



International Federation of  
Biosafety Associations

## IFBA Sample Policy and Procedures

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## Transportation of Infectious Materials Policies and Procedures

Title: <b>Transportation of Infectious Materials Policies and Procedures</b>	Approved by:
Version No: <b>1.0</b>	Approved on:
Effective:	Supersedes:

### 1.0 PURPOSE & SCOPE

The transportation of infectious and potentially infectious materials is subject to strict requirements for classification, packaging, labelling, and documentation. The purpose of this Standard Operating Procedure (SOP) is to describe the procedures for safely transporting infectious materials from the laboratory both within the country and internationally. **This SOP is intended to supplement (not replace) the required certification training in the transportation of infectious materials.**

### 2.0 REFERENCES

WHO Guidance on the Regulations for the Transportation of Infectious Substances  
[http://apps.who.int/iris/bitstream/10665/149288/1/WHO\\_HSE\\_GCR\\_2015.2\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/149288/1/WHO_HSE_GCR_2015.2_eng.pdf)

WHO How to Safely Ship Human Blood Samples from Suspected Ebola cases within a Country by Road, Rail and Sea  
<http://www.who.int/csr/resources/publications/ebola/blood-shipment/en/>

UN Model Regulations on the Transportation of Dangerous Goods  
[http://www.unece.org/trans/danger/publi/unrec/rev18/18files\\_e.html](http://www.unece.org/trans/danger/publi/unrec/rev18/18files_e.html)

ICAO Technical Instructions For The Safe Transport of Dangerous Goods by Air  
<http://www.icao.int/safety/DangerousGoods/Pages/technical-instructions.aspx>

IATA Dangerous Goods Regulations  
<https://www.iata.org/whatwedo/cargo/dgr/Pages/index.aspx>

### 3.0 RESPONSIBILITY

It is the responsibility of the Laboratory Supervisor to provide appropriate packaging materials, to ensure all infectious materials transported out of the laboratory comply with the appropriate regulations, and that all shippers are trained on these procedures.

It is the responsibility of the Biosafety Officer to provide guidance on the proper procedures for transporting infectious materials.

It is the responsibility of all employees to participate in training for the shipment of infectious materials and ensure that appropriate regulations are followed.

#### **4.0 Glossary of TERMS and DEFINITIONS**

**“Infectious Substance”**: substances which are known or are reasonably expected to contain pathogens. Pathogens are defined as microorganisms (including bacteria, viruses, rickettsiae, parasites, fungi) and other agents such as prions, which can cause disease in humans or animals.

**“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 humans or animals. Infectious substances meeting these criteria which cause disease in humans or both in humans and animals shall be assigned to United Nations number UN 2814. Infectious substances which cause disease only in animals shall be assigned to UN 2900. 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.

**“Category B”**: an infectious substance which does not meet the criteria for inclusion in Category A. Infectious substances in Category B shall be assigned to UN 3373. The proper shipping name of UN 3373 is BIOLOGICAL SUBSTANCE, CATEGORY B.

**“Exempt Specimen”**: substances that do not contain infectious substances or that are unlikely to cause disease in humans or animals; substances containing microorganisms which are non-pathogenic to humans or animals; substances in a form that any present pathogens have been neutralized or inactivated such that they no longer pose a health risk; environmental samples (including food and water samples) which are not considered to pose a significant risk of infection; dried blood spots, collected by applying a drop of blood onto absorbent material; faecal occult blood screening samples; blood or blood components which have been collected for the purposes of transfusion. Human or animal specimens (patient specimens) for which there is minimal likelihood that pathogens are present are not subject to dangerous goods regulations if the specimen is transported in a packaging which will prevent any leakage, and which is marked with the words, “Exempt human specimen” or, “Exempt animal specimen”, as appropriate.

**“Patient Specimen”**: 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.

**“Cultures”**: the result of a process by which pathogens are intentionally propagated.

## **5.0 PROCEDURES**

### **5.1 Introduction**

Infectious substances are transported within or across international borders for a variety of different reasons. It is incumbent upon shippers to ensure packaging and shipping conditions meet regulatory requirements to preserve the integrity of materials and facilitate their timely arrival at destination. The efficient transport and transfer of infectious substances also requires good coordination between the sender, the carrier, and the receiver to ensure that the material is transported safely and arrives on time and in good condition. Such coordination depends upon effective communication between the three parties.

