EUROPEAN UNION

Brussels
SANTE/G2/MMK/ise (2017) 2676910

Subject: **85th Annual General Session of the OIE - May 2017**

Dear Director General,

Please find attached, for your informal information, annexes indicating the intended positions of the European Union (EU) on the reports of the Terrestrial and Aquatic Animal Health Standards Commissions to be raised and drafts proposed for adoption at the 85th OIE General Session in May 2017 in Paris.

We take this opportunity to inform you that the EU supports the adoption of the draft revised chapters of the OIE *Terrestrial Manual* to be proposed for adoption in May 2017.

We trust you will find this useful and we thank you for your continued cooperation.

Yours sincerely,

Dr Roberto Andrea Balbo CVO and OIE Delegate Malta	Dr Bernard Van Goethem Director for Crisis Management in Food, Animals and Plants European Commission, DG Health and Food Safety

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Annexes: 2

Copy: All Directors / Chief Veterinary Officers of the EU 28 and Iceland, Liechtenstein, Norway, Switzerland, and Albania, FYROM, Montenegro, Serbia and Turkey

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Annex 1

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

Original: English

February 2017

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

Paris, 13–24 February 2017

EU comment
The EU would like to commend the OIE for its work and thank in particular the Code Commission for having taken into consideration EU comments on the Terrestrial Code submitted previously.
A number of general comments on this report of the February 2017 meeting of the Code Commission as well as the intended positions of the EU on the draft Terrestrial Code chapters proposed for adoption at the 85th OIE General Session are inserted in the text below, while specific comments are inserted in the text of the respective annexes to the report.
Please note that the EU positions re. Annexes 4 to 20 (part A) as well as the EU comments on Annex 37 are appended to this document, while the EU comments on Annexes 21 to 36 (part B) and Annex 51 (part E) as well as on Item 5.7. will be provided to the OIE separately by 12 July 2017.
Furthermore, please note that the EU refrains from commenting on Annexes 42 to 50 (part D) at this stage (see EU comment on Item 6.1. below for rationale).
In general, the EU notes the unusually large number of annexes to this report. As there are limits to the capacity of experts to process OIE standard setting documents and provide meaningful comments of the expected quality, the EU would like to recall a previous comment asking for the Code Commission to strictly adhere to its work programme priorities. Instead, there seems to be a tendency in recent times to submitting ever increasing numbers of texts for member countries comments, some of which prior to having been thoroughly reviewed by the Code Commission itself for time constraints (see for example Item 6.1. of this report). In international standard setting, quality should always prevail over quantity and haste. Furthermore, as regards ongoing and future work on the Code, there seems to be an urgent need to better align the work programmes and priorities of the Code Commission and the Scientific Commission. A procedure should preferably be developed or strengthened for this coordination of work programmes. This becomes evident in section 2b) of Annex 3 (report of the joint meeting of both Commissions), where the 5 key priorities for 2017 of both Commissions' work programmes do not seem to match very well.
The EU would like to stress once again its continued commitment to participate in the work of the OIE and to offer all technical support needed by the Code Commission and its ad hoc groups for future work on the Terrestrial Code.

The OIE Terrestrial Animal Health Standards Commission (the Code Commission) met at OIE Headquarters in Paris from 13–24 February 2017. 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 September 2016 meeting: Argentina, Australia, Belize, Canada, Chile, Costa Rica, Guatemala, Japan, Korea, Malaysia, Mexico, New Zealand, Nigeria, Norway, Singapore, South Africa, Switzerland, Thailand, the United Kingdom, the United States of America (USA), and Uruguay, the Member States of the European Union (EU) and 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 OIE PRRS Reference Laboratory (Poland), the European Forum of Farm Animal Breeders (EFFAB), International Dairy Federation (IDF) and the International Coalition for Animal Welfare (ICFAW). 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 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 4, 7, 9, 10, 11, 13, 14, 16, 17, 18, 21, 23bis, 24, 26, 27, 29 and 30, 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 that were supported by a rationale and documented its responses. However, because of the large volume of work, the Code 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 or obvious logic are not examined by the Code Commission as they are difficult to evaluate and respond to. Similarly if comments are resubmitted without modification or new justification, the Code Commission will not, as a rule, repeat previous explanations for decisions. The Code Commission encourages Member Countries to refer to previous reports when preparing comments on longstanding issues. The Code Commission also draws the attention of Member Countries to those instances where the Scientific Commission for Animal Diseases (the Scientific Commission), the Biological Standards Commission, a Working Group or an *ad hoc* Group has addressed specific Member Countries comments or questions and proposed answers or amendments. In such cases the rationale is described in the Scientific Commission's, Biological Standards Commission's, Working Group's or *ad hoc* Group's reports and the Code Commission encourages Member Countries to review its report together with those of the Scientific Commission, Biological Standards Commission, Working Groups and *ad hoc* Groups.

Member Countries should note that texts in Part A of this report are proposed for adoption at the 85th General Session in May 2017. Texts in Part B are submitted for comments. The reports of meetings (Working Group and *ad hoc* Groups) and other related documents are attached for information in Part C. The questionnaires related to official recognition of disease status have been reviewed and revised and are attached for comment in Part D.

Comments on **Parts B** & **D** of the report must reach OIE Headquarters **by 12 July 2017** in order for them to be considered at the September 2017 meeting of the Code Commission. Comments received after the due date will not be submitted to the Code Commission for its consideration.

All comments should be sent to the OIE Standards Department at: standards.dept@oie.int.

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. Proposed deletions should be indicated in '~~strikethrough~~' and proposed additions with 'double underline'. Examples of how this can be done are attached as **Annex 41**. 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 Code Commission's working documents. Member Countries are also requested **not** to reproduce the full text of a chapter as this makes it easy to miss comments while preparing the working documents.

Item 1 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 13 February 2017. Dr Eloit welcomed the Code Commission members and thanked them for their support and commitment to achieving OIE objectives.

Among other matters, Dr Eloit and Dr Stone discussed the forthcoming session of the Council and the proposals that it will consider in relation to the new procedure for the election of experts and the provisional budget, in particular noting the increased costs of supporting the standards setting functions of the OIE (convening of *ad hoc* Groups and field missions to support status recognition). The Director General also expressed her appreciation for the willingness of the members to work closely with the Secretariat to improve the functioning and efficiency of the Specialist Commissions. Dr Stone also noted the efforts of the Headquarters to improve the efficiency across all of the Specialist Commissions through enhanced coordination systems that would provide stronger direction and support to their work programmes, improve internal communication, and strengthen understanding of roles and responsibilities in particular between the risk assessment functions of the Scientific Commission and the risk management functions of the Code Commission.

Dr Etienne Bonbon, on behalf of the Code Commission, thanked Dr Eloit and Dr Stone for their support. Dr Bonbon also noted that the Code Commission welcomed the improved transparency in the process for elections as it was important to have the best expertise to support the standards development process. Dr Bonbon noted that the Code Commission had already had a discussion on its work programme, priorities and management of the meetings heavy agenda. Dr Bonbon highlighted one of the difficulties in managing such an extensive work programme was the access to the *ad hoc* Group reports, and in particular when they were proposing new or revised chapters. He noted that the view of the Code Commission was that these reports should be reviewed by the relevant Headquarters Secretariat in order to identify issues relevant to the Code Commission so that these issues could be shared with the members of the Code Commission and added to its work programme according to priorities. In response the Director General agreed that it was important for OIE Headquarters to decide what is relevant to each Commission in order to better align the work programmes and priorities and that this could be managed through better coordination by OIE Headquarters.

Item 2 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**.

Item 3 COOPERATION WITH OTHER SPECIALIST COMMISSIONS

a) Meeting with the President of the Aquatic Animal Health Standards Commission

The President of the Code Commission met with the President of the Aquatic Animal Health Standards Commission (Aquatic Animals Commission) during the week when both Commissions were meeting. The Presidents discussed issues of mutual interest in the *Terrestrial* and *Aquatic Codes*, notably:

– alignment of Glossary terms, in particular the definition for zoning and the ongoing review of definitions used in the *Terrestrial Code*;

– proposed revisions to Chapter 1.2. in the *Aquatic Code* (criteria for listing); and the proposed development of a guidance document on the application of the criteria for listing an OIE disease.

The Aquatic Animals Commission agreed that this meeting was important in facilitating harmonisation of relevant chapters in the two *Codes* when under review by the respective Commissions.

b) Meeting with the Presidents of the Biological Standards Commission and the Scientific Commission

The President of the Code Commission met with the Biological Standards Commission and the President of the Scientific Commission on 10 February 2017 to discuss and highlight several issues of mutual interest, notably:

– Chapter 12.10. 'Infection with *Burkholderia mallei*' (glanders) in regards to comments from a Member Country on diagnostic testing for both *B. mallei* and *B. pseudomallei* (the pathogenic agent for melioidosis). The President of the Biological Standards Commission indicated that from

a diagnostic perspective the two diseases are very difficult to distinguish both in terms of clinical signs and serological assays (see Item 4.14.);

– Chapter 8.X. '*Mycobacterium tuberculosis* complex' in regards to comments from a Member Country on the implications for trade of including pathogenic agent that can also be found in humans (see Item 4.11.);

– Chapter 15.X. draft new chapter on infection with porcine reproductive and respiratory syndrome virus in regards to Member Countries comments relating to the implication of including vaccine strains in the case definition (see Item 4.16.); and

– Chapter 15.1. 'Infection with African swine fever viru's in relation to the proposal to amend the incubation period. The Presidents agreed to keep 15 days even though the *Manual* states 'The incubation period in nature is usually 4–19 days'. This is because 19 days is an extreme, exceptional value and is not considered to be a useful reference value. The Biological Standards Commission will ask reference laboratories to look at the question in more detail (see Item 4.15.).

c) Report on the Joint Meeting of the Terrestrial Animal Health Standards Commission and the Scientific Commission for Animal Diseases

The Code Commission and the Scientific Commission met on 16 February to discuss issues of mutual interest. The report of this joint meeting is attached as **Annex 3**.

Item 4 TEXTS PROPOSED FOR ADOPTION AT THE GENERAL SESSION IN MAY 2017

Table 1. Lists of texts proposed for adoption at 85th General Session

Item	Annexes in Part A	Chapters/Articles	Title
4.1	4	-	Glossary A, A′ and A"
4.2	5	1.2.1.	Criteria for the inclusion of diseases, infections and infestations in the OIE list
4.3	6	1.3.	Diseases, infections and infestations listed by the OIE (the Preamble)
4.4	7	2.X.	Draft new chapter on criteria applied by the OIE for assessing the safety of commodities
4.5	8	4.16.3.	High health status horse subpopulation
4.6	9	5.3.	OIE procedures relevant to the Agreement on the Application of Sanitary and Phytosanitary Measures on the World Trade Organization
4.7	10	6.X.	Draft new chapter on prevention and control of *Salmonella* in bovines
4.8	11	6.Y.	Draft new chapter on prevention and control of *Salmonella* in pigs
4.9	12	7.11.6.	Animal welfare and dairy cattle production systems
4.10	13	7.12.	Welfare of working equids
4.11	14	8.X.	Infection with *Mycobacterium tuberculosis* complex
4.12	15	10.4.25.	Infection with avian influenza viruses
4.13	16	11.11.	Infection with lumpy skin disease
4.15	17	15.1.	Infection with African swine fever virus
4.16	18	15.X.	Draft new chapter on Infection with porcine

Item	Annexes in Part A	Chapters/Articles	Title
			reproductive and respiratory syndrome virus
4.17	19	4.11.4.	Somatic cell nuclear transfer in production livestock and horses
4.18	20	2.1.	Import risk analysis

Item4.1. Glossary Part A, A′ and A″

Comments were received from Argentina, Australia, Belize, Chile, Costa Rica, Guatemala, Norway and EU.

Glossary Part A – Amendments

At its meeting in September 2016, the Code Commission proposed revised definitions for several terms in the Glossary. In examining and responding to Member Countries comments the Code Commission made the following amendments or observations:

Animal Health Status: the term *compartment* was added for consistency with amendments made to other *Terrestrial Code* chapters.

Captive Wild [animal]: the Code Commission noted that there was an error in the text of the report of its last meeting; the word in square brackets should have been *animal* and not *species*.

Notification: the Code Commission considered that the inclusion of relevant health information is part of the procedure detailed in Chapter 1.1. and therefore does not need to be included in the definition. Furthermore, in respect to a Member Country comment on the inclusion of *infection* or *infestation*, it noted that this is related to the ongoing work on the definition for *disease*, which could not be addressed at this time.

Pathogenic Agent: in examining a number of Member Countries comments and considering the opinion of the Scientific Commission, the Code Commission was of the opinion that the proposal to define the term 'pathogenic agent' appeared to be confusing in the context of the *Terrestrial Code* because not all pathogenic agents are ''organisms'' (for example BSE and scrapie). In order to reconcile these issues the Code Commission proposed not to add a new definition for pathogenic agent but rather considered that common dictionary definitions are sufficient. However, it noted that there was a need to ensure the term was used consistently throughout the *Code* (see **Item 7.4**).

Consequently, the Code Commission requested that in preparing the 2017 edition of the *Terrestrial Code* the OIE Headquarters replace, where relevant, similar terms currently used in the *Terrestrial Code* with 'pathogenic agent', as well as other terms that are used inconsistently, namely: *slaughterhouse/abattoir*, *herd* or *flock*, 'oocytes' instead of 'ova', 'oocytes and embryos' instead of 'embryos and oocytes' (see **Item 7.4.).**

EU comment

The EU agrees in principle with this proposed procedure for modifications of the Code which, for the most part, are purely editorial. We also appreciate the circulation of an Annex 51 as Part E of the present report, prepared by the OIE Headquarters, bringing to the attention of member countries the editorial modifications which the OIE intends to introduce in the 2017 edition of the Code. While commending the OIE Headquarters for this important and extensive work, we would nevertheless like to provide some comments to the OIE, as some of the changes proposed would lead to occasional odd wording and some inconsistencies. Detailed comments will be provided separately by 12 July.

The revised definitions are attached in **Annex 4** (Glossary **Part A**) and are proposed for adoption at the 85th General Session in May 2017.

Glossary Part A′– Deletions

In response to a Member Country comment proposing to retain the definition for *zoonosis* the Code Commission did not consider that it was necessary to retain this as the term is well defined in dictionaries and text books.

The proposed deleted definitions are attached in **Annex 4** (Glossary **Part A′**) and are proposed for adoption at the 85th General Session in May 2017.

Glossary Part A" Amendments to definitions of a purely editorial nature and provided for Member Countries' information

At its meeting in September 2016, the Code Commission noted numerous editorial mistakes in the Glossary and proposed editorial changes that do not introduce any changes in the meaning but provide consistency and remove inaccuracies. In examining supportive Member Countries comments the Code Commission noted that the changes proposed by it were editorial and that there was no rationale for proposing other changes at this time. Another Member Country proposed to amend the definition for *Animal Identification System* to *Animal Traceability System*, but the Code Commission did not agree to amend because the term "animal traceability system" is not used in the *Terrestrial Code,* and the term *Animal Identification System* fits correctly where it is used in the *Terrestrial Code.*

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

EU position

The EU thanks the OIE and supports the adoption of this modified glossary (parts A, A' and A'').

Item 4.2. Criteria for the inclusion of diseases, infections and infestations in the OIE list (Article 1.2.1.)

Comments were received from Australia, Switzerland and EU.

The Code Commission noted that unless a new definition of 'disease' is adopted or the definition is removed from the Glossary, it was not relevant to make any changes to the criteria as proposed by Member Countries. However, once a decision is made, the whole *Terrestrial Code* will be reviewed to identify where there is a need to modify the term 'diseases, infections and infestations'.

The revised Article 1.2.1. is attached as **Annex 5** and is proposed for adoption at the 85th General Session in May 2017.

EU position

The EU supports the adoption of this modified article.

Item 4.3. Diseases, infections and infestations listed by the OIE (the Preamble of Chapter 1.3.)

Comments were received from Switzerland and EU.

Noting the comments received were in support of the revised preamble, the Code Commission made no further changes.

The revised preamble to Chapter 1.3. is attached as **Annex 6** and is proposed for adoption at the 85th General Session in May 2017.

EU position

The EU supports the adoption of this modified chapter.

Item 4.4. Draft new Chapter on criteria applied by the OIE for assessing the safety of commodities (Chapter 2.X.)

Comments were received from Argentina, Switzerland, USA, EU, AU-IBAR and IDF.

In examining Member Countries comments on the two articles in this chapter the Code Commission made minor editorial changes. It considered that the text of the chapter will provide clear guidance to OIE experts to assist them in assessing the safety of commodities and that no further clarification was required.

The draft new Chapter 2.X. is attached as **Annex 7** and is proposed for adoption at the 85th General Session in May 2017.

EU position

The EU thanks the OIE and supports the adoption of this new chapter.

Item 4.5. High health status horse subpopulation (Article 4.16.3.)

Comments were received from Switzerland and EU.

The Code Commission noted the comments in support of the adoption of this article and made no further changes. However, it noted that the chapters on horse diseases may need further revision in light of lessons learnt from the Olympic Games and other international events, and requested that OIE Headquarters provide feedback on the benefits or problems in relation to the use of the principle of high health, high performance (HHP) horse subpopulation.

The revised Article 4.16.3. is attached as **Annex 8** and is proposed for adoption at the 85th General Session in May 2017.

EU position

The EU supports the adoption of this modified article.

Item 4.6. 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 Australia, Belize, Canada, Costa Rica, Guatemala, Switzerland and EU.

In respect of a Member Country proposal to amend the wording in Article 5.3.1. to exactly mirror the wording in the WTO SPS Agreement, the Code Commission wished to draw the attention of Member Countries to the *User Guide* which gives detailed explanation on the relationship between this chapter and the WTO SPS Agreement. Furthermore, it considered that the text as it is currently worded is appropriate to the *Terrestrial Code*.

In examining a Member Country proposal to replace 'live animals and animal products' with 'commodities', the Code Commission was of the view that the *Terrestrial Code* should represent the intent of the WTO SPS Agreement and the language used (animal health), so did not make the proposed change. In response to another Member Country proposal to add the term 'processing systems and export systems' it was agreed that the inclusion of 'processing systems' added clarity. However it considered that the term 'export systems' is covered in the animal health management system.

The Code Commission noted with regard to a proposal from a Member Country to include 'infection and infestation' after the word '*diseases'* in Article 5.3.2. that current work on the Glossary to either modify or remove the definition of '*disease'* may address this in the future.

In response to Member Countries comments on Article 5.3.3., the Code Commission made minor editorial changes by including the wording 'in its territory' to clarify that an importing country's animal and human health can be protected. The Code Commission did not support a proposal to change

'assured' to 'satisfied' because the exporting country should demonstrate that its measures meet the level of protection required by the importing country.

In respect of a Member Country comment on the first paragraph of Article 5.3.4., to replace the word 'judgement' with 'determination', the Code Commission noted in its February and September 2016 meeting reports that this issue had been thoroughly discussed and that in respect of equivalence, the 'judgement' is a decision based on the process of 'determination'. Therefore the Code Commission did not accept this proposal at that part of the text dealing with the decision.

The Code Commission did not support a Member Country proposal to include reference to 'the country status' in point 3) of Article 5.3.5, as 'country status' is not a sanitary measure. In response to a proposal to replace 'should' with 'shall', the Code Commission reminds Member Countries that except in the cases either referring to the obligation of disease notification or referring to the incubation period of specific disease, the language used in the *Terrestrial Code* for recommendations is always 'should'.

In response to a Member Country proposal to delete reference to 'informally' from Article 5.3.6., the Code Commission explained that the intent of the article is to provide guidance to Member Countries on the steps to be taken in the determination of equivalence, which provides for either a formal agreement between the importing and exporting country in the form of a high level treaty, or a more informal agreement such as the exchange of letters, and therefore it did not accept the proposed change.

In considering comments from Member Countries on Article 5.3.8., the Code Commission agreed in principle with the proposal to change the title of the OIE informal procedure for dispute mediation, to align it with the text. However it noted that the procedure is the responsibility of OIE Headquarters, and as the procedure is currently under review it would not be appropriate for the Code Commission to make the change at this time. OIE Headquarters will consider the proposal to change 'informal' to 'voluntary' in its review of the process.

The revised Chapter 5.3. is attached as **Annex 9** and is proposed for adoption at the 85th General Session in May 2017.

EU position

The EU thanks the OIE and supports the adoption of this modified chapter.

Item 4.7. Draft new Chapter on prevention and control of Salmonella in bovines (Chapter 6.X.)

Item 4.8. Draft new Chapter on prevention and control of Salmonella in pigs (Chapter 6.Y.)

Comments on Chapter 6.X. were received from Australia, Canada, Japan, Mexico, Norway, Switzerland, Thailand, USA, EU, AU-IBAR and IDF.

Comments on Chapter 6.Y. were received from Australia, Canada, Belize, Costa Rica, Guatemala, Japan, Nigeria, Norway, Switzerland, Thailand, USA, EU and AU-IBAR.

The Code Commission noted that the two Chapters, 6.X. and 6.Y., had been developed to ensure alignment, when relevant, and appreciated that many Member Countries submitted the same comments for both chapters to ensure further alignment.

In response to Member Countries comments, the Code Commission noted the following points that were relevant to both chapters.

The Code Commission did not agree with a Member Country comment regarding the use of the term 'wildlife' throughout the chapter and noted that the use of the term 'wildlife' or 'birds' or 'rodents' takes into consideration the context. For example, sometimes the defined term 'wildlife' is too broad for the context and so only 'wild birds' was used. Also, on some occasions rodents were listed along with other wildlife in order to emphasise the importance of the rodents. The Code Commission also reminded Member Countries that an editorial amendment has been proposed to the glossary definitions of 'captive wild animal', 'feral animal' and 'wild animal' with the word 'animal' being replaced with

'[animal]', to show more clearly the possible use of the terms in the context of different diseases affecting different species. Should this be adopted terms such as 'wild birds' would appear in italics.

In response to a Member Country comment regarding the implication of these chapters for international trade, the Code Commission reiterated that these chapters are intended to provide guidance for the prevention and control of *Salmonella* (which is not an OIE listed disease) and are not intended to be used to elaborate conditions for trade. The Code Commission also noted that these draft chapters are similar in status to the recently adopted Codex Guidelines for the Control of Non-typhoidal *Salmonella* spp. in Beef and Pork Meat (CAC/GL 87-2016).

The Code Commission reminded Member Countries that, as noted in its February 2016 report, "the definitions for 'feed' and 'feed ingredient' would be moved to the Glossary once these chapters are adopted, as they will appear in more than one *Terrestrial Code* chapter.''

The Code Commission did not accept a Member Country comment to reword the first sentence in Articles 6.X.4. and 6.Y.4. because it considered it to be clear as currently written.

The Code Commission agreed to change 'manure' to 'faecal waste' in both chapters to ensure consistency, noting that faecal waste is used because the term manure is too restrictive, based on the *Oxford English Dictionary* definition of manure as 'animal dung used for fertilising land'.

The Code Commission agreed to amend the point in Articles 6.X.4. and 6.Y.4. that mentions good farming practices and hazard analysis and critical control points (HACCP) to clarify that it may not always be possible to implement HACCP at the primary production level.

The Code Commission agreed to amend the first sentence of Articles 6.X.5. and 6.Y.5. to emphasise the importance of biosecurity in the prevention and control of *Salmonella*.

The Code Commission agreed to add a new point 4) *bis* to Articles 6.X.5. and 6.Y.5. for the prevention of contamination of feed and water, including water for irrigation. It also agreed to add 'water supply' into point 5) of these articles.

The Code Commission did not agree to include 'equipment' in point 9) of Articles 6.X.5. and 6.Y.5. noting that it is addressed in point 12).

The Code Commission agreed to include 'domestic animals' in point 8) of Articles 6.X.5. and 6.Y.5. noting the potential role of domestic animals in the contamination of feed.

The Code Commission agreed to delete the example in point 5) of Articles 6.X.7. and 6.Y.7. agreeing that it was up to the Veterinary Services or stakeholders to determine the most suitable period for isolation of newly introduced animals. The Code Commission noted that the December 2015 report of the *ad hoc* Group on *Salmonella* in pigs and cattle provided references supporting four weeks as the most appropriate time period for separation.

In point 2) of Articles 6.X.9. and 6.Y.9. the Code Commission agreed to move 'where practicable' so it is relevant to the text regarding 'access of animals, birds, rodents and wildlife' noting that feed should always be handled in a hygienic manner.

In point 5) of Articles 6.X.11. and 6.Y.11. the Code Commission reminded Member Countries that the inclusion of clinical enteric salmonellosis during the last iteration was to highlight the risk of developing antimicrobial resistance when treating salmonellosis. It was agreed that the treatment of any clinical salmonellosis with antimicrobial agents should be done in accordance with Chapter 6.9. and thus the word 'enteric' could be deleted.

The Code Commission agreed to add a reference to Chapter 4.13. in Articles 6.X.12 and 6.Y.12. whilst acknowledging that Chapter 4.13. needs revision to address disinfection in more detail. The Code Commission agreed to include the revision of Chapter 4.13. in its work programme.

For reasons of consistency the word 'serotypes' was used instead of 'types' where relevant throughout the text.

The following comments are specific to Chapter 6.X. Draft new Chapter on prevention and control of Salmonella in bovines.

The Code Commission agreed with a Member Country comment concerning the inconsistent use of the term 'cattle' in the *Terrestrial Code* noting that in some chapters this term is not defined at all or sometimes is defined but with a varying list of species, and sometimes the *Code* uses the term 'bovid' rather than cattle.

The Code Commission agreed that in light of the *Oxford English Dictionary* definition for the noun 'bovine' which is 'an animal of the cattle group, which also includes buffaloes and bison' it would replace the term 'cattle' with 'bovine(s)' and specify in Article 6.X.3. which species are included in the use of the term 'bovine'. The Code Commission agreed to gradually amend all relevant chapters of the *Code* in this manner as they are reviewed.

The Code Commission noted that the definition for 'semi-intensive systems' was deleted because this term is not used in the chapter.

The Code Commission did not agree to amend point 4) of Article 6.X.4. to include milk and meat as this was already addressed in points 1) and 2) of this article.

The Code Commission did not agree to delete 'biosecurity' from the last paragraph in Article 6.X.6. as it considered that some biosecurity measures were applicable in extensive bovine production systems.

As stated in the Code Commission's September 2016 meeting report the Code Commission did not agree to align text in Article 6.X.7. with that in Article 6.Y.7. regarding the introduction of bovines as a risk factor for introducing *Salmonella* because it was not considered relevant to this article that applies to intensive and extensive bovine production systems, which differ significantly from pig production systems.

The Code Commission agreed to delete the text referring to 'washing of live animals to reduce contamination of meat at slaughter' in Article 6.X.12. because there is lack of consistent evidence regarding the efficacy of washing dirty hides (Reference: FAO/WHO. 2016. Interventions for the control of non-typhoidal Salmonella spp. in beef and pork: Meeting report and systematic review. Microbiological Risk Assessment Series No. 30. Rome. 276 pp).

The Code Commission did not accept a Member Country comment to include text regarding use of artificial insemination or embryo transfer to minimise introduction of *Salmonella* in Article 6.X.16. noting that this is already addressed in point 3) of Article 6.X.7.

The following comments are specific to Chapter 6.Y. Draft new Chapter on prevention and control of Salmonella in pigs.

The Code Commission did not agree to amend the definition for 'commercial pig production systems' to include marketing of products because this is not in the remit of the OIE.

The Code Commission did not agree to change 'will' to 'may' in point 2) of Article 6.Y.4. noting that the text as read is factual and accurate, i.e. when one limits the source of contamination one will reduce the likelihood of infection.

The Code Commission agreed to add a new sentence in Article 6.Y.5. for reasons of consistency with the corresponding Article 6.X.5. in order to stress the importance of applying a biosecurity plan.

The Code Commission did not agree to amend text in Article 6.Y.7. to emphasise that the introduction of pigs into a herd is the most important factor because it considered that the current wording is correct as written and implies that it is an important factor in all herds but qualifies its importance between low, moderate and high prevalence herds.

The Code Commission did not agree to the deletion of the reference to pre- or probiotics, requested to ensure consistency between chapters, noting that there is more evidence supporting the efficacy of these in pigs.

The Code Commission did not agree to delete the second sentence in Article 6.Y.9. regarding the importance of feed as sources of *Salmonella* in low prevalence situations, noting that whilst these measures are important in all regions they are especially important in low prevalence regions, and that the text as written qualifies this point.

The Code Commission did not agree to reinstate the article on stress, nor to add a new point on stress in Article 6.Y.11., noting that stress is already addressed in other articles in the chapter.

Whilst the Code Commission noted the proposal to include a new article to address post-weaning preventive measures, the Code Commission referred this comment to OIE Headquarters requesting an expert opinion and report back to the Code Commission.

The draft new Chapter 6.X. is attached as **Annex 10** and is proposed for adoption at the 85th General Session in May 2017.

EU position

The EU thanks the OIE and supports the adoption of this new chapter.

The draft new Chapter 6.Y. is attached as **Annex 11** and is proposed for adoption at the 85th General Session in May 2017.

EU position

The EU thanks the OIE and supports the adoption of this new chapter.

Item 4.9. Animal welfare and dairy cattle production systems (Article 7.11.6.)

Comments were received from Japan, Switzerland, USA, the EU, AU-IBAR, ICFAW and IDF.

The Code Commission considered Member Countries comments on the revised point 5) of Article 7.11.6. and noted several Member Countries were supportive of the proposed text. Noting that the chapter was adopted relatively recently (May 2015), the Code Commission requested OIE Headquarters consider the comments made on other text during the next revision of the chapter.

The Code Commission did not accept the Member Countries suggestions to modify its proposal, as the new wording would not improve clarity. It also insisted that the currently proposed text, even if it is considered as a design-based criterion, is only conditioned to the primary choice of the design of resting spaces and has a clear beneficial impact on the welfare of dairy cattle. Therefore the Code Commission decided to leave the existing proposal as it is.

The revised Article 7.11.6. is attached as **Annex 12** and is proposed for adoption at the 85th General Session in May 2017.

EU position

The EU thanks the OIE for its work. The EU can support the adoption of this chapter's modified article.

Item 4.10. Welfare of working equids (Chapter 7.12.)

Comments were received from Canada, Switzerland, Thailand, USA, EU and ICFAW.

The Code Commission noted comments in support of the revised text and reviewed several Member Countries comments on Article 7.12.2., and did not agree to expand the scope of the chapter to include 'equine-assisted therapy' or 'hippotherapy' as this is considered to be a subset of leisure activities and as such, is excluded from the chapter.

The Code Commission did not accept a Member Country suggestion to delete the text that excludes equids used in research or for the production of biopharmaceuticals and equids kept solely for the

production of meat, as the former are addressed in Chapter 7.8., while the latter are not considered working equids.

The Code Commission did not accept a Member Country suggestion to replace the words 'five freedoms' with 'five domains', because the use of 'five freedoms' is consistent with Article 7.1.2.

In response to a Member Country comment on the last bullet point under behaviour indicating stress in Article 7.12.4., the Code Commission replaced the word 'and' by 'or' to improve clarity of the text. In the same bullet point, the Code Commission did not accept the suggestion to insert the word 'irregular' as a qualifier for defaecation as the word 'abnormal' in the beginning of the sentence is sufficient to convey the intent of the text.

In response to a Member Country comment to add 'sub-optimal body condition score' as an example of an attribute of physical appearance that may indicate compromised welfare, the Code Commission did not accept the suggestion because ''emaciation'' is sufficient in conveying the intent of the text; that is, any abnormal thinness caused by lack of nutrition or by disease. The Code Commission also noted that a single harmonised body condition scoring system does not exist, so the chapter will not give specific recommendations relating to body condition scores.

The Code Commission did not accept a Member Country proposal to remove the fifth paragraph of Article 7.12.9. as the text was a consensus from expert opinion. The Code Commission further explained that it is not possible to define precisely the meaning of ''long period'' because variables such as temperature influence the length of time.

The Code Commission did not accept a Member Country comment in the first paragraph of Article 7.12.11. to replace ''should be discouraged'' with ''is unacceptable'', to maintain the consistency with other chapters, to give recommendation to Member Countries through positive actions while avoiding value judgements.

The Code Commission did not accept a Member Country comment to remove a text that limits the working hours of working equids to six hours per day in Article 7.12.12. Although this recommendation is a management based measure, it is supported by expert opinion of an *ad hoc* Group. The Code Commission also expressed that limiting the working hours has a positive effect on the welfare of working equids, and indicated that it is not possible to compare working equids with dairy cows, since lactation is not considered a 'working activity' (neither is standing still); it is a physiologic response that cannot be controlled. The Code Commission further commented that more scientific arguments are needed to support the deletion of the text.

The Code Commission accepted the suggestion of a Member Country, with modifications, of the first paragraph of Article 7.12.13., and added a sentence to highlight the importance of removing dirt and any debris before fitting a harness to avoid wounds.

The revised Chapter 7.12. is attached as **Annex 13** and will be proposed for adoption at the 85th General Session in May 2017.

EU position

The EU thanks the OIE for its work and for taking an EU comment into account. The EU can support the adoption of this modified chapter. A comment is inserted in the text of Annex 13.

Item 4.11. Draft new Chapter on infection with Mycobacterium tuberculosis complex (Chapter 8.X.)

Comments were received from Australia, Belize, Canada, Mexico, Switzerland, USA, EU and AU-IBAR.

In considering the general comments received from two Member Countries (one in support and the other opposed), the Code Commission reminded Member Countries that this chapter had been under discussion for many years including the lengthy discussion and debate on the inclusion of New World camelids and that several opportunities had been provided for Member Countries to comment. Therefore, the Code Commission was surprised to note that a Member Country was still questioning the

scientific rationale for the inclusion of *Mycobacterium tuberculosis* in this chapter. The Code Commission further noted that in regards to the question of the scientific rationale, the Scientific Commission had provided a list of peer-reviewed papers demonstrating the impact of *M. tuberculosis* in livestock and wildlife and that the inclusion of *M. bovis, M. caprae* and *M. tuberculosis* in the chapter was intended to manage the human and animal health risks associated with the disease.

- Alexander KA, Pleydell E, Williams MC, Lane EP, Nyange JF, Michel AL, *et al.* Mycobacterium tuberculosis: An Emerging Disease of Free-Ranging Wildlife. Emerg Infect Dis.
- Romero B, Rodríguez S, Bezos J, Díaz R, Copano MF, Merediz I, *et al.* Humans as Source of Mycobacterium tuberculosis Infection in Cattle, Spain. Emerg Infect Dis.
- Fetene T, Kebede N, Alem G. Tuberculosis infection in animal and human populations in three districts of western Gojam, Ethiopia. Zoonoses Public Health. 2011;58:47–53.PubMed doi:10.1111/j.1863-2378.2009.01265.x.
- Chen Y, Chao Y, Deng Q, Liu T, Xiang J, Chen J, Potential challenges to the Stop TB Plan for humans in China; cattle maintain M. bovis and M. tuberculosis. Tuberculosis (Edinb). 2009;89:95–100. DOIPubMed
- Prasad HK, Singhal A, Mishra A, Shah NP, Katoch VM, Thakral SS, Bovine tuberculosis in India: potential basis for zoonosis. Tuberculosis (Edinb). 2005;85:421–8. DOIPubMed

In response to the same Member Country question regarding freedom from infection from all the prescribed species of *M. tuberculosis* complex the Code Commission noted that a case of tuberculosis is defined if the pathogenic agent is isolated from an animal sample, but not humans. The Code Commission further noted that the possibility of reverse zoonosis cannot be dismissed in order to protect the animals. Furthermore, in respect of the same Member Country's view that African buffaloes (*Syncerus caffer*) were excluded from the chapter, the Code Commission recalled former discussion on wildlife. While in many countries wildlife can be a reservoir for the disease as is noted in Article 8.X.1. they are not included in the case definition, rather only included in the risk assessment for herd freedom. Furthermore, the *ad hoc* Group as well as the Scientific Commission considered that African buffaloes do not play a role in maintaining the disease. They are usually infected as spill over from domestic animals rather than the other way around. The same Member Country also questioned the rationale for the use of 'herd free' instead of the use of compartmentalisation to help address 'safe trade'. The Code Commission noted that the concept of herd freedom was extensively discussed (between it and the Scientific Commission) and widely and successfully implemented for both tuberculosis and brucellosis as well as others, and in their opinion referring only to free compartment will lead to unjustified trade restrictions.

The Code Commission noted that in line with changes being made to other *Code* chapters, the use of the term 'cattle' would be reviewed and replaced where appropriate with 'bovines'.

The Code Commission addressed specific comments in each of the articles as follows:

Article 8.X.1.: in response to a proposal to expand the species of New World camelids, the Code Commission reconfirmed that the inclusion of the species was limited to those for which there is a published source supporting their epidemiological role, and further clarified the sentence by deleting 'domestic', as this is stated in the chapeau of the article.

The Code Commission made a minor amendment to Articles 8.X.4. and 8.X.5. to clarify that measures should be periodically reassessed.

In Article 8.X.6., the Code Commission changed 'evidence' to 'occurrence' for clarity and consistency with other chapters and added the word 'known' to the term wildlife reservoirs in point 2 c) to make it clear that this point applies to known reservoirs such as badgers, possums and some wild cervids.

In considering a comment in relation to the validity and reliability of intradermal testing in goats, the Code Commission noted previous discussion on this issue during its February 2016 meeting. It decided to add a new point 3 b) providing for testing of goats to be exported. The proposed measures are based on the requirements for bovines and on field evidence that tuberculin test performance in goats is similar to that in bovines for individual testing. The following rationale supported the inclusion of the provision.

A study of tuberculosis in goats in New Zealand considered the sensitivity of the tuberculin test to be 80%, certainly better than merely examining for clinical signs.

- Sanson R.L. (1998). Tuberculosis in goats. Surveillance. Vol.15, No.2; 7–8.

A review article in the OIE's *Scientific and Technical Review* reports sensitivity of the tuberculin test in goats to be 100%, 38%, >95% and 87% in various studies. The same article cites sensitivity of the Bovigam test in goats as 100%, 83.7% and 87.2%. These sensitivities are, with one exception, adequate for most purposes and so a testing requirement should be introduced into this article.

- Cousins D.V., Florisson N. (2005). A review of tests available for use in the diagnosis of tuberculosis in non-bovine species. *Rev. sci. tech. Off. int. Epiz.*, 24 (3), 1039–1059.

In responding to a Member Country proposal to delete Article 8.X.14. the Code Commission agreed that there was not enough information to recommend tuberculosis risk management measures suitable for 180 Member Countries for the importation of milk and milk products from goats. In order to study this issue more fully the Code Commission requires more information on the management of tuberculosis in goats, including protocols for herd freedom. Consequently, the Code Commission urges Member Countries to provide information to OIE Headquarters on their national tuberculosis control programmes for goats, as the Code Commission is aware that several Member Countries have protocols for certifying herd freedom.

The draft new Chapter 8.X. is attached as **Annex 14** and is proposed for adoption at the 85th General Session in May 2017.

EU position

The EU thanks the OIE and supports the adoption of this new chapter.

Item 4.12. Infection with avian influenza viruses (Article 10.4.25.)

Comments were received from Switzerland and EU.

The Code Commission noted Member Countries comments in support of the adoption of the revised article.

In considering the adoption of this revised article the Code Commission extensively discussed the need for further revision of this chapter to take account of the differences among Member Countries in terms of notification to the OIE, the differing needs when responding to either LPAI or HPAI outbreaks and when recovering free status, the impacts of unjustified barriers to trade being implemented by some Member Countries, and the need to include articles on safe commodities and the need to expand those on surveillance.

The Code Commission requested OIE Headquarters to provide it with expert advice on the following aspects:

a) Disease and case definitions;

b) Appropriate sanitary measures including trade requirements and safe commodities;

c) Outbreak management of LPAI and HPAI;

d) Recovery of free status; and

e) Surveillance.

The Code Commission included the revision of Chapter 10.4. on its work programme, as a priority area for new work, with a view to discussion of the expert advice requested above, at its September 2017 meeting.

The revised Article 10.4.25. is attached as **Annex 15** and is proposed for adoption at the 85th General Session in May 2017.

EU position

The EU supports the adoption of this modified article.

Item 4.13. Infection with lumpy skin disease (Chapter 11.11.)

Comments were received from Australia, New Zealand, Switzerland, EU and EFFAB.

The Code Commission noted a Member Country comment in support of the proposed chapter, in particular the modifications proposed in Article 11.11.3. *bis* regarding recovery of free status in the case of preventive vaccination. In responding to the general comment of another Member Country that the draft chapter was not sufficiently developed to consider adoption, the Code Commission noted that the current chapter is outdated and of no significant use to countries dealing with lumpy skin disease and that these countries consider the need for this revised chapter is a matter of urgency and, therefore, any additional questions about vaccination and inactivation could be dealt with after the chapter is adopted. In addition it was also suggested that the same Member Country review in more depth the report of the *ad hoc* Group as there seemed to be some misinterpretation of the report.

In line with a more general comment by Member Countries on the use of the term 'cattle' throughout the *Code* the Code Commission replaced it with 'bovine' or 'bovines', as appropriate throughout the chapter. For clarity and consistency with changes made to other chapters, 'evidence' was replaced with 'occurrence' where relevant throughout the chapter.

In Article 11.11.3. in response to a Member Country comment and in agreement with the advice from the Scientific Commission, the Code Commission added 'For at least three years vaccination has been prohibited in' at the beginning of point 2) and 'For at least two years vaccination has been prohibited' in point 3).

In examining a Member Country comments on Article 11.11.3. *bis*, the Code Commission and the Scientific Commission did not agree with the deletion of point 1 b). However, they agreed there was a need to address the possibility of emergency vaccination, and the Code Commission added 'the slaughter or killing of the last case, or after the last vaccination if emergency vaccination has been used, whichever occurred last,' and deleted 'a stamping-out policy has been applied' in both points a) and b). In response to the same Member Country proposal that vaccination be prohibited and vaccinated animals be permanently identified and removed from the population, the Code Commission considered that prohibition of vaccination could not be included in this article as this was a prerequisite condition for free status, and further noted that identification is covered in Article 11.11.14. In regards to the proposal to delete point 2) the Code Commission considered that the point was clear and that it was implicit that if vaccination is used the status of the country would change and would not be free.

