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COMMITTEE OF EXPERTS ON THE TRANSPORT OF DANGEROUS GOODS AND ON THE GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS

Sub-Committee of Experts on the
Transport of Dangerous Goods

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OTHER BUSINESS

Transport of Biological Materials – UN Model Regulations

Transmitted by the European Biosafety Association (EBSA)

Background

This is a draft document seeking comments before it is submitted as an official working paper to the July meeting. The necessary consequential changes will be incorporated into the document before official submission for the July meeting. Written comments are welcomed at the following address ebsa-office@ebsaweb.eu

Transport regulations have been the concern of international and national bodies.

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity was developed to specifically focus on transboundary movement of any living modified organism (LMO) resulting from modern biotechnology. The objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of LMOs (GMOs) that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements, but recognizing that modern biotechnology has great potential for human well-being if developed and used with adequate safety measures for the environment and human health.

However, current requirements for GMOs and GMMOs according to the UN Model regulations seem not to be in complete harmony with the Cartagena Protocol. Furthermore the definitions of GMO are not clear, leading to non-compliance. In light of gaps in the UN Model Regulations national and international bodies are prepared to propose transport requirements. The Conference of the Parties to the Convention on Biological Diversity serving as the meeting of the Parties to the Cartagena Protocol on Biosafety at its last meeting (MOP3) reviewed Article 18.3 on the consideration of the need for and modalities of developing standards with regard to identification, handling, packaging and transport practices for transboundary movements of

living modified organisms and noted that given the complexity of existing rules and standards that there is a need for further consultation and invited Parties to the Protocol other governments and relevant international organizations to submit by November 2007 views and information on: (i) the adequacy of existing rules and standards for identification, handling, packaging and transport of goods and substances to address concerns relating to living modified organisms that are subject to transboundary movement, and (ii) on gaps that may exist that may justify a need to develop new rules and standards, or to call upon relevant international bodies to modify or expand their existing rules and standards, as appropriate.

Other organizations are concerned about the introduction and spread of plant pathogens that might pose an environmental risk and economic danger (International Plant Protection Convention,IPPC) or that might have serious impact on food and agriculture if used as biological weapons (Australia Group and others) and promote appropriate measures for their control. Next to, for example, licensing and phytosanitary requirements, internationally accepted transport regulations are highly needed. Although national requirements may be in place, current UN Model Regulations do not consider plant pathogens that may pose an important risk to the environment.

It is EBSA's position that transport regulations on dangerous goods should include biologicals that may pose a risk to public health, animal health and/or the environment.

To ensure harmonized regulations, it is EBSA's view that transport regulations should remain the responsibility of the UN Committee of Experts on the Transport of Dangerous Goods which produces the UN Model Regulations on the Transport of Dangerous Goods (Model Regulations). An analysis of the different categories of biologicals, see Annex 1, indicates that certain categories are not currently covered by the Model Regulations or are not clearly defined.

1. Genetically modified organisms (GMOs) or living modified organisms (LMOs), as described in the Cartagena Protocol on Biosafety, are addressed by the Model Regulations under Class 9, but their definitions are not clear and their packing requirements and documentation are out of proportion with the risk they may pose. We propose changes to address both aspects.

2. Organisms that may pose a risk to the environment such as some plant pathogens - quarantine plant pathogens and dual-use plant pathogens that pose a biosecurity risk - are not currently subject to the UN Model Regulations although they may pose a serious risk to the environment, agricultural economy and the food supply. In fact, the transport of those plant pathogens is not covered by any international regulation although it may be covered under some national regulations; therefore we propose to add them to the Model Regulations.

Because of its complexity, the transport of animals has been excluded from this review, although EBSA recognize that a revision is needed. Animals, ranging from invertebrate to vertebrate, include among others, infected animals, pests, vectors of pathogens, GMO animals. Probably, at least, invertebrate animals within these categories should be incorporated into the UN Model Regulations at a later stage.

Proposals

◊ Infectious substances

Model Regulations define infectious substances as:

> 2.6.3.1.1 *Infectious substances* are substances which are known 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.

Plant pathogens, in particular quarantine and regulated non-quarantine plant pathogens, as well as dual use plant pathogens are currently regulated in the country of origin and/or destination by National Plant Protection Organizations (NPPO) or through regulations aimed at controlling organisms that may be used illegally to cause harm to public health or the environment (dual-use), all of which may have severe economic impact on food and agriculture.

Typically these organisms are used in research environments and are not meant for intentional release into the environment.

- They are shipped in small quantities.
- They need to be properly packaged to prevent their unintended release into the environment.
- They include microorganisms, viruses and viroids.

Although some countries have defined packing instructions, currently there are no international regulations dictating how to package and ship these organisms.

