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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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Item 7 of the provisional agenda

MISCELLANEOUS PROPOSALS OF AMENDMENTS TO THE MODEL REGULATIONS ON THE TRANSPORT OF DANGEROUS GOODS

Transport of Genetically Modified Micro-organisms and Organisms or Living Modified Organisms (LMOs)

Transmitted by the European Biosafety Association (EBSA)[*]

Background

1. A draft version of a document proposing changes for genetically modified organisms and micro-organisms regulations and the addition of some plant pathogens was presented at the 32nd session of the Sub-Committee as informal document UN/SCETDG/32/INF.32. Recommendations made during the session and received subsequently invites EBSA to separate the document into two and to align the genetically modified organisms and microorganisms with the definitions of the Cartagena Protocol on Biosafety.

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

[*] In accordance with the programme of work of the Sub-Committee for 2007-2008 approved by the Committee at its third session (refer to ST/SG/AC.10/C.3/60, para. 100 and ST/SG/AC.10/34, para. 14)

3. 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 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.

4. However, current requirements for LMOs according to the UN Model regulations seem not to be in complete harmony with the Cartagena Protocol. Furthermore the definitions of LMO 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 third Meeting of the Parties (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.

5. To ensure harmonized regulations, it is EBSA's view that transport regulations should remain the responsibility of the UN Sub-Committee of Experts on the Transport of Dangerous Goods which produces the UN Model Regulations on the Transport of Dangerous Goods (Model Regulations).

6. 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 as follows:

Definitions and classifications

7. The Model Regulations define GMMOs and GMOs as follows:

> *2.9.1.2 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.*

8. With the aim of harmonization, we propose to adopt the definition of the Cartagena Protocol on Biosafety that has been broadly accepted by more than 140 countries and which reads:

> **"Living Modified Organism" (LMO) means any biological organism, with the exception of human beings, that possesses a novel combination of genetic material obtained through the use of modern biotechnology;**
>
> **"Living organism" means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;**
>
> **"Modern biotechnology" means the application of:**
>
> **(a) In vitro nucleic acid techniques, including recombinant deoxynucleic acid (DNA) and direct injection of nucleic acid into cells or organelles; or**
>
> **(b) Fusion of cells beyond of taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;**

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

> *2.9.2.1* (c) *GMMOs or GMOs which do not meet the definition of infectious substances (see 2.6.3) but which are capable of altering animals, plants or microbiological substances in a way not normally the result of natural reproduction. They shall be assigned to UN 3245*

10. This definition is ambiguous and when interpreted strictly it excludes most non-infectious LMOs since most of the LMOs, if accidentally released into the environment, may cross with other individuals of the same or closely related species as part of their natural reproduction.

11. Finally some LMOs are not subject to the Model Regulations as defined in:

> *2.9.2.1 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.*

12. Although this definition probably intends to exempt LMOs 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 LMOs that have received an authorization from the appropriate national authorities for release into the environment for the purpose of a field trial.

Exemptions

13. EBSA proposes the following exemptions:

LMOs 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 or UN 3373 as appropriate;

(b) They are commercially authorized for use by the appropriate national authorities of the States of origin, transit 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 or the environment. These LMOs 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 LMOs."

14. In summary living modified organisms would be shipped as UN 3245 (LMOs) if:

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

(b) They are not commercially approved in the countries of origin, transit and destination; or

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

Packing instruction and documentation

15. Materials that meet the definition of LMO are non-infectious for humans and animals. They may pose limited hazard to humans, animals or the environment. The risk posed by LMO 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 LMO materials pose no immediate consequence. In case of loss of containment, there is time for containment and clean-up. Therefore, EBSA proposes 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, labelled 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 an LMO 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.

[1] as defined in the European "Council Directive 98/81/EC of 26 October 1998 amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms" and the World Health Organisation (WHO) Laboratory Biosafety Manual, second revised edition [http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/]

Annex

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

CHAPTER 2.6

CLASS 6.2 – TOXIC SUBSTANCES AND INFECTIOUS SUBSTANCES

2.6.3 Division 6.2 - Infectious substances

2.6.3.1 *Definitions*

…

2.6.3.1.5 ***Living modified organism (LMO)*** ~~*Genetically modified micro-organisms and organisms (GMMOs or 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.~~ means any biological organism, with the exception of human beings, that possesses a novel combination of genetic material obtained through the use of modern biotechnology;

2.6.3.1.5.1 *Living organism* means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;

2.6.3.1.5.2 *Modern biotechnology* means the application of:

(a) In vitro nucleic acid techniques, including recombinant deoxynucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

(b) Fusion of cells beyond taxonomic family, that overcome natural physiological, reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;

…

2.6.3.4 *Living modified organisms (LMOs)* ~~**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.~~ LMOs meeting the definition of an infectious substance shall be assigned to UN 2814, UN 2900 or UN 3373 as appropriate. Other LMOs shall be classified according to Chapter 2.9.

