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Federal Expert Committee for Biosafety FECB

# *Transport of infectious substances and genetically modified organisms*

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2008



# *Topics*

- National and international transport regulations
- Definition / classification
- Packaging requirements
- Outlook



# *Legal Basis*

- **Gene Technology Law**
- **Law on the Protection of the Environment**
- **Ordinance on the Contained Use of Microorganisms:**

Art. 14 Transport

- <sup>1</sup> Anyone transporting genetically modified or pathogenic microorganisms must observe applicable, national and international transport regulations regarding labelling and packaging.
- <sup>2</sup> These transport regulations apply by analogy to the transport of genetically modified or pathogenic organisms, in particular genetically modified animals and plants, and plant-pathogenic microorganisms



# *International and National Transport-Regulations*

Mode of Transport	International	National
	UN Model Regulations	
Road	ADR	SDR
Railway	RID	RSD
Air	ICAO / IATA	LTrV
Sea / Inland Waterways	IMO / ADN	ADNR / BSV
Post	LPM	
Dangerous Goods		GGBV



See BSO-Manual for abbreviations:

<http://www.bafu.admin.ch/biotechnologie/01744/02964/index.html?lang=en&download=NHZLpZig7t,lnp6l0NTU042l2Z6ln1ad1lZn4Z2qZpnO2YUq2Z6gpJCEeYR,fmym162dpYbUzd,Gpd6emK2Oz9aGodetmqaN19XI2IdvoaCVZ,s-.pdf>



# Definitions

- **Infectious Substances (class 6.2, ADR 2.2.62):**

Substances which are known or are reasonably expected to contain pathogens

- Infectious substances, affecting humans (Category A)
- Infectious substances, affecting animals only (Category A)
- Biological products (Category B)
- Clinical waste (Category B)

- **Genetically modified microorganisms and organisms (class 9, ADR 2.2.9):**

Genetically modified microorganisms (GMMOs) and genetically modified organisms (GMOs) are microorganisms and organisms in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally. They are assigned to Class 9 (UN No. 3245) if they do not meet the definition of infectious substances, but are capable of altering animals, plants or microbiological substances in a way not normally the result of natural reproduction.

- **Plant pathogens**

Not subject to dangerous goods regulations, but subject to containment ordinance.

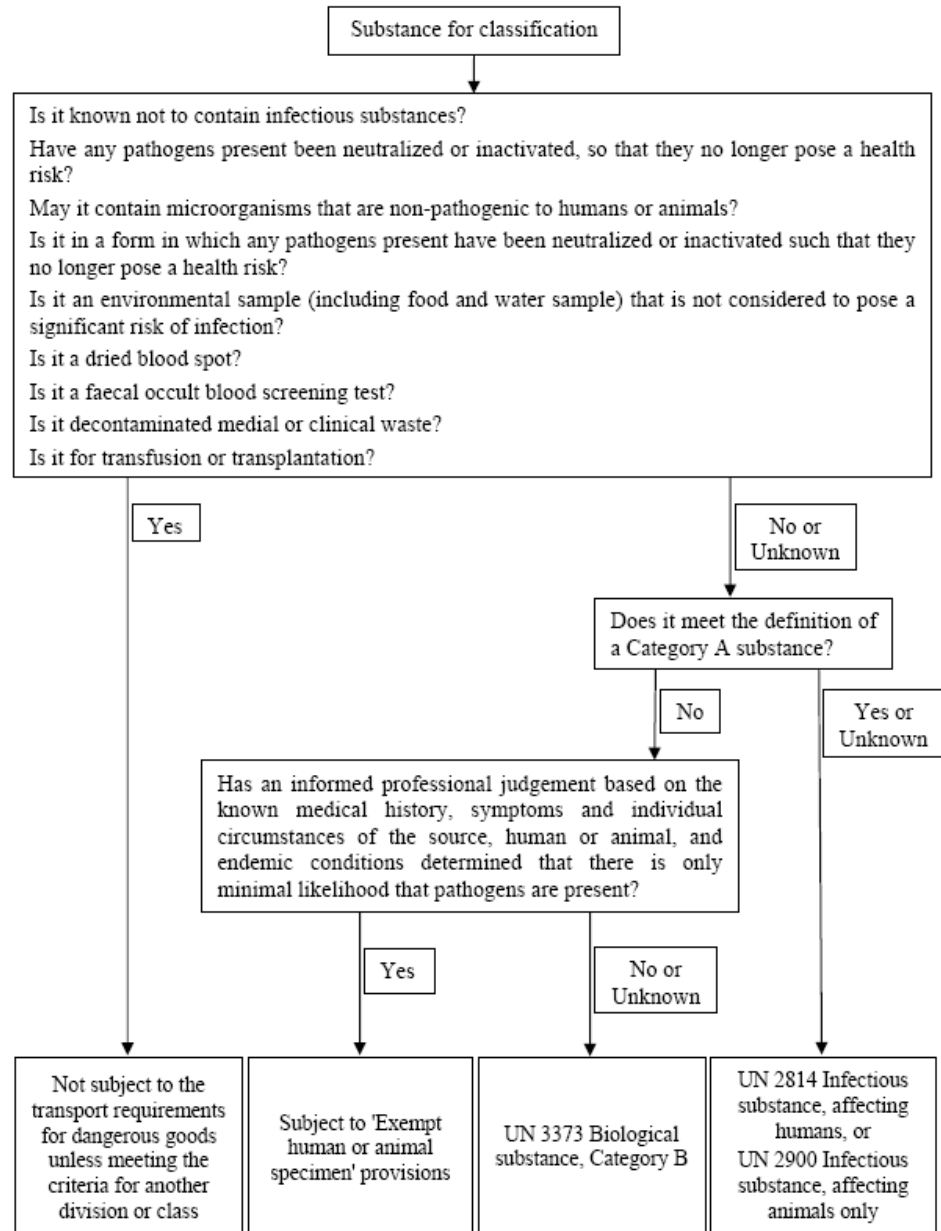
Plant toxins have to be assigned to UN 3172 or UN 3462, respectively (class 6.1, ADR 2.2.61).



