



WORKING PAPER

**DANGEROUS GOODS PANEL (DGP)
WORKING GROUP MEETING (DGP-WG/16)**

Montreal, 17 to 21 October 2016

Agenda Item 2: Development of recommendations for amendments to the *Technical Instructions for the Safe Transport of Dangerous Goods by Air (Doc 9284)* for incorporation in the 2019-2020 Edition

2.3: Part 3 — Dangerous Goods List, Special Provisions and Limited and Excepted Quantities

CLASSIFICATION CRITERIA FOR INFECTED ANIMALS

(Presented by M. Samaan)

SUMMARY

This working paper invites the DGP-WG to discuss, comment, and provide suggestions on a proposal to revise the classification criteria for infected animals in the UN Model Regulations contained in a joint WHO/FAO working paper submitted for consideration at the 50th Session of the United Nations Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals (UNCETDG) (28 November to 6 December 2016).

Action by the DGP-WG: The DGP-WG is invited to discuss and provide comments and suggestions on the proposed amendments to the UN Model Regulations contained in Appendix D. The comments will be taken into consideration when the proposal is considered at the 50th Session of the UNCETDG.

1. INTRODUCTION AND BACKGROUND

1.1 The classification criteria for infected animals in the Technical Instructions was addressed and discussed at the twenty-fifth meeting of the Dangerous Goods Panel (DGP-WG/25, Montreal, 19 to 30 October 2015), and amendments to the Technical Instructions and the Supplement were agreed (see paragraph 3.3 of the DGP-WG/25 Report). The amendments initiated a need for amending the text of similar paragraphs in the UN Model Regulations.

1.2 The World Health Organization (WHO) and the Food and Agriculture Organization (FAO) submitted a working paper to the UN Sub-Committee of Experts on the Transport of Dangerous Goods at the 49th Session (27 June to 6 July 2016) proposing an amendment to the text of the UN Model Regulations. The jointly submitted working paper (see ST/SG/AC.10/C.3/2016/35, reproduced in Appendix A) addressed an inconsistency in the classification criteria for animal material which was related to the text of paragraph 2.6.3.6.2 of the UN Model Regulations under “Infected animals”. The joint working paper was revised during the 49th Session with two options provided for consideration (see ST/SG/49/INF.72, reproduced in Appendix B).

1.3 The Sub-Committee’s decision was to give time for competent authorities to provide comments via email communication, and a new revised proposal would be submitted for decision at the 50th Session of the UNCETDG in December 2016.

1.4 WHO and FAO circulated by email a revised proposal to the Committee delegates in August for feedback. Comments received from Canada and the United States are included in this working paper (see Appendix C).

1.5 WHO and FAO amended the draft revised proposal which was submitted to the UNCETDG Secretariat in early September (see ST/SG/AC.10/C.3/2016/77, reproduced in Appendix D).

1.6 WHO would like to present the proposed amendment provided in Appendix D to DGP-WG/16 for discussion so as to collect further comments/thoughts to refine the proposal to ensure alignment between the Technical Instructions and the Model Regulations.

2. ACTION BY THE DGP-WG

2.1 The DGP-WG is invited to discuss and provide comments and suggestions on the proposed amendments to the UN Model Regulations contained in Appendix D. The comments will be taken into consideration when the proposal is considered at the 50th Session of the UNCETDG in December 2016.

APPENDIX A

**PROPOSED AMENDMENT TO CLASSIFICATION CRITERIA FOR INFECTED ANIMALS
SUBMITTED BY THE WORLD HEALTH ORGANIZATION (WHO) AND THE FOOD AND
AGRICULTURE ORGANIZATION OF THE UNITED NATIONS (FAO) FOR
CONSIDERATION BY THE UNITED NATIONS SUB-COMMITTEE OF EXPERTS ON THE
TRANSPORT OF DANGEROUS GOODS AT THE 49TH SESSION**

(ST/SG/AC.10/C.3/2016/35)



**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

APPENDIX B

REVISION TO THE PROPOSED AMENDMENT TO CLASSIFICATION CRITERIA FOR INFECTED ANIMALS IN ST/SG/AC.10/C.3/2016/35 (APPENDIX A) SUBMITTED BY THE WORLD HEALTH ORGANIZATION (WHO) AND THE FOOD AND AGRICULTURAL ORGANIZATION (FAO) FOR CONSIDERATION BY THE UNITED NATIONS SUB-COMMITTEE OF EXPERTS ON THE TRANSPORT OF DANGEROUS GOODS AT THE 49TH SESSION

(ST/SG/49/INF.72)

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

1 July 2016

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

**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.

APPENDIX C

QUESTIONS AND COMMENTS RECEIVED FROM UNCETDG DELEGATES ON THE WHO/FAO REVISED PROPOSAL (CONTAINED IN APPENDIX B)

1. COMMENTS FROM THE UNITED STATES DEPARTMENT OF AGRICULTURE, ANIMAL AND PLANT HEALTH INSPECTION SERVICE

We have reviewed the most recent document (<http://www.unece.org/fileadmin/DAM/trans/doc/2016/dgac10c3/UN-SCETDG-49-INF72e.pdf>) and deem Option 2 a better choice for various reasons as well, including the fact that Option 1 appears to restrict animal material transported for disposal ONLY. It is important to note that animal material (e.g., carcasses) may also be transported for further testing (e.g., diagnosis, necropsy, etc.) as part of USDA's mission (this could very well be the case with other governmental, academic, and private institutions as well). For example, collecting field specimens for surveillance purposes (i.e., further testing), or die-offs due to outbreaks. Also, this may occur domestic or internationally.