For this reason EBSA consider that plant pathogens should be included in the definition of infectious substances and the definition should read as follows:

> ***Infectious substances*** **are substances which are known 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, animals or <u>plants.</u>**
>
> For EBSA ***Plant pathogens*** **are agents which fall into one of the following groups only:**
>
> - **Organisms that are classified as quarantine pests according to the International Plant Protection Convention (IPPC) under their International Standards for Phytosanitary Measures ISPM No.5 (latest edition) in the exporting and importing countries**
> - **Organisms which are defined as regulated non-quarantine pests according to the International Plant Protection Convention (IPPC) under their International Standards for Phytosanitary Measures ISPM No.5 (latest edition) in the exporting and importing countries**

- **"dual-use" organisms such as Australia group agents** [http://australiagroup.net]**, Select Agents organisms** [7 CFR Part 331], **or others appearing in national regulations on the subject.**

Although invertebrate animals that are either plant pests or vectors of plant diseases also pose a risk to the environment, they are excluded from this regulation as they are dealt by other regulations and may need competent authority approval.

Notes:

- According to the IPPC definition [ISPM No.5] a quarantine pest is a pest of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled [FAO, 1990; revised FAO, 1995; IPPC 1997].

- A non-quarantine pest is a pest whose presence in plants for planting affects the intended use of those plants, with an economically unacceptable impact and which is therefore regulated within the territory of the importing contracting party [IPPC ISPM No.5].

- dual-use agents are those that may also be used to cause intentional harm to the environment and which have an economic impact on food and agriculture and which are regulated nationally or regionally such as Australia group agents [http://australiagroup.net], Select Agent organisms [7 CFR Part 331], dual-use organisms [Regulation (EC) 1504/2004] or national regulation on this subject.

As plant pathogens do not pose a risk to transporters, compared to the Category A infectious substances and that the impact of loss of containment is to the environment with time for containment and clean-up, EBSA proposes a new Packing Instruction for these plant pathogens in line with their risk, providing good containment of the material, but without being fully marked, labeled and documented as is the case for UN 3373.

◊ Genetically Modified Organisms (GMOs)

The Model Regulations define GMMOs and GMOs as follows:

> *3.9.1.2 Genetically Modified Micro-organisms (GMMOs) and Genetically Modified Organisms (GMOs) are micro-organisms and organisms in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally.*

A. The Model Regulations then proceed to classify GMMOs or GMOs as follows:

> *3.9.2.5.1 Genetically modified organisms and micro-organisms which do not meet the definition of infectious substances but which are capable of altering animals, plants or microbiological substances in a way which is not normally the result of natural reproduction. They must be assigned to UN 3245*

This definition is ambiguous and when interpreted strictly it excludes most non-infectious GMOs and GMMOs since most of the GMOs and GMMOs, if accidentally released into the environment, do not alter organisms in a way that is not normally the result of natural reproduction.

We propose the following definition:

GMMOs or GMOs shall be assigned to UN3245 except when:

a) they meet the definition of an infectious substance. These shall be assigned to UN 2814, UN 2900, UN 3373 or UN XXXX as appropriate;

b) commercially authorized for use by the appropriate national authorities of the States of origin and destination. These are not subject to these Regulations;

c) they are used at the lowest containment level[1], at the exporting and importing countries, since they represent a negligible risk for man, animals, plants or the environment. These GMMOs and GMOs are not subject to these Regulations if transported in a packaging which is of adequate strength for its capacity, mass and intended use so as to prevent any loss and which is marked with the words: "Exempt GMMOs" or "Exempt GMOs" as appropriate.

C. Finally some GMOs and GMMOs are not subject to the Model Regulations as defined in:

> *3.9.2.5.2 GMMOs or GMOs are not subject to these Regulations when authorized for use by the appropriate national authorities of the States of origin, transit and destination.*

Although this definition probably intents to exempt GMMOs or GMOs that have a 'commercial' authorization by the appropriate national authorities in the States of origin, transit and destination, it may be interpreted to also include for example GMOs that have received an authorization from the appropriate national authorities for release into the environment for the purpose of a field trial.

Transit State(s): The shipper does not have knowledge nor control of the route the shipment will take to reach the destination. At the same time if the material has been commercially approved for use in the States of origin and destination, it means that it has undergone a risk assessment in both places and found to pose a low or negligible risk. Furthermore, the content of the shipment will be identified as containing GMOs or GMMOs according to the Cartagena Protocol documentation requirements (Article 18.2) permitting transit states to identify those shipments. Therefore we propose the following definition:

[1] as defined in Directive 98/81/EC and the World Health Organisation (WHO) Laboratory Biosafety Manual [http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/]

"GMOs or GMMOs are not subject to these Regulations when commercially authorized for use by the appropriate national authorities of the States of origin and destination."