The international regulations for the transport of infectious substances by any mode of transport are based upon the recommendations made by the United Nations Committee of Experts on the Transport of Dangerous Goods (UNCETDG) and are presented in the form of *Model Regulations on the Transportation of Dangerous Goods*. Many countries adopt the UN Model Regulations in their entirety to stand as their national legislation, while some countries apply variations. The *Technical Instructions for the Safe Transport of Dangerous Goods by Air*, published by the International Civil Aviation Organization (ICAO), are legally binding international regulations for shipments by air. The International Air Transport Association (IATA) publishes *Dangerous Goods Regulations* that incorporate the ICAO provisions, and may add further restrictions. These rules apply on all international flights. For national flights (i.e. flights within one country), national civil aviation authorities apply national legislation. Some airlines will not carry dangerous goods at all, while others will carry only a very limited range of goods.

The *WHO Guidance on the Regulations for the Transportation of Infectious Substances* provide practical guidance to facilitate compliance with applicable international regulations for the transport of infectious substances and patient specimens by all modes of transport, both nationally and internationally. Additional information for the shipment of human blood samples potentially infected with Ebola virus have also been provided.

### **5.2 Training**

Dangerous goods regulations require all personnel involved in transport to undergo appropriate training. Appropriate training and education, commensurate with the shipper's responsibilities, will provide the shipper with the necessary degree of familiarity with applicable requirements, addressing identification, classification, packaging, marking, labelling, refrigeration, and required documentation for the transport of infectious substances. Training must be provided before any shipments of infectious materials are prepared and periodically thereafter.

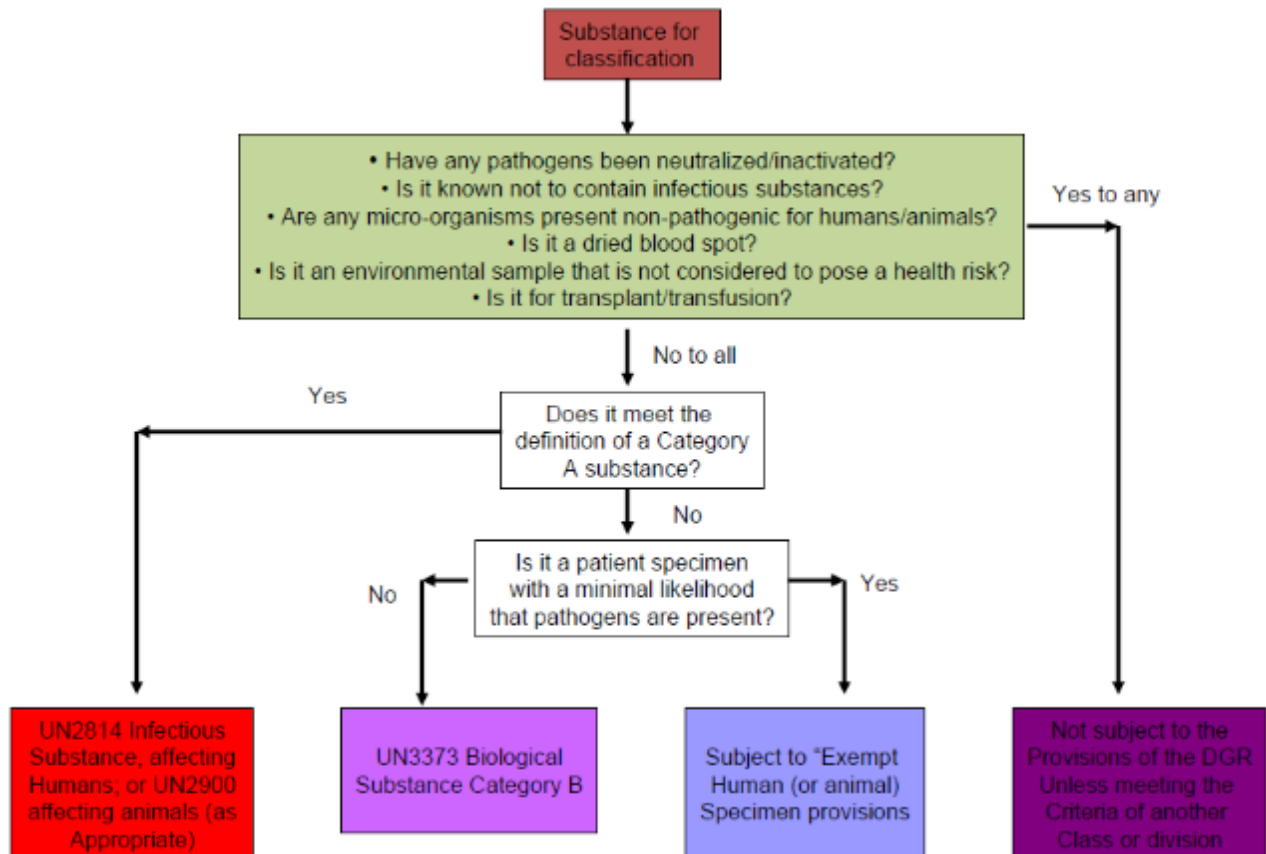
### **5.3 Planning & Advance Arrangements**

