

Organisation Mondiale de la Santé Animale World Organisation for Animal Health Organización Mundial de Sanidad Animal

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REPORT OF THE MEETING OF THE OIE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Paris, 5-16 September 2016

The OIE Terrestrial Animal Health Standards Commission (the Code Commission) met at OIE Headquarters in Paris from 5–16 September 2016. The list of participants is attached as **Annex 1**.

The Code Commission thanked the following Member Countries for providing written comments on draft texts circulated after the Commission's February 2016 meeting and the 84th General Session meeting in May 2016: Argentina, Australia, Canada, Chile, China, Chinese Taipei, Colombia, Japan, Korea, Mexico, New Zealand, Norway, Malaysia, Singapore, South Africa, Switzerland, Thailand, the United States of America (USA), Uruguay, the Member States of the European Union (EU), the African Union Interafrican Bureau for Animal Resources (AU-IBAR) on behalf of African Member Countries of the OIE. Comments were also received from the European Animal Protein Association (EAPA), the International Coalition for Animal Welfare (ICFAW), the International Embryo Transfer Society (IETS) and three regional organisations; the Association of Southeast Asian Nations (ASEAN), the Comité Veterinario Permanente del CONOSUR (CVP, representing Argentina, Bolivia, Brazil, Chile, Paraguay and Uruguay) and Quadrilateral Group (Quads; representing Australia, Canada, New Zealand and USA). Some comments were received too long after the deadline to be considered.

The Code Commission reviewed Member Countries' comments that had been submitted on time with rationale and amended texts in the OIE *Terrestrial Animal Health Code* (the *Terrestrial Code*) where appropriate. The amendments are shown in the usual manner by 'double underline' and 'strikethrough' and may be found in the Annexes to the report. In Annexes 5, 8, 9, 10, 11, 14, 17, 18, 19 and 21, amendments made at this meeting are highlighted with a coloured background in order to distinguish them from those made previously. The Code Commission considered all Member Countries' comments and documented its responses. However, because of the large volume of work, the Commission was not able to draft a detailed explanation of the reasons for accepting or not each of the comments received and focused its explanations on the major ones.

Furthermore, Member Countries are reminded that comments submitted without a rationale are difficult to evaluate and respond to. Similarly if comments are resubmitted without modification or new justification, the Commission will not, as a rule, repeat previous explanations for decisions. The Commission encourages Member Countries to refer to previous reports when preparing comments on longstanding issues. The Commission also draws the attention of Member Countries to those instances where the Scientific Commission for Animal Diseases (the Scientific Commission) or an *ad hoc* Group has addressed Member Countries' comments and proposed amendments. In such cases the rationale for such amendments is described in the Scientific Commission's or *ad hoc* Group's report, and the Code Commission encourages Member Countries to review its report together with those of the Scientific Commission and *ad hoc* Groups.

Member Countries should note that texts in Part A of this report are submitted for comments with the intention of proposing them for adoption at the 85th General Session in May 2017. Texts in Part B are submitted for comments only, and are not expected to be presented for adoption at the 85th General Session. Comments received will be addressed during the Commission's meeting in February 2017. The reports of meetings (Working Group and *ad hoc* Group) and other related documents are also attached for information in Part C of this report.

The Code Commission again strongly encourages Member Countries to participate in the development of the OIE's international standards by submitting comments on this report, and prepare to participate in the process of adoption at the General Session. Comments should be submitted as word files rather than pdf files because pdf files are difficult to incorporate into the Code Commission's working documents. Comments should be submitted as specific proposed text changes, supported by a structured rationale for each proposed change. Proposed changes should be incorporated in the text drafted by the Code Commission: proposed deletions should be indicated in 'strikethrough' and proposed additions with 'double underline'. If the text drafted by the Code Commission already includes modifications in strikethrough and double-underline, the Member Country's proposed changes should be highlighted. If the text drafted by the Code Commission already includes highlighted parts, the Member Country's proposed changes should be highlighted in a different colour. Member Countries should not use the automatic 'track-changes' function provided by word processing software as such changes are lost in the process of collating Member Countries' submissions into the Commission's working documents.

Comments on this report must reach OIE Headquarters **by 12 January 2017** to be considered at the February 2017 meeting of the Code Commission.

All comments should be sent to the OIE Standards Department at: standards.dept@oie.int. Member Countries are advised to please note the change in email address.

A. MEETING WITH THE DIRECTOR GENERAL

The Code Commission met with Dr Monique Eloit, Director General, and Dr Matthew Stone, Deputy Director General (International Standards and Science), on 5 September 2016. Dr Eloit welcomed the Code Commission members and thanked them for their support and commitment to achieving OIE objectives.

Dr Eloit introduced Dr Stone who has recently joined the OIE Headquarters. Dr Eloit also introduced Ms Ann Backhouse, the new Head of the Standards Department. The Standards Department will be dedicated to the elaboration of standards, the strengthening of collaboration and coordination across the four Specialist Commissions and strengthening the role of the Secretariat to better support the work of the Commissions.

Among other matters, Dr Eloit reiterated the commitment of the OIE to the implementation of the key objectives of the Sixth Strategic Plan, in particular the plan to improve the selection process for membership of the Specialist Commissions. Dr Eloit noted that the forthcoming session of the Council will consider a paper on the proposed draft procedure for the selection of experts. Dr Eloit also noted that she had initiated a review of the terms of reference and membership of the three permanent working groups in order to ensure they are still relevant to the work of the OIE.

B. ADOPTION OF THE AGENDA

The draft agenda circulated prior to the meeting was discussed, updated, and agreed. The adopted agenda of the meeting is attached as **Annex 2**.

C. MEETING WITH THE AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

The President of the Code Commission and the President of the Aquatic Animal Health Standards Commission (Aquatic Animals Commission) met on 12 September to discuss issues of mutual interest, notably:

- proposed revisions to glossary definitions of 'zone/region', 'infected zone', 'free zone', 'containment zone' and 'protection zone' in the Terrestrial Code;
- planned global revision to the glossary of the *Terrestrial Code* by the Code Commission;
- proposed new procedures that could be used when undertaking an assessment of a disease against the criteria for listing;
- proposed drafting of a new chapter on the slaughter and killing of farmed reptiles for skins and meat in the Terrestrial Code;
- proposed restructuring of Section 4 of the *Aquatic* and *Terrestrial Codes*;
- update on the revised draft new chapter on criteria for assessing the safety of commodities (Chapter 2.X.).

D. MEETING WITH THE BIOLOGICAL STANDARDS COMMISSION

Previously to the meeting of the Code Commission, the President of the Code Commission met with the Biological Standards Commission (Laboratories Commission) to discuss issues of mutual interest. The main discussion points were as follows:

a) The alignment of the spelling of disease names between the Code and Manual

In response to the Code Commission's request, seeking opinion on the alignment of the spelling of disease names, especially on the spelling of 'foot and mouth disease virus' with that of the International Committee on Taxonomy of Viruses (ICTV); 'foot-and-mouth disease virus' with two hyphens, the Laboratories Commission advised that it was preferable to retain in the *Code* and *Manual* the name 'foot and mouth disease' without hyphens while also noting that there may be differences between the name of the virus and the name of the disease.

b) Update of Chapter 4.8. Collection and processing of in-vitro produced embryos/oocytes from livestock and horses

In response to a Member Country's comment on the lack of details in the *Manual* about tests that are recommended in the Chapter 4.8. for materials such as 'oocytes', 'non-viable *in-vitro* produced embryos', and 'fluids' used and generated during processing of *in-vitro* produced embryos, the Laboratories Commission noted that currently there is not sufficient available scientific data to assess the risk of disease transmission by *in-vitro* produced embryos or oocytes, nor is there funding for such research. The two Commissions agreed that there is a need for the OIE Headquarters to raise awareness among Member Countries on this issue and to generate financial resources to conduct the necessary research that will assist the Commissions to update the *Code* and *Manual*.

c) The current definition of infection with bluetongue virus (Chapter 8.3.)

In response to the Code Commission's request for advice regarding the exclusion of non-pathogenic serotypes of bluetongue virus (BTV) and live vaccine strains of bluetongue virus from the definition of infection with bluetongue virus, the Laboratories Commission advised that (i) it is appropriate to retain reference to vaccine strains in the definition of BTV, as they may cause disease and reassort with wild strains, and (ii) at the present time it is not possible to make definitive assessments of a BTV strain's pathogenicity, even though epidemiological information may indicate lack of clinical pathologies associated with some BTV infections.

d) The list of susceptible species included in the case definition in the draft new chapter on infection with Mycobacterium tuberculosis complex (draft new Chapter 8.X.)

In response to the Code Commission's request for advice regarding the inclusion of New World camelids in the list of susceptible species in the definition of a case of *infection* with *Mycobacterium tuberculosis* complex, the Laboratories Commission sought the advice of experts on diseases of camelids, who noted that New World camelids were susceptible to *M. tuberculosis* complex, and though the significance of this susceptibility in the epidemiology of the disease varies depending on the type of breeding, New World camelids could be considered a potential source of the pathogenic agent. In view of these facts, the Laboratories Commission recommended that New World camelids be included in the list of susceptible species and not be placed 'under study'.

E. REPORT ON THE JOINT MEETING OF THE CODE COMMISSION AND THE SCIENTIFIC COMMISSION FOR ANIMAL DISEASES

The Code Commission and the Scientific Commission met on 8th September to discuss issues of mutual interest. The report of this joint meeting is attached as **Annex 3**.

F. EXAMINATION OF MEMBER COUNTRIES' COMMENTS AND WORK OF RELEVANT EXPERT GROUPS

In addition to amendments explained below, the Code Commission made amendments, as appropriate to correct grammar, to improve syntax, consistency and clarity and to align with the standard Code format.

Headquarters staff informed the Code Commission that some Member Countries continue to submit comments without a supporting rationale and that the decision had been taken by the Director General that any comments without a rationale will not be submitted to the Code Commission because such comments are difficult for it to evaluate and respond to.

Item 1 General comments of OIE Member Countries

General comments were received from Australia and New Zealand.

The Code Commission agreed with a Member Country's comment to continue to include in its report a table of contents and make it similar to that used in the reports of the Aquatic Animals Commission as this would assist Member Countries to navigate the report.

Item No.	Texts for Member Countries' comments and proposed for adoption in May 2017	Part A: Annex No.
2	Glossary Part A, A' and A"	Annex 4
4	Criteria for the inclusion of diseases, infections and infestations in the OIE list (Article 1.2.1.)	Annex 6
5	Disease listed by the OIE (the Preamble of Chapter 1.3.)	Annex 7
7	Draft new chapter on criteria for assessing the safety of commodities (Chapter 2.X.)	Annex 8
10	OIE procedures relevant to the Agreement on the Application of Sanitary and Phytosanitary Measures on the World Trade Organisation (Chapter 5.3.)	Annex 9
12 a)	Draft new chapter on prevention, detection and control of <i>Salmonella</i> in cattle (Chapter 6.X.)	Annex 10
12 b)	Draft new chapter on prevention, detection and control of <i>Salmonella</i> in pigs (Chapter 6.Y.)	Annex 11
13 f)	Animal welfare and dairy cattle production systems (Article 7.11.6.)	Annex 12
13 g)	Welfare of working equids (Chapter 7.12.)	Annex 13
16	Draft new chapter on infection with <i>Mycobacterium tuberculosis</i> complex (Chapter 8.X.)	Annex 14
17	Infection with Avian influenza viruses (Article 10.4.25.)	Annex 15
18	Infection with Lumpy skin disease (Chapter 11.11.)	Annex 16
21 b)	Infection with Burkholderia mallei (Glanders) (Chapter 12.10.)	Annex 17
19	Infection with African swine fever virus (Chapter 15.1.)	Annex 18
20	Draft new chapter on infection with porcine reproductive and respiratory syndrome virus (Chapter 15.X.)	Annex 19
21 a)	High health status subpopulation (Article 4.16.3.)	Annex 20
Item No.	Texts for Member Countries' comments	Part B: Annex No.
2	Glossary Part B and B'	Annex 5
8 a)	Zoning and compartmentalisation (Chapter 4.3.)	Annex 21
8 b)	Draft new chapter on vaccination (Chapter 4.X.)	Annex 22

Item No.	Texts for Member Countries' comments	Part B: Annex No.
9 b)	Collection and processing of <i>in vitro</i> derived embryos from livestock and equids (Chapter 4.8.)	Annex 23
9 c)	Somatic cell nuclear transfer in production livestock and horses (Article 4.11.4.)	Annex 24
11 b)	Harmonisation of national antimicrobial resistance surveillance and monitoring programmes (Chapter 6.7.)	Annex 25
13 b)	Draft new article on guiding principles on the use of animal based measures (Article 7.1.X.)	Annex 26
13 h)	Draft new chapter on animal welfare and pig production systems (Chapter 7.X.)	Annex 27
14	Infection with bluetongue virus (Chapter 8.3.)	Annex 28
22	Work programme	Annex 29
Item No.	Annexes for Member Countries' information:	Part C: Annex No.
13 a)	The report of the Animal Welfare Working Group	Annex 30
13 k)	The report of the ad hoc Group on Animal Welfare and Pig Production Systems	Annex 31

Item 2 Glossary

a) OIE Standard and OIE Guideline

The Code Commission acknowledged the Headquarters' decision to postpone discussion on the proposed definitions of OIE standard and OIE guideline until the OIE Council considers this issue at its September 2016 meeting. The Commission will be updated on outcomes of the Council at its February 2017 meeting.

b) Definitions proposed for revision in the last Code Commission report

Comments were received from Argentina, Australia, Canada, China, Colombia, New Zealand, Norway, Switzerland, USA, Uruguay, EU and AU-IBAR.

