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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

Thirty-fourth session
Geneva, 1-9 December 2008
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

Transmitted by the European Biosafety Association (EBSA)¹

1. Following the discussions of informal document UN/SCETDG/32/INF.32 and document ST/SG/AC.10/C.3/2008/29 during the 32nd and 33rd sessions of the Sub-Committee and the subsequent comments from members of the Sub-Committee, EBSA proposes the following amendments to the UN Model Regulations:

Part 2, Chapter 2.6

2. Under 2.6.3.1 Definitions, delete the definition of GMMO and GMO:

~~2.6.3.1.5 Genetically modified microorganisms and organisms are microorganisms and organisms in which the genetic material has been purposely altered through genetic engineering in a way that does not occur naturally.~~

¹ 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. Delete section 2.6.3.4:

~~2.6.3.4 **Genetically modified microorganisms and organisms**~~

~~2.6.3.4.1 Genetically modified microorganisms not meeting the definition of infectious substance shall be classified according to Chapter 2.9.~~

Justification:

4. GMMOs and GMOs are classified as Class 9, therefore the definition should appear under Class 9 (2.9.1.2).
5. If GMMOs or GMOs are toxic or infectious substances, then the requirements for transporting those materials apply, see Special Provision 219.

Part 2, Chapter 2.9

6. Reword paragraph 2.9.2.1 as follows: (new wording underlined):

“(a) GMMOs or GMOs which do not meet the definition of toxic (see 2.6.2) or 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.~~

GMMOs or GMOs are not subject to these Regulations when authorized for use by the competent authorities of the Governments of the countries of origin, ~~transit~~ and destination.

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

Justification

7. Based on the discussions at the 33rd session and the comments received subsequently, EBSA proposes to keep the existing definitions of GMOs and GMMOs instead of changing to the wording and definitions of the Cartagena Protocol.
8. The definition under 2.9.2.1 (c) is ambiguous and different from the definition on 2.9.1.2, so it is eliminated.
9. In the second paragraph of (c), the word “transit” has been eliminated. Is approval of a country of transit necessary for a GMMO or GMO, that is properly contained, during transport if it is authorized for use in the country of origin and destination? Cartagena Protocol does not have special requirements for transit states.
10. Genetically modified live animals must be transported in such a way that ensures survival of the animal during transport. The genetic modification of the live animal does not add a risk during transport, the decision is based mainly on the potential impact that such an animal species may have on introduction into the importing country environment.

Part 3, Chapter 3.3, Special Provisions applicable to certain articles or substances

11. Amend of Special Provision 219 to read as follows, (new wording underlined):

219 Genetically modified microorganisms (GMMOs) and genetically modified organisms (GMOs) packed and marked in accordance with packing instruction P904 are not subject to any other requirements in these Regulations.

If GMMOs or GMOs meet the definition in Chapter 2.6 of a toxic substance or an infectious substance and the criteria for inclusion in Division 6.1 or 6.2 in accordance with Chapter 2.6 shall be transported as UN 2814, UN 2900 or UN 3373, as appropriate the requirements in these Regulations for transporting toxic substances or infectious substances apply.

Justification

12. GMMOs and GMOs pose negligible to nil risk during transport. The marking, labeling and documentation requirements associated with their classification of Class 9, Miscellaneous dangerous substances and articles are onerous and do not add anything towards safety.

13. The Cartagena Protocol has requirements for documentation that are detailed and clearly designate the material as GMOs and GMMOs, therefore, continuing to impose the use of the dangerous goods transport document would not add anything to safety.

Part 4, Chapter 4.1

Replace Packing Instruction P904 by the following packing instruction based on P650 with a new additional requirement

4.1.4.1 Packing instructions concerning the use of packagings (except IBCs and large packagings)

P904	PACKING INSTRUCTIONS	P904
This instruction applies to UN 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; or		
2. The packaging shall be of good quality, strong enough to withstand the shocks and loadings normally encountered during transport, 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 transport by vibration or by changes in temperature, humidity or pressure.		

- (a) The packaging shall consist of at least three components:
 - (i) A primary receptacle;
 - (ii) A secondary packaging; and
 - (iii) An outer packaging of which either the secondary or the outer packaging shall be rigid.
- (b) Primary receptacles shall be packed in secondary packagings in such a way that, under normal conditions of transport, 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.
- (c) At least one surface of the outer packaging shall have a minimum dimension of 100 mm × 100 mm.
- (d) For liquid substances
 - (i) The primary receptacle(s) shall be leakproof;
 - (ii) The secondary packaging shall be leakproof;
 - (iii) 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;
 - (iv) 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) For solid substances
 - (i) The primary receptacle(s) shall be siftproof;
 - (ii) The secondary packaging shall be siftproof;
 - (iii) 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;
 - (iv) If there is any doubt as to whether or not residual liquid may be present in the primary receptacle during transport then a packaging suitable for liquids, including absorbent materials, shall be used.

3. For transport, the mark illustrated below shall be displayed on the external surface of the outer packaging on a background of a contrasting colour and shall be clearly visible and legible. The mark shall be in the form of a square set at an angle of 45° (diamond-shaped) with each side having a length of at least 50 mm; the width of the line shall be at least 2 mm and the

letters and numbers shall be at least 6 mm high. The proper shipping name “GENETICALLY MODIFIED ORGANISMS” or “GENETICALLY MODIFIED MICROORGANISMS” in letters at least 6 mm high shall be marked on the outer packaging adjacent to the diamond-shaped mark.



4. 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.
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.
6. GMMOs or GMOs assigned to UN 3245 which are packed and marked in accordance with this packing instruction are not subject to any other requirement in these Regulations.

Additional requirement:

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