In summary genetically modified organisms and genetically modified micro-organisms would be shipped as UN 3245 (GMOs or GMMOs) if:

a) they do not meet the definition of an infectious substance ; or

b) they are not commercially approved in the countries of origin and destination; or

c) they represent a risk to humans, animals, plants or the environment that is not negligible.

Materials that meet the definition of GMO or GMMO are non-infectious for humans and animals and do not meet the proposed definition of infectious to plants. They may pose limited hazard to humans, animals or the environment. The risk posed by GMO and GMMO materials transported as UN 3245 is not greater than that posed by Category B infectious substances (UN 3373) and, as opposed to the high and immediate risk of infection posed by Category A infectious organisms, these GMO and GMMO materials pose no immediate consequence. In case of loss of containment, there is time for containment and clean-up. Therefore, EBSA propose a new Packing Instruction for UN 3245 that offers good containment of the material but that reflects the low risk that this category represents. Accordingly, EBSA consider that fully marked, labeled and documented packages are not required for this category, similarly to UN 3373. The proposal provides for a clear indication on the package that the material is a GMO or GMMO which is sufficient for the handling of the material during transport and emergency situations. Furthermore, these materials are accompanied by documentation (invoices or other documents) that provide greater details on the material as required by Article 18 of the Cartagena Protocol on Biosafety.

Proposed changes (in blue) to relevant paragraphs in the Model Regulations

CHAPTER 2.6

CLASS 6 - TOXIC AND INFECTIOUS SUBSTANCES

Introductory notes

NOTE 1*: Genetically modified micro-organisms and organisms which do not meet the definition of an infectious substance shall be considered for classification in Class 9 and assignment to UN 3245.*

***NOTE 2**: Toxins from plant, animal or bacterial sources which do not contain any infectious substances or toxins that are contained in substances which are not infectious substances, shall be considered for classification in Division 6.1 and assignment to UN 3172.*

2.6.1 Definitions

Class 6 is divided into two divisions as follows:

(a) Division 6.1 *Toxic substances*
These are substances liable either to cause death or serious injury or to harm human health if swallowed or inhaled or by skin contact;

(b) Division 6.2 *Infectious substances*
Infectious substances are substances which are known 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 or plants.

2.6.3 Division 6.2 - Infectious substances

2.6.3.1 *Definitions*

For the purposes of these Regulations:

2.6.3.1.1 *Infectious substances* are substances which are known 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 or plants.

2.6.3.1.1.1 *Plant pathogens* are agents which fall into one of the following groups only:

a. *quarantine organism* is a pest of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled as stated by the International Plant Protection Convention (IPPC) under their International Standards for Phytosanitary Measures ISPM No.5 (latest edition) in the exporting and importing countries.

b. *regulated non-quarantine pest* is an organism whose presence in plants for planting affects the intended use of these plants, with an economically unacceptable impact and which is therefore regulated within the territory of the importing contracting party, as stated by IPPC under their International Standards for Phytosanitary Measures ISPM No.5 (latest edition) in the exporting and importing country.

c. *dual-use agents* that may also be used to cause intentional harm to the environment and which have an economic impact on food and agriculture and which are regulated as defined by Australia group [http://australiagroup.net], Select

Agent organisms [7 CFR Part 331], dual-use organisms [Regulation (EC) 1504/2004] or national regulation on this subject, see Table 1.

Note: Although invertebrate animals that are either plant pests or vectors of plant diseases also pose a risk to the environment, they are excluded from this regulation as they are dealt by other regulations and may need competent authority approval.

2.6.3.1.2 *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.

2.6.3.1.3 *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 in 2.6.3.1.4.

2.6.3.1.4 *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.

2.6.3.1.5 *Genetically modified micro-organisms (GMMOs) and genetically modified organisms (GMOs)* are micro-organisms and organisms in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally.

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

2.6.3.1.7 *Biological wastes* are wastes derived from the medical treatment of animals or humans, from bio-research or waste containing plant pathogens

2.6.3.2 *Classification of infectious substances*

2.6.3.2.1 Infectious substances shall be classified in Division 6.2 and assigned to UN 2814, UN 2900, UN 3291, ~~or~~ UN 3373, or UN XXXX as appropriate.

2.6.3.2.2 Infectious substances are divided into the following categories:

2.6.3.2.2.1 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 humans or animals. Indicative examples of substances that meet these criteria are given in the table in this paragraph.

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 both in humans and animals shall be assigned to UN 2814. Infectious substances which cause disease only in animals shall be assigned to UN 2900.
(b) Assignment to UN 2814 or UN 2900 shall 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.