The Code Commission agreed with a Member Country proposal to add a maximum period to point 3), in Article 11.11.5. and added 'one year' for clarity.

In response to another Member Country proposal to delete Article 11.11.5. neither the Code Commission nor the Scientific Commission supported the proposal and considered that the article provides sufficient risk mitigation measures to ensure trade of animals from infected countries is safe. In respect of point 5), the Code Commission included the provision of testing during quarantine in order to encourage safe trade. In response to the same Member Country proposal for the OIE to develop a protocol based around sequential PCR testing the Code Commission noted that the *Terrestrial Manual* provides sufficient guidance in this regard.

In response to a Member Country proposal to increase the residency period for donor males and donor females from 28 to 180 days, in point b) of Article 11.11.6., point b) of Article 11.11.7. and point b) of Article 11.11.8., the Code Commission considered this was unnecessary as the recommendations in these articles are for importation from countries or zones free from LSD and any animal would have been imported in compliance with the relevant import conditions (Article 11.11.4. or Article 11.11.5.). In response to another Member Country proposal to replace 'regularly' with 'annually' in point c) of Article 11.11.7. and point c) of Article 11.11.8. the Code Commission considered that the manufacturer's instructions should be sufficient.

In examining a Member Country comment in respect of the periods relative to testing, the Code Commission amended point c) iii) of Article 11.11.7. to 28 days and 21 days respectively, and in point iv) changed 14 days to 28 days. This was to clarify the different testing periods relative to the incubation period (28 days) or the time necessary for seroconversion (21 days).

In response to a Member Country questioning the scientific evidence supporting the control measures for the importation of milk and milk products in Article 11.11.10., the Code Commission replied that milk *per se* is considered a low risk material. The Code Commission also relies on the advice of experts who have pointed out that there is no reason to assume that LSDV would not be inactivated by pasteurisation that has been shown to be effective against closely related viruses, and many other viruses. This deductive assessment is supported by decades of empirical observation on the safety of milk and milk products with respect to LSD.

The Code Commission moved Article 11.11.11. to before Article 11.11.14. to improve the flow of the chapter and for consistency with other chapters. In response to a Member Country comment it added a new point 3) in Articles 11.11.12. and 11.11.13., to read 'the necessary precautions were taken after processing to avoid contact of the commodities with any potential source of LSDV.'

In response to a Member Country comment proposing the revision of Article 11.11.14. on surveillance regarding vaccination, serology and subclinical disease, the Code Commission and the Scientific Commission considered the current surveillance articles are sufficient to support Member Countries' surveillance strategies. The Code Commission made some amendments to the article which may address the Member Country concerns and added a new sentence at the end of point 3) to address other Member Countries comments regarding the possible interference of maternal antibodies.

The draft revised Chapter 11.11. is attached as **Annex 16** and is proposed for adoption at the 85th General Session in May 2017.

EU position

The EU thanks the OIE and in general supports the adoption of this modified chapter. Comments are inserted in the text of Annex 16.

Item 4.14. Infection with *Burkholderia mallei* (glanders) (Chapter 12.10.)

Comments were received from Argentina, Australia, Canada, Chile, Singapore, Switzerland, USA and EU.

The Code Commission noted that the Biological Standards Commission had undertaken a revision of the *Terrestrial Manual* Chapter 2.5.11. Glanders, in order to include provisions in relation to meliodosis. The *Manual* chapter will be circulated for Member Countries' comments and proposed for adoption at the 86th General Session in May 2018.

In order to inform its discussion in September 2017, the Code Commission asked OIE Headquarters to provide a more detailed expert analysis and consideration of Member Countries comments, advice received from the Scientific Commission and the new *Manual* chapter. The results of the expert analysis should be provided to the Code Commission by the end of June 2017, in order to allow it to fully consider the advice in preparation for its meeting in September 2017.

Item 4.15. Infection with African swine fever virus (Chapter 15.1.)

Comments were received from Belize, Canada, Costa Rica, Guatemala, Korea, New Zealand, Nigeria, Singapore, South Africa, Switzerland, USA and EU.

The Code Commission considered Member Countries comments and scientific advice provided by the Scientific Commission and made further revisions to this chapter.

The Code Commission made editorial changes throughout the chapter to replace 'housed' with 'captive' and deleted 'farmed free range' and replaced it with 'free ranging'.

In responding to a general comment from a Member Country that measures apparently based on the draft revised chapter had not proven successful in a region recently affected by ASF, the Code Commission noted that the measures implemented were not exactly similar to those proposed in the revised chapter, and agreed with the advice from the Scientific Commission that measures appropriate from a scientific and technical perspective should still be implemented fully by all relevant stakeholders of Member Countries in order to be effective.

In examining Member Countries comments on this chapter, in particular repeated requests from a Member Country to exclude *captive wild pigs*, the Code Commission reiterated its previous explanations on this point and draws the attention of the Member Country to its September 2016 report in which the following explanation was provided.

> *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.*

In other words captive wild pigs are included with domestic pigs not because they are at increased risk of being exposed to ASF but because the animals and their products pose a greater risk of disseminating the disease.

A Member Country proposed the inclusion of 'wild boars' in Article 15.1.1.; this was seen as unnecessary, as by definition, wild pig includes wild boars.

For clarity and consistency with other disease-specific chapters, the Code Commission included the words 'the occurrence' before 'infection' in the definition of the disease. Further amendments were made to point 2) to include reference to 'pathological lesions' after 'showing clinical signs' and to delete 'whether or not clinical signs or pathological lesions consistent with ASF are present' at the end of the paragraph as this is contradictory and unnecessary. In response to Member Countries comments regarding the proposed change to the incubation period (15 to 19 days), the issue was discussed with the Scientific Commission and the Biological Standards Commission and it was agreed to retain the original incubation period of 15 days as it is consistent both with the *Terrestrial Manual* and scientific evidence.

In examining Member Countries comments on the general criteria for the determination of the ASF status of a country, zone or compartment (Article 15.1.2.), the Code Commission made the following observations:

- Point 1) clearly articulates the investigation in relation to pigs showing clinical signs;
- Point 2) allows for situations where organisations, other than the Veterinary Authority, such as hunting associations, might have awareness programmes;
- Points 5) and 6), as in point 2) above, noted that others besides the Veterinary Authority can play a role in surveillance (hunters, etc.); and
- Point 7), agreed to rearrange the point to clarify that the action taken is stated first, followed by the conditions, and identifying roles and responsibilities as the biosecurity is a key aspect of the chapter.

In response to a Member Country request to delete the paragraph related to commodities that can be safely traded, the Code Commission reminded Member Countries that the purpose of the *Code* is to provide recommendations and guidelines in order to facilitate safe trade and therefore did not propose to delete this point.

The Code Commission agreed with the advice provided by the Scientific Commission, in relation to a Member Country comment to remove reference to surveillance and *Ornithodoros* ticks, in Article 15.1.3. in that *Ornithodoros* ticks remain infectious for their entire life, thus surveillance needs to be longer if ticks are involved.

In Article 15.1.3. *ter*, the Code Commission made minor editorial amendments for clarity.

In response to a Member Country requesting the rationale for removing acaricide treatment from Article 15.1.4., the rationale was explained in the September 2014 Scientific Commission meeting report referring to the *ad hoc* Group conclusions: 'The Group (convened in April 2014) suggested removing the reference to ticks and acaricide treatment since this was considered ineffective.' The Code Commission reminds Member Countries that the reports of its meetings should always be read in conjunction with the report of *ad hoc* Groups and, where relevant, of the Scientific Commission, as it is not always possible to include specific comments on every proposal.

In responding to a Member Country proposal to include Veterinary Authority to clarify that it is the Veterinary Authorities' responsibility to carry out the action of *stamping out*, the Code Commission considered it was unnecessary as it is implicit.

In responding to a Member Country comment on Article 15.1.5. that there was a need to clarify what is meant by 'necessary precautions', the Code Commission added 'until the shipment' at the end of point 3) and considered that there was no need for a list of examples.

In response to an editorial change to point b) of Article 15.1.9. proposed by a Member Country, the Code Commission noted that the text was consistent with other *Code* chapters and with the articles in this chapter in relation to the collection of embryos.

Several Member Countries proposed the inclusion of a new point c) referencing the need to retain the provision for serological testing; in response the Code Commission restated the rationale for its decision in September 2016.

> *The Code Commission did not accept a MC's suggestion to test donor males, as such an additional requirement is considered unnecessary in terms of risk mitigation and impractical for pig semen production.*
>
> *The Code Commission clarified that the publication provided by a MC to support its request to reinstate the testing regime in Article 15.1.9. was found to be incorrect and the document cited in the said publication does not exist. After thorough review of the scientific literature and consultation with the Scientific Commission, the Code Commission did not accept the MC's comment, as the putative risk of transmission of ASFV through semen could be mitigated by point a) and point b) of Article 15.1.9.*

Furthermore, while it has been widely assumed that ASFV would be likely to be transmitted in porcine semen, there is no peer-reviewed evidence to support this. Some authors have suggested that ASFV can be found in boar semen and even transmitted to recipient sows. However, the only evidence for this provided in any of these sources appears to be a personal communication by D.H. Schlafer in 1984 published in a conference proceedings. This alleged observation has never been published in any peer-reviewed paper and is not supported by any epidemiological data on ASF spread.

The Code Commission made an editorial change to point 2) of Article 15.1.10 for consistency with articles in other disease chapters, the point now reads 'the semen used to fertilise the oocytes complied with the conditions referred to in Articles 15.1.7. or 15.1.8., as relevant.'

In considering a Member Country comment on Article 15.1.13., the Code Commission reiterated its decision from September 2016 in that '*In response to Member Countries' concerns and to be consistent with Article 15.1.12., the Code Commission 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. The Code Commission also reiterated that, as noted in the User's Guide, the absence of an article or import conditions on any given commodity does not mean that trade in that commodity cannot be conducted safely, or that Member Countries cannot apply appropriate measures.'*

In response to a proposal from a Member Country to delete point 2) of Article 15.1.17. (reinstated), in not accepting this proposal, the Code Commission noted that the rationale provided was not strong enough to support the proposal and that, as Article 15.1.21.ter provides procedures for the inactivation

of ASFV in skins and trophies, an importing country that does not wish to accept these types of products can do so based on its own risk assessment. The same Member Country also proposed deletion of similar points in Article 15.1.17. *bis* and Article 15.1.17. *ter*, which was not accepted either.

A Member Country requested the scientific information on which the provisions for procedures for inactivation of ASFV were based. The Code Commission notes that the provisions of these articles have been under discussion for several years, some of which has included review of scientific articles by *ad hoc* Groups on both ASF and CSF as well as the Scientific Commission. The provisions are based on the best available scientific evidence and informed by common effective practices that have been used by Member Countries for many years.

The Code Commission provided the following references to supporting scientific papers:

Turner, C and Williams, SM (1999). Laboratory-scale inactivation of African swine fever virus and swine vesicular disease virus in pig slurry. *Journal of Applied Microbiology*. Volume 87, Issue 1, pages 148–157.

Wieringa-Jelsma, Tinka, et al. 'Virus inactivation by salt (NaCl) and phosphate supplemented salt in a 3D collagen matrix model for natural sausage casings.' *International journal of food microbiology* 148.2 (2011): 128-134

http://www.cfsph.iastate.edu/Factsheets/pdfs/african_swine_fever.pdf

http://www.oie.int/fileadmin/Home/eng/Animal_Health_in_the_World/docs/pdf/Disease_cards/AFRICAN_SWINE_FEVER.pdf

The Code Commission made minor editorial changes to the abovementioned articles for clarity and to align them with other disease chapters of the *Code*.

The Code Commission agreed to change 'Competent Authority' to 'Veterinary Authority' in Article 15.1.27. as it agrees with the Member Country that animal disease control programmes should be under the control of the Veterinary Authority.

The draft revised Chapter 15.1. is attached as **Annex 17** and is proposed for adoption at the 85th General Session in May 2017.

EU position

The EU thanks the OIE and supports the adoption of this modified chapter.

Item 4.16. Draft new Chapter on infection with porcine reproductive and respiratory syndrome virus (Chapter 15.X.)

Comments were received from Argentina, Australia, Chile, Mexico, New Zealand, Singapore, South Africa, Switzerland, USA, the EU and the OIE PRRS Reference Laboratory (Poland).

The Code Commission made several changes to the chapter including throughout the chapter where appropriate, changing the word 'outbreak' to 'case' for consistency with other disease chapters. Furthermore, in relation to requests from a Member Country to exclude *captive wild pigs*, the Code Commission reiterated its previous explanations on this point and draws the attention of the Member Country to its September 2016 report in which the following explanation was provided.

> *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.*

In other words captive wild pigs are included with domestic pigs not because they are at increased risk of being exposed to PRRS but because they pose a greater risk of themselves or their products disseminating the disease.

The Code Commission amended the wording in the preamble to point 1) to read 'The following defines the occurrence of *infection* with PRRSV', this for clarity and consistency with amendments proposed to other disease chapters in the *Code*.

In order to address an issue raised by Member Countries, the Code Commission amended point 1) to read 'PRRSV, excluding vaccine strains, has been isolated from samples from a domestic or wild pig'. Consequently, amendments were also made to point 3) to address the issue of isolation of a live PRRS vaccine strain. In examining the Member Countries comments on point 3) it was confirmed that the isolation of any PRRS virus including vaccine-like virus in an unvaccinated animal is considered a case.

In respect to the strong opposition to the inclusion of 'maternally-derived immunity' the Code Commission agreed that it is impossible to discriminate between maternally-derived immunity and naturally-acquired immunity and therefore for clarity amended point 4) by adding 'unless they are demonstrated to be' and deleted 'or maternally-derived immunity'.

The Code Commission examined numerous lengthy and irreconcilable Member Countries comments on whether or not meat was a safe commodity and whether or not it should be included in Article 15.X.2. In order to resolve this, the Code Commission further noted that formerly proposed Article 15.X.12. provided recommendations for the importation of fresh meat of domestic and captive wild pigs with ante- and post-mortem inspection and reinstated an Article 15.X.12. into the chapter (see below) and deleted reference to meat in Article 15.X.2. In addition, as the definition of meat includes blood, and meat has now been deleted from this article, it was considered appropriate to reinstate a reference to 'blood products' (point 5) as it was not clear what is meant by 'blood by-products'.

Editorial changes were made to Article 15.X.3. in response to a number of inconsistencies with other chapters, and in order to address some Member Countries comments. One Member Country proposed to insert a reference to 'capable of detecting the presence of *infection* with PRRSV even in the absence of clinical signs' at the end of point 3), however the Code Commission considered it more appropriate to include the reference in Article 15.X.13. on surveillance (see below).

In response to a Member Country comment in regards to the use of inactivated and modified live vaccines, the Code Commission agreed with the advice provided by the Scientific Commission that immunity after vaccination lasts an average of nine months and that existing point 5) and point 6) provide sufficient guidance.

In responding to a Member Country proposal to change the term Veterinary Authority to Veterinary Services in Article 15.X.4. (and other following articles) the Code Commission considered the proposal was redundant as it is implicit that the Veterinary Services are responsible for the actions identified in this chapter.

In examining a Member Country proposal to include a reference to the need for laboratory results to corroborate clinical signs in point 1) of Article 15.X.5., the Code Commission did not consider the rationale provided was sufficient to support the proposal.

The Code Commission made minor amendments to the points in Article 15.X.6., to address Member Countries comments. However, it did not accept the rationale to delete point 1) as isolation alone with no information on the herd of origin is not considered an appropriate risk management option, nor did it consider there was a justification to include testing in the herd of origin. The inclusion of '28 days' (twice the incubation period) in point 4) was considered appropriate to clarify the time for isolation for animals prior to entry into an artificial insemination centre.

In examining a Member Country proposal for Article 15.X.7., the Code Commission considered that the need for testing is redundant as the animals are for slaughter and 'appropriate biosecurity' during transport is sufficient. It also noted that this point is consistent with other chapters.

In response to a proposal to add additional sampling of males in Article 15.X.8, the Code Commission noted that the animals are in a free country or zone and therefore testing would be unnecessary.

The Code Commission examined Member Countries comments and proposed amendments to the text, in Article 15.X.9., for clarity, in particular, noting that (i) testing cannot be done on the same day as

semen collection, (ii) serological testing may not be the best technique in the case of herd testing for donor males. With regards to a proposal from a Member Country to include further testing, it noted that the requirements should be the same as for live animals and therefore did not include additional requirements. In its discussion on this article the Code Commission also referred Member Countries to the relevant article of the *Terrestrial Manual* Chapter 2.8.6.

In considering a Member Country comment on Article 15.X.11. the Code Commission considered the safety of embryos is addressed through the requirements included in point b) and further cited a recent scientific article on the safety of embryos, which Member Countries are encouraged to consider.

> Haijing Zhao, Guangyuan Zhao, Wenjun Wang. "Susceptibility of porcine preimplantation embryos to viruses associated with reproductive failure" [Theriogenology 86(7) (2016) 1631e1636] http://www.sciencedirect.com/science/article/pii/S0093691X16302588

The Code Commission reinstated an Article 15.X.12. for the importation of pig meat, requiring certification that the meat comes from animals that passed ante- and post-mortem inspection with favourable results (see above point on Article 15.X.2.)

In regards to Article 15.X.13. Introduction to surveillance, the Code Commission made minor amendments to clarify that surveillance should be capable of detecting PRRSV in the absence of clinical signs and did not agree with a proposal from a Member Country to include reference to virus circulation as it was covered in the current text.

In response to a request from a Member Country to include examples in Article 15.X.15. the Code Commission considered that the inclusion of examples for the establishment of proximities around outbreaks, in the case of PRRSV, was not appropriate, and that Member Countries should choose the most appropriate options particular to their circumstances.

The proposed draft new Chapter 15.X. is attached as **Annex 18** and is proposed for adoption at the 85th General Session in May 2017.

EU position

The EU thanks the OIE and in general supports the adoption of this new chapter. Comments are inserted in the text of Annex 18.

Item 4.17. Somatic cell nuclear transfer in production livestock and horses (Article 4.11.4.)

Comments were received from Switzerland and EU.

In view of the comments received in support of the proposed revised Article, the Code Commission made no changes and noted that this limited change could be adopted at the upcoming General Session.

The revised Article 4.11.4. is attached as **Annex 19** and is proposed for adoption at the 85th General Session in May 2017.

EU position

The EU supports the adoption of this modified article.

Item 4.18. Import risk analysis (Chapter 2.1.)

The Code Commission noted in its review of the Glossary that 'transparency' appears in one chapter only, Chapter 2.1. Its placement in the Glossary arose because originally risk analysis was covered in two chapters. These were later merged into a single chapter, but 'transparency' remained in the Glossary. Noting this, the Code Commission removed the italics from the word 'transparency' in Article 2.1.1.

The Code Commission consequently revised point 4) of Article 2.1.3., inserting the sentence defining transparency that was deleted from the Glossary, to read:

Consistency in *risk assessment* methods should be encouraged and transparency is essential in order to ensure fairness and rationality, consistency in decision making and ease of understanding by all the interested parties. Transparency means the comprehensive documentation of all data, information, assumptions, methods, results, discussion and conclusions used in the risk analysis.

Since this proposed new text is in fact only a movement from the Glossary to the chapter, the revised Article 2.1.3. is attached as **Annex 20** and is proposed for adoption at the 85th General Session in May 2017.

EU position

The EU in general supports the adoption of this modified chapter. Comments are inserted in the text of Annex 20.

5. Texts circulated for Member Countries' comments

Table 2. Lists of texts circulated for Member Countries' comments

Item	Annexes in Part A	Chapters/Articles	Title
5.1	21	-	Glossary B
5.2	22	5.3.	Zoning and compartmentalisation (clean text)
5.2	22 *bis*	5.3.	Zoning and compartmentalisation (marked up text)
5.3	23	4.X.	Draft new Chapter on vaccination
5.4	24	4.8.	Collection and processing of *in vitro* derived embryos from livestock and equids
5.6	25	6.1.	The role of the Veterinary Services in food safety (clean text)
5.6	25 *bis*	6.1.	The role of the Veterinary Services in food safety (marked up text)
5.7a)	-	-	Definitions ('therapeutic use', 'preventive use', 'growth promotion') as proposed by the *ad hoc* Group on AMR
5.7b)	26	6.7.	Harmonisation of national AMR surveillance and monitoring programmes
5.8	27	7.1.X.	Draft new article on guiding principles on the use of animal based measures
5.9	28	7.X.	The draft new Chapter on AW and pig production systems
5.10	29	8.3.	Infection with bluetongue virus
5.11	30	8.8.	Infection with foot and mouth disease virus
7.3	37	-	Work programme

Item 5.1. Glossary Part B

Comments were received from Australia, Canada, Chile, Nigeria, Norway, Singapore, EU and AU-IBAR.

In examining Member Countries comments on the proposed revised definitions, the Code Commission made a number of changes to the proposed definitions, which are presented for further comment in the corresponding Annex. In light of the discussion on the proposed definition of disease (see last paragraph below), the terms 'infection and infestation' were reinstated.

Animal Welfare – In examining the proposal of the AWWG (see Item 6.9.) to modify the definition, the Code Commission considered that 'General Considerations' was more appropriate sub-heading than 'Introduction'. It also noted that it would be more clear and succint if only the first paragraph of the

modified text was used as the definition for animal welfare in the Glossary of the *Code*. The definition now reads '*Animal welfare* means the state of well-being of an animal in relation to the condition in which it lives'.

Containment Zone – In light of its discussion on Chapter 4.3., the Code Commission replaced the word 'outbreaks' with 'cases', included 'sanitary' after 'biosecurity'. In response to a Member Country proposal to include reference to 'where disease investigation is being carried out to establish suspicion or confirm an outbreak', the Code Commission considered that this was an activity that would be carried out and was not appropriate to include in a definition.

Free Zone – Deleted 'disease' and reinstated 'infection and infestation'.

Infected Zone – Replaced 'diagnosed' with 'confirmed' and reordered the wording to improve readability.

Protection Zone – In response to numerous Member Countries comments, the Code Commission proposed a new text, in order to add clarity to what a protection zone is as articulated in Article 4.3.6.

Zone – For clarity added 'animal' before 'health status' and included 'defined by the Veterinary Authority'.

Compartment – Accepted proposals from a Member Country to include 'animal' before 'health status' and to clarify that the control measures would be applied 'in a country or zone'.

Vaccination – Noting the objective of vaccination as described in the proposed new Chapter 4.X., and for clarity and consistency with other *Code* chapters, the Code Commission replaced 'of a vaccine comprising antigens appropriate to the' with 'with the intention of' and replaced 'disease to be controlled' with 'pathogenic agent'. It did not agree with a proposal to include reference to 'national legislation' as this was addressed in the chapter.

The Code Commission considered the numerous Member Countries comments in regards to the definition of *disease.* The majority of these comments did not support the proposed change to the definition, the Code Commission noting this was linked to its proposal on a definition of pathogenic agent. As the current definition brings confusion about the understanding of the term *disease*, *infection* or *infestation* the Code Commission considered that the *Oxford English Dictionary* definition is appropriate for the purposes of the *Code*, as is also the case for 'pathogenic agent', and therefore proposed to delete the term 'disease' from the Glossary. This will result in consequential changes to the *Cod*e where the term 'disease' will need to be unitalicised, replaced by 'infection and infestation' or changed to exactly what is meant, i.e. clinical or pathological signs. It further noted that this would not affect the definition of 'listed disease' or 'emerging disease' and would bring further clarity to the use of the terms *infection* and *infestation*.

The revised definitions are attached in **Annex 21** and are proposed for Member Countries 'comments.

EU comment

The EU thanks the OIE and in general supports the proposed changes to the glossary. Comments are inserted in the text of Annex 21.

Item 5.2. Zoning and compartmentalisation (Chapter 4.3.)

Comments were received from Argentina, Australia, Canada, Chile, New Zealand, Norway, USA, EU and AU-IBAR.

The Code Commission noted a general comment from Member Countries and agreed to consider whether there was a need to develop a separate chapter on the application of zoning as is the case for compartmentalisation and has included this in its work programme for further consideration. For consistency throughout the chapter the Code Commission changed 'distinct' to 'specific', replaced 'animals' and 'animal products' with 'commodities' and 'herd/flock' with 'herd or flock' as appropriate.

In examining several Member Countries comments on Article 4.3.1. the Code Commission made the following observations and where appropriate made minor amendments:

- Included the term 'or prevention', to clarify that establishing or maintaining a subpopulation with a specific health status could be for the purpose of disease prevention, disease control or international trade;
- Clarified that the use of a compartment was also a tool to control the disease in a country or zone;
- Did not consider there was a need to add further clarification to the text of the third paragraph, as this article is a general one and it is obvious that a country may have more than one zone or compartment;
- Included reference to 'facilitate disease control and the continuation of trade'.

In considering Member Countries comments on Article 4.3.2. the Code Commission made several amendments including changing 'distinct' to 'specific' for consistency with other chapters, added text to clarify the cooperation between industry and the *Veterinary Services* and to clarify the reference to the principles and criteria in Chapters 3.1. and 3.2.

It did not agree with the proposal of a Member Country to reorder a sentence relating to 'assessment of resources needed and available' as in its view reordering the words changed the intent of the sentence. The purpose of the assessment is to determine the resources needed and if they are available to establish and maintain the zone or compartment. In response to a comment from the same Member Country the Code Commission noted that '*sanitary measures*', a defined term that includes e.g. vaccination and import and export measures, are not a subset of '*biosecurity*' and did not agree to delete '*sanitary measures*'.

In response to a proposal to include 'audit' with 'inspections' the Code Commission did not agree as audit is covered in the second sentence.

The Code Commission agreed with a proposal from a Member Country to include reference to 'in consultation with the *Veterinary Services*, if appropriate' in the paragraph relating to industry responsibilities and agreed to change 'animals' to 'commodities' for consistency as commodities include animals and animal products.

In considering Member Countries comments on Article 4.3.3. the Code Commission replaced 'industry' with 'operators', changed 'animals' to 'commodities' but did not agree with a proposal to include 'with trading partners when requested'. In response to two Member Countries comments on the last paragraph in this article, one proposing to delete the paragraph and the other to delete the last sentence, the Code Commission noted that this paragraph was a key part of the article and to delete it, or the last sentence, would be to limit everything that is in the *Code*. The intent of this chapter is to provide the ability for countries to establish different types of zones but to list every example of a type of zone is not feasible. This sentence provides the necessary flexibility to allow Member Countries to protect their health status, to control diseases and to facilitate trade.

In examining Member Countries comments in relation to Article 4.3.4, the Code Commission noted a number of comments opposed to the deletion of 'infection or infestation' that was linked to the proposal on the definition of *disease*, which was as yet unresolved. Thus it agreed to reinstate the terms 'infection or infestation' in this chapter.

In response to a proposal to delete the second last sentence in this article, the Code Commission did not agree with the rationale and noted that the text was consistent with other *Code* chapters such as those on brucellosis, classical swine fever and tuberculosis. The Code Commission amended the last sentence to include 'principles determined for its definition and establishment are respected'.

The Code Commission did not support a proposal to move Article 4.3.5. Infected Zone to follow Article 4.3.6. Protection Zone as it did not agree with the rationale and considered the current proposed order more logical. In line with changes made in other disease chapters, the Code Commission also replaced 'diagnosed' with 'confirmed' and reordered the sentence to clarify that there may also be areas of the country that are apparently free from the disease but that status may not have been formally confirmed.

In considering comments from Member Countries in relation to the first paragraph in Article 4.3.6. the Code Commission reworded the first sentence to clarify that a protection zone can be established to prevent the introduction of a pathogenic agent from adjacent countries or zones to an animal population. It also included the term 'commodities' in point 5) for consistency with other articles.

The Code Commission in agreement with the advice of a member of the Scientific Commission clarified whether or not measures implemented in a *protection zone* established in a *free* country or *zone* would affect the status of the rest of the *free* country or *zone* and added a new paragraph at the end of the article to further clarify this.

In response to a number of Member Countries comments the Code Commission made several amendments, including some of an editorial nature, to Article 4.3.7. as follows:

- added 'epidemiologically-linked' to the first paragraph to clarify that it is possible to have more than one *containment zone* provided the *outbreaks* in different containment zones are not epidemiologically-linked;
- added 'infestation' to point 2);
- replaced 'clear' with 'animal' before 'identification' in point 4), but did not agree to include 'and registered'. Moreover, while recognising that strict animal movement control should be in place, individual specific identification may be desirable but not always feasible and the method used should be decided by the Member Countries;
- replaced 'evidence' with 'occurrence' to be consistent with the disease chapters where it states 'A case is defined as an occurrence of, etc.';
- in point 6 b) added 'for at least two incubation periods' for consistency with point a) and in agreement with the advice from a member of the Scientific Commission;
- amended the third last paragraph by adding 'Once the containment zone has been established' and ' regain free status' rather than the free status being reinstated; and
- amended the final paragraph to reference the relevant disease-specific chapters or, if there are none, Article 1.4.6.

In examining Member Countries comments on Article 4.3.8. the Code Commission acknowledged that while the OIE has procedures for official recognition of the status for six listed diseases (Chapter 1.6.), for others, Member Countries may recognise each other's status through bilateral agreements or processes. In the final paragraph of this article the Code Commission added 'in accordance with Chapter 5.3.' and replaced 'certifies' with 'demonstrates' for clarity.

The draft revised Chapter 4.3. is attached as **Annex 22** and is proposed for Member Countries' comments.

EU comment

The EU thanks the OIE and in general supports the proposed changes to this chapter. Comments are inserted in the text of Annex 22bis.

Item 5.3. Draft new Chapter on vaccination (Chapter 4.X.)

Comments were received from Australia,, Costa Rica, Guatemala, Japan, New Zealand, Norway, Singapore, Switzerland, USA, EU, AU-IBAR and IDF.

The Code Commission noted the comments of a large number of Member Countries in support of this draft new chapter. In responding to a proposal to include more focus on animal welfare as an argument in favour of vaccination, the Code Commission noted animal welfare was covered in Article 4.X.1. Throughout the chapter the Code Commission also changed the word 'non-vaccinated' to 'unvaccinated' as this is the correct term in English.

In examining Member Countries comments on this draft new chapter, the Code Commission made a number of changes to Article 4.X.1. In response to a Member Country proposal to change 'pathogenic' to 'causative' it has been explained previously that in order to improve the consistency of language in the *Code* a decision was taken to use the term 'pathogenic agent' in the future. The Code Commission rearranged the words 'control and prevent' and amended 'prevent' to 'prevention' for improved logic and in the context of the description of vaccination. In response to Member Countries comments it also

amended the reference to the relevant general and specific recommendations of the *Terrestrial Manual* rather than just Chapter 1.1.8. The Code Commission did not support a proposal to include reference to the reduction of the development of antimicrobial resistance in the introduction as it was already covered indirectly by reduction of the use of antimicrobial agents in animals. In response to a proposal to add reference to cost benefit analysis, it noted that this was covered in Article 4.X.4.

In response to an organisation's proposal to include reference to vaccination for diseases not under official control programmes, the Code Commission added a sentence to the end of the paragraph with the objective to highlight that the recommendations in this chapter could be used for any diseases for which vaccines exist.

In examining Member Countries comments on Article 4.X.2. Definitions, the Code Commission made a minor editorial change to 'purpose' and in response to Member Countries comments made the following observations:

- noting that vaccination is either to respond to an increased risk or to outbreaks, it did not support a proposal to amend the definition of 'emergency vaccination' or to include a new definition of 'preventive vaccination';

- for clarity it expanded on the text in Article 4.X.3.;

- in respect of Member Countries comments in comparing the definitions to those used in the Manual on WAHIS notification procedures it noted that the Manual on WAHIS notification procedures should be consistent with the *Code* and this would be done by OIE Headquarters once the chapter was adopted;

- noted that a vaccination strategy is part of the overall vaccination programme and thus there was no need for a new definition; and

- did not agree with a proposal to amend the definition of 'population immunity' to include 'herd immunity' as epidemiologists consider that immunity does not apply only to herds, there can be many types of epidemiological units.

The Code Commission considered several proposals to amend Article 4.X.3. including one to limit the scope to 'official' control programmes; it considered this was unnecessary as it was now addressed in Article 4.X.1, and Article 4.X.3. also deals with control programmes under the Veterinary Authority. For further clarity it added reference to the need to take into account the disease, 'its impact and zoonotic potential' to the first paragraph.

In response to Member Countries comments on point 1), the Code Commission added reference to 'prevalence and impact', included 'prevention' and 'control' and 'prevent the introduction of a pathogenic agent from an infected adjacent country or zone' to further clarify that the objective of a vaccination programme includes the need to take preventive measures. It made a further amendment to the final paragraph of this article in order to clarify that vaccination programmes should be 'integrated with other' ongoing animal health related activities.

In examining Member Countries comments on Article 4.X.4. the Code Commission made the following amendments and observations with regards to the considerations when launching a vaccination programme:

Point 1) – included a new point 1) 'the epidemiology of the disease';

Point 1) *bis* – added 'by means other than vaccination' for clarity;

Points 2) and 3) – deleted reference to 'increased' as it was not considered to be a necessary part of the criteria;

Point 3) *bis* – added reference to 'the zoonotic potential of the disease' as the potential impact on humans is an important consideration;

Point 4) – reworded the point to clarify the need to consider the extent of potential exposure of the animal population;

Point 5) – deleted reference to 'an insufficient' in reference to the level of population immunity;

Point 7) – included 'programme' for clarity;

Point 8) – amended the text to add clarity to the type of resources that need to be considered, particularly in regards to human resources as these may be already dedicated to other control measures in the event of a disease outbreak; and

Point 9) – amended the text regarding the need for an appropriate cost-benefit analysis.

In examining Member Countries comments on Article 4.X.5, in relation to vaccination strategies the Code Commission made minor amendments to the article and noted the following:

Blanket vaccination – this term is used to mean all animals at risk, as opposed to targeted vaccination. Further, in response to a question concerning the use of the terms 'area' and 'zone', the Code Commission noted that the term 'area' is used only in the geographical sense while 'zone' is used in the sense defined in the *Code.*

Ring vaccination – for clarity deleted the word 'primarily' and replaced 'establishment' with 'location' and 'boundary' with 'limit'.

Barrier vaccination – in response to a proposal to include mention of 'protection zone' the Code Commission in agreement with the Scientific Commission noted that there are other measures of control (i.e. enhanced surveillance, movement control) implemented in a protection zone. The Code Commission also considered that there was no need to include examples in the definition.

Targeted vaccination – in examining Member Countries comments on this definition, the Code Commission noted that the criteria to define the subpopulation could be very broad and that the reasons for targeted vaccination can be numerous (e.g. in response to disease, epidemiology of the disease, exposure, importing country requirements) and therefore deleted the wording 'defined by a greater likelihood of exposure and severity of the consequences.'

In consideration of the logical flow of the chapter the Code Commission rearranged Articles 4.X.6 and 4.X.7. Article 4.X.6 is now 'choice of vaccine' and made minor amendments to include the need for consideration of 'marketing authorisation', a term used in other chapters of the *Code*, a new point to address the 'ability to be monitored for vaccine-induced antibodies' and safety for the 'users and consumers' as well as the environment.

Article 4.X.7. was changed to read 'Other critical elements of a vaccination programme'. In responding to Member Countries comments on old Article 4.X.6. the Code Commission:

- Included a new point 1), to address the need for a legal basis for undertaking a vaccination programme, as well as the need to consider compensation for farmers and possible side effects;
- Vaccination coverage – amended the second sentence to read 'The vaccination programme should define the minimum vaccination coverage necessary to achieve a sufficient population immunity to fulfil the objectives of the programme.' It also included reference to the 'efficacy of the vaccine' for clarity in the last sentence and in response to Member Countries comments proposing the inclusion of 'virulence of the pathogen' the Code Commission and the Scientific Commission did not agree as they considered this was already covered in the epidemiology of the disease;
- Stakeholder involvement – changed 'government agencies' to 'governmental organisations' for consistency with other *Code* chapters;
- Timing of vaccination programmes – added the words 'necessary to attain or maintain' in order to clarify that the objective of the vaccination campaign could also be to maintain population immunity;
- Auditing of the vaccination campaigns – for clarity changed 'actors' to 'participants' and deleted 'involved'; added a new point b) *bis* 'number of animals vaccinated compared to census figures for the relevant animal population' as it was considered a useful indicator. However, the Code

Commission in agreement with the Scientific Commission did not agree to add 'taking into account the primary course of vaccinations if more than one is required' to the existing point b) as it was considered unnecessary. In response to a proposal to include reference to 'serological post vaccination monitoring' the Code Commission in agreement with the Scientific Commission noted that post vaccination monitoring is covered in Article 4.X.9.

In examining Member Countries comments on Article 4.X.8. the Code Commission noted the need to address the legal aspects of a vaccination programme and included it as a new point under Article 4.X.7. The Code Commission made further amendments to this article as follows:

- Procurement of vaccines – Point 1) Replaced 'registration procedure' with 'marketing authorisation'; made a correction to the name of the VICH; did not support the view that 'procurement' should be replaced by 'availability' ;

- Implementation of the vaccination programme – added 'establishment of' before 'standard operating *procedure' for clarity. In response to a Member Country comment regarding disposal of waste, added a new point e) bis) 'determine the disposition of partially used or unused containers of vaccine'. In order to address the need for appropriate biosecurity measures by vaccinators added a new point e) ter) but did not agree with the need to include reference to appropriate training for vaccinators, as the list is to identify what should be included in a SOP, which would be used by trained vaccinators. In order to avoid confusion in point i) deleted the term 'vaccination site' as this is generally understood to mean the injection site on the* animal rather than the location where vaccination takes place.

In considering Member Countries comments on Article 4.X.9., the Code Commission noted that the guidelines on foot and mouth disease vaccination and post-vaccination monitoring published jointly by the FAO and OIE provided excellent guidance. However, it was not an appropriate reference to include in an adopted standard. To further clarify the need for periodical evaluation and monitoring during the campaign it amended the preamble to the article and included a new paragraph at the end to highlight that if the objectives and targets of the vaccination programme were not achieved, this should be identified and addressed.

In response to a Member Country comment the Code Commission replaced 'adverse reaction' with 'side effects' in point 3) and in response to several Member Countries comments in relation to reduction of incidence, prevalence or clinical signs, it amended point 4) to include 'or impact of the disease'.

In responding to Member Countries comments on Article 4.X.10., the Code Commission replaced 'sufficient' with 'more appropriate' in point 3), to clarify that alternative methods may actually be more efficient rather than merely sufficient and noted that cost-benefit analysis was covered in Article 4.X.4. However, it agreed that a revised cost-benefit analysis could provide useful information for a decision on whether or not to continue with the vaccination programme and included a new point 6).

In response to Member Countries comments that the first sentence of Article 4.X.11. was too general and that while it may be true that for some diseases vaccination may be an alternative to stamping-out, it is not applicable to all diseases, the Code Commission inserted 'several' after 'eradicate' in the first sentence.

In response to a Member Country proposal to delete the last sentence of paragraph 3, the Code Commission noted that this was in fact a key element in the chapter, in that, unless specified in disease-specific chapters, the use of systematic (preventive) or emergency vaccination in response to a threat should not *per se* affect the disease status or disrupt trade. It also noted that Member Countries having an officially recognised disease free status should inform the OIE of any change in the vaccination policy. To address the Member Countries concerns the Code Commission amended the first sentence of the third paragraph of the article to replace 'a change' with 'in the absence of cases and an increase'.

The draft new Chapter 4.X. is attached as **Annex 23** for Member Countries' comments.

EU comment

The EU thanks the OIE and in general supports this proposed new chapter. Comments are inserted in the text of Annex 23.

Item 5.4. Collection and processing of *in vitro* derived embryos from livestock and equids (Chapter 4.8.)

Comments were received from Australia, Singapore, Switzerland and EU.

The Code Commission noted the comments of a Member Country supporting the proposed changes. It also noted that some others were not supported by scientific rationale and that in order to reconcile some of these comments it would require additional scientific expertise and in cases where Member Countries referred to other bodies such as IETS that it is not appropriate to just include these references without some analysis of the material to be referenced.

The following observations were made in respect of Member Countries comments on the chapter;

Article 4.8.2 .– In response to a proposal to insert the word 'audit' as a more rigorous aspect inspection, the Code Commission noted that audit is encompassed in the meaning of a regular inspection carried out by an Official Veterinarian.

Article 4.8.3. – Noted in terms of practicality it is easier to protect laboratories from rodents and insects rather than keep them completely free. Agreed in principle to a proposal from Member Countries to include reference to the need for a laminar flow facility in which to handle or process the oocytes and embryos, but as there was no proposed text the Code Commission did not consider this further and invites the Member Countries to provide a specific text for its consideration at its September 2017 meeting.

In response to the same Member Countries proposal to add a reference to the IETS manual and a question as to whether the list of diseases for donor animals should be reviewed in point 2) of Article 4.8.4., the Code Commission requested the OIE Headquarters to provide scientific advice in regards to these two proposals. In addition, the Code Commission also invited Member Countries to provide information on diseases that can be transmitted through semen and embryos.

The Code Commission accepted Member Countries proposal to insert 'slicing techniques' in the text of Article 4.8.4 concerning the recovery of oocytes so as to complete the list of methods that are available for collection.

In response to the same Member Countries comments to insert reference to 'a pool of at least three washes of the washing medium used for the oocytes or the embryos' in Article 4.8.5., the Code Commission noted that there was a need for a supporting scientific rationale before it could consider this inclusion. The Member Countries are invited to provide supporting rationale for such an inclusion. It also noted that in regard to the same Member Countries general comment on this article, relating to the inclusion of validated tests in the *Terrestrial Manual*, it would request OIE Headquarters to refer the proposal to the Biological Standards Commission.

The Code Commission accepted a Member Country comment to insert new text 'and be collected and processed in accordance with Chapter 4.5.' for clarity.

The Code Commission also accepted a proposal from the same Member Country to insert new text 'or semen for fertilisation of oocytes' in Article 4.8.6., recognising the role of the health status of donors from which semen is collected.

The revised Draft Chapter 8.3. is attached as **Annex 24** for Member Countries' comments.

EU comment

The EU thanks the OIE and in general supports the proposed changes to this chapter. Comments are inserted in the text of Annex 24.

Item 5.5. Report of the Animal Production Food Safety Working Group

OIE Headquarters informed the Code Commission of the activities noted in the report of the December 2016 meeting of the Animal Production Food Safety Working Group (Working Group). The Code Commission endorsed the report.

