

EU COMMENTS

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

ANNEX 3

EU COMMENTS

**ON THE PROPOSED CHANGES TO THE
OIE MANUAL OF DIAGNOSTIC TESTS AND VACCINES FOR
TERRESTRIAL ANIMALS
PRESENTED FOR COMMENTS IN MARCH 2020¹**

¹ The chapters can be downloaded from the following address:
http://web.oie.int/download/Terr_Manual/MAILING_MARCH_2020.zip

EU COMMENTS

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

SUMMARY:

Item	Chapter	Title	Page
1	2.1.2.	Biotechnology in the diagnosis of infectious diseases	3
2	3.1.7.	Epizootic haemorrhagic disease (infection with epizootic hemorrhagic disease virus)	4
3	3.1.8.	Foot and mouth disease (infection with foot and mouth disease virus)	5
4	3.1.10.	Japanese encephalitis (vaccine section)	6
5	3.1.11.	Leishmaniosis	7
6	3.1.15.	Paratuberculosis (Johne's disease)	8
7	3.1.21.	<i>Trypanosoma evansi</i> Infection (surra in all species)	9
8	3.3.3.	Avian infectious laryngotracheitis	10
9	3.3.4.	Avian influenza (infection with high pathogenicity avian influenza viruses)	11
10	3.3.5.	Avian mycoplasmosis (<i>M. gallisepticum</i> , <i>M. synoviae</i>)	12
11	3.4.2.	Bovine babesiosis	13
12	3.4.4.	Bovine genital campylobacteriosis	14
13	3.4.5.	Bovine spongiform encephalopathy	15
14	3.4.8.	Contagious bovine pleuropneumonia (infection with <i>Mycoplasma mycoides</i> subsp. <i>mycoides</i>)	16
15	3.4.11.	Haemorrhagic septicaemia	17
16	3.4.1.	Lumpy skin disease	18
17	3.4.16.	Animal trypanosomes of African origin (excluding infection with <i>Trypanosoma evansi</i> and <i>T. equiperdum</i>)	19
18	3.5.8.	Equine piroplasmiasis	20
19	3.6.2.	Rabbit haemorrhagic disease	21
20	3.7.4.	Contagious caprine pleuropneumonia	22
21	3.7.8.	Ovine pulmonary adenomatosis (adenocarcinoma)	23
22	3.7.9.	Peste des petits ruminants (NB: Vaccine section only)	24
23	3.8.1.	African swine fever (NB: Introduction only)	25
24	3.9.2.	Camelpox	26
25	3.9.5.	Cysticercosis (including infection with <i>Taenia solium</i>)	27
26	3.x.xx.	Middle East respiratory syndrome	28

EU COMMENTS

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

2.1.2. Biotechnology in the diagnosis of infectious diseases

General comments

The EU thanks the OIE and supports the proposed changes to this chapter.

Specific comments

None

EU COMMENTS

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

3.1.7. Epizootic haemorrhagic disease (infection with epizootic hemorrhagic disease virus)

General comments

The EU thanks the OIE and in general supports the proposed changes to this chapter.

Specific comments

LINES 429-432: This statement is not related to EHD and rather speculative. In addition, no scientific reference is provided. Perhaps a general reference to the bluetongue chapter would be more appropriate.

EU COMMENTS

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

3.1.8. Foot and mouth disease (infection with foot and mouth disease virus)

General comments

The EU supports the proposed changes to this chapter.

Specific comments

None

EU COMMENTS

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

3.1.10. Japanese encephalitis (vaccine section)

General comments

The EU thanks the OIE and in general supports the proposed changes to this chapter.

Specific comments

LINES 216, 217: typo, should be “equine”.

EU COMMENTS

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

3.1.11. Leishmaniosis

General comments

The EU thanks the OIE and supports the proposed changes to this chapter.

Specific comments

None

EU COMMENTS

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

3.1.15. Paratuberculosis (Johne's disease)

General comments

The EU thanks the OIE and in general supports the proposed changes to this chapter.

However, it is unclear why the CFT method has been included as new Section 2.2. while it is being deleted entirely from Table 1. Indeed, there is no scientific reference provided, and the text in Section 2.2. seems contradictory i.e. it says the test is not fit for control purposes yet it seems to indicate that countries prescribe it for individual animal testing prior to movement (*"The CFT works well on clinically suspect animals, but does not have sufficient specificity to enable its use in the general population for control purposes. Nevertheless, it is often demanded by countries that import cattle."*). As CFT is deleted from Table 1, the text in Section 2.2. should either be more explicit to avoid any confusion (i.e. the text should state that CFT is not recommended for control purposes nor for individual animal testing prior to international movement), or be removed entirely from the chapter.