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 is not exhaustive. Infectious substances, including new or emerging pathogens, which do not appear in the table but which meet the same criteria shall be assigned to Category A. In addition, if there is doubt as to whether or not a substance meets the criteria it shall be included in Category A.*

NOTE 3: *In the following table, the micro-organisms written in italics are bacteria, mycoplasmas, rickettsia or fungi.*

INDICATIVE EXAMPLES OF INFECTIOUS SUBSTANCES INCLUDED IN CATEGORY A IN ANY FORM UNLESS OTHERWISE INDICATED (2.6.3.2.2.1 (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 haemorrhagic fever virus Dengue virus (cultures only) Eastern equine encephalitis virus (cultures only) *Escherichia coli*, verotoxigenic (cultures only) Ebola virus Flexal virus *Francisella tularensis (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 Kyasanur Forest disease virus Lassa virus Machupo virus Marburg virus Monkeypox virus *Mycobacterium tuberculosis (cultures only)* Nipah virus Omsk haemorrhagic fever virus Poliovirus (cultures only) Rabies virus (cultures only) *Rickettsia prowazekii (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 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) *Mycoplasma mycoides* - 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)

2.6.3.2.2.2 Category B: An infectious substance which does not meet the criteria for inclusion in Category A or which is a plant pathogen. Infectious substances in Category B shall be assigned to UN 3373 in case of human or animal pathogens or to UN XXXX in case of plant pathogens.

NOTE: *The proper shipping name of UN 3373 is "BIOLOGICAL SUBSTANCE, CATEGORY B" and the proper shipping name of UN XXXX is "INFECTIOUS SUBTANCE AFFECTING PLANTS only".*

2.6.3.2.3 *Exemptions*

2.6.3.2.3.1 Substances which do not contain infectious substances or substances which are unlikely to cause disease in humans, ~~or~~ animals or plants are not subject to these Regulations unless they meet the criteria for inclusion in another class.

2.6.3.2.3.2 Substances containing microorganisms which are non-pathogenic to humans, ~~or~~ animals or plants are not subject to these Regulations unless they meet the criteria for inclusion in another class.

2.6.3.2.3.3 Substances in a form that any present pathogens have been neutralized or inactivated such that they no longer pose a health or environmental risk are not subject to these Regulations unless they meet the criteria for inclusion in another class.

2.6.3.2.3.4 Environmental samples (including food and water samples) which are not considered to pose a significant risk of infection are not subject to these Regulations unless they meet the criteria for inclusion in another class.

2.6.3.2.3.5 Dried blood spots, collected by applying a drop of blood onto absorbent material, or faecal occult blood screening tests and blood or blood components which 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 Regulations.

2.6.3.2.3.6 Human or animal specimens for which there is minimal likelihood that pathogens are present are not subject to these 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. The packaging should meet the following conditions:

(a) The packaging should consist of three components:

(i) a leak-proof primary receptacle(s);

(ii) a leak-proof secondary packaging; and

(iii) an outer packaging of adequate strength for its capacity, mass and intended use, and with at least one surface having minimum dimensions of 100 mm × 100 mm;

(b) For liquids, absorbent material in sufficient quantity to absorb the entire contents should be placed between the primary receptacle(s) and the secondary packaging so that, during transport, any release or leak of a liquid substance will not reach the outer packaging and will not compromise the integrity of the cushioning material;

(c) When multiple fragile primary receptacles are placed in a single secondary packaging, they should be either individually wrapped or separated to prevent contact between them.

NOTE 1: *An element of professional judgment is required to determine if a substance is 1exempt under this paragraph. That judgment should be based on the known medical history, symptoms and individual circumstances of the source, human or animal, and endemic local conditions. Examples of specimens which may be transported under this paragraph include the blood or urine tests to monitor cholesterol levels, blood glucose levels, hormone levels, or prostate specific antibodies (PSA); those required to monitor organ function such as heart, liver or kidney function for humans or animals with non-infectious diseases, or for therapeutic drug monitoring; those conducted for insurance or employment purposes and are intended to determine the presence of drugs or alcohol; pregnancy test; biopsies to detect cancer; and antibody detection in humans or animals in the absence of any concern for infection (e.g. evaluation of vaccine induced immunity, diagnosis of autoimmune disease, etc).*

NOTE 2: For air transport, packagings for specimens exempted under this paragraph shall meet the conditions in (a) to (c).

2.6.3.3 ***Biological products***

2.6.3.3.1 For the purposes of these Regulations, 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 Regulations;

(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 shall 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, competent authorities may require these biological products to be in compliance with local requirements for infectious substances or may impose other restrictions.*

2.6.3.4 Genetically ***modified micro-organisms and organisms***

2.6.3.4.1 Genetically modified micro-organisms not meeting the definition of infectious substance shall be classified according to Chapter 2.9.

