ANNEX 2

DRAFT EU COMMENTS

ON THE PROPOSED CHANGES TO THE

OIE MANUAL OF DIAGNOSTIC TESTS AND VACCINES FOR TERRESTRIAL ANIMALS

PRESENTED FOR COMMENTS IN NOVEMBER 2012

DRAFT EU COMMENTS
On the proposed changes to the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals

SUMMARY:

DRAFT EU COMMENTS
On the proposed changes to the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals

CHAPTER 1.1.1: Collection of diagnostic specimens

General comments

The EU can in general support this revised chapter and has a few specific comments.

Specific comments

LINE 27: Please replace the word "transport" by "storage", in line with the amended title of the chapter. Furthermore, the EU suggests adding a reference also to Chapter 1.1.2 "Transport of specimens of animal origin" to this first paragraph.

LINES 38 and 42: Please add a full stop.

DRAFT EU COMMENTS
On the proposed changes to the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals

CHAPTER 1.1.2: Shipment of diagnostic specimens

General comments

The EU can in general support this revised chapter and has some specific comments.

Specific comments

LINE 93: Please replace the word "shipper" by "sender" in order to avoid confusion. Indeed, "sender" is the term used in the preceding paragraph and as title of the point a) at line 95.

LINES 228 and 245: Please replace the word "shipper" by "sender" also here in order to avoid confusion.

LINES 278-279: The title doesn't seem to match the content of this section. Therefore, the EU suggests the following wording: "Additional information on WHO, UN and other international and national transport guidance"

DRAFT EU COMMENTS
On the proposed changes to the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals

CHAPTER 1.1.3: Biosafety and biosecurity in the veterinary microbiology laboratory and animal facilities

General comments

The EU can in general support this revised chapter and has some specific comments.

Specific comments

LINE 22: Please insert the word "Terrestrial" before the word "Manual".

LINE 174: Please remove the parenthesis around "or may be qualitative".

LINE 175: Please add a full stop after the parenthesis.

LINE 313: Please add "including continuing training of personnel" at the end of the sentence (after "management reviews"). Indeed, training and continuous education of personnel is a key component of biorisk management.

DRAFT EU COMMENTS
On the proposed changes to the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals

CHAPTER 1.1.5: Principles and methods of validation of diagnostic assays for infectious diseases

General comments

This represents a welcome updating of general guidelines for test validation – the suggested approach is more pragmatic but the chapter still has sufficient detail to describe the "ideal" situation for validation. This provides a framework to work towards but, importantly, the chapter recognises that in the "real world" it is sometimes difficult to carry out some validations steps. There are sound practical suggestions to how to deal with common challenges while at the same time emphasising that it is important to recognise and where possible calculate uncertainty in results. The chapter is has good advice throughout that has managed to strike the right balance between detail and providing overall guidance. The approach of a step wise path to validation has been supplemented with more emphasis on the need for continual validation and the desirability of efforts such as on-going data analysis and ring trials.
The EU therefore in general supports this revised chapter and has some specific comments.

Specific comments

LINES 43-45: There seems to be an issue with the wording of this sentence. It is suggested to delete the words "This chapter also provides" (lines 43-44) and "the chapter's appendices" (line 45), as the guidelines are not part of the chapter and will be pulished on the OIE's website.

LINE 136: Please replace "optimization" by "optimisation" (for consistency with lines 274 and following).

LINE 739 [description under Table 2]: Please insert "OIE" before "validation guideline" (for consistency and to avoid confusion).

LINE 883: Similarly, please insert "OIE validation" before the word "guideline".

DRAFT EU COMMENTS
On the proposed changes to the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals

CHAPTER 2.1.4x: Crimean-Congo haemorrhagic fever

General comments

The EU can in general support the proposed new chapter and has some specific comments.

Specific comments

LINES 18-19: The EU suggests deleting the sentence "*The S segment is ambisense RNA, i.e. has bi-directional coding*", as to our knowledge it has not been demonstrated that the S-segment of CCHFV codes for an additional protein than the nucleocapsid protein.