Specific comments

None

EU COMMENTS

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

3.1.21. *Trypanosoma evansi* Infection (surra in all species)

General comments

The EU supports the proposed changes to this chapter.

Specific comments

None

EU COMMENTS

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

3.3.3. Avian infectious laryngotracheitis

General comments

The EU in general supports the proposed changes to this chapter.

Specific comments

LINE 95: editorial, “using” should be deleted.

EU COMMENTS

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

3.3.4. Avian influenza (infection with high pathogenicity avian influenza viruses)

General comments

The EU thanks the OIE and in general supports the proposed changes to this chapter. We note with appreciation the changes proposed in this first step that attempt to align the Manual chapter with the corresponding Code chapter currently under revision and up for adoption next year. We look forward to the full review of this Manual chapter – in parallel with Chapter 3.3.14. on Newcastle Disease – in the next round (2020-2021) for which our comments submitted previously (December 2019, available here https://ec.europa.eu/food/sites/food/files/safety/docs/ia_standards_oie_eu_position_terrestrial_manual_201909.pdf) remain pertinent.

As already indicated in the past, the EU is of the opinion that the Manual should as a general rule not contain any information on notification obligations of member countries. Indeed, this is the remit of the Code and subject to regular changes. Having information in this regard in the Manual that is possibly diverging from the Code would be highly confusing, could lead to international trade problems, and is thus inappropriate. We therefore suggest deleting all such information from this and other Manual chapters.

Specific comments in relation to the above are inserted below.

Specific comments

LINES 2-4 (TITLE): for consistency with the definitions given in this Manual chapter and in the Terrestrial Code, the title should be “HIGH PATHOGENICITY AVIAN INFLUENZA (INFECTION WITH HIGH PATHOGENICITY AVIAN INFLUENZA VIRUSES)”.

LINE 109: for the same reason (see article 10.4.1 2] a] of the Terrestrial Code), this should be replaced by “1) HPAI as an infection of poultry by an avian influenza virus that meets the definition of high pathogenicity”.

LINES 289-301: For the reasons explained in the general comment box above, the EU suggests deleting this section entirely. Indeed, no reference to notifiability (neither as listed nor emerging disease) should be made at all in the OIE Manual.

EU COMMENTS

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

3.3.5. Avian mycoplasmosis (*M. gallisepticum*, *M. synoviae*)

General comments

The EU thanks the OIE and supports the proposed changes to this chapter.

Specific comments

None

EU COMMENTS

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

3.4.2. Bovine babesiosis

General comments

The EU in general supports the proposed changes to this chapter.

Specific comments

LINE 264: for consistency and accuracy, we suggest deleting “room temperature” and keep only the actual temperature (20–25°C) also here (NB without the brackets).

LINES 269, 274, 358, 463, 534: typo, brackets should be removed around 20–25°C.

EU COMMENTS

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

3.4.4. Bovine genital campylobacteriosis

General comments

The EU supports the proposed changes to this chapter.

Specific comments

None

EU COMMENTS

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

3.4.5. Bovine spongiform encephalopathy

General comments

The EU thanks the OIE and in general supports the proposed changes to this chapter. A specific comment is included below.

Specific comments

LINES 414-415: The reference to EU legislation is slightly inaccurate as to the chapter and annex where approved tests are listed. The correct reference to Regulation (EC) No 999/2001 (available here: <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1591112973636&uri=CELEX:02001R0999-20191214>) should be as follows:

“[...] are listed in ~~Annex C~~ point 4 of Chapter C of Annex X of to the TSE Regulation (EC No 999/2001 and subsequent amendments).”

EU COMMENTS

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

3.4.8. Contagious bovine pleuropneumonia (infection with *Mycoplasma mycoides* subsp. *mycoides*)

General comments

The EU thanks the OIE and supports the proposed changes to this chapter.

Specific comments

None

EU COMMENTS

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

3.4.11. Haemorrhagic septicaemia

General comments

The EU supports the proposed changes to this chapter.

Specific comments

None

EU COMMENTS

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

3.4.1. Lumpy skin disease

General comments

The EU thanks the OIE and supports the proposed changes to this chapter.

Specific comments

None

EU COMMENTS

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

3.4.16. Animal trypanosomes of African origin (excluding infection with *Trypanosoma evansi* and *T. equiperdum*)

General comments

<p>The EU thanks the OIE and supports the proposed changes to this chapter.</p>
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Specific comments

None

EU COMMENTS

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

3.5.8. Equine piroplasmosis

General comments

The EU supports the proposed changes to this chapter.