2.6.3.5 ***~~Medical or clinical waste~~*** ***Biological*** ***Waste***

2.6.3.5.1 Medical or clinical wastes containing Category A infectious substances shall be assigned to UN 2814 or UN 2900 as appropriate. Medical or clinical wastes containing infectious substances in Category B shall be assigned to UN 3291.

2.6.3.5.2 Medical or clinical wastes which are reasonably believed to have a low probability of containing infectious substances shall be assigned to UN 3291.

For the assignment, international, regional or national waste catalogues may be taken into account.

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.".*

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

2.6.3.5.4 Infectious waste containing plant pathogens will be assigned to UN XXXX and described as "WASTE, INFECTIOUS SUBSTANCES AFFECTING PLANTS only"

2.6.3.6 ***Infected animals***

2.6.3.6.1 Unless an infectious substance cannot be consigned by any other means, live animals shall not be used to consign such a substance. A live animal which has been intentionally infected and is known or suspected to contain an infectious substance shall only be transported under terms and conditions approved by the competent authority.

2.6.3.6.2 Animal material affected by pathogens of Category A or which would be assigned to Category A in cultures only, shall be assigned to UN 2814 or UN 2900 as appropriate.

CHAPTER 2.9

CLASS 9 – MISCELLANEOUS DANGEROUS SUBSTANCES AND ARTICLES

2.9.1 Definitions

2.9.1.1 *Class 9 substances and articles (miscellaneous dangerous substances and articles)* are substances and articles which, during transport present a danger not covered by other classes.

2.9.1.2 Genetically modified microorganisms (GMMOs) and genetically modified organisms (GMOs) are micro-organisms and organisms in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally.

2.9.2 Assignment to Class 9

2.9.2.1 Class 9 includes, inter alia:

1) environmentally hazardous substances which are not covered by other classes;
2) elevated temperature substances (i.e. substances that are transported or offered for transport at temperatures equal to or exceeding 100 °C in a liquid state or at temperatures equal or exceeding 240 °C in a solid state);
3) GMMOs or GMOs that shall be assigned to UN3245 except when:

d) they meet the definition of an infectious substance. These shall be assigned to UN 2814, UN 2900, UN 3373 or UN XXXX as appropriate
e) commercially authorized for use by the appropriate national authorities of the States of origin and destination. These are not subject to these Regulations
f) they are used at the lowest containment level, as defined in Directive 98/81/EC and the WHO Biosafety Manual, since they represent a negligible risk for man, animals, plants or the environment for exporting and importing countries. These GMMOs and GMOs are not subject to these Regulations if transported in a packaging which is of adequate strength for its capacity, mass and intended use so as to prevent any loss and which is marked with the words: “Exempt GMMOs” or “Exempt GMOs” as appropriate.

Packing Instructions

P620 PACKING INSTRUCTION P620

No changes required.

P621 PACKING INSTRUCTION P621

No changes required

P650 PACKING INSTRUCTION P650

No changes required

New packing instruction for "**Infectious substances, affecting plants** only "

P6XX	**PACKING INSTRUCTION**	**P6XX**

This packing instruction applies to UN No. XXXX

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

(2) The packaging shall consist of at least three components:

(a) a primary receptacle;

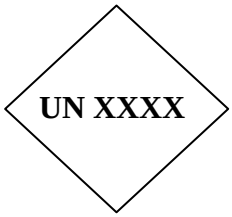
(b) a secondary packaging; and

(c) an outer packaging

of which either the secondary or the outer packaging shall be rigid.

(3) Primary receptacles shall be packed in secondary packagings in such a way that, under normal conditions of carriage, they cannot break, be punctured or leak their contents into the secondary packaging. Secondary packagings shall be secured in outer packagings with suitable cushioning material. Any leakage of the contents shall not compromise the integrity of the cushioning material or of the outer packaging.

(4) For transport, the mark illustrated below shall be displayed on the external surface of the outer packaging on a background of a contrasting color and shall be clearly visible and legible. The mark shall be in the form of a circle with a minimum diameter of 50 mm; the width of the line shall be at least 2 mm. The proper shipping name "INFECTIOUS SUBSTANCE, AFFECTING PLANTS and the UN number UN XXXX in letters and numbers at least 6 mm high shall be marked on the outer packaging adjacent to the mark. In case of waste containing INFECTIOUS SUBSTANCE AFFECTING PLANTS, the proper shipping name must be preceded by the word "waste".



Infectious substance, affecting plants

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

(6) The completed package shall be capable of successfully passing the drop test in 6.3.2.5 as specified in 6.3.2.2 to 6.3.2.4 at a height of 1.2 m. Following the appropriate drop sequence, there shall be no leakage from the primary receptacle(s) which shall remain protected by absorbent material, when required, in the secondary packaging.