# Flowchart for the classification of infectious substances

Source: Guidance on regulations for the transport of infectious substances 2007-2008, WHO

## Flowchart for the classification of infectious substances and patient specimens





# *Infectious substances: Exemptions*

## **Not considered as infectious substances (ADR 2.2.62.1.5):**

- Substances unlikely to cause disease
- Microorganisms which are non-pathogenic to humans and animals
- Substances which have been neutralized or inactivated
- Infectious substances with concentrations at a natural level (food stuff, water, air and soil samples, living persons)
- Blood (components) for the use of transfusion or transplantation
- Biological products for purposes of final packaging or use for personal health care
- Human or animal specimens with minimal likelihood that pathogens are present: „Exempt human (animal) specimen“



# *Classification*

- **Infectious Substances (class 6.2, ADR 2.2.62):**  
Substances which are known or are reasonably expected to contain pathogens
  - Infectious substances, affecting humans (Category A)
  - Infectious substances, affecting animals only (Category A)
  - Biological products (Category B)
  - Clinical waste (Category B)





# *Infectious Substances: Category A*

## **Category A substance (ADR, 2.2.62.1.4.1):**

An infectious substance (...) which is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals.

## **List of category A substances (ADR, 2.2.62.1.4.1)**

The list of these substances (mainly bacteria and viruses of risk groups 3 and 4) is not exhaustive.

## **Assignment to**

- UN 2814 “Infectious substance, affecting humans”
- UN 2900 “Infectious substance, affecting animals only”



# Category A substances: Examples

INDICATIVE EXAMPLES OF INFECTIOUS SUBSTANCES INCLUDED IN CATEGORY A IN ANY FORM UNLESS OTHERWISE INDICATED (2.2.62.1.4.1)	
UN Number and name	Micro-organism
UN No. 2814 Infectious substances affecting humans	<i>Bacillus anthracis (cultures only)</i> <i>Brucella abortus (cultures only)</i> <i>Brucella melitensis (cultures only)</i> <i>Brucella suis (cultures only)</i> <i>Burkholderia mallei - Pseudomonas mallei – Glanders (cultures only)</i> <i>Burkholderia pseudomallei – Pseudomonas pseudomallei (cultures only)</i> <i>Chlamydia psittaci - avian strains (cultures only)</i> <i>Clostridium botulinum (cultures only)</i> <i>Coccidioides immitis (cultures only)</i> <i>Coxiella burnetii (cultures only)</i> Crimean-Congo hemorrhagic fever virus Dengue virus (cultures only) Eastern equine encephalitis virus (cultures only) <i>Escherichia coli, verotoxigenic (cultures only)</i> Ebola virus Flexal virus <i>Francisella tularensis (cultures only)</i> Guanarito virus Hantaan virus Hantaviruses causing hantavirus pulmonary 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 (cultures only)</i> Nipah virus Omsk hemorrhagic fever virus Poliovirus (cultures only)



# *Infectious substances: Category B*

## **Category B substance (ADR 2.2.62.1.4.2):**

An infectious substance which does not meet the criteria for inclusion in Category A

### **Assignment to**

- UN 3373, Biological product, Category B
- UN 3291, Clinical waste

➡ Formerly named „Diagnostic specimen“ or „Clinical specimen“

➡ Infectious substances assigned to UN No. 3373 which are packed and packages which are marked in accordance with this packing instruction are not subject to any other requirement in ADR (ADR 4.1.4.1, P650).



