

**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

20 June 2022

Sixtieth session

Geneva, 27 June – 6 July 2022

Item 3 of the provisional agenda

Listing, classification and packaging

Classification of Monkeypox virus

Transmitted by the expert from Germany

Introduction

1. The current outbreak of Monkeypox has triggered a debate in Germany on the classification of material and patient samples contaminated with the Monkeypox virus. According to the table in 2.6.3.2.2.1 of the UN Model Regulations, the Monkeypox virus is assigned to Category A, UN 2814 INFECTIOUS SUBSTANCE, AFFECTING HUMANS. This assignment, however, should be restricted to cultures of Monkeypox.
2. The Monkeypox virus was assigned to risk group 3 according to international guidelines (e.g. EU Directive 2000/54/EC). In the UN Model Regulations, it is classified as a pathogen of Category A (indicative list of pathogens of Category A, 2.6.3.2.2.1). This classification seems to be disproportionate, as it is inconsistent with the classification of other viruses of risk groups 3 and 4. Therefore, Germany believes it needs to be corrected.
3. The classification as risk group 3 is reserved to pathogens that can cause severe human disease, but for which effective prevention or treatment is available. There are two vaccines available for the prevention of Monkeypox, which are already licensed in the United States and in Canada (ACAM2000 as well as the newer vaccine JYNNEOS (also called Imvanex)). There is medication for the treatment of Monkeypox (Tecovirimat), which has recently also been licensed in the European Union. In contrast, risk group 4 comprises pathogens that can also cause severe human disease, but against which there is typically no effective prevention or treatment.
4. In the Model Regulations, a similar differentiation as for the risk groups is made with regard to Category A: here, the restriction “Category A (cultures only)” is assigned to pathogens of risk group 3, whereas for pathogens of risk group 4, Category A applies without restrictions.
5. The classification of the Monkeypox virus in Category A (without restrictions) is thus not justified by the risk group assigned to it and does not correspond to the assessment of other viruses of risk group 3 in the UN Model Regulations. Neither the transmissibility of Monkeypox virus nor the risk of spread among the population as compared to other viruses of risk group 3 (e.g. Hepatitis B virus, Hepatitis C virus, Human Immunodeficiency virus, Poliovirus, Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)) constitute particular grounds to assess the Monkeypox virus in the UN Model Regulations like the viruses of risk group 4 (e.g. Ebola virus, Marburg virus).

6. The current accumulation of cases of Monkeypox infection in non-endemic countries does not change this assessment. Transmission requires close physical contact or prolonged close contact or can also occur when using the same clothing or bed linen (1., 2.). This means that there is no or a very low risk of a general spread of the Monkeypox virus among the population. Moreover, large parts of the population may be at least partially protected against the disease because smallpox vaccinations were still administered during their childhood (3.). This means that especially the older generations, to whom a pathogen like the Monkeypox virus would normally pose a particular risk, might be in a good immunological situation.

7. Therefore, it is proposed to treat the Monkeypox virus like other viruses of risk group 3 and accordingly classify it as “Category A (cultures only)”. The restriction “cultures only” allows for the carriage of materials that are contaminated with relevant pathogens, e.g. diagnostic samples, and of clinical wastes in accordance with UN 3373 or UN 3291. In contrast, UN 2814, which is mandatory for pathogens of Category A, involves considerably higher costs and additional administrative effort and thus constitutes an enormous problem, especially considering the increased volume of samples in connection with the Monkeypox virus.

8. Germany is also preparing a multilateral agreement for ADR to allow for the carriage of patient samples and other materials potentially contaminated with the Monkeypox virus in accordance with UN 3373 or UN 3291 in the near future.

Proposal

9. In 2.6.3.2.2.1 amend the table “Indicative examples of infectious substances included in Category A in any form unless otherwise indicated (2.6.3.2.2.1 (a))” to read as follows (new text is underlined):

For UN 2814, in the column headed “Microorganism”, add “(cultures only)” after “Monkeypox virus”.

References

1. <https://www.cdc.gov/poxvirus/monkeypox/transmission.html>
 2. <https://www.who.int/emergencies/disease-outbreak-news/item/2022-DON385>
 3. <https://journals.asm.org/doi/10.1128/CVI.00148-07>
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