In responding to Member Countries' comments, and in view of the current revision of Chapter 4.3., the Code Commission made consequential changes to the Glossary definitions of containment zone, free zone, infected zone, protection zone and zone/region.

It also reflected in these changes the proposed modification of the definitions of *disease*, *infection* and *infestation*, and the proposed new definition of 'pathogenic agent' (see points c) and d) below).

Containment zone

The Code Commission accepted Member Countries' suggestions to improve the clarity and to align the definition of *containment zone* with that proposed in the revised Chapter 4.3., and proposed to replace 'infection' with 'disease', which it considered appropriate in respect of the proposed revised definition of *disease*. It also introduced additional changes in order to align the definition with that proposed by the *ad hoc* Group on Foot and Mouth Disease (FMD) that met in June 2016.

Free zone

The Code Commission proposed to delete 'infection or infestation', in order to better align the definition of *free zone* with the proposed revised definition of *disease*.

Infected zone

In response to Member Countries' comments, the Code Commission simplified and clarified the definition of *infected zone*.

Protection zone

The Code Commission proposed to delete 'that may include, but are not limited to, vaccination, movement control and an intensified...surveillance' in order to allow more generic use of the terms *biosecurity* and *sanitary measures*. In response to Member Countries' comments on the use of the terms 'pathogen' and 'pathogenic agent', the Code Commission proposed to replace 'pathogen' with 'pathogenic agent of a specific disease' in order to align the definition of *protection zone* with that used in Chapter 4.3., and to use the term 'pathogenic agent' for which a new definition is proposed.

Zone/Region

On the advice of the *ad hoc* Group on FMD, with support of the Scientific Commission, the Code Commission proposed to replace 'distinct' with 'specific' in order to give the definition of 'zone' a broader application. It also proposed to delete '/region', as this term is not used in the *Code*, and to delete 'infection or infestation' in order to better align the definition with the proposed revised definition of *disease*.

The revised definitions are attached in <u>Annex 5</u> (Glossary **Part B**) for Member Countries' comments.

c) Proposal of a new definition for 'pathogenic agent'

The Code Commission noted that throughout the *Code* many different terms are used for the same concept such as pathogen, aetiological agent, causative agent etc. In order to improve clarity throughout the *Code* and to align terminology in the two *Codes*, it proposed to add to the Glossary the same definition for "pathogenic agent" used in the *Aquatic Code*, namely;

Pathogenic agent

means an organism that causes or contributes to the development of a disease.

The Code Commission agreed that should this new definition be adopted, it would replace, where relevant, similar terms currently used in the *Code* with 'pathogenic agent'. Similar terms that would be considered for replacement include: pathogen, aetiological agent, pathogenic organism, pathogenic micro-organism, pathogenic bacteria, causative pathogen, animal pathogen, bacterial pathogen.

The Code Commission proposed that this task be carried out by Headquarters under the guidance of the Code Commission as it would be a significant task and care would be needed in order to consider the necessity, sense and syntax of any amendment. The Code Commission noted that there are approximately 300 instances where consideration would be given to replacing an existing term with "pathogenic agent". Some terms would remain unchanged where it is considered not appropriate to change them.

The Code Commission proposed that where minor revisions of text are required to improve syntax, these amendments would be circulated for Member Countries' comments. However, whenever pathogenic agent simply replaces another closely aligned or similar term these amendments would be done, once the new definition for "pathogenic agent" is adopted, as part of the update of the next edition of the *Code*.

The revised definition is attached in <u>Annex 4</u> (Glossary Part A) for Member Countries' comments and is proposed for adoption at the 85th General Session in May 2017.

d) Overall revision of the Glossary

Further to the above specific proposal, the Code Commission begin an overall revision of the Glossary.

Indeed, the Code Commission noted that as presented in the User's Guide, "key terms and expressions used in more than one chapter in the *Terrestrial Code* are defined in the Glossary", "in the case where common dictionary definitions are not deemed to be adequate" for the purpose of the *Code*.

The Code Commission undertook an extensive review of the terms defined in the Glossary to ensure that this was in fact the case and also took this opportunity to edit some terms for clarity and consistency.

The Code Commission noted that the rationale for some amendments of definitions are included under the relevant agenda items.

Given the extensive review of the Glossary, the Code Commission proposed to present amendments in three categories.

Proposed deletions

The Code Commission proposed to delete the definitions for 'quality', 'travel', 'transport', 'transporter' and 'zoonosis' because these terms are adequately defined in the *Oxford English Dictionary* and in French and Spanish reference dictionaries, and are rarely, if ever, italicised in the *Code*. These terms thus do not meet the criteria to be included in the Glossary. Moreover, the definition for 'transport' is too restrictive as it does not address non-commercial purposes. In addition, the Code Commission proposed that, as it reviews relevant chapters in the *Code*, 'transport' be changed to 'transportation', where relevant, because the word 'transport' is often used incorrectly.

Furthermore, the Code Commission proposed to delete the definitions of the term 'post-journey period', which is not used in the *Code*.

The proposed deleted definitions are attached in <u>Annex 4</u> (Glossary **Part A'**) for Member Countries' comments and are proposed for adoption at the 85th General Session in May 2017.

Proposed amendments related to the revision of chapters

In the process of reviewing chapters of the *Code*, the Code Commission noted inconsistencies between the current definitions of some terms and their actual meaning in the chapters.

When reviewing Chapters 1.1., 1.2., 1.3. and 4.3., and the related comments from Member Countries, the Code Commission noted the necessity to revise the definitions of *animal health status*, *disease*, *infection*, *infestation* and *notification*. For further details, the Code Commission advised that Member Countries should refer to the texts in Items 3 and 8 of this report.

When reviewing Chapter 4.3., and the related comments from Member Countries, the Code Commission noted the necessity to revise the definition of *compartment*. The words 'disease prevention and control or' have been added between the words 'for the purpose of' and 'international trade'. Other amendments also have been made to improve clarity.

When reviewing the draft new Chapter 4.X. on vaccination, the Code Commission noted the necessity to revise the definition of *vaccination*. For further details, the Code Commission advised that Member Countries should refer to the text in Item 8 b of this report.

When reviewing Chapter 15.1., and the related comments from Member Countries, the Code Commission noted the necessity to make an editorial amendment to the definitions of *captive wild animal*, *feral animal* and *wild animal*. The word 'animal' was replaced with '[species]', to show more clearly the possible use of the terms in the context of different diseases affecting different species (e.g. 'wild birds', 'captive wild pigs', 'wild ruminants', 'feral equids').

The revised definitions of *animal health status*, *captive wild animal*, *feral animal*, *infection*, *infestation*, *notification*, and *wild animal* are attached in <u>Annex 4</u> (Glossary Part A) for Member Countries' comments and are proposed for adoption at the 85th General Session in May 2017.

The revised definitions of *compartment*, *disease*, and *vaccination* are attached in <u>Annex 5</u> (Glossary **Part B'**) for Member Countries' comments.

Amendments to definitions of a purely editorial nature and provided for Member Countries' information

When reviewing the Glossary, the Code Commission noted numerous editorial mistakes, which may refer to the three versions or only the English version. The proposed changes do not introduce any changes in the meaning but provide consistency and remove inaccuracies.

These amendments are attached in <u>Annex 4</u> (Glossary **Part A''**) for Member Countries' information and will be reflected in the 2017 edition of the Code.

The editorial amendments are described in the following table.

Glossary terms	Rationale for and description of the change			
-	· · ·			
ANIMAL HANDLER	Editorial The word 'and/' have been deleted because of possible confusion and for correct syntax.			
ANIMAL IDENTIFICATION SYSTEM	Editorial The unnecessary symbols such as parentheses around plural s and a slash (/) have been deleted for correct syntax.			
ANIMAL WELFARE	Editorial The unnecessary symbol, a slash (/), has been deleted and replaced with 'and', for correct syntax.			
FLOCK	Editorial The words 'For the purpose of the <i>Terrestrial Code</i> ' has been deleted because it is an error, these words already appear at the beginning of the glossary.			
HERD	Editorial For the same reason as above.			
INCUBATION PERIOD	Editorial The word 'which' has been replaced with 'that' to correct grammar. (English version only)			
INTERNATIONAL VETERINARY CERTIFICATE	Editorial A slash (/) and the word 'or' have been deleted for correct syntax. The word 'which' has been replaced with 'that' to correct grammar. (English version only)			
KILLING	Editorial The word 'which' has been replaced with 'that' to correct grammar. (English version only)			
OFFICIAL VETERINARIAN	Editorial The word 'and/' and a slash (/) have been deleted for correct syntax.			
QUARANTINE STATION	Editorial The unnecessary symbols such as parentheses around plural s have been deleted. At the last sentence, the word 'and' has been replaced with 'or' to improve clarity and for correct syntax.			
RESPONSIBLE DOG OWNERSHIP	Editorial The words '(as defined above)' have been deleted because it was an error due to previous versions.			
SAFE COMMODITY	Editorial The word 'which' has been replaced with 'that' to correct grammar. (English version only)			
SLAUGHTER	Editorial For the same reason as above.			
STUNNING	Editorial For the same reason as above.			

Item 3 Notification of diseases, infections and infestations, and provision of epidemiological information (Chapter 1.1.)

Comments were received from Australia and EU.

In line with the general review of Glossary definitions (see Item 2), the Code Commission proposed to amend the definition of *notification* to improve clarity and ensure consistency.

In response to several Member Countries' comments the Code Commission discussed the current definition of *disease* in the Glossary and agreed it was confusing because the definition is tautological. This issue was further discussed when reviewing Chapter 4.3. and an amendment of the definition was proposed (See Item 8 a).

The Code Commission noted a Member Country's comment requesting consideration of the notification requirement for an 'outbreak' in future developments of World Animal Health Information System (WAHIS) and requested that this comment on point 6 of Article 1.1.2. be forwarded to the OIE World Animal Health Information and Analysis Department (WAHIAD).

Item 4 Criteria for the inclusion of diseases, infections and infestations in the OIE list (Chapter 1.2.)

Comments were received from EU.

In response to Member Countries' comments and consideration of translation issues, the Code Commission proposed to make an editorial change to Article 1.2.1. and delete 'of listed diseases' in paragraph 2. This change was made because of issues in the French and Spanish translations and to avoid repetition and improve clarity.