LINES 78-79: The necessity to conduct laboratory tests in maximum security facilities pertains only to work with live virus, which should be specified here. In some endemic countries, laboratory tests for CCHF are conducted in BSL 2 and BSL 3 laboratories.

LINE 97: Since nowadays nucleic acid detection techniques are the most used diagnostic tool, the EU suggests inserting the words "detection of viral RNA and/or" before the words "isolation of virus from serum or liver specimens".

LINE 111: Similarly, the words "PCR or" should be inserted before the "isolation in mammalian cells".

LINES 117-118: Today, several validated and very sensitive PCR methods are available and are often used as gold standard methods for the identification of CCHV. The results of the PCR tests are confirmed by sequencing and serology. On the other hand, virus isolation requires a high containment laboratory which limits use of these assays (reference: Emerg Infect Dis. 2012 Dec;18(12):1958-65. and PLoS Negl Trop Dis. 2012;6(6):e1706).
The EU therefore suggests amending the sentence as follows:
"Molecular-based diagnostic assays, such as the reverse transcriptase polymerase chain reaction (RT-PCR), serve as the front-line tool in the diagnosis of CCHF […]"

LINE 121: Please replace "8" by "a few", as depending on the laboratory and methodology used, results can be available in less than 8 hours.

LINES 292-295: Since it seems difficult to draw convincing conclusions from this one study, the EU suggests deleting the sentence starting with "Mice orally immunised […]".

DRAFT EU COMMENTS
On the proposed changes to the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals

CHAPTER 2.1.10: Screwworm (*Cochliomyia hominivorax* and *Chrysomya bezziana*)

General comments

The EU can support this revised chapter.

Specific comments

None

DRAFT EU COMMENTS
On the proposed changes to the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals

CHAPTER 2.1.13: Rabies (vaccine section)

General comments

The EU can in general support this revised chapter and has some specific comments.

Specific comments

LINES 39-40: The EU suggests removing the word "high" before "risk" and only leave "risk", as the level of risk is clearly variable between carnivorous pets and certain livestock (i.e. cattle). Furthermore, the wording "should be included in any national vaccination programmes" is rather prescriptive and should be replaced by "would benefit from inclusion in any national vaccination programme".

LINE 59: The EU suggests inserting the words "coding for rabies virus glycoprotein" before the words "into a vector" to clarify that only part of the genome is inserted into a vector and not the whole genome.

LINES 294 and 306: In both lines, please add "or an alternative test if shown to generate equivalent results" at the end of the sentence as other test methods may also be used if they produce equivalent results (e.g. FAVN).

LINE 643: As it is not clear what exactly is meant by "virulent challenge test", the EU suggests replacing this by "using the virulent virus strain in the challenge tests".

LINE 653: Please remove the "0" after the word "Ten" (typo).

LINE 678: It should be clarified what is meant by a labelling system, i.e. it has to be clear that labels are not required directly on the bait itself as this is not possible in practice.

LINE 680: The EU suggests deleting the words "in the field", as it is not possible in practice to maintain 25 °C over a period of 5 days under field conditions, especially during certain times of the year and in certain parts of the world e.g. in Central Europe.

DRAFT EU COMMENTS
On the proposed changes to the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals

CHAPTER 2.1.20: West Nile fever

General comments

The EU can in general support this revised chapter and has some specific comments.

Specific comments

LINE 100: A sentence should be added at the end of this paragraph saying that, unlike veterinary vaccines available for horses, there are no vaccines available for use in humans.

LINE 120: Please replace "WHV" by "WNV" (typographical error).

LINE 142: The rationale for selecting the PCR described by Eiden *et al*. should be made clear, i.e. if it has the best sensitivity and specificity, that should be mentioned.

LINE 160: As regards the clause "it is important that the designs of PCR tests are constantly monitored", the EU is of the opinion that it is not sufficient to simply monitoring their designs. Indeed, PCR tests need to be monitored and updated in response to detection of novel viruses where appropriate. Therefore, the EU suggests adding the words "and updated if and when necessary" at the end of the sentence.

