



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

Sixtieth session

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Item 7 of the provisional agenda

Global harmonization of transport of dangerous goods regulations with the Model Regulations

Alternative text suggestion for paragraph 2.9.2 on genetically modified micro-organisms and genetically modified organisms

Transmitted by the expert from the Netherlands*

Introduction

1. During the fifty-ninth session of the Sub-Committee a working document (ST/SG/AC.10/C.3/2021/38) was presented by the International Civil Aviation Organization (ICAO) and the World Health Organization (WHO) to add explanatory wording on the transport of genetically modified micro-organisms (GMMOs) and genetically modified organisms (GMOs).

2. As explained in document ST/SG/AC.10/C.3/2021/38, concerns had been raised on the timely transport of COVID-19 vaccines containing GMMOs or GMOs. During the fifty-seventh session of the Sub-Committee, it was confirmed that, by definition, GMMOs were not subject to the UN Model Regulations when authorized for use by the competent authorities of the countries of origin, transit and destination. The Sub-Committee confirmed that this includes vaccines in clinical trials.

3. At the fifty-ninth session, there was wide support for the intention of the proposal by ICAO and WHO to amend the wording in paragraph 2.9.2. The text as adopted in the fifty-ninth session of the Sub-Committee reads as follows (adopted text underlined):

"Genetically modified micro-organisms (GMMOs) and genetically modified organisms (GMOs)

3245 GENETICALLY MODIFIED MICRO-ORGANISMS or
3245 GENETICALLY MODIFIED ORGANISMS

GMMOs and GMOs which do not meet the definition of toxic substances (see 2.6.2) or infectious substances (see 2.6.3) 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 countries of origin, transit and destination.

Pharmaceutical products (such as vaccines) that are ready for use, including those in clinical trials, and that contain GMMOs or GMOs are not subject to these Regulations.

* A/75/6 (Sect.20), para. 20.51

Genetically modified live animals shall be transported under terms and conditions of the competent authorities of the countries of origin and destination."

4. However, some delegates expressed concern on the wording of the proposal and wondered whether it would lead to a relaxation of the current regulations. For example, the wording "ready for use" led to a discussion as it was not clear what it exactly meant. Some delegations thought it should be clear that these pharmaceutical products should be authorized for use, not ready for use.

5. Also, the wording "Pharmaceutical products" raised concern as the applicability would be broader than currently stated in the Model Regulations. The representative of ICAO explained that this wording was necessary to also include the facilitation of the transport of new drugs to alleviate COVID-19 symptoms.

6. The expert from the Netherlands would like to propose an alternative text to take account of the concerns about the adopted text and at the same time providing the necessary clarity as requested by ICAO and WHO on the transport of pharmaceutical products containing GMMOs or GMOs.

Proposal

7. Amend the following sentence in 2.9.2 as follows (new text in **bold and underlined**):

"Genetically modified micro-organisms (GMMOs) and genetically modified organisms (GMOs)

3245 GENETICALLY MODIFIED MICRO-ORGANISMS or
3245 GENETICALLY MODIFIED ORGANISMS

GMMOs and GMOs which do not meet the definition of toxic substances (see 2.6.2) or infectious substances (see 2.6.3) shall be assigned to UN 3245.

GMMOs or GMOs (**including pharmaceutical products such as vaccines, containing or consisting of GMMOs or GMOs, including those used in clinical trials**) are not subject to these Regulations when authorized for use by the competent authorities of the countries of origin, transit and destination.

Genetically modified live animals shall be transported under terms and conditions of the competent authorities of the countries of origin and destination."