The revised Article 1.2.1. is attached at <u>Annex 6</u> for Member Countries' comments and is proposed for adoption at the 85th General Session in May 2017.

Item 5 Disease listed by the OIE (Chapter 1.3.)

Comments were received from Australia, Colombia and EU.

In response to Member Countries' comments the Code Commission proposed an amendment to the preamble to clarify the purpose of this chapter and to ensure a clear cross reference to Chapter 1.2., whilst avoiding repetition of existing text in other chapters.

The revised preamble of Chapter 1.3. is attached at <u>Annex 7</u> for Member Countries' comments and is proposed for adoption at the 85th General Session in May 2017.

Item 6 Animal health surveillance (Chapter 1.4.)

Comments were received from Australia, Canada, Malaysia, New Zealand, Switzerland, USA, EU and AU-IBAR.

The Code Commission reviewed the comments of the Member Countries on Article 1.4.6. and proposed relevant amendments. In addition, it proposed the inclusion of new text on early detection systems and the amendment of the definition of *early detection system*. However, Chapter 1.4. should be further reviewed by experts and a new version will be proposed for comments after the next Code Commission meeting.

Item 7 Draft new chapter on criteria for assessing the safety of commodities (2.X.)

Comments were received from Argentina, Australia, Canada, China, Chile, Colombia, Malaysia, New Zealand, Switzerland, Uruguay, EU and CVP.

In response to several Member Countries' comments, the Code Commission agreed to amend the title to more clearly reflect the application of these criteria, i.e. "Criteria applied by the OIE for assessing the safety of commodities". The Code Commission also amended the title in the Spanish version to ensure consistency with the definition of *safe commodity*.

In response to a Member Country's comment the Code Commission agreed to change the word 'assumed' to 'expected' in Article 2.X.1. as it was a more appropriate word for this context.

The Code Commission did not agree with a Member Country's comment to add 'organ' because it considered that 'tissue' has a wider meaning. Nor did it agree to add texts regarding the potential for later contamination of the commodity, as the criteria are about the safety of the commodity itself.

The Code Commission carefully debated a Member Country's comment regarding point 1 of Article 2.X.2., but did not change the proposed text because the proposed amendments did not improve clarity.

The Code Commission did not agree with Member Countries' comments to change 'animal product' to 'commodity' in Article 2.X.2. point 1 because the first sentence of this article is explicit that commodities are derived from animal products.

The revised Chapter 2.X. is attached at <u>Annex 8</u> for Member Countries' comments and is proposed for adoption at the 85th General Session in May 2017.

Item 8 Disease prevention and control

a) Zoning and compartmentalisation (Chapter 4.3.)

Comments were received from Australia, Canada, Chile, Chinese Taipei, New Zealand, Norway, Switzerland, Thailand, USA, Uruguay, EU and AU-IBAR.

The Code Commission, responding to Member Countries' comments, made various amendments to the text to improve grammar, syntax and clarity. Particular attention was paid to the amendments that affected the definitions in the Glossary and in the specific articles reviewed.

In response to a Member Country's comment regarding the deletion of the text "For the purposes of the *Terrestrial Code*, 'zoning' and 'regionalisation' have the same meanings", the Code Commission noted that this sentence had not been deleted from the *Code* but rather put in Article 5.3.7. where it is more appropriate.

In response to a Member Country's comment, the Code Commission accepted the recommendation to move the full text concerning the purpose of the chapter to the beginning of the introduction.

In response to Member Countries' comments on the definitions of *disease*, *infection* and *infestation*, the Code Commission proposed amended versions of these definitions in the Glossary. The Code Commission proposed a new definition for *disease* that includes non-clinical infection or infestation. If adopted, this would lead to relevant updates of the *Code* in various chapters. This will align the definition in both the *Terrestrial Code* and the *Aquatic Code*, will improve clarity and avoid repetitions, tautologies or confusions that may be currently found in the *Code*.

The Code Commission did not accept a Member Country's comment to insert new text in the third paragraph of Article 4.3.1., as introduction and specific recommendations are made in the following articles.

The Code Commission did not accept a Member Country's proposal to extensively revise Article 4.3.1. because many issues raised had been dealt with when responding to comments from other Member Countries.

The Code Commission did not accept the proposal of a Member Country to change the word 'recommendation' to 'guidelines' in Article 4.3.1., since OIE standards and guidelines both give recommendations.

In response to Member Countries' comments, the Code Commission confirmed that as stated in the User's Guide, in the absence of specific recommendations for zoning in disease-specific chapters, a Member Country can use the recommendations in Chapter 4.3. for any disease. The Code Commission, together with other Specialist Commissions and the Headquarters, will strive to propose new recommendations for diseases for which there are no current provisions.

In response to a Member Country's comment on bilateral recognition of trading countries in Article 4.3.2., the Code Commission did not accept to move this text, as the logic of the chapter is first explaining different aspects of zoning and then to give provisions for bilateral recognition.

The Code Commission did not accept a proposal to include 'animal products' after 'identification' in the General Considerations of Article 4.3.2., as the *Code* does not provide recommendations for identification and traceability of animal products.

A Member Country's suggestion to replace the word 'wildlife' with 'vector' was not accepted but the Code Commission included the word 'vector', which is relevant in that sentence.

The Code Commission, in answer to a Member Country's comment, added the word 'biosecurity' in the fifth paragraph of Article 4.3.2.

In response to Member Countries' comments suggesting replacement of 'movement certification' with 'movement document' in the last paragraph of Article 4.3.2., the Code Commission did not accept the proposed modifications because the proposed changes were not congruent with the definition of *Veterinary Services*.

The Code Commission accepted the suggestion of a Member Country to reinsert, with modifications, the paragraph on industry responsibilities at the end of Article 4.3.2, and in doing so, also addressed comments from another Member Country.

In response to a Member Country's comment on point 2 of Article 4.3.3., 'factors defining a compartment', the Code Commission did not accept the suggested change because this point associated with general factors related to any compartment and not to specific elements of a particular compartment.

The Code Commission added a paragraph to Article 4.3.3. to take into account Member Countries' comments related with the establishment of different types of zones.

In response to a Member Country's comment on 'free zone' at the start of the first paragraph of Article 4.3.4., the Code Commission modified the text and this modification was also reflected in the Glossary.

The Code Commission did not accept the proposal of a Member Country to remove "one or more species" from the third paragraph of Article 4.3.4., as the rationale was not persuasive. The *Code* allows the possibility to have a free status for single species only.

In response to Member Countries' comments on the third paragraph of Article 4.3.4., on ongoing surveillance, the Code Commission did not accept the addition of the proposed text as it considered it was covered adequately in the article on infected zones. Taking into account these comments, the Code Commission modified the second paragraph of the same article for clarity and to emphasise that surveillance should always be the objective.

In response to Member Countries' suggestion to delete the sentence on maintenance of status in the fourth paragraph of Article 4.3.4., the Code Commission did not accept the suggestion, as it is important to highlight the need for ongoing surveillance. Nevertheless, amendments were made to improve clarity.

In answer to Member Countries' comments on the definition of *infected zone*, the Code Commission modified the text in Article 4.3.5., and this modification was also reflected in the Glossary.

The Code Commission did not accept Member Countries' comments to partly delete the last sentence of the article because measures to regain free status in a previously free zone are necessary.

In response to Member Countries' comments, the Code Commission modified the first paragraph of Article 4.3.6. for clarity.

The Code Commission in response to a Member Country's suggestion did not modify point 2 of Article 4.3.5. because it is already indicated that vaccination is optional.

In response to a Member Country's comment to add more detail in point 7 of Article 4.3.6., the Code Commission did not consider it to be appropriate to be more prescriptive on this point.

In response to a range of comments on Article 4.3.7., the Code Commission confirmed that the use of zoning, depending on the situation, is the responsibility of the *Veterinary Authority* and should not be too detailed in the *Code* and that if horizontal chapters apply in any situation, they should be read in conjunction with the disease-specific chapters. The Code Commission asked that the Headquarters consider developing the User Guide to address this point (precedence of chapters) and avoid confusion in the future.

In response to a Member Country's comment regarding deletion of reference to contingency plan, the Code Commission pointed out that the concept of contingency planning already appears elsewhere in the *Code* and is well understood. The Article 3.2.14. recommends that Member Countries have a contingency plan that is based on a rapid response.

In response to Member Countries' comments the Code Commission modified Article 4.3.7. and the definition of *containment zone* in order to include different options for the management of that zone.

The chapter now provides more clarity regarding the concept of when containment zones can be used and for what purpose. The chapter also provides more clarity in regards to the regaining of free status of a containment zone.

The Code Commission did not agree to add the word 'establishments' in the article on containment zone as, by definition, the establishments are included in the zone.

The Code Commission did not accept a Member Country's proposal to replace 'last detected case' with 'completion of stamping-out' because a stamping-out policy is not always the control strategy taken to eradicate a disease from a containment zone.

In order to address a number of Member Countries' comments the Code Commission made several amendments to ensure clarity and consistency.

The revised Chapter 4.3. is attached as **Annex 21** for Member Countries' comments.

b) Draft new chapter on vaccination (Chapter 4.X.)

The Code Commission considered the revised draft chapter along with the report of the *ad hoc* Group on Vaccination (convened in March 2016). The *ad hoc* Group considered recommendations from the three Specialist Commissions and restructured and split the draft chapter into more articles to be aligned with established format of the *Code* along with several other specific amendments. The Code Commission commended the work of the *ad hoc* Group, considered the revised draft and redrafted sections for further clarity and to take into account the practical implementation of vaccination programmes and to ensure that other standards related directly to vaccines were referenced.

In addition to the above, in reviewing the chapter the Code Commission agreed to use the term 'pathogenic agent' rather than 'disease causing agent' to be consistent with other relevant chapters of the *Code*, which had also been reviewed during its meeting.

When discussing the definitions, the Code Commission noted the term *vaccination* was already defined in the Glossary but with a different meaning. The Code Commission revised the definition of *vaccination* to align it with the new draft chapter.

The proposed new Chapter 4.X. is attached as **Annex 22** for Member Countries' comments.

c) Draft new chapter on management of outbreaks of listed diseases (Chapter 4.Y.)

The Code Commission noted that a new chapter on management of outbreaks of listed diseases (Chapter 4.Y.) had been drafted by experts but because of time constraints it was unable to consider it.

The Code Commission agreed to examine the text between meetings and noted that the Headquarters would seek feedback from the other Specialist Commissions.

The Code Commission will review the draft at its February 2017 meeting.

Item 9 Semen and embryos

a) Collection and processing of bovine, small ruminant and porcine semen (Chapter 4.6.)

A comment was received from Australia.

The Code Commission noted that in the past, in relation to the report of its September 2014 meeting, some other Member Countries also commented about inconsistencies between this chapter and disease-specific chapters in both the *Code* and the *Manual*. While noting the effort made by Headquarters to correct these inconsistencies, the Code Commission considered that it is difficult to keep updated cross-references from this chapter to disease-specific chapters. The Code Commission discussed the value of this chapter in addition to Chapter 4.5. and disease-specific chapters, and discussed two options: (1) developing a single complete chapter that includes detailed testing requirements without cross references and (2) simplifying the existing chapter by including only general conditions applicable to semen collection and handling.

In view of the amount of time and expertise needed, the Code Commission decided to stop reviewing this chapter for the moment and recommended that the review be continued with the input from experts of the OIE Collaborating Centre on reproductive diseases.

b) Collection and processing of *in vitro* derived embryos from livestock and equids (Chapter 4.8.)

Comments were received from Australia and the IETS.

In answering a Member Country's request to seek expert advice on the risks associated with trade of *in vitro* produced embryos, the production of which has increased greatly worldwide, the Code Commission reviewed the proposal received from the IETS and modified the text of Article 4.8.7.

The Code Commission changed the order of 'embryo' and 'oocyte' in the title, for consistency, and removed the reference to 'rinderpest' in Article 4.8.4. point 2, as this disease has already been eradicated globally. The Code Commission also made some editorial modifications, including some relating to the existing definitions of *slaughterhouse/abattoir* and *shipment* and the proposed definition of 'pathogenic agent'.