(7) For liquid substances:

P6XX	PACKING INSTRUCTION	P6XX
(a) The primary receptacle(s) shall be leakproof; (b) The secondary packaging shall be leakproof; (c) If multiple fragile primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated to prevent contact between them;		
(d) Absorbent material shall be placed between the primary receptacle(s) and the secondary packaging. The absorbent material shall 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 shall be capable of withstanding, without leakage, an internal pressure of 95 kPa (0.95 bar).		
(8) For solid substances: (a) The primary receptacle(s) shall be siftproof; (b) The secondary packaging shall be siftproof; (c) If multiple fragile primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated to prevent contact between them; (d) If there is any doubt as to whether or not residual liquid may be present in the primary receptacle during carriage then a packaging suitable for liquids, including absorbent materials, shall 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 regulations shall be met. When used, ice or dry ice shall be placed outside the secondary packagings or in the outer packaging or an overpack. Interior supports shall 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 shall be leakproof. If carbon dioxide, solid (dry ice) is used, the packaging shall be designed and constructed to permit the release of carbon dioxide gas to prevent a build-up of pressure that could rupture the packagings and the package (the outer packaging or the overpack) shall be marked "Carbon dioxide, solid" or "Dry ice"'. (b) The primary receptacle and the secondary packaging shall 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 shall either be clearly visible or be reproduced on the outside of the overpack.		
(11) Infectious substances assigned to UN XXXX which are packed and packages which are marked in accordance with this packing instruction are not subject to any other requirement in these regulations.		
(12) Clear instructions on filling and closing such packages shall be provided by packaging		

P6XX	PACKING INSTRUCTION	P6XX
	manufacturers and subsequent distributors to the consignor or to the person who prepares the package to enable the package to be correctly prepared for carriage.	
(13)	Other dangerous goods shall not be packed in the same packaging as 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 Regulations need met.	

P904	PACKING INSTRUCTION	P904
This instruction applies to UN No. 3245.		
The following packagings are authorized, provided the general provisions of **4.1.1** and **4.1.3** are met: (1) Packagings according to packing instruction P001 or P002 conforming to the packing group III performance level; (2) Packagings, which need not conform to the packaging test requirements of Part 6, but conforming to the following: (a) An inner packaging comprising: (i) a watertight primary receptacle(s); (ii) a watertight secondary packaging which is leakproof; (iii) absorbent material placed between the primary receptacle(s) and the secondary packaging. The absorbent material shall be in a 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; (iv) if multiple fragile primary receptacles are placed in a single secondary packaging they shall be individually wrapped or separated to prevent contact between them; (b) An outer packaging shall be strong enough for its capacity, mass and intended use, and with a smallest external dimension of at least 100 mm; (3) For transport, the mark illustrated below shall be displayed on the external surface of the outer packaging on a background of a contrasting color and shall be clearly visible and legible. The mark shall be in the form of a circle with a minimum diameter of 50 mm; the width of the line shall be at least 2 mm and the letters and the numbers at least 6mm. The proper shipping name “GENETICALLY MODIFIED ORGANISMS OR MICRO-ORGANISMS” as appropriate in letters at least 6 mm high shall be marked on the outer packaging adjacent to the mark. In case of waste containing “GENETICALLY		

P904	PACKING INSTRUCTION	P904

MODIFIED ORGANISMS OR MICRO-ORGANISMS" the proper shipping name must be preceded by the word "waste".

(4) Genetically modified organisms or Genetically modified microorganisms UN 3245 which are packed and packages which are marked in accordance with this packing instruction are not subject to any other requirement in these regulations.

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

Additional requirements:

Dry ice and liquid nitrogen

When carbon dioxide, solid, (dry ice) is used as a refrigerant, the packaging shall be designed and constructed to permit the release of the gaseous carbon dioxide to prevent the build up of pressure that could rupture the packaging and the package (the outer packaging or the overpack) shall be marked "Carbon dioxide, solid" or "Dry ice"'.

Substances consigned in liquid nitrogen or dry ice shall be packed in primary receptacles that are capable of withstanding very low temperatures. The secondary packaging shall also be capable of withstanding very low temperatures and, in most cases, will need to be fitted over the primary receptacle individually.