The Code Commission agreed with the Working Group recommendation to use the word 'foodborne' in this chapter given that this is the internationally accepted format rather than 'food-borne'. The Code Commission agreed that once this chapter is adopted, this format will be applied throughout the *Code* to ensure consistency.

The Code Commission noted the Working Group recommendation to consider reviewing the definitions for Veterinary Services and Competent Authority used in the glossary to better reflect the role that these entities play in food safety. The Code Commission agreed to consider this recommendation as part of future work that will consider a broader review of these definitions.

The Code Commission noted that the Working Group had discussed the control of Shiga toxin-producing *Escherichia coli* (STEC) and had reiterated that it is an important pathogen in bovines and potentially other species for both public health and trade reasons. The Code Commission agreed to add this to its work programme and to monitor outcomes of relevant work underway by the Codex Alimentarius Commission and the FAO/WHO expert group, and to consider undertaking relevant work when Codex undertakes new work.

The Code Commission noted the substantial work undertaken by the Working Group to revise Chapter 6.1. 'Role of Veterinary Services in food safety' (see **Item 5.7.**).

The Code Commission reviewed the draft Terms of Reference for the development of a revised draft Chapter 6.2. 'Control of biological hazards of animal health and public health importance through ante- and post-mortem meat inspection' developed by the Working Group and requested that OIE Headquarters proceed with convening an expert group to undertake this work.

The report of the Animal Production Food Safety Working Group is attached as **Annex 38** for Member Countries' information.

Item 5.6. The role of the Veterinary Services in food safety (Chapter 6.1.)

OIE Headquarters noted that the Animal Production Food Safety Working Group (Working Group), at its December 2016 meeting, had considered the extensive number of Member Countries comments received on this chapter following circulation of a revised chapter in the Code Commission's February 2016 report.

The Code Commission was informed that the Working Group had considered all Member Countries comments and made a significant number of changes to improve the readability and refocus the text on the role of Veterinary Services, as opposed to the function of a food safety system. It also made amendments to better distinguish between the role of the Competent Authority and Veterinary Services to address the concern that in some countries the role and responsibilities of the Veterinary Service along the food chain differ depending on the role of the Competent Authority.

The Code Commission reminded Member Countries that the rationale for the changes made by the Working Group are presented in the Working Group's December 2016 meeting report which is presented in **Annex 38**.

The Code Commission reviewed the amended chapter and made some additional amendments of an editorial nature.

The revised Chapter 6.1. is presented as clean text and showing track changes in **Annex 25** and **Annex 25bis**, respectively, for Member Countries' comments. Member Countries are requested to use the clean version as the basis for their comments.

EU comment

The EU thanks the OIE and in general supports the proposed changes to this chapter. Comments are inserted in the text of Annex 25bis.

Item 5.7. Antimicrobial resistance

a) Report of the *ad hoc* Group on Antimicrobial Resistance (January 2017)

OIE Headquarters presented the report of the *ad hoc* Group on Antimicrobial Resistance which met in January 2017. The Code Commission thanked OIE Headquarters for providing an update on this important work and noted that in addition to reviewing Member Countries comments on Chapter 6.7., the *ad hoc* Group had also proposed amendments to Chapter 6.8., which was not currently on the Code Commission's work programme.

The Code Commission took note of the advancement of the collection of data for the 2016 annual report and the revised definition proposed for 'therapeutic use' and of new definitions proposed for 'preventative use' and 'growth promotion' that were intended to be included in Chapter 6.8. of the *Terrestrial Code*. It also noted that the definition of 'growth promotion' was in line with the definition used by the Codex Alimentarius Commission. Member Countries' are invited to comment on the following definitions as proposed by the *ad hoc* Group:

Therapeutic use: Administration of an antimicrobial agent to animals to prevent, control or treat infection or disease. The Veterinary Medicinal Products (VMP) containing antimicrobial agents should only be used on the prescription of a veterinarian or other suitably trained person authorised to prescribe VMP containing antimicrobial agents in accordance with national legislation and under the supervision of a veterinarian.

Preventative use: Administration of an antimicrobial agent targeted to animals at risk for a specific infection(s) or in a specific situation where disease is likely to occur if the drug is not administered, with an appropriate dose and for a limited duration. The Veterinary Medicinal Products (VMP) containing antimicrobial agents should only be used on the prescription of a veterinarian or other suitably trained person authorised to prescribe VMP containing antimicrobial agents in accordance with national legislation and under the supervision of a veterinarian

Growth promotion: Use of antimicrobial substances to increase the rate of weight gain and/or the efficiency of feed utilization in animals by other than purely nutritional means. The term does NOT apply to the use of antimicrobial agents for the specific purpose of treating, controlling, or preventing infectious diseases, even when an incidental growth response may be obtained. This definition is in line with the definition developed by Codex Alimentarius in CAC/RCP 61-2005.

Noting that it is important to make a distinction between preventive use and use for growth promotion, the Code Commission agreed it would include revision of Chapter 6.8 on its work programme. Comments from Member Countries will be considered in the context of this review.

The Code Commission noted that the OIE planned to organise a second Global conference on antimicrobial resistance and the prudent and responsible use of antimicrobials in the near future.

EU comment

The EU will provide comments on Item 5.7. separately by 12 July 2017.

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

Comments were received from Australia, Japan, New Zealand, Switzerland, Thailand, USA and EU.

The Code Commission noted the support of a Member Country for the proposed changes in this chapter; it also noted in regards to another Member Country comment that the OIE would continue to work closely with the Codex Alimentarius Commission and other relevant international bodies in regards to antimicrobial resistance in order to avoid any contradictions, gaps or duplications.

In examining Member Countries comments on Chapter 6.7. the Code Commission also took into account responses provided by the Scientific Commission and the *ad hoc* Group (mentioned above). In this regard, wherever 'surveillance' or 'monitoring' in relation to programmes is mentioned in the chapter, the text has been revised so it reads 'surveillance and monitoring'.

The Code Commission agreed with Member Countries comments that Article 6.7.3. was too long and amended the layout of the chapter in order to improve readability.

Article 6.7.1. – In response to a Member Country proposal to include reference to 'in their feed' in the objectives, the Code Commission noted that surveillance is in animals and food and at this stage of the chapter there is no value to add feed, as it is only one of many routes of exposure and not a specific objective of the surveillance of antimicrobial resistance in animals. However, in response to a proposal by Member Countries, the Code Commission considered it appropriate to insert a new text 'sampling and testing of feed ingredients or feed' as a component of national antimicrobial resistance monitoring and surveillance programmes in Article 6.7.3., and another new text 'feed samples should preferably be taken at the feed mill and animal' in Article 6.7.5.

Article 6.7.2. – The Code Commission deleted reference to 'targeted' as it was considered unnecessary as 'active surveillance and monitoring' conveyed the same meaning. In response to a Member Country comment that the OIE should be more assertive in encouraging cooperation it amended the last sentence of the chapeau of this article by deleting 'should be encouraged' and inserting 'The OIE encourages' at the beginning of the sentence which now reads 'The OIE encourages cooperation between all Member Countries conducting antimicrobial resistance surveillance.'

Article 6.7.4. Sampling – In response to Member Countries comments on the introductory text to Table 1, the Code Commission agreed with the *ad hoc* Group proposals to address these comments and added two new paragraphs:

'The sample should avoid bias and provide a representative sample whilst taking into account the expected prevalence of the resistance phenotype and the desired level of precision and confidence.'

'The sample size calculation in Table 1 is based on independent samples. If there is any clustering at the *establishment* or animal level, the sample size should be adjusted accordingly.'

The Code Commission agreed with Member Countries suggestion to insert text 'Resource allocation should be guided by production volume and the prevalence of resistant bacteria' as it acknowledged that a population of food producing animals can contribute significantly to production without showing crucial prevalence of resistant bacteria.

Regarding products of animal origin intended for human consumption, the Code Commission agreed with the same Member Countries suggestion and the rationale provided, and inserted 'produced locally or imported' so that both locally and imported products can be considered in surveillance and monitoring programmes. In response to a comment from the same Member Countries on the type of samples to be collected it agreed to include 'representative of the batch' at the beginning of point 5) for clarity. However in the same point it did not agree with a proposal to include 'should be representative of the herd, flock or population to be tested' as it noted that faecal samples are commonly collected at the slaughterhouse/abattoir and to include this point would complicate the sampling process and was adequately covered in the article concerning sampling strategy.

The Code Commission agreed with a Member Country comment to delete a paragraph contained in Article 6.7.4. under the heading 'Type of sample to be collected', as the content of the paragraph has already been captured in Table 2.

Article 6.7.5. – The section 'Bacterial isolates' was changed to 'Bacteria subject to surveillance and monitoring' for clarity and reformatted to assist with readability. In examining Member Countries comments on this section the Code Commission made the following amendments:

- replaced 'guide veterinarians in prescribing treatments' with 'provide data to inform their decisions';

- included a reference to 'good agricultural practice' in the point regarding 'existence of quality assurance programmes'.

The Code Commission agreed with the *ad hoc* Group that it was not appropriate or necessary to include additional pathogens in Table 3. The table is not intended to be an exhaustive list, but to provide a core set of pathogens for surveillance and others can be added by individual countries.

A Member Country commented that zoonanthroponosis, or reverse zoonosis, should be included in Article 6.7.5. The Code Commission and the *ad hoc* Group considered the inclusion unnecessary as zoonanthroponotic bacterial agents, irrespective of the direction of transmission, have already been covered by the current chapter.

In response to two Member Countries comments on bacterial recovery rate in Article 6.7.8., the Code Commission agreed with the *ad hoc* Group to replace the word 'recovery' with 'isolation', and inserted the wording 'bacterial isolation methods' in a following point of the same article.

In response to a Member Country request to clarify point 6) in Article 6.7.8., the Code Commission agreed with the *ad hoc* Group to insert a new text 'The number of isolates regarded as resistant should be reported as a proportion of the number of isolates tested' for clarity.

The Code Commission did not accept a Member Country comment to modify point 7) to include the quantitative aspect of antimicrobial resistance surveillance as it has already been mentioned in other points of Article 6.7.8., particularly point 9).

The revised Draft Chapter 6.7. is attached as **Annex 26** for Member Countries' comments.

EU comment

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

Item 5.8. Draft new article on guiding principles on the use of animal based measures (Article 7.1.X.)

Comments were received from Australia, Canada, New Zealand, Norway, USA, EU, ICFAW and IDF.

The Code Commission agreed with the comment of Member Countries to modify the title of the new Article 7.1.X. to reflect that measures, other than animals-based measures, are also mentioned in the article.

The Code Commission did not accept several Member Countries comments to make reference to resources and management practices in point 1) of the article as they are already addressed in point 5) of the article.

The Code Commission agreed in principle with a Member Country proposal to add 'five freedoms' in the text. However as the 'five freedoms' are described in Article 7.1.2. of the *Code*, it inserted a reference to that article.

The Code Commission agreed with an organisation's proposal to add new text to point 2), relating to the use of a combination of approaches to assess the welfare of animals. However, it considered it more appropriate to insert the new text in point 3) to improve its clarity.

In response to some Member Countries comments to insert new text relating to equivalent animal-based measures, the Code Commission did not agree as it would allow the use of animal-based measures that are not recommended in OIE animal welfare standards in the *Code*.

The Code Commission did not agree with a modification to point 5) proposed by several Member Countries and an organisation as the rationale did not support the modification. In the same point, it did not support the deletion of the entire point as the modified title of Article 7.1.X. now reflects the need for measures other than animal-based measures.

The new Article 7.1.X. Guiding principles for the use of measures to assess animal welfare of the Chapter 7.1. is attached as **Annex 27** for Member Countries' comment.

EU comment

The EU thanks the OIE for its work on this new draft article and for taking EU comments into account. The EU can agree with the proposed changes in the modified draft article. Comments are inserted in the text of Annex 27.

Item 5.9. Report of the *ad hoc* Group and the draft new Chapter on animal welfare and pig production systems (Chapter 7.X.)

Comments from Australia, Canada, Chile, Costa Rica, Guatemala, Japan, New Zealand, Norway, Switzerland, Thailand, USA, EU, AU-IBAR, and ICFAW.

The Code Commission noted that the *ad hoc* Group on Animal Welfare and Pig Production Systems extensively reviewed draft Chapter 7.X., at its second meeting in January 2017. In examining the text the Code Commission made some additional modifications to the draft chapter. The Code Commission invited Member Countries to review the report of the *ad hoc* Group for more extensive responses to Member Countries' comments.

The report of the *ad hoc* Group is attached as **Annex 39** for Member Countries' information.

In the first paragraph of Article 7.X.1. the Code Commission accepted the inclusion of the scientific name of pigs proposed by a Member Country. However, the Code Commission decided to remove the subspecies 'domesticus' and insert the word 'domestic' in Article 7.X.2. to make clear that the chapter refers to domestic pigs but not *captive wild pigs* as defined in the *Code*.

The Code Commission further discussed the rationale for excluding *captive wild pigs* in the Chapter despite their important role in the epidemiology of pig diseases. However, noting that this chapter is intended to give recommendations for the animal welfare of pigs in production systems, it noted that it had insufficient information on the way in which *captive wild pigs* are managed to draft criteria and recommendations.

For more clarity in the text, the word 'however' was removed from the Article 7.X.2. and the word 'domestic' was added to this article.

To improve clarity of point 2) in Article 7.X.4., the Code Commission removed the word 'risk' from the text because 'risk', as defined in the *Code*, has a meaning different from the intent of this chapter.

The Code Commission modified point 5) of the Article 7.X.4. to replace the word 'performance' by 'efficiency' as the latter is more appropriate to describe reproduction issues.

For more clarity the Code Commission transferred the last sentence of point 7) of the Article 7.X.4. to the end of article 7.X.7., prior to the criteria.

The second paragraph of Article 7.X.8. was amended for clarity, and the word 'animals' was replaced by 'pigs'. The word 'increasing' was deleted as it has already been addressed by the word 'abnormal' in the text.

To maintain consistency with other *Code* chapters on animal welfare, in the title of Article 7.X.9., the Code Commission replaced the word 'watering' with 'water provision', and removed the words 'of the animals'.

The Code Commission edited the penultimate paragraph of Article 7.X.9. to provide clarity and consistency by replacing the word 'palatable' with 'drinkable', and removing the wording 'that does not inhibit drinking and'.

In Article 7.X.10. the Code Commission deleted the word 'innate' to maintain consistency with the other chapters, as well as the word 'very' as this adjective is inappropriate in standards.

The Code Commission in Article 7.X.12. (formerly 7.X.6.) in response to a Member Country comment and considering that pigs are social animals that prefer living in groups, deleted the wording 'housing systems where' and replaced it with 'should preferably be housed' in order to maintain consistency with other chapters.

In the fourth paragraph of Article 7.X.13. the Code Commission removed the words 'high level of' as it considered that 'high level' was already addressed by the word 'abnormal'.

The wording 'or pastures' was added in the sixth paragraph of Article 7.X.14. in recognition that an outdoor system may include both paddocks and pastures and the words have different meanings in different countries.

In the second paragraph of Article 7.X.20., the words 'an average', 'at the age' and 'recommended' were deleted for consistency with other chapters.

In order to maintain consistency with other *Code* chapters on animal welfare, the Code Commission replaced the word 'bowel' with 'gut', and the word 'reduced' with the word 'less' before diarrhoea. The word 'preventive' was deleted, and the word 'agents' was added after 'antimicrobial' because 'antimicrobial agent' is a defined term.

For clarity, the Code Commission accepted a proposal to modify the fifth paragraph of Article 7.X.20. replacing 'as well as a proper dietary provisions' by 'and appropriate diet'.

The Code Commission revised point 1) of Article 7.X.24. on Biosecurity and prevention as follows, for clarity and to group the activities more appropriately:

- first point added 'especially from different sources';
- disagreed with a proposal to include 'semen' in the point relating to feed and bedding so included it as a new point 2) in place of 'young animals coming from different sources', which it considered was already covered in point 1);
- included 'vehicles' in the point relating to equipment, tools and facilities;
- included 'air' in the point relating to water and deleted 'supply';
- reordered the point relating to waste, as waste includes manure, garbage and disposal of dead animals.

The revised Draft Chapter 7.X. is attached as **Annex 28** for Member Countries' comments.

EU comment

The EU thanks the OIE for its work on this new draft chapter and for taking many of the EU comments into account. The EU can in general agree with the proposed changes in this modified chapter. Furthermore the EU would also like to reiterate some previous comments, due to their relevance, as indicated in the text of Annex 28.

Item 5.10. Infection with bluetongue virus (Chapter 8.3.)

Comments were received from Australia, Mexico, Singapore, Switzerland, EU and AU-IBAR.

The Code Commission noted that this chapter had been adopted with the intention of further examining the case definition, and that the Member Countries comments on the proposed revisions were mainly editorial rather than technical and one was in support of the proposed revised chapter.

Article 8.3.1. – In examining Member Countries comments the Code Commission agreed in principle with a proposal to amend point 3), and inserted 'a live BTV' to clarify the link with point 2) and point 4). However, it did not support the inclusion of reference to 'virulent revertant or reassortant'. It also inserted new text 'showing clinical signs consistent with bluetongue, or epidemiologically linked to

a suspected or confirmed case', acknowledging the additional circumstances where antigen or RNA may be detected.

Article 8.3.4. – The Code Commission noted Member Countries comments on this article and that there was no principle against a country being seasonally free, so amended the sub-heading to include 'country or' and amended the first paragraph to reflect the inclusion of this principle.

Regarding the recommendations on the presentation of an international veterinary certificate in various articles throughout the chapter, the word 'and' has been inserted after the clause 'showed no clinical sign of bluetongue on the day of shipment [or collection]' to convey the intended recommendations.

Article 8.3.9. – In response to Member Countries comment in support of deleting points c) and d), the Code Commission did not consider it was necessary to add further text to clarify that conditions in Article 8.3.9. apply only during the seasonally free period.

Article 8.3.11. – The Code Commission made changes to this article to make it consistent with proposals already included in Article 8.3.9.

The revised Draft Chapter 8.3. is attached as **Annex 29** for Member Countries' comments.

EU comment

The EU thanks the OIE and in general supports the proposed changes to this chapter. However, one important comment is inserted in the text of Annex 29.

Item 5.11. Infection with foot and mouth disease virus (Chapter 8.8.)

Comments on the report of the February 2016 meeting of the Code Commission were received from Argentina, Australia, Brazil, Chinese Taipei, Japan, Mexico, New Zealand, Switzerland, EU and AU-IBAR.

The Code Commission noted that it had considered this chapter at its February 2016 meeting and since that time the Scientific Commission and an *ad hoc* Group had also reviewed the chapter, including Member Countries comments. It further noted that during its September 2016 meeting it had reviewed the proposals from the Scientific Commission and the *ad hoc* Group, and that it had been apparent at that time that there was still a large amount of work to be done on this chapter, and that it would continue to review this chapter before its February 2017 meeting. At this meeting the Code Commission noted the three outstanding issues that it needed to work on were the case definition, protection zone and the introduction of vaccinated animals. Further editorial amendments would also need to be made to align this chapter with other disease-specific chapters that have been reviewed at this meeting.

Member Countries are requested to consider the reports of the meetings mentioned above in analysing this revised chapter as this report will only explain the rationale for the inclusion of new articles or new text.

Article 8.8.1. point 6) – The Code Commission included a new sentence to clarify that the transmission of FMDV from African buffaloes to domestic livestock is rare.

Article 8.8.2. point e) – The Code Commission included reference to Articles 8.8.9. *bis*, 8.8.11. and 8.8.11. *bis* which address the recommendations for the direct transfer and importation of both vaccinated and unvaccinated animals and addressed the introduction of animals for slaughter by adding a new text 'Any animals introduced for *slaughter* were subjected to ante- and post-mortem inspections in accordance with Chapter 6.2. with favourable results. For ruminants the head, including the pharynx, tongue and associated lymph nodes, is either destroyed or treated in accordance with Article 8.8.31'.

In order to address the concerns of many Member Countries and the proposals of the *ad hoc* Group in regards to an incursion of potentially infected African buffaloes, the Code Commission agreed with the Scientific Commission and the *ad hoc* Group that there was a need to address the consequences of a small group of potentially infected wild African buffaloes entering a country or zone free from FMD and included a new paragraph which reads 'A country or zone free from FMD may maintain its free status despite an incursion of potentially infected African buffaloes provided that the surveillance programme substantiates the absence of transmission of FMDV.'

Article 8.8.3. – The Code Commission agreed with the proposal of the Scientific Commission and the *ad hoc* Group to include new text to address the introduction of vaccination in a country or zone free

from FMD where vaccination was not previously practised, changing status to 'free from FMD where vaccination is practised' and the possibility to define a protection zone where vaccination is practised. It also made the proposed amendments to include 'two years' and '12 months' to improve clarity and to align with proposed changes to the questionnaires in Chapter 1.6.

Article 8.8.4. – Amended the title to read 'Compartment free from FMD where vaccination is not practised' in light of the inclusion of a new Article 8.8.4. *bis* 'Compartment free from FMD where vaccination is practised'.

Article 8.8.4. *bis*. – In response to Member Countries comments, the Code Commission agreed with the proposal of the Scientific Commission and the *ad hoc* Group, that there was a need to include provisions for a compartment where vaccination is practised given that stricter provisions for surveillance and biosecurity would be in place.

Article 8.8.6. – The Code Commission agreed with a proposal by the Scientific Commission to reorder the wording in the first paragraph for clarity, and included the word 'previously' for further clarity. It made the same amendments to the first paragraph of Article 8.8.7. and included additional wording to point 1 c) to address Member Countries comments to provide provisions shortening the recovery period in some specific situations. In response to a proposal from the same Member Countries, the Code Commission agreed with the Scientific Commission and the *ad hoc* Group not to include provisions to allow recovery of freedom with vaccination after three months in the situation where no additional round of vaccination (emergency vaccination) is carried out.

Article 8.8.9. *bis* – The Code Commission agreed to the proposal of the Scientific Commission and the *ad hoc* Group to include a new article to allow inter-zone movements of animals for direct slaughter without the need for testing and made some editorial changes to the text proposed for clarity. The Code Commission did not agree with the proposal to add a new Article 8.8.9. *ter,* as there was no rationale for introducing provisions on importation of unvaccinated animals from a free country or zone for slaughter into a free country or zone.

Article 8.8.10. – The Code Commission reworded the title of this article for clarity and included a new point 4) 'if previously vaccinated, comply with point 4) of Article 8.8.11.'

Article 8.8.11. – The Code Commission considered the proposal from the *ad hoc* Group for alternate text for this article but it considered it more appropriate to split the proposal and added a new Article 8.8.11. *bis* to include recommendations for vaccinated animals destined for slaughter. The Code Commission made several amendments to Article 8.8.11. and included a new point 4) to include provision for testing of vaccinated animals as it did not agree with the *ad hoc* Group proposal to include measures linked to the status of an importing country on a health certificate, this being contrary to the principles of the *Code*.

Article 8.8.12. – The Code Commission considered the proposal from the *ad hoc* Group to include text recommending the prohibition of feeding of swill to exported domestic ruminants and pigs. However, noting that there are provisions in the chapter relating to the inactivation of FMDV in swill (new Article 8.8.31. *bis*) and that it was not appropriate for the *Code* to impose this on Member Countries, it added a new point 2) 'pigs have not been fed with swill not complying with Article 8.8.31. *bis*.' It accepted a proposal to include reference to 'official control programme' and inserted this at the beginning of point 4) (formerly point 3)).

In response to a Member Country comment on testing after semen collection in Articles 8.8.15. and 8.8.16., the Code Commission considered that the question of an upper time limit should be addressed and requested that OIE Headquarters consult with relevant experts in order to address these questions so that it might reconsider this issue at its September 2017 meeting.

In considering the recommendations in Articles 8.8.20. to 8.8.23. (including a new Article 8.8.22. *bis*), the Code Commission noted that there were no recommendations applicable to importation of game meat or small ruminants from infected countries or zones. It requested that OIE Headquarters look at the possibility of developing these recommendations in order to address what it considers to be a significant gap in this chapter.

Article 8.8.22. – The Code Commission agreed with the proposal of the Scientific Commission and the *ad hoc* Group to split point c) into two points. However, it did not agree with a Member Country that the point as written was open to ambiguity and considered that with the proposed change of layout it was clear. In response to the same Member Country comment it agreed to include 'FMD-susceptible' before 'animals' in point d) for clarity.

Article 8.8.22. *bis* – The Code Commission agreed with the proposal of the *ad hoc* Group to include a new article to include 'recommendations for importation from countries or zones infected with FMDV, where an official control programme exists' for fresh meat of domestic pigs. It made several amendments to the proposed article for consistency and clarity.

Article 8.8.26. – The Code Commission agreed with the proposal of a Member Country to include a new point 2) 'the necessary precautions were taken after processing to avoid contact of the products with any potential sources of FMDV.'

Articles 8.8.26. to 8.8.28. – As proposed by the *ad hoc* Group, the Code Commission included 'zones' in the title of these articles for consistency and improved clarity.

Article 8.8.31. *bis* – For consistency with other chapters and to address the proposal of the *ad hoc* Group to include provisions related to swill, the Code Commission added a new article based on the same provisions contained in other disease-specific chapters.

Article 8.8.39. – In response to a Member Country comment, the Code Commission agreed with the proposal to amend the last point under 7) to read 'an increase in the incidence or extension of distribution of FMD that cannot be addressed by the programme', and agreed with the *ad hoc* Group that is not possible to list all of the problems that may have an impact on FMD control.

Article 8.8.40. – In response to a Member Country comment the Code Commission agreed with the Scientific Commission and the *ad hoc* Group that sampling should be representative rather than selective and that there was no strong rationale for including additional text.

Article 8.8.42. – In response to a Member Country comment the Code Commission made several amendments to this article to improve the clarity.

In regards to the diagrams in Figures 1 to 3, the Code Commission requested that the Biological Standards Commission be asked to consider their inclusion in the *Terrestrial Manual*.

The revised Draft Chapter 8.8. is attached as **Annex 30** for Member Countries' comments.

EU comment

The EU thanks the OIE and in general supports the proposed changes to this chapter. Comments are inserted in the text of Annex 30.

Item 5.12. Bovine spongiform encephalopathy (Chapter 11.4.)

The Code Commission recalled that it had reviewed Member Countries comments on the revised chapter circulated for comment in its February 2015 meeting report, and on the chapter adopted in May 2015, at its September 2015 meeting. At that time it had requested OIE Headquarters to convene an *ad hoc* group (different from the one for status recognition) to specifically address these Member Countries comments and recommend appropriate updates to the BSE Chapters in the *Manual* and the *Code*.

The Code Commission reviewed the report of the *ad hoc* Group on Bovine Spongiform Encephalopathy (BSE) which met 23 to 25 August 2016 and noted that there were still some outstanding issues that should be addressed, such as surveillance, risk assessment and specified risk materials. In particular, it noted that this chapter was subject to ongoing discussion within the Scientific Commission in relation with official recognition of disease status, and so it would be premature to commence its own revision at this meeting. However, the chapter will remain on its work programme for discussion in September 2017.

6. New amendments or draft new Chapters proposed for the *Terrestrial Code*

Table 3. Lists of new texts proposed for the *Terrestrial Code*

Item	Annexes in Part B/D	Chapters/Articles	Title
6.1	42	1.6.	Procedures for self-declaration and for official recognition by the OIE (revised questionnaires)
6.2	31	6.Z.	Draft new Chapter on introduction to recommendations for veterinary public health
6.3	32	4.Y.	Draft new Chapter on management of outbreaks of listed diseases
6.5	33	8.4.	Infection with *Brucella abortus*, *B. melitensis* and *B. suis*
6.6	34	8.15.2.	Infection with rinderpest virus
6.7	35	15.2.	Infection with classical swine fever virus
6.9	36	7.1.1.	Introduction to the recommendations for animal welfare

Item 6.1. Procedures for self-declaration and for official recognition by the OIE (Chapter 1.6.)

The questionnaires related to official recognition of disease status have been reviewed and revised by OIE Headquarters and the Scientific Commission. In view of time constraints and the large volume of questionnaires and the number of proposed changes, the Code Commission was unable to undertake a thorough review during its February 2017 meeting, but considered that these questionnaires could nevertheless be proposed for Member Countries' comments.

It also noted that in light of ongoing work to strengthen the procedures for self-declaration and for official recognition, it was essential to propose amendments to Chapter 1.6. and requested OIE Headquarters to undertake the necessary review as soon as possible.

The Code Commission finally noted that the questionnaires would have to be revised on a more regular basis and that in view of the time it would take for their adoption it might be more appropriate for them to be removed from the *Code* and maintained by OIE Headquarters (e.g. accessible on the OIE website), so they could be revised by OIE Headquarters and the Scientific Commission on a more regular basis. Member Countries are invited to provide their views on the possibility of taking the questionnaires out of the *Code* in the frame of a thorough review of the chapter.

EU comment

The EU agrees that it is desirable to update the questionnaires whenever necessary. This should be continued within the well-established OIE standard setting process, with involvement of both the OIE Scientific and Code Commissions and member country experts via comments, and final adoption as international standard by the World Assembly. Indeed, in light of ongoing efforts to strengthen the procedures for official OIE recognition of country disease status, as stipulated in the OIE Sixth Strategic Plan, it would be of fundamental importance to maintain the questionnaires in the OIE Code, in order not to jeopardise the credibility of the entire process and in order to ensure the respect in international trade of the official country status granted by the OIE to its member countries.

Furthermore, in order to improve clarity and readability of the current Chapter 1.6., the EU would support a separation of the questionnaires into individual chapters, which could be included in a separate section of the Code and preceded by an introductory chapter clearly setting out the general principles of the procedures applying for all diseases (both for official OIE disease / risk status and for self-declaration).

The revised questionnaires are included as **Annexes** 42–50 for Member Countries' comments.

EU comment

Considering

- that the revised questionnaires are not provided with modifications marked in the usual way (double underline and strikethrough), which makes reviewing very cumbersome and time consuming;

- that the Code Commission, due to time constraints, has itself not thoroughly reviewed these documents at its February 2017 meeting;

- the large number of annexes and the large volume of the documents submitted for member country comments with the present Code Commission report;

- the limited overall capacity of its experts to review OIE documents;

the EU refrains for the time being from commenting the documents provided as Annexes 42 to 50.

At the same time, we request that these documents be resubmitted for member country comment at a later stage, after a proper review by the Code Commission, and with all changes compared to the current version of Chapter 1.6. shown by double underline and strikethrough.

Item 6.2. Draft new Chapter on introduction to recommendations for veterinary public health (Chapter 6.Z.)

In considering its previous discussions on chapters in Section 6, Veterinary Public Health, the Code Commission identified a need to address the introduction to the recommendations in this section, and drafted an introductory chapter.

The proposed draft new Chapter 6.Z. is attached as **Annex 31** for Member Countries' comments.

EU comment

The EU in general supports this proposed new chapter. Some comments are inserted in the text of Annex 31.

Item 6.3. Draft new Chapter on management of outbreaks of listed diseases (Chapter 4.Y.)

The Code Commission recalled that this proposed new chapter had been on its work programme since February 2016.

The Code Commission drafted a new Chapter 4.Y., based on the guiding document on the OIE website that had been elaborated by the Scientific Commission, and on the guide to Good Emergency Management Practises published by the FAO.

The Code Commission recognised that the draft document was technically sound and noted the current structure which included short succinct articles was a good basis for guidance.

The proposed draft new Chapter 4.Y. is attached as **Annex 32** for Member Countries' comments.

EU comment

The EU will provide comments on Annex 32 separately by 12 July 2017.

Item 6.4. Draft new Chapter on the slaughter and killing of farmed reptiles for their skins and meat (Chapter 7.X.)

The Code Commission congratulated the *ad hoc* Group on its work and noted that this *ad hoc* Group had been conducted electronically. While good progress has been made on the chapter, it considered there is a need for further work before the draft new chapter is ready to be submitted to Member Countries for comment.

In view of time constraints, the Code Commission did not examine the chapter in detail but requested OIE Headquarters to review it and provide a revised version for its meeting in September 2017. In revising the chapter, the following points need to be addressed:

1) The structure of the draft new chapter should align with the latest animal welfare chapters of the *Code*, for example, Chapter 7.5. The draft new chapter should be arranged in the following order: general considerations, outcome-based measurables or criteria, and recommendations with more detailed points.

2) Content in the draft new chapter such as definition of terms, reference to the *Code* glossary terms, and duplicated points should be reviewed for consistency.

3) Where advantages are contrasted with disadvantages in several articles listing stunning or killing methods, they should rather be addressed as recommendations, showing linkages to general considerations and outcome-based measures, and to how animal welfare risks are mitigated.

4) The Code Commission recommended not using tables and encouraged the *ad hoc* Group to present the same content in the format of recommendations.

Item 6.5. Infection with *Brucella abortus*, *B. melitensis* and *B. suis* (Chapter 8.4.)

Comments were received from Korea.

In response to a question seeking clarification as to the scientific rationale for the exclusion of castrated males from the testing in Article 8.4.10., the Code Commission noted that the amendment had been made to correct an inconsistency in the testing regime and to better align it with point 3 b) of Article 8.4.13. The Code Commission agreed with the Scientific Commission that 'castrated males' do not play any real role in the epidemiology of brucellosis. They further confirmed that 'castrated males' should be excluded from the testing regime in Chapter 8.4. It can also be inferred from the report of the December 2013 meeting of the *ad hoc* Group on *Brucella* in that 'castrated males', by definition, do not belong to the category of sexually mature animals.

The Code Commission made also a minor editorial amendment to the article.

The revised Article 8.4.10. is attached as **Annex 33** for Member Countries' comments.

EU comment

The EU in general supports the proposed changes to this article. A comment is inserted in the text of Annex 33.

Item 6.6. Infection with rinderpest virus (Article 8.15.2.)

Comments were received from the UK and the FAO-OIE Rinderpest Joint Advisory Committee (JAC).

Two proposals to review the definition of rinderpest virus containing material were referred by OIE Headquarters to the Scientific Commission.

In considering the proposals, the Code Commission agreed with the Scientific Commission that sera that has been subjected to an appropriate heat treatment or that has shown to be free from rinderpest virus genome sequences should be excluded from the definition. It also agreed that that full length genomic material should be considered as a potential risk and thus be included in the definition.

In respect of the proposal to delete 'clinical' from 'clinical material' the Code Commission replaced it with 'pathological material' which is already defined in the Glossary and is considered more

appropriate in this context. Additional editorial amendments were made to correct grammar, improve syntax and for consistency with the standard *Code* format.

The revised Article 8.15.2. is attached as **Annex 34** for Member Countries' comments.

EU comment

The EU in general supports the proposed changes to article 8.15.2. Comments are inserted in the text of Annex 34.

Item 6.7. Infection with classical swine fever virus (Chapter 15.2.)

The Code Commission noted that Chapter 15.2. had been last adopted after revision in May 2013, when the procedure for official recognition was expanded to include CSF. It also noted that an *ad hoc* Group had met in July 2016, to address the scientific comments received since the last adoption, and to update the chapter based on the recommendations made by a previous CSF *ad hoc* Group, and also on the African swine fever (ASF) and FMD *ad hoc* Groups for further harmonisation. However, in noting this progress the Code Commission did not consider the current structure of many of the proposals of the *ad hoc* Group were in line with other *Code* chapters and made a large number of structural changes to the proposals in relation to the chapter including, where appropriate, amending subheadings of articles for consistency with other chapters.

The Code Commission also made a number of changes to align the chapter with other disease-specific chapters that it had worked on during this meeting.

In response to a general comment from a Member Country to include additional provisions for importation of skins and trophies other than from domestic and captive wild pigs, the Code Commission noted that point 2) of Article 15.2.21 would apply.

Article 15.2.1. – In examining Member Countries comments and the *ad hoc* Group proposals on this article, the Code Commission considered that the logical flow was for the description (moved from the end of the article) of the chapter to come before the case definition and rearranged the wording in the case definition for consistency and readability. It included the words 'the occurrence of' for clarity in the chapeau to the third paragraph and included the amended proposal from the *ad hoc* Group.

Article 15.2.2. – Considering this article relates to criteria, the Code Commission amended the text for clarity and consistency.

Article 15.2.3. – The Code Commission discussed a Member Country comment made during the adoption of the revised chapter at the 81st General Session in May 2013 regarding historical freedom. The Code Commission noted that historical freedom is mentioned in Chapter 1.4. and so applies by default. In 2013, the Code Commission and the Scientific Commission agreed that historical freedom would not need to be mentioned specifically in every disease-specific chapter. This approach will be harmonised in the relevant chapters (AHS and PPR) in the future. The Code Commission also amended the title of the article for clarity and reworded the second last paragraph to improve readability.

Article 15.2.4. – The Code Commission also amended the title of the article for clarity, reworded the paragraph to improve readability and deleted reference to 'management system' after the word 'biosecurity' for consistency as the definition of biosecurity includes management.

Article 15.2.5. – The Code Commission also amended the title of the article for clarity and included a reference in the penultimate paragraph to Article 15.2.3.

Article 15.2.6. – In considering the *ad hoc* Group proposal on this article, the Code Commission did not agree with the inclusion of a reference to Article 15.2.4. as this article relates to recovery of status for a previously free country or zone, whereas Article 15.2.4. relates to a compartment free from CSF.

Article 15.2.6. *bis* – The Code Commission agreed with the proposal of the *ad hoc* Group to include a new article on direct transfer of pigs within a country from an infected zone to a free zone for slaughter. In considering the proposal the Code Commission made several amendments for consistency with other

chapters and to clarify the requirement for ante- and post-mortem inspection in accordance with Chapter 6.2.

Article 15.2.6. *ter* – The Code Commission agreed with the proposal of the *ad hoc* Group to include a new article on the direct transfer of pigs within a country from a containment zone to a free zone for slaughter. In considering the proposal the Code Commission made several amendments for consistency with other chapters and to clarify the requirement for ante- and post-mortem inspection in accordance with Chapter 6.2.

Article 15.2.7. and Article 15.2.8. were amended for clarity and consistency with other chapters.

Article 15.2.9. – In considering the provision in point 2) regarding the period of quarantine, the Code Commission noted that for clarity the word 'isolation' should replace 'kept' to make it clearer that the pigs should be isolated in a quarantine station, and amended the period from 40 to 28 days, and included 'on a sample collected' to clarify that the serological test should be performed on a sample collected at least 21 days after entry to the quarantine station, in accordance with the recommendation of the *ad hoc* Group.

Article 15.2.10. – Minor editorial amendments for clarity and consistency with other chapter including reference to 'donor males' rather than 'donor animals' and reference to 'in accordance' rather than 'in conformity'.

Article 15.2.11. – The Code Commission agreed with the proposal of the *ad hoc* Group to include a provision for an establishment with the addition of a surveillance requirement of at least 12 months point a) and a new point c i) since transmission of CSFV via semen is scientifically proven. It also made editorial amendments for clarity and consistency with other chapter including reference to 'donor males' rather than 'donor animals' and reference to 'in accordance' rather than 'in conformity'.

Article 15.2.12. – The Code Commission agreed with the proposal of the *ad hoc* Group to amend the article to align the requirements for donor females in accordance with the amended draft chapter on ASF.

Article 15.2.13. – The Code Commission agreed with the proposal of the *ad hoc* Group to amend the article to align it with Article 15.2.11. and made additional amendments for clarity and consistency, including removing the reference to 'since birth' as donor females need to be at least three months of age anyway.

Article 15.2.14. – The Code Commission made minor amendments to the article in accordance with the proposal of the *ad hoc* Group.

Article 15.2.14. *bis* – The Code Commission considered the rationale of the *ad hoc* Group, that the concept of CSF free compartments allowed trade of fresh meat from infected countries, while compartmentalisation would not be applicable for the importation of fresh meat from wild and feral pig from infected countries. Whilst it agreed in principle to include a new article with provisions for fresh meat from domestic pigs it did not consider the article was consistent with other chapters which had articles on safe commodities. It made several amendments to the chapter to strengthen the controls which should be in place such as transport directly to an approved slaughterhouse/abattoir without coming into contact during transport or slaughter with other pigs which do not fulfil the required conditions for export.

Article 15.2.15. – The Code Commission noted that the inclusion of the new Article 15.2.4. *bis,* as proposed by the *ad hoc* Group addressed the concerns raised by a Member Country in relation to this article and the absence of an article on fresh meat from infected countries.

Article 15.2.16. – The title of the article was amended to 'Recommendations for the importation of meat products of pigs' as it was in agreement with the *ad hoc* Group, that the intended use of the meat products was irrelevant since the objective is to mitigate the risk posed by the products regardless of their intended use.

Article 15.2.17. – The Code Commission considered that this article relating to importation of other pig products did not logically sit before the articles on bristles, litter and manure and skins and trophies,

there was also some question as to what 'other' products it referred to so it was moved and became Article 15.2.21. *bis*.

Article 15.2.18. – This article was considered to be a duplication of Article 15.2.17. so it was deleted.

Articles 15.2.19. to 15.2.21. – The Code Commission made minor editorial amendments to ensure consistency with other *Code* chapters.

Article 15.2.23. – In considering the inclusion of the different styles of hams in this article, the Code Commission noted that they would be covered by dry cured pig meat and such specificity was unnecessary and so deleted points 3 a) and b).

Article 15.2.24. – In response to Member Countries comments on the procedure for the inactivation of CSFV in casings, the Code Commission noted that the *ad hoc* Group had studied an EFSA opinion that the effectiveness of phosphate supplemented dry salt was superior to dry salt alone for a number of viruses. The *ad hoc* Group also noted that Wijnker *et al.* (2008) had demonstrated that it is possible eliminate CSFV from porcine sausage casings by treating them with phosphate supplemented salt and storing them for 30 days at temperatures over 4 °C. Wieringa-Jelsma *et al.* (2011) demonstrated that a combined treatment using phosphate supplemented salt and storage at 20 °C or higher for a period of 30 days is effective to inactivate CSFV. The Code Commission agreed with the *ad hoc* Group not to include dry salt as the only inactivation method.

Article 15.2.25. *bis* – The Code Commission noted that the Scientific Commission had reviewed scientific literature compiled by OIE Headquarters and concluded that boiling was currently the only method with enough scientific justification that would inactivate CSFV in bristles. The *ad hoc* Group also agreed that boiling bristles in water for at least 30 minutes would inactivate CSFV. The *ad hoc* Group could not find scientific evidence supporting other inactivation treatments such as the use of 0.5% formalin as suggested by some Member Countries.

