of test animal (mg/kg).

6.2.1.2 LD_{50} for acute dermal toxicity is that dose of the substance which, administered by continuous contact for 24 hours with the bare skin of albino rabbits, is most likely to cause death within 14 days in half of the animals tested. The number of animals tested must be sufficient to give a statistically significant result and be in conformity with good pharmacological practices. The result is expressed in mg/kg body mass.

6.2.1.3 LC_{50} for acute toxicity on inhalation is that concentration of vapour, mist or dust which, administered by continuous inhalation for one hour to both male and female young adult albino rats, is most likely to cause death within 14 days in half of the animals tested. A solid substance should be tested if at least 10 per cent (by mass) of its total mass is likely to be dust in a respirable range, e.g. the aerodynamic diameter of that particle-fraction is 10 µm or less. A liquid substance should be tested if a mist is likely to be generated in a leakage of the transport containment. Both for solid and liquid substances more than 90 per cent (by mass) of a specimen prepared for inhalation toxicity should be in the respirable range as defined above. The result is expressed in mg/L of air for dusts and mists or in mL/m^3 of air (parts per million) for vapours.

6.2.2 Assignment of packing groups

6.2.2.1 Substances of Division 6.1, including pesticides, are allocated among the three packing groups, according to the degree of their toxic hazards in transport as follows:

a) Packing Group I — Substances and preparations presenting a very severe toxicity risk;

b) Packing Group II — Substances and preparations presenting a serious toxicity risk;

c) Packing Group III — Substances and preparations presenting a relatively low toxicity risk.

6.2.2.2 In making this grouping, account must be taken of human experience in instances of accidental poisoning, and of special properties possessed by any individual substance, such as liquid state, high volatility, any special likelihood of penetration, and special biological effects.

6.2.2.3 In the absence of human experience, the grouping must be based on the available data from animal experiments. Three possible routes of administrations must be examined. These routes are exposure through:

i) oral ingestion;

ii) dermal contact; and

iii) inhalation of dusts, mists, or vapours.

6.2.2.3.1 Appropriate animal tests for the various routes of exposure are described in 6.2.1. When a substance exhibits a different order of toxicity by two or more of these routes of administration, the highest degree of danger must be assigned.

6.2.2.4 The criteria to be applied for grouping a substance according to the toxicity it exhibits by all three routes of administration are presented in the following paragraphs.

6.2.2.4.1 The grouping criteria for the oral and dermal routes as well as for inhalation of dusts and mists are as shown in Table 2-8.

Note. — Substances meeting the criteria of Class 8 and with an inhalation toxicity of dusts and mists (LC_{50}) leading to Packing Group I are only accepted for an allocation to Division 6.1 if the toxicity through oral ingestion or dermal contact is at least in the range of Packing Group I or II. Otherwise, an allocation to Class 8 is made when appropriate (see 8.2.3).

6.2.2.4.2 The criteria for inhalation toxicity of dusts and mists in 6.2.1.1 are based on LC_{50} data relating to 1-hour exposures, and where such information is available, it must be used. However, where only LC_{50} data relating to 4-hour exposures to dusts and mists are available, such figures can be multiplied by four and the product substituted in the above criteria, i.e. LC_{50} (4 h) × 4 is considered the equivalent of LC_{50} (1 h).

6.2.2.4.3 Liquids having toxic vapours must be assigned to the packing groups shown in Table 2-9, where V is that saturated vapour concentration in the air of the substance in mL/m^3 at 20°C and standard atmospheric pressure.

Table 2-8. Grouping criteria for administration through oral ingestion, dermal contact and inhalation of dusts and mists

Packing group	*Oral toxicity LD_{50} (mg/kg)*	*Dermal toxicity LD_{50} (mg/kg)*	*Inhalation toxicity by dusts and mists LC_{50} (mg/L)*
I	#5	#40	#0.5
II	>5, #50	>40, #200	>0.5, #2
III	solids: >50, #200 liquids: >50, #500	>200, #1 000	>2, #10

Note.— Tear gas substances having toxicity data corresponding to Packing Group III values are nevertheless included in Packing Group II.

Table 2-9. Criteria for inhalation

Packing Group I	V $ 10 LC_{50} and LC_{50} # 1 000 mL/m^3
Packing Group II	V $ LC_{50} and LC_{50} # 3 000 mL/m^3 and not meeting the criteria for Packing Group I
Packing Group III	V $ 0.2 LC_{50} and LC_{50} # 5 000 mL/m^3 and not meeting the criteria for Packing Groups I and II

6.2.2.4.4 In Figure 2-1, the criteria according to 6.2.2.4.3 are expressed in graphical form, as an aid to easy classification. However, because of approximations inherent in the use of graphs, substances on or near packing group borderlines must be checked using numerical criteria.

6.2.2.4.5 The criteria for inhalation toxicity of vapours in 6.2.1.1 are based on LC_{50} data relating to 1-hour exposures, and where such information is available, it must be used. However, where only LC_{50} data relating to 4-hour exposures to the vapours are available, such figures can be multiplied by two and the product substituted in the above criteria, i.e. LC_{50} (4 h) × 2 is considered the equivalent of LC_{50} (1 h).