LINE 368: As regards the sentence "In contrast to the IgM capture ELISA, vaccinated horses often test positive in the indirect or competitive ELISA tests", this could be interpreted as indirectly stating that vaccinated horses will not be positive by capture ELISA, even after recent vaccination. This should be made clear, preferably with a reference for the evidence, as it has implications for international trade. Furthermore, a reference to table 1 would be useful here in this connection.

DRAFT EU COMMENTS
On the proposed changes to the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals

Section 2.2: Apinae – Introduction note on bee diseases

General comments

The EU can in general support the proposed changes to this introductory note but has some specific comments, the last of which is important.

Specific comments

LINES 4-7: The EU suggests slightly redrafting this first paragraph in order to improve readability and clarity, and to add a sentence on the characteristic and the epidemiological implications of honey bee colonies being a super-organism, as follows:

"[…]. There are many thousands of bee species, most of which are not social, but solitary insects. The honey bees, *Apis* species, are a family of social insects, which live in colonies. A honey bee colony is a super-organism with important implications for disease epidemiology, where disease transmission both at the individual level and at the colony level needs to be considered. […]."

LINE 11: Please add the words "that are currently recognised" after the words "There are 24 races of A. mellifera", as more might be discovered in the future.

LINE 27: Please replace the word "medication" by "medicinal products", as this is the correct term used in other OIE standards.

LINES 30-31: Since sampling of dead bees, if present, can be very important in the diagnosis of bee diseases, the EU suggests amending the sentence by adding the following:

"When sampling a colony of bees for diagnosis of diseases, sampling of dead bees in or outside of the hive, if present, might best reflect the health status of the colony. If live bees are to be sampled, these must first be killed with diethyl ether or in a deep freezer (–20°C) overnight."

LINES 36-39: The EU strongly suggests removing this last sentence, as it refers to the listing of diseases of honey bees in the Terrestrial Code and the criteria for so doing, and is therefore misplaced here and does not add to this introductory text.

DRAFT EU COMMENTS
On the proposed changes to the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals

CHAPTER 2.2.4: Nosemosis of honey bees

General comments

The EU can in general support this revised chapter and has some specific comments.

Specific comments

LINE 7: As both *Nosema* species can infect both species, the EU suggests replacing the words "The latter" by the following:

"Both parasites are cross-infective between host species. *Nosema ceranae* has recently been detected […]"

LINE 11: Please replace the word "in" by the word "at" before the words "high temperature" (language).

LINE 31: Please replace the word "fumigation" by the words "treatments of honey bees", as not only fumigation but also other types of antibiotic treatments are prohibited in many countries.

LINE 44: For clarity reasons, please replace the words "This method" by "Staining"

LINE 81: Please replace the word "defeacation" by the word "defecation" (typo).

LINE 218: The recommended PCR method might not be the best alternative for molecular diagnostics. Several molecular diagnostic markers have been compared in a recent publication (Erler *et al*., 2011. Parasitol. Res. 110(4): 1403–1410.), and problems with misamplification have been reported. Recently, and in press, an alternative qualitative PCR method has been recommended by many researchers (Fries *et al*., 2013, Journal of Apicultural Research 52(1)), and could possibly be considered also here.

LINE 120: Please replace the word "to" by the word "of" before the words "the hive" (language).

DRAFT EU COMMENTS
On the proposed changes to the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals

CHAPTER 2.2.5: Small hive beetle infestation (*Aethina tumida*)

General comments

The EU can in general support this revised chapter and has some specific comments.

Specific comments

LINE 45: Please replace the word "Greater" by the word "More" before the words "than 1000 adult beetles" (language).

LINE 109: Please add the words "levels of" before "infestations" (language).

LINES 124 and 167: The words "et al." should be italicised.

LINE 142: Please remove the word "in" before "which you" (language).

LINE 175: Please replace the word "per" by "in accordance with" (language).

LINE 176: Please replace the words "We make no specific trap recommendations here" by "No specific trap recommendations are made here" (language).

DRAFT EU COMMENTS
On the proposed changes to the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals

CHAPTER 2.3.2: Avian infectious bronchitis

General comments

The EU can in general support this revised chapter and has some specific comments.