Additional comments for consideration are as follows:

- a) The classification of live animals or body parts from intentionally infected animals needs to be clarified. Could that be achieved by updating the definition of "Cultures"? Elsewhere in the regs? Also, see next bullet.
- b) We believe that a previous APHIS concern regarding the definition of "Cultures" (2.6.3.1.3) has not been addressed. Will the definition be updated in such a manner that it is very clear it does include (or not) live (and/or dead) intentionally infected animals, or animals that may reasonably be expected to contain an infectious substance by an appropriate authority? Grant it, transportation of live animals may require a very different approach as animal welfare regulations and importation/transport permits may dictate certain transportation requirements. The new language seem to categorize dead animals (e.g., carcasses) under the definition of "Animal Material." Also, the definition of "Patient Specimens" does not include whole animals, but rather materials collected from animals.

The regulations currently state:

"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"

Originally, the regulations stated:

“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).”

Furthermore,

“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.”

The regulation as written seems to be contradictory. Are infected (or suspected to be infected) live animals regulated or not? OR perhaps Section 2.6.3.6.1 above as written may refer to additional requirements (above and beyond UN Transportation Regulations) that may need to be followed when transporting live animals? Again, this needs to be clarified.

The competent authority in this case may very well be OIE, FAO, USDA, or the CDC. Also, animal welfare regulations may apply, which may stipulate live animal transportation requirements. Having said that, if we were to take into account a sound risk assessment, these live animals could very well be shedding infectious substances (e.g., viruses) during transport. Therefore, should be transported in such a manner that transportation personnel is protected, as well as the public and the environment.

2. **COMMENTS FROM CANADA ON THE SUBJECT PAPER:**

- a) Section 1.2.1 “Definitions”, adding the purpose “...for disposal purposes” to the current definition in the Model regulations:

Question: Is there a reference for the original intention? Why exclude animal material intended for human consumption?

- b) Paragraph 2.6.3.1.4, definition of “Patient Specimens”. Canada is in agreement with the revised text under point 11.2 in the revised proposal below.
- c) Paragraph 2.6.3.6.2; With the proposed change from affected to infected, the modification provides clarity. However, animal material infected with bacillus anthracis would be classified as Category B. Is this the intention of paragraph 2.6.3.6.2?

APPENDIX D

**REVISION TO AMENDMENT PROPOSED IN ST/SG/49/INF.72 (APPENDIX B) SUBMITTED
BY THE WORLD HEALTH ORGANIZATION (WHO) AND THE FOOD AND
AGRICULTURAL ORGANIZATION (FAO) FOR CONSIDERATION BY THE UN SUB-
COMMITTEE OF EXPERTS ON THE TRANSPORT OF DANGEROUS GOODS AT THE
50TH SESSION**

(ST/SG/AC.10/C.3/2016/77)



**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****Fiftieth Session**

Geneva, 28 November-6 December 2016

Item 2 (c) of the provisional agenda

**Recommendations made by the Sub-Committee
on its forty-seventh, forty-eighth
and forty-ninth sessions and pending issues:
listing, classification and packing****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 of the forty-ninth session. At that session two amendment options were proposed in a revised informal document INF.72 following a working group discussion. Option 2 was favoured in the discussion after, but more time was required for delegates to consult with competent authorities and for further consultation by email.

2. The proposed amendments are 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.

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).

Background

3. In section 1.2.1 (Definitions of the Model Regulations), the definition of “Animal material” requires the addition of a term 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 food and feed derived from animals (specifically of animal origin) such as “Meat and bone meal”. Addition of feedstuffs and specifying the origin of both foodstuffs and feedstuffs, will achieve clarity.

4. Paragraphs 2.6.3.1.3 and 2.6.3.1.4 are in the Model Regulations to help classification of infectious substances, in particular those listed as Category A (cultures only).

5. 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 induced infection starts a process to propagate pathogens. The introduction of this paragraph was probably related to transport of large quantity of animal carcasses affected by pathogens listed under Category A (cultures only).

6. 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.

7. 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.

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

9. 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, by the competent authority, in line with the provisions related to Division 6.2 in the Model Regulations, this working document presents the proposed amendments to resolve the above mentioned inconsistencies.

Proposal

10. The following amendments are proposed. 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 or feedstuffs derived from animals.

Rationale: According to definitions by FAO, “Food” refers to edible material consumed by human and “Feed” refers to edible material consumed by animals (not including human). Adding both in the above definition covers both types of material and adding its source reaffirms its origin.

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~~, by 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.