6.2.2.4.6 Mixtures of liquids that are toxic by inhalation must be assigned to packing groups according to 6.2.2.4.7 or 6.2.2.4.8.

6.2.2.4.7 If LC_{50} data is available for each of the toxic substances comprising a mixture, the packing group may be determined as follows:

a) Estimate the LC_{50} of the mixture using the formula:

$$\alpha LC_{50}\ (\text{mixture}) = \frac{1}{\sum_{i=1}^{n} \frac{f_i}{LC_{50_i}}}$$

where f_i = mole fraction of the i^{th} component substance of the liquid, and

where LC_{50i} = mean lethal concentration of the i^{th} component substance in mL/m^3.

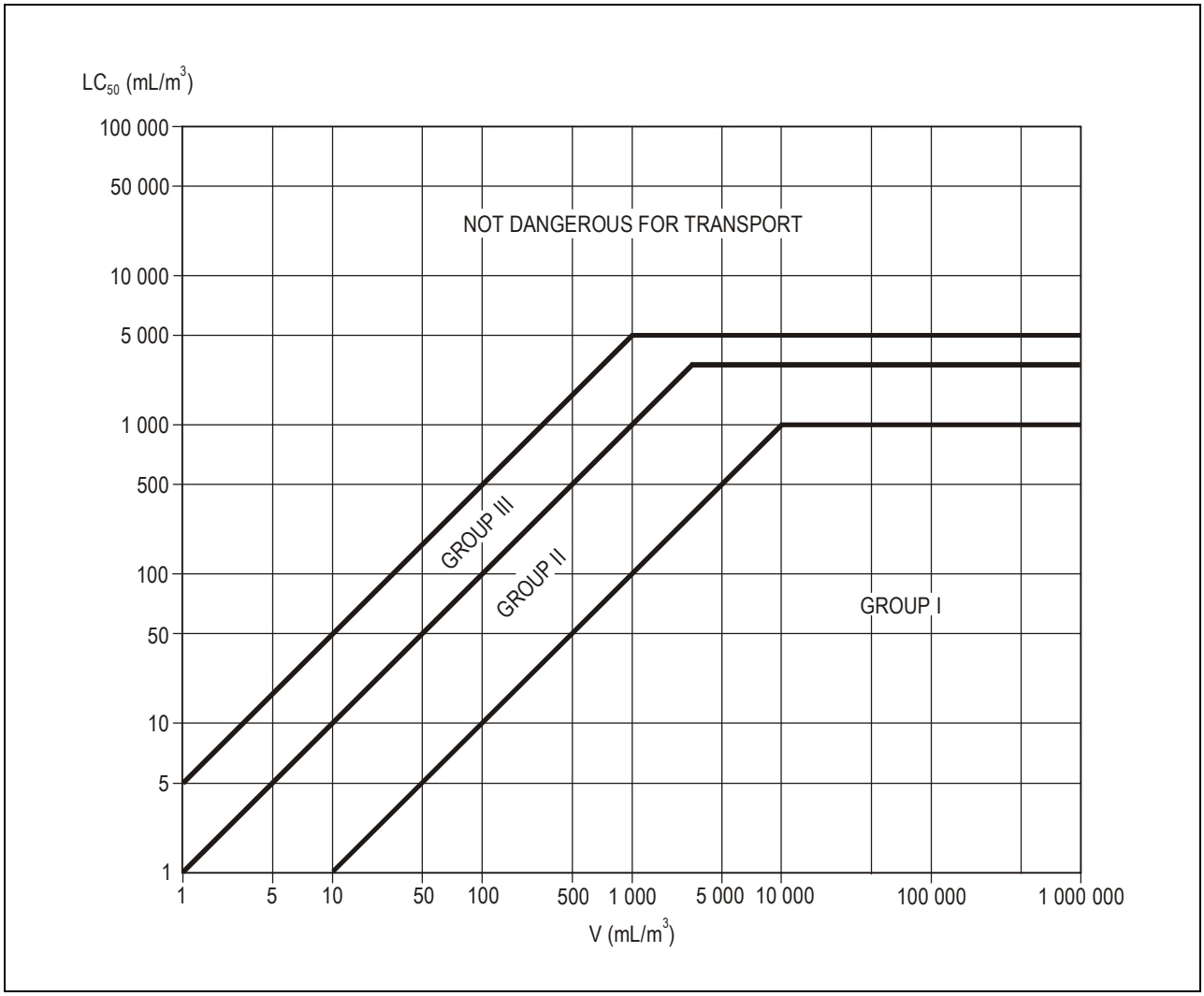


Figure 2-1. Criteria for inhalation of vapours

b) Estimate the volatility of each component substance using the formula:

$$V_i = P_i \times \frac{10^6}{101.3} \text{ mL/m}^3$$

where P_i = partial pressure of the i^{th} component substance in kPa at 20°C and one atmosphere pressure.

c) Calculate the ratio of the volatility to the LC_{50} using the formula:

$$R = \sum_{i=1}^{n} \frac{V_i}{LC_{50_i}}$$

d) Using the calculated values LC_{50} (mixture) and R, the packing group for the mixture is determined:

Packing Group I: R $\geq$ 10 and LC_{50} (mixture) $\leq$ 1 000 mL/m^3

Packing Group II: R $\geq$ 1 and LC_{50} (mixture) $\leq$ 3 000 mL/m^3 and not meeting criteria for Group I

Packing Group III: R $\geq$ 1/5 and LC_{50} (mixture) $\leq$ 5 000 mL/m^3 and not meeting criteria for Group I or II

6.2.2.4.8 In the absence of LC_{50} data on the toxic constituent substances, the mixture may be assigned a packing group based on the following simplified threshold toxicity tests. When these threshold tests are used, the most restrictive packing group must be determined and used for transporting the mixture.

a) A mixture is assigned to Packing Group I only if it meets both of the following criteria:

i) A sample of the liquid mixture is vaporized and diluted with air to create a test atmosphere of 1 000 mL/m^3 vaporized mixture in air. Ten albino rats (5 male and 5 female) are exposed to the test atmosphere for 1 hour and observed for 14 days. If 5 or more of the animals die within the 14-day observation period, the mixture is presumed to have an LC_{50} equal to or less than 1 000 mL/m^3.

ii) A sample of the vapour in equilibrium with the liquid mixture at 20°C is diluted with 9 equal volumes of air to form a test atmosphere. Ten albino rats (5 male and 5 female) are exposed to the test atmosphere for 1 hour and observed for 14 days. If 5 or more of the animals die within the 14-day observation period, the mixture is presumed to have a volatility equal to or greater than 10 times the mixture LC_{50}.

b) A mixture is assigned to Packing Group II only if it meets both of the following criteria, and the mixture does not meet the criteria for Packing Group I:

i) A sample of the liquid mixture is vaporized and diluted with air to create a test atmosphere of 3 000 mL/m^3 vaporized mixture in air. Ten albino rats (5 male and 5 female) are exposed to the test atmosphere for 1 hour and observed for 14 days. If 5 or more of the animals die within the 14-day observation period, the mixture is presumed to have an LC_{50} equal to or less than 3 000 mL/m^3.

ii) A sample of the vapour in equilibrium with the liquid mixture at 20°C is used to form a test atmosphere. Ten albino rats (5 male and 5 female) are exposed to the test atmosphere for 1 hour and observed for 14 days. If 5 or more of the animals die within the 14-day observation period, the mixture is presumed to have a volatility equal to or greater than the mixture LC_{50}.

c) A mixture is assigned to Packing Group III only if it meets both of the following criteria, and the mixture does not meet the criteria for Packing Groups I or II:

i) A sample of the liquid mixture is vaporized and diluted with air to create a test atmosphere of 5 000 mL/m^3 vaporized mixture in air. Ten albino rats (5 male and 5 female) are exposed to the test atmosphere for 1 hour and observed for 14 days. If 5 or more of the animals die within the 14-day observation period, the mixture is presumed to have an LC_{50} equal to or less than 5 000 mL/m^3.

ii) The vapour pressure of the liquid mixture is measured and if the vapour pressure is equal to or greater than 1 000 mL/m^3, the mixture is presumed to have a volatility equal to or greater than 1/5 the mixture LC_{50}.

6.2.3 Methods for determining oral and dermal toxicity of mixtures

6.2.3.1 When classifying and assigning the appropriate packing group to mixtures in Division 6.1, in accordance with the oral and dermal toxicity criteria in Table 2-8, it is necessary to determine the acute LD_{50} of the mixture.

6.2.3.2 If a mixture contains only one active substance, and the LD_{50} of that constituent is known, in the absence of reliable acute oral and dermal toxicity data on the actual mixture to be transported, the oral or dermal LD_{50} may be obtained by the following method:

LD_{50} value of preparation =

$$\frac{LD_{50} \text{ value of active substance} \times 100}{\text{percentage of active substance by mass}}$$

6.2.3.3 If a mixture contains more than one active constituent, there are three possible approaches that may be used to determine the oral or dermal LD_{50} of the mixture. The preferred method is to obtain reliable acute oral and dermal toxicity data on the actual mixture to be transported. If reliable and accurate data are not available, then either of the following methods may be performed:

a) classify the formulation according to the most hazardous constituent of the mixture as if that constituent were present in the same concentration as the total concentration of all active constituents; or

b) apply the formula:

$$\frac{C_A}{T_A} + \frac{C_B}{T_B} + \frac{C_Z}{T_Z} = \frac{100}{T_M}$$

where:

C = the per cent concentration of constituent A, B ... Z in the mixture

T = the oral LD_{50} values of constituent A, B ... Z

T_M = the oral LD_{50} value of the mixture.

Note.— This formula can also be used for dermal toxicities provided that this information is available on the same species for all constituents. The use of this formula does not take into account any potentiation or protective phenomena.

6.2.4 Classification of pesticides

6.2.4.1 All active pesticide substances and their preparations for which the LC_{50} and/or LD_{50} values are known and which are classified in Division 6.1 must be classified under appropriate packing groups in accordance with the criteria given in 6.2.2. Substances and preparations which are characterized by subsidiary risks must be classified according to the precedence of hazards table (Table 2-1) with the assignment of appropriate packing groups.