Specific comments

LINE 9: The EU suggests replacing "bacterial pathogens leading to" by "other pathogens including bacteria. This can lead to", as also other types of pathogens may be involved.

LINE 11: Please replace the words "an ascending" by "a rising" (language).

LINE 13: Please replace the word "isolation" by "detection methods".

LINE 18: Please remove the word "only" in the parenthesis, as also other birds may be affected.

LINE 19: Please insert the words "and/or monitoring" after "sero-diagnosis".

LINE 26: Please replace the word "embryos" by "embryonated eggs" and insert the word "chicken" before "tracheal organ cultures".

LINE 28: Please replace the word "usually" by "often".

LINE 83: Please insert the words "and/or identifying" before "the causative" and add "of IBV" at the end of the sentence.

LINE 120: Please insert the words "SPF embryonated chicken" before "eggs".

LINE 121: Please insert the word "SPF" before "embryonated"; and "and/or" before "TOCs".

LINE 197: Please insert the words "for example" before "Massachusetts".

LINE 198: Please replace the word "are" by "may be" after "JMK".

LINE 200: Please insert the following after the words "have also been developed":

"[…] and primer sets may be used based on contemporary IBV serotypes circulating in a geographic region inserted".

LINE 264: Please insert the word "serial" before "sera from young".

LINE 351: Please insert the word "strain" before "(United Kingdom)".

LINE 355: Please add the words "subject to local legislative requirements" at the end of the sentence.

LINE 385: Please replace the words "relatively hard to please" by "being excessive as".

LINE 386: Please insert the words "in egg production" before "may be regarded as satisfactory".

LINE 389: Please insert the words "in egg production" before "for Massachusetts types to be".

LINE 421: Please insert the word "chicken" between "SPF" and "eggs".

DRAFT EU COMMENTS
On the proposed changes to the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals

CHAPTER 2.4.15: Malignant catarrhal fever

General comments

The EU can in general support this revised chapter and has some specific comments.

Specific comments

LINE 6: The word "constitute" should be replaced by "constitutes" (typographical error).

LINES 155-160: This seems to be redundant with lines 97-102 and should be edited to reduce repetitions.

LNES 169-170: It is not clear what is meant by "segregate the management of sheep". The EU therefore suggests rewording the sentence as follows:

"Equally, every reasonable effort must be taken to segregate bison and farmed deer from sheep".

LINE 293: As the infection is always present and 100% are infected, the term "epizootic" does not seem to be correct as that implies an incidence above the expected. Rather, it is an endemic (or enzootic) disease with a very high incidence.

DRAFT EU COMMENTS
On the proposed changes to the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals

CHAPTER 2.1.18: *Trypanosoma evansi* infection (surra)

General comments

The EU can support this revised chapter.

Specific comments

None

DRAFT EU COMMENTS
On the proposed changes to the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals

CHAPTER 2.5.3: Dourine

General comments

The EU can in general support this revised chapter and has some specific comments.

Specific comments

LINES 356-361: This paragraph should be moved up, to the end of section B. Diagnostic techniques.

DRAFT EU COMMENTS
On the proposed changes to the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals

CHAPTER 2.5.5: Equine encephalomyelitis (Eastern & Western)

General comments

The EU can support this revised chapter.

Specific comments

None

DRAFT EU COMMENTS
On the proposed changes to the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals

CHAPTER 2.5.6: Equine infectious anaemia

General comments

The EU can support this revised chapter.

Specific comments

None

DRAFT EU COMMENTS
On the proposed changes to the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals

CHAPTER 2.5.10: Equine viral arteritis

General comments

The EU can support this revised chapter.

Specific comments

None

DRAFT EU COMMENTS
On the proposed changes to the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals

CHAPTER 2.5.11: Glanders

General comments

The EU can in general support this revised chapter and has some specific comments.