Careful planning and advance arrangements are required between the shipper (sender, consignor), the carrier, and the receiver (consignee). The shipper is responsible for making advance arrangements with the receiver, including investigating the need for import permits from national authorities. The shipper also makes advance arrangements with the carrier to ensure that the shipment will be accepted for appropriate transport, and that the shipment is undertaken by the most direct routing. Shippers must notify the receiver of

transportation arrangements once these have been made, well in advance of the expected arrival time. The receiver (consignee) arranges for the most timely and efficient collection on arrival and must acknowledge receipt to the sender.

#### 5.4 Classification

Dangerous goods are assigned UN numbers and proper shipping names according to their hazard classification and their composition. Proper shipping names are used to clearly identify the dangerous article or substance. Infectious substances are classified in Division 6.2 and divided into Category A, Category B and exempt substances. They are assigned to UN 2814, UN 2900, UN 3291 or UN 3373, as appropriate.



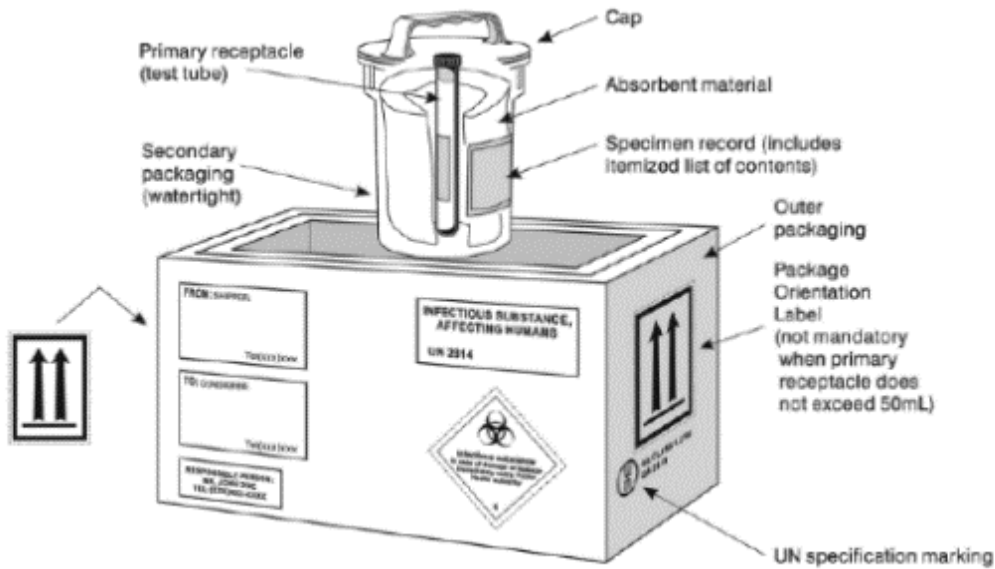
*(See Appendix A for indicative examples of Category A microorganisms)*

