



**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****Forty-ninth session**

Geneva, 27 June – 6 July 2016

Item 3 of the provisional agenda

Listing, classification and packing**Classification of infected animals****Transmitted by the World Health Organization (WHO) and the Food
and Agricultural Organization (FAO)¹****Introduction**

1. The International Civil Aviation Organization (ICAO) presented an information paper to the forty-eighth session of the Sub-Committee highlighting issues raised in relation to classification criteria for infected animals which the twenty-fifth meeting of the ICAO Dangerous Goods Panel (DGP) determined needed to be considered by the Sub-Committee (informal document INF.39 (48th session)). This document is in follow-up to discussions on that paper. It contains a proposal to address inconsistencies between the following paragraphs in the Model Regulations: 2.6.3.1.3; 2.6.3.1.4; 2.6.3.6.1 and 2.6.3.6.2.

2. Sub-section 2.6.3.6 contains the regulations related to consigning live animals intentionally infected and animal material affected by pathogens. Paragraph 2.6.3.6.1 clearly renders the requirements for transporting intentionally infected and known or suspected of containing infectious substances to the competent authority.

3. Paragraph 2.6.3.6.1 refers to intentionally infecting animals. Such a technique is a scientifically proven method for propagating pathogens (culturing pathogens) for research purposes, and in such conditions, an intentionally infected animal would meet the definition in paragraph 2.6.3.1.3 for “*Cultures*” as a whole, alive or dead, or in part (specimens; affected animal material from such intentionally infected animals). Accordingly, the whole

¹ In accordance with the programme of work of the Sub-Committee for 2015–2016 approved by the Committee at its seventh session (see ST/SG/AC.10/C.3/92, paragraph 95 and ST/SG/AC.10/42, para. 15).

animal or an affected material driven from such intentionally infected animal would be assigned as Category A if the pathogen used in such infection process is of Category A or which would be assigned to Category A in cultures only.

4. Paragraph 2.6.3.6.2 relates to animal material from infected animals without clarifying whether such infection was natural or intentionally induced for the purpose of propagating pathogens. The absence of such clear demarcation induces an inconsistency with paragraph 2.6.3.1.4 for the following reasons:

(a) Paragraphs 2.6.3.1.3 and 2.6.3.1.4 are in the regulations to help in the classification of infectious substances listed under Category A pathogens as (Culture only).

(b) Under 2.6.3.1.4, it does not specify the condition of the human or animal whether live or dead, nor does it address the condition of natural or intentional infection. If a patient specimen is obtained from a human or animal, regardless of whether alive or dead, for the purposes stated under this paragraph is transported, and the pathogen is listed under Category A culture only pathogens, it would be transported as Category B.

(c) Paragraph 2.6.3.6.2 assigns affected material into Category A if the material is driven from animal, while under paragraph 2.6.3.1.4 it would be transported as Category B if the material is driven from human or animal.

(d) The above results in a contradiction with respect to classification for the same pathogen depending on whether the specimen is driven from an animal or from a human.

(e) Furthermore, the definition under paragraph 2.6.3.1.3 clearly differentiates a culture from patient specimens with the word “intentionally”. Such demarcation is achieved in paragraph 2.6.3.6.1, but not in 2.6.3.6.2 which produces a contradiction in the classification of the same infectious substance using articles 2.6.3.1.4 and 2.6.3.6.2 as in the below example.

(f) According to paragraph 2.6.3.6.2; animal material (e.g. liver tissue) affected with *Bacillus anthracis* would be shipped as a Category A infectious substance, while the same tissue from a human or animal affected by *Bacillus anthracis* would be shipped as Category B in accordance with paragraph 2.6.3.1.4

(g) Considering the risk-based approach for classifying infectious substances, paragraph 2.6.3.6.2 needs to be revisited to avoid such inconsistency.

Proposal

5. The following proposed amendments will remove such inconsistency:

(a) Paragraph 2.6.3.6.2 to be modified to limit the source of affected animal material to those obtained from intentionally infected animals for the purpose of propagating the pathogens as follows: (new text is underlined): “Animal material from animals intentionally infected for the purpose of propagating pathogens of Category A or which would be assigned to Category A in cultures only, shall be assigned to UN No. 2814 or UN 2900 as appropriate. Animal material infected by pathogens of Category B other than those which would be assigned to Category A if they were in cultures shall be assigned to UN No. 3373.”

(b) As such, animal material from naturally infected live or dead animals would follow the normal classification described under paragraph 2.6.3.1.4 or they will meet the classification requirements of Category A under paragraph 2.6.3.2.2.1 if the pathogen is unknown and the appropriate authority classifies the causative infectious substance as such. For example: In case of a massive die-off in birds occurs, and it was caused by an unknown pathogen that would meet the definition of Category A under paragraph 2.6.3.2.2.1, the pathogen would be transported as Category A infectious substance even if it is not listed in 2.6.3.2.2.1(a) table under Category A (culture only), based on the appropriate risk assessment of the outbreak by the competent authority. The same classification will apply in case of a human outbreak with an unknown pathogen that meets the definition of Category A.

Extract from the Model Regulations of the above paragraphs is listed below to assist in highlighting the inconsistency:

2.6.3.1.3 *Cultures* are the result of a process by which pathogens are **intentionally propagated**. This definition does not include human or animal patient specimens as defined in 2.6.3.1.4

2.6.3.1.4 *Patient Specimens* are human or *animal materials*, collected directly from humans or animals, including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluid swabs, and body parts being transported for purposes such as research, diagnosis, investigational activities, disease treatment and prevention.

2.6.3.6.1 Unless an infectious substance cannot be consigned by any other means, live animals shall not be used to consign such a substance. A live animal which has been **intentionally infected** and is known or suspected to contain an infectious substance shall only be transported under terms and conditions approved by the competent authority.

2.6.3.6.2 *Animal material* affected by pathogens of Category A or which would be assigned to Category A in cultures only, shall be assigned to UN No. 2814 or UN No. 2900 as appropriate. Animal material affected by pathogens of Category B other than those which would be assigned to Category A if they were in **cultures** shall be assigned to UN No. 3373