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.~~ Living modified organisms (LMOs) means any biological organism, with the exception of human beings, that possesses a novel combination of genetic material obtained through the use of modern biotechnology.

2.9.2 Assignment to Class 9

2.9.2.1 Class 9 includes, inter alia:

(a) Environmentally hazardous substances which are not covered by other classes;

(b) 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);

(c) LMOs that shall be assigned to UN3245 except when:

(i) They meet the definition of an infectious substance. These shall be assigned to UN 2814, UN 2900 or UN 3373 as appropriate;

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

(iii) 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 or the environment for exporting and importing countries. These LMOs 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 LMOs.”

* as defined in the European “Council Directive 98/81/EC of 26 October 1998 amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms” and the World Health Organisation (WHO) Laboratory Biosafety Manual, second revised edition
[http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/]

CHAPTER 3.2

DANGEROUS GOODS LIST

UN No.	Name and description	Class or division	Subsi-diary risk	UN packing group	Special provi-sions	Limited and excepted quantities		Packagings and IBCs		bulk containers	
								Packing instruction	Special packing provisions	Instruc-tions	Special provisions
(1)	(2)	(3)	(4)	(5)	(6)	(7a)	(7b)	(8)	(9)	(10)	(11)
-	**3.1.2**	**2.0**	**2.0**	**2.0.1.3**	**3.3**	**3.4**	**3.5**	**4.1.4**	**4.1.4**	**4.2.5 / 4.3.2**	**4.2.5**
3245	~~GENETICALLY MODIFIED MICROORGANISMS or GENETICALLY MODIFIED ORGANISMS~~ LIVING MODIFIED ORGANISMS	9			219	0	E0	P904 IBC99			

CHAPTER 3.2

SPECIAL PROVISIONS APPLICABLE TO CERTAIN ARTICLES OR SUBSTANCES

219 ~~Genetically modified microorganisms and genetically modified organisms~~ Living modified organisms which meet the definition of an infectious substance and the criteria for inclusion in Division 6.2 in accordance with Chapter 2.6 shall be transported as UN 2814, UN 2900 or UN 3373, as appropriate.

APPENDIX A

LIST OF GENERIC AND N.O.S. PROPER SHIPPING NAMES

Class or Division	Subsidiary Risk	UN No	Proper Shipping Name
			CLASS 9
			General entries
9		3245	~~GENETICALLY MODIFIED MICROORGANISMS or GENETICALLY MODIFIED ORGANISMS~~ LIVING MODIFIED ORGANISMS

ALPHABETICAL INDEX OF SUBSTANCES AND ARTICLES

~~GENETICALLY MODIFIED MICRORGANISMS~~	~~9~~	~~3245~~
~~GENETICALLY MODIFIED ORGANISM~~	~~9~~	~~3245~~
LIVING MODIFIED ORGANISMS	9	3245

CHAPTER 4.1

USE OF PACKAGINGS, INCLUDING INTERMEDIATE BULK CONTAINERS (IBCs) AND LARGE PACKAGINGS

4.1.4 List of packing instructions

4.1.4.1 Packing instructions concerning the use of packagings

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, when shipping liquids. 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 which shall be strong enough for its capacity, mass and intended use, and the smallest external dimension shall be 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 square set at an angle of 45º (diamond-shaped) with each side having a length of at least 50 mm; width of the line shall be at least 2 mm and the letters and the numbers at least 6mm. The proper shipping name "LIVING MODIFIED ORGANISMS" in letters at least 6 mm high shall be marked on the outer packaging adjacent to the mark. In case of waste containing "LIVING MODIFIED ORGANISMS" the proper shipping name must be preceded by the word "WASTE".

(4) 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.

(5) Living modified organisms UN 3245 which are packed and marked in accordance with this packing instruction are not subject to any other requirement in these regulations.

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.

Living modified animals

Living modified animals shall only be transported under terms and conditions approved by the competent authorities of the exporting and importing countries.