# *Infectious substances: Examples*

<b>Material</b>	<b>Risk Group Category</b>	<b>Class UN number</b>	<b>ADR Pack. Instr.</b>	<b>Documenta- tion</b>	<b>Label</b>
Bacillus anthracis Culture	3 A	6.2 UN 2814	P 620	Dangerous goods transport documents	Biohazard
Bacillus anthracis Patient specimen	3 B	6.2. UN 3373	P 650	none	UN 3373 diamond
Influenza pandemic strain	2-4 A	6.2 UN 2814	P 620	Dangerous goods transport documents	Biohazard
Influenza vaccine	none (a)	none (a)	none (a)	none (a)	none (a)
Influenza vaccine research	B	6.2. UN 3373	P 650	none	UN 3373 diamond

a) Vaccines are considered as biological products which do not fall under dangerous goods regulations



# *Genetically modified organisms*

## **GMOs (ADR 2.2.9.1.11)**

Genetically modified organisms not meeting the definition of an infectious substance, but which are capable of altering animals, plants or microbiological substances in a way which is not normally the result of natural reproduction.

## **Assignment to**

- UN 3245, genetically modified organisms

➡ **Stricter transport requirements than for Category B substances!**

➡ **P904 is not suited for genetically modified animals and plants!**



# *Packing provisions*

## **Packaging (ADR 4.1)**

- UN 2814 / UN 2900: P 620 Category A
- UN 3373: P 650 Category B
- UN 3291: P 621 Clinical waste
- UN 3245: P 904 GMOs

## **General Requirements**

- Triple packaging
- Marking



## **Specific requirements (except for UN 3373)**

- Dangerous goods transport documents (ADR 5.4.1)
- Instruction in writing (ADR 5.4.3)
- Biohazard label



# Example for P 620 (Category A)



## Further provisions / restrictions:

- Training of persons involved
- Security provisions
- Safety adviser
- Carrier
- No transport by Swiss Post!

# *Example for P 650 (Category B)*

- Packaging are similar to P 620
- P 620 does not need a UN certified packaging
- Differences with respect to stability, marking and labelling

➔ **Biological Products Category B can be transported by Swiss Post!**



Leakproof  
primary  
receptacle

Absorbent and  
padding material

Leakproof secondary  
packaging

Marking and Labelling

Rigid outer packaging





# *Infectious substances: Examples*

<b>Material</b>	<b>Risk Group Category</b>	<b>Class UN number</b>	<b>ADR Pack. Instr.</b>	<b>Documenta- tion</b>	<b>Label</b>
Bacillus anthracis Culture	3 A	6.2 UN 2814	P 620	Dangerous goods transport documents	Biohazard
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Influenza pandemic strain	2-4 A	6.2 UN 2814	P 620	Dangerous goods transport documents	Biohazard
Influenza vaccine	none (a)	none (a)	none (a)	none (a)	none (a)
Influenza vaccine research	B	6.2. UN 3373	P 650	none	UN 3373 diamond

a) Vaccines are considered as biological products which do not fall under dangerous goods regulations



# *Important*

Your responsibilities as consignor / sender (ADR 1.4):

- Correct classification
- Correct packaging
- Correct marking and labelling
- Documentation

Further obligations:

- Export and import of biological material:
  - ➡ Additional regulations must be complied with!
  - ➡ See BSO-Manual or contact FOPH

BSO-Manual:

[http://www.bafu.admin.ch/biotechnologie/01744/02964/index.html?lang=en&download=NHZLpZig7t,lnp6I0NTU042l2Z6ln1ad1lZn4Z2qZpnO2Yuq2Z6gp\]CEeYR,fmym162dpYbUzd,Gpd6emK2Oz9aGodetmqaN19XI2IdvoaCVZ,s-.pdf](http://www.bafu.admin.ch/biotechnologie/01744/02964/index.html?lang=en&download=NHZLpZig7t,lnp6I0NTU042l2Z6ln1ad1lZn4Z2qZpnO2Yuq2Z6gp]CEeYR,fmym162dpYbUzd,Gpd6emK2Oz9aGodetmqaN19XI2IdvoaCVZ,s-.pdf)