However, the Code Commission noted that more scientific data were needed to further improve Chapter 4.8. The Code Commission and the Laboratories Commission noted that currently there is no sufficient available scientific data to assess the risk of disease transmission in *in vitro* produced embryos or oocytes, nor is there funding for such research. The two Commissions agreed that there is a need for the OIE Headquarters to raise awareness among Member Countries on this issue and to generate financial resources to conduct the necessary research that will assist the Commissions to update the *Code* and *Manual*.

The revised Chapter 4.8. is attached as **Annex 23** for Member Countries' comments.

c) Somatic cell nuclear transfer in production livestock and horses (Chapter 4.11.)

A comment was received from New Zealand.

The Code Commission modified the terminology in Article 4.11.4. points 2 and 4, after considering the rationale submitted by the Member Country, as follows:

"Risks themselves are neither 'qualitative' nor 'quantitative'; it is the assessments which are one or the other. The glossary definition of 'qualitative risk assessment' is "an assessment where the outputs on the likelihood of the outcome or the magnitude of the consequences are expressed in qualitative terms such as 'high', 'medium', 'low' or 'negligible'". This contradicts the statement in 2. above that such descriptors are 'semi-quantitative'.

Chapter 2.1. of the *Code* nowhere mentions 'semi-quantitative risk assessment'. The OIE publication Handbook on Import Risk Analysis for Animals and Animal Products: Volume 1 Introduction and Qualitative Risk Analysis (second edition, 2010. World Organisation for Animal Health, Paris. Pages 36-37.) states:

[...] all risk analyses inevitably include a degree of subjectivity. Nevertheless, because many people find numbers seductive and reassuring, some analysts use so-called semi-quantitative methods in the mistaken view that they are somehow more 'objective' than strictly qualitative techniques. [...] However, a number of significant problems may arise from adopting a semi-quantitative approach in an import risk analysis. It is sometimes employed as a means of combining various qualitative estimates, by assigning numbers to them, to produce a summary measure or to prioritise risks. The numbers may be in the form of probability ranges or scores, which may be weighted before being combined by addition, multiplication or similar mathematical operations. The numbers, ranges, weights and methods of combination chosen are usually quite arbitrary, and need careful justification to ensure transparency.

It should be recognised that numbers assigned to categories cannot legitimately be manipulated mathematically and statistically. For example, one type of semi-quantitative method that has been used in some risk analyses involves dividing the probability range 0 to 1 into a number of arbitrary intervals [...] and giving each of these a qualitative descriptor such as 'negligible', 'extremely low', 'very low' and so on. The risk assessor uses the qualitative descriptors for the probability of each step of the risk assessment. The probability of the all steps in the pathway occurring is then calculated by multiplying the arbitrary probability intervals ascribed to each qualitative descriptor. Finally the product of this multiplication is converted back to a qualitative descriptor. While it might superficially appear objective, this type of semi-quantitative assessment is flawed, and leads to conclusions that are statistically and logically incorrect (Morris and Cogger, 2006).

In summary, semi-quantitative assessments give a misleading impression of objectivity and precision, and lead to inconsistent outcomes. Assigning numbers to subjective estimates does not result in a more objective assessment, particularly when the numbers chosen and their method of combination are arbitrary."

The revised Article 4.11.4. is attached as **Annex 24** for Member Countries' comments.

Item 10 OIE procedures relevant to the Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization (Chapter 5.3.)

Comments were received from Colombia, New Zealand, Switzerland, Thailand, EU and AU-IBAR.

The Code Commission in general agreed with a Member Country's comment that this chapter should be consistent with other documents such as the *Codex Alimentarius*.

In agreeing with Member Countries about the need for clarification of the meaning of 'zone' and 'region' following the proposed deletion of 'region' from the Glossary and proposal to delete references to 'regionalisation' from Chapter 4.3., the Code Commission drafted a sentence at the beginning of Article 5.3.7. stating that the OIE definition of 'zone' has the same meaning as 'region' and 'area' used in the SPS Agreement.

The Code Commission did not accept a suggestion by some Member Countries to replace 'judgements' with 'determination' in the first paragraph of Article 5.3.3., noting that this issue was thoroughly discussed at its meeting in February 2016: 'judgement' is a decision based on the process of 'determination'.

The Code Commission did not accept a suggestion by some Member Countries to replace 'consider' with 'include' in the first paragraph of Article 5.3.4. point 2, noting that 'consider' conveys the meaning of an intention to deliberate about an issue. The Code Commission, while accepting a suggestion by some Member Countries and correcting the second paragraph of the same point by replacing 'managing' with 'to manage,' did not agree to replace 'the' with 'each.'

The Code Commission accepted a suggestion by some Member Countries and added 'safe commodities' in Article 5.3.4. point 3 as a principle to determine equivalence of sanitary measures.

In response to a comment by a Member Country that the meaning of 'informal agreement' is unclear, the Code Commission modified Article 5.3.6. point 8.

The Code Commission did not accept a Member Country's suggestion to elaborate Article 5.3.7. point 2 a), as 'partnership' in the existing text includes the commitment of all partners. The Code Commission also noted that Chapter 4.3. details such commitment.

In response to a Member Country's comment on Article 5.3.7. point 2a, the Code Commission noted the importance of referring to 'other premises' not containing animals and clarified the text accordingly.

In response to a Member Country's comment on Article 5.3.7. point $2 \, b$) i), the Code Commission reiterated the difference between zoning and compartmentalisation, the latter of which is not based on geographical factors.

The revised Chapter 5.3. is attached at <u>Annex 9</u> for Member Countries' comments and is proposed for adoption at the 85th General Session in May 2017.

Item 11 Veterinary public health

a) The role of the Veterinary Services in food safety (Chapter 6.1.)

Comments were received from Japan, Malaysia, New Zealand, Norway, Switzerland, USA, EU and AU-IBAR.

Given the extensive number of Member Countries' comments received on this chapter, the Code Commission requested that all comments be referred to the Animal Production Food Safety Working Group for its consideration when it next meets in December 2016. The Commission will review the revised chapter at its February 2017 meeting.

b) Harmonisation of national antimicrobial resistance surveillance and monitoring programmes (Chapter 6.7.)

The Code Commission considered Member Countries' comments and proposals from the *ad hoc* Group on Antimicrobial Resistance (AMR) and the Scientific Commission, and made relevant amendments.

In Article 6.7.2. the Code Commission agreed with a Member Country's comment to delete 'in bacteria' in point 1 to clarify that the intent of this sentence is to assess and determine trends and sources of AMR in bacteria and also sources of resistant bacteria.

In Article 6.7.3. the Code Commission agreed with a Member Country's comment to add 'animal feed' in point 1 because it is a potential source of AMR in animals and a route to humans via food. However it did not agree to delete 'in therapy' at the end of this paragraph because the text reflects the objective of this chapter as outlined in Chapter 6.6.

The Code Commission did not agree with a Member Country's comment to amend points 2 a) and b) as it considered the current text was clear and the list of examples is not an exhaustive one.

The Code Commission agreed with a Member Country's suggestion to change 'faecal' to 'faeces' which is the appropriate noun.

The Code Commission amended point 6 based on comments provided by the *ad hoc* Group and the Scientific Commission to include examples of bacterial isolates that could be included in surveillance and monitoring programmes. The rationale for these proposed amendments is provided in the following extract from the report of the meeting of the *ad hoc* Group on Antimicrobial Resistance held in January 2016:

"The Group agreed that veterinary pathogens included in the table should have global or widespread animal health relevance and agreed not to develop regional tables. Food-producing animals were targeted as a starting point for programmes which could be adapted to include other animals according to national requirements. The Group considered that the table was an attempt at prioritisation of relevant veterinary pathogens and suggested additional criteria for inclusion in the *Terrestrial Code* to help OIE Member Countries devise suitable national monitoring programmes. These included:

- Impact on animal health and welfare;
- Implication of antimicrobial resistance in the pathogen for therapeutic options in veterinary practice;
- Impact on food security and on production (economic importance of associated diseases);
- Bacterial diseases responsible for the majority of veterinary antimicrobial usage (stratified by usage of different classes or their importance);
- Existence of validated susceptibility testing methodologies for the pathogen.

The Table of suggested veterinary pathogens in Article 6 a) of Chapter 6.7. of the *Terrestrial Code* was developed by the Group reflecting the above considerations. Some veterinary pathogens, such as *Brachyspira* spp. and *Histophilus somnii* (formerly *Haemophilus somnus*), were not included in the table, even though they are considered important, because they are fastidious and technically difficult to test and there is no internationally agreed standard methodology for testing them. Validation of susceptibility testing methodologies should be encouraged for these veterinary pathogens."

The Code Commission did not accept a Member Country comment to amend point b i) as it considered it clear as written. However, the Code Commission did accept the proposal to amend the second paragraph to allow consideration of private laboratories and to reflect current practices in sampling and surveillance for *Campylobacter*."

The Code Commission agreed to amend point c) to clarify that sampling should be done at the slaughterhouse/abattoir.

The Code Commission agreed to amend the text in point 8 to clarify that data should be reported both qualitatively and quantitatively.

The Code Commission agreed to add two new sub-points in point 9: '(ix) exposure of animals to antimicrobial agents; (x) bacterial recovery rate', as these also provide useful information.

The revised Chapter 6.7. is attached as **Annex 25** for Member Countries' comments.

Item 12 Veterinary public health: zoonoses and food safety

a) Draft new chapter on prevention and control of Salmonella in commercial cattle production systems (Chapter 6.X.)

Comments were received from Australia, China, Chinese Taipei, Colombia, Japan, Malaysia, New Zealand, Norway, Switzerland, EU and AU-IBAR.

The Code Commission considered Member Countries' comments and made relevant amendments.

In response to a Member Country's comment that some recommendations are out of the defined scope of this chapter, the Code Commission noted that this chapter includes only those risk management measures that can be controlled at the farm level.

The Code Commission agreed to make the following amendments throughout the entire chapter: i) change 'types' of *Salmonella*; ii) delete 'it is recommended that' from the chapeau of several articles and add 'should' into each point to align with the convention used in the *Code*.

In Article 6.X.1. the Code Commission agreed to delete 'For example' in paragraph 1.

The Code Commission did not agree to add S. Dublin in the introductory text because it considered it to be sufficient as written; it did not agree to delete 'age' because it is a factor in dissemination and persistence; and did not agree to add 'infection' after 'Salmonella' as this would be inconsistent with Chapter 6.Y.

In Article 6.X.2., the Code Commission did not agree to include breeder cattle because they are covered in the definition of commercial cattle production systems; it did not agree to amend this article as it did not consider that the proposed changes improved readability.

In Article 6.X.3., the Code Commission agreed to add *B. javanicus* as it is a commercially farmed species in Asia. It updated the reference to the recently adopted Codex Guidelines for the Control of Nontyphoidal *Salmonella* spp. in Beef and Pork Meat (CAC/GL 87-2016) and removed 'under study'.

In Article 6.X.4., the Code Commission agreed to amend the first sentence to improve readability. It changed 'concentration' to 'amount', agreeing that this was a better term to use. It agreed to add 'or water' after contamination acknowledging that this is a potential source of contamination. It agreed to add new paragraph before the last paragraph referring to the importance of good farming practices and principles of hazard analysis and critical control points when designing prevention and control measures.

In Article 6.X.5., the Code Commission agreed to delete the example in the first paragraph as it considered it unnecessary. It agreed to replace 'biosecurity management plan' with 'biosecurity plan' given that biosecurity plan is a defined term in the Glossary. The Code Commission noted that although the current definition for 'biosecurity plan' only covers zones and compartments, it considered it to be applicable to this chapter. The Code Commission noted that it would revise this definition at its next meeting to better reflect the broader use of this term throughout the *Code*.