#### 5.5 Preparation of Shipments for Transport

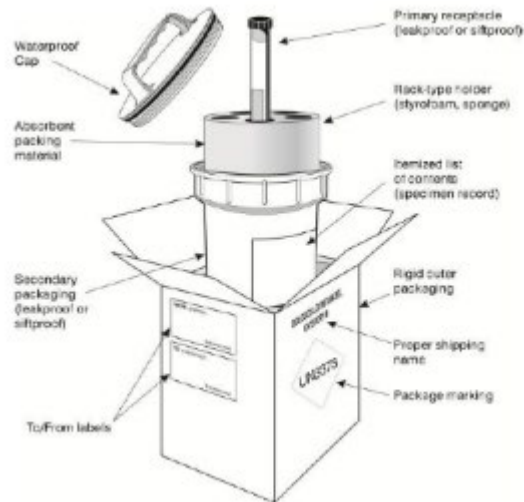
Because of the differences in the hazards posed by Category A infectious substances (UN 2814 and UN 2900) and Category B infectious substances (UN 3373), there are variations in the packaging, labelling, and documentation requirements for the two categories. For air transport of Category A infectious substances, the maximum quantity limits per package are 50 ml for passenger aircraft and 4 litres for cargo aircraft. For air transport of Category B infectious substances, the maximum quantity limits per primary receptacle is 1 litre, and the outer packaging must not contain more than 4 litres.

Infectious materials must be packaged to withstand leakage of contents, shocks, temperature and pressure changes, and other conditions that may occur during handling in transportation. As such, it is important that shippers purchase and use certified packaging according to the triple packaging principle. The three elements include: primary receptacle, leak-proof secondary container, and durable rigid outer container.

Example of triple packaging system for the packaging and labelling of Category A infectious substances:



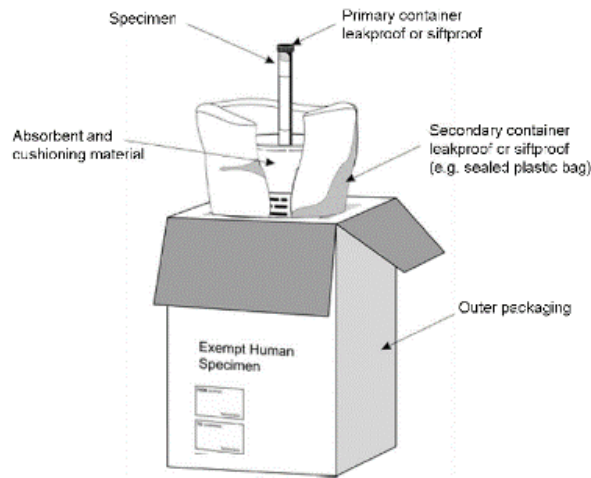
Example of triple packaging system for the packaging and labelling of Category B infectious substances:



Patient specimens that have a minimal likelihood of containing pathogens are exempt from many of the shipping requirements, and professional judgement must be used to determine if a specimen contains pathogens. If there is more than a “minimal likelihood” that the specimen contains pathogens, it must be shipped as Category A or Category B infectious substances. Patient specimens unlikely to contain pathogens are only exempt from the

regulations if the specimen is transported in a package which will prevent any leakage and is marked with the words “Exempt Human Specimen” or “Exempt Animal Specimen”, as appropriate.

Example of triple packaging system for the packaging and labelling of Exempt Specimens:



Shipping packages can be reused if appropriately disinfected. Before reusing a package, the shipper must make sure all markings and labels reflect the substances actually being shipped. If the shipper plans on shipping an empty package, all non-applicable markings and labels must be removed or covered.

## 5.6 Refrigerants

Refrigerants may be used to stabilize infectious substances in Categories A and B during transit. Ice, ice pads, or dry ice shall be placed outside the secondary receptacle or in an outer packaging. Wet ice shall be placed in a leak-proof container; the outer packaging shall also be leak-proof. Dry ice must not be placed inside the primary or secondary receptacle because of the risk of explosions and a specially designed insulated packaging must be used to contain dry ice and permit the release of carbon dioxide gas. The secondary receptacle shall be secured within the outer package to maintain the original orientation of the inner packages after the refrigerant has melted or dissipated.