6.2.4.2 If the oral or dermal LD_{50} value for a pesticide preparation is not known, but the LD_{50} value of its active substance(s) is known, the LD_{50} value for the preparation may be obtained by applying the procedures in 6.2.3.

Note.— LD_{50} toxicity data for a number of common pesticides may be obtained from the most current edition of the document The WHO Recommended Classification of Pesticides by Hazard and Guidelines to Classification *available from the International Programme on Chemical Safety, World Health Organization (WHO), 1211 Geneva 27, Switzerland. While that document may be used as a source of LD_{50} data for pesticides, its classification system should not be used for purposes of transport classification of, or assignment of packing groups to, pesticides which must be in accordance with these Instructions.*

6.2.4.3 The proper shipping name used in the transport of the pesticide must be selected on the basis of the active ingredient, of the physical state of the pesticide and any subsidiary risks it may exhibit.

... 6.3 DIVISION 6.2 — INFECTIOUS SUBSTANCES

6.3.1 Definitions

For the purposes of these Instructions:

6.3.1.1 *Infectious substances* are substances which are known to contain, 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.

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.

6.3.1.3 *Cultures* (laboratory stocks) are the result of a process by which pathogens are intentionally propagated. This definition does not include patient specimens as defined below in 2.6.3.1.5. ~~pathogens are amplified or propagated 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 or clinical purposes.~~

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

6.3.1.5 *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.

6.3.2 Classification of infectious substances

6.3.2.1 Infectious substances must be classified in Division 6.2 and assigned to UN 2814, UN 2900 or UN 3373 as appropriate.

6.3.2.2 Infectious substances are divided into the following categories:

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 in otherwise healthy ~~to~~ humans or animals. Indicative examples of substances that meet these criteria are given in Table 2-10.

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 in both humans and animals must be assigned to UN 2814. Infectious substances which cause disease only in animals must be assigned to UN 2900.

b) Assignments to UN 2814 or UN 2900 must be based on the known medical history and symptoms of the source human or animal, endemic local conditions, or professional judgement 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 2.— The following table (Table 2-10) is not exhaustive. Infectious substances, including new or emerging pathogens, which do not appear in Table 2-10 but which meet the same criteria must be assigned to Category A. In addition, if there is doubt as to whether or not a substance meets the criteria it must be included in Category A.

Note 3.— In Table 2-10, the micro-organisms written in italics are bacteria, mycoplasma, rickettsiae or fungi.

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 must be assigned to UN ~~3373 except that cultures as defined in 6.3.1.3 must be assigned to UN 2814~~

~~or UN 2900 as appropriate.~~

Note.— The proper shipping name of UN 3373 is ***Diagnostic specimens*** *or* ***Clinical specimen*** ***or Biological substance, category B***.

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 Instructions unless they meet the criteria for inclusion in another class.

6.3.2.4 Blood or blood components that 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 Instructions.

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 Instructions. Examples are: foodstuffs, water samples, living persons and substances that have been treated so that the pathogens have been neutralized or deactivated so that they no longer pose a health risk.

6.3.2.6 A live animal that has been intentionally infected and is known or suspected to contain an infectious substance must not be transported by air unless the infectious substance contained cannot be consigned by any other means. Infected animals may only be transported under terms and conditions approved by the appropriate national authority.

6.3.3 Biological products

For the purposes of these Instructions, 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 Instructions.

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 must 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, appropriate national authorities may require these biological products to be in compliance with local requirements for infectious substances or may impose other restrictions.

6.3.4 Genetically modified micro-organisms and organisms

Genetically modified micro-organisms not meeting the definition of infectious substances must be classified according to Chapter 9.

6.3.5 Medical or clinical wastes

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

6.3.5.2 Medical or clinical wastes that are reasonably believed to have a low probability of containing infectious substances must 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.***

6.3.5.3 Decontaminated medical or clinical wastes that previously contained infectious substances are not subject to these Instructions unless they meet the criteria for inclusion in another class.

Table 2-10. Indicative examples of infectious substances included in Category A in any form unless otherwise indicated (6.3.2.2.1 (a))

UN Number and Proper Shipping Name	*Micro-organism*
UN 2814 Infectious substances affecting humans	*Bacillus anthracis (cultures only)* *Brucella abortus (cultures only)* *Brucella melitensis (cultures only)* *Brucella suis (cultures only)* *Burkholderia mallei – Pseudomonas mallei* – Glanders *(cultures only)* *Burkholderia pseudomallei – Pseudomonas pseudomallei (cultures only)* *Chlamydia psittaci* – avian strains (cultures only) *Clostridium botulinum (cultures only)* *Coccidioides immitis (cultures only)* *Coxiella burnetii (cultures only)* Crimean-Congo hemorrhagic fever virus Dengue virus (cultures only) Eastern equine encephalitis virus (cultures only) *Escherichia coli*, verotoxigenic (cultures only) Ebola virus