Specific comments

None

EU COMMENTS

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

3.6.2. Rabbit haemorrhagic disease

General comments

The EU thanks the OIE and in general supports the proposed changes to this chapter which has significantly improved.

We would like to point out that mortality events caused by RHDV2 in wild North American leporids (Black-tailed jackrabbit *Lepus californicus*, Antelope jackrabbit *Lepus alleni*, Desert cottontail *Sylvilagus audubonii* and Mountain cottontail *Sylvilagus nuttalli*) have recently been reported to the OIE through WAHIS (see for example https://www.oie.int/wahis_2/public/wahid.php/Reviewreport/Review?reportid=34197). The data is so new that it has not yet been published in the scientific literature. We would nevertheless invite the OIE to revise the information on susceptible species in the chapter accordingly (with reference to WAHIS since no peer-reviewed papers are available yet).

Specific comments in relation to this as well as two others are included below.

Specific comments

LINE 110: we suggest adding 'and various hare (*Lepus*) and cottontail (*Sylvilagus*) species in North America' after 'mountain hare (*L. timidus*)'.

LINE 124: we suggest adding 'and wild *Lepus* and *Sylvilagus* species' after 'in European rabbits'

LINE 337: we suggest keeping the reference Stoerckle Berger *et al.*, 1992 because renal mesangial cell positivity is not described in Neimanis *et al.*, 2018.

LINE 337: we suggest removing '(decreased myeloid-to erythroid ratio)' as that does not refer to immunostaining in cells.

EU COMMENTS

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

3.7.4. Contagious caprine pleuropneumonia

General comments

The EU thanks the OIE and supports the proposed changes to this chapter.

Specific comments

None

EU COMMENTS

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

3.7.8. Ovine pulmonary adenomatosis (adenocarcinoma)

General comments

The EU supports the proposed changes to this chapter.

Specific comments

None

EU COMMENTS

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

3.7.9. Peste des petits ruminants (NB: Vaccine section only)

General comments

The EU thanks the OIE and supports the proposed changes to this chapter.

Specific comments

None

EU COMMENTS

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

3.8.1. African swine fever (NB: Introduction only)

General comments

The EU supports the proposed changes to this chapter.

Specific comments

None

EU COMMENTS

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

3.9.2. Camel pox

General comments

The EU thanks the OIE and supports the proposed changes to this chapter.

Specific comments

None

EU COMMENTS

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

3.9.5. Cysticercosis (including infection with *Taenia solium*)

General comments

The EU in general supports the proposed changes to this chapter.

Specific comments

LINES 60-63: editorial, these lines seem to be a repetition of lines 50-53 and should be deleted.

EU COMMENTS

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

3.x.xx. Middle East respiratory syndrome

General comments

The EU cannot support this proposed new chapter as presented. The specific comments below should be taken into account before the chapter is proposed for adoption.

Specific comments

LINES 7-8: Spelling of MERS-CoV should preferably be harmonised between the Manual and the Code (see Annex 13 of the February meeting report of the Code Commission).

LINES 18-20: The last sentence of this paragraph should be deleted. Indeed, MERS-CoV will likely be proposed for listing in Chapter 1.3. of the Terrestrial Code at the General Session in 2021 (see Annex 13 of the February 2020 meeting report of the Code Commission), at the same time this Manual chapter will likely be proposed for adoption. Therefore, once the disease is listed, it will no longer be considered as an emerging disease as regards notification obligations. Furthermore, since Manual chapters as a matter of principle should not contain information on notification obligations (as this is the remit of the Code), no reference to notification obligations should be included at all in this chapter. Reference is made to the general comment box in the EU comment on Chapter 3.3.4. on avian influenza.

LINES 30-33: The text seems inappropriate for the OIE Manual, as it is rather speculative. We would thus suggest deleting the first two sentences of this section, leaving only the last one.

LINE 46: as the chapter is to be adopted in 2021, the information should be updated as of 2020 (i.e. replace “(2019)” with “(2020)”, if the statement is still correct as of 2020).

LINE 62: in order to avoid any confusion, we suggest inserting the words “in camel” after “Clinical signs of disease”.

LINE 80: We suggest inserting the word “naturally” before “infected”.

LINES 413-431: Again, the text on vaccines is speculative, especially the second paragraph of this section which is also too detailed taking into account that it talks about vaccine candidates only, not licensed vaccines. We clearly do not support such detailed information on vaccine candidates in an OIE Manual chapter, which is an international standard, not a review article. The last sentence especially should be deleted (LINES 430-431).