Section 2.6.3.1.1.1 Table 1 – Dual use organisms that are have an impact on the environment (plant pathogens)

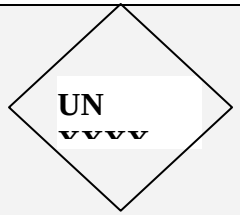
Australia Group[1]	Select Agents[2]	Dual-Use[3]
Control List Of Plant Pathogens For Export Control Core List **Bacteria** PB1. *Xanthomonas albilineans* PB2. *Xanthomonas campestris* pv. *citri* **Fungi** PF1. *Colletotrichum coffeanum* var. *virulans* (*Colletotrichum kanawae*) PF2. *Cochliobolus miyabeanus* (*Helminthosporium oryzae*) PF3. *Microcyclus ulei* (syn. *Dothidella ulei*) PF4. *Puccinia graminis* (syn. *Puccinia graminis* f. sp. *tritici*) PF5. *Puccinia striiformis* (syn. *Puccinia glumarum*) PF6. *Pyricularia grisea*/*Pyricularia oryzae* **Genetically-modified Micro-organisms** PG1. Genetically-modified micro-organisms or genetic elements that contain nucleic acid sequences associated with pathogenicity derived from the plant pathogens identified on the export control list.	**USDA only agents and toxins** **Plants** • *Candidatus* Liberobacter africanus • *Candidatus* Liberobacter asiaticus • *Peronosclerospora philippinesis* • *Ralstonia solanacearum*, race 3, biovar 2 • *Sclerophthora rayssiae* var. *zeae* • *Synchytrium endobioticum* • *Xanthomonas oryzae* pv. *oryzicola* • *Xylella fastidiosa* (citrus variegated chlorosis strain)	a. **Viruses**, whether natural, enhanced or modified, either in the form of «isolated live cultures» or as material including living material which has been deliberately inoculated or contaminated with such cultures, as follows: 1. Potato Andean latent tymovirus; 2. Potato spindle tuber viroid; b. **Bacteria**, whether natural, enhanced or modified, either in the form of «isolated live cultures» or as material which has been deliberately inoculated or contaminated with such cultures, as follows: 1. *Xanthomonas albilineans*; 2. *Xanthomonas campestris* pv. *citri* including strains referred to as *Xanthomonas campestris* pv. *citri* types A,B,C,D,E or otherwise classified as *Xanthomonas citri*, *Xanthomonas campestris* pv. *aurantifolia* or *Xanthomonas campestris* pv. *citrumelo*; 3. *Xanthomonas oryzae* pv. *oryzae* (*Pseudomonas campestris* pv. *oryzae*); 4. *Clavibacter michiganensis* subsp. *sepedonicus* (*Corynebacterium michiganensis* subsp. *sepedonicum* or *Corynebacterium epedonicum*); 5. *Ralstonia solanacearum* Races 2 and 3 (*Pseudomonas solanacearum* Races 2 and 3 or *Burkholderia solanacearum* Races 2 and

		3); c. **Fungi**, whether natural, enhanced or modified, either in the form of «isolated live cultures» or as material which has been deliberately inoculated or contaminated with such cultures, as follows: 1. *Colletotrichum coffeanum* var. *virulans* (*Colletotrichum kahawae*); 2. *Cochliobolus miyabeanus* (*Helminthosporium oryzae*); 3. *Microcyclus ulei* (syn. *Dothidella ulei*); 4. *Puccinia graminis* (syn. *Puccinia graminis* f. sp. *tritici*); 5. *Puccinia striiformis* (syn. *Puccinia glumarum*); 6. *Magnaporthe grisea* (*Pyricularia grisea*/*Pyricularia oryzae*).

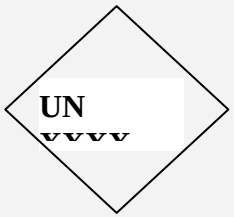
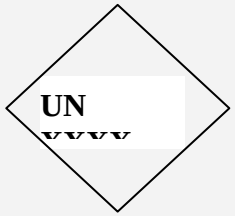
[1] http://australiagroup.net
[2] 7 CFR Part 331
[3] Regulation (EC) 1504/2004

Annex 1. Summary of all categories of infectious substances and genetically modified microorganisms (GMMs) and organisms (GMOs)

Category	Public Health Risk	Animal Health Risk	Environment Risk	UN Model Reg.	PI	Marking/Labeling	Documents	Summary reference to 15th revised edition.
CLASS 6.2 INFECTIOUS SUBSTANCES								
Infectious to humans and animals	Medium to high	Medium to high	Low	UN 3373 or UN 2814	P650 or P620	BIOLOGICAL SUBSTANCE, CATEGORY B  INFECTIOUS SUBSTANCE, AFFECTING HUMANS Fully marked and labeled package including hazard label for division 6.2	No transport document required. Transport documentation	2.6.3.2.2.2 2.6.3.2.2.1
Infectious to animals only	Low	Medium to high	Low	UN 3373 or UN 2900	P650 or P620	BIOLOGICAL SUBSTANCE, CATEGORY B  INFECTIOUS	No transport document required. Transport documentation	2.6.3.2.2.2 2.6.3.2.2.1