Article 15.2.25. *ter* – The Code Commission noted that the *ad hoc* Group provided the following references to support the proposal to include the procedures for the inactivation of CSFV in litter and manure from pigs and accepted its inclusion.

- *Anette Bøtner and Graham J. Belsham. - Virus survival in slurry: Analysis of the stability of foot-and-mouth disease, classical swine fever, bovine viral diarrhoea and swine influenza viruses Volume 157, Issues 1–2, 25 May 2012, Pages 41–49.*

- *Eefke Weesendorp, Arjan Stegeman and Willie L.A. Loeffen. - Survival of classical swine fever virus at various temperatures in faeces and urine derived from experimentally infected pigs. Volume 132, Issues 3–4, 10 December 2008, Pages 249–259.*

- *Factors affecting the infectivity of tissues from pigs with classical swine fever: Thermal inactivation rates and oral infectious dose Lucie Cowan a,c, Felicity J. Haines a, Helen E. Everett a, Bentley Crudgington a, Helen L. Johns a, Derek Clifford b, Trevor W. Drew a, Helen R. Crooke a.*

Article 15.2.27. – The Code Commission agreed with the *ad hoc* Group proposals to include a new point c) appropriate laboratory testing capability for CSF diagnosis, and a new paragraph that gives further guidance on the need to review surveillance strategies. However, they did not support a Member Country proposal to delete the second paragraph of point 2 a) as it was important as part of a contingency plan for personnel involved in surveillance to be able to call on outside expertise if required. In regards to this point the Code Commission also reworded the sentence for clarity.

Article 15.2.28. – In considering the *ad hoc* Group proposals the Code Commission agreed to amendments it had proposed to this article and noted some of the Member Country comments on this article related to Spanish translation and these would be referred to OIE Headquarters. In point 4) the Code Commission included reference to 'in a herd' in the second paragraph, merged paragraphs three and four and did not support the proposal of a Member Country to delete 'and the requirements for statistical validity' in this article as it agreed with the *ad hoc* Group that survey design should not be compromised when using sera collected for other purposes.

Article 15.2.31. – In responding to a Member Country comment on this article the Code Commission and *ad hoc* Group did not agree with replacing 'surveillance' with 'monitoring' as the term surveillance is more appropriate as monitoring can imply that no further action is taken. In examining the Member Countries comments, and considering opinions of the *ad hoc* Group and the Scientific Commission in relation to Article 15.2.32., which includes complex diagrams, the Code Commission requested that OIE Headquarters ask the Biological Standards Commission to consider how these might be included in the *Terrestrial Manual* in the future.

The revised draft Chapter 15.2. is attached at **Annex 35** for Member Countries' comments.

EU comment

The EU thanks the OIE and in general supports the proposed changes to this chapter. Comments are inserted in the text of Annex 35.

Item 6.8. Report of the *ad hoc* Group on Animal Welfare and Laying Hens Production Systems

The Code Commission congratulated the *ad hoc* Group on its work. However, it considered that further work is still needed to better align the text with other animal welfare chapters and for consistency before the chapter can be circulated for Member Countries' comments. In this regard, the Code Commission noted that the format (i.e. alphabetical order) used in the newly developed chapter, specifically in articles that describe the 'Criteria or measurables for welfare of pullets or hens' and recommendations could create confusion for some members.

The Code Commission requested that OIE Headquarter revise this chapter with input from the members of the Code Commission in order to present a revised hapter for the next meeting in September 2017.

Item 6.9. Proposed amendment of OIE definition of 'animal welfare' by the Animal Welfare Working Group

The OIE Animal Welfare Working Group (AWWG), at an informal meeting during the 4th Global OIE Conference on Animal Welfare held in Guadalajara Mexico the 6–8 December 2016, discussed the need to update the current definition of 'animal welfare' in the *Code*.

The Code Commission agreed in principle with the rationale provided by the AWWG that there was a need to update the current definition to take into account updated terminology that is widely accepted in animal welfare science.

In examining the proposal of the AWWG the Code Commission considered that 'General Considerations' was more appropriate sub-heading than 'Introduction'. It also noted that it would be more clear and succint if only the first paragraph of the modified text was used as the definition for animal welfare in the Glossary of the *Code*. In order to improve readibility it also separated the article into three paragraphs. The Code Commission agreed to delete the words 'coping with' as the phrase 'coping with the conditions in which it lives' implies that it might only be applicable to animals dealing with negative situations. However, it is widely accepted that animal welfare considerations are not limited solely to coping with negative situations. In response to the proposal to include 'refers to animal's quality of life' the Code Commission noted that this subjective wording might have different interpretations for some Member Countries and could not be included in an OIE standard. In order to address these issues, the definition was amended to read 'Animal welfare means the state of well-being of an animal in relation to the condition in which it lives.'

The Code Commission modified the new second paragraph in agreement with the proposal of the AWWG to delete the term 'innate' in relation to behaviour, as the latest scientific information has invalidated the implications that behavious could either be innate or acquired and rearranged the wording to add clarity.

The revised Article 7.1.1. of the Chapter 7.1. is attached as **Annex 36** for Member Countries' comment.

EU comment

The EU thanks the OIE for its work on the definition of animal welfare and Article 7.1.1. The EU welcomes the proposed changes in the definition and general

considerations, as referring to "state of well-being" instead of "coping" does not limit the term "welfare" solely to coping with negative situations. The EU can agree with the proposed changes in the modified article. Comments are inserted in the text of Annex 36.

Item 7. Other issues

Item 7.1. Report of an *ad hoc* Group on Veterinary Paraprofessionals

OIE Headquarters provided an overview of the OIE's work on veterinary paraprofessionals (VPPs) in response to the OIE Sixth Strategic Plan and a recommendation of the 4th OIE Global Conference on Veterinary Education. The Code Commission was informed that pursuant to the plan to develop recommendations for core competencies and guidelines of curricular requirements, the first *ad hoc* Group meeting held in November 2016 developed a working draft of competencies. It covered three themes identified as important for VPPs working in the veterinary services, animal health field work, and veterinary public health field work and laboratory diagnosis.

The *ad hoc* Group, taking into account the wide variation among existing training programmes, considered that the recommendations for competencies should be structured as three levels: basic, intermediate and advanced. The *ad hoc* Group will work to develop further substance to the working draft of competencies so that the draft recommendations for core competencies can be presented to the Code Commission at its September 2017 meeting. The work on developing guidelines for curricula requirements will follow.

OIE Headquarters also noted that, as with the 'OIE Recommendations on the Competencies of graduating veterinarians ('Day 1 graduates') to assure National Veterinary Services of quality' (OIE Day 1 Competencies) and 'OIE Guidelines on Veterinary Education Core Curriculum,' the documents to be developed for VPPs would not be part of the OIE standards but rather guidance for Member Countries. Nonetheless, any suggestions and advice from the Member Countries and the Code Commission would be highly appreciated for this ongoing work.

The Code Commission acknowledged the importance of this new initiative of the OIE and noted that there is no plan to change the current definition of 'veterinary paraprofessional.' Reflecting the discussion at the time of the development of the Day 1 Competencies, some members of the Code Commission commented that recommendations of competencies with different levels might be difficult for some Member Countries to apply.

The report of the *ad hoc* Group is attached as **Annex 40** for Member Countries' information.

Item 7.2. General comments of Member Countries on the texts circulated after the Code Commission's September 2016 meeting

Comments were received from Switzerland and EU.

The Code Commission considered general comments and reflected them in its work programme and in the relevant agenda items.

Item 7.3. Update of the Code Commission's work programme

The Code Commission made the following observations with regards to its work programme and simplified its format:

- The date of first adoption and last revision of each chapter will appear in the 2017 *Terrestrial Code*;
- OIE Headquarters will review the User's Guide for consistency with the User's Guide to the *Aquatic Code*;

- Noted there had been no progress on the revision of Chapter 1.4. 'Animal health surveillance', to which Member countries have already sent comments, notably on Article 1.4.6. and the need of an article on early warning system, and requested OIE Headquarters to provide an update for its September 2017 meeting;

- Noted that increasingly *ad hoc* groups were proposing changes to chapters that often were not on the Code Commission's work programme and requested that, to enable better management of its agenda, OIE Headquarters (i) consider the priority modifications to chapters already identified in the Code Commission's work programme; (ii) review *ad hoc* group reports and provide timely advice to the Code Commission so that these could be adequately included in its work programme;

- Noted that several items still required additional follow-up by OIE Headquarters (notably Chapters 7.5. and 7.6. for which a need for thorough review was identified).

The updated work programme is attached as **Annex 37** for Member Countries' information and comments.

EU comment

The EU thanks the OIE and supports the future work programme of the Code Commission. Specific comments are inserted in the text of Annex 37.

Item 7.4. Editorial corrections for the 2017 Edition of the *Terrestrial Code* including proposed replacement of similar terms currently used in the *Code* with 'pathogenic agent'

During its September 2016 meeting and in reviewing the Glossary, 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. At the request of the Code Commission, and under its guidance, the OIE Headquarters has undertaken a review of the use of these terms throughout the *Code* (see **Item 4.1**.).

During this review, a number of other editorial inconsistencies were identified:

– slaughterhouse to be replaced by slaughterhouse/abattoir;

– herd/flock to be replaced by herd or flock;

– ova to be replaced by oocytes;

– embryos/oocytes the forward slash will be replaced by either 'and' or 'or'

– the order of the terms 'embryos' and 'oocytes' will reversed to show oocytes before embryos.

The updated *Code* will be circulated as Annex XX during April 2017. Corrections have been made, using track changes, and are provided to Member Countries for information. As the changes proposed are indeed purely editorial Member Countries' comments are not sought on these proposed changes.

Item 7.5. Date of next meetings

The Code Commission agreed that the dates for its next meetings would be 18–29 September 2017 and, tentatively, 19 February to 2 March 2018.

Annexe/…

Annex 4

GLOSSARY (PART A—AMENDMENTS)

EU position

The EU thanks the OIE and supports the adoption of this modified glossary (parts A, A' and A'').

ANIMAL HEALTH STATUS

means the status of a country, ~~or a~~ *zone* or *compartment* with respect to an *animal disease* in accordance with the criteria listed in the relevant disease-specific chapter or Chapter 1.4. of the *Terrestrial Code* ~~dealing with the *disease*~~.

CAPTIVE WILD [ANIMAL]

means an *animal* that has a phenotype not significantly affected by human selection but that is captive or otherwise lives under direct human supervision or control, including zoo *animals* and pets.

FERAL [ANIMAL]

means an *animal* of a domesticated species that now lives without direct human supervision or control.

INFECTION

means the entry and development or multiplication of ~~an~~ ~~infectious~~ pathogenic agent in the body of humans or *animals*.

INFESTATION

means the external invasion or colonisation of *animals* or their immediate surroundings by arthropods, which may cause ~~*disease*~~ clinical signs or are potential *vectors* of ~~infectious~~ pathogenic agents.

NOTIFICATION

means the procedure by which:

a) the *Veterinary Authority* informs the *Headquarters*,

b) the *Headquarters* inform the *Veterinary Authority*,

of the occurrence ~~of an outbreak~~ of *disease*, ~~or~~ *infection* or *infestation* in accordance with Chapter 1.1.

~~***PATHOGENIC AGENT***~~

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

WILD [ANIMAL]

means an *animal* that has a phenotype unaffected by human selection and lives independent of direct human supervision or control.

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— Text deleted.

Annex 4 (contd)

GLOSSARY (PART A—DELETIONS)

~~***POST-JOURNEY PERIOD***~~

~~means the period between *unloading* and either recovery from the effects of the *journey* or *slaughter* (if this occurs before recovery).~~

~~***QUALITY***~~

~~is defined by International Standard ISO 8402 as 'the totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs'.~~

~~***TRANSPORT/TRANSPORTATION***~~

~~means the procedures associated with the carrying of *animals* for commercial purposes from one location to another by any means~~.

~~***TRANSPORTER***~~

~~means the person licensed by the *Competent Authority* to transport *animals*~~.

~~***TRAVEL***~~

~~means the movement of a *vehicle/vessel* or *container* carrying *animals* from one location to another.~~

~~***ZOONOSIS***~~

~~means any *disease* or *infection* which is naturally transmissible from *animals* to humans.~~

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— Text deleted.

Annex 4 (contd)

GLOSSARY (PART A—EDITORIAL)

ANIMAL HANDLER

means a person with a knowledge of the behaviour and needs of *animals* who, with appropriate experience and a professional and positive response to an *animal*'s needs, can achieve effective management and good *welfare*. Competence should be gained through formal training ~~and/~~or practical experience.

ANIMAL IDENTIFICATION SYSTEM

means the inclusion and linking of components such as identification of *establishments* or ~~/~~owners, the person~~(s)~~ responsible for the *animal*~~(s)~~, movements and other records with *animal identification*.

ANIMAL WELFARE

means how an *animal* is coping with the conditions in which it lives. An *animal* is in a good state of *welfare* if (as indicated by scientific evidence) it is healthy, comfortable, well nourished, safe, able to express innate behaviour, and if it is not suffering from unpleasant states such as pain, fear and distress. Good *animal welfare* requires *disease* prevention and veterinary treatment, appropriate shelter, management, nutrition, humane handling and humane *slaughter* and ~~/~~*killing*. *Animal welfare* refers to the state of the *animal*; the treatment that an *animal* receives is covered by other terms such as animal care, animal husbandry, and humane treatment.

FLOCK

means a number of *animals* of one kind kept together under human control or a congregation of gregarious *wild animals*. ~~For the purposes of the *Terrestrial Code*, a~~ A *flock* is usually regarded as an *epidemiological unit*.

HERD

means a number of *animals* of one kind kept together under human control or a congregation of gregarious *wild animals*. ~~For the purposes of the *Terrestrial Code*, a~~ A *herd* is usually regarded as an *epidemiological unit*.

INCUBATION PERIOD

means the longest period ~~which~~ that elapses between the introduction of the pathogen into the *animal* and the occurrence of the first clinical signs of the *disease*.

INTERNATIONAL VETERINARY CERTIFICATE

means a certificate, issued in accordance with Chapter 5.2., describing the animal health and~~/or~~ public health requirements ~~which~~ that are fulfilled by the exported *commodities*.

KILLING

means any procedure ~~which~~ that causes the *death* of an *animal*.

OFFICIAL VETERINARIAN

means a *veterinarian* authorised by the *Veterinary Authority* of the country to perform certain designated official tasks associated with animal health ~~and/~~or public health and inspections of *commodities* and, when appropriate, to certify in accordance with Chapters 5.1. and 5.2.

Annex 4 (contd)

QUARANTINE STATION

means an *establishment* under the control of the *Veterinary Authority* where *animals* are maintained in isolation with no direct or indirect contact with other *animals*, to ensure that there is no transmission of specified pathogen~~(s)~~ outside the *establishment* while the *animals* are undergoing observation for a specified length of time and, if appropriate, testing ~~and~~ or treatment.

RESPONSIBLE DOG OWNERSHIP

means the situation whereby a person ~~(as defined above)~~ accepts and commits to perform various duties in accordance with the legislation in place and focused on the satisfaction of the behavioural, environmental and physical needs of a dog and to the prevention of risks (aggression, *disease* transmission or injuries) that the dog may pose to the community, other *animals* or the environment.

SAFE COMMODITY

means a *commodity* ~~which~~ that can be traded without the need for risk mitigation measures specifically directed against a particular listed *disease*, *infection* or *infestation* and regardless of the status of the country or *zone* of origin for that *disease*, *infection* or *infestation*.

SLAUGHTER

means any procedure ~~which~~ that causes the *death* of an *animal* by bleeding.

STUNNING

means any mechanical, electrical, chemical or other procedure ~~which~~ that causes immediate loss of consciousness; when used before *slaughter*, the loss of consciousness lasts until *death* from the *slaughter* process; in the absence of *slaughter*, the procedure would allow the *animal* to recover consciousness.

— Text deleted.

Annex 5

CHAPTER 1.2.

CRITERIA FOR THE INCLUSION OF DISEASES, INFECTIONS AND INFESTATIONS IN THE OIE LIST

EU position

The EU supports the adoption of this modified article.

Article 1.2.1.

Introduction

This chapter describes the criteria for the inclusion of *diseases*, *infections* and *infestations* in Chapter 1.3.

The objective ~~of listing *diseases*~~ is to support Member Countries by providing information needed to take appropriate action to prevent the transboundary spread of important animal *diseases*, including *zoonoses.* This is achieved by transparent, timely and consistent *notification*.

Each *listed disease* normally has a corresponding chapter that ~~to~~ assists Member Countries in the harmonisation of *disease* detection, prevention and control, and provides standards for safe *international trade* in *animals* and their products.

The requirements for *notification* are detailed in Chapter 1.1.

Principles and methods of validation of diagnostic tests are described in Chapter 1.1.5. of the *Terrestrial Manual*.

[...]

— Text deleted.

Annex 6

CHAPTER 1.3.

DISEASES, INFECTIONS AND INFESTATIONS LISTED BY THE OIE

EU position

The EU supports the adoption of this modified chapter.

Preamble

The ~~following~~ *diseases*, *infections* and *infestations* in this chapter ~~are~~ have been assessed in accordance with Chapter 1.2. and constitute ~~included in~~ the OIE list of terrestrial animal diseases.

In case of modifications of this list adopted by the World Assembly of Delegates, the new list comes into force on 1 January of the following year.

[…]

— Text deleted.

Annex 7

CHAPTER 2.X.

CRITERIA APPLIED BY THE OIE FOR ASSESSING THE SAFETY OF COMMODITIES

EU position

The EU thanks the OIE and supports the adoption of this new chapter.

Article 2.X.1.

~~**Assessing the safety of animal products from a country or zone not free from a specific listed disease**~~

General provisions

For the purposes of this chapter the word 'safety' is applied only to animal and human health considerations for *listed diseases*.

In many *disease*-specific chapters, ~~Article X.X.2.~~the second article lists ~~*animal* products~~ *commodities* that can be traded from a country or *zone* regardless of its status with respect to ~~not free from~~ the specific *listed disease*. The criteria for their inclusion ~~of *animal* products~~ in the list of *safe commodities* are based on the absence of the pathogenic agent in the traded ~~*animal* products~~ *commodity*, either due to its absence in the tissues from which the ~~*animal* products~~ *commodity* ~~are~~ is derived or to its inactivation by the processing or treatment that the *animal* products have undergone.

The assessment of the safety of the ~~*animal* products~~ *commodities* using the criteria relating to processing or treatment can only be undertaken when processing or treatments are well defined. It may not be necessary to take into account the entire process or treatment, so long as the steps critical for the inactivation of the ~~pathogen~~ pathogenic agent of concern are considered.

It is ~~assumed~~ expected that processing or treatment (i) uses standardised protocols, which include the steps considered critical in the inactivation of the pathogenic agent of concern; (ii) is conducted in accordance with Good Manufacturing Practices; and (iii) that any other steps in the treatment, processing and subsequent handling of the *animal* product do not jeopardise its safety.

Article 2.X.2.

Criteria

For an *animal* product to be considered a *safe commodity* for *international trade*, it should comply with the following criteria:

1) There is strong evidence that the pathogenic agent is not present in the tissues from which the *animal* product is derived ~~at a~~ in an amount ~~concentration~~ able to cause *infection* in a human or *animal* by a natural exposure route. This evidence is based on the known distribution of the pathogenic agent in an infected *animal*, whether or not it shows clinical signs of *disease*.

OR

2) If the pathogenic agent may be present in, or may contaminate, the tissues from which the *animal* product is derived, the standard processing or treatment ~~normally~~ applied to produce the ~~*animal* product~~ *commodity* to be traded, while not being specifically directed at this ~~pathogen~~ pathogenic agent, inactivates ~~the pathogen~~ it to the extent that possible *infection* of a human or *animal* is prevented through its action, which is:

a) physical (e.g. temperature, drying, irradiation);

or

b) chemical (e.g. iodine, pH, salt, smoke);

or

c) biological (e.g. fermentation);

or

d) a combination of *a)* to *c)* above.

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— Text deleted.

Annex 8

CHAPTER 4.16.

HIGH HEALTH STATUS HORSE SUBPOPULATION

EU position

The EU supports the adoption of this modified article.

[…]

Article 4.16.3.

Recommendations for the Veterinary Authorities

Organisations that are responsible for ensuring compliance with this chapter should be authorised and supervised by the *Veterinary Authorities*. *Veterinary Authorities* are ~~also~~ encouraged to develop specific protocols for the temporary importation of horses of high health status entering the country for the purpose of competition at equestrian events or for their onward movement to other such events and for their return to their country of usual residence.

Veterinary Authorities are encouraged to recognise the international biosecurity plan developed by the FEI and IFHA on the basis of the OIE *Handbook for the Management of High Health, High Performance Horses.* ~~the relevant OIE biosecurity guidelines (under study).~~

- Text deleted.

Annex 9

CHAPTER 5.3.

OIE PROCEDURES RELEVANT TO THE AGREEMENT ON THE APPLICATION OF SANITARY AND PHYTOSANITARY MEASURES OF THE WORLD TRADE ORGANIZATION

EU position

The EU thanks the OIE and supports the adoption of this modified chapter.

Article 5.3.1.

The Agreement on the Application of Sanitary and Phytosanitary Measures and role and responsibility of the OIE

The *Agreement on the Application of Sanitary and Phytosanitary Measures* (SPS Agreement) specifically encourages the Members of the World Trade Organization to base their *sanitary measures* on international standards, guidelines and recommendations, where they exist. Members may choose to implement *sanitary measures* more stringent ~~adopt a higher level of protection~~ than ~~that provided by~~ those in international standards, ~~texts~~ if these are deemed necessary to protect animal or human health and are scientifically justified by a *risk analysis* ~~there is a scientific justification or if the level of protection provided by the relevant international texts is considered to be inappropriate~~. In such circumstances, Members ~~are subject to obligations relating to *risk assessment* and to~~ should adopt a consistent approach ~~of~~ to *risk management*.

~~The SPS Agreement encourages Governments to make a wider use of risk analysis: WTO Members shall undertake an assessment as appropriate to the circumstances of the actual risk involved.~~

To promote transparency, ~~The~~ the SPS Agreement, in Article 7, obliges WTO Members to notify changes in, and provide relevant information on, *sanitary measures* ~~which~~ that may, directly or indirectly, affect international trade.

The SPS Agreement recognises the OIE as the relevant international organisation responsible for the development and promotion of international animal health standards, guidelines, and recommendations affecting trade in live *animals* and animal products.

Article 5.3.2.

Introduction ~~on~~ to the ~~judgement~~ determination of the equivalence of sanitary measures

The importation of *animals* and animal products involves a degree of *risk* to ~~the~~ *animal ~~health status~~* and human health ~~status of~~ in an *importing country*. The estimation of that *risk* and the choice of the appropriate *risk management* option~~(s)~~ are made ~~more~~ difficult by differences among the animal health management systems and animal production and processing systems in Member Countries. However, ~~It is now recognised that~~ significantly different ~~animal health and production~~ systems and measures ~~can provide~~ may achieve equivalent animal and human health protection for the purposes of *international trade*~~, with benefits to both the importing country and the exporting country~~.

~~These~~ The recommendations in this chapter are intended to assist Member Countries to determine whether *sanitary measures* arising from different ~~animal health and production~~ systems ~~may provide~~ achieve the same level of animal and human health protection. They discuss principles ~~which might~~ that may be utilised in a ~~judgement~~ determination of equivalence, and outline a step-wise process for trading partners to follow ~~in facilitating a judgement of equivalence~~. These provisions are applicable whether equivalence applies ~~at the level of~~ to specific measures or on a systems-wide basis, and whether equivalence applies to specific areas of trade or *commodities*, or in ~~generally~~ general.

Annex 9 (contd)

Article 5.3.3.

General considerations on the ~~judgement~~ determination of the equivalence of sanitary measures

Before trade in *animals* or their products ~~may~~ occurs, an *importing country* ~~must~~ should be ~~satisfied~~ assured that ~~its~~ *animal ~~health status~~* and human health in its territory will be appropriately protected. In most cases, the *risk management* measures adopted ~~drawn up~~ will rely in part on judgements made about the *animal health management* and animal production system~~(s)~~ in the *exporting country* and the effectiveness of *sanitary measures* ~~procedures~~ applied ~~undertaken~~ there. Systems operating in the *exporting country* may differ from those in the *importing country* and from those in other countries with which the *importing country* has traded. Differences may be ~~with respect to~~ in infrastructure, policies ~~and/~~or operating procedures, *laboratory* systems, approaches to control of ~~the pests and~~ *diseases*, *infections* and *infestations* present, border security and internal movement controls.

~~International recognition of the legitimacy of different approaches to achieving the importing country's appropriate level of protection (ALOP) has led to the principle of equivalence being included in trade agreements, including the SPS Agreement of the WTO.~~

If trading partners agree that the measures applied achieve the same level of health protection, these measures are considered equivalent. Benefits of applying equivalence may include:

1) minimising costs associated with international trade by ~~tailoring~~ allowing *sanitary measures* to be tailored ~~animal health measures~~ to local circumstances;

2) maximising animal health outcomes for a given level of resource input;

3) facilitating trade by achieving the required health protection through less trade restrictive *sanitary measures*; and

4) decreased reliance on relatively costly commodity testing and isolation procedures ~~in bilateral or multilateral agreements~~.

The *Terrestrial Code* recognises equivalence by recommending alternative *sanitary measures* for many *diseases*, *infections* and *infestations* ~~pathogenic agents~~. Equivalence may be ~~gained~~ achieved, for example, by enhanced *surveillance* and monitoring, by the use of alternative test, treatment or isolation procedures, or by combinations of the above. To facilitate the ~~judgement~~ determination of equivalence, Member Countries should base their *sanitary measures* on the OIE standards~~,~~ and guidelines ~~and recommendations of the OIE~~.

~~It is essential to apply a scientific~~ Member Countries should use *risk analysis* to ~~the extent practicable in~~ establish~~ing~~ the basis for a ~~judgement~~ determination of equivalence.

Article 5.3.4.

Prerequisite considerations ~~in a judgement~~ for the determination of equivalence

1) Application of risk assessment

~~Application of the discipline of *risk*~~ *Risk assessment* provides a structured basis for judging equivalence among different *sanitary measures* as it allows a comparison ~~close examination to be made~~ of the effect of a measure~~(s)~~ on a particular step~~(s)~~ in the importation pathway~~, and the relative~~ with the effect~~s~~ of a proposed alternative measure~~(s) on the same or related steps~~.

A ~~judgement~~ determination of equivalence should ~~needs to assess~~ compare the effectiveness of the *sanitary measures* ~~in terms of its effectiveness~~ against ~~regarding~~ the particular *risk* or group of *risks* against which ~~it the measure is~~ they are designed to protect. ~~Such an assessment may include the following elements: the purpose of the measure, the level of protection achieved by the measure and the contribution the measure makes to achieving the ALOP of the importing country.~~

2) Categorisation of sanitary measures

Proposals for equivalence may ~~be in terms of a measure comprising~~ consider a single component ~~of a measure~~ (e.g. an isolation or sampling procedure, a test or treatment requirement, a certification procedure) or multiple components (e.g. a production system for a *commodity*) of a measure, or a combination of measures. ~~Multiple components or combinations of measures~~ Measures may be applied consecutively or concurrently.

Sanitary measures are ~~those~~ described in ~~each~~ the *disease*-specific chapter of the *Terrestrial Code* ~~which are used for~~ to manage *risks* ~~reduction and are appropriate for particular~~ posed by that *diseases~~,~~* *infection* or *infestation*. ~~*Sanitary measures* may be applied either alone or in combination and include test requirements, processing requirements, inspection or certification procedures, quarantine confinements, and sampling procedures.~~

For the purposes of ~~judging~~ determining equivalence, *sanitary measures* can be broadly categorised as:

a) infrastructure~~:~~ including the legislative base (e.g. animal health law) and administrative systems (e.g. organisation of *Veterinary Services* ~~national and regional animal health authorities, emergency response organisations~~);

b) programme design and~~/~~implementation~~:~~ including documentation of systems, performance and decision criteria, *laboratory* capability, and provisions for certification, audit and enforcement;

c) specific technical requirement~~:~~ including requirements applicable to the use of secure facilities, treatment (e.g. retorting of cans), specific test (e.g. ELISA) and procedures (e.g. pre-export inspection).

~~A *sanitary* *Sanitary* *measure(s)*~~ proposed for a ~~judgement~~ determination of equivalence may fall into one or more of these categories, which are not mutually exclusive.

In some cases, such as a method for pathogen inactivation, a comparison of specific technical requirements may suffice. In many instances, however, ~~a judgement as to~~ assessment of whether the same level of protection ~~is likely to~~ will be achieved may only be ~~able to be~~ determined through an evaluation of all relevant components of an *exporting country*'s *animal health management* systems and animal production systems. ~~For example, a judgement of equivalence for a specific sanitary measure at the programme design/implementation level may require a prior examination of infrastructure while a judgement of equivalence for a specific measure at the specific technical requirement level may require that the specific measure be judged in its context through examination of infrastructure and programmes.~~

Article 5.3.5.

Principles for ~~judgement~~ determination of equivalence

~~In conjunction with the above considerations,~~ ~~judgement~~ Determination of the equivalence of *sanitary measures* should be based on application of the following principles:

1) an *importing country* has the right to set the level of protection it deems appropriate ~~(its ALOP)~~ in relation to human and animal life and health in its territory; this ~~ALOP~~ may be expressed in qualitative or quantitative terms;

2) the *importing country* should be able to describe the reason for each *sanitary measure* i.e. the level of protection intended to be achieved by application of the identified measure against a ~~*hazard*~~ *risk*;

3) an *importing country* should recognise that *sanitary measures* different from the ones it has proposed may be capable of ~~providing~~ achieving the same level of protection, in particular, it should consider the existence of *free zones* or *compartments*, and of *safe commodities*;

4) the *importing country* should, upon request, ~~enter into consultations~~ consult with the *exporting country* with the aim of facilitating a ~~judgement~~ determination of equivalence;

5) any *sanitary measure* or combination of *sanitary measures* can be proposed for ~~judgement~~ determination of equivalence;

6) an interactive process should be followed that applies a defined sequence of steps, and utilises an agreed process for exchange of information, so as to limit data collection to that which is necessary, to minimise administrative burden, and to facilitate resolution of claims;

7) the *exporting country* should be able to demonstrate objectively how the alternative *sanitary measure~~(s)~~* proposed as equivalent will provide the same level of protection;

8) the *exporting country* should present a submission for equivalence in a form that facilitates ~~judgement~~ determination by the *importing country*;

Annex 9 (contd)

9) the *importing country* should evaluate submissions for equivalence in a timely, consistent, transparent and objective manner, and in accordance with appropriate *risk assessment* principles;

10) the *importing country* should take into account any knowledge of and prior experience with the *Veterinary Authority* or other *Competent Authority* of the *exporting country*;

10bis) the *importing country* should take into account any arrangements it has with other *exporting countries* on similar issues;

10ter) the *importing country* may also take into account any knowledge of the *exporting country's* arrangements with other *importing countries*;

11) the *exporting country* should provide access to enable the procedures or systems ~~which~~ that are the subject of the equivalence ~~judgement~~ determination to be examined and evaluated upon request of the *importing country*;

12) the *importing country* should be the sole ~~determinant~~ judge of equivalence, but should provide to the *exporting country* a full explanation for its judgement;

13) to facilitate a ~~judgement~~ determination of equivalence, Member Countries should base their *sanitary measures* on relevant OIE standards and guidelines, where these exist. However, they may choose to implement more stringent *sanitary measures* if these are scientifically justified by a *risk analysis*;

14) to allow the ~~judgement~~ determination of equivalence to be reassessed if necessary, the *importing country* and the *exporting country* should keep each other informed of significant changes to infrastructure, health status or programmes ~~which~~ that may bear on the ~~judgement~~ determination of equivalence; and

15) appropriate technical assistance from an *importing country*, following a ~~should give positive consideration to a~~ request by an *exporting* ~~developing~~ *country*, ~~for appropriate technical assistance that would~~ may facilitate the successful completion of a ~~judgement~~ determination of equivalence.

Article 5.3.6.

Sequence of steps to be taken in ~~judgement~~ determination of equivalence

There is no single sequence of steps ~~which~~ that ~~must~~ should be followed in all ~~judgements~~ determinations of equivalence. The steps that trading partners choose will generally depend on the circumstances and their trading experience. Nevertheless, ~~The~~ the interactive sequence of steps described below may be useful for assessing any ~~all~~ *sanitary measures* irrespective of their categorisation as infrastructure, programme design~~/~~ and implementation or specific technical requirement components of an *animal health management* system or ~~and~~ animal production system.

This sequence assumes that the *importing country* is meeting its obligations under the WTO SPS Agreement and has in place a transparent measure based either on an international standard or a *risk analysis*.

Recommended steps are:

1) the *exporting country* identifies the measure~~(s)~~ for which it wishes to propose an alternative ~~measure(s),~~ and requests from the *importing country* a reason for its *sanitary measure* in terms of the level of protection intended to be achieved against a ~~*hazard*(s)~~ *risk*;

2) the *importing country* explains the reason for the measure~~(s),~~ in terms that ~~which~~ would facilitate comparison with an alternative *sanitary measure*~~(s)~~ and consistent with the principles set out in these provisions;

3) the *exporting country* demonstrates the case for equivalence of an alternative *sanitary measure*~~(s)~~ in a form ~~which~~ that facilitates evaluation ~~analysis~~ by an *importing country*;

4) the *exporting country* responds to any technical concerns raised by the *importing country* by providing relevant further information;

5) ~~judgement~~ determination of equivalence by the *importing country* should take~~s~~ into account as appropriate:

   a) the impact of biological variability and uncertainty;

   b) the expected effect of the alternative *sanitary measure*~~(s) on all relevant hazards~~;

   c) OIE standards and guidelines;

   d) ~~application of solely *qualitative* frameworks where it is not possible or reasonable to conduct *quantitative*~~ the results of a *risk assessment*;

6) the *importing country* notifies the *exporting country* of its judgement and its ~~the underlying~~ reasons within a reasonable period of time. The judgement:

   a) ~~recognition~~ recognises ~~of~~ the equivalence of the *exporting country's* alternative *sanitary measure*~~(s)~~; or

   b) request~~s~~ ~~for~~ further information; or

   c) ~~rejection~~ rejects ~~of~~ the case for equivalence of the alternative *sanitary measure*~~(s)~~;

7) an attempt should be made to resolve any differences of opinion over judgement of a case~~, either interim or final,~~ by using an agreed mechanism such as ~~to reach consensus (e.g.~~ the OIE informal procedure for dispute mediation~~), or by referral to an agreed expert~~ (Article 5.3.8.);

8) depending on the category of measures involved, the *importing country* and the *exporting country* may informally acknowledge the equivalence or enter into a formal ~~or informal~~ agreement of equivalence ~~agreement~~ giving effect to the judgement ~~or a less formal acknowledgement of the equivalence of a specific measure(s) may suffice~~.

An *importing country* recognising the equivalence of an *exporting country's* alternative *sanitary measure*~~(s) needs to~~ should ensure that it acts consistently with regard to applications from third countries for recognition of equivalence applying to the same or a very similar measure~~(s)~~. Consistent action does not mean however that a specific measure~~(s)~~ proposed by several *exporting countries* should always be judged as equivalent because ~~as~~ a measure~~(s)~~ should not be considered in isolation but as part of a system of infrastructure, policies and procedures, in the context of the animal health situation in the *exporting country*.

Article 5.3.7.

Sequence of steps to be taken in establishing a zone~~/~~ or ~~compartment and having it recognised for international trade purposes

The terms '*zone*' and 'zoning' in the *Terrestrial Code* have the same meaning as 'region', 'area' and 'regionalisation' in the SPS Agreement of the WTO.

The establishment ~~There is no single sequence of steps which should be followed in establishing~~ of a disease-free *zone* or a *compartment* is described in Chapter 4.3 and should be considered by trading partners when establishing *sanitary measures* for trade. ~~The steps that the Veterinary Services of the importing country and the exporting country choose and implement will generally depend on the circumstances existing within the countries and at their borders, and their trading history. The recommended~~ Recommended steps are:

1. For zoning

   a) The *exporting country* identifies a geographical area within its territory, which, based on *surveillance*, it considers to contain an animal *subpopulation* with a distinct health status with respect to a specific *disease*~~/specific diseases~~, *infection* or *infestation*~~, based on surveillance~~.

   b) The *exporting country* describes in the *biosecurity plan* for the *zone* the measures ~~which are being, or will be,~~ applied to distinguish such an area epidemiologically from other parts of its territory, in accordance with the recommendations in the *Terrestrial Code*.

Annex 9 (contd)

c) The *exporting country* provides:

i) the above information to the *importing country*, with an explanation of why the area can be treated as an epidemiologically separate *zone* for *international trade* purposes;

ii) access to enable the procedures or systems that establish the *zone* to be examined and evaluated upon request by the *importing country*.

d) The *importing country* determines whether it accepts such an area as a *zone* for the importation of *animals* ~~and~~ or animal products, taking into account:

i) an evaluation of the *exporting country's Veterinary Services*;

ii) the result of a *risk assessment* based on the information provided by the *exporting country* and its own research;

iii) its own animal health situation with respect to the *disease*~~(s)~~ concerned; and

iv) other relevant OIE standards or guidelines.

e) The *importing country* notifies the *exporting country* of its ~~determination~~ judgement and ~~the underlying~~ its reasons, within a reasonable period of time, being:

i) recognition of the *zone*; or

ii) request for further information; or

iii) rejection of the area as a *zone* for *international trade* purposes.

f) An attempt should be made to resolve any differences over recognition of the *zone*~~, either in the interim or finally,~~ by using an agreed mechanism ~~to reach consensus~~ such as the OIE informal procedure for dispute mediation (Article 5.3.8.).

g) The *Veterinary Authorities* of the *importing* and *exporting countries* should enter into an ~~formal~~ agreement recognising the *zone*.

2. For compartmentalisation

a) Based on discussions with the relevant industry, the *exporting country* identifies within its territory a *compartment* comprising an animal *subpopulation* contained in one or more *establishments*, ~~or~~ and other premises operating under common management practices and ~~related to~~ *biosecurity plan*. The *compartment* contains an identifiable animal *subpopulation* with a distinct health status with respect to a specific *disease*~~(s)~~. The *exporting country* describes how this status is maintained through a partnership between the relevant industry and the *Veterinary Authority* of the *exporting country*.

b) The *exporting country* examines the *compartment's biosecurity plan* and confirms through an audit that:

i) the *compartment* is epidemiologically closed throughout its routine operating procedures as a result of effective implementation of its *biosecurity plan*; and

ii) the *surveillance* and monitoring programme in place is appropriate to verify the status of such a *subpopulation* with respect to ~~such~~ the disease~~(s)~~ in question.

c) The *exporting country* describes the *compartment*, in accordance with ~~the recommendations in the *Terrestrial Code*~~ Chapters 4.3. and 4.4.

d) The *exporting country* provides:

i) the above information to the *importing country*~~,~~ with an explanation of why such a *subpopulation* can be treated as an epidemiologically separate *compartment* for *international trade* purposes; and

ii) access to enable the procedures or systems that establish the *compartment* to be examined and evaluated upon request by the *importing country*.

e) The *importing country* determines whether it accepts such a *subpopulation* as a *compartment* for the importation of *animals* or ~~and~~ animal products, taking into account:

i) an evaluation of the *exporting country's Veterinary Services*;

ii) the result of a *risk assessment* based on the information provided by the *exporting country* and its own research;

iii) its own animal health situation with respect to the disease~~(s)~~ concerned; and

iv) other relevant OIE standards or guidelines.

f) The *importing country* notifies the *exporting country* of its ~~determination~~ judgement and ~~the underlying~~ its reasons, within a reasonable period of time, being:

i) recognition of the *compartment*; or

ii) request for further information; or

iii) rejection of such a *subpopulation* as a *compartment* for *international trade* purposes.

g) An attempt should be made to resolve any differences over recognition of the *compartment*~~, either in the interim or finally,~~ by using an agreed mechanism ~~to reach consensus~~ such as the OIE informal procedure for dispute mediation (Article 5.3.8.).

h) The *Veterinary Authorities* of the *importing* and *exporting countries* should enter into an ~~formal~~ agreement recognising the *compartment.*

~~*i) The Veterinary Authority of the exporting country should promptly inform importing countries of any occurrence of a disease in respect of which the compartment was defined.*~~

Article 5.3.8.

The OIE informal procedure for dispute mediation

OIE ~~shall~~ maintains ~~its existing~~ a voluntary in-house mechanism~~s~~ for assisting Member Countries to resolve differences. In-house procedures that ~~which~~ will apply are that:

1) Both parties agree to give the OIE a mandate to assist them in resolving their differences.

2) If considered appropriate, the Director General of the OIE recommends an expert, or experts, and a chairman, as requested, agreed by both parties.

3) Both parties agree on the terms of reference and working programme, and to meet all expenses incurred by the OIE.

Annex 9 (contd)

4) The expert or experts are entitled to seek clarification of any of the information and data provided by either country in the assessment or consultation processes, or to request additional information or data from either country.

5) The expert or experts ~~shall~~ submit a confidential report to the Director General of the OIE, who ~~will~~ then transmits it to both parties.

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Annex 10

DRAFT CHAPTER 6.X.

PREVENTION AND CONTROL OF *SALMONELLA* IN COMMERCIAL ~~CATTLE~~ BOVINE PRODUCTION SYSTEMS

EU position

The EU thanks the OIE and supports the adoption of this new chapter.

Article 6.X.1.

Introduction

Nontyphoidal salmonellosis is one of the most common foodborne ~~food-borne~~ bacterial diseases in the world with *Salmonella* Enteritidis and *S.* Typhimurium (including monophasic variants) being the predominant serotypes identified in humans in most countries. *S.* Enteritidis is primarily associated with *poultry* while *S.* Typhimurium may be present in many mammalian and avian hosts. ~~In addition, a~~ These serotypes and several others occur at variable prevalence in ~~cattle~~ bovines depending on the region. In some countries *S.* Dublin and *S.* Newport may also cause salmonellosis in humans. ~~limited number of other serotypes associated with cattle may cause salmonellosis in humans, for example, *S.* Dublin and *S.* Newport.~~

~~As is the case in most food producing *animals*, *Salmonella infection*~~ in ~~cattle~~ bovines is mostly subclinical, although clinical *disease* such as enteritis, septicaemia or abortion ~~can~~ may occur. Subclinical *infection*, ~~can be of variable duration~~ including a carrier state, can be of variable duration and can play an important role in the spread of *Salmonella* within and between *herds* and pose a public health *risk*.

