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International Air Transport Association ("IATA") 2007 Regulatory Changes Infectious Substance Category A, Biological Substance Category B, & Patient Specimen Shipments

ELECTRONIC VERSION – www.casingcorp.com/iata_changes.htm

Highlights

On January 1, 2007, two proper shipping names "Diagnostic Specimen" and "Clinical Specimen", are abandoned and replaced with "Biological Substance Category B". The UN3373 label continues to be required together with a Biological Substance Category B label.

Under this modified regulatory structure, there are three categories of regulated substances:

1. Infectious Substance Category A, (please see Table below (reference IATA DGR, Table 3.6.D.; The IATA 2007 Category A list is identical to the 2006 Category A list.),

2. Biological Substance Category B, and

3. Patient Specimen: Category B patient specimen, exempt human specimen, exempt animal specimen.

Under the 2005 and 2006 IATA DGR, infectious organisms intentionally propagated or cultured in a laboratory, and not listed in Infectious Substance, Category A, were considered dangerous goods and required to follow Division 6.2 packaging and documentation requirements, UN2814 or UN2900 as appropriate.

Under the 2007 IATA regulations, if a culture of a pathogenic organism is not listed in Category A (IATA DGR 3.6.D), it is classified in Biological Substance Category B. This is a significant change.

Re-classification of cultured pathogens gives the shipper the choice to ship these specimens under IATA packing instruction 650, Biological Substance Category B, without dangerous goods disclosure or Class 6.2 packaging.

Exempt human or animal specimens, the third category, are described below as well as in 3.6.2.2.3.1 of the IATA DGR.

Be certain to review acceptance policies with your carrier to verify that Category A OR B substances are transportable by your carrier. As of September 29, 2006, Lufthansa Airlines was the only carrier to refuse Category B shipments aboard their aircraft. Other carriers may refuse to accept Risk Group IV specimens under the old risk group classification system.

Other air carriers are now accepting the new Biological Substance Category B labels and packaging, in order to avoid disruption of shipments at the end of 2006. For information about current availability of the new labels and packaging, please call or email us.

DEFINITIONS

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.

Cultures are the result of a process by which pathogens are intentionally propagated. This definition does not include human or animal patient specimens.

Patient specimens are those 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.

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

Classification

For transport purposes, the classification of infectious substances according to risk groups was removed from the DGR in the 46th edition.

Infectious substances are now classified as category A or category B.

There is no relationship between Risk Groups and category A and B.

Category A Infectious Substances are infectious substances in a form that, when exposure to it occurs, is capable of causing permanent disability, life threatening or fatal disease in otherwise healthy humans or animals. They are assigned the following proper shipping name and UN number:

- Infectious Substance, affecting humans UN2814; or
- Infectious Substance, affecting animals UN2900

Assignment to UN2814 or UN2900 is to 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. If there is any doubt as to whether or not a pathogen falls within this category it must be transported as a Category A Infectious Substance.

To assist in the assignment of an infectious substance into category A, see the indicative list provided in IATA Table 3.6.D included below. The list is not exhaustive. Infectious Substances, including new or emerging pathogens, which do not appear in the table but which meet the same criteria must be assigned to Category A.

Category B Infectious Substances are Infectious Substances that do not meet the criteria for inclusion in category A. They are assigned the following proper shipping name and UN number:

- Biological Substance Category B
- UN3373

(1) This information was extracted from the guidance document developed by IATA and ICAO. It was updated based upon interviews of representatives of the carriers and the regulatory agencies. The 48th edition of the IATA Dangerous Goods Regulations is now available through IATA in Montreal, CA. (Phone 514 390 6746)