



# How to Classify Biological Commodities for Transport

One of the more challenging aspects of shipping biological commodities of all types is the regulatory requirement to determine whether or not there are infectious pathogens present and to classify the shipment for transport purposes. The following discussion is designed to present a clear and coherent set of guidelines for classifying biological commodities in compliance with the regulations.

## The Regulations

The rules for transporting biologicals are contained in the United Nations/ICAO/IMO dangerous goods transport regulations as well as regional laws such as the ADR (Europe) and 49CFR/TDG (USA and Canada) and in the transport laws of most national governments. Fortunately, most national laws are purposely harmonized with the UN international regulations so that in general the requirements for classifying biologicals are standard worldwide.

The principal behind the regulations is quite simple: there is a fear that a package of biologicals may contain infectious pathogens that, if released, could cause infection and illness or death among those who become



exposed. This fear translates into a precautionary set of strict rules for identifying, classifying, packaging, and documenting any shipment that even remotely bears the possibility of presenting such a risk. This then includes human and animal blood, tissue, body parts, and any other biological commodity. Any such commodity is considered dangerous goods (HAZMAT) for transport purposes and must be classified as such.

## Common Scenarios

On a practical level, there are certain common scenarios that are found in the determination of whether or not to ship a biological commodity as dangerous goods. The regulations recognize that there are some scenarios in which a clear “black and white” determination cannot be made, so they allow for a professional judgment based on accepted medical/scientific principles as to whether there are “likely” or “unlikely” to be infectious pathogens present. Once that judgment has been made, or in the case of a lack of such judgment, the regulations are fairly clear on how to proceed, as illustrated by the following examples:

### Scenario 1

**It is known that the commodity contains infectious pathogens -- e.g., human blood samples taken from patients with HIV, Ebola, or other known infectious diseases.**

There are 2 categories of infectious substances, Category A and Category B. Category A substances are those for which there is no treatment and a strong possibility of epidemic illness and death should they be



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released into the world. A list of indicative pathogens of this category is available in the regulations. It is possible to think of them as the World Health Organization's Risk Group 4 or Biohazard Level 4 pathogens. Examples include Ebola, Hantaan, and Variola. This category also includes laboratory cultures of pathogens otherwise excluded from the list. These items are subject to strict packaging and documentation requirements, as might be expected, and fall under the proper shipping name Infectious Substance, affecting humans (or animals) and carry the identifying UN number UN2814 (or UN2900).

All other known infectious pathogens, for which there is treatment and which do not entail the risk of large-scale community infection, fall into Category B. These are shipped under the proper shipping name Biological substance, Category B, UN 3373. It is possible to think of these as the old World Health Organization Risk Groups 2-3 or Biohazard Level 2-3 pathogens. Examples include HIV, HPV, Hepatitis C, and so on.

Both Category A and Category B shipments require specific marking and labeling of the package and Category A has detailed and fairly complex documentation rules.

### Scenario 2:

**It is not known whether the commodity contains infectious pathogens but there is some likelihood owing to observed patient symptoms or other medical/scientific reasons.**

In this case the shipment must be classified as a Biological substance,



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Category B, inasmuch as it is likely to contain infectious pathogens in the qualified judgment of the shipper. It should be noted that the use of this proper shipping name does not require the identification of the specific pathogen, so the lack of definitive diagnosis is not an issue. Further, if after testing the commodity is found in fact not to contain infectious substances, the shipper has not violated the regulations by over-classifying because the rules for this scenario had been followed.

### Scenario 3:

#### **It is not known whether there are infectious pathogens present.**

This scenario requires a medical/scientific judgment call on the part of a qualified professional in the field, i.e., the medical or scientific staff. If it is felt that it is very unlikely that infectious pathogens are present, then the shipment should be described precisely as to what it is (e.g., human tissue) and be tendered as “not-restricted” (non-hazardous). This is perfectly acceptable under the regulations. If it is not possible to make a judgment, then it is acceptable to use “Biological substance, Category B” and ship it as hazardous.

It is important to note that the proper shipping name “Biological substance, Category B” implies that either it is known that there are infectious pathogens present or it is likely that this is the case. Therefore, this classification should not be used in cases where it is thought unlikely that infectious pathogens are present even though no testing has been done. It is against the law to misclassify commodities even as a precaution.



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### Scenario 4:

**It is highly unlikely that there are infectious pathogens present – e.g., human tissue samples collected for the purpose of determining transplant compatibility, DNA samples, etc.**

Classify this type of shipment as “not-restricted” (non-hazardous). There is another category which can be used, “Exempt Human Specimens” but is designed for employee drug test samples and the like, not medical specimens or lab research samples.

## Accuracy is Paramount

### Scenario 5:

**The shipment contains blood or blood products collected for the purpose of (eventual) transfusion or body parts intended for transplant.**

The regulations are very specific here: these items are excluded from the dangerous goods regulations and must be shipped as not restricted. A description of the commodity and the fact that it is for transfusion or transplant must appear on the shipping papers to support this classification.

## Conclusion

Looking at it plainly, if the commodity is likely to contain infectious pathogens, or if it may possibly contain infectious pathogens, or if no medical judgment can be made, then classify it as dangerous goods. If the commodity is unlikely to contain infectious pathogens or contains blood or body parts for transfusion/transplant, then classify it as not restricted.



## Conclusion

When faced with the task of classifying a biological commodity it is important to keep in mind the principle that accuracy is paramount. As long as careful medical/scientific judgments are made with the accuracy principle in mind, the shipment will comply with the regulations. On the other hand, it is not acceptable to either under or over classify; in fact, it is against the law to declare a shipment as dangerous goods when it is not, and of course vice-versa.

QuickSTAT's regulatory experts are always available to assist in explaining the rules and the shipping options available for each of the scenarios listed above.

## About QuickSTAT

QuickSTAT specializes in shipping time- and temperature-sensitive clinical research samples, investigational drugs, biological materials, clinical supplies and dangerous goods. Our experts are dedicated to making sure your worldwide shipments get to wherever they are going on time, integrity intact.



### About the Author

Michael Gotz has developed IATA-certified Dangerous Goods training programs and has been a panelist in numerous IATA Dangerous Goods international conferences. He is the author of published journal articles on the subject of the air transport of hazardous commodities.

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