Dry ice is classified by UN 1845 as a Class 9 miscellaneous hazard. If dry ice is used to ship infectious substances in Category A, the details shall appear on the shipper’s Declaration for Dangerous Goods. The outermost packaging must carry the dry ice hazard label, the UN number and the proper shipping name followed by the words “AS COOLANT” (e.g. *UN 1845, CARBON DIOXIDE, SOLID, AS COOLANT*) and an indication of the net quantity of dry ice in kilograms.



## 5.7 Documentation

For shipments of Category A and Category B infectious substances by air, the shipper is required to complete the air waybill indicating the nature of the goods. For UN 2814 and UN 2900, an itemized list of contents shall be enclosed between the secondary packaging and the outer packaging. A Shipper's Declaration of Dangerous Goods must be completed when shipping Category A infectious substances assigned to UN2814 or UN2900 (*See Appendix B*). The declaration is not required for shipping Category B infectious substances; for the air waybill, the "Nature and Quantity of Goods" box must show "UN 3373", the text "BIOLOGICAL SUBSTANCE, CATEGORY B" and the number of packages.

## 5.8 Incidents and Spills

International regulations require the reporting of incidents to the relevant competent transport authorities in addition to the necessary health authorities. This applies to both categories of infectious substances, but particularly Category A. Operators are also required to report mis-declared or undeclared infectious substances in the mail, baggage, or cargo to the appropriate national transport authorities.

The appropriate response in the event of exposure to any infectious substance is to wash or disinfect the affected area as soon as possible, regardless of the agent. Even if an infectious substance comes into contact with non-intact skin, washing of the affected area with soap and water or with an antiseptic solution can reduce the risk of infection. Medical advice should be obtained any time there is a suspected exposure to infectious substances resulting from a damaged package. The following procedure for clean-up can be used for spills of all infectious substances. The person must be trained on such procedure before performing these steps:

- Wear gloves and protecting clothing, including face and eye protection.
- Cover the spill with a paper towels to contain it.
- Gently pour an appropriate disinfectant over paper towels and the immediately surrounding area (5% bleach solutions are generally appropriate, but for spills on aircraft, quaternary ammonium disinfectants should be used).
- Apply the disinfectant concentrically beginning at the outer margin of the spill area, working towards the centre.
- After 30 minutes of contact, clean up the spill materials. If there is broken glass or other sharps involved, use a dustpan or tongs to collect the materials and deposit them into a puncture-resistant container for disposal.
- Clean and disinfect the area of the spillage.
- Dispose of contaminated materials into a leak-proof, puncture-resistant waste disposal container for autoclaving or incineration.
- Report the incident to the competent authority, informing them that the site has been decontaminated.



## APPENDIX A – Indicative Examples of Category A Infectious Substances

(The table provided below is an indicative list taken from the 18th edition of the United Nations Model Regulations)