Specific comments

LINE 269: The use of CFT in donkeys should not be discouraged, as only a relatively small number of donkeys' sera cause diagnostic difficulties in CFT. Therefore, the EU suggests replacing the clause "; it is not to be used in donkeys" by the following:

"; when used in donkeys, particular care is necessary to avoid misdiagnosis".

DRAFT EU COMMENTS
On the proposed changes to the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals

CHAPTER 2.5.13: Venezuelan equine encephalomyelitis

General comments

The EU can support this revised chapter.

Specific comments

None

DRAFT EU COMMENTS
On the proposed changes to the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals

CHAPTER 2.7.5: Contagious agalactia

General comments

The EU can support this revised chapter.

Specific comments

None

DRAFT EU COMMENTS
On the proposed changes to the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals

CHAPTER 2.7.11: Peste des petits ruminants

General comments

The EU can in general support this revised chapter and has some specific comments.

Specific comments

LINES 215-216: This sentence is confusing, as it is unclear why one would want to demonstrate antibodies to confirm diagnosis which itself was based on antibody-detection tests. The EU therefore suggests deleting the sentence, or replacing it with the following:

"The demonstration of antibodies in PPRV infected goats and sheep can be used to support a diagnosis based on clinical signs, but such antibodies may also arise from vaccination with any of the current PPRV vaccines."

LINE 355: The clause "usually with at least 1–10 CPE" is not clear in this context. Perhaps the authors mean "at least 1-10 TCID50/cell"; if so, this would seem too high an infectious dose to be reasonable or even achievable, especially if the working seed is only 105/ml. An infection with 0.01 TCID50/cell would seem reasonable.

LINE 377: In the opinion of the EU, 10-15 hours seems much too short to see PPR CPE, especially for those laboratories still using plain Vero cells rather than the new cell lines bearing the virus receptor (SLAM). Perhaps the authors meant to write 10-15 days, although a reasonable value according to experience of EU laboratory experts would be 7-10 days.

LINES 401-404: This insertion to push the usefulness of trehalose is not appropriate and should be deleted, as trehalose is just one of a number of alternative freeze-drying additives which have been tried out. Until definitive data is published, comments such as "dramatically improves" should not be included.

LINE 428: The minimum dose given is not explained, and may be a hang over from when this section only dealt with the Nigeria/75/1 vaccine. The EU is of the opinion that there should be clear directions given for what constitutes a "dose", such as "100 times the minimum protective dose as established for the vaccine in question; for the Nigeria/75/1 vaccine this comes to 102.5 TCID50 per dose", or "the minimum protective dose plus 2 logs...". Furthermore, the EU is of the opinion that a description of what is meant by a "dose" should come under "Batch potency"(lines 478 on). However, the first reference to a "dose" comes in line 458. It is necessary to define what is meant by a dose before this point, perhaps at the beginning of the section on safety and efficacy.

LINES 456-477: These paragraphs are a bit unclear, due to language. The EU therefore suggests the following alternative wording:

"For the target host safety test, the PPR vaccine must be reconstituted with normal saline. The mixed contents of five bottles are reconstituted in the diluent to give solutions of 100 doses/ml and 0.1 dose/ml). Six goats and six sheep, all approximately 1-year old and free from PPR antibodies are used. Vaccinate two goats and two sheep subcutaneously with 100 doses per animal; vaccinate two goats and two sheep subcutaneously with 0.1 dose per animal; keep the remaining animals as in-contact controls. The animals are subjected to daily clinical examination for 3 weeks including recording of rectal temperatures. At the end of this period, blood is taken from all animals for the preparation of sera. All animals are challenged by subcutaneous injection of a 1 ml suspension of pathogenic PPRV previously tested for inducing PPR clinical signs in sheep and goats. The animals are observed and their body temperature measurements are recorded daily for 2 weeks.
The vaccine is considered as safe if no abnormal clinical observation has been made with the vaccinated animals, in particular those which have received the highest dose.
Efficacy is proven if all vaccinated animals resist the challenge while the in-contact animals remain susceptible to the challenge virus."

LINES 482-497: This section describes how to perform a VNT test, which is covered thoroughly in Article 3(a) in the previous section. The EU therefore suggests replacing this paragraph with the following sentence:

"The titration of neutralising antibody is as given in section 3(a) above."