Herd size and stocking density may influence the ~~*risk*~~ likelihood of introduction, dissemination or persistence of *Salmonella*; however, this is also dependent on geographical region, husbandry and other factors such as season and age.

Salmonella serotypes and their *prevalence* in ~~cattle~~ bovines may vary considerably within and between farms, countries and regions. It is important for *Veterinary Authorities* and producers to consider serotypes of *Salmonella*, their occurrence and the *disease* burden in ~~cattle~~ bovine and human populations ~~if~~ when they develop~~ing~~ and implement~~ing~~ strategies for the prevention and control of *Salmonella* in commercial ~~cattle~~ bovine production systems.

Article 6.X.2.

Definitions

For the purposes of this chapter:

Commercial ~~cattle~~ bovine production systems: means those systems ~~where~~ in which the purpose of the operation includes some or all of the following: breeding, rearing and management of ~~cattle~~ bovines for the production of *meat* ~~and *meat products*~~ or *milk* ~~and *milk products*~~.

Intensive ~~cattle~~ bovine production systems: means commercial systems ~~where~~ in which ~~cattle~~ bovines are in confinement and are fully dependent on humans to provide for basic animal needs such as food, shelter and water on a daily basis.

Extensive ~~cattle~~ bovine production systems: means commercial systems ~~where~~ in which ~~cattle~~ bovines have the freedom to roam outdoors, and where the ~~cattle~~ bovines have some autonomy over diet selection (through grazing), water consumption and access to shelter.

Feed: means any material (single or multiple), whether processed, semi-processed or raw, which is intended to be fed directly to terrestrial *animals* (except bees).

Feed ingredient: means a component part or constituent of any combination or mixture making up a feed, whether or not it has a nutritional value in the *animal*'s diet, including feed additives. Ingredients are of plant (including aquatic plants) or terrestrial or aquatic animal origin, or other organic or inorganic substances.

Annex 10 (contd)

~~**Semi-intensive cattle production systems:** means commercial systems in which cattle are exposed to any combination of both intensive and extensive husbandry methods, either simultaneously or variably according to changes in climatic conditions or physiological state of the cattle.~~

Article 6.X.3.

Purpose and scope

~~The purpose of this~~ This chapter ~~is to~~ provides recommendations for the prevention and control of *Salmonella* in commercial ~~cattle~~ bovine production systems in order to reduce the burden of *disease* in ~~cattle~~ bovines and the *risk* of human illness through foodborne ~~food-borne~~ contamination as well as human *infections* resulting from direct or indirect contact with infected ~~cattle~~ bovines ~~(e.g. via faeces or abortion material)~~.

For the purposes of this chapter a bovine means *Bos taurus, B. indicus, B. javanicus* and *B. grunniens*, water buffaloes (*Bubalus bubalis*) and bison (*Bison bison* and *B. bonasus*).

This chapter applies to bovines ~~cattle (*Bos taurus, B. indicus, B. javanicus* and *B. grunniens*), water buffaloes (*Bubalus bubalis*) and wood bison (*Bison bison* and *B. bonasus*)~~ kept in commercial ~~cattle~~ bovine production systems.

This chapter should be read in conjunction with the Codex Alimentarius Code of Hygienic Practice for Meat (CAC/RCP 58-2005), ~~and the Codex Alimentarius~~ Code of Hygienic Practice for Milk and Milk Products (CAC/RCP 57-2004), Code of Practice ~~of~~ on Good Animal Feeding (CAC/RCP 54-2004), and the Guidelines for the Control of Nontyphoidal *Salmonella* spp. in Beef and Pork Meat (CAC/GL 87-2016), and the OIE/FAO Guide to Good Farming Practices for Animal Production Food Safety.

Article 6.X.4.

Objectives of prevention and control measures

~~It is recommended that~~ Prevention ~~prevention~~ and control measures ~~be~~ may focus ~~focused~~ on those serotypes of *Salmonella* of greatest consequence to ~~cattle~~ bovines ~~or~~ and public health. These measures will also contribute to the reduction of other serotypes.

~~Reduction of *Salmonella* in cattle in primary production may reduce the level of the pathogen:~~

~~1) entering the *slaughterhouse/abattoir* and therefore decrease the *risk* of beef contamination during *slaughter* and dressing procedures;~~

~~2) in *milk* and *milk products*;~~

~~3) in the farm environment, thereby reducing the risk of dissemination of *Salmonella* and contact *infections* in humans.~~

Prevention and control measures in commercial ~~cattle~~ bovine production systems may:

1) reduce the prevalence and amount of *Salmonella* entering the *slaughterhouse/abattoir* and therefore decrease the challenge to the *slaughter* and dressing procedures and the likelihood of bovine *meat* contamination;

2) reduce the likelihood of *Salmonella* contamination in *milk;*

3) reduce *Salmonella* contamination of the environment via ~~cattle~~ bovine faecal waste, which in turn will limit *infection* of animals (including *wildlife*);

4) reduce the likelihood of *infections* in humans through contact with infected ~~cattle~~ bovines or contaminated materials or water.

While control in the primary production phase can decrease the number of animals carrying or shedding *Salmonella*, controls after primary production are also important to minimise the contamination and cross-contamination of carcasses and *meat products*.

~~When appropriate, good~~ Good farming practices and, when appropriate, the principles of hazard analysis and critical control points (HACCP) should be taken into account when designing prevention and control measures.

Articles 6.X.5. to 6.X.~~14~~16. provide recommendations for the prevention and control of *Salmonella* in commercial ~~cattle~~ bovine production systems. These recommendations may also ~~have beneficial effects on the occurrence of~~ contribute to the prevention and control of some other *infections* ~~and *diseases*~~.

Article 6.X.5.

Biosecurity

Biosecurity is ~~intended~~ essential to ~~assist with the prevention~~ prevent and control ~~of~~ *Salmonella*. A *biosecurity plan* should be developed according to the commercial ~~cattle~~ bovine production system employed. The applicability of the measures, described below, will vary according to the type of commercial ~~cattle~~ bovine production system.

When including *Salmonella* as part of a *biosecurity plan* the following should be addressed:

1) location, design and management of the *establishment*;

2) veterinary supervision of ~~cattle~~ bovine health;

3) management of the introduction and mixing of ~~cattle~~ bovines;

4) training of personnel in their responsibilities and their role in animal health, human health and food safety;

4bis) prevention of contamination of feed and water, including for irrigation;

5) maintenance of records including data on ~~cattle~~ bovine health, production, movements, feeding, water supply, medications, *vaccination*, ~~and~~ mortality, and cleaning and *disinfection* of farm buildings and equipment;

6) availability of test results to the farm operator when *Salmonella surveillance* is conducted;

7) removal of unwanted vegetation and debris that could attract or harbour pests around ~~cattle~~ premises for bovines;

8) minimising the entry of domestic animals and *wild* birds into ~~cattle~~ buildings for bovines and feed stores;

9) cleaning and *disinfection* procedures for buildings in which ~~cattle~~ bovines are handled or housed, in accordance with Chapter 4.13.;

10) control of pests such as rodents and arthropods and regular assessment of effectiveness;

11) control and hygienic procedures for entry and movement of persons and *vehicles*;

12) cleaning and *disinfection* of equipment and *vehicles* identified as posing a *risk*;

13) storage and disposal of dead animals, bedding, faeces and other potentially contaminated farm waste in a manner that minimises the likelihood of dissemination of *Salmonella* and prevents the direct or indirect exposure of humans, livestock and *wildlife* to *Salmonella*. Particular care should be taken when ~~cattle~~ bedding and faeces of bovines are applied to land used for horticultural crops intended for human consumption;

14) procedures for prevention of dissemination of *Salmonella* when an animal is suspected or known to be infected.

Annex 10 (contd)

Article 6.X.~~5~~6.

Location and design of establishments for bovines ~~cattle establishment~~

When making decisions on the location and design of ~~cattle~~ *establishments* for bovines, it is recommended that ~~mitigation~~ reduction of the ~~*risk*~~ likelihood of transfer of ~~pathogens~~ pathogenic agents, including *Salmonella*, from major sources of contamination be considered. Sources of *Salmonella* may include other livestock *establishments* or areas of application or disposal of contaminated waste or effluent. ~~Transfer~~ Other sources and *vectors* of *Salmonella* ~~between *establishments* may involve carriage by~~ include *vehicles*, equipment, water-courses, ~~persons~~ personnel, domestic animals, ~~*wild*~~ birds, rodents, flies and ~~other~~ *wildlife*.

~~It is recommended that the~~ The design of intensive ~~cattle~~ bovine production systems should consider the following:

1) management of faecal waste to minimise contamination of the *establishment*;

2~~1~~) adequate drainage for the site and control of run-off water and untreated waste water;

3~~2~~) use of materials for construction that facilitate effective cleaning and *disinfection*;

4~~3~~) control of ~~the points of~~ entry and movement of *vehicles*, equipment and persons;

5) preventing contamination of feed and water during storage and distribution;

6~~4~~) ~~cattle~~ handling and movements of bovines to minimise stress and spread of *Salmonella* ~~*infection*~~;

7~~5~~) separation of ~~cattle~~ bovines according to likelihood of ~~different~~ *infection* with, or susceptibility to, *Salmonella* ~~*risk* status~~;

8~~6~~) restriction of entry of domestic animals, ~~*wild*~~ birds, rodents, flies and other relevant *wildlife*.

In extensive ~~cattle~~ bovine production systems, location and design options may be limited; however, applicable *biosecurity* ~~measures~~ should be considered.

~~Article 6.X.6.~~

~~**Biosecurity management plan**~~

~~Biosecurity measures that include management and physical factors designed to reduce the *risk* of introduction, establishment and spread of animal *diseases*, *infections* or *infestations* to, from and within an animal population would also be expected to assist with the prevention and control of *Salmonella*.~~

~~When developing a biosecurity management plan it is recommended that the following be taken into consideration:~~

~~1) Veterinary supervision of cattle health.~~

~~2) Management of introduction and mixing of cattle.~~

~~3) Training of personnel in their responsibilities and their role in animal health, human health and food safety.~~

~~4) Maintenance of records including data on cattle health, production, movements, medications, *vaccination*, and mortality, and cleaning and *disinfection* of farm buildings and equipment.~~

~~5) Availability of test results to the farm operator when *Salmonella surveillance* is conducted.~~

~~6) Removal of unwanted vegetation and debris that could attract or harbour pests around cattle premises .~~

~~7) Minimising the entry of wild birds into cattle buildings and feed stores.~~

~~8) Cleaning and *disinfection* procedures for buildings in which cattle are handled or housed. For example, the cleaning and *disinfection* procedures for intensive calf housing, calving areas and sick pens after emptying may include feeders, drinkers, floor, walls, aisles, partitions between pens, and ventilation ducting.~~

~~When disinfectants are used they should be applied at an effective concentration after a complementary cleaning procedure.~~

~~9) Control of pests such as rodents and arthropods when required and regular assessment of effectiveness.~~

~~10) Control of persons and *vehicles* entering the *establishment*.~~

~~11) Cleaning and *disinfection* of *vehicles* and equipment identified as a *risk*.~~

~~12) Storage and disposal of cattle carcasses, bedding, faeces and other potentially contaminated farm waste in a safe manner to minimise the risk of dissemination of *Salmonella* and to prevent the direct or indirect exposure of humans, livestock and *wildlife* to *Salmonella*. Particular care to be taken when cattle bedding and faeces are used as fertiliser for horticultural crops intended for human consumption.~~

Article 6.X.7.

Management of ~~cattle~~ introductions of bovines into the establishment

To minimise the ~~*risk*~~ likelihood of introducing *Salmonella* through ~~cattle~~ introductions of bovines ~~, it is recommended that~~:

1) ~~There be~~ good communication within the ~~cattle~~ bovine industry should be encouraged to raise awareness of the ~~*risk*~~ likelihood of introducing *Salmonella* through cattle introductions~~.~~;

2) ~~The number of separate sources of cattle for breeding or rearing be kept to as few as possible. For example in a closed dairy *herd* it is possible to introduce new genetic material solely by semen or embryos.~~ consideration should be given to minimising the number of sources of replacement ~~cattle~~ bovines;

3) ~~the introduction of~~ new genetic material should be introduced through the use of semen and embryos ~~be considered~~ whenever practicable;

4~~3~~) if possible, ~~cattle~~ bovines should be sourced directly from *herds* of origin because live animal markets or other places where ~~cattle~~ bovines from multiple properties are mixed for resale may increase the ~~*risk*~~ likelihood of spread of *Salmonella* and other ~~*infections*~~ infectious agents among ~~cattle~~ bovines~~.~~;

5~~4~~) newly introduced ~~cattle~~ bovines should be kept separate from the rest of the *herd* for a suitable period before mixing with other ~~cattle~~ bovines~~, e.g. four weeks~~.;

~~5) Where appropriate, for example with cattle of unknown status, pooled faecal samples from introduced cattle could be taken to assess their *Salmonella* status.~~

6) ~~where~~ when appropriate, testing of animals for *Salmonella* prior to introduction or mixing with other ~~cattle~~ bovines should be considered to inform subsequent control measures, for example, when introducing ~~cattle~~ bovines of unknown status.

Article 6.X.8.

~~On farm cattle~~ ~~M~~management of bovines on farm

To ~~minimise~~ reduce the ~~*risk*~~ likelihood of transferring *Salmonella* among ~~cattle~~ bovines~~, it is recommended that~~:

1) ~~cattle~~ bovines with suspected salmonellosis or otherwise sick should be separated from healthy ~~cattle~~ bovines;

Annex 10 (contd)

2) care of healthy ~~cattle~~ bovines should be carried out prior to care of ~~cattle~~ bovines with suspected salmonellosis~~.~~;

3) priority should be given to the hygienic management of calving areas, for example keeping perinatal ~~cattle~~ bovines separated from sick ~~cattle~~ bovines and maintaining a clean environment~~.~~;

4) ~~cattle~~ bovines should be segregated according to age;

5~~4~~) when possible, the 'all-in-all-out' principle for production cohorts should be used. In particular, the unnecessary mixing of different age groups ~~during rearing~~, especially of calves, should be avoided~~.~~;

6~~5~~) consideration should be given to the potential for between-herd transmission of *Salmonella* via breeding, rearing and grazing of ~~cattle~~ bovines from multiple sources on a single site, for example shared pasture, ~~and~~ heifer rearing~~.~~ or sharing of bulls;

7~~6~~) consideration should be given to the potential for between-herd transmission of *Salmonella* through direct contact between ~~cattle~~ bovines across boundary lines or indirectly, for example through contamination of water courses.

Article 6.X.9.

~~Feed and water~~ Feed and feed ingredients

~~1.~~ ~~Compound feed~~ ~~Feed and feed ingredients~~

~~Compound feed~~ Feed and feed ingredients can be sources of *Salmonella infection* for ~~cattle~~ bovines. For the effective control of *Salmonella* ~~it is recommended that~~:

1~~a~~) ~~Where~~ when appropriate, ~~compound~~ feed and feed ingredients should be produced, handled, stored, transported and distributed according to Good Manufacturing Practices, considering Hazard Analysis Critical Control Points (HACCP) principles and recommendations in accordance with Chapter 6.3.

2~~b~~) ~~Compound where practical,~~ ~~feed~~ Feed and feed ingredients should be transported, ~~and~~ stored and fed in a ~~hygienic~~ manner that minimises contamination by ~~manure~~ faecal waste and, where practicable, minimises access by domestic animals, ~~wild~~ birds, rodents and ~~other~~ *wildlife*.

~~2.~~ ~~Water~~

~~Where there is reason to be concerned about *infection* of cattle with *Salmonella* from contaminated water, measures be taken to evaluate and minimise the *risk*. For example sediment in water troughs may act as a reservoir for contamination.~~

Article 6.X.10.

Water

~~Drinking water~~ Water for drinking should be of an appropriate quality. When there is reason to be concerned about *infection* of ~~cattle~~ bovines with *Salmonella* from contaminated water, measures should be taken to evaluate and minimise the *risk*. For example sediment in water troughs may act as a reservoir for contamination. Where practicable, untreated surface water should be avoided as a water source.

Article 6.X.~~10~~11.

~~Prevention, treatment and control~~ Additional prevention and control measures

1) The immune status of calves is important and therefore care should be taken to ensure that newborn calves consume adequate amounts of high quality colostrum in accordance with Article 7.9.5. (point 3*c*)) and Article 7.X.5. Raw milk from infected cows should not be fed to calves.

~~1)~~ ~~*Antimicrobial agents* may modify normal flora in the gut and increase the likelihood of colonisation by *Salmonella*. If *antimicrobial agents* are used, they should be used in accordance with Chapter 6.9. *Antimicrobial agents* should not be used to control subclinical *infection* with *Salmonella* in cattle because the effectiveness of the treatment is limited, they may increase the risk of *Salmonella* colonisation, and their use can contribute to the development of antimicrobial resistance.~~

2) *Vaccination* may be ~~used~~ considered as part of a *Salmonella* control programme. Vaccine production and use should be in accordance with Chapter 1.1.6. of the *Terrestrial Manual*. The protective effect of vaccines is generally serotype-specific ~~and few licensed vaccines are available for cattle~~ and is influenced by factors such as timing of *vaccination* in relation to exposure.

~~3)~~ ~~Use of probiotics may reduce colonisation of cattle by *Salmonella* and shedding of *Salmonella;* however, efficacy is variable.~~

3~~4~~) ~~Because conditions such as~~ A number of conditions, for example liver fluke and infection with bovine viral diarrhoea virus, may increase the susceptibility of ~~cattle~~ bovines to *Salmonella*~~,~~; therefore, control of ~~these~~ such conditions is recommended.

~~5)~~ ~~The immune status of calves is important and therefore care should be taken to ensure that new born calves consume adequate amounts of high quality colostrum.~~

4) Stress may increase the susceptibility of ~~cattle~~ bovines to *Salmonella*. Management of potentially stressful situations, such as mixing of groups of ~~cattle~~ bovines, may reduce the likelihood of clinical disease or shedding of *Salmonella*.

5) *Antimicrobial agents* may modify normal flora in the gut and increase the likelihood of colonisation by *Salmonella*. In circumstances when *antimicrobial agents* are considered necessary for the treatment of clinical ~~enteric~~ salmonellosis, they should be used in accordance with Chapter 6.9. Furthermore, *antimicrobial agents* should not be used to control subclinical *infection* with *Salmonella* in ~~cattle~~ bovines because the effectiveness of the treatment is limited, they may increase the risk of *Salmonella* colonisation, and their use can contribute to the development of antimicrobial resistance.

Article 6.X.~~11~~12.

Transportation

~~Hygienic maintenance of *vehicles* is recommended~~ *Vehicles* should be properly cleaned and disinfected after transportation of animals, in accordance with Chapter 4.13.

When transporting animals from multiple *establishments*, ~~it is recommended that~~ the *Salmonella* status of the *establishments* should be considered to avoid cross-contamination of ~~cattle~~ bovines.

In addition, the relevant recommendations in Chapters 7.2., 7.3. and 7.4. apply.

~~When transporting animals from multiple *establishments*, it is recommended that the *Salmonella* status of the *establishments* be considered to avoid cross-contamination of cattle.~~

Article 6.X.~~12~~13.

Lairage

Relevant aspects of *lairage* management include consideration of effective cleaning and *disinfection* between groups, minimising mixing of ~~separate groups~~ animals that have not continuously been kept together and managing stress.

In addition, the relevant recommendations in Articles 7.5.1., 7.5.3. and 7.5.4. apply.

Annex 10 (contd)

Article 6.X.14.

Cleanliness of hides

Cleanliness of hides can be achieved by applying suitable practices during housing (for example additional clean bedding), transport and lairage. Dirty hides increase the *risk* of microbial contamination of carcasses during the *slaughter* process. ~~Contamination can be reduced by hide washing of the live animal or of the slaughtered animal before hide removal.~~

Article 6.X.~~13~~15.

Surveillance ~~in cattle~~ for *Salmonella* in commercial ~~cattle~~ bovine production systems

Surveillance data provide information to assist the *Competent Authorities* in their decision making regarding the requirement for, and design of, control programmes and in setting and verifying performance objectives. ~~Sampling and testing methods, frequency and type of samples required should be determined by the *Veterinary Services*.~~

Standards for diagnostic tests are described in the *Terrestrial Manual*. In addition, other sampling and testing methodologies such as testing of bulk milk or serum samples by ELISA may provide useful information on *herd* or individual animal status. Boot swab samples from communal areas in ~~cattle~~ housing for bovines, slurry samples, or caecal or lymph node~~s~~ samples collected post-mortem can also be useful for microbiological testing. Some serotypes of *Salmonella* such as *S*. Dublin can be difficult to detect ~~through~~ using microbiological methods.

~~If *vaccination* is used,~~ If serology is used as the *surveillance* method, it may not be possible to distinguish between vaccinated and infected ~~cattle~~ bovines ~~by means of serological testing~~.

Article 6.X.~~14~~16.

Prevention and control in low prevalence regions

In regions where *Salmonella infection* of ~~cattle~~ bovines is uncommon, it may be possible to maintain low prevalence status or eliminate *infection* from *herds* through a combination of good farming practices, *herd surveillance,* individual testing, movement controls, ~~and possible~~ ~~or~~ and removal of persistent carriers.

Text deleted

Annex 11

DRAFT CHAPTER 6.Y.

PREVENTION AND CONTROL OF *SALMONELLA* IN COMMERCIAL PIG PRODUCTION SYSTEMS ~~PIG HERDS~~

EU position

The EU thanks the OIE and supports the adoption of this new chapter.

Article 6.Y.1.

Introduction

Nontyphoidal salmonellosis is one of the most common foodborne bacterial diseases in the world with *Salmonella* Enteritidis and *S.* Typhimurium (including monophasic variants) being the predominant serotypes identified in ~~most countries.~~ humans in most countries. *S*. Enteritidis is primarily associated with *poultry* while *S*. Typhimurium may be present in many mammalian and avian hosts. These serotypes and several others occur at variable prevalence in pigs depending on the region. In some countries *S*. Infantis and *S*. Choleraesuis may cause salmonellosis in humans.

Salmonella infection in pigs is mostly subclinical, although clinical *disease* such as enteritis and septicaemia in weaned pigs may occur. Subclinical *infection,* including a carrier state, can be of variable duration and can play an important role in the spread of *Salmonella* within and between *herds* and pose a public health *risk*.

~~As is the case in most food producing *animals*, *Salmonella infection* in pigs is mostly subclinical and of variable duration. Pigs with subclinical *infection* play an important role in the spread of *Salmonella* between *herds* and pose a public health risk.~~

Salmonella serotypes and their *prevalence* in pigs may vary considerably within and between farms, ~~regions and~~ countries and regions. It is important for *Veterinary Authorities* and producers to consider ~~the~~ ~~types~~ serotypes of *Salmonella*, their occurrence and the *disease* burden ~~and their prevalence~~ in pig and human populations when they develop~~ing~~ and implement~~ing~~ strategies for the prevention and control of *Salmonella* in commercial pig production systems ~~*Salmonella* reduction strategies~~.

Article 6.Y.2.

Definitions

For the purpose of this chapter:

Commercial pig production systems: means those systems in which the purpose of the operation includes some or all of the following: breeding, rearing and management of pigs for the production of *meat*.

Feed: means any material (single or multiple), whether processed, semi-processed or raw, which is intended to be fed directly to terrestrial *animals* (except bees).

Feed ingredient: means a component part or constituent of any combination or mixture making up a feed, whether or not it has a nutritional value in the *animal*'s diet, including feed additives. Ingredients are of plant (including aquatic plants) or terrestrial or aquatic animal origin, or other organic or inorganic substances.

Article 6.Y.~~2~~3.

Purpose and scope

This chapter provides recommendations for the prevention and control of *Salmonella* in commercial pig production systems in order to reduce the burden of *infection* in pigs and the *risk* of human illness through

foodborne ~~food-borne~~ contamination as well as human *infections* resulting from direct or indirect contact with infected pigs.

~~To combat the occurrence of food-borne salmonellosis, a pre-harvest pathogen reduction strategy can assist in reducing the presence of *Salmonella* in pig *meat*.~~

This chapter ~~provides recommendations on the prevention and control of *Salmonella* in domestic pigs kept for commercial breeding and production from farm to slaughter. It~~ should be read in conjunction with the Codex Alimentarius Code of Hygienic Practice for Meat (CAC/RCP 58-2005), Code of Good Animal Feeding (CAC/RCP 54-2004), and the Guidelines for the Control of Nontyphoidal *Salmonella* spp. in Beef and Pork Meat (CAC/GL 87-2016) ~~and the Codex Alimentarius Code of Hygienic Practice for Meat (CAC/RCP 58-2005)~~, and the OIE/FAO Guide to Good Farming Practices for Animal Production Food Safety.

~~Article 6.Y.3.~~

~~**Surveillance in pig herds for *Salmonella***~~

~~Where justified by *risk assessment*, *surveillance* should be carried out to identify the occurrence and distribution of *Salmonella* in pig *herds*. *Surveillance* data will provide information to assist the *Competent Authorities* in their decision making regarding the requirement for, and design of, control programmes. Sampling and testing methods, frequency and type of samples required should be determined by the *Veterinary Services* based on the *risk assessment*.~~

~~Serological testing, usually using 'meat juice' at slaughter, is a common method for assessing exposure to *Salmonella* in pig *herds*. Benefits of serological testing include low cost per test, high throughput capability and the potential for automation of tests. Collection of samples at the *slaughterhouse/abattoir* enables centralised sampling of multiple *herds*. Serological testing does not detect exposure to all serotypes and does not provide information on the serotypes present.~~

~~Microbiological testing identifies serotypes present in pig *herds* and can provide epidemiological information on likely sources of *Salmonella* and on the presence of strains with higher public health risk, including those with enhanced virulence or resistance to *antimicrobial agents*. Bacteriological sampling of individual pigs has low sensitivity but this can be overcome by repeated sampling, by pooling of samples (such as individual faecal samples or mesenteric lymph nodes) or sampling naturally pooled material (such as sampling of faeces from the floor of pig pens).~~

~~Communication of the results of post-mortem *Salmonella* testing that are relevant to the *Salmonella* status of pigs at *herd* level to the *herd* manager or *veterinarian* is an important element of a *Salmonella* control programme.~~

~~Article 6.Y.4.~~

~~**Definitions**~~

~~**Feed:** means any material (single or multiple), whether processed, semi-processed or raw, which is intended to be fed directly to terrestrial *animals* (except bees).~~

~~**Feed ingredient:** means a component part or constituent of any combination or mixture making up a feed, whether or not it has a nutritional value in the *animal*'s diet, including feed additives. Ingredients are of plant (including aquatic plants) or terrestrial or aquatic animal origin, or other organic or inorganic substances.~~

Article 6.Y.~~5~~4.

~~**Prevention**~~ **Objectives of prevention and control measures**

Prevention and control measures may focus on those serotypes of *Salmonella* of greatest consequence to pigs and public health. These measures will also contribute to the reduction of other serotypes.

Prevention and control measures in commercial pig production systems may:

1) reduce the prevalence and amount of *Salmonella* entering the *slaughterhouse/abattoir* and therefore decrease the challenge to the *slaughter* and dressing procedures and the likelihood of pig *meat* contamination;

2) reduce *Salmonella* contamination of the environment via pig faecal waste ~~manure~~, which in turn will limit *infection* of animals (including *wildlife*);

3) reduce the likelihood of *infections* in humans through contact with infected pigs or contaminated materials or water.

While control in the primary production phase can decrease the number of animals carrying or shedding *Salmonella,* controls after primary production are also important to minimise the contamination and cross-contamination of carcasses and *meat products*.

~~When appropriate, good~~ Good farming practices and, when appropriate, the principles of hazard analysis and critical control points (HACCP) should be taken into account when designing prevention and control measures.

Articles 6.Y.~~6~~5. to 6.Y.~~18~~14. provide recommendations for the prevention and control of *Salmonella* ~~at *herd* level~~ in commercial pig production systems. ~~Contamination of pig *meat* can be reduced by measures taken during the *slaughter* process. Reduction of *Salmonella* in pigs entering the *slaughterhouse/abattoir* enhances the effectiveness of such measures.~~ These recommendations ~~will~~ may also contribute to the prevention and control of some ~~have beneficial effects on the occurrence of~~ other *infections* ~~and *diseases*~~.

Article 6.Y.~~6~~5.

Biosecurity ~~measures~~

~~It is important to have biosecurity measures in place to reduce the risk of introduction of *Salmonella* or the entry of new strains of *Salmonella* into pig *herds,* the spread of these strains across the *herd,* as well as to minimise prevalence of existing strains.~~

Biosecurity is ~~intended~~ essential to ~~assist with the prevention~~ prevent and control ~~of~~ *Salmonella*. A *biosecurity plan* should be developed according to the commercial pig production system employed. The choice of specific measures will vary according to the type of commercial pig production system.

When including *Salmonella* as part of a *biosecurity plan* the following should be addressed:

~~It is recommended that biosecurity measures include the following:~~

1) location, design and management of the *establishment*; ~~Development and implementation of a *biosecurity plan* including management strategies for the prevention and control of *Salmonella*.~~

2) veterinary supervision of pig health;

3) management of the introduction and mixing of pigs;

4~~2~~) training of personnel ~~regarding~~ in their responsibilities and ~~the significance of~~ their role in ~~improving~~ animal health, human health~~,~~ ~~and~~ and food safety~~.~~;

4bis) prevention of contamination of feed and water, including for irrigation;

5~~3~~) maintenance of records including data on pig health, production, movements, feeding, water supply, medications, *vaccination*, mortality, ~~*surveillance,*~~ and cleaning and *disinfection* of farm buildings and equipment~~.~~;

6) availability of test results to the farm operator when *Salmonella surveillance* is conducted;

~~4) veterinary supervision of pig health and *Salmonella* control.~~

7~~5~~) removal of unwanted vegetation and debris that could attract or harbour pests around pig housing~~.~~;

8~~6~~) ~~prevention of~~ minimising the entry of domestic animals and *wild* birds into pig ~~houses and~~ buildings and feed stores~~.~~;

Annex 11 (contd)

9~~7~~) cleaning and *disinfection* procedures for buildings in which pigs are handled or housed in accordance with Chapter 4.13.; ~~Cleaning and *disinfection* procedures for pig housing, general equipment, transportation equipment and animal walkways. The cleaning and *disinfection* procedures for pig housing after emptying should include at least feeders, drinkers, floor, walls, aisles, partitions between pens, and ventilation ducting. All visible organic material should be removed before *disinfection* with a suitable *disinfectant* at an effective concentration. *Disinfectants* should be used in accordance with Chapter 4.13~~.

10~~8~~) control of pests such as rodents and arthropods, and regular assessment of effectiveness; ~~Procedures for the control of vermin such as rodents and arthropods should be in place and regular checks should be carried out to assess effectiveness. When the presence of vermin is detected timely control actions should be taken to prevent the development of unmanageable populations; for example, the placement of baits for rodents where they are nesting.~~

11~~9) Controlled access of persons and *vehicles* entering the *establishment*.~~ control and hygienic procedures for entry and movement of persons and *vehicles*;

12~~10~~) *biosecurity* ~~measures~~ applied to all personnel and visitors entering the *establishment.* ~~This~~ As a minimum, this should include hand washing and changing into clean clothes and footwear provided by the *establishment*. Similar precautions are recommended when ~~moving~~ they move between separate *epidemiological units* on large farms~~.~~;

~~11) *vehicles* and equipment identified as a *risk* in the *biosecurity plan* should be cleaned and *disinfected* before entering the *establishment*.~~

13) cleaning and *disinfection* of equipment and *vehicles* identified as posing a *risk*;

14~~12~~) ~~pig carcasses,~~ storage and disposal of dead animals, bedding, faeces and other potentially contaminated farm waste ~~should be stored and disposed of~~ in a ~~safe~~ manner ~~to~~ that minimises the ~~risk~~ likelihood of dissemination of *Salmonella* and ~~to~~ prevents the direct or indirect exposure of humans, livestock and *wildlife* to *Salmonella*. Particular care should be taken when pig bedding and faeces are applied to land used ~~to fertilise~~ for horticultural crops intended for human consumption~~.~~;

15) procedures for prevention of dissemination of *Salmonella* when an animal ~~animals~~ ~~are~~ is suspected or known to be infected.

Article 6.Y.~~7~~6.

~~**Facility**~~ **Location and design of pig establishments**

When making decisions on the location and design of pig *establishments,* reduction of the likelihood of transfer of ~~pathogens~~ pathogenic agents, including *Salmonella*, from major sources of contamination should be considered. Sources of *Salmonella* may include other livestock *establishments* or areas of application or disposal of contaminated waste or effluent. Other sources and *vectors* of *Salmonella* include *vehicles*, equipment, water-courses, personnel, domestic animals, birds, rodents, flies and *wildlife*.

The design of commercial pig production systems should consider the following:

~~Good design of pig units facilitates the management and control of pathogens.~~

~~It is recommended that facility design consider the following:~~

1) ~~location~~ proximity of other livestock *establishments*, ~~in relation to~~ and *wild* bird and rodent populations;

2) management of faecal waste to minimise contamination of the *establishment*;

3~~2~~) adequate drainage for the site and control of run-off water and untreated waste water;

4~~3~~) use of smooth impervious materials for construction of pig houses to enable effective cleaning and *disinfection*;

54) ~~surrounding~~ paving the area immediately surrounding ~~indoor~~ pig houses or indoor *establishments* with concrete or other impervious material. ~~to~~ This will facilitate rodent control and minimise recontamination after ~~facilitate~~ cleaning and *disinfection*;

65) a control~~led~~ of entry and movement of *vehicles*, equipment and persons, ~~point to prevent the entry of unwanted *animals* and people;~~ for example, locate delivery and collection points away from pig housing or feed storage;

7) preventing contamination of feed and water during storage and distribution;

~~6) a sign indicating restricted entry at the entrance to the *establishment*;~~

87) pig ~~flow~~ handling and movements to minimise stress and spread of *Salmonella* ~~*infection*~~;

98) ~~prevention of entry of *wild* birds, rodents and *feral animals*;~~ restriction of entry of domestic animals, *wild* birds, rodents, flies and other relevant *wildlife*.

~~9) location of delivery and collection points away from pig housing or feed storage.~~

Article 6.Y.7.

Management of ~~new~~ pig introductions into the establishment

Introduction of pigs into a *herd* is ~~an important~~ a *risk* factor, especially in moderate and high prevalence regions. To minimise the likelihood of introducing *Salmonella* by replacement pigs:

1) good communication along the pig production chain should be encouraged to raise awareness of the *risk* of introducing *Salmonella* through pig introductions;

2) consideration should be given to minimising the number of sources for both replacement breeding stock and rearing pigs, and matching *Salmonella herd* status in terms of *Salmonella* freedom or occurrence of priority serotypes such as *S.* Typhimurium;

3) new genetic material should be introduced through the use of semen whenever practicable;

4) if possible, pigs should be sourced directly from *herds* of origin because live animal markets or other places where pigs from multiple properties are mixed for resale may increase the likelihood of spread of *Salmonella* and other infectious agents among pigs;

5) newly introduced pigs should be kept separate from the rest of the *herd* for a suitable period before mixing with other pigs~~, e.g. four weeks~~;

6) when appropriate, testing of pigs for *Salmonella* prior to introduction or mixing with other pigs should be considered to inform subsequent control measures, for example, when introducing pigs of unknown status.

Article 6.Y.8.

Moving and mixing of pigs

The moving and mixing of pigs increases the likelihood of spread of *Salmonella*. To minimise the spread of *Salmonella*:

1) the number of pig movements and mixing of pigs should be minimised;

2) if possible, the 'all-in-all-out' system with a single age group of pigs should be used. In particular, the addition to younger groups of pigs held back from older groups should be avoided;

3) sick pigs should be segregated from healthy ones.

Annex 11 (contd)

Article 6.Y.~~8~~9.

Feed and feed composition

1. Feed and feed ingredients

Feed and feed ingredients can be sources of *Salmonella* for pigs. This is especially important in *herds*, countries or regions of low prevalence. To minimise the spread of *Salmonella* through feed:

a) feed and feed ingredients should be produced, handled, stored, transported and distributed in accordance with Chapter 6.3.;

b) ~~when practicable,~~ feed and feed ingredients should be transported, stored and fed in a ~~hygienic~~ manner that minimises contamination by ~~manure~~ faecal waste and, where practicable, minimises access by domestic animals, birds, rodents and *wildlife*;

c) when practicable, ~~feeds~~ feed should be treated with heat, or with approved bactericidal or bacteriostatic treatments such as organic acids.

~~*Salmonella* contaminated feed and feed ingredients are known to be important sources of *infection* for pigs. Therefore, feed and feed ingredients should be produced, handled, stored, transported and distributed according to Good Manufacturing Practices, considering Hazard Analysis Critical Control Points (HACCP) principles and recommendations in accordance with Chapter 6.3.~~

~~For the effective control of *Salmonella* it is recommended that:~~

~~1) Feed and feed ingredients should come from monitored sources.~~

~~2) Heat treated feeds are used and may also include the addition of bactericidal or bacteriostatic treatments, e.g. organic acids. Where heat treatment is not possible, the use of bacteriostatic or bactericidal treatments or processes should be considered.~~

~~3) Cooling systems and dust control in feed ingredient processing plants and compound feed mills should be managed to avoid recontamination of feed and feed ingredients with *Salmonella*.~~

~~4) Feed should be stored and transported in a hygienic manner that prevents exposure to possible residual *Salmonella* contamination.~~

~~5) Access to feed by wild birds and rodents should be prevented.~~

~~6) Spilled feed should be cleaned up immediately to remove attractants for *wild* birds, rodents and other pests.~~

2. Feed composition

When *Salmonella* is present in a pig *herd,* the composition of feed may influence the occurrence of *Salmonella* in individual pigs.

For the control of *Salmonella* the following be considered:

a) liquid feed that is fermented or containing *milk products* has a protective effect due to the presence of beneficial bacteria and lowered pH;

b) coarsely ground feed may reduce the occurrence of *Salmonella* by slowing gastric transit (thereby increasing exposure to gastric acid) and reducing dysbacteriosis. Coarsely ground feed ingredients may be fed alongside pelleted feed;

c) fine grinding needed to produce heat treated pellets may result in dysbacteriosis which favours the colonisation and multiplication of *Salmonella* in the intestine. Therefore, heat treated pellets are more appropriate for situations in which *Salmonella* is uncommon;

d) when wheat is the predominant feed ingredient, reducing the proportion of this ingredient may reduce the occurrence of *Salmonella* because the rapid fermentation of wheat promotes dysbacteriosis.

Annex 11 (contd)

Article 6.Y.~~9~~10.

Water

~~For the effective control~~ Water for drinking should be of an appropriate quality. To minimise the spread of *Salmonella* through water~~, it is recommended that~~:

1) the ~~drinking~~ water supply should be monitored and controlled to maintain it free from *Salmonella* contamination~~.~~;

2) water holding tanks ~~are~~ should be enclosed~~.~~;

3) water supply and delivery systems should not be accessible to birds, rodents, or *wildlife*;

4) the water delivery system ~~is~~ should be regularly cleaned and disinfected. For example in an 'all-in-all-out' system this ~~would~~ occurs before restocking.

~~Article 6.Y.10.~~

~~**Feed composition**~~

~~For the control of *Salmonella* it is recommended that the following be considered when determining feed composition:~~

~~1) slower gastric transit time of ingested feed increases exposure of *Salmonella* to stomach acid resulting in decreased survival.~~

~~2) modified fermentation conditions in the gastrointestinal tract may enhance colonisation by protective bacteria and thereby suppress the colonisation and multiplication of *Salmonella*.~~

~~3) liquid feed that is fermented has a protective effect due to the presence of beneficial bacteria and low pH levels; for example, the inclusion of fermented *milk products*.~~

~~Where *Salmonella* is present in a pig *herd*, the composition of feed may influence the occurrence of *Salmonella* in individual pigs. For the effective control of *Salmonella* it is recommended that:~~

~~4) feed should be coarsely ground.~~

~~5) where feed is wheat based, reducing the proportion of wheat may reduce the occurrence of *Salmonella* in pigs.~~

~~6) coarsely ground material may be added to pelleted feed.~~

~~Article 6.Y.11.~~

~~**Pig flow management**~~

~~The movement and mixing of pigs increase the risk of spread of *Salmonella*. For the effective control of *Salmonella* it is recommended that:~~

~~1) The number of pig movements and mixing of pigs between weaning and dispatch for *slaughter* should be minimised.~~

~~2) If possible, the 'all-in-all-out' single age group principle should be used. In particular, the addition to younger groups of pigs held back from older groups should be avoided.~~

~~Article 6.Y.12.~~

~~**Management of new pig introductions**~~

~~To minimise the risk of new introductions of *Salmonella* in replacement pigs in a *herd*, it is recommended that:~~

~~1) There is good communication along the pig production chain to ensure that steps are taken to minimise the introduction and dissemination of *Salmonella*.~~

~~2) A closed *herd* policy is applied with the introduction of new genetic material by semen only.~~

Annex 11 (contd)

~~3) The number of separate sources for both replacement breeding stock and rearing pigs are as few as possible.~~

~~4) Newly introduced pigs are kept separate from the rest of the *herd* for a suitable period before incorporating with other pigs, e.g. four weeks.~~

~~5) Replacement breeding pigs are of a similar *Salmonella* status to that of the *herd*, for example a *Salmonella* free *herd* should source replacements from *Salmonella* free *herds*; or *herds* that are free of specific *Salmonella* serotypes such as *S.* Typhimurium should avoid introducing pigs from breeding *herds* infected with such serotypes.~~

~~6) Where appropriate, pooled faecal samples from introduced pigs are taken to assess their *Salmonella* status.~~

~~Article 6.Y.13.~~

~~**Stress reduction**~~

~~Given that stress may increase the multiplication and shedding of *Salmonella* by pigs and their susceptibility to *infection*, it is important to consider management measures that reduce stress.~~

Article 6.Y.~~14~~11.