UN Number and Proper Shipping Name	*Micro-organism*
	Flexal virus *Francisella tularensis (cultures only)* Guanarito virus Hantaan virus ~~Hantaviruses causing hantavirus pulmonary syndrome~~ Hantavirus causing hemorragic fever with renal syndrome Hendra virus Hepatitis B virus (cultures only) Herpes B virus (cultures only) Highly pathogenic avian influenza virus (cultures only) Human immunodeficiency virus (cultures only) Japanese Encephalitis virus (cultures only) Junin virus Kyasanur Forest disease virus Lassa virus Machupo virus Marburg virus Monkeypox virus *Mycobacterium tuberculosis (cultures only)* Nipah virus Omsk hemorrhagic fever virus *Poliovirus (cultures only)* Rabies virus (cultures only) *Rickettsia rickettsii (cultures only)* *Rickettsia rickettsii* (cultures only) Rift Valley fever virus (cultures only) *Russian spring-summer encephalitis virus (cultures only)* Sabia virus *Shigella dysenteriae 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)* *Yersinia pestis* (cultures only)
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) Goatpox 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) Swine vesicular disease virus (cultures only) Vesicular stomatitis virus (cultures only)

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650	PACKING INSTRUCTION 650	650

This packing instruction applies to UN 3373.

1) The packaging must be of good quality, strong enough to withstand the shocks and loadings normally encountered during transport, including transhipment 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 must be constructed and closed to prevent any loss of contents that might be caused under normal conditions of transport by vibration or by changes in temperature, humidity or pressure.

2) The packaging must consist of three components:

   a) a primary receptacle;

   b) a secondary packaging; and

   c) a rigid outer packaging.

3) Primary receptacles must 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 must be secured in outer packagings with suitable cushioning material. Any leakage of the contents must not compromise the integrity of the cushioning material or of the outer packaging.

4) For transport, the mark illustrated below must be displayed on the external surface of the outer packaging on a background of a contrasting colour and must be clearly visible and legible. The mark must 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 must be at least 2 mm, and the letters and numbers must be at least 6 mm high. The proper shipping name "Diagnostic specimen", ~~or~~ "Clinical specimen", or "Biological substance, category B" in letters at least 6 mm high must be marked on the outer package adjacent to the diamond-shaped mark.



5) At least one surface of the outer packaging must have a minimum dimension of 100 mm × 100 mm.

6) The completed package must be capable of successfully passing the drop test in 6;6.2 as specified in 6;6.1.5 of the Instructions except that the height of the drop must not be less than 1.2 m.

7) For liquid substances:

   a) The primary receptacle(s) must be leakproof and must not contain more than 1 litre;

   b) The secondary packaging must be leakproof;

   c) 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;

   d) Absorbent material must be placed between the primary receptacle(s) and the secondary packaging. The absorbent material must be in quantity sufficient to absorb the entire contents of the primary receptacle(s) so that any release of the liquid substance will not compromise the integrity of the cushioning material or of the outer packaging;

   e) The primary receptacle or the secondary packaging must be capable of withstanding, without leakage, an internal pressure of 95 kPa (0.95 bar);

   f) The outer package must not contain more than 4 litres. This quantity excludes ice, dry ice or liquid nitrogen when used to keep specimens cold.

8) For solid substances:

   a) The primary receptacle(s) must be siftproof and must not exceed the outer packaging mass limit;

   b) The secondary packaging must be siftproof;

   c) 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;

   d) Except for packages containing body parts, organs or whole bodies, the outer package must not contain more than 4 kg. This quantity excludes ice, dry ice or liquid nitrogen when used to keep specimens cold;

   e) 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, must be used.

9) Refrigerated or frozen specimens: ice, dry ice and liquid nitrogen:

   a) When dry ice or liquid nitrogen is used to keep specimens cold, all applicable requirements of these Instructions must be met. When used, ice or dry ice must be placed outside the secondary packagings or in the outer packaging or an overpack. Interior supports must 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 must be leakproof. If carbon dioxide, solid (dry ice) is used, the packaging must be designed and constructed to permit the release of carbon dioxide gas to prevent a build-up of pressure that could rupture the packagings;

   b) The primary receptacle and the secondary packaging must maintain their integrity at the temperature of the refrigerant used as well as the temperatures and the pressures which could result if refrigeration were lost.

10) When packages are placed in an overpack, the package markings required by this packing instruction must either be clearly visible or be reproduced on the outside of the overpack.

11) 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 Instructions except for the following:

   a) the proper shipping name, UN number and the name, address and telephone number of a person responsible must be provided on a written document (such as an air waybill) or on the package;

   b) classification must be in accordance with 2;6.3.2;

   c) the incident reporting requirements in 7;4.4 must be met; and

   d) the inspection for damage or leakage requirements in 7;3.1.3 and 7;3.1.4;

   e) passengers and crew members are prohibited from transporting infectious substances either as, or in, carry-on baggage or checked baggage or on their person.

12) Clear instructions on filling and closing such packages must be provided to the consignor or to the person who prepares the package (e.g. patient) by packaging manufacturers and subsequent distributors to enable the package to be correctly prepared for transport.

13) Other dangerous goods must 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 Instructions need be met.