LINES 498-500: It is somewhat unclear what this paragraph is saying. If it is allowed for some animals in the potency test not to give antibodies, then the allowable failure rate must clearly be stated. Otherwise this paragraph should be removed.

LINES 501-527: In this part, some of the previous information has been removed, such as the duration of immunity. It should be noted that this information needs to be established for each vaccine, and that it is known for the Nigeria/75/1 vaccine to be at least 3 years.

LINES 504-505: Although it is stated that the vaccine should be known to be safe for all breeds of targeted animals, validation for such vaccines is only ever done on a limited number of breeds. The available vaccines have not been specifically validated as safe for more than one or two breeds of livestock, and for no wildlife species. This sentence is therefore misleading. The EU suggests replacing it either with information of breeds for which validated safe use has been established, or to possibly replace the word "breeds" with "species".

LINE 507: Please replace "study has" with either "studies have" or "a study has" (language).

LINE 523: Please insert "a" before "country".

LINES 532-534: These lines on the use of trehalose should be deleted, for the same reasons given above.

DRAFT EU COMMENTS
On the proposed changes to the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals

CHAPTER 2.8.9: Swine vesicular disease

General comments

The EU can in general support this revised chapter and has some specific comments.

Specific comments

LINE 20: Please replace the words "or VI tests" by "test or by isolation of virus".

LINE 24: Please replace "to SVD virus" by "detection".

LINE 61: Please replace "transported in phosphate buffered" by "transported in 0.04M phosphate buffered".

LINES 110-111: Centrifugation speed should be given as (xg) and not (rpm) unless rotor reference is indicated. Clarification of suspension should be harmonised with that described for FMDV (2000g for 10 minutes) since sample can also be used for FMDV detection.
Therefore, the EU suggests replacing "clarified by centrifugation at 10000 rpm for 20-30 minutes in a high speed centrifuge" by "clarified by centrifugation at 2000g for 10 minutes".

LINE 114: Please replace "clarified by centrifugation at 10000 rpm for 20-30 minutes in a high speed centrifuge" by "clarified by centrifugation at 2000g for 10 minutes" (same rationale as above).

LINE 142: Please replace "the reference reaction" by "the reference method".

LINE 178: It is indicated that plates can be stored for more than 2-3 weeks if stabilised. An indication on how to stabilise the plates would be useful.

LINES 191-192: Again, centrifugation speed should be given as (xg) and not (rpm) unless rotor reference is indicated.

LINE 209: Please replace "RNAsi inhibitor" by "RNase inhibitor" (typo).

LINE 220: It is indicated that staining solution is added to samples before loading on gel. This should be indicated as an option, as the gel can also be stained after electrophoresis which reduces contamination of equipment by the staining solution.

LINE 253: Please replace "will react positively" by "may react positively".

LINE 278: The EU suggests adding an indication on the volume. Therefore, please replace the words "per serum" by "per serum and a volume of 50 µl."

DRAFT EU COMMENTS
On the proposed changes to the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals

CHAPTER 2.9.8: Mange

General comments

The EU can support this revised chapter.

Specific comments

None

DRAFT EU COMMENTS
On the proposed changes to the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals

GUIDELINE 3.5: Biorisk Analysis: Biological agent-specific risk assessments

General comments

The EU can in general support this guideline and has some specific comments.

Specific comments

TABLE under example # 1: As anthrax is not known to be transmitted by direct contact between animals but rather by contact with body fluids from dead infected animals, the EU suggests the following alternative wording for the first column (Risk assessment):

"Transmissible by contact with body fluids from infected animals or carcasses, excretions of infected animals, or contaminated environment".

Furthermore, in the same table and column, since the risk of contracting anthrax from carcasses at necropsy is mainly associated with the contact between body fluids from the infected carcass and wounds on skin or mucous membranes and less so with inhalation, the EU suggests the following alternative wording:

"Necropsy: body fluids released, environment contaminated, risk of human exposure by contact with body fluids and by inhalation."