~~**Pig treatments**~~ **Additional prevention and control measures**

1) *Vaccination* may be considered as part of a *Salmonella* control programme. Vaccine production and use should be in accordance with Chapter 1.1.6. of the *Terrestrial Manual*. The protective effect of vaccines is generally serotype-specific and is influenced by factors such as timing of *vaccination* in relation to exposure.

2) *Antimicrobial agents* may modify normal flora in the gut and increase the likelihood of colonisation by *Salmonella*. In circumstances when *antimicrobial agents* are considered necessary for the treatment of clinical ~~enteric~~ salmonellosis, they should be used in accordance with Chapter 6.9. Furthermore, *antimicrobial agents* should not be used to control subclinical *infection* with *Salmonella* in pigs because the effectiveness of the treatment is limited, they may increase the risk of *Salmonella* colonisation, and their use can contribute to the development of antimicrobial resistance.

~~*Antimicrobial agents* may modify normal flora in the gut and increase the likelihood of colonisation by *Salmonella*. If *antimicrobial agents* are used for the control of clinical *infections* in pigs, they should be used in accordance with Chapters 6.7., 6.8., 6.9. and 6.10.~~

~~*Antimicrobial agents* should not be used to control subclinical *infection* with *Salmonella* in pigs because the effectiveness of the treatment is limited and can contribute to the development of antimicrobial resistance.~~

~~2) *Vaccination* may be used as part a *Salmonella* control programme. Vaccine production and use should be in accordance with Chapter 2.9.9. of the *Terrestrial Manual*.~~

~~Vaccines for *Salmonella* in pigs may increase the threshold for *infection* and reduce the level of excretion of the organism. The protective effect of vaccines is serotype specific and few licensed vaccines are available for pigs.~~

~~If serology is used as the *surveillance* method, it may not be possible to distinguish between *vaccination* and *infection* with a field strain.~~

~~If live vaccines are used:~~

~~*a)* it is important that field and vaccine strains be easily differentiated in the laboratory;~~

~~*b)* the vaccine strain should not be present at the time of *slaughter*.~~

3) Where approved by the *Competent Authority*, ~~Organic~~ organic acids, probiotics and prebiotics may be added to feed or water to reduce shedding of *Salmonella* by pigs. However, efficacy is variable.

Article 6.Y.~~15~~12.

Transportation

Vehicles should be properly cleaned and disinfected after transportation of animals, in accordance with Chapter 4.13.

When transporting animals from multiple *establishments,* the *Salmonella* status of the *establishments* should be considered to avoid cross-contamination of pigs.

In addition, the relevant recommendations in Chapters 7.2., 7.3. and 7.4. apply.

Article 6.Y.~~16~~13.

Lairage

Lairage ~~can~~ may be used at various stages in pig production, for example accumulation of weaned pigs before movement to nursery *herds*, holding finisher pigs before transport to *slaughter* and holding pigs at the *slaughterhouse/abattoir* before *slaughter*. ~~Important aspects of *lairage* management include effective cleaning and *disinfection* between groups, minimising mixing of separate groups and managing stress.~~

Relevant aspects of *lairage* management include consideration of effective cleaning and *disinfection* between groups, minimising mixing of animals that have not continually been kept together and managing stress.

In addition, the relevant recommendations in Articles 7.5.1., 7.5.3. and 7.5.4. apply.

Article 6.Y.14.

Surveillance for *Salmonella* in commercial pig production systems

Surveillance data provide information to assist the *Competent Authorities* in their decision making regarding the requirement for, and design of, control programmes and in setting and verifying performance objectives. Harmonised *surveillance* systems to determine the occurrence of *Salmonella* at *herd* level are in place in some countries. Communication between *slaughterhouses/abattoirs*, *Veterinary Services* and the *herd* manager or *veterinarian* of the results of *Salmonella surveillance* systems is an important element of a *Salmonella* control programme.

Standards for diagnostic tests are described in the *Terrestrial Manual*. Serological testing, usually using 'meat juice' at *slaughter*, is one method for assessing exposure to *Salmonella* in pig *herds*. Benefits of serological testing include low cost per test, high throughput capability and the potential for automation of tests. Collection of samples at the *slaughterhouse/abattoir* enables centralised sampling of multiple *herds*. While serology is a useful tool for *risk* ranking of *herds*, serological testing does not detect exposure to all serotypes or differentiate between different serotypes within the serogroups included in the antigenic range of the test or the level of *Salmonella* in pigs at *slaughter*. If serology is used as the *surveillance* method, it may not be possible to distinguish between vaccinated and infected pigs.

Serological testing gives no indication of excretion of *Salmonella* in the *herd* and does not reflect how infectious is the tested group.

Microbiological testing, with additional phenotyping or genotyping, identifies serotypes of *Salmonella* present in pig *herds* and can provide epidemiological information on likely sources of *Salmonella* and on the presence of strains with enhanced virulence or resistance to *antimicrobial agents*. Bacteriological sampling of individual pigs has low sensitivity but this can be overcome by sampling at *herd* level or repeated sampling of individual animals. Pooling of samples (such as individual faecal samples or mesenteric lymph nodes) or sampling naturally pooled material (such as sampling of faeces from the floor of pig pens) will decrease the costs. Some serotypes of *Salmonella* such as *S.* Choleraesuis can be difficult to detect using microbiological methods.

Annex 11 (contd)

Article 6.Y.~~17~~15.

Prevention and control in low prevalence regions

In regions where *Salmonella infection* of pigs is uncommon, it may be possible to maintain low prevalence status or eliminate *infection* from *herds* through a combination of good farming practices, *herd surveillance,* individual testing, movement controls, and removal of persistent carriers.

~~In regions where *Salmonella infection* of pigs is uncommon it may be possible to eliminate *infection* from individual *herds* by means of a test and removal policy. This can be accomplished by placing movement controls on the *herd*, repeated bacteriological sampling of groups of pigs and culling of persistently infected pigs. Movement controls can be lifted after two rounds of negative tests and confirmation of implementation of effective prevention and control measures as described in Articles 6.Y.5. to 6.Y.14.~~

~~It may be possible to attempt this approach in individual *herds*, for example in valuable breeding *herds*, in higher prevalence regions. However, the risk of reintroduction of *infection* must be low to achieve success with this approach.~~ In individual *herds*, for example valuable breeding *herds*, in higher prevalence regions, the success of this approach is dependent upon a low likelihood of reintroduction of *infection*.

Article 6.Y.~~18~~16.

Outdoor pig production

~~As far as possible~~ Where practicable, the prevention and control measures described in Articles 6.Y.5. to 6.Y.~~14~~15. should also be applied to outdoor pigs in commercial pig production systems to reduce *Salmonella infection* ~~in pigs~~. In addition, ~~It~~ it is recommended that:

1) field rotation programmes be used to minimise *Salmonella* contamination and accumulation in soil and surface water and therefore ingestion by pigs;

2) systems used to provide feed, and where possible water, ~~be provided using troughs or bird proof hoppers~~ be designed to minimise attraction of, or access by, ~~of~~ *wild* birds;

3) the location of other outdoor pig *herds* and the concentration and behaviour of *wild* birds in the area be considered ~~when establishing outdoor pig~~ *herds*.

~~Article 6.Y.19.~~

~~**Live animal markets**~~

~~Live animal markets pose a significant risk of spreading *Salmonella* and other *infections* and *diseases* among pigs. If possible, sourcing replacement pigs from live animal markets should be avoided. Precautions should be taken to prevent the spread of *Salmonella* from markets to pig *herds* by personnel or *vehicles*.~~

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— Text deleted.

Annex 12

CHAPTER 7.11.

ANIMAL WELFARE AND DAIRY CATTLE PRODUCTION SYSTEMS

EU position

The EU thanks the OIE for its work. The EU can support the adoption of this chapter's modified article.

[..]

Article 7.11.6.

Recommendations on system design and management including physical environment

1. […]

2. […]

3. […]

4. […]

5. Flooring, bedding, resting surfaces and outdoor areas

In all production systems cattle need a well-drained and comfortable place to rest. All cattle in a group should have sufficient space to lie down and rest at the same time.

Particular attention should be given to the provisions for areas used for calving. The environment in such areas (e.g. floors, bedding, temperature, calving pen and hygiene) should be appropriate to ensure the welfare of calving cows and new born calves.

In housed systems calving areas should be thoroughly cleaned and provided with fresh bedding between each calving. Group pens for calving should be managed based on the principle 'all in - all out'. The group calving pen should be thoroughly cleaned and provided with fresh bedding between each animal group. The time interval between first and last calving of cows kept in the same group calving pen should be minimised.

Outdoor calving pens and fields should be selected to provide the cow with a clean and comfortable environment.

Floor management in housed production systems can have a significant impact on cattle welfare. Areas that compromise welfare and are not suitable for resting (e.g. places with excessive faecal accumulation, or wet bedding) should not be included in the determination of the area available for cattle to lie down.

Slopes of the pens should allow water to drain away from feed troughs and not pool the pens.

Flooring, bedding, resting surfaces and outdoor yards should be cleaned as conditions warrant, to ensure good hygiene, comfort and minimise risk of diseases and injuries.

In pasture systems, stock should be rotated between fields to ensure good hygiene and minimise risk of diseases and injuries.

Bedding should be provided to all animals housed on concrete. In straw, sand or other bedding systems such as rubber mats, crumbled-rubber-filled mattresses and waterbeds, the bedding should be suitable (e.g. hygienic, non-toxic) and maintained to provide cattle with a clean, dry and comfortable place ~~in~~ on which to lie.

The design of a standing, or cubicle, or free stall, should be such that the animals can stand and lie comfortably on a solid surface (e.g. length, width and height should be appropriate for the size of the largest animal). There should be sufficient room for the animal to rest and to rise adopting normal postures, to move its head freely as it stands up, and to groom itself without difficulty. Where housing design provides only individual spaces ~~are provided~~ for cows to rest, there should be at least one space per cow.

Alleys and gates should be designed and operated to allow free movement of cattle. Floors should be designed to minimise slipping and falling, promote foot health, and reduce the risk of claw injuries.

If a housing system includes areas of slatted floor, cattle, including replacement stock, should have access to a solid lying area. The slat and gap widths should be appropriate to the hoof size of the cattle to prevent injuries.

If cattle have to be tethered whether indoors or outdoors, they should, as a minimum, be able to lie down, stand up, maintain normal body posture and groom themselves unimpeded. Cows kept in tie stall housing should be allowed sufficient untethered exercise to prevent welfare problems. When tethered outdoors they should be able to walk. *Animal handlers* should be aware of the higher risks of welfare problems where cattle are tethered.

Where breeding bulls are in housing systems, care should be taken to ensure that they have sight of other cattle with sufficient space for resting and exercise. If used for natural mating, the floor should not be slatted or slippery.

Outcome-based measurables: morbidity rates, especially lameness and injuries (e.g. hock and knee injuries and skin lesions), behaviour (e.g. altered locomotion and posture, altered lying time, grooming and not using the intended lying areas), changes in weight and body condition, physical appearance (e.g. hair loss, cleanliness score), growth rate.

[…]

— Text deleted.

Annex 13

CHAPTER 7.12.

WELFARE OF WORKING EQUIDS

EU position

The EU thanks the OIE for its work and for taking an EU comment into account. The EU can support the adoption of this modified chapter. Furthermore, the EU would ask the OIE to consider a comment in Article 7.12.7 at the next meeting of the Code Commission.

Article 7.12.1.

Introduction

In many countries, working equids, used for transport and traction, contribute directly and indirectly to households' livelihoods and benefit communities as a whole. Working equids may be of direct or indirect use in production and commercial activities.

Specifically, they contribute to agricultural production and food security by transporting, for instance, water and fodder for other livestock, firewood and other daily needs to the homestead and agricultural products to the market. They provide draught power for agricultural work and transport. They may supply manure, *milk*, *meat* and hides for household use or income.

The welfare of these working equids is often poor because their owners lack sufficient resources to meet their needs or have insufficient knowledge of the appropriate care of equids. Certain working contexts, such as working in construction industries or in harsh environments, may present a particular risk to their welfare.

Article 7.12.2.

Scope

This chapter applies to horses, donkeys and mules that are destined, used for or retired from traction, transport and generation of income. Equids used in sports or competitions, leisure activities, research or kept solely for the production of *meat* or biopharmaceuticals, ~~or research~~ are excluded.

For the purposes of this chapter, harness means all parts of the driving harness, saddle, bridle and bit that are used to control the working equid, act as a braking system when pulling a cart, hold loads in place and transfer power to attached carts or agricultural implements.

Article 7.12.3.

Responsibilities

All organisations with defined responsibilities as outlined below should have personnel with the requisite knowledge and skill to perform their duties.

1. Veterinary Authority

   The *Veterinary Authority* is responsible for implementation of animal health and welfare policies, legislation~~s~~, ~~policies~~ and programmes. However, in the case of working equids, the responsibility may be shared with other government agencies, institutions and relevant stakeholders.

2. Other government agencies

   The responsibilities of other government agencies ~~will~~ depend on the range of working equid uses and contexts.

   For example those agencies responsible for regulating industrial and construction activities, whether for

environmental or labour compliance, may also have a responsibility for the working equids involved in the industry.

Particularly in urban areas, the transport or other responsible agency may have legislative authority in dealing with traffic circulation and have a role to play in ensuring a safe environment for working equids as well as other road users.

Environmental protection agencies may regulate and enforce measures to prevent working equids from accessing sources of contamination.

The agency responsible for public health may have legislative authority in dealing with *zoonoses.*

Education authorities have a responsibility in schools and agricultural, *veterinary paraprofessional* and veterinary training institutions. A component on welfare of working equids should be included in animal health and production curricula. ~~Appropriate education and training will prevent many welfare problems~~.

3. Local government authorities

Local government authorities are responsible for many services and programmes that relate to health, safety and public good within their jurisdiction. In many countries the legislative framework gives authority to local government agencies with regard to aspects of transport, agriculture, public health, environmental health and inspection, and compliance activities including those in relation to animal health measures and responsibility for abandoned and stray animals.

In many countries local government agencies are responsible for the development and enforcement of legislation relating to equine drawn carts and carried loads in traffic, *animal identification* (registration), licensing and disposal of dead animals.

4. Private veterinarians

Private *veterinarians* are responsible for providing services and advice to working equid owners or handlers and play an important role in *disease surveillance* because they may be the first to see an equid suffering from a *notifiable disease*. They may also play a role (often in liaison with the police or other local authorities) in dealing with cases of neglect that ~~can~~ lead to welfare problems.

Two-way communication between the private *veterinarians* and *Veterinary Authority*, often via the medium of a veterinary professional organisation, is important and the *Veterinary Authority* is responsible for setting up appropriate mechanisms for this interaction.

Private *veterinarians* may also have a responsibility in supervising and coordination of *veterinary para-professionals* involved in delivering animal health services.

5. Non-governmental organisations

Relevant non-governmental organisations (NGOs) and intergovernmental organisations should understand the role of working equids and may help to collect and provide information to support policy formulation, to advocate and promote health and welfare of working equids.

Local NGOs are potential partners of the *Veterinary Services* in the development and implementation of working equid health and welfare programmes.

NGOs may also contribute, together with *veterinarians* and *Competent Authorities*, in educating the public in the importance of *animal welfare* of working equids.

6. Working equid owners and users

Owners and users are ultimately responsible for the welfare of their working equids by ensuring their animals' "five freedoms" (Article 7.1.2).

Article 7.12.4.

Criteria or measurables for the welfare of working equids

The following outcome-based measurables can be useful indicators of *animal welfare*. The use of these indicators

and the appropriate thresholds should be adapted to the different situations where working equids are used.

1. Behaviour

Presence or absence of certain equine behaviours could indicate an *animal welfare* problem, including fear, depression or pain. Behaviours differ between horses, donkeys and mules and a good understanding of normal behaviour of each species is required.

Some behaviours may not be uniquely indicative of one type of problem; they may be exhibited for a variety of causes. Depression, apathy, dullness and lethargy in equids that are normally active and alert ~~can be~~ are indicative of a welfare problem. Changes in eating or drinking patterns may indicate a welfare problem, especially a decreased feed intake. This might also be an indicator of dental problems, poor feed quality or even feed contamination.

Behaviours indicating discomfort or pain:

– head pressing, teeth grinding, grunting, food dropping, and inability to eat normally. Such behaviours may indicate disease or pain;

– depression, circling, foot pawing, flank watching, inability to stand up, rolling. Such behaviour may indicate abdominal or other discomfort;

– disturbance of ground or bedding. Such behaviours may indicate disease, abdominal pain~~,~~ or malnutrition;

– weight shifting, foot pawing, reluctance to move or abnormal movement. Such behaviours may indicate leg, foot, spinal or abdominal pain;

– head shaking or avoidance of head contact. Such behaviours may indicate head, ear or ocular discomfort;

– itching, rubbing, self-inflicted abrasions. Such behaviours may indicate skin problems or parasites;

– restlessness, agitation and anxiety, rigid stance and reluctance to move, lowered head carriage, fixed stare and dilated nostrils, clenched jaw, aggression and reluctance to be handled, may indicate non-specific pain in horses. In donkeys, these behaviours are more subtle and may not be recognised;

– vocalisation, rolling, kicking at abdomen, flank watching and stretching may indicate abdominal pain in horses. In donkeys, dullness and depression;

– weight-shifting, limb guarding, abnormal weight distribution, pointing, hanging and rotating limbs, abnormal movement and reluctance to move may indicate limb and foot pain in horses. These signs are more subtle in donkeys, although repeated episodes of lying down are reportedly more indicative;

– headshaking, abnormal bit behaviour, altered eating, anorexia and quidding may indicate head and dental pain.

Behaviours indicating fear or anxiety:

– unusual avoidance of humans, especially when handlers or objects associated with their handling come close;

– a reluctance by the working equids to engage in their use for traction or transport or even a cessation and aggressive behaviour, especially when fitting equipment or loading is undertaken.

Behaviours indicating stress:

– oral stereotypies: crib biting, aerophagia (“wind sucking”);

– locomotive stereotypies: stable walking, weaving;

– abnormal vocalisation, agitation ~~and~~ or defaecation.

2. Morbidity

Morbidity, including incidence of *disease*, lameness, injuries or post-procedural complications, may be a direct or indirect indicator of the *animal welfare* status.

Understanding the aetiology of the *disease* or syndrome is important for detecting potential *animal welfare* problems. Scoring systems, such as those used to score lameness and body condition, ~~can~~ provide additional information.

3. Mortality

Mortality, like morbidity, may be a direct or indirect indicator of the *animal welfare* status. Depending on the context, causes of mortality should be investigated as well as temporal and spatial patterns of mortality and possible relationship with husbandry and handling practices. Necropsy is useful in establishing the cause of *death.*

4. Body condition and physical appearance

Poor or changing body condition or physical appearance may be an indicator of compromised animal welfare and health and scoring systems help to provide objectivity.

Observation of physical appearance often provides an indication of animal welfare and health. Attributes of physical appearance that may indicate compromised welfare include:

– feet or limb abnormalities,

– wounds or injuries,

– dehydration or signs of heat stress,

– abnormal discharges,

– presence of parasites,

– abnormal coat or hair loss,

– excessive soiling with faeces, mud or dirt,

– emaciation.

5. Handling responses

Poor human-animal interactions can lead to or be caused by improper handling. This may include bad driving and inappropriate restraint methods, or the misuse of whips and sticks, and can result in fear and distress.

Indicators include:

– aversive or apathetic responses to fitting of equipment and loads,

– defensive responses from the equid to the owner or user such as threatening facial expressions, kicking, biting and avoiding human contact.

6. Complications due to management practices

Some management practices, such as castration and hoof care, are commonly performed in working equids to facilitate handling and improve human safety and *animal welfare*.

Working equids are shod for two main reasons; to prevent hoof wear and to improve performance. Many equids cope well without shoes and, if they are coping well, are best unshod. However, poor hoof care and farriery predispose the working equid to injury and infection, and can result in changes to the size, shape and function of the hoof. Untreated abnormalities of the foot can create long-term problems in other parts of the leg and body due to change in gait and weight bearing.

If management practices such as these are not performed properly, *animal welfare* may be compromised.

Indicators of such problems include:

– post-procedure *infection* and swelling;

– post-procedure lameness;

– myiasis;

– behaviour indicating pain or fear;

– mortality.

It is important to note that some practices are not based on evidence and are inherently bad for welfare. Evidence of firing, nasal slitting, lampas cutting and harmful substances applied to wounds should be identified as indicators of poor welfare.

7. Lameness

Traditionally, lameness has been defined as any alteration of the horse's gait. In addition, lameness can manifest in such ways as a change in attitude or performance. These abnormalities can be caused by pain in the neck, withers, shoulders, back, loin, hips, legs or feet. Identifying the source of the problem is essential for proper treatment. Lameness or gait abnormalities are the most common signs of working equids seen by *veterinarians*. Various scoring systems are available to assess the degree of lameness.

Indicators of such problems include:

– hoof conformation abnormalities;

– unequal weight bearing;

– hoof and pastern axis and angles;

8. Fitness to work

Fitness to work is the state or condition of being physically sound and healthy, especially as a result of exercise and proper nutrition, to perform work well. Various factors such as the animal's age, breed or physiological state (e.g. pregnancy) may influence its fitness to work.

Indicators of an equid's inability to carry out the work demanded of it include the presence of heat stress, lameness, poor body condition or weight loss, harness related wounds and aversive behavioural responses to, for example, harness or equipment fitting.

Article 7.12.5.

Recommendations

Articles 7.12.7. to 7.12.13. provide recommendations for measures applied to working equids.

Each recommendation includes a list of relevant outcome-based measurables derived from Article 7.12.4. This does not exclude other measures being used when appropriate.

Article 7.12.6.

Feeding and provision of water

1. Feeding

Equids are natural grazers that eat small quantities ~~amounts~~ but eat often. Their natural diet is mainly grasses, which have a high roughage content. Horses in particular should be fed frequently with a predominantly fibre-based diet: ~~either~~ grass, hay or a suitable and safe alternative in order to mimic their natural feeding pattern as closely as possible.

Energy, fibre, protein, mineral (including trace minerals) and vitamin contents in the diet of working equids, their balance, safety, digestibility and availability are major factors determining the power of the animals, their growth and overall productivity and their health and welfare.

Working equids should be provided with access to an appropriate quantity of balanced and safe feed, of adequate quality to meet their specific physiological and working needs. In case of feed shortages, the *animal handler* should ensure that the period of reduced feeding is as short as possible and that mitigation strategies are implemented if welfare and health are at risk of being compromised.

Annex 13 (contd)

If supplementary feed is not available, steps should be taken to avoid starvation, including *slaughter*, sale or relocation of the animals, or humane *killing*.

Owners and handlers should allow working equids to forage whenever possible and allow for an adequate number of working breaks to allow the animals to eat. Long fibre forage is important for digestion. Cut green forage should be provided when grazing is not possible. Dry long fibre forage ~~is important and~~ should be provided when adequate green forage is not available.

Inadequate diets and feeding systems may contribute to *diseases*, stress, discomfort or to abnormal behaviour in working equids and should be avoided. *Animal handlers* should be aware of the animals' nutritional needs and consult an expert for advice on ration formulation and feeding programmes when needed.

2. Provision of water

The most important nutrient for the welfare of working equids is water. Working equids need regular and adequate access to palatable, safe water that meets their physiological and work requirements which may vary.

Outcome-based measurables: behaviour, morbidity, mortality, body condition and physical appearance, and fitness to work.

Article 7.12.7.

Shelter

Effective shelter should be provided for working equids both in the resting and working environments. Shelter should provide protection against adverse weather conditions and against predators and injury as well as good ventilation and the ability to rest comfortably. Resting space should be dry, clean and large enough for the equid to lie down, get up and turn around easily.

1. Heat stress

Heat stress is a common condition in working equids in hot, humid environments and *animal handlers* should be aware of the risk that heat stress poses. Equid owners and handlers should be aware of how to prevent it through provision of appropriate shade or shelter along with sufficient drinking water and avoiding work at extreme high temperatures. Owners may also be trained in effective treatment of hyperthermia as timely veterinary assistance may not be available.

Behaviours which indicate heat stress include increased respiratory rate and effort; flared nostrils; increased head movement and lack of response to the environment.

EU comment

The EU asks the OIE to consider the following inclusion at the end of the above sentence.

"And sweating"

Justification

Extreme Horse Sweating is an important clinical symptom of heat stress.

Reference: bsi-schwarzenbek material for drivers' courses on animal welfare

Outcome-based measurables: behaviour, morbidity, mortality, body condition and physical appearance and fitness to work.

2. Cold

Protection from extreme cold weather conditions should be provided when these are likely to create a serious risk to the welfare of equids, particularly of neonates and young animals and others that are physiologically compromised. Such a protection could be provided by extra bedding, blankets or shelter.

Care should be taken that, in an attempt to protect against the cold, ventilation and air quality are not compromised

Behaviour which indicates suffering from cold stress includes shivering and huddling together.

Outcome-based measurables: behaviour, mortality and body condition and physical appearance.

3. Protection from predators and injury

Working equids should be kept safe from predators and from road accidents, which are common occurrences if equids are left free to roam. If working equids are housed alongside horned cattle, care should be taken to protect them from injury. Enclosures used should be structurally sound and free of sharp edges, protrusions and other features that could cause injury.

Outcome based measurables: behaviour, morbidity, mortality, body condition and physical appearance and lameness.

Article 7.12.8.

Management

1. Biosecurity

Biosecurity plans should be designed, commensurate with the desired health status of the equid population or *herd* and current disease risk. These *biosecurity plans* should be promoted with stakeholders for effective implementation and should address the control of the major sources and pathways for spread of pathogens by:

a) equids,

b) other *animals* and *vectors*,

c) people,

d) equipment

e) *vehicles*,

f) air,

g) water supply,

h) feed.

Outcome-based measurables: morbidity, mortality, changes in body condition and physical appearance.

2. Animal health management

Effective national programmes for the prevention and treatment of working equid *diseases* and conditions require clear roles and responsibilities to be defined for official and private animal health service personnel as well as for owners.

Owners and handlers of working equids should be aware of signs of ill-health, *disease*, distress and injuries. If they suspect the presence of disease and are not able to manage it, they should seek advice from *veterinarians* or other qualified persons.

Non-ambulatory working equids should have access to feed and water at all times. They should not be transported or moved unless absolutely necessary for treatment or diagnosis. Such movements should be done carefully using methods that avoid dragging or excessive lifting.

When treatment is attempted, equids that are unable to stand unaided and refuse to eat or drink should be euthanised in accordance with Chapter 7.6., as soon as recovery is deemed unlikely.

Outcome-based measurables: morbidity, mortality, behaviour, body condition and physical appearance.

Article 7.12.9.

Handling and management practices

Management practices should be accomplished expertly and with the proper equipment and pain relief if appropriate. Painful husbandry procedures should be performed under the recommendation or supervision of a *veterinarian.*

Drivers and handlers should be trained to acquire good management skills.

Poor management practices include bad handling, inappropriate restraint such as too tight tethering or hobbling, the working of animals that are unfit or immature, poor housing that does not protect the equids from adverse weather conditions, inadequate handling equipment, excessive number of working hours, underfeeding, lack of access to water, lack of resting periods, working under heat stress, overloading, beating or whipping and some traditional practices.

Competent Authorities and v*eterinarians* should educate owners and handlers of working equids to cease unsafe, ineffective and inhumane practices and also encourage good management and handling skills.

Working equids should not be kept confined indoors for long periods.

Working equids should not be tethered or hobbled continuously. In situations where temporary hobbling is necessary, the *animal handlers* should ensure sufficient distance between the two hobbled legs to allow the equid to stand naturally and move without risk of injury.

When temporary tethering is necessary working equids should be able to lie down, and if tethered outdoors, turn around and walk. The tethering site should be free from obstructions that may entangle the tether. Adequate water, feed and supervision should be provided; if necessary, action should be taken by moving the animals to areas providing shade or shelter.

Mares in season should not be tethered near stallions; mares about to foal or with a foal should not be tethered.

Equipment used to hobble should be designed for that purpose. The parts of the hobbles which are in contact with the skin should not be made from material that causes pain or injury.

Owners and users of working equids should be discouraged from using whips and harmful goads such as sticks. Instead humane training practices for equids should be promoted which focus on developing good driving practices.

Outcome based measurables: behaviour, morbidity, mortality, body condition and physical appearance, lameness and fitness to work.

Article 7.12.10.

Behaviour

Animal handlers should be familiar with normal and abnormal behaviour of each type of working equid in order to interpret the welfare implications of what is being observed.

~~Good~~ Human-animal interaction should be positive in order not to compromise the welfare of the working equid.

Different natural behaviours and social interactions between horses, mules and donkeys should be taken into account.

Outcome-based measurables: behaviour, body condition and physical appearance, and fitness to work.

Article 7.12.11.

End of working life

Consideration should be given to end of life issues.

Abandonment of equids should be discouraged. The *Competent Authorities* should develop and implement guidance or legislation to prevent abandonment while taking steps to make provision for abandoned animals to ensure their welfare.

When working equids need to be *slaughtered or killed*, recommendations in Chapters 7.5 and 7.6 should be followed to avoid the equid suffering a prolonged and painful *death* by abandonment, neglect or disease or acute, painful death such as being eaten by *wild animals*, or hit by a road vehicle.

Article 7.12.12.

Appropriate workloads

Equids continue to develop until over the age of five years so consideration should be given, according to workload, as to when working life commences. In general this should be three years of age or more but never less than two years of age. Animals that are subjected to excessive work too young in life will usually suffer from leg and back injuries in later life, resulting in a much-reduced working life.

Consideration should be given to the animal's overall condition, and other factors such as climate, and the work load should be adjusted accordingly. In particular, special considerations should be given to old animals and to mares three months before and after foaling, in order to not jeopardise pregnancy and allow the foal sufficient suckling access and resting time.

~~Mares should not be ridden or worked three months before and after foaling.~~

~~Special considerations should be given to old animals.~~

In general, animals should work a maximum of six hours per day and should be given at least one, preferably two, full day's rest in every seven-day period. ~~Consideration should be given to the animal's physical condition and age and the work load should be adjusted accordingly.~~

Consideration should be given to the weather conditions (work should be reduced in very hot weather). Breaks should be given at least every two hours and drinkable water should be provided.

All animals should receive sufficient good quality feed corresponding to their individual requirements. Drinkable water and roughage should be available to aid digestion.

Sick or injured animals should not be worked. Any animal that has been under veterinary treatment should not be returned to work until advised by the *veterinarian.*

Outcome based measurables: behaviour, body condition and physical appearance, handling response lameness and fitness to work.

Article 7.12.13.

Farriery and harnessing

1. Farriery

   Owners and handlers should routinely clean and check the hooves of the working equid before and after work.

   Hoof trimming and shoeing of working equids should only be performed by persons with the necessary knowledge and skills.

   Outcome based measurables: behaviour, body condition and physical appearance, lameness and fitness to work.

2. Harnessing

   A properly designed, well-fitted and comfortable harness allows the working equid to pull the equipment to the best of its ability, efficiently and without risk of pain or injuries. Harness injury should be prevented by using properly fitted and adjusted harness which is checked daily for damage and repaired promptly as necessary. Equids should be appropriately groomed before harnessing and checked after work for signs of rubbing and hair loss and the source of any problems should be removed through maintenance and padding where required.

   Harness should not have sharp edges which could cause injury; should fit well so that it does not cause wounds or chafing caused by excess movement; should be smoothly shaped or padded so that loads imposed on the working equids' bodies are spread over a large area; and should not impede the animal's movement or normal breathing or restrict blood supply.

Carts should be maintained to ensure accurate balancing and appropriate tyre pressure. For draught equids the use of swingletrees is recommended so as to balance the pull and thus as a result reduce the risk of sores from the harness.

Owners should ensure effective harnessing and good riding and driving practices.

Bits should be of a simple type (such as a straight bar snaffle), depending on work, but should always be smooth, appropriately sized for the equid and kept clean. Inappropriate materials such as thin cord or wire should never be used as bits or to repair bits.

Outcome based measurables: Behaviour, body condition and physical appearance, lameness and fitness to work.

- Text deleted.

Annex 14

DRAFT CHAPTER 8.X.

INFECTION WITH *MYCOBACTERIUM TUBERCULOSIS* COMPLEX

EU position

The EU thanks the OIE and supports the adoption of this new chapter.

Article 8.X.1.

General provisions

The recommendations in this chapter are intended to manage the human and animal health risks associated with *infection* of animals with a member of the *Mycobacterium tuberculosis (M. tuberculosis)* complex.

For the purposes of ~~this chapter~~ the *Terrestrial Code*, *M. tuberculosis* complex comprises *M. bovis*, *M. caprae* and *M. tuberculosis,* but excludes vaccine strains.

Many different domestic and *wild animal* species belonging to diverse mammalian taxa are known to be susceptible to *infection* with *M. tuberculosis* complex. Their epidemiological significance depends on the degree of susceptibility, the husbandry system, the density, spatial distribution and ecology of populations as well as the pathogenesis and transmission pathways. In some geographical regions, certain *wild animal* species can act as reservoirs.

For the purposes of this chapter, 'animals' means domestic and *captive wild* animal populations of the following categories:

1) Bovids: this term means ~~cattle~~ bovines (*Bos taurus*, *B. indicus, B. frontalis, B. javanicus* and *B. grunniens*), water buffaloes *(Bubalus bubalis)*, and bison (*Bison bison* and *B. bonasus*)~~.~~;

2) Cervids: this term means red deer *(Cervus elaphus elaphus)*, wapiti/elk *(C. elaphus canadensis)*, sika *(C. nippon)*, samba *(C. unicolor unicolor)*, rusa *(C. timorensis)*, roe deer *(Capreolus capreolus)*, fallow deer *(Dama dama)*, white-tailed, black-tailed and mule deer (*Odocoileus* spp.) and reindeer/caribou *(Rangifer tarandus)*~~.~~;

3) Goats *(Capra hircus)*;

~~4) New World Camelids (under study).~~

4) New World camelids: this term means alpacas *(Lama guanicoe pacos)* and ~~domestic~~ llamas *(Lama guanicoe glama)*.

The chapter deals not only with the occurrence of clinical signs caused by *infection* with *M. tuberculosis* complex, but also with the presence of *infection* with *M. tuberculosis* complex in the absence of clinical signs.

For the purposes of the *Terrestrial Code*, the following defines the occurrence of *infection* with *M. tuberculosis* complex:

– A member of *M. tuberculosis* complex has been identified in a sample from an animal or a product derived from that animal;

OR

– positive results to a diagnostic test have been obtained and there is an epidemiological link to a *case* of *infection* with *M. tuberculosis* complex or there is other reason to suspect *infection* with *M. tuberculosis* complex.

When authorising import or transit of *commodities* listed in this chapter, with the exception of those listed in Article 8.X.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the *M. tuberculosis* complex *infection* status of the animal population of the country, *zone* or *herd* of origin.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

Annex 14 (contd)

Article 8.X.2.

Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any *M. tuberculosis* complex-related conditions, regardless of the *M. tuberculosis* complex *infection* status of the animal populations of the country, *zone* or *herd* of origin:

1) *fresh meat* and *meat products* originating from animals that have been subjected to ante- and post-mortem inspections as described in Chapter 6.2.;

2) cured hides, skins and trophies;

3) gelatine, collagen, tallow and *meat-and-bone meal*.

Article 8.X.3.

Country or zone historically free from infection with *M. tuberculosis* complex in specified animal categories

A country or *zone* may be considered historically free from *infection* with *M. tuberculosis* complex in specified animal categories when the ~~conditions~~ requirements of point 1 *a)* of Article 1.4.6. have been met for the relevant animal categories.

Article 8.X.4.

Country or zone free from infection with *M. tuberculosis* complex in bovids

1) To qualify as free from *infection* with *M. tuberculosis* complex in bovids, a country or *zone* should satisfy the following requirements:

   a) *infection* in animals is a *notifiable disease* in the entire country;

   b) a *surveillance* programme based on regular testing of all *herds* has been in place for at least three years and for the past three years this testing has demonstrated that *infection* with *M. tuberculosis* complex was not present in at least 99.8% of the *herds* representing at least 99.9% of the bovids in the country or *zone*;

   c) a *surveillance* programme in accordance with Chapter 1.4. is in place to detect *infection* with *M. tuberculosis* complex in the country or *zone* through ante- and post-mortem inspections of bovids as described in Chapter 6.2.;

   d) regulatory measures have been implemented for the early detection of *infection* with *M. tuberculosis* complex in bovids;

   e) bovids and their germplasm introduced into the country or *zone* comply with the recommendations in Articles 8.X.7., 8.X.10. and 8.X.12.

2) To maintain the status as free from *infection* with *M. tuberculosis* complex in bovids, a country or *zone* should satisfy the following requirements:

   a) the requirements in points 1 *a)*, 1 *c)*, 1 *d)* and 1 *e)* above are met;

b) a *surveillance* programme based on regular testing of bovids is in place in the country or *zone* to detect *infection* with *M. tuberculosis* complex in accordance with Article 1.4.4.;

c) once the *surveillance* programme described in point *b)* has demonstrated that *infection* with *M. tuberculosis* complex has not been present in at least 99.8% of the *herds* representing 99.9% of the bovids in the country or *zone* for two consecutive years, *surveillance* may be maintained through ante- and post-mortem inspections as described in Chapter 6.2.;

3) The country or *zone* status of free from *infection* with *M. tuberculosis* complex in bovids is not affected by the occurrence of *infection* with *M. tuberculosis* complex in other animal categories or *feral* or *wild animals* provided that measures ~~have been implemented~~ intended to prevent transmission of *infection* with *M. tuberculosis* complex to bovids have been implemented and are periodically reassessed.

Article 8.X.5.

Country or zone free from infection with *M. tuberculosis* complex in cervids

1) To qualify as free from *infection* with *M. tuberculosis* complex in cervids, a country or *zone* should satisfy the following requirements:

a) *infection* with *M. tuberculosis* complex in animals is a *notifiable disease* in the entire country;

b) regular testing of all cervid *herds* has been in place for at least three years and for the past three years this testing has demonstrated that *infection* with *M. tuberculosis* complex was not present in at least 99.8% of the *herds* representing at least 99.9% of the cervids in the country or *zone*;

c) a *surveillance* programme is in place to detect *infection* with *M. tuberculosis* complex in the country or *zone* through ante- and post-mortem inspections as described in Chapter 6.2.;

d) regulatory measures have been implemented for the early detection of *infection* with *M. tuberculosis* complex in cervids;

e) cervids and their germplasm introduced into the country or *zone* comply with the recommendations in Articles 8.X.7., 8.X.11. and 8.X.12.

2) To maintain the status as free from *infection* with *M. tuberculosis* complex in cervids, a country or *zone* should satisfy the following requirements:

a) the requirements in points 1 *a)*, 1 *c)*, 1 *d)* and 1 *e)* above are met;

b) a *surveillance* programme based on regular testing of cervids is in place in the country or *zone* to detect *infection* with *M. tuberculosis* complex in accordance with Article 1.4.4.;

c) once the *surveillance* programme described in point *b)* has demonstrated that *infection* with *M. tuberculosis* complex has not been present in at least 99.8% of the *herds* representing 99.9% of the cervids in the country or *zone* for two consecutive years, *surveillance* may be maintained through ante- and post-mortem inspections as described in Chapter 6.2.

3) The country or *zone* status free from *infection* with *M. tuberculosis* complex in cervids is not affected by the occurrence of *infection* with *M. tuberculosis* complex in other animal categories or *feral* or *wild animals* provided that measures ~~have been implemented~~ intended to prevent transmission of *infection* with *M. tuberculosis* complex to cervids have been implemented and are periodically reassessed.

Article 8.X.6.

Herd free from infection with *M. tuberculosis* complex in bovids or cervids

1) To qualify as free from *infection* with *M. tuberculosis* complex, a *herd* of bovids or cervids should satisfy the following requirements:

a) the *herd* is in a country or *zone* free from *infection* with *M. tuberculosis* complex in bovids or in cervids and is certified free by the *Veterinary Authority*;

OR

b) the *herd* ~~meets~~ satisfies the following ~~conditions~~ requirements:

i) *infection* with *M. tuberculosis* complex in animals is a *notifiable disease* in the entire country;

ii) no ~~evidence~~ occurrence of *infection* with *M. tuberculosis* complex has been detected in the *herd* for at least the past 12 months;

iii) bovids or cervids in the *herd* have shown no clinical signs of *infection* with *M. tuberculosis* complex or lesions at ante- or post-mortem inspections for at least the past 12 months;

iv) two tests have been performed with negative results at a minimum interval of six months on all bovids or cervids over six weeks of age present in the *herd* at the time of testing. The first test was performed at least six months after the removal of the last *case*;

v) bovids or cervids and their germplasm introduced into the *herd* comply with Articles 8.X.7., 8.X.10., 8.X.11. and 8.X.12.;

vi) for at least the past 12 months, there has been no ~~evidence~~ occurrence of *infection* with *M. tuberculosis* complex in other *herds* of the same *establishments* or measures have been implemented to prevent any transmission of *infection* with *M. tuberculosis* complex from these other *herds*;

2) to maintain the free status, either:

a) the requirements in point 1 *a)* are met;

OR

b) the requirements in points 1 *b) i)* to *iii)*, *v)* and *vi*) are met and bovids or cervids in the *herd:*

i) showed a negative result to an annual test to ensure the continuing absence of *infection* with *M. tuberculosis* complex;

OR

ii) showed a negative result to a test every two years to ensure the continuing absence of *infection* with *M. tuberculosis* complex if it has been confirmed that the annual percentage of *herds* infected with *M. tuberculosis* complex is not more than 1% of all *herds* in the country or *zone* during the past two years;

OR

iii) showed a negative result to a test every three years to ensure the continuing absence of *infection* with *M. tuberculosis* complex if it has been confirmed that the annual percentage of *herds* infected with *M. tuberculosis* complex is not more than 0.2% of all *herds* in the country or *zone* during the past four years;

OR

iv) showed a negative result to a test every four years to ensure the continuing absence of *infection* with *M. tuberculosis* complex if it has been confirmed that the annual percentage of *herds* infected with *M. tuberculosis* complex is not more than 0.1% of all *herds* in the country or *zone* during the past six years;

OR

c) ~~When there is a known *wildlife* reservoir of *M. tuberculosis* complex, all *herds* in the country or *zone* are covered by a *surveillance* programme in accordance with point 1c) of Articles 8.X.4. and 8.X.5 and all *herds* identified as being at risk of *infection* with *M. tuberculosis* complex, based on;~~ the requirements in points 1 *b) i)* to *iii)*, *v)* and *vi)* are met; and

i) the risk of transmission of *infection* with *M. tuberculosis* complex from known *wildlife* reservoirs has been assessed through active *surveillance*;

ii) all *herds* identified as being at risk are subjected to a testing programme commensurate with the assessed epidemiological risk of *infection* with *M. tuberculosis* complex. In identifying *herds* at risk, the following should be considered:

~~*i)*~~ — a location associated with suspected or confirmed *infection* with *M. tuberculosis* complex in *wildlife*; or

~~*ii)*~~ — a history of *infection* with *M. tuberculosis* complex within last five years; or

~~*iii)*~~ — an epidemiological link with *herds* in either of the two points above;~~. are subjected to a testing programme commensurate with the assessed epidemiological risk of *infection* with *M. tuberculosis* complex.~~

Article 8.X.7.

Recommendations for the importation of bovids ~~and~~ or cervids for breeding or rearing

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the bovids ~~and~~ or cervids:

1) showed no clinical signs of *infection* with *M. tuberculosis* complex on the day of shipment;

2) *a)* originate from a *herd* free from *infection* with *M. tuberculosis* complex that is in a country or *zone* free from *infection* with *M. tuberculosis* complex; or

b) originate from a *herd* free from *infection* with *M. tuberculosis* complex and have been tested for *infection* with *M. tuberculosis* complex with negative results within 30 days prior to shipment; or

c) have been isolated for at least ~~90 days~~ six months prior to shipment including protection from contact with ~~animal~~ any reservoir~~s~~ of *M. tuberculosis* complex and all isolated animals showed negative results to at least two consecutive tests carried out at a six-month interval, with the second test performed within 30 days prior to shipment.

Article 8.X.8.

Recommendations for the importation of goats for breeding or rearing

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

1) *infection* with *M. tuberculosis* complex in animals is a *notifiable disease* in the entire country;

2) the goats showed no clinical signs of *infection* with *M. tuberculosis* complex on the day of shipment;

3) either:

a) the goats ~~were~~ have been kept since birth in *herds* in which no *case* of *infection* with *M. tuberculosis* complex has been detected for the past three years; or

b) have been isolated for at least six months prior to shipment including protection from contact with any reservoir of *M. tuberculosis* complex and all isolated animals showed negative results to at least two consecutive tests carried out at a six-month interval, with the second test performed within 30 days prior to shipment.

Article 8.X.9.

Recommendations for the importation of bovids ~~and~~ or cervids for slaughter

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the bovids ~~and~~ or cervids:

Annex 14 (contd)

1) showed no clinical signs of *infection* with *M. tuberculosis* complex on the day of shipment;

2) either:

a) originate from a country, *zone* or *herd* free from *infection* with *M. tuberculosis* complex;

or

b) are *not* being culled as part of an eradication programme against *infection* with *M. tuberculosis* complex and were tested for *infection* with *M. tuberculosis* complex with negative results within 30 days prior to shipment.

Article 8.X.10.

Recommendations for the importation of semen of bovids

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

1) the donor males showed no clinical signs of *infection* with *M. tuberculosis* complex on the day of collection of the semen;

2) the donor males ~~either~~:

a) were kept in an *artificial insemination centre* complying with the provisions of Chapter 4.5. and complied with Article 4.6.2.; or

b) were kept in a *herd* free from *infection* with *M. tuberculosis* complex that is in a country or *zone* free from *infection* with *M. tuberculosis* complex; or

c) were kept in a *herd* free from *infection* with *M. tuberculosis* complex and showed negative results to a test~~s~~ performed within 30 days prior to collection of the semen, ~~carried out annually and the semen~~ which was collected, processed and stored in ~~conformity~~ accordance with ~~the provisions of~~ Articles 4.5.~~3~~4., ~~to~~ 4.5.5., and ~~Articles~~ 4.6.5. to 4.6.7.

Article 8.X.11.

Recommendations for the importation of semen of cervids

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

1) the donor males showed no clinical signs of *infection* with *M. tuberculosis* complex on the day of collection of the semen;

2) the donor males either:

a) were kept in a *herd* free from *infection* with *M. tuberculosis* complex in a country or *zone* free from *infection* with *M. tuberculosis* complex ~~and which only accepts cervids from free *herds* in a free country, or *zone*~~; or

b) were kept in a *herd* free from *infection* with *M. tuberculosis* complex and showed negative results to a test~~s~~ performed within 30 days prior to collection of the semen, ~~carried out annually and the semen~~ which was collected, processed and stored in ~~conformity~~ accordance with ~~the provisions of~~ Articles 4.5.~~3~~4., ~~to~~ 4.5.5., and ~~Articles~~ 4.6.5. to 4.6.7.

Article 8.X.12.

Recommendations for the importation of embryos of bovids ~~and~~ or cervids

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

1) the donor females either:

a) originated from a *herd* free from *infection* with *M. tuberculosis* complex in a country or *zone* free from *infection* with *M. tuberculosis* complex; or

b) were kept in a *herd* free from *infection* with *M. tuberculosis* complex, and were subjected to a test for *infection* with *M. tuberculosis* complex with negative results during an isolation period of 30 days in the *establishment* of origin prior to collection;

2) the semen used for embryo production complied with Article 8.X.10. or 8.X.11.;

3) the embryos were collected, processed and stored in accordance with the relevant provisions of Chapters 4.7. to 4.9.

Article 8.X.13.

Recommendations for the importation of milk and milk products of bovids

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the *milk* or *milk products*:

1) have been derived from bovids in a *herd* free from *infection* with *M. tuberculosis* complex; or

2) were subjected to pasteurisation or any combination of control measures with equivalent performance as described in the Codex Alimentarius Code of Hygienic Practice for Milk and Milk Products.

~~Article 8.X.14.~~

~~**Recommendations for the importation of milk and milk products of goats**~~

~~*Veterinary Authorities* of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:~~

~~1) *infection* with *M. tuberculosis* complex in animals is a *notifiable disease* in the entire country and the *milk* or *milk products* have been derived from goats kept in *herds* in which no case of *infection* with *M. tuberculosis* complex has been detected for the past three years;~~

~~OR~~

~~2) the *milk* or *milk products* were subjected to pasteurisation or any combination of control measures with equivalent performance as described in the Codex Alimentarius Code of Hygienic Practice for Milk and Milk Products.~~

- - - - - - - - - - - - - -

— Text deleted.

Annex 15

CHAPTER 10.4.

INFECTION WITH AVIAN INFLUENZA VIRUSES

EU position

The EU supports the adoption of this modified article.

[…]

Article 10.4.25.

Procedures for the inactivation of avian influenza viruses in eggs and egg products

The following times for industry standard temperatures are suitable for the inactivation of avian influenza viruses present in eggs and egg products:

	Core temperature (°C)	Time
Whole egg	60	188 seconds
Whole egg blends	60	188 seconds
Whole egg blends	61.1	94 seconds
Liquid egg white	55.6	870 seconds
Liquid egg white	56.7	232 seconds
Plain or pure egg yolk	60	288 seconds
10% salted yolk	62.2	138 seconds
Dried egg white	67	20 hours
Dried egg white	54.4	~~513~~ 50.4 hours
Dried egg white	51.7	73.2 hours

The listed temperatures are indicative of a range that achieves a 7-log kill of avian influenza virus. These are listed as examples in a variety of egg products, but ~~Where~~ when scientifically documented, variances from these times and temperatures and for additional egg products may also be suitable when they achieve ~~the~~ equivalent inactivation of the virus.

[…]

- Text deleted.

Annex 16

CHAPTER 11.11.

INFECTION WITH LUMPY SKIN DISEASE VIRUS

EU position

The EU thanks the OIE and in general supports the adoption of this modified chapter. Comments are inserted in the text below.

Article 11.11.1.

General provisions

Lumpy skin disease (LSD) susceptible animals are ~~cattle~~ bovines (*Bos indicus* and *B. taurus*) and water buffaloes (*Bubalus bubalis*) and ~~occasionally~~ certain *wild* ruminants.

For the purpose of the *Terrestrial Code*, LSD is defined as an *infection* of ~~cattle~~ bovines ~~(*Bos indicus* and *B. taurus*)~~ and water buffaloes ~~(*Bubalus bubalis*)~~ with lumpy skin disease virus (LSDV).

The following defines *infection* with LSDV:

EU comment

For consistency with other chapters, the EU suggests inserting the words "the occurrence of" before the word "infection" in the chapeau above.

1) LSDV has been isolated from a sample from ~~cattle~~ a bovine or a water buffalo~~es~~; or

2) antigen or nucleic acid specific to LSDV, excluding vaccine strains, has been identified in a sample from ~~cattle~~ a bovine or a water buffalo~~es~~ showing clinical signs consistent with LSD, or epidemiologically linked to a suspected or confirmed *case*, or giving cause for suspicion of previous association or contact with LSDV; or

3) antibodies specific to LSDV~~, which are not a consequence of *vaccination*,~~ have been identified in a sample from ~~cattle~~ a bovine or a water buffalo~~es~~ that either show~~s~~ clinical signs consistent with LSD, or ~~are~~ is epidemiologically linked to a suspected or confirmed *case*.

EU comment

The EU notes that no explanation is provided by the Code Commission in its report as to why the words "which are not a consequence of vaccination" are proposed for deletion in point 3) above. The EU invites the Code Commission to confirm that this is due to the fact that according to experts, it is not possible to differentiate antibodies elicited by vaccination from those resulting from infection (i.e. no DIVA strategies are available for LSD).

For the purposes of the *Terrestrial Code*, the *incubation period* for LSD shall be 28 days.

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Article 11.11.2.

Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any LSD related conditions regardless of the status of the animal population of the *exporting country*:

1) skeletal muscle *meat*;

2) casings;

3) gelatine and collagen;

4) tallow;

5) hooves and horns~~;~~.

~~6) horns.~~

Article 11.11.3.

Country or zone free from LSD

A country or a *zone* may be considered free from LSD when *infection* with LSDV is notifiable in the entire country, importation of ~~cattle~~ bovines and water buffaloes and their *commodities* is carried out in accordance with this chapter, and either:

1) the country or *zone* is historically free as described in point 1 *a)* of Article 1.4.6.; or

2) for at least three years, ~~the country or *zone* *vaccination*, has not reported any *case* of *infection* with LSDV~~ and a clinical *surveillance* programme in accordance with Article 11.11.14. has demonstrated no ~~evidence~~ occurrence of *infection* with LSDV ~~in the country or *zone* for at least three years~~; or

EU comment

The EU notes a possible inconsistency between point 2) above and Article 11.11.14. Indeed, whereas point 2) above refers to a "clinical surveillance programme" and seems to suggest that a three year clinical surveillance programme is sufficient to demonstrate country or zone freedom, the "general principles" section of the surveillance Article (i.e. point 1) of Article 11.11.4. below) states that the surveillance strategy should "detect the presence of infection with LSDV even in the absence of clinical signs". To avoid confusion, the EU suggests inserting the words "unless specified otherwise in the present chapter" after "even in the absence of clinical signs" in point 1) of Article 11.11.4.

3) for at least two years, ~~the country or *zone* *vaccination*, has not reported any *case* of *infection* with LSDV~~ and a clinical, virological and serological *surveillance* programme in accordance with Article 11.11.14. has demonstrated no ~~evidence~~ occurrence of *infection* with LSDV ~~in the country or *zone* for at least two years~~.

A country or *zone* free from LSD that is adjacent to an infected ~~area~~ country or *zone* should include a *zone* in which *surveillance* is conducted in accordance with Article 11.11.14.

A country or *zone* free from LSD will not lose its status as a result of introduction of seropositive or vaccinated ~~cattle~~ bovines or water buffaloes or their *commodities*, provided they were introduced in accordance with this chapter.

Article 11.11.3bis.

Recovery of free status

1) When a *case* of LSD occurs in a country or *zone* previously free from LSD, one of the following waiting periods is applicable to regain free status:

a) when a *stamping-out policy* has been applied:

– 14 months after the *slaughter* or *killing* of the last *case*, or after the last *vaccination* if emergency *vaccination* has been used, whichever occurred last, ~~a *stamping-out policy* has been applied~~ and during which period clinical, virological and serological *surveillance* has been conducted in accordance with Article 11.11.14.;

~~b)~~ – 26 months after the *slaughter* or *killing* of the last *case*, or after the last *vaccination* if emergency *vaccination* has been used, whichever occurred last, ~~a *stamping-out policy* has been applied~~ and during which period clinical *surveillance* alone has been conducted in accordance with Article 11.11.14.;

~~b~~c) when a *stamping-out policy* is not applied, Article 11.11.3. applies.

2) When preventive *vaccination* is conducted in a country or *zone* free from LSD, in response to a threat but without the occurrence of a *case* of LSD, free status may be regained eight months after the last *vaccination* when clinical, virological and serological *surveillance* has been conducted in accordance with Article 11.11.14.

EU comment

For reasons of clarity and consistency with Article 11.11.3., the EU suggests adding "has demonstrated no occurrence of infection with LSDV" at the end of both indents of point 1 a) as well as at the end of point 2) above.

Article 11.11.4.

Recommendations for importation from countries or zones free from LSD

For domestic ~~cattle~~ bovines and water buffaloes

EU comment

The EU notes that the titles of Articles 11.11.4. and 11.11.5. are the only places in this chapter that refer to "domestic" bovines. Indeed, Article 11.11.1., where the susceptible animals and the case definition are provided, refers to "bovines", not to domestic "bovines". Similarly, Articles 11.11.6. to 11.11.9. refer to "bovines", not "domestic bovines". While the difference between the two may not be relevant in practice, this inconsistency may still give rise to confusion. The EU therefore suggests either inserting the word "domestic" in Article 11.11.1. (and throughout the chapter as appropriate), or deleting it from the titles of Articles 11.11.4. and 11.11.5.

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

1) showed no clinical sign of LSD on the day of shipment;

2) come from a country or *zone* free from LSD.

EU comment

The EU notes that the wording of the article above does not explicitly exclude the importation of seropositive animals from a free country or zone. Indeed, for example in application of point 2 of Article 11.11.3bis., the country or zone could regain freedom while still having vaccinated animals. The EU invited the Code Commission to consider clarifying at its next meeting whether there should be an explicit mention in the present chapter that under certain conditions, trade in seropositive, vaccinated animals is safe.

Article 11.11.5.

Recommendations for importation from countries or zones not free from LSD

For domestic ~~cattle~~ bovines and water buffaloes

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

1) showed no clinical sign of LSD on the day of shipment;

2) were kept since birth, or for the past 60 days prior to shipment, in an *epidemiological unit* where no *case* of LSD occurred during that period;

3) were vaccinated against LSD according to manufacturer's instructions ~~at least~~ between 60 days and one year prior to shipment;

4) were demonstrated to have antibodies at least 30 days after *vaccination*;

5) were kept in a *quarantine station* for the 28 days prior to shipment during which time they were subjected to an agent identification test with negative results.

Article 11.11.6.

Recommendations for importation from countries or zones free from LSD

For semen of ~~cattle~~ bovines and water buffaloes

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor males:

   a) showed no clinical sign of LSD on the day of collection;

   b) were kept in a free country or *zone* for at least 28 days prior to collection;

2) the semen was collected, processed and stored in accordance with Chapters 4.5. and 4.6.

Article 11.11.7.

Recommendations for importation from countries or zones not free from LSD

For semen of ~~cattle~~ bovines and water buffaloes

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor males:

   a) showed no clinical sign of LSD on the day of collection and the following 28 days;

   b) were kept for the ~~past~~ 60 days prior to collection, in an *artificial insemination centre* where no *case* of LSD occurred during that period;

   c) ~~and~~ EITHER:

      i) were ~~regularly~~ vaccinated regularly against LSD according to manufacturer's instructions, the first *vaccination* being administrated at least 60 days prior to the first semen collection; and

      ii) were demonstrated to have antibodies against LSDV at least 30 days after *vaccination*;

      OR

      iii) were subjected to a serological test to detect antibodies specific to LSDV, with negative results, at least every ~~14~~ 28 days throughout the collection period and one test ~~14~~ 21 days after the final collection for this consignment; and

      iv) were subjected to agent detection by PCR conducted on blood samples collected at commencement and conclusion of, and at least every ~~14~~ 28 days during, semen collection for this consignment, with negative results; ~~and~~

   d~~v~~) the semen to be exported was subjected to agent detection by PCR;

2) the semen was collected, processed and stored in accordance with Chapters 4.5. and 4.6.

Article 11.11.8.

Recommendations for importation from countries or zones free from LSD

For embryos of ~~cattle~~ bovines and water buffaloes

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor females:

   a) showed no clinical sign of LSD on the day of collection of the embryos;

   b) kept for at least 28 days prior to collection in a free country or *zone*;

2) the embryos were collected, processed and stored in accordance with Chapters 4.7., 4.8. and 4.9., as relevant;

3) the semen used for the production of the embryos complied with Article 11.11.6. or 11.11.7., as relevant.

Article 11.11.9.

Recommendations for importation from countries or zones not free from LSD

For embryos of ~~cattle~~ bovines and water buffaloes

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor females:

   a) showed no clinical sign of LSD on the day of collection and the following 28 days;

   b) were kept in an *establishment* where no *case* of LSD occurred during the 60 days prior to collection;

   c) ~~and~~ EITHER:

      i) were ~~regularly~~ vaccinated regularly against LSD according to manufacturer's instructions, the first *vaccination* being administrated at least 60 days prior to the first collection; and

      ii) were demonstrated to have antibodies against LSDV at least 30 days after *vaccination*;

      OR

      iii) were subjected to a serological test to detect antibodies specific to LSDV, with negative results, on the day of collection and at least 21 days after collection; ~~and~~

   d~~iv~~) were subjected to agent detection by PCR with negative results on a blood sample on the day of collection;

2) the semen used for the production of the embryos complied with Article 11.11.6. or 11.11.7., as relevant;

3) the embryos were collected, processed and stored in accordance with Chapters 4.7., 4.8. and 4.9.

Article 11.11.10.

Recommendations for the importation of milk and milk products

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the *milk* or the *milk products*:

1) have been derived from animals in a country or *zone* free from LSD;

OR

2) were subjected to pasteurisation or any combination of control measures with equivalent performance as described in the Codex Alimentarius Code of Hygienic Practice for Milk and Milk Products.

~~Article 11.11.11.~~

~~**Recommendations for importation of products of animal origin from cattle and water buffaloes intended for agricultural or industrial use**~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:~~

~~1) these products have been derived from animals that have been kept in a country or *zone* free from LSD since birth or for at least the past 28 days; or~~

~~2) these products have been processed to ensure the destruction of the LSDV.~~

Article 11.11.11~~12~~.

Recommendations for importation of meal and flour from blood, meat other than skeletal muscle, or bones from ~~cattle~~ bovines and water buffaloes

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) these products ~~have been~~ were derived from animals in a country or *zone* free from LSD; or

2) *a)* the products were processed using heat treatment to a minimum internal temperature of 65°C for at least 30 minutes;

b) the necessary precautions were taken after processing to avoid contact of the *commodities* with any potential source of LSDV.

Article 11.11.12~~13~~.

Recommendations for importation of hides of ~~cattle~~ bovines and water buffaloes

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) these products ~~have been~~ were derived from *animals* that ~~have~~ had been kept in a country or *zone* free from LSD since birth or for at least the past 28 days; ~~or~~

OR

2) these products ~~had have been~~ were~~;~~: ~~processed to ensure the destruction of LSDV, in premises controlled and approved by the *Veterinary Authority* of the *exporting country*.~~

a) derived from animals which ~~have~~ had undergone ante- and post-mortem inspection in accordance with Chapter 6.2. with favourable results; and

b) dry-salted or wet-salted for a period of at least 14 days prior to dispatch; or

c) treated for a period of at least seven days in salt (NaCl) with the addition of 2% sodium carbonate (Na_2CO_3); or

d) dried for a period of at least 42 days at a temperature of at least 20°C; and

3) the necessary precautions were taken after processing to avoid contact of the *commodities* with any potential source of LSDV.

EU comment

According to explanations provided in Item 4.13. of the Code Commission report, the deleted Article 11.11.11. is to be reinserted here, as Article 11.11.14. Thus, the surveillance article below would be numbered "11.11.14." instead of "11.11.13.". This is relevant also as regards the references to the surveillance article, which throughout the chapter is referred to as "Article 11.11.14."

Article 11.11.13~~14~~.

Surveillance

1. General principles of surveillance

A Member Country should justify the *surveillance* strategy chosen as being adequate to detect the presence of *infection* with LSDV even in the absence of clinical signs, given the prevailing epidemiological situation in accordance with Chapter 1.4. and Chapter 1.5. under the responsibility of the *Veterinary Authority.*

The ~~*Veterinary Authority*~~ *Veterinary Services* should implement programmes to raise awareness among farmers and workers who have day-to-day contact with livestock, as well as *veterinary paraprofessionals*, *veterinarians* and diagnosticians, who should report promptly any suspicion of LSD.

In particular Member Countries should have in place:

a) a formal and ongoing system for detecting and investigating *cases* ~~*outbreaks of disease*~~;

b) a procedure for the rapid collection and transport of samples from suspected *cases* ~~*of infection* with LSDV~~ to a *laboratory* for diagnosis;

c) a system for recording, managing and analysing diagnostic and *surveillance* data.

2. Clinical surveillance

Clinical *surveillance* is essential for detecting *cases* of *infection* with LSDV and requires the physical examination of susceptible animals.

Surveillance based on clinical inspection provides a high level of confidence of detection of *disease* if a sufficient number of clinically susceptible animals is examined regularly at an appropriate frequency and investigations are recorded and quantified. Clinical examination and ~~diagnostic~~ *laboratory* testing should be pre-planned and applied using appropriate types of samples to clarify the status of suspected *cases*.

3. Virological and serological surveillance

An active programme of *surveillance* ~~programme~~ of susceptible populations to detect evidence of *infection* with LSDV is useful to establish the status of a country or *zone*. Serological and molecular testing of ~~cattle~~ bovines and water buffaloes may be used to detect presence of *infection* with LSDV in naturally infected animals.

The study population used for a serological survey should be representative of the population at risk in the country or *zone* and should ~~include~~ be restricted to susceptible unvaccinated animals. Identification of vaccinated animals may minimise interference with serological *surveillance* and assist with recovery of free status.

4. Surveillance in high-risk areas

Disease-specific enhanced *surveillance* in a free country or *zone* should be carried out over an appropriate distance from the border with an infected country or *zone*, based upon geography, climate, history of *infection* and other relevant factors. The *surveillance* should be carried out over a distance of at least 20 kilometres from the border with that country or *zone*, but a lesser distance could be acceptable if there are relevant ecological or geographical features likely to interrupt the transmission of LSDV. A country or *zone* free from LSD may be protected from an adjacent infected country or *zone* by a *protection zone*.

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— Text deleted.

Annex 17

CHAPTER 15.1.

INFECTION WITH AFRICAN SWINE FEVER VIRUS

EU position

The EU thanks the OIE and supports the adoption of this modified chapter.

Article 15.1.1.

General provisions

~~The~~ Suids ~~pig and its close relatives~~ are the only natural non-arthropod hosts for African swine fever virus (ASFV). These include all varieties of *Sus scrofa* (pig), both domestic and *wild*, and African *wild* suid species including warthogs (*Phacochoerus* spp.), bushpigs (*Potamochoerus* spp.) and the giant forest hog (*Hylochoerus meinertzhageni*).

For the purposes of this chapter, a distinction is made among ~~between~~: ~~domestic pigs (permanently captive and farmed free range pigs) and wild pigs (including feral pigs and wild boar) as well as between *Sus scrofa* and African pig species.~~

- domestic and *captive wild* pigs, permanently captive or farmed free range, used for the production of *meat*, or other commercial products or use, or for breeding;
- *wild* and *feral* pigs;
- African *wild* suid species.

All varieties of *Sus scrofa* are susceptible to the pathogenic effects of ASFV, while the African *wild* suids ~~pigs~~ are not and may act as reservoirs of the virus ~~*infection*~~. Ticks of the genus *Ornithodoros* are the only known natural arthropod hosts of the virus and act as reservoirs and biological *vectors* ~~of the *infection*~~.

For the purposes of the *Terrestrial Code*, African swine fever (ASF) is defined as an *infection* of suids with ASFV.

The following defines the occurrence of *infection* with ASFV:

1) ASFV has been isolated from samples from a suid;

OR

2) antigen or nucleic acid specific to ASFV has been detected in samples from a suid showing clinical signs or pathological lesions suggestive of ASF or epidemiologically linked to a suspected or confirmed *case* of ASF, or from a suid giving cause for suspicion of previous association or contact with ASFV~~, whether or not clinical signs or pathological lesions consistent with ASF are present~~;

OR

3) antibodies specific to ASFV have been identified in samples from a suid showing clinical signs or pathological lesions consistent with ASF, or epidemiologically linked to a suspected or confirmed *case* of ASF, or giving cause for suspicion of previous association or contact with ASFV.

For the purposes of the *Terrestrial Code*, the *incubation period* in *Sus scrofa* ~~is~~ shall be 15 ~~19~~ days.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

Annex 17 (contd)

Article 15.1.2.

General criteria for the ~~Determination~~ determination of the ASF status of a country, zone or compartment

~~The African swine fever (ASF) status of a country, *zone* or *compartment* can only be determined after considering the following criteria in domestic and wild pigs, as applicable:~~

1) ASF ~~should be~~ is a *notifiable disease* in the entire ~~whole~~ country, and all suids showing clinical signs suggestive of ASF are subjected to appropriate field and *laboratory* investigations;

2) an ongoing awareness programme is in place to encourage reporting of all ~~*cases*~~ suids showing signs suggestive of ASF;

3) the *Veterinary Authority* has current knowledge of, and authority over, all domestic and *captive wild* pig *herds* in the country, *zone* or *compartment*;

4) the *Veterinary Authority* has current knowledge of ~~about~~ the species of *wild* and *feral* pigs and African *wild* suids present, their distribution ~~population~~ and habitat ~~of *wild* pigs~~ in the country or *zone*~~.~~;

5) for domestic and *captive wild* pigs, an appropriate *surveillance* programme in accordance with Articles15.1.22. to 15.1.25. and 15.1.27. is in place;

6) for *wild* and *feral* pigs, and for African *wild* suids, if present in the country or *zone*, a *surveillance* programme is in place in accordance with Article 15.1.26., considering the presence of natural and artificial boundaries, the ecology of the *wild* and *feral* pig and African *wild* suid populations and an assessment of the likelihood of ASF spread including taking into account the presence of *Ornithodoros* ticks where relevant;

7) the domestic and *captive wild* pig populations are separated by appropriate *biosecurity*, effectively implemented and supervised, from the *wild* and *feral* pig and African *wild* suid populations, based on the assessed likelihood of spread within the *wild* and *feral* pig and African *wild* suid populations, and *surveillance* in accordance with Article 15.1.26.~~.~~; ~~the domestic and *captive wild* pig population should be separated by appropriate *biosecurity*, effectively implemented and supervised, from the *wild* and *feral* pig and African *wild* suid populations and~~ they are also protected from *Ornithodoros* ticks where relevant.

Commodities of domestic or *captive wild* pigs can be traded safely in accordance with the relevant articles of this chapter from countries complying with the provisions of this article, even if they notify *infection* with ASFV in *wild* or *feral* pigs or African *wild* suids.

Article 15.1.3.

Country or zone free from ASF ~~free country, zone or compartment~~

1. ~~Historically free status~~ Historical freedom

   A country or *zone* may be considered free from ASF without ~~formally applying a~~ pathogen-specific *surveillance* ~~programme~~ if the provisions of point 1 *a)* of Article 1.4.6. are complied with.

2. ~~Free status as a result of an eradication programme~~ Freedom in all suids

   A country or *zone* which does not meet the conditions of point 1 above may be considered free from ASF when it complies with all the criteria of Article 15.1.2. and when:

   a) *surveillance* in accordance with Articles 15.1.22. to 15.1.27. has been in place for the past three years;

   b) there has been no *case* of *infection* with ASFV during the past three years; this period can be reduced to 12 months when the *surveillance* has demonstrated no evidence of presence or involvement of *Ornithodoros* ticks;

   c) pig *commodities* are imported in accordance with Articles 15.1.5. to 15.1.17.

Annex 17 (contd)

3. Freedom in domestic and captive wild pigs

A country or *zone* which does not meet the conditions of point 1 or 2 above ~~or a *compartment*~~ may be considered free from ASF in domestic and *captive wild* pigs when it complies with all the criteria of Article 15.1.2. and when:

a) *surveillance* in accordance with Articles 15.1.22. to 15.1.27. has been in place for the past three years;

b~~a~~) there has been no ~~*outbreak*~~ *case* of *infection* with ASFV in domestic or *captive wild* pigs during the past three years; this period can be reduced to 12 months when the *surveillance* has demonstrated no evidence of presence or involvement of *Ornithodoros* ticks;

~~*b) no evidence of ASFV *infection* has been found during the past 12 months;~~

~~*c) *surveillance* has been in place in domestic pigs for the past 12 months;~~

c~~*d*~~*)* ~~imported domestic~~ pigs and pig *commodities* are imported in accordance ~~comply~~ with ~~the requirements of in~~ Article~~s~~ 15.1.5. ~~or~~ to ~~Article~~ 15.1.~~6~~17.

~~AND~~

~~Based on *surveillance*, ASF *infection* has been demonstrated not to be present in any wild pig population in the country or *zone*, and:~~

~~*e) there has been no clinical evidence, nor virological evidence of ASF in wild pigs during the past 12 months;~~

~~*f) no seropositive wild pigs have been detected in the age class 6–12 months during the past 12 months;~~

~~*g) imported wild pigs comply with the requirements in Article 15.1.7.~~

Article 15.1.3bis.

Compartment free from ASF

The establishment of *compartment* free from ASF should follow the relevant requirements of this chapter and the principles in Chapters 4.3. and 4.4.

Article 15.1.3ter.

Establishment of a containment zone within a country or zone free from ASF

In the event of limited *outbreaks* of ASF within a country or *zone* previously free from ASF, including within a *protection zone*, a *containment zone*, which includes all *outbreaks*, may be established for the purpose of minimising the impact on the entire country or *zone*.

In addition to the requirements for the establishment of a *containment zone* outlined in point 3 of Article 4.3.3., the *surveillance* programme should take into account the presence and potential role of *Ornithodoros* ticks and of *wild* and *feral* pigs and African *wild* suids and any measures in place to avoid their dispersion.

The free status of the areas outside the *containment zone* is suspended while the *containment zone* is being established. The free status of these areas outside the *containment zone* may be reinstated irrespective of the provisions of Article 15.1.4., once the *containment zone* is clearly established. It should be demonstrated that *commodities* for *international trade* either have originated outside the *containment zone* ~~unless these *commodities*~~ or comply with the provisions in Articles 15.1.6., 15.1.9., 15.1.11. and Articles 15.1.13. to 15.1.17.

The recovery of the free status of the *containment zone* should follow the provisions of Article 15.1.4.

Annex 17 (contd)

Article 15.1.4.

Recovery of free status

Should an ~~ASF~~ *outbreak* of ASF occur in a previously free country~~,~~ or *zone* ~~or *compartment*~~, ~~the free~~ its status may be restored three months after the *disinfection* of the last infected *establishment*, provided that:

~~where *surveillance* has been carried out with negative results, either:~~

1) ~~three months after the last *case* where~~ a *stamping-out policy* ~~is~~ has been implemented ~~practised and in the case where ticks are suspected to be involved in the epidemiology of the *infection*~~, and, in the case where ticks are suspected or known to be involved in the epidemiology of the *infection*, has been followed by ~~acaricide treatment and~~ the use of sentinel pigs in the infected *establishments* for two months; ~~or~~

2) *surveillance* in accordance with Article 15.1.25. has been carried out with negative results.

~~2~~) ~~where a *stamping-out policy* is not practised~~ Otherwise, the provisions of point 2 of Article 15.1.3. apply ~~should be followed~~.

~~AND~~

~~Based on *surveillance*, ASF *infection* has been demonstrated not to be present in any wild pig population in the country or *zone*.~~

Article 15.1.5.

Recommendations for importation from ~~ASF free~~ countries, zones or compartments free from ASF

For domestic and *captive wild* pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that ~~the animals~~:

1) the animals showed no clinical sign of ASF on the day of shipment;

2) the animals were kept in a~~n ASF free~~ country, *zone* or *compartment* free from ASF since birth or for at least the past ~~40 days~~ three months;

3) if the animals are exported from a free *zone* or *compartment* within an *infected* country or *zone*, necessary precautions were taken to avoid contact with any source of ASFV until shipment.

Article 15.1.6.

Recommendations for importation from countries or zones ~~considered infected with~~ not free from ASF

For domestic and *captive wild* pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

1) showed no clinical sign of ASF on the day of shipment;

2) and either:

   a) were kept since birth or for the past ~~40 days~~ three months in a~~n ASF free~~ *compartment* free from ASF~~.~~; or

   b) were kept in a *quarantine station*, isolated for 30 days prior to shipment, and were subjected to a virological test and a serological test performed at least 21 days after entry into the *quarantine station*, with negative results.

~~Article 15.1.7.~~

~~**Recommendations for importation from ASF free countries or zones**~~

~~For wild pigs~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the *animals*:~~

~~1) showed no clinical sign of ASF on the day of shipment;~~

~~2) have been captured in an ASF free country or *zone*;~~

~~and, if the *zone* where the *animal* has been captured is adjacent to a *zone* with *infection* in wild pigs:~~

~~3) were kept in a *quarantine station* for 40 days prior to shipment, and were subjected to a virological test and a serological test performed at least 201 days after entry into the *quarantine station*, with negative results.~~

Article 15.1.8.

Recommendations for importation from ~~ASF free~~ countries, zones or compartments free from ASF

For semen of domestic and *captive wild* pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor ~~*animals*~~ males:

   a) were kept in a~~n ASF free~~ country, *zone* or *compartment* free from ASF since birth or for at least ~~40 days~~ three months prior to collection;

   b) showed no clinical sign of ASF on the day of collection of the semen;

2) the semen was collected, processed and stored in ~~conformity~~ accordance with ~~the provisions of~~ Chapters 4.5. and 4.6.

Article 15.1.9.

Recommendations for importation from countries or zones ~~considered infected with~~ not free from ASF

For semen of domestic and *captive wild* pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor ~~*animals*~~ males:

   a) were kept ~~in an ASF free *compartment*~~ since birth or for at least ~~40 days~~ three months prior to collection in an *establishment,* in which *surveillance* in accordance with Articles 15.1.22. to 15.1.24. demonstrates that no *case* of ASF has occurred in the past three years; this period can be reduced to 12 months when the *surveillance* demonstrates that there is no evidence of tick involvement in the epidemiology of the *infection*;

   b) showed no clinical sign of ASF on the day of collection of the semen ~~and for the following 40 days~~;

2) the semen was collected, processed and stored in ~~conformity~~ accordance with ~~the provisions of~~ Chapters 4.5. and 4.6.

Annex 17 (contd)

Article 15.1.10.

Recommendations for importation from ~~ASF free~~ countries, zones or compartments free from ASF

For *in vivo* derived embryos of domestic pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor females:

   ~~a)~~ ~~were kept in an ASF free country, *zone* or *compartment* since birth or for at least 40 days prior to collection;~~

   a) were kept in a country, *zone* or *compartment* free from ASF since birth or for at least three months prior to collection;

   b) showed no clinical sign of ASF on the day of collection of the embryos;

2) the semen used to fertilise the oocytes complied with ~~fertilisation was achieved with semen meeting~~ the conditions referred to in Articles 15.1.7. or 15.1.8., as relevant;

3~~2~~) the embryos were collected, processed and stored in ~~conformity~~ accordance with the relevant provisions of Chapters 4.7. and 4.9.~~, as relevant.~~

Article 15.1.11.

Recommendations for importation from countries or zones ~~considered infected with~~ not free from ASF

For *in vivo* derived embryos of domestic pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor females:

   a) were kept ~~in an ASF free~~ ~~*compartment*~~ since birth or for at least ~~40 days~~ three months prior to collection in an *establishment*, in which *surveillance* in accordance with Articles 15.1.22. to 15.1.24. demonstrates that no *case* of ASF has occurred in the past three years; this period can be reduced to 12 months when the *surveillance* demonstrates that there is no evidence of tick involvement in the epidemiology of the *infection*;

   b) showed no clinical sign of ASF on the day of collection of the embryos ~~and for the following 40 days~~;

   c) were subjected to a serological test performed at least 21 days after collection, with negative results;

2) the semen used to fertilise the oocytes complied with ~~fertilisation was achieved with semen meeting~~ the conditions referred to in Article 15.1.7. or 15.1.8., as relevant;

3~~2~~) the embryos were collected, processed and stored in ~~conformity~~ accordance with the relevant provisions of Chapters 4.7. and 4.9.~~, as relevant.~~

Article 15.1.12.

Recommendations for importation from ~~ASF free~~ countries, zones or compartments free

from ASF

For *fresh meat* of domestic and *captive wild* pigs

Annex 17 (contd)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *fresh meat* comes from animals which:

1) have been kept in an ASF free country, *zone* or *compartment* free from ASF since birth or for at least the past 40 days, or which have been imported or introduced in accordance with Article 15.1.5. or 15.1.6.;

2) have been slaughtered in an approved *slaughterhouse*/*abattoir*, where they have been subjected with favourable results to ante- and post-mortem inspections in accordance with Chapter 6.2., and have been found free of any sign suggestive of ASF.

Article 15.1.12bis.

Recommendations for importation from countries or zones not free from ASF

For *fresh meat* of domestic and *captive wild* pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the entire consignment of *fresh meat* comes from animals which originated from *herds* in which *surveillance* in accordance with Articles 15.1.22. to 15.1.24. demonstrates that no *case* of ASF has occurred in the past three years. This period can be reduced to 12 months when the *surveillance* demonstrates that there is no evidence of tick involvement in the epidemiology of the *infection.* In addition, samples from a statistically representative number of animals were tested for ASF, with negative results;

2) the entire consignment of *fresh meat* comes from animals which have been slaughtered in an approved *slaughterhouse*/*abattoir*, have been subjected with favourable results to ante- and post-mortem inspections in accordance with Chapter 6.2.;

3) necessary precautions have been taken after *slaughter* to avoid contact of the *fresh meat* with any source of ASFV.

Article 15.1.13.

Recommendations for importation ~~from ASF free countries or zones~~ of fresh meat of wild and feral pigs

~~For fresh meat of wild pigs~~

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that~~:~~

~~1)~~ the entire consignment of *fresh meat* comes from animals which:

1~~a~~) ~~have been killed in an ASF free country or *zone* -~~have been killed in a country or *zone* free from ASF in accordance with point 1) or 2) of Article 15.1.3.;

2~~b~~) have been subjected with favourable results to a post-mortem inspection in accordance with Chapter 6.2. in an ~~approved~~ examination ~~centre~~ facility approved by the *Veterinary Authority* for export purposes, ~~and have been found free of any sign suggestive of ASF;~~.

~~and, if the *zone* where the *animal* has been killed is adjacent to a *zone* with *infection* in *wild* pigs:~~

~~2)~~ ~~samples has been collected from every animal killed and has been subjected to a virological test and a serological test for ASF, with negative results.~~

Annex 17 (contd)

Article 15.1.14.

Recommendations for the importation of meat products of pigs ~~(either domestic or wild), or for products of animal origin (from fresh meat of pigs) intended for use in animal feeding, for agricultural or industrial use, or for pharmaceutical or surgical use, or for trophies derived from wild pigs~~

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the products:

1) have been prepared:

   a) exclusively from *fresh meat* meeting the relevant conditions ~~laid down~~ in Articles 15.1.12., 15.1.12bis. ~~or~~ and 15.1.13.~~, as relevant~~;

   b) in a processing ~~establishment~~ facility:

      i) approved by the *Veterinary Authority* for export purposes;

      ii) processing only *meat* meeting the relevant conditions ~~laid down~~ in Article 15.1.12. or 15.1.13.~~, as relevant~~;

OR

2) have been processed in a~~n~~ ~~establishment~~ facility approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of ~~the~~ ASFV in accordance with Article 15.1.19., and that the necessary precautions were taken after processing to avoid contact of the product with any source of ASFV.

~~Article 15.1.15.~~

~~**Recommendations for the importation of pig products of animal origin (from pigs, but not derived from fresh meat) intended for use in animal feeding and for agricultural or industrial use**~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that these products:~~

~~1) have been prepared:~~

   ~~*a)* exclusively from *fresh meat* meeting the conditions laid down in Articles 15.1.12. or 15.1.13., as relevant;~~

   ~~*b)* in a processing establishment:~~

      ~~*i)* approved by the *Veterinary Authority* for export purposes;~~

      ~~*ii)* processing only *meat* meeting the conditions laid down in Articles 15.1.12. or 15.1.13., as relevant;~~

~~OR~~

~~2) have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the ASFV, and that the necessary precautions were taken after processing to avoid contact of the product with any source of ASFV.~~

Article 15.1.16.

Recommendations for the importation of bristles ~~(from pigs)~~

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that ~~these products~~ bristles:

1) originated from domestic or *captive wild* pigs in ~~come from an ASF free~~ a country, *zone* or *compartment* free from ASF and have been processed in a facility approved by the *Veterinary Authority* for export purposes; or

2) have been processed in a facility approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of ~~the~~ ASFV in accordance with one of the processes listed in Article 15.1.21bis., and that the necessary precautions were taken after processing to avoid contact of the product with any source of ASFV.

~~Article 15.1.17.~~

~~**Recommendations for the importation of litter and manure (from pigs)**~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that these products:~~

~~1) come from an ASF free country, *zone* or *compartment*; or~~

~~2) have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the ASFV, and that the necessary precautions were taken after processing to avoid contact of the product with any source of ASFV.~~

Article 15.1.17. (Reinstated)

Recommendations for the importation of litter and manure from pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products:

1) originated from domestic or *captive wild* pigs in a country, *zone* or *compartment* free from ASF; or

2) have been processed in a facility approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the ASFV in accordance with one of the processes listed in Article 15.1.21ter., and that the necessary precautions were taken after processing to avoid contact of the product with any source of ASFV.

Article 15.1.17bis.

Recommendations for the importation of skins and trophies from suids

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products:

1) originated from suids in a country or *zone* free from ASF in accordance with point 1 or point 2 of Article 15.1.3. and have been processed in a facility approved by the *Veterinary Authority* for export purposes; or

2) originated from domestic or *captive wild* pigs in a country, *zone* or *compartment* free from ASF and have been processed in a facility approved by the *Veterinary Authority* for export purposes; or

3) have been processed in a facility approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of ASFV in accordance with one of the procedures referred to in Article 15.1.21., and that the necessary precautions were taken after processing to avoid contact of the product with any source of ASFV.

Article 15.1.17ter.

Recommendations for the importation of other pig products

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products:

1) originated from domestic or *captive wild* pigs in a country, *zone* or *compartment* free from ASF and have been prepared in a processing facility approved by the *Veterinary Authority* for export purposes;

Annex 17 (contd)

OR

2) have been processed in a facility approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of ASFV, and that the necessary precautions were taken after processing to avoid contact of the product with any source of ASFV.

Article 15.1.18.

Procedures for the inactivation of ASFV in swill

For the inactivation of ASFV in swill, one of the following procedures should be used:

1) the swill is maintained at a temperature of at least 90°C for at least 60 minutes, with continuous stirring; or

2) the swill is maintained at a temperature of at least 121°C for at least 10 minutes at an absolute pressure of 3 bar; or

3) the swill is subjected to an equivalent treatment that has been demonstrated to inactivate ASFV.

Article 15.1.19.

Procedures for the inactivation of ASFV in meat

For the inactivation of ASFV in *meat*, one of the following procedures should be used:

1. Heat treatment

   Meat should be subjected to one of the following:

   a) heat treatment in a hermetically sealed container with a Fo value of 3.00 or more; or

   b) heat treatment for at least 30 minutes at a minimum temperature of 70°C, which should be reached throughout the *meat*.

2. Dry cured pig meat

   Meat should be cured with salt and dried for a minimum of six months.

Article 15.1.20.

Procedures for the inactivation of ASFV in casings of pigs

For the inactivation of ASFV ~~present~~ in *casings* of pigs, the following procedures should be used: treating for at least 30 days either with dry salt (NaCl) or with saturated brine (Aw < 0.80), or with phosphate supplemented dry salt containing 86.5% NaCl, 10.7% Na_2HPO_4 and 2.8% Na_3PO_4 (weight/weight/weight)~~, and kept~~ at a temperature of ~~greater than~~ 12°C or above during this entire period.

Article 15.1.21.

Procedures for the inactivation of ASFV in skins and trophies

For the inactivation of ASFV in skins and trophies, one of the following procedures should be used:

1) boiling in water for an appropriate time so as to ensure that any matter other than bone, tusks or teeth is removed; or

2) soaking, with agitation, in a 4% (w/v) solution of washing soda (sodium carbonate–Na_2CO_3) maintained at pH 11.5 or above for at least 48 hours; or

3) soaking, with agitation, in a formic acid solution (100 kg salt [NaCl] and 12 kg formic acid per 1,000 litres water) maintained ~~at~~ below pH 3.0 for at least 48 hours; wetting and dressing agents may be added; or

4) in the case of raw hides, treating for at least 28 days with salt (NaCl) containing 2% washing soda (sodium carbonate–Na_2CO_3); or

5) treatment with 1% formalin for a minimum of six days.

Article 15.1.21bis.

Procedures for the inactivation of ASFV in bristles

For the inactivation of ASFV ~~present~~ in bristles for industrial use, one of the following procedures should be used:

1) boiling for at least 30 minutes;

2) immersion for at least 24 hours in a 1% solution of formaldehyde.

Article 15.1.21ter.

Procedures for the inactivation of ASFV in litter and manure from pigs

For the inactivation of ASFV ~~present~~ in litter and manure of pigs, one of the following procedures should be used:

1) moist heat treatment for at least one hour at a minimum temperature of 55°C;

2) moist heat treatment for at least 30 minutes at a minimum temperature of 70°C.

Article 15.1.22.

Introduction to surveillance

Articles 15.1.22. to 15.1.27. provide recommendations for *surveillance* for ASF, and are complementary to Chapters 1.4. and 1.5. The impact and epidemiology of ASF may vary in different regions of the world, as does the routine *biosecurity* in different production systems. The *surveillance* strategies employed for determining ASF status should be adapted to the situation. The approach used should take into account the presence of *wild* or *feral* pigs or African *wild* suids, the presence of *Ornithodoros* ticks, and the presence of ASF in adjacent countries or *zones*.

Surveillance for ASF should be in the form of an ongoing programme designed to establish that susceptible populations in a country, *zone* or *compartment* are free from *infection* with ASFV or to detect the introduction of ASFV into a free population. Consideration should be given to the specific characteristics of ASF epidemiology which include:

– the role of swill feeding;

– the impact of different systems of production of domestic and *captive wild* pigs;

– the role of *wild* and *feral* pigs and African *wild* suids on the maintenance and spread of the *disease*;

– whether *Ornithodoros* ticks are present and the role they may play in the maintenance and spread of the *disease*;

– the lack of pathognomonic gross lesions and clinical signs;

– the occurrence of carriers;

– the genotypic variability of ASFV.

Annex 17 (contd)

Article 15.1.23.

General conditions and methods for surveillance

1) A *surveillance* system in accordance with Chapter 1.4. and under the responsibility of the *Veterinary Authority* should address the following:

a) a formal and ongoing system for detecting and investigating *cases* of ASF;

b) a procedure for the rapid collection and transport of samples from suspected *cases* to a *laboratory*;

c) appropriate *laboratory* testing capability for ASF diagnosis;

d) a system for recording, managing and analysing diagnostic and *surveillance* data.

2) The ASF *surveillance* programme should:

a) include an *early detection system* throughout the production, marketing and processing chain for reporting suspected *cases*. Diagnosticians and those with regular contact with pigs should report promptly any suspicion of ASF to the *Veterinary Authority*. The reporting system under the *Veterinary Authority* should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary paraprofessionals*) by government or private sector awareness programmes targeted to all relevant stakeholders. Personnel responsible for *surveillance* should be able to seek expertise in ASF diagnosis, epidemiological evaluation and control;

b) conduct, when relevant, regular and frequent clinical inspections and *laboratory* testing of high-risk groups (for example, where swill feeding is practised), or those adjacent to an ASF infected country or *zone* (for example, bordering areas where infected *wild* and *feral* pigs or African *wild* suids are present).

Article 15.1.24.

Surveillance strategies

1. Introduction

The population covered by *surveillance* aimed at detecting *disease* and *infection* should include domestic, *captive wild*, *wild* and *feral* suid populations within the country or *zone*. *Surveillance* should be composed of random and non-random approaches using clinical, virological and serological methods appropriate for the *infection* status of the country or *zone*.

The strategy employed to establish the prevalence or absence of *infection* with ASFV may be based on randomised or non-randomised clinical investigation or sampling at an acceptable level of statistical confidence. If an increased likelihood of *infection* in particular localities or *subpopulations* can be identified, targeted sampling may be an appropriate strategy. This may include:

a) specific high-risk *wild* and *feral* suid populations and their proximity;

b) farms which feed swill;

c) pigs reared outdoors.

Risk factors may include, for example, temporal and spatial distribution of past *outbreaks*, and pig movements and demographics.

Member Countries should review their *surveillance* strategies whenever an increase in the *risk* of incursion of ASFV is perceived. Such changes include but are not limited to:

- an emergence or an increase in the prevalence of ASF in countries or *zones* from which live pigs or products are imported;
- an increase in the prevalence of ASF in *wild* or *feral* suids in the country or *zone*;
- an increase in the prevalence of ASF in adjacent countries or *zones*;
- an increased entry of, or exposure to, infected *wild* or *feral* suid populations from adjacent countries or *zones*;
- evidence of involvement of ticks in the epidemiology of ASF as demonstrated by *surveillance* implemented in accordance with Chapter 1.5.

2. Clinical surveillance

Clinical *surveillance* is the most effective tool for detecting ASF due to severe clinical signs and pathology associated with *infection* with ASFV. However, due to the clinical similarity with other *diseases* such as classical swine fever, porcine reproductive and respiratory syndrome and erysipelas, and those associated with porcine circovirus 2 *infection*, clinical *surveillance* should be supplemented, as appropriate, by serological and virological *surveillance*.

Clinical signs and pathological findings are useful for early detection; in particular, any *cases* where clinical signs or lesions suggestive of ASF are accompanied by high mortality should be investigated without delay.

Wild and *feral* suids rarely present the opportunity for clinical observation, but should form part of any *surveillance* scheme and should, ideally, be monitored for virus as well as antibodies.

3. Virological surveillance

Virological *surveillance* is important for early detection, differential diagnosis and for systematic sampling of target populations. It should be conducted:

a) to investigate clinically suspected *cases*;

b) to monitor at risk populations;

c) to follow up positive serological results;

d) to investigate increased mortality when ASF cannot be ruled out;

e) to confirm eradication after a *stamping-out policy* has been applied.

Molecular detection methods can be applied to large-scale screening for the presence of virus. If targeted at high-risk groups, they provide an opportunity for early detection that can considerably reduce the subsequent spread of ASFV. Epidemiological understanding of the pathways of spread of ASFV can be greatly enhanced by molecular analyses of viruses in endemic areas and those involved in *outbreaks* in areas previously free from ASF. Therefore, ASFV isolates should be sent to an OIE Reference Laboratory for further characterisation.

4. Serological surveillance

Serology is an effective and efficient *surveillance* tool. Serological *surveillance* aims at detecting antibodies against ASFV. Positive ASFV antibody test results can indicate an ongoing or past *outbreaks*, since some animals may recover and remain seropositive for a significant period, possibly life. This may include carrier animals. However, ASF serology is not suitable for early detection.

It may be possible to use sera collected for other survey purposes for ASF *surveillance*. However, the principles of survey design and the requirement for statistical validity should not be compromised.

Annex 17 (contd)

Article 15.1.25.

Surveillance ~~procedures~~ for recovery of free status

In addition to the general conditions described in Articles 15.1.3. and 15.1.4., a Member Country seeking recovery of free status for the entire country or a *zone*, including for a *containment zone*, should show evidence of an active *surveillance* programme to demonstrate no evidence of *infection* with ASFV.

The domestic and *captive wild* pig populations should undergo regular clinical and pathological examinations and virological and serological testing, planned and implemented according to the general conditions and methods described in this chapter.

This *surveillance* programme should include:

1) *establishments* in the proximity of the *outbreaks*;

2) *establishments* epidemiologically linked to the *outbreaks*;

3) animals moved from or used as sentinels or to repopulate affected *establishments*;

4) all *establishments* where contiguous culling has been carried out;

5) *wild* and *feral* suid populations in the area of the *outbreaks*.

Article 15.1.26.

Surveillance for ASFV in wild and feral pigs and African wild suids

1) The objective of a *surveillance* programme is either to demonstrate that *infection* with ASFV is not present in *wild* and *feral* suids or, if known to be present, to estimate the geographical distribution of the *infection*.

   Surveillance in *wild* and *feral* suids presents additional challenges including:

   a) determination of the distribution, size and movement patterns of the *wild* and *feral* suid population;

   b) relevance and practicality of assessing the possible presence of *infection* with ASFV in the population;

   c) determination of the practicability of establishing a *zone* taking into account the degree of interaction with domestic and *captive wild* pigs within the proposed *zone*.

   The geographic distribution and estimated size of *wild* and *feral* suid populations should be assessed as a prerequisite for designing a population monitoring system following Chapter 1.4.

2) For implementation of the *surveillance* programme, the limits of the area over which *wild* and *feral* pigs range should be defined. *Subpopulations* of *wild* and *feral* suids may be separated from each other by natural or artificial barriers.

3) The *surveillance* programme may include animals found dead, road kills, animals showing abnormal behaviour and hunted animals, and may also include awareness campaigns targeted at hunters and farmers.

4) There may be situations where a more targeted *surveillance* programme can provide additional assurance. The criteria to define high risk areas for targeted *surveillance* include:

   a) areas with past history of ASF;

   b) subregions with large populations of *wild* or *feral* pigs or African *wild* suids;

   c) border regions with ASF affected countries or *zones*;

d) interface between *wild* and *feral* pig populations, and domestic and *captive wild* pig populations;

e) areas with farms with free-ranging and outdoor pigs;

f) areas with a high level of hunting activity, where animal dispersion and feeding as well as inappropriate disposal of waste can occur;

g) other risk areas determined by the *Veterinary Authority* such as ports, airports, garbage dumps and picnic and camping areas.

Article 15.1.27.

Surveillance for arthropod vectors

Vector surveillance aims at defining the type and distribution of ticks of the genus *Ornithodoros*. Any species of *Ornithodoros* should be considered to be a potential *vector* or reservoir of ASFV. The virus is generally transmitted transstadially. Transovarial transmission has been observed only in ticks of the *Ornithodoros moubata* complex.

The ~~*Competent*~~ *Veterinary Authority* should have knowledge of the presence, distribution and identity of *Ornithodoros*, taking into account climatic or habitat changes that may affect distribution.

When *vector surveillance* is considered necessary, a sampling plan in accordance with Chapter 1.5. should take into account the biology and ecology of species present and, in particular, the favoured habitat of these species in burrows and structures associated with pig production. The plan should also take into account the distribution and density of pigs in the country or *zone*.

Sampling methods include CO_2 trapping and flagging, and vacuuming of burrows or structures.

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— Text deleted.

Annex 18

CHAPTER 15.X.

INFECTION WITH PORCINE REPRODUCTIVE AND RESPIRATORY SYNDROME VIRUS

EU position

The EU thanks the OIE and in general supports the adoption of this new chapter. Comments are inserted in the text below.

Article 15.X.1.

General provisions

The pig is the only natural host for porcine reproductive and respiratory syndrome virus (PRRSV).

For the purposes of the *Terrestrial Code*, porcine reproductive and respiratory syndrome (PRRS) is defined as an *infection* of domestic and *captive wild* pigs with PRRSV.

The following defines the occurrence of *infection* with PRRSV:

1) ~~a strain of~~ PRRSV, excluding vaccine strains, has been isolated from a sample~~s~~ from a domestic or *captive wild* pig;

OR

2) ~~viral~~ antigen ~~has been identified,~~ or ~~viral~~ ribonucleic acid specific to PRRSV, which is not a consequence of *vaccination,* has been ~~demonstrated to be present~~ detected in a sample~~s~~ from a domestic or *captive wild* pig epidemiologically linked to a confirmed or suspected ~~*outbreak*~~ *case* of PRRS, or giving cause for suspicion of previous association or contact with PRRSV, with or without clinical signs consistent with PRRS;

OR

3) a live PRRSV vaccine strain has been isolated or antigen or ribonucleic acid specific to a live PRRSV vaccine strain has been detected in a sample~~s~~ from a domestic or *captive wild* pig that is unvaccinated, or has been vaccinated with an inactivated vaccine, or with a different vaccine strain, showing clinical signs suggestive of PRRS, or epidemiologically linked to a suspected or confirmed *case*;

EU comment

The EU notes a degree of inconsistency in the case definitions in the different disease specific chapters. This should preferably be avoided. Reference is made to the EU comments on the case definition of Chapter 8.3. (see Annex 29), which are applicable also here.

OR

4~~3~~) ~~virus-specific~~ antibodies specific ~~against~~ to PRRSV, ~~that are not~~ unless they are demonstrated to be a consequence of *vaccination* ~~or maternally-derived immunity~~, have been identified in samples from a domestic or *captive wild* pig in a *herd* showing clinical signs consistent with PRRS, or epidemiologically linked to a confirmed or suspected *outbreak* of PRRS, or giving cause for suspicion of previous association or contact with PRRSV.

~~OR~~

~~4) the detection of a vaccinal or vaccine-like virus in a non-vaccinated domestic or *captive wild* pig.~~

For the purposes of the *Terrestrial Code*, the *incubation period* ~~for~~ of PRRS ~~is~~ shall be 14 days. ~~Pigs are usually infective between days 3~~ three ~~and 40~~ days post-*infection*~~, but can remain so for several months.~~

Commodities of domestic or *captive wild* pigs can be traded safely in accordance with the relevant articles of this chapter, even if *exporting countries* inform the OIE of the presence of *infection* with PRRSV in *wild* or *feral* pigs. ~~A Member Country should not impose bans on the trade in *commodities* of domestic and *captive wild* pigs in response to information on the presence of *infection* with PRRSV in *wild* or *feral* pigs.~~

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual.*

Article 15.X.2.

Safe commodities

When authorising import or transit of the following *commodities* and any products made from these *commodities* and containing no other tissues from pigs, *Veterinary Authorities* should not require any PRRS related conditions, regardless of the PRRS status of the *exporting country, zone* or *compartment*:

1) hides, skins and trophies;

2) bristles;

3) ~~*meat* and~~ *meat products* ~~from pigs that have passed ante- and post-mortem inspections~~;

EU position

As explained in previous EU comments, according to a scientific opinion of the European Food Safety Authority (https://www.efsa.europa.eu/en/efsajournal/pub/239), there is no PRRS-risk associated with fresh pig meat. The OIE recommendations should be based on science and risk analysis and should not create unjustified barriers in trade. The EU is therefore not content with the proposed deletion of meat from the list of safe commodities.

However, noting the wording of the newly proposed Article 15.X.12., the EU can nevertheless support the changes to point 3) above on the condition that that newly proposed Article 15.X.12. is kept unchanged.

4) *meat-and-bone meal*;

5) blood ~~by~~-products;

6~~5~~) *casings*;

7~~6~~) gelatine.

Article 15.X.3.

Country, zone or compartment free from PRRS

A country, *zone* or *compartment* may be considered free from PRRS when following conditions are met:

1) PRRS is a *notifiable disease* in the entire country;

2) an *early detection system* is in place;

3) *surveillance* in accordance with Articles 15.X.13~~15~~. to 15.X.16~~18~~. has been in place for at least 12 months~~, capable of detecting the presence of *infection* with PRRSV even in the absence of clinical signs~~;

4) there has been no ~~evidence of~~ occurrence of *infection* with PRRSV ~~has been found~~ in domestic and *captive wild* pigs during the past 12 months;

EU comment

While in principle supporting the change of "evidence of" to "occurrence of" in point 4) above, the EU suggests the following changes, in order to be in line with the amended wording as suggested in other chapters (e.g. Chapter 8.X.):

"4) ~~there has been~~ no occurrence of infection with PRRSV has been detected in domestic [...]".

Indeed, the occurrence of infection needs to be detected; occurrence per se would be unknown if it were not detected.

For reasons of consistency across the Code, the same changes should be introduced in other disease specific chapters (e.g. 15.1. and 15.2.).

5) no *vaccination* against PRRS with inactivated vaccines has been carried out during the past 12 months;

6) no *vaccination* against PRRS with modified live vaccines has been carried out during the past 24 months;

~~6)~~ ~~measures are in place to prevent the introduction of PRRSV;~~

7~~8~~) ~~imported~~ pigs and pig *commodities* are imported or introduced in accordance with ~~comply with the requirements in~~ Articles 15.X.5. to 15.X.12~~14~~.

Article 15.X.4.

Recovery of free status

Should a PRRS *outbreak* occur in a previously free country, *zone* or *compartment*, the free status may be restored three months after the disposal or *slaughter* of the last *case*, provided that:

– ~~by means of~~ a *stamping-out policy* or the *slaughter* of all susceptible animals in the infected *herds* followed by ~~cleaning and~~ *disinfection* of the ~~farm~~ *establishments*, has been implemented; ~~a modified stamping-out policy with or without *emergency vaccination*. Free status can be regained three months after the culling of the last *case* or vaccinated pig provided.~~

– *surveillance* ~~is~~ has been carried out in accordance with Articles 15.X.13~~15~~. to 15.X.16~~18~~. with negative results.

Where a *stamping-out policy* or depopulation by means of *slaughter* ~~*modified stamping-out policy* is~~ are not practised, ~~the provisions of~~ Article 15.X.3. applies.

Article 15.X.5.

Recommendations for importation from countries, zones or compartments free from PRRS

For domestic and captive wild pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

1) showed no clinical sign of PRRS on the day of shipment;

2) were kept in a country, *zone* or *compartment* free from PRRS since birth or for at least the past three months.

Article 15.X.6.

Recommendations for importation from countries or zones not free from PRRS

For domestic and captive wild pigs for breeding or rearing

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the ~~*animals*~~ pigs*:*

1) were kept, since birth or for at least three months prior to isolation, in an *establishment* in which no *infection* with PRRSV was detected within that period;

2) showed no clinical sign of PRRS on the day of shipment;

3~~2~~) have not been vaccinated against PRRS nor are they the progeny of vaccinated sows;

4~~3~~) were isolated for 28 days by application of *biosecurity* and subjected to a serological test for *infection* with PRRSV, with negative results, on two occasions, at an interval of not less than 21 days, the second test being performed within 15 days prior to shipment.

Article 15.X.7.

Recommendations for importation from countries or zones not free from PRRS

For domestic and captive wild pigs for slaughter

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals showed no clinical sign of PRRS on the day of shipment.

The pigs should be transported directly with appropriate *biosecurity* from the *place of shipment* to the *slaughterhouse*/*abattoir* for immediate *slaughter*.

~~Article 15.X.8.~~

~~**Recommendations for importation of wild and feral pigs**~~

~~Regardless of the PRRS status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the *animals:*~~

~~1)~~ ~~showed no clinical sign of PRRS on the day of shipment;~~

~~2)~~ ~~were isolated in a *quarantine station*, and were subjected to a serological test for PRRS, with negative results, on two occasions, at an interval of not less than 21 days, the second test being performed within 15 days prior to shipment;~~

~~3)~~ ~~have not been vaccinated against PRRS.~~

Article 15.X.8~~9~~.

Recommendations for importation from countries, zones or compartments free from PRRS

For semen of domestic and captive wild pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor ~~*animals*~~ males:

   a) were kept in a country, *zone* or *compartment* free from PRRS since birth or for at least three months prior to collection;

   b) showed no clinical sign of PRRS on the day of collection of the semen;

2) the semen was collected, processed and stored in ~~conformity with the provisions of~~ accordance with Chapters 4.5. and 4.6.

Article 15.X.9~~10~~.

Recommendations for importation from countries or zones not free from PRRS

For semen of domestic and captive wild pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor ~~*animals*~~ males have not been vaccinated against PRRS and:

   ~~a)~~ ~~and either:~~

   a~~i~~) were kept, since birth or for at least three months prior to entry into the pre-entry isolation facility in an *establishment* in which no pigs have been vaccinated against PRRS and no *infection* with PRRSV was detected within that period ~~without any evidence of PRRS~~;

   b~~ii~~) showed no clinical sign of PRRS on the day of entry into the pre-entry isolation facility and were ~~serologically tested~~ subjected to a serological test with negative results on samples collected on the same day ~~the day of entry into the pre-entry isolation facility~~;

   c~~iii~~) were kept in the pre-entry isolation facility for at least 28 days and were subjected to a serological test with negative results on samples collected ~~at least~~ no less than 21 days after entry;

   d~~iv~~) either:

      i) have been kept in an *artificial insemination centre* where, at least every month, serum samples from a statistically representative ~~sample~~ number of all donor males ~~is~~ are subjected ~~are all boars are subjected~~, ~~at least every month,~~ to an ~~serological~~ appropriate test for *infection* with PRRSV with negative results~~, at least every month~~. The sampling scheme should be designed to ensure that all donor males are tested every 12 months and at least once during their stay;

      OR

      ii~~b~~) ~~or~~ have been kept in an *artificial insemination centre* where all donor males

      ~~*i)* have been kept in an *artificial insemination centre* where all boars~~ were subjected to serological and virological examinations for *infection* with PRRSV, with negative results, on serum samples taken ~~seronegative for PRRS~~ on the day of collection;

      ~~*ii)* a sample of semen from each collection for export has been tested for PRRSV nucleic acid with negative results;~~

~~OR~~

2) the semen was collected, processed and stored in ~~conformity with the provisions of~~ accordance with the relevant articles in Chapters 4.5. and 4.6.

EU comment

The EU thanks the Code Commissions for having addressed its previous concerns on the article above. We note however that there are still questions as to whether the proposed sampling regime gives sufficient safety to ensuring semen free of PRRS for international trade. Indeed, we are aware of a case report (Nathues *et al*., 2014) that indicates that the frequent importation of boar semen from non-PRRSV-free countries, even if boar studs are declared PRRSV negative, poses a risk of PRRSV introduction. According to that case report, even a biweekly PRRSV monitoring did not prevent the introduction of infectious semen into a previously free country. This also confirms findings of an earlier risk assessment (Nathues *et al*., 2013), according to which current monitoring protocols in many boar studs cannot be considered sufficient for a timely detection of infection in the stud. The EU therefore suggests the Code Commission revise the above article at its next meeting with a view to even further clarifying the level of sampling to be reached in

the boar stud. This could be achieved by a amending the second sentence of point 1 d i) as follows:

"The sampling scheme should be designed with a specified level of confidence to ensure that PRRSV is not circulating at the artificial insemination centre and all donor males are tested every 12 months and at least once during their stay;"

References:

Nathues *et al.*, 2014, Transboundary and Emerging Diseases. An Outbreak of Porcine Reproductive and Respiratory Syndrome Virus in Switzerland Following Import of Boar Semen.

Nathues *et al.*, 2013, Transboundary and Emerging Diseases. Risk assessment of the introduction of porcine reproductive and respiratory syndrome virus via boar semen into Switzerland as an example of a PRRSV-free Country.

Article 15.X.10~~11~~.

Recommendations for importation of *in vivo* derived embryos of domestic and captive wild pigs from countries, zones or compartments free from PRRS

~~Regardless of the PRRS status of the country of origin,~~ *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1) the donor females were kept in a country, *zone* or *compartment* free from PRRS since birth or for at least three months prior to collection;

2) the donor females showed no clinical sign of PRRS on the day of collection ~~of the embryos~~;

3) the embryos were collected, processed and stored ~~in conformity with the relevant provisions of~~ in accordance with Chapters 4.7. ~~and~~ or 4.9., as relevant;

4) the semen used for the production of embryos complied with the provisions of Article 15.X.8. or 15.X.9.

Article 15.X.11~~12~~.

Recommendations for importation of *in vivo* derived embryos of domestic and captive wild pigs from countries or zones not free from PRRS

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor females:

   a) showed no clinical sign of PRRS on the day of collection;

   b) were subjected to a serological test for *infection* with PRRSV, with negative results, on two occasions, at an interval of not less than 21 days, the second test being performed within 15 days prior to embryo collection;

2) the embryos were collected, processed and stored in accordance with Chapters 4.7. or 4.9., as relevant;

3) the semen used for the production of embryos complied with the provisions of Article 15.X.8. or 15.X.9.

Article 15.X.12.

Recommendations for importation of fresh meat of domestic and captive wild pigs

Regardless of the PRRS status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *fresh meat* comes from pigs that

have been slaughtered in an approved *slaughterhouse/abattoir* and have been subjected with favourable results to ante- and post-mortem inspections in accordance with Chapter 6.2.

~~Article 15.X.12.~~

~~**Recommendations for importation of fresh meat of domestic and captive wild pigs**~~

~~Regardless of the PRRS status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *fresh meat*:~~

~~1) either:~~

~~*a)* comes from pigs that were kept in a country, *zone* or *compartment* free from PRRS since birth or for at least the past three months; or~~

~~*b)* does not contain:~~

~~– tonsils;~~

~~– thymus;~~

~~– lymph nodes of the head, neck, or thoracic or abdominal viscera;~~

~~2) comes from pigs that have been slaughtered in a *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections in accordance with Chapter 6.2. with favourable results.~~

~~does not contain lymphoid tissues of the head and neck, and thoracic and abdominal viscera; and~~

~~2) comes from *animals* which:~~

~~*a)* showed no clinical signs suggestive of PRRS within 24 hours before *slaughter*;~~

~~*b)* have been slaughtered in a *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections in accordance with Chapter 6.2.~~

~~Article 15.X.13.~~

~~**Recommendations for importation of fresh meat of wild and feral pigs**~~

~~Regardless of the PRRS status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *fresh meat*;~~

~~1) does not contain lymphoid tissues of the head and neck, and thoracic and abdominal viscera; and~~

~~2) comes from *animals* which:~~

~~*a)* have been subjected to a post-mortem inspection in accordance with Chapter 6.2. in an approved examination centre;~~

~~*b)* have been found free from any sign suggestive of PRRS.~~

~~Article 15.X.14.~~

~~**Recommendations for importation of offal**~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the entire consignment of offal or products containing offal comes from pigs coming from *establishments* located in a PRRS free country, *zone* or *compartment*.~~

Article 15.X.13~~15~~.

Introduction to surveillance

The following defines the principles and provides a guide to the *surveillance* for PRRS, complementary to Chapter 1.4. This may be for the entire country, a *zone* or a *compartment*. Guidance is also provided for Member Countries seeking recovery of PRRS status for the entire country, for a *zone* or for a *compartment*, following an *outbreak* and for the maintenance of PRRS status.

Surveillance should be capable of detecting the presence of *infection* with PRRSV even in the absence of clinical signs. *Surveillance* for PRRS should be in the form of a continuing programme designed to establish that domestic and *captive wild* pig populations in a country, *zone* or *compartment* are free from *infection* with PRRSV or to detect the introduction of PRRSV into a population already defined as free. Consideration should be given to the specific characteristics of PRRS epidemiology that include:

– the role of pig-to-pig contact;

– the role of semen in transmission of the virus;

– the ~~existence~~ possible occurrence of aerosol transmission ~~over short distances~~;

– the existence of two distinct genotypes of PRRSV, also with antigenic and virulence variability among strains of both genotypes;

– the frequency of clinically inapparent *infections*, particularly in older ~~*animals*~~ pigs;

– the possible occurrence of long-term virus-shedding even in the presence of antibodies;

– the lack of a differentiating test for vaccinal antibodies and the inherent risks associated with the use of modified live vaccines for PRRS.

Veterinary Authorities may have information on the genotype prevailing in the country but it should not be assumed that ~~the absence of~~ the other genotype ~~should not be assumed~~ is absent. Therefore, ~~molecular~~ virological and serological tests used for *surveillance* should be able to detect both genotypes and antibodies to both genotypes with similar sensitivity.

Article 15.X.14~~16~~.

General conditions and methods for surveillance

1) A *surveillance* system in accordance with Chapter 1.4. and under the responsibility of the *Veterinary Authority* should be in place and ~~including~~ include the following ~~aspects~~ elements:

   a) formal and ongoing system for detecting and investigating *outbreaks* of PRRS;

   b) a system for recording, managing and analysing diagnostic and *surveillance* data.

Annex 18 (contd)

2) ~~The~~ Any PRRS *surveillance* programme should:

a) include ~~a system for~~ the reporting and investigation of suspected *cases*. Diagnosticians and those with regular contact with pigs should report promptly any suspicion of PRRS to the *Veterinary Authority*;

b) implement, when relevant, regular and frequent clinical inspections and *laboratory* testing of populations at high-risk of contracting or spreading *disease*, such as *artificial insemination centres* and nucleus *herds*, *establishments* in high pig density areas or with ~~low~~ lax *biosecurity* ~~measures~~.

Article 15.X.15~~17~~.

Surveillance strategies

1. Introduction

The objective of *surveillance* is to estimate the *prevalence* of *infection*, demonstrate freedom ~~from *infection*~~ or ~~to~~ detect introduction of PRRSV as soon as possible.

~~Serology in unvaccinated populations is often the most effective and efficient *surveillance* methodology. In some *animals*, antibodies against PRRSV can disappear after approximately three to six months in the absence of further exposure and this should be considered when interpreting serological *surveillance* results.~~

~~In some circumstances such as clinical *disease* investigations and in high risk populations, virological *surveillance* may provide advantage through earlier detection.~~

The *surveillance* strategy chosen should be justified as adequate to detect the presence of *infection* with PRRSV in accordance with Chapter 1.4. and the epidemiological situation. Cumulative results of targeted and general *surveillance* will increase the level of confidence in the *surveillance* strategy.

2. Clinical surveillance

Clinical signs and pathological findings are useful for early detection. Episodes of high morbidity or mortality in young piglets and reproductive disorders in sows should also be investigated. Highly pathogenic strains may affect pigs of all ages and can include severe respiratory signs. In PRRSV *infections* involving low virulence strains, clinical signs may not be present or are seen only in young *animals*. Therefore, clinical *surveillance* should be supplemented by serological and virological *surveillance*.

3. Virological surveillance

In some circumstances such as clinical disease investigations and in high-risk populations, virological *surveillance* may provide an advantage through earlier detection.

Virological *surveillance* should be conducted:

a) to monitor high-risk populations;

b) to investigate clinically suspected *cases*;

c) to follow up positive serological results.

Molecular detection methods are most commonly used for virological *surveillance* and can be also applied to large-scale screening. If targeted at high-risk populations, they provide an opportunity for early detection that can considerably reduce the subsequent spread of *disease*. Molecular analysis can provide valuable information on genotype circulating in the country and enhance epidemiological understanding of the pathways of spread in endemic areas and those involved in *outbreaks* in *disease* free areas.

4. Serological surveillance

Serology in unvaccinated populations is often the most effective and efficient *surveillance* methodology. In some pigs, antibodies against PRRSV can disappear after approximately three to six months in the absence of further exposure and this should be considered when interpreting serological *surveillance* results.

In the absence of a test differentiating infected from vaccinated animals (DIVA), serology in vaccinated populations is less useful.

Maternal antibodies are generally detectable until four to eight weeks of age. The collection of samples should therefore take account of the type of *herd* and the age structure of the pigs, with an emphasis on older pigs. However, in countries or *zones* where *vaccination* has been recently discontinued, targeted serological *surveillance* of young unvaccinated ~~*animals*~~ pigs older than eight weeks can indicate the presence of *infection*.

Article 15.X.16~~18~~.

Additional surveillance requirements for recovery of free status

In addition to the general conditions described in this chapter, a Member Country declaring the recovery of country, *zone* or *compartment* PRRS free status should provide evidence of an active *surveillance* programme to demonstrate absence of *infection* with PRRSV.

This *surveillance* programme should cover:

1) *establishments* in the proximity of the *outbreaks*;

2) *establishments* epidemiologically linked to the *outbreaks*;

3) ~~*animals*~~ pigs moved from or used to repopulate affected *establishments*.

The pig *herds* should undergo regular clinical, pathological, virological and serological examinations, planned and implemented according to the general conditions and methods described in these recommendations. ~~To regain PRRS free status, the *surveillance* approach should provide at least the same level of confidence as within the original declaration of freedom.~~

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— Text deleted.

Annex 19

CHAPTER 4.11.

SOMATIC CELL NUCLEAR TRANSFER IN PRODUCTION LIVESTOCK AND HORSES

EU position

The EU supports the adoption of this modified article.

[Article 4.11.1.]

[…]

Article 4.11.4.

Background: risk analysis–general principles

1) *Risk analysis* in general includes *hazard* identification, *risk assessment*, *risk management* and *risk communication*. The *risk assessment* is the component of the analysis that estimates the *risks* associated with a *hazard* (see Chapter 2.1.). These principles are routinely used by regulators in making decisions about experimental or commercial releases. These analyses can then be used to determine whether the outcomes require management or regulation. *Risk management* is the process by which *risk* managers evaluate alternative actions or policies in response to the result~~(s)~~ of the *risk assessment* taking into consideration the various social, economic, and legal considerations that form the environment in which such activities occur.

2) For animal *diseases*, particularly those listed in the *Terrestrial Code*, there is broad agreement concerning the likely *risks* and *risk~~s~~* *assessments* can be qualitative or quantitative (see Chapter 2.1.). In *disease* scenarios it is more likely that a *qualitative risk assessment*, in which 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', is all that is required. *Qualitative assessments* do not require mathematical modelling to carry out routine decision-making. *Quantitative risk assessments* ~~or semi-quantitative risk assessments~~ assign magnitudes to the *risks* in numerical terms (e.g. 1/1,000,000)~~ or descriptive (high/medium/low) terms~~.

3) In the context of animal cloning, two broad categories of *risk assessments* are considered: absolute *risk assessment* and comparative *risk assessments*. Absolute *risk assessments* characterise *risk* independent of a comparator (e.g. the likelihood of an animal transmitting a specific livestock *disease*). A comparative *risk assessment* (or relative *risk assessment*) puts the *risk* in the context of a comparator. For example the degree to which an animal produced by one reproductive technology can transmit a particular *disease* to another animal of the same species compared with the degree to which a similar animal produced by another reproductive technology transmits the same *disease* to another animal of same species.

4) Regardless of the methodology used, *hazard* identification is an early step in all science-based *risk assessments*. In the context of assessing the *risks* associated with animal cloning (SCNT) and starting with the embryo and moving on through animal clone development and subsequent progeny, it is important to be clear at this juncture that only a comparative ~~semi-quantitative~~ *risk assessment* can be completed. A systematic, absolute, *quantitative risk assessment* of potential *risks* is difficult, due to the relative newness of the technology, and the variability in outcomes among laboratories and species cloned. Furthermore, with the technology of SCNT there is no introduced *hazard* from the insertion of novel genes (which may potentially happen in transgenesis). Thus, to analyse what factors contribute to animal health *risks*, the existing baseline must be analysed.

5) In short, the specific points where the *risk assessment* needs to be focused need to be identified. As illustrated in the accompanying diagram – the focus is to look at the basics of creating an embryo – using current terminology, starting from the selection of donor of oocyte and the cells to the creation of an embryo by the cloning methodology. The second phase will focus on the recipient of the embryo clone and the animal health and care considerations for the animals. The actual embryo clone that is born as an offspring is the third part of the paradigm that needs clear recommendations for assessment, and the next generation, either the progeny of the animal clone (which is a result of normal sexual reproduction) or animals produced by recloning (clones of clones) is the fourth and final stage.

[Article 4.11.5.]

[…]

— Text deleted.

Annex 20

CHAPTER 2.1.

IMPORT RISK ANALYSIS

EU position

The EU in general supports the adoption of this modified chapter. We note however that part of the glossary definition of "Transparency" (i.e. the 2nd sentence) is not captured in point 4 of Article 2.1.3.

Also, we note that the definition of "Transparency" is currently not proposed for deletion from the glossary (see Annex 4, Glossary Part A – Deletions), and suggest that both changes (to Chapter 2.1. and the corresponding changes to the glossary) be preferably be done at the same time.

Furthermore, we note that there is no urgency in adopting this change. As a general principle, it is preferable that Member Countries be given the opportunity to comment on changes in Code chapters before these are proposed for adoption.

Finally, a specific comment is inserted in the text below.

Article 2.1.1.

Introduction

The importation of *animals* and animal products involves a degree of *disease risk* to the *importing country*. This *risk* may be represented by one or several *diseases* or *infections*.

The principal aim of import *risk analysis* is to provide *importing countries* with an objective and defensible method of assessing the *disease risks* associated with the importation of *animals*, animal products, animal genetic material, feedstuffs, biological products and *pathological material*. The analysis should be transparent. This is necessary so that the *exporting country* is provided with clear reasons for the imposition of import conditions or refusal to import.

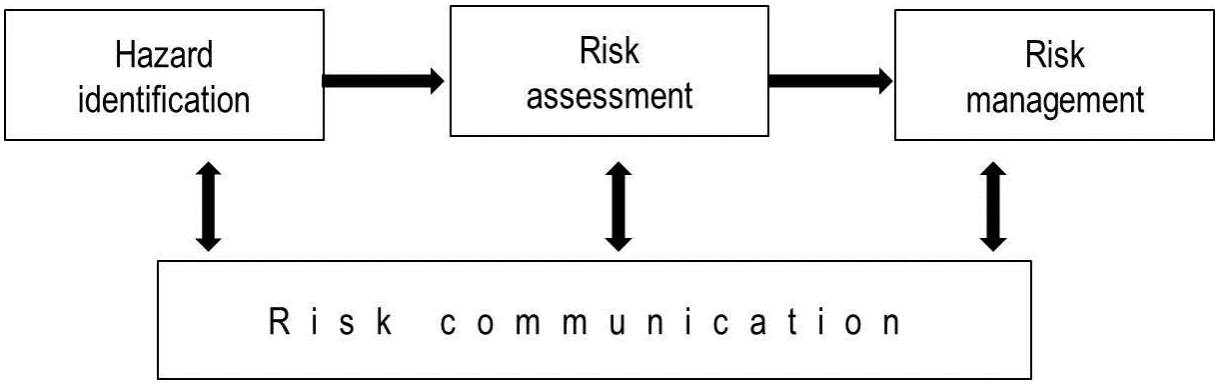
Transparency is also essential because data are often uncertain or incomplete and, without full documentation, the distinction between facts and the analyst's value judgements may blur.

EU comment

The EU suggests replacing "the analyst's value judgements may blur" by "the analyst's value opinion may be unclear" in the paragraph above, as these terms seem to better capture the intended. Indeed, the analyst does not "judge", nor is the distinction "blurred".

This chapter provides recommendations and principles for conducting transparent, objective and defensible *risk analyses* for *international trade*. The components of *risk analysis* are *hazard* identification, *risk assessment*, *risk management* and *risk communication* (Figure 1).

Fig. 1. The four components of risk analysis



The *risk assessment* is the component of the analysis which estimates the *risks* associated with a *hazard*. *Risk assessments* may be qualitative or quantitative. For many *diseases*, particularly for those *diseases* listed in this *Terrestrial Code* where there are well developed internationally agreed standards, there is broad agreement concerning the likely *risks*. In such cases it is more likely that a qualitative assessment is all that is required. Qualitative assessment does not require mathematical modelling skills to carry out and so is often the type of assessment used for routine decision making. No single method of import *risk assessment* has proven applicable in all situations, and different methods may be appropriate in different circumstances.

The process of import *risk analysis* usually needs to take into consideration the results of an evaluation of *Veterinary Services*, zoning, compartmentalisation and *surveillance* systems in place for monitoring of animal health in the *exporting country*. These are described in separate chapters in the *Terrestrial Code*.

[Article 2.1.2.]

[…]

Article 2.1.3.

Principles of risk assessment

1) *Risk assessment* should be flexible to deal with the complexity of real life situations. No single method is applicable in all cases. *Risk assessment* should be able to accommodate the variety of animal *commodities*, the multiple *hazