

Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals

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Listing, classification and packing

Comments on ST/SG/AC.10/C.3/2016/35: Classification of infected animals – revised proposal

**Transmitted by the World Health Organization (WHO) and the Food
and Agricultural Organization (FAO)¹**

Introduction

1. This document is in follow-up to discussions on the working document ST/SG/AC.10/C.3/2016/35.
2. It contains two options (option 1 and option 2) to address inconsistencies between the following section/paragraphs in the Model Regulations: 1.2.1; 2.6.3.1.4; and 2.6.3.6.2, and the rationales behind the proposed amendments.

Background

3. Subsection 1.2.1 (Definitions), the definition of “Animal material”, needs further clarification in relation to “animal foodstuffs”. The word foodstuffs is used as human food in section 7.1.7.1 (Division 6.1 Toxic substances) and 2.2.2.4 (foodstuffs, including carbonated beverages in relation to Gases in Part 2.2) in the Model Regulations. The original intention to include “animal foodstuffs in section 1.2.1 was to describe feed for animals specifically of animal origin such as “Meat and bone meal”.
4. Subsection 1.2.1 (Definitions), the definition of “Animal material”, needs further clarification to avoid conflict with paragraph 2.6.3.1.4 which defines what is considered as a “Patient specimen”.
5. Paragraphs 2.6.3.1.3 and 2.6.3.1.4 are to help classification of infectious substances, in particular those listed as Category A (Cultures only).
6. Paragraph 2.6.3.6.2 relates to animal material from infected animals without clarifying whether such infection was natural or intentionally induced. An intentionally

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).

induced infection starts a process to propagate pathogens. The demarcation of natural or intentional infection is therefore needed for proper classification within Class 6.2, infectious substances.

7. Paragraph 2.6.3.6.2 enforces a specific classification on animal material affected by pathogens of Category A which creates inconsistency with definitions in section 1.2.1 and paragraph 2.6.3.1.4. without clearly defining the basis for such enforced classification.

8. Paragraph 2.6.3.6.2 classifies animal material affected by pathogens of Category A (Cultures only) similar to the definition set forth under paragraph 2.6.3.1.3, i.e. as Cultures. Such enforced classification opens the door for two possible classification for an animal material affected by pathogens of Category A (cultures only). In other words, as per the definition in 2.6.3.1.4, such animal material would be classified as category B, while as paragraph 2.6.3.6.2, it will be classified as Category A.

9. The criteria for classification of infectious substances is well defined in paragraph 2.6.3.2; which is risk based. It is expected that users of these regulations should follow these criteria when classifying infectious substances.

10. The current text in paragraphs 1.2.1, 2.6.3.1.4 and 2.6.3.6.2 need to be amended in order to ensure clarity and proper, consistent and risk based classification of infectious substances in line with the provisions related to Class 6.2 in the Model Regulations, this informal paper presents two proposals with amendments to be introduced in specific paragraphs to resolve the above mentioned inconsistencies.

Option 1

11. The following proposed amendments will remove such inconsistency. New text is underlined and deleted text is ~~strike through~~:

1. Section 1.2.1, Definition of animal material, to be modified as follows:

Animal material means animal carcasses, animal body parts, or ~~animal foodstuffs~~ feedstuffs derived from animals, transported for the purposes of disposal.

Rationale: introducing the purpose of transport, in this case, “for disposal”, clearly differentiates animal material from patient specimens for the purpose of classification. Additionally, “animal foodstuff” should be replaced by “feedstuffs derived from animals” which is the correct terminology. An example of this category is ‘meat and bone meal’ the transport of which became an international issue in mid-90s.

2. Paragraph 2.6.3.1.4 to be modified as follows:

Patient Specimens are ~~human or animal materials,~~ those 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.

Rationale: removing the words “animal material”, eliminates the inconsistency between this definition and the definition of animal material under 1.2.1. it also differentiates the purposes for consigning the material whether for disposal or for research, diagnosis, investigational activities, disease treatment and prevention

3. Paragraph 2.6.3.6.2 to be modified as follows:

“Animal material naturally affected ~~infected~~ by pathogens of Category A ~~or which would be assigned to Category A if they were in cultures only~~ shall be assigned to UN No. 2814 or UN No. 2900 as appropriate. Animal material naturally affected ~~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. The competent authority may determine that classification as Category A is warranted based on the risk assessment of the infectious substance concerned.”

Rationale: Introducing the word “naturally” clearly facilitates the classification of infectious substances of Category A in culture only. If the animals were intentionally infected, it would meet the criteria for Category A culture only, and would be classified as Category A infectious substances. if the animal material is from naturally infected animals, with pathogen which are of Category A in culture only, it will follow the definition of patient specimen and will be consigned as Category B. Adding the text related to competent authority, gives a room for such authority, be it national or international, to determine higher or more stringent classification (Category A).

Option 2

12. The following proposed amendments are alternative to proposal #1. New text is underlined and deleted text is ~~strikethrough~~:

1. Section 1.2.1, Definition of animal material, to be modified as follows:

Animal material means animal carcasses, animal body parts, or ~~animal foodstuffs~~ feedstuffs derived from animals.

Rationale: “animal foodstuffs” should be replaced by “feedstuffs derived from animals” which is the correct terminology. An example of this category is ‘meat and bone meal’ the transport of which became an international issue in mid-90s.

2. Paragraph 2.6.3.1.4 to be modified as follows:

Patient Specimens are ~~human or animal materials~~, those 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.

Rationale: removing the words “animal material”, eliminates the inconsistency between this definition and the definition of animal material under 1.2.1.

3. Paragraph 2.6.3.6.2 to be modified as follows:

“Animal material affected by pathogens of Category A ~~or which would be assigned to Category A if they were in cultures only~~, pathogens of Category B shall be assigned to UN No. 2814, or UN No. 2900 or UN No. 3373 as appropriate following the criteria defined in 2.6.3.2. 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.~~”

Rationale: the proposed changes removes the enforced classification for animal material affected by pathogens of Category A if they were in cultures only, ensures

consistency with the risk based approach defined under 2.6.3.2, renders the responsibility of classification to the competent authority and eliminates the inconsistency with paragraph 2.6.3.1.4.