The Code Commission agreed to add 'feeding' in point 5 agreeing this is an important source of infection. It agreed that some text should be deleted from point 9 regarding cleaning and disinfection as it considered that this level of detail was more appropriate for Chapter 4.13. It proposed to address this level of detail and relevant Member Countries' comments in future revision of Chapter 4.13. The Code Commission added a new point 14 to address procedures in the case of a suspected or confirmed infected animal.

The Code Commission did not agree to delete 'cattle buildings' noting that the applicability of the measures depends on the type of production system as described in the introductory text to this article. The Code Commission did not agree to add some suggested new points in this article as it considered these were already covered and more detail was not necessary.

In Article 6.X.6., the Code Commission did not accept to delete the words 'and water' in point 5 because it is relevant in the designing of cattle establishments. It did not agree to add a reference to semi-intensive cattle production systems because it was not deemed necessary, especially as there is no specific definition for this production system.

It addressed a comment regarding the importance of age and segregation in point 7 by the inclusion of a new point 4 in Article 6.X.8. that addresses segregation according to age. The Code Commission considered this to be a better placement for this point.

In Article 6.X.7., the Code Commission amended point 6 to clarify when testing should be done.

In Article 6.X.8., the Code Commission amended point 1 to improve clarity.

In Article 6.X.10., the Code Commission agreed to change 'drinking water' to 'water for drinking' to avoid confusion with potable water for human consumption.

The Commission did not agree to align text in the similar article in Chapter 6.Y. because it was not considered relevant to this article that applies to intensive and extensive cattle production systems, which differ significantly from pig production systems.

In Article 6.X.11., the Code Commission agreed to amend point 5 to emphasise the fact that antimicrobial agents may modify normal flora in the gut and increase the likelihood of colonisation by *Salmonella* and to emphasise that the use of antimicrobial agents should be limited to the treatment of clinical enteric salmonellosis. The Code Commission agreed to add a new point 4 to recognise the potential role of stress.

The Code Commission did not agree to include information already detailed in Chapter 6.9.

In Article 6.X.12., the Code Commission agreed to reword the first sentence to provide a more precise recommendation regarding cleaning and disinfection after transportation of animals.

In Article 6.X.14., the Code Commission agreed to delete the reference to slaughtered animals acknowledging that this measure is addressed in Codex standards.

In Article 6.X.15., the Code Commission agreed to delete the second reference to serological testing at the end of the second paragraph, agreeing it was unnecessary.

In Article 6.X.16., the Code Commission did not agree with a comment regarding the use of 'possible' as this is addressed by 'may be possible' at the beginning of the sentence. The 'or' was changed to 'and' before removal of persistent carriers as this is the correct term for a list.

The revised Chapter 6.X. is attached as <u>Annex 10</u> for Member Countries' comments and is proposed for adoption at the 85th General Session in May 2017.

b) Draft new chapter on prevention and control of Salmonella in commercial pig production systems (Chapter 6.Y.)

Comments were received from Australia, Canada, Chinese Taipei, Colombia, Japan, Malaysia, New Zealand, Norway, Switzerland, USA, EU and AU-IBAR.

The Code Commission considered Member Countries' comments and made relevant amendments.

The Code Commission also ensured any relevant amendments made to Chapter 6.X. were made to this chapter.

The Code Commission agreed to make the following amendments throughout the entire chapter: i) change 'types' of *Salmonella*; ii) delete 'it is recommended that' from the chapeau of several articles and add 'should' into each point to align with the convention used in the *Code*.

The Code Commission did not agree to include some concepts such as a focus on breeding pigs that are referenced in a scientific opinion, noting that the expert *ad hoc* Group that drafted this chapter was familiar with that reference and had deemed some points not relevant to the OIE chapter. In addition the comment did not include any proposed new text.

In Article 6.Y.1., the Code Commission agreed to delete 'for example' and 'also' in the last sentence of the first paragraph to improve clarity and align with amendments to Article 6.X.1.

In Article 6.Y.3., the Code Commission did not agree to add 'contamination of the environment' because it is already addressed by the wording 'indirect contact'.

The Commission updated the reference to the recently adopted Codex Guidelines for the Control of Nontyphoidal *Salmonella* spp. in Beef and Pork Meat (CAC/GL 87-2016) and removed 'under study'.

In Article 6.Y.4., the Code Commission agreed to amend the first sentence to improve readability. It agreed to change 'concentration' to 'amount' agreeing that this was a better term to use. It agreed to add 'or water' after contamination acknowledging that this is a potential source of contamination. It agreed to add a new paragraph before the last paragraph referring to the importance of good farming practices and principles of hazard analysis and critical control points when designing prevention and control measures.

The Code Commission did not agree to change 'will' to 'may' in point 2 because it is correct as written, i.e. reducing contamination will limit infection.

In Article 6.Y.5., the Code Commission agreed to delete the example in the first paragraph as it considered it unnecessary. It agreed to replace 'biosecurity management plan' with 'biosecurity plan' given that biosecurity plan is a defined term in the Glossary. The Code Commission noted that although the current definition for 'biosecurity plan' only covers zones and compartments it considered it to be applicable to this chapter. The Code Commission noted that it would revise this definition at its next meeting to better reflect the broader use of this term throughout the *Code*.

As in the draft Chapter 6.X. the Code Commission agreed to add 'feeding' in point 5 agreeing this is an important source of infection. It agreed that some text should be deleted from point 9 regarding cleaning and disinfection as it considered that this level of detail was more appropriate for Chapter 4.13. The Code Commission proposed to address this level of detail and relevant Member Countries' comments in the future revision of Chapter 4.13.

The Code Commission agreed to add a new point 15 to address procedures in the case of suspected or confirmed infected animals.

The Code Commission did not agree to add some suggested new points in this article as it considered these were already covered and more detail was not necessary.

In Article 6.Y.6., the Code Commission did not agree to amend point 4 regarding the area immediately surrounding pig houses because it considered the text as written is clear and is also aligned with similar points in other chapters, e.g. Chapter 6.4. The Code Commission did not agree to delete the words 'and water' in point 7 because it is relevant in the designing of pig establishments. The Code Commission addressed a comment regarding the importance of age and segregation by the inclusion of a new point 4 in Article 6.Y.8. that addresses segregation according to age. The Code Commission considered this to be a better placement for this point.

In Article 6.Y.7., the Code Commission agreed to amend the first sentence to clarify that introduction of pigs is a risk factor in all herds but especially important in moderate and high prevalence regions. The Code Commission amended point 6 to clarify when testing should be done.

In Article 6.Y.8., the Code Commission agreed to amend point 1 to clarify that pig movement and mixing of pigs should be minimised throughout their whole life. The Code Commission agreed to add a new point to address the importance of segregating sick pigs to minimise the spread of *Salmonella*.

In Article 6.Y.9., the Code Commission agreed to amend point c) to acknowledge differences in what may be possible in different countries.

The Code Commission did not agree to delete the sentence in point 1 regarding low prevalence regions as it considered it important to emphasise the difference between such regions.

In Article 6.Y.10., the Code Commission agreed to change 'drinking water' to 'water for drinking' to avoid confusion with potable water for human consumption. The Code Commission agreed to add a new point to address the importance of preventing access of birds, rodents and wildlife to the water supply and delivery systems.

In Article 6.Y.11., the Code Commission agreed to amend point 2 to emphasise the fact that antimicrobial agents may modify normal flora in the gut and increase the likelihood of colonisation by *Salmonella* and to emphasise that the use of antimicrobial agents should be limited to the treatment of clinical enteric salmonellosis. It did not agree to include information already detailed in Chapter 6.9.

The Code Commission agreed with a comment regarding the importance of considering the use of vaccines as alternatives to antimicrobial agents but did not agree to include such text in this article as it is a general principle not specific to Salmonella and as it is addressed in Article 6.9.7. point 2a).

In Article 6.Y.12., the Code Commission agreed to reword the first sentence to provide a more precise recommendation regarding cleaning and disinfection after transportation of animals.

In Article 6.Y.14., the Code Commission agreed to delete a second reference to serological testing at the end of the second paragraph agreeing it was unnecessary. It agreed to add a new paragraph describing the limitations of using serology. It also agreed to amend the last paragraph to improve clarity regarding bacteriological sampling of individual pigs to overcome low sensitivity.

In Article 6.Y.15., the Code Commission did not agree with a comment regarding the use of 'possible' as this is addressed by 'may be possible' at the beginning of the sentence. The 'or' was changed to 'and' before removal of persistent carriers as this is the correct term for a list.

The revised Chapter 6.Y. is attached as <u>Annex 11</u> for Member Countries' comments and is proposed for adoption at the 85th General Session in May 2017.

Item 13 Animal welfare

a) Report of Animal Welfare Working Group (AWWG)

The Code Commission noted the report of the AWWG and the amendments proposed for animal welfare chapters. The Code Commission noted the recommendations of the AWWG on the need to conduct an extensive review of Chapters 7.5. and 7.6.

The report of the AWWG meeting is attached as **Annex 30** for Member Countries' information.

b) Draft Article 7.1,X. on guiding principles on the use of animal-based measures

The Code Commission welcomed the proposal of the AWWG on a new article on guiding principles for the use of animal-based measures to be included in Chapter 7.1. The Code Commission reviewed the draft text and amended it to simplify the text and align it with the established *Code* format and conventions. The objective of this article will be to support Member Countries in the use of outcome-based measurables in implementing the animal welfare chapters.

The new draft Article 7.1.X. is attached as **Annex 26** for Member Countries' comment.

c) Methods of killing farmed reptiles for their skins and meat

The Code Commission discussed the new work on methods of slaughter and killing of reptiles. The Code Commission recalled that the step taken to begin this work was the adoption during the last General Session, of a modified definition of *animal* that now includes reptiles.

The Code Commission recommended that the OIE develop a stand-alone chapter rather than include new material in Chapter 7.5. that specifically concerns slaughter of animals kept primarily for food production. In addition it is already complex and the inclusion of reptiles would reduce the readability of the chapter.

The Code Commission recommended that the OIE develop a draft chapter on the slaughter and killing of farmed reptiles for their skins and meat, based on a draft document already provided by experts. It requested that OIE headquarters establish an electronic *ad hoc* group, to undertake this review in order to provide the Code Commission expects to receive with a proposed new draft Chapter 7.Y. for its February 2017 meeting.

d) Slaughter of animals (Chapter 7.5.) and Killing of animals for disease control purposes (Chapter 7.6.)

Comments were received from Argentina, Australia, Canada, Chile, Colombia, Mexico, New Zealand, Norway, Singapore, Switzerland, Thailand, Uruguay, USA, EU, AU-IBAR, ASEAN, CVP, and ICFAW.

The Code Commission decided not to pursue the review of the Member Countries' comments on the proposed text in Chapters 7.5. and 7.6., and in particular Article 7.5.7. on the method for waterbath stunning for poultry, due to the large number of often irreconcilable comments. In order to achieve a consistently structured format and to review these chapters with up to date scientific data, the Code Commission asked the Headquarters to undertake a concomitant review of these two chapters, utilising specific expertise in these areas.

e) Animal welfare and broiler chicken production systems (Chapter 7.10.)

Comments were received from Australia and EU.

The Code Commission considered that Member Countries' proposals to amend this chapter were not substantive or triggered by new science. Therefore, the Code Commission decided not to modify the chapter, a revised version of which was adopted at the OIE General Session in May 2016.

f) Animal welfare and dairy cattle production systems (Chapter 7.11.)

Comments were received from Australia, Uruguay, USA and EU.

The Code Commission considered Member Countries' comments received before or during the May 2016 General Session.

The Code Commission did not accept a Member Country's suggestion to replace the terms 'mortality rate' and 'morbidity rate' by 'mortality' and 'morbidity' respectively, as the Member Country did not submit a rationale.

In response to Member Countries' comments, the Code Commission proposed new wording to point 5 of Article 7.11.6. to avoid confusion, by clarifying provisions that apply in situations where housing design provides only individual spaces for cows to rest.

The Code Commission decided that the review of comments received after the General Session in May 2016 will be postponed until the next revision of the chapter.

The revised Article 7.11.6. point 5 is attached as <u>Annex 12</u> for Member Countries' comment and is proposed for adoption at the 85th General Session in May 2017.

g) Welfare of working equids (Chapter 7.12.)

Comments were received from Australia, USA, EU and AU-IBAR.

The Code Commission analysed all Member Countries' comments received before and after the General Session. The comments were positive, in particular those from the African Region Member Countries, due to the role of working equids on the continent.

The Code Commission considered some linguistic modifications of the text proposed by Member Countries and made the relevant amendments accordingly.

The Code Commission did not accept comments on the introductory section because the concerns of Member Countries were all found to be addressed in the first and second paragraphs.

In Article 7.12.2., the Code Commission did not accept the suggestion of a Member Country to modify text to include hinnies, as 'mule' is already a generic term for crossbreeds of horses and donkeys.

In Article 7.12.3., the Code Commission did not accept a proposed change in the first paragraph, as it is already covered in the existing text. In points 1, 2, 3 and 4, the Code Commission accepted the proposed modification from Member Countries and modified the accompanying text.

In Article 7.12.4., the Code Commission accepted the comment of a Member Country in order to clarify that the signs mentioned are always an indication of welfare problems. It also accepted the proposal of a Member Country to include some new indicators of stress.

In point 5 the Code Commission did not accept a Member Country's comment in relation to handling responses. Injury is not a response to improper handling, but the result of bad human-animal interaction.

In the points 5, 7 and 8 of the above mentioned article, the Code Commission did not accept Member Countries' comments as they were not justified and did not add to the value of the text.

In Article 7.12.6., the Code Commission accepted, with modification, the comment of a Member Country concerning recommendations for feeding. In the same recommendation, it did not accept to add the specific wording proposed by a Member Country about consideration of cold weather as it is already included in the text, in Article 7.12.7.

In Article 7.12.9., the Code Commission did not agree with a Member Country's suggestion to add text concerning a specific painful procedure, as the rationale given was not persuasive and did not reflect the reality of the management of these species in working conditions. Nevertheless, the Code Commission could accept to modify this recommendation if it were to receive a more robust justification. In the same article it did not accept the inclusion of new text on pain management, as it is already included in the article.

In Article 7.12.1. point 2, concerning appropriate workloads, the Code Commission analysed Member Countries' comments and in general agreed with the advice of the AWWG that it is possible to include input-based recommendations in the animal welfare chapters of the *Code*, if they are clearly linked with a welfare outcome. In case of limiting the work load of pregnant mares, the experts justified this through the necessity of the foal to have access to mother's milk during a specific period of time, which is supported by the available scientific research. Regarding the recommendations for the limits to duration of work, the Code Commission agrees that the expert experience clearly links welfare problems with animals working more than six hours per day or more than six days in a row. Therefore, it only modified the text in alignment with Member Countries comments for clarity.

The revised Chapter 7.12. is attached as <u>Annex 13</u> for Member Countries' comment and is proposed for adoption at the 85th General Session in May 2017.

h) Report of *ad hoc* Group and the draft Chapter 7.X. on Animal Welfare and pig production systems

The Code Commission reviewed the draft Chapter 7.X. on animal welfare and pig production systems, produced by the *ad hoc* Group at its March 2016 meeting and found the draft chapter is generally well written and well balanced. The Code Commission edited the draft chapter to ensure the correct use of glossary-defined terms and also to ensure correct English is used throughout the text. The report of the *ad hoc* Group is attached as **Annex 31** for Member Countries' information.

The revised Draft Chapter 7.X. is attached as **Annex 27** for Member Countries' comments.

Item 14 Infection with bluetongue virus (Chapter 8.3.)

A comment was received from Australia.

The Code Commission considered the revised chapter and made some general observations and noted that the OIE Headquarters needed to look at the vector borne chapters for consistency, in particular the use of '[disease] free' and 'seasonally free' in the chapters.

The President of the Code Commission also noted he had discussed with the President of the Laboratories Commission the following (see above D c):

- the strains of bluetongue virus, and concluded that it was not possible to explicitly exclude non-pathogenic strains from the case definition, as there are currently no means to differentiate between pathogenic and non-pathogenic;
- the vaccine strains, and concluded that the case definition should include them if found in a non-vaccinated animal or an animal that was vaccinated against another strain or with an inactivated vaccine.

The Code Commission decided that since the chapter had been adopted with the intention of further looking at the case definition, it should also look at the other Member Countries' comments.

In order to maintain consistency the Code Commission clarified that 'samples' should be 'a sample' and 'identified in a sample from' should be used consistently across all the chapters of the *Code*.

The Code Commission made amendments to implement advice from the Laboratories Commission and inserted a new point 3 of Article 8.3.1. to read "antigen or ribonucleic acid specific to a BTV vaccine strain has been detected in samples from a ruminant or camelid that is unvaccinated or has been vaccinated with an inactivated vaccine, or with a different vaccine strain."

The Code Commission noted that it had already removed 'seasonally free country' from other chapters, which only refer to 'seasonally free zones', the zone covering possibly the entire territory of a country. After the completion of the first round of harmonisation on vector-borne disease chapters, it noted that there are still some inconsistencies among the chapters. The Code Commission also noted an inconsistency in Article 8.3.7. regarding the importation from zones seasonally free from *bluetongue* and made modifications to point 5 in order to fix the inconsistency. If adopted, this modification will also apply to Chapter 8.7.

The Code Commission agreed with a Member Country's proposal to amend Article 8.3.9., which was supported by a strong rationale, and made the appropriate amendments including the addition of a new point regarding reference to Article 8.3.10.

The Code Commission also noted that the article is about 'free zone' or 'seasonally free zone' and that the inserted concept of a 'seasonally free period' was confusing and irrational. In order to avoid this in the future, it considers that this should be referred to as the 'free season' and when the chapter is adopted this subsequent change will need to be made to other relevant chapters i.e. Chapter 8.7.

The Code Commission agreed that there were still inconsistencies with other chapters and in answer to Member Countries comments at the General Session on Article 8.3.9. made appropriate amendments.

The Code Commission agreed with the comment of a Member Country in regards to the need to clarify the requirement to test bulls every seven days and made the appropriate changes to Article 8.3.10.

The revised Chapter 8.3. is attached as **Annex 28** for Member Countries' comments.

Item 15 Infection with foot and mouth disease virus (Chapters 8.8.)

Comments were received from Argentina, Australia, Canada, China, Chinese Taipei, Colombia, Japan, Korea, Mexico, New Zealand, South Africa, Switzerland, Thailand, USA, EU, AU-IBAR, and Ouads.

The Code Commission considered the input from the Scientific Commission and the report of the *ad hoc* Group that had met in June 2016, as well as a number of comments received after the General Session in May 2016. After lengthy discussions, including with the Scientific Commission, it became apparent that there was a large amount of work yet to be done on this chapter, especially the inclusion of new concepts regarding zoning and movements of animals. The Code Commission, conscious of Member Countries' concerns regarding the short timeframe that they had been given to comment on the chapter, formed the view that, as this was not an urgent situation, and in order to ensure full consideration of all comments and proposals of the Member Countries, the *ad hoc* Group and the Scientific Commission, more time was needed to continue the development of this chapter. Therefore the Code Commission postponed further discussion on this chapter until its meeting in February 2017.

Before the next meeting, members of the Code Commission will continue to review the revised chapter, making note of any particular concerns or questions for further discussion in February 2017. Members of the Code and Scientific Commissions are encouraged to exchange views between the sessions via email, based on proposals of the Headquarters, which will work to review the document and identify issues that may require further expertise.

Item 16 Infection with Mycobacterium tuberculosis complex (draft new Chapter 8.X.)

Comments were received from Australia, Canada, China, Japan, New Zealand, Norway, Switzerland, EU and AU-IBAR.

Extract from the report of the February 2016 meeting of the Code Commission:

"After reviewing the *ad hoc* Group report and consultation with the Scientific Commission, the Code Commission concluded it currently had insufficient information to include New World camelids in the list of susceptible species. It asked Headquarters and both the Laboratories Commission and the Scientific Commission to re-evaluate the significance of infection with M. tuberculosis complex in New World camelids along with the available diagnostic and risk management tools to determine whether they should be included in the case definition or not.

Member Countries' observations that compliance with the provisions of Article 8.X.14. point 1 requires that goats are kept in a herd that has been subjected to a testing regime, were referred to the Laboratories Commission and the Scientific Commission to support further consideration of the development of such a testing regime to demonstrate herd freedom from infection with *M. tuberculosis* complex in goats."

In response to Member Countries' comments, and after receiving opinions from experts and the Laboratories and Scientific Commissions, the Code Commission re-inserted the definition for New World camelids in Article 8.X.1. Indeed, while *M. tuberculosis* in domesticated New World camelids is not common, they may, nevertheless, be infected with *M. tuberculosis* complex by spill over from wildlife and cattle and may themselves be a source of *M. tuberculosis* for cattle and humans. This is especially the case when they are reared in intensive conditions. However, due to the current lack of validation of sensitive and specific tests, it was not possible for the Code Commission to draft articles on free status of countries, zones or herds for New World camelids. Similarly, it was not possible for the Code Commission to draft articles on free status of countries, zones or herds for goats.

The Code Commission did not accept a Member Country's proposal to include milk that has been subject to pasteurisation as a safe commodity, considering it necessary to keep it in Article 8.X.14., since pasteurisation, as described in the Codex Code of hygienic practice for milk and milk products (CAC/RCP 57-2004), specifically addresses the control of *tuberculosis*.

The Code Commission did not agree to a Member Country's proposal to delete meat-and-bone meal from point 3 of Article 8.X.2., as the *ad hoc* Group had added these commodities based on scientific evidence that normal processes to produce meat-and-bone meal inactivates *Mycobacteria*.

The Code Commission agreed with the proposal of Member Countries regarding surveillance and included a reference to a surveillance programme in Article 8.X.4. point 1 b) to add clarity and consistency. However, in response to the question from a Member Country seeking a more rigorous scientifically-based alternative to the defined design prevalence, it noted that it would wait for the Member Country to provide such a scientifically-based alternative.

In response to a Member Country's comment concerning point 3 of Article 8.X.4. and the fact that many countries are implementing programmes to eradicate *M. bovis* in bovids, and that a spillover infection of *M. tuberculosis* of human origin in bovids should not affect a country or zone free from M. bovis, the Code Commission noted that the chapter refers to the status of a country or zone as free from *M. tuberculosis* complex in species listed in Article 8.X.1., and that included *M. tuberculosis* in bovids.

A further comment regarding point 3 of Article 8.X.4. was considered but no change was made to the text since suggested modifications did not improve clarity.

In response to a Member Country's comments on point 3 of Article 8.X.5., no change was made to the text since it was considered that the suggested modifications did not improve clarity.

In answer to comments of Member Countries, in regards to maintenance of free herd status in the presence of wildlife reservoirs, the Code Commission incorporated several amendments to Article 8.X.6. in order to provide clearer recommendations.

In answer to a Member Country's question regarding intradermal testing, the Code Commission was not in a position to modify point 2c) of Article 8.X.7., the point was referred to the Laboratories Commission for further expert advice.

The Code Commission, in answer to a Member Country's comment, proposed to delete some text of point 3 *a*) of Article 8.X.8., as it does not consider that keeping an animal in a free herd for six months is adequate, given the long incubation period of infection with *M. tuberculosis* complex.

The Code Commission did not modify point 1 of Article 8.X.14. as requested by a Member Country, since there is currently no realistically-attainable definition of a herd free from infection with *M. tuberculosis* complex in goats.

The revised Chapter 8.X. is attached as <u>Annex 14</u> for Member Countries' comments and is proposed for adoption at the 85th General Session in May 2017.

Item 17 Infection with Avian influenza viruses (Chapter 10.4.)

The purpose of the discussion on this item was primarily to consider new data provided by an expert on Article 10.4.25. in regards to the virus inactivation time/temperature table.

The new research data on pasteurisation of dried egg white to inactivate avian influenza virus was based on experiments conducted by the OIE Collaborating Centre for Research on Emerging Avian Diseases. Based on the outcome of this research the Code Commission agreed with the proposed changes to the table at Article 10.4.25. as follows:

- Plain or pure egg yolk: temperature 60°C, time 288 seconds inserted as a new line;
- Dried egg white: temperature 54.4°C, time changed to 50.4 hours;
- Dried egg white: temperature changed to 51.7°C, time changed to 73.2 hours.

In order to be clear these are representative examples only for a variety of egg products, rather than an exhaustive list of all possible products and treatments, the Code Commission made some changes to the explanatory text under the table as follows: "These are listed as examples in a variety of egg products, but where scientifically documented, variances from these times and temperatures and for additional egg products may also be suitable when they achieve equivalent outcomes".

In addition, while recalling that it had considered Member Countries' comments on Articles 10.4.1. to 10.4.3. at its February 2016 meeting, the Code Commission discussed the potential improvement of the current chapter that might provide more helpful guidance to the Member Countries for a better transparency in the global epidemiological situation of the disease or for an effective control of the disease. This should be further discussed in a future meeting.

The revised Article 10.4.25. is attached as <u>Annex 15</u> for Member Countries' comments and is proposed for adoption at the 85th General Session in May 2017.

Item 18 Lumpy skin disease (Chapter 11.11.)

Comments were received from Australia, Chinese Taipei, New Zealand, USA, EU and AU-IBAR.

The Code Commission reviewed all comments from Member Countries and advice from the Scientific Commission, and amended the text accordingly.

The Code Commission agreed with the proposal from the Scientific Commission to add a new draft Article 11.11.3bis on the recovery of free status, based on the report of the *ad hoc* Group on Lumpy Skin Disease (LSD) held in January 2016, and further discussions with various experts of that Group. The Code Commission considered it important to encourage Member Countries that face higher risk of introduction (e.g. because of infection in neighbouring countries) to use vaccination as a preventive measure, and to allow Member Countries that have effectively controlled LSD after a first incursion to regain their status more rapidly.

The Code Commission did not agree with a Member Country's proposal on Article 11.11.5. on the availability of serological tests, and agreed with the Scientific Commission that a test is still needed for trade to demonstrate the immunisation, even if the test is not perfect, and this is the reason why there is also a need for 28 days of quarantine.

The Code Commission rejected the proposed deletion in Article 11.11.10. as the experts consulted by the Scientific Commission in the OIE Reference Laboratory indicated that "there is no doubt of inactivation of LSDV in milk through pasteurisation."

The Code Commission did not agree with the suggestion of a Member Country to delete Article 11.11.11. it recalled that in all articles where it states "intended for agricultural or industrial use", these articles concern products that are not destined for animal feed or human consumption.

In response to a Member Country's comment on point 1 of Article 11.11.11., the Code Commission did not accept to modify the text as in a free country or zone the relevant period to consider is the incubation period, not the infective period.

In response to a Member Country's proposal to amend Article 11.11.13., the Code Commission did not agree for same reason as in Article 11.11.11.

In response to a Member Country's comment the Code Commission agreed to modify the point 2 of Article 11.11.13. in order to introduce different types of treatments to inactivate LSDV in hides and skins. Moreover, it noted that once imported, soaking dried hides overnight in the presence of 5% of non-ionic detergent, which is the normal first step in processing dried hides for tanning, will also inactivate LSDV in or on the hides.

The Code Commission accepted to modify Article 11.11.14., points 1 and 3, for better clarity.

The revised Chapter 11.11. is attached at <u>Annex 16</u> for Member Countries' comments and is proposed for adoption at the 85th General Session in May 2017.

Item 19 Infection with African swine fever virus (Chapter 15.1.)

Comments were received from Australia, Canada, Colombia, China, Japan, Korea (Rep. of), Malaysia, New Zealand, Norway, South Africa, Switzerland, USA, EU, AU-IBAR and CVP.

The Code Commission reviewed all comments from Member Countries and advice from the Scientific Commission, and amended the text accordingly.

The Code Commission firstly did not accept a Member Country's suggestion to add captive wild pigs together with wild and feral pigs in Article 15.1.1. The Code Commission agreed with the Scientific Commission, in that captive wild pigs do not play the same role as wild and feral pigs in the epidemiology of the disease. They are rather comparable to domestic pigs, because, by definition, they are under human control and supervision, can have contact with domestic pigs and their meat is more widely traded. That is why they are considered jointly with domestic pigs in terms of risk assessment and management. The Code Commission furthermore stated that there is no genetic consideration involved in making the distinction in this article, only production systems.

In response to a Member Country's comment, the Code Commission did not agree to reintroduce a paragraph after point 3 of Article 15.1.1., as this text was not deleted but paraphrased at end of Article 15.1.2.

In response to a Member Country's comment on Article 15.1.1. on the incubation period in *Sus scrofa*, and as in Article 2.8.1. of the *Manual* the range of incubation is 4 to 19 days, the Code Commission proposed to modify the incubation period from 14 to 19 days. The Code Commission noted that Member Countries should not rely on the fact sheet only and that the fact sheet on the OIE web page should be formally reviewed by the Scientific Commission. Also, it did not accept to add 'for ASFV' after 'incubation period' since it is obvious that the incubation period in this article relates to ASF.

In response to a Member Country's comment, the Code Commission agreed with the Scientific Commission to modify points 6 and 7 of Article 15.1.2., as *Orthinodoros* ticks are not always involved in the epidemiology of the infection.

The Code Commission did not accept the comment from a Member Country requesting the deletion of the last paragraph of Article 15.1.2. It considered it was essential to keep the text referring to the safe trade of pig commodities when applying provisions of the chapter of the *Code*.

In response to a question by a Member Country, the Code Commission confirmed that importing and exporting countries should follow the relevant chapters of Section 5 of the *Code* to agree on import conditions.

In response to Member Country comments the Code Commission amended point 1 of Article 14.1.3. to make it consistent with Article 1.4.6.

The Code Commission did not accept a Member Country's comment regarding surveillance in wild and feral pigs. It noted that this surveillance is required even when determining freedom in domestic and captive wild pigs as it is included in point 6 of Article 15.1.2.

The Code Commission accepted a Member Country's comments in point 2 b) of Article 15.1.3., as *Ornithodoros* ticks could be present but not involved.

In response to Member Countries' request to add feral pigs to domestic and captive wild, the Code Commission pointed out that this category could not be considered in a system of production because, according to the definition, they are not under human supervision.

The Code Commission in response to a Member Country's comment did not accept the deletion of Article 15.1.3bis, agreeing with the statement of the Scientific Commission, that:

"in establishing a compartment in order to ensure adequate separation of the compartment from the adjacent animal population with different health status, an evaluation of the local epidemiological situation and geographical factors supporting the spread of the disease is needed. *Ornithodoros* are not comparable to culicoides and flying vectors, and can be effectively controlled. They have low mobility. Stomoxis or other flying vectors have not been demonstrated to play an epidemiological role in the spread of ASF, besides the experimental study quoted for stomoxis. With reference to the Mellor's study, the Commission highlighted that it was experimental conditions. The control of ASF in some European countries has proven the efficiency of the concept of fencing. In addition, double-fencing and tick control have been used successfully for years in several southern African countries. The application for a compartment will obviously differ in area where ticks play a role from area where ticks do not play a role."

In Article 15.1.4. the Code Commission responded to a Member Country that once a compartment loses its status, the reestablishment of freedom in Article 15.1.3.bis would apply and therefore there is no need for specific requirements.

The Code Commission accepted a Member Country suggestion to modify the text in point 1 of the condition to recover the status.

In response to a Member Country's comments on Article 15.1.5. points 2 and 3, the Code Commission did not agree to add supplementary requirements, as in the requirement for free status, the separation of animals in terms of biosecurity is already included, and free zones or compartments should only import animals according to the relevant conditions of the chapter.

In response to Member Countries' comments on Article 15.1.9., the Code Commission did not accept the reinsertion of point c). Although some authors have suggested that ASFV might be found in boar semen and even transmitted to recipient sows, the only evidence for this provided in any of the sources is a single personal communication by DH Schlafer in 1984, without any details or scientific justification. More recently, Maes $et\ al.\ 2008$ stated that there is no published evidence to support this hypothesis.

The Code Commission did not accept either the suggestion of a Member Country on the previously commented point to conduct a test every time on the donor males as it is not necessary since they are included in the surveillance programme of the herd. The Code Commission noted that the same comment was already explained in its February 2016 report.

In Article 15.1.10., the Code Commission accepted the recommendation from the Scientific Commission and the *ad hoc* Group to indicate that the semen used to produce the embryos should comply with the relevant articles and amended the text accordingly.

In response to a Member Country's comment on Article 15.1.12bis, the Code Commission did not accept the modification as it did not add to the coherence of the article, especially when read together with point 3 of the same article.

The Code Commission did not accept the proposal of a Member Country in point 2 of Article 15.1.13., as it is not possible to carry out ante-mortem inspection on wild animals.

The Code Commission reiterated its position of its February 2016 meeting in response to Member Countries' concerns regarding Article 15.1.13. and considered the original text to be consistent with Article 15.1.12. It modified Article 15.1.13. to only describe conditions of importation of fresh meat of wild and feral pigs from countries and zones free from ASF in the wild population because there is currently no satisfactory management method uniformly applicable to all OIE Member Countries for importation of fresh meat of wild and feral pigs from countries and zones infected with ASFV in the wild population. However, the Code Commission also reiterated that, as noted in the User's Guide, the absence of an article on import conditions for any given commodity does not necessarily mean that trade in that commodity cannot be conducted safely, or that Member Countries cannot apply appropriate measures.

The Code Commission did not consider a Member Country's suggestion to remove meat sourced from a country not free from ASF in point 1 a) of Article 15.1.14., as the proposal lacked scientific rationale.

The Code Commission agreed with a Member Country's comment on Article 15.1.17., on the reinsertion of the article. The Code Commission noted in agreement with the Scientific Commission that such recommendations are useful to ensure that there are some risk mitigation options for the Member Countries trading those commodities.

Following a Member Country's comment, the Code Commission modified the text of points 1 and 2 of Article 15.1.17bis to take into account the differences between countries free in all suids and countries free only in domestic and captive wild pigs.

In response to a Member Country's comment on Article 15.1.19. on the inactivation of ASFV in meat, and after a review of literature, the Code Commission deleted the words 'under study', and updated the required treatment for dried cured pig meat from countries or zones not free from ASF, in order to give clear guidance to trading Member Countries.

The Code Commission accepted the proposal of a Member Country to delete part of the text in Article 15.1.21bis, on the way solutions of formaldehyde are prepared.

The Code Commission addressed a comment of the Scientific Commission by modifying Article 15.1.22. to include the domestic and captive wild pigs in the production systems.

The Code Commission addressed Member Countries' comment, on Article 15.1.24., by accepting changes proposed by the Scientific Commission.

In response to a Member Countries' request for clarification on the use of the term 'flagging' in Article 15.1.27., the Code Commission provided the following reference: "CO₂ flagging - an improved method for the collection of questing ticks". Gherman CM, A Mihalca AD, Dumitrache MO, Györke A, Oroian I, Sandor M and Cozma V (2012). Parasit Vectors. 2012 Jun 21; 5:125. doi: 10.1186/1756-3305-5-125.

The revised Chapter 15.1. is attached at <u>Annex 18</u> for Member Country comments and is proposed for adoption at the 85th General Session in May 2017.

Item 20 Draft new chapter on infection with porcine reproductive and respiratory syndrome (Chapter 15.X.)

Comments were received from Argentina, Australia, Canada, Chile, China, Colombia, New Zealand, USA, EU and AU-AIBAR.

In response to a Member Country's comment on the General provisions, the Code Commission reviewed the advice of the *ad hoc* Group experts that wild pigs have no significant epidemiological role in the infection of PRRS in domestic pig populations, as well as the comment provided by the Scientific Commission reconfirming such advice based on an EFSA publication (http://www.efsa.europa.eu/en/efsajournal/pub/239). Thus, it did not accept the request of the Member Country to consider including wild pigs in the definition of PRRS. The Code Commission noted the fact that an animal is susceptible does not imply automatically that such animal plays a significant epidemiological role, and regretted that the comment was not supported by any scientific rationale. Nevertheless, it reiterated that the lack of reference to a specific risk management measure in the *Code* does not mean that measures cannot be taken so long as risk analysis is conducted to justify such measures.

The Code Commission did not accept a Member Country's suggestion to delete 'captive wild pig' from the definition of the PRRS in the General provision, noting that 'captive wild pig' is, by definition, under direct human supervision or control and as such may play a role comparable to domestic pigs (see also Item 19).

The Code Commission did not accept a Member Country's suggestion to include 'modified live vaccine' in Article 15.X.1., noting that such addition is unnecessary as a PRRS vaccine strain is always derived from a live virus and the phrase 'a different vaccine strain' covers this.

The Code Commission did not accept a Member Country's suggestion about point 4 of Article 15.X.1. to add sentences that elaborate the existing condition, noting the comment by the Scientific Commission that such a statement referring to control measures should not be a part of the definition of *infection*. However, it modified the point to include maternally-derived immunity, as this is considered relevant and would respond to another Member Country's comment.

Following a Member Country's comment on the incubation period, after considering advice from the Scientific Commission, the Code Commission deleted the sentence regarding infectivity, as it is confusing and not used anywhere in the chapter.

After reviewing the rationales provided by some Member Countries (quoted below), the Code Commission accepted their suggestion to include *fresh meat* in point 3 of Article 15.X.2., noting the advice from the *ad hoc* Group and the Scientific Commission that there is no evidence of transmission of the virus via fresh meat, and adding a reference to 'ante- and post-mortem inspection' consistent with other chapters. The Code Commission, however, did not accept another suggestion to reinstate 'blood by-products,' as such products are covered by *meat* by definition.

"Fresh meat belongs to the list of safe commodities. In addition, blood by-products which had been on the list, should be reinstated to the list. The OIE *ad hoc* Group on PRRSV, as well as the Scientific Commission and the European Food Safety Authority, had made the same determination. In its 23–25 June 2015 report, the *ad hoc* Group on PRRSV notes that "The experts agreed that based on their experience and on current scientific literature, there was no evidence to suggest that meat, as defined in the *Terrestrial Code*, poses a risk for transmission of PRRS virus.", and should be considered as safe provided that they have been derived from pigs that have passed ante- and post-mortem inspections in accordance with Chapter 6.2. It was also noted that blood by-products were included in the definition of *meat*. Considering the epidemiology of the disease, the Group concluded that these commodities as defined in the Terrestrial Code, pose no additional risk for transmission of PRRS virus".

Further, data from PRRSV free countries demonstrate the lack of additional risk through the legal importation of pork and pork products from PRRSV positive countries. Since the late 1980's when PRRSV was first observed in the EU, countries such as Sweden, Norway, Finland, and Switzerland have remained PRRSV-free. Prior to 2002, the feeding of swill to pigs was legal in all four countries. Indeed, during the 13 year period between 1990, when PRRSV became established in the EU, and 2002, when the ban on swill feeding was implemented, the total amount of pork imported into Sweden, Norway, Finland and Switzerland from PRRSV-positive countries was more than 500,000 tons without a single PRRS outbreak linked to imported pork products. The historical data supports the fact that the risk of introducing PRRSV through the legal importation of fresh/chilled/frozen pork is virtually non-existent. Between 1990 and 2001, New Zealand remained PRRSV free while importing more than 59,000 tons of pork from PRRSV-positive countries, including between 1998 and 2001, a period in which there were no restrictions on swill feeding and over 40,000 tons of pork were imported from PRRSV-endemic countries, accounting for approximately 80% of total pork imports (Murray, Noel, and Howard Pharo. 2006. "Import risk analysis: Porcine reproductive and respiratory syndrome (PRRS) virus in pig meat." In Biosecurity New Zealand Ministry of Agriculture and Forestry. Wellington, New Zealand). This additional evidence shows that these commodities present no risk."

"The relevant scientific opinion of the European Food Safety Authority (http://www.efsa.europa.eu/en/efsajournal/pub/239) states that "Historically, pig meat from PRRSv-infected countries has been imported into PRRSv free countries [...] over the past decade without any evidence of dissemination of PRRSv. [...] Thus, there is to date no documented field evidence to support or quantify the overall risk of importing PRRSv infected meat".

Indeed, there is no scientific information suggesting that fresh meat poses a risk of transmission of PRRS under field conditions, and to date there is no evidence that trade in meat ever resulted in the introduction or spread of PRRSv. As regards spread across countries and continents, the OIE Manual chapter on PRRS rather states that "it is assumed these viruses were introduced through the movement of swine or semen"; however potential transmission via meat is not mentioned."

The Code Commission did not agree with a Member Country's suggestion to add a specific time period to Article 15.X.3., as such time period is captured in the point 4 of the same article, and also for consistency with other chapters.

In response to a Member Country's comment, the Code Commission agreed to delete a phrase concerning 'capability' from point 3 of Article 15.X.3., as it would not add any value in the design of surveillance.

The Code Commission did not accept a Member Country's proposal to amend the time period from 12 months to 24 months in point 5 of Article 15.X.3., as the use of live vaccine poses different risks from the case of inactivated vaccine.

After examining a Member Country's proposal to amend point 7 of Article 15.X.3., the Code Commission decided to delete the point 7 and modify the point 8, noting that the suggested point is well covered by the point 8.

In response to a Member Country's comment, the Code Commission agreed to delete the comma between 'herds' and 'followed' in the first point of Article 15.X.4. to avoid contradiction, noting that 'cleaning and disinfection' is part of the 'stamping-out policy' by definition.

The revised Chapter 15.X. is attached at <u>Annex 19</u> for Member Countries' comments and is proposed for adoption at the 85th General Session in May 2017.

Item 21 Equine diseases

a) High health-high performance (HHP) horses: Chapter 4.16.3. and review of report of *ad hoc* expert Group on HHP Veterinary Certificates

In Article 4.16.3., the Code Commission deleted 'under study' and replaced the words "the relevant OIE biosecurity guidelines" with "the OIE *Handbook for the Management of High Health, High Performance Horses*", as the Handbook has been already published on the OIE website.

The Code Commission noted that it will further consider updating the existing chapters on equine diseases to take into account proposals made by the *ad hoc* Group on HHP Veterinary Certificates.

The revised Article 4.16.3. is attached at <u>Annex 20</u> for Member Countries' comments and is proposed for adoption at the 85th General Session in May 2017.

b) Infection with Burkholderia mallei (Glanders) (Chapter 12.10.)

The Code Commission recalled that they had addressed all Member Countries' comments at its meeting in February 2016, except for the issue of surveillance for which they had requested advice from the Scientific Commission to enable the inclusion of new text.

Comments were received from Australia, Canada, Chile, New Zealand, Singapore, Switzerland, South Africa, Uruguay, USA, EU and AU-IBAR

A Member Country's comment concerning the inability to differentiate infection with *B. mallei* from infection with *B. pseudomallei* by the complement fixation test was referred to the Laboratories Commission and OIE Headquarters for advice.

Throughout the chapter, where appropriate, the Code Commission replaced 'glanders' with 'infection with *B. mallei*' in response to Member Countries' comments and for consistency with the convention adopted for the naming of listed diseases.

In response to Member Countries' comments the Code Commission added a clause to Article 12.10.2. cross referencing Article 1.4.6. point $1\ a$) for historical freedom requirements.

The Code Commission considered a Member Country's suggestion of 'passive surveillance for glanders based on clinical observations and laboratory testing' only, insufficient for demonstration of zone or country freedom from infection with *B. mallei*.

On the basis of a recommendation from the Scientific Commission, the Code Commission replaced 12 months with six months in Article 12.10.2. point 2 *b*).

In response to Member Countries' comments and to align with standard *Code* format the Code Commission renumbered Article 12.10.2. to make four points. In point 4 it replaced 'stamping out' as the point of reference with 'after disinfection of the last infected establishment' for precision.

The Code Commission did not accept a Member Country's suggestion that the word 'including' is unnecessary in Article 12.10.3. point 2.

On the basis of advice from the Scientific Commission, the Code Commission did not accept a Member Country's suggestion to replace '6 months' with '12 months' in Article 12.10.3. point 4.

In answer to a Member Country's comment that 'a surveillance programme for infection with *B. mallei* without a serological testing component is quite inadequate', the Code Commission noted that the current *Manual* chapter on glanders (adopted in May 2015) provides a table of fit-for-purpose tests that enables a Member Country to design a surveillance programme.

The Code Commission agreed with a Member Country's suggestion that the text 'imported in accordance with Article 12.10.5.' is unnecessary in Article 12.10.4. point 2 for horses coming from free countries.

The Code Commission did not agree with a Member Country's suggestion to re-insert 'prescribed' in Article 12.10.4. point 2 b) because the *Manual* no longer categorises tests as 'prescribed' but describes them as fit for different purpose.

The Code Commission did not agree with a Member Country's suggestion to delete point 2 of Article 12.10.5. as points 1 and 3 alone provide insufficient risk mitigation.

The Code Commission did not agree with a Member Country's proposal to re-instate text proposed in September 2015 in Articles 12.10.6. and 12.10.7., as no evidence or rationale was offered to support the re-instatement of the text.

In response to a Member Country's comment questioning the relevance of the reference to articles in Chapter 4.6. (which applies to bovine, small ruminant and porcine semen) in this chapter, the Code Commission noted that the articles listed include relevant recommendations for horses (and that Chapter 4.6. is proposed for revision).

In response to a Member Country's comment the Code Commission amended the language in Article 12.10.7. point 3 for consistency with other chapters of the *Code*.

Following Member Countries' comments suggesting that the article on surveillance (12.10.8.) be reviewed again with the aim of providing more disease-specific standards for surveillance for infection with *B. mallei* and the development of recommendations for defining a compartment free from infection with *B. mallei*, the Code Commission received the requested information from the Scientific Commission to support development of new articles on surveillance (Articles 12.10.8. and 12.10.9.) which have been inserted in the draft revised chapter.

In discussing the proposed revised Article 12.10.8. and new article 12.10.9., the Code Commission did not agree to include the term 'compartment' as the chapter contains provisions for free country or free zone only.

After revising the Scientific Commission's proposed phrase 'Estimate the distribution', the Code Commission included 'surveillance should allow the estimation of the prevalence and the determination of the distribution of the infection'.

In the section on serological surveillance, the Code Commission noted that the details in regards to specific testing prescribed for this surveillance was already included in the *Manual* and therefore did not need be repeated in the *Code* chapter.

The revised Chapter 12.10. is attached at <u>Annex 17</u> for Member Countries' comments and is proposed for adoption at the 85th General Session in May 2017.

G. OTHER ISSUES

Item 22 Update of the Code Commission's work programme

The Code Commission's work programme is attached at **Annex 29** for Member Countries' comments.

Item 23 Other issues

a) Consideration on listing of chronic wasting disease (CWD) of cervids

A comment was received from New Zealand.

The Code Commission reviewed a Member Country's comment regarding the possible listing of CWD. It asked the Headquarters to further study that proposal and possibly gather expertise from relevant epidemiologists who would assess the disease data against the criteria of Chapter 1.2.

b) Review of conclusions and recommendations adopted at the Fourth OIE Global Conference on Veterinary Education

The Code Commission noted the recommendations adopted at the 2016 Global Conference on Veterinary Education and congratulated the OIE on this conference, offering to remain at the disposal of the OIE to help in regard to reviewing any follow up work required.

c) Dates of next meetings

The 2017 Code Commission meetings are scheduled for February 13–24, and September 18–29 inclusive (the September meeting dates are tentative upon confirmation from the Director General).

Annexes/...