						SUBSTANCE, AFFECTING ANIMALS only Fully marked and labeled package including hazard label for division 6.2		
Infectious to plants, including dual use agents	Low	Low	Medium to high	UN XXXX	New P6XX	 INFECTIOUS SUBSTANCE, AFFECTING PLANTS	No transport documentation	New UN XXXX and name Develop new packing instruction
Non-infectious organisms (to humans, animals or **plants**)	Low	Low	Low	Exempt for human and animal; Not covered for plants				Adapt 2.6.3.2.3.1 and 2.6.3.2.3.2 All non-infectious organisms should be exempt including non-infectious to plants
Human or animal specimens for which there is minimal likelihood that pathogens are present	Low	Low	Low	Exempt		EXEMPT HUMAN SPECIMEN or EXEMPT ANIMAL SPECIMEN		2.6.3.2.3.6
Products that have received commercial approval (pharmaceuticals, vaccines …)	Low	Low	Low	Exempt				2.6.3.3.1(a)

GMMO or GMO infectious to humans / animals	Medium to high	Medium to high if zoonotic	Low	UN 3373 or UN 2814	P650 or P620	BIOLOGICAL SUBSTANCE, CATEGORY B  INFECTIOUS SUBSTANCE, AFFECTING HUMANS Fully marked and labeled package including hazard label for division 6.2	No transport document required. Transport documentation	2.6.3.2 2.9.2.1 2.6.3.2 2.9.2.1
GMMO or GMO infectious to animals	Low	Medium to high	Low	UN 3373 or UN 2900	P650 or P620	BIOLOGICAL SUBSTANCE, CATEGORY B  INFECTIOUS SUBSTANCE, AFFECTING ANIMALS only Fully marked and labeled package including hazard label for division 6.2	No transport document required Transport documentation	2.6.3.2 2.9.2.1 2.6.3.2 2.9.2.1

GMMO or GMO infectious to plants	Low	Low	Medium to high	UN XXXX	New P6XX	 INFECTIOUS SUBSTANCE, AFFECTING PLANTS only	No transport documentation	New UN XXXX and name. Develop new packing instruction
Medical waste containing infectious waste containing Cat. A organisms	High	High	Low	UN 2814 or UN 2900	P620	INFECTIOUS SUBSTANCE, AFFECTING HUMANS or INFECTIOUS SUBSTANCE, AFFECTING ANIMALS only Fully marked and labeled package (class 6.2 hazard label)	Transport documentation	2.6.3.5.1
Medical waste, all other (includes animal waste)	Medium to high	Medium to high	Medium to high	UN 3291 Infectious to plants not covered	P621 IBC620 LP621	CLINICAL WASTE, UNSPECIFIED, N.O.S. or (BIO) MEDICAL WASTE, N.O.S or REGULATED MEDICAL WASTE, N.O.S Fully marked and labeled package	Transport documentation	2.6.3.5.1 2.6.3.5.2
Waste containing plant pathogens	Low	Low	Medium to high	Not covered Proposal: use same UNXXXX as for plant pathogens	Proposal: use same packing instruction as for plant pathogens	 WASTE, INFECTIOUS SUBSTANCE AFFECTING PLANTS only	No transport documentation	Use same UN XXXX as for plant pathogens and add the word waste in front of proper shipping name

CLASS 9 MISCELLANEOUS DANGEROUS SUBSTANCES AND ARTICLES								
2.9.1.2 genetically modified microorganisms and genetically modified organisms								
Non-infectious GMMOs or GMOs	Low	Low	Medium to high	Currently UN 3245 Problem: no clear definition Proposal: new definition with exemption for lowest containment level	Currently P904	Currently fully marked and labeled (hazard label class 9) package Proposal: only special marking and name: GENETICALLY MODIFIED MICROORGANISMS or GENETICALLY MODIFIED ORGANISMS **UN 3245**	Currently: transport documentation Proposal: no transport documentation	Adapt 2.9.2.1 text Adapt P904
Commercially approved GMMOs or GMOs	Low	Low	Low	Exempt, but definition is not clear, it does not include the word '*commercial*'				Adapt 2.9.2.1 text: clarify that it is 'commercially' approved
GMMOs or GMOs used at the lowest containment level	Low	Low	Low	Currently UN 3245 Proposal: exempt	Currently P904	EXEMPT GENETICALLY MODIFIED MICROORGANISMS or EXEMPT GENETICALLY MODIFIED ORGANISMS		Adapt 2.9.2.1 text
Waste containing GMMOs or GMOs	Low	Low	Medium to high	UN 3245	Currently P904	Currently fully marked and labeled (hazard label class 9)	Currently: transport	Use UN 3245 and add the

						package Proposal: only special marking and name WASTE, GENETICALLY MODIFIED MICROORGANISMS or WASTE, GENETICALLY MODIFIED ORGANISMS **UN 3245**	documentation Proposal: No transport documentation	word waste in front of proper shipping name

Note: Animals are excluded from this review