Changes to Table 3:1

Add the following new entry in appropriate alphabetic order to Table 3-1:

		Name	Un No.	Class or division	Subsidiary risk	Labels	State variations	Special provisions	UN packing group	Passenger Aircraft	Cargo Aircraft
		Biological substance, category B	3373	6.2				A141		See 650	See 650

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APPENDIX C

Comments from Olivier Kervella, UN/ECE Secretariat

Referring to your message of 13 August, my comments on the proposal by the Government of the United States of America to implement the decision taken in July by the UN Sub-Committee of Experts on the Transport of Dangerous Goods as from 1 January 2005 for air transport are as follows:

1) The texts adopted by the Sub-Committee are not yet UN Recommendations. They are still subject to review next December and formal endorsement by the Committee. Once endorsed, they will be officially published between June 2005 for the English version and December 2005 for other UN official languages. Competent authorities for inland transport in most UN Member States which do not participate in the work of the Committee are not likely to be made aware of these new provisions before they have been officially published and disseminated.

One new document on Division 6.2 provisions has been announced by Canada for discussion next December. The secretariat also intends to raise a few questions with respect to the new transport conditions for cultures of pathogens of risk group 2, presently assigned to UN 2814 or UN 2900, and which would be assigned to UN 3373 according to the July decisions. The questions will be related to the fact that, by assigning P650 to these cultures of risk group 2 pathogens, they will also be exempted from training requirements, transport documentation requirements, biohazard marking/labelling requirements, decontamination in case of spillage and segregation from foodstuff requirements.

Other questions, which are not relevant for air transport, arise with respect to road and rail transport, e.g. classification of animal carcasses contaminated with category B infectious substances and related transport conditions, classification of wastes as UN 2900 and their carriage in bulk containers.

As a consequence, the UN secretariat recommends that any text adopted by ICAO for implementation as from 1 January 2005 should be based on the UN recommendations to be adopted in December 2004 rather than on the Sub-Committee's decisions of July 2004.

2) As mentioned by the UN secretariat and the representative of OTIF during the July session, it is not legally possible to bring into force by 1 January 2005 new amendments to RID/ADR that would reflect the texts which will be adopted by the Committee next December. The same situation occurs for maritime transport. As far as the road/air interface is concerned, should ICAO decide to implement the new UN Recommendations as from 1 January 2005, this should not be a problem for substances presently assigned to UN 3373 as diagnostic specimens, since no transport documentation and no proper shipping name marking are required under ADR. However, this is likely to cause a problem of disharmony for shipments of Category B cultures to Europe, since such cultures shipped as UN 3373 BIOLOGICAL CATEGORY B under the ICAO Technical Instructions, would have to be declared as UN 2814 or UN 2900 INFECTIOUS SUBSTANCE for onward shipment by road, with indication of the pathogen name in the transport document and application of ADR transport conditions by road transport operators.

Although it would be possible for competent authorities of ADR Contracting Parties to conclude multilateral agreements to solve this problem of disharmony, it has to be borne in mind that this would depend on the individual willingness of each country and national legal procedures, i.e. that signature of such special agreements is neither systematic nor simultaneous. Therefore, the UN secretariat suggests that, should ICAO decide to publish a supplement for application as from 1 January 2005, this supplement should include a warning for consignors and freight forwarders that the inland transport

regulations in most countries are expected to be in line with the already published 2005-2006 ICAO TI, and before using the derogations of the Supplement, they should check whether they are legally acceptable for inland transport in the receiving country.

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APPENDIX D

Comments from World Organization of Animal Health (OIE)

The World Organisation for Animal Health (OIE) supports the recent request by the U.S. Department of Transportation, Washington D.C. for an addendum to be issued to the 2005-2006 ICAO Technical Instructions (TI) to take into account four of the amendments recently adopted by the United Nations Sub-Committee of Experts on the Transport of Dangerous Goods (UNSCETDG). The amendments pertain to the requirements for the transport of infectious substances and will enhance national disease control, prevention, and surveillance programmes of the 167 OIE Member Countries. These amendments will also aid disease diagnosis, which will facilitate the OIE programmes to promote disease reporting and the safe trade of animals and animal products. The following is additional information and justification concerning two of these items.

Table of Category A agents:

Background: The OIE evaluated those microorganisms that are animal pathogens on the table of indicative examples of Category A agents and concluded that the risk of infecting animals with any of these agents during transport is extremely low. The method of transmission of these agents is usually by contact or insect vectors, and transmission through contaminated environment is very rare. Transmission usually only occurs when there is contamination of an animal holding facility and this is very unlikely during shipping. Many of the animal disease agents on this table are important because of their impact on trade and not because of their transmissibility. The OIE developed a proposal that attempted to give comparable treatment for agents of similar risk and it was submitted to the UNSCETDG during its July 2004 meeting and accepted. The following is the accepted proposal:

In the table with the indicative examples of Category A agents, under UN 2814, add '(cultures only)' after 'Rabies virus', 'Rift Valley fever virus' and 'Venezuelan equine encephalitis virus'. Under UN 2900, in this table, delete 'African horse sickness virus' and 'Bluetongue virus', insert 'Velogenic' before 'Newcastle disease virus' , and add '(cultures only)' after each microorganism in the list.

