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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**

**Fifty-ninth session**
Geneva, 29 November – 8 December 2021
Item 7 of the provisional agenda
**Global harmonization of transport of dangerous goods regulations with the Model Regulations**

# Exclusion of pharmaceutical products from UN 3245

**Submitted by the International Civil Aviation Organization (ICAO) and the World Health Organization (WHO)***

## Introduction

1. Genetically modified micro-organisms (GMMOs) and genetically modified organisms (GMOs) are substances assigned to Class 9 in accordance with provision 2.9.2 of the UN Recommendations. When GMMOs and GMOs were introduced in the Recommendations, the intent was to protect the environment from their inadvertent release during transport and it was not the intention to include pharmaceutical products containing GMOs or GMMOs.

2. Bearing in mind that pharmaceutical products, including vaccines and those that are in clinical trial phase, are, by definition, intended to be administered to humans or animals, it is least likely to cause any significant consequences to logistics personnel or to the environment in the case of inadvertent events during transportation. Albeit such extremely low risks for transportation of these pharmaceutical products and their palpable benefits for public and individual health, some cases were reported where it took prolonged time for clearance and complex administrative modalities, including emergency deployment of Ebola vaccine.

3. There has been an extensive discussion involving diverse stakeholders on the safe, compliant and timely shipment of the newly developed various biological types of vaccines for COVID-19 late 2020, especially given that some of the vaccines were based on a viral vector platform that is deemed as GMMO and should conform to the provision 2.9.2 mentioned above.

4. At the fifty-seventh session of the TDG Sub-Committee, WHO expressed concern if vaccines containing GMMOs were regulated for transport as UN 3245 that could cause complications in transport. The Sub-Committee expressed the view 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 (see 2.9.2). The Sub-

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

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Committee agreed that vaccines authorized for use, including those in clinical trials, are not subject to the UN Model Regulations as currently written.

5. Nevertheless, ICAO and WHO are of the opinion that a clearer text in the UN Model Regulations would help to avoid problems with the diverse stakeholders involved when shipping pharmaceutical products containing GMMOs or GMOs ready for use, and therefore this proposal of completing 2.9.2 is submitted.

# Proposal

6. ICAO and WHO proposes adding in 2.9.2 Assignment to Class 9 a last sentence to read as follows (new text in bold 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**."