UN Number and Proper Shipping Name	Microorganism
<b>UN 2814 Infectious substance, affecting humans</b>	<i>Bacillus anthracis</i> (cultures only)
	<i>Brucella abortus</i> (cultures only)
	<i>Brucella melitensis</i> (cultures only)
	<i>Brucella suis</i> (cultures only)
	<i>Burkholderia mallei</i> – <i>Pseudomonas mallei</i> – glanders (cultures only)
	<i>Burkholderia pseudomallei</i> – <i>Pseudomonas pseudomallei</i> (cultures only)
	<i>Chlamydia psittaci</i> – avian strains (cultures only)
	<i>Clostridium botulinum</i> (cultures only)
	<i>Coccidioides immitis</i> (cultures only)
	<i>Coxiella burnetii</i> (cultures only)
	Crimean-Congo haemorrhagic fever virus
	Dengue virus (cultures only)
	Eastern equine encephalitis virus (cultures only)
	<i>Escherichia coli</i> , verotoxigenic (cultures only) <sup>1</sup>
	Ebola virus
	Flexal virus
	<i>Francisella tularensis</i> (cultures only)
	Guanarito virus
	Hantaan virus
	Hantaviruses causing haemorrhagic fever with renal syndrome
	Hendra virus
	Hepatitis B virus (cultures only)
	Herpes B virus (cultures only)
	Human immunodeficiency virus (cultures only)
	Highly pathogenic avian influenza virus (cultures only)
	Japanese Encephalitis virus (cultures only)
	Junin virus
	Kysanur Forest disease virus
	Lassa virus
	Machupo virus
	Marburg virus
	Monkeypox virus
	<i>Mycobacterium tuberculosis</i> (cultures only) <sup>1</sup>
	Nipah virus
	Omsk haemorrhagic fever virus
	Poliovirus (cultures only)
	Rabies virus (cultures only)
	<i>Rickettsia prowazekii</i> (cultures only)
	<i>Rickettsia rickettsii</i> (cultures only)
	Rift Valley fever virus (cultures only)
Russian spring-summer encephalitis virus (cultures only)	
Sabia virus	
<i>Shigella dysenteriae</i> type 1 (cultures only) <sup>1</sup>	
Tick-borne encephalitis virus (cultures only)	

	Variola virus
	Venezuelan equine encephalitis virus (cultures only)
	West Nile virus (cultures only)
	Yellow fever virus (cultures only)
	<i>Yersinia pestis</i> (cultures only)
<b>UN 2900 Infectious substance, affecting animals only</b>	African swine fever virus (cultures only)
	Avian paramyxovirus Type 1 – Velogenic Newcastle disease virus (cultures only)
	Classical swine fever virus (cultures only)
	Foot and mouth disease virus (cultures only)
	Lumpy skin disease virus (cultures only)
	<i>Mycoplasma mycoides</i> – contagious bovine pleuropneumonia (cultures only)
	Peste des petits ruminants virus (cultures only)
	Rinderpest virus (cultures only)
	Sheep-pox virus (cultures only)
	Goatpox virus (cultures only)
	Swine vesicular disease virus (cultures only)
Vesicular stomatitis virus (cultures only)	

# APPENDIX B – Shipper’s Declaration of Dangerous Goods

## SHIPPER’S DECLARATION FOR DANGEROUS GOODS

Print Form

Shipper <div style="background-color: #e0e0ff; height: 40px; width: 100%;"></div>		Air Waybill No. Page <input style="width: 20px;" type="text"/> of <input style="width: 20px;" type="text"/> Pages Shipper's Reference Number <i>(optional)</i>				
Consignee <div style="background-color: #e0e0ff; height: 40px; width: 100%;"></div>		For optional use for Company logo name and address				
Two completed and signed copies of this Declaration must be handed to the operator.		<b>WARNING</b>  Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties.				
<b>TRANSPORT DETAILS</b>						
This shipment is within the limitations prescribed for: <i>(delete non-applicable)</i>		Airport of Departure: <div style="background-color: #e0e0ff; height: 20px; width: 100%;"></div>				
<input type="checkbox"/> PASSENGER AND CARGO AIRCRAFT	<input type="checkbox"/> CARGO AIRCRAFT ONLY					
Airport of Destination: <div style="background-color: #e0e0ff; width: 150px; height: 15px;"></div>		Shipment type: <i>(delete non-applicable)</i> <input checked="" type="checkbox"/> NON-RADIOACTIVE <input type="checkbox"/> RADIOACTIVE				
<b>NATURE AND QUANTITY OF DANGEROUS GOODS</b>						
Dangerous Goods Identification						
UN or ID No.	Proper Shipping Name	Class or Division (Subsidiary Risk)	Pack- ing Group	Quantity and type of packing	Packing Inst.	Authorization
Additional Handling Information <div style="background-color: #e0e0ff; height: 30px; width: 100%;"></div>						
I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations. I declare that all of the applicable air transport requirements have been met.					Name/Title of Signatory <div style="background-color: #e0e0ff; height: 20px; width: 100%;"></div> Place and Date <div style="background-color: #e0e0ff; height: 20px; width: 100%;"></div> Signature <i>(see warning above)</i>	