Under UN 2814, on the table, the Centers for Disease Control recommended replacing 'Hantaviruses causing hantavirus pulmonary syndrome' with 'Hantavirus causing haemorrhagic fever with renal syndrome'. This was also accepted by the UNSCETDG.

Justification for 1 January 2005 implementation: Implementation delays will severely impact long-standing domestic and international animal and human disease control and surveillance programmes. The delay will increase the cost and add restrictions associated with having to declare and ship routine surveillance specimens to meet UN2900 or UN 2814 requirements. If this change is delayed, the shipping restrictions on tissues submitted for disease diagnosis and surveillance will significantly curtail international and domestic animal disease diagnostic and control programmes. It could restrict the movement of samples from suspected disease outbreaks to the 155 OIE Reference Laboratories that provide diagnostic support for much of the world. These shipping requirements will have a significant impact on the developing world as this is the only place that many of these diseases in this table are endemic. Restrictions on shipping of diagnostic specimens from these countries to Reference Laboratories, plus the increased cost of shipping, will adversely impact programmes in these countries to control animal diseases and increase food production. These restrictions improperly promote the idea that these specimens pose a significant animal and human health risk as defined by the definition for Category A agents. Once ingrained, attempting to change this public perception may prove difficult at a later date. Increased public fears may also lead to non-acceptance of packages by shippers, which will further limit

animal and human disease surveillance and control efforts. Shippers may consider the requirements to be excessive and be tempted to not identify the package as an infectious substance.

Cultures of Category B agents

In the 13th edition of the Model Regulations, cultures of Category B agents had to be shipped using P 620 packaging. A number of international and national organisations requested that this requirement be deleted, and the UNSCETDG made the following change, which deleted the requirement. This is the approved change:

2.6.3.2.2.2 Delete 'except that cultures, as defined in 2.6.3.1.3, shall be assigned to UN 2814 or UN 2900 as appropriate.'

Justification for 1 January 2005 implementation: The Category B agents are by definition less serious and many of the agents are endemic in much of the world and consequently the risk does not justify assigning these cultures to Category A. The more stringent requirement for shipping these cultures would significantly impact the capability to characterise isolates. The correct identification of an isolate by a qualified laboratory is a key element in initiating the appropriate disease control programme. Often the local laboratory, that isolates the agent, does not have the capability to do a complete identification or cannot do the molecular testing to confirm the epidemiology of the disease. In many cases, the current classification prevents the submission of cultures to reference laboratories for further characterisation. This amendment will facilitate identification of cultures and allow the appropriate response by local, national and international animal and human health officials. Implementation of this amendment will have a great impact on developing countries that rely on the OIE Reference Laboratories to provide complete characterisation of Category B agents. If the amendment is not approved, the shippers may consider the requirements to ship Category B cultures to be excessive and not identify the package as an infectious substance.

In summary, these amendments are extremely important to insure that appropriate and justifiable requirements are in place that will insure the safe shipment of these very low risk infectious agents. 1 January 2005 implementation will play an important role in supporting international and national animal and human disease control, prevention and surveillance programmes. We thank you in advance for your attention to this important issue.

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APPENDIX E

Comments from J. Code

Recommended Change	UN 14th edition of the TDG Model Regulations	ICAO Adoption of UN decisions through Addendum
Amend P650 to authorize the use of the new proper shipping name for category B infectious substances, '**Biological Substance, Category B'**	In December 2004 it is anticipated the UN will take a final decision to introduce in the 14th edition of the TDG Model Regulations a new shipping name for UN 3373 'Biological Substance, Category B' which will replace the shipping names 'Diagnostic Specimen' and Clinical Specimen'.	**2005/2006 TI's Text:** The shipping name 'Diagnostic Specimens' or 'Clinical Specimens' is to be displayed on the Category B package and on the Category B document that is either separate from the package or affixed to the package. **ICAO DGP 19 Report** It was further considered that the continued use of the term "diagnostic specimen" was at the root of much of the confusion which continued to surround this issue. The problem was that, in common usage, diagnostic specimens could be substances in Category A, Category B or not dangerous goods of Division 6.2 at all, whereas "diagnostic specimen" was the proper shipping name (PSN) for substances in Category B. It was suggested that the proper solution to this dilemma would be to change the PSN for Category B substances to something other than "diagnostic specimens". There was general agreement with this point of view, and it was agreed that it should be communicated to the UNSCETDG. **Impact Statement:** Choosing an appropriate shipping name to reduce the confusion created by the names 'Diagnostic Specimen' or 'Clinical Specimen' receives the full support of Canada. However, prior to taking the decision to adopt the UN recommended shipping name, consideration should be given to the impact that decision will have on those members of industry who have already purchased pre-printed packaging and documents which display either the 'Diagnostic Specimens' or Clinical Specimens' shipping name as required in the 2005/2006 TI's. A reasonable approach may be to issue an Addendum that permits the use of all three

Recommended Change	**UN 14th edition of the TDG Model Regulations**	**ICAO Adoption of UN decisions through Addendum**
		names until January, 2007: · C Diagnostic Specimen · C Clinical Specimen · C Biological Substance, Category B It should be noted that the decision taken by the Panel should have no impact on the other modes of transport, as they do not require the shipping name on the package or document. **Recommendation:** Following ratification by the UN and support of the ICAO DGP Canada recommends that an Addendum to the 2005/2006 TI's be issued which permits as a third choice the use of the shipping name 'Biological Substance, Category B'.
Amend the indicative list of category A infectious substances	In December 2004 it is anticipated the UN will take a final decision to introduce in the 14th edition of the TDG Model Regulations amendments to the Category A Indicative List to reflect WHO and OIE recommendations. **(2.a)** Replace "Hantaviruses causing hantavirus pulmonary syndrome" with "Hantavirus causing hemorragic fever with renal syndrome"; **(2.b)** Add "(cultures only)" after Rabies virus, Rift Valley fever virus and Venezuelan equine encephalitis virus; **(2.c)** Insert "Velogenic" before Newcastle disease virus; **(2.d)** Add "(cultures only)" after all animal microorganisms on the Category A list; **(2.e)** Delete African horse sickness virus & Bluetongue virus from the Category A list.	**2005/2006 TI's Text:** The Indicative List of Category A Infectious Substances in the 2005/2006 TI's will not reflect the changes proposed by the UN. **Impact Statement:** A person classifying infectious substances uses the Indicative List as a quick reference to determine whether or not an Infectious Substance would be considered a 'Category A' substance. However, with respect to the proposed additions to the list, that person is obligated to classify any infectious substance as Category A if, when exposure to it occurs, it is capable of causing permanent disability, life-threatening or fatal disease to humans or animals. Therefore the additions should be classified as Category A whether or not they're on the list. For those substances removed from the list the worst that can happen is that they will still be classified as Category A Infectious Substances and will be transported in compliance with the more stringent provisions of for UN2814 and 2900 infectious substances provisions until the revised list is published. **Recommendation**

Recommended Change	**UN 14th edition of the TDG Model Regulations**	**ICAO Adoption of UN decisions through Addendum**
		Following ratification by the UN and support of the ICAO DGP Canada recommends that an Addendum to the 2005/2006 TI's be issued which amends the Category A Indicative List to reflect the changes made to the list at the UN. In future it is recommended the Indicative List be maintained in the TI's on a biennial basis and that should the UN make changes to that list prior to the end of the biennium those changes be posted on a public ICAO Website. A Note should be added to the ICAO TI's which refers to this website.
Amend the definition of cultures and add a definition for patient specimens	In December 2004 it is anticipated the UN will take a final decision to introduce in the 14th edition of the TDG Model Regulations the following amendments: **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 below in 2.6.3.1.4.". **Patient specimens**: 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.". **Category B infectious substances definition:** Amend the definition of Category B infectious substances in 2;6.3.2.2.2 by deleting the words "except that cultures as defined in 6.3.1.3 must be assigned to UN 2814 or UN 2900 as appropriate. **Consequential amendment in paragraph 2;6.3.5.1:** Delete "or containing Category B infectious substances in cultures" in the first sentence and ", other than in cultures, " in the last sentence.	**2005/2006 TI's Text:** a) The definition of cultures in the 2005/2006 TI's is: *'Cultures* (laboratory stocks) are the result of a process by which pathogens are amplified or propagated 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 or clinical purposes.' b) All Category B cultures are to be transported as if they were a Category A infectious substance. **ICAO DGP 19 Report** It was agreed that further clarification of the definition of cultures in 2; 6.3.1.3 was needed and that the UNSCETDG should also be approached on this matter. **Impact Statement:** a) The new UN definitions and consequential amendments differentiate between "Culture" when used by the research community vs. the medical community. b) The removal of Category B cultures from Category A will enhance safety by providing the health industry with a more economically viable and equally safe way of

Recommended Change	**UN 14th edition of the TDG Model Regulations**	**ICAO Adoption of UN decisions through Addendum**
		transporting the specimens collected for patient care and long standing disease surveillance programs. The amendment will emphasize these specimens do not pose the same public health risk as Category-A infectious substances. **Recommendation** Following ratification by the UN and support of the ICAO DGP Canada recommends that an Addendum to the 2005/2006 TI's be issued which adopts in full the amendments made by the UN to the text referring to cultures.
Amend the definition of Category A infectious substances in 2;6.3.2.2.1	In December 2004 it is anticipated the UN will take a final decision to introduce in the 14th edition of the TDG Model Regulations the following amendments: The words "in otherwise healthy" were added after "fatal disease" and the word "to" was deleted before "humans" so that the text now reads "...life threatening or fatal disease in otherwise healthy humans or animals."	**2005/2006 TI's Text:** The 2005/2006 TI's define Category A Infectious Substances as: '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 humans or animals. Indicative examples of substances that meet these criteria are given in the table in this paragraph.' **Impact Statement:** No impact is known at this time. **Recommendation**: This amendment is not considered so critical as to require publication in an Addendum. However, if an Addendum is published to address the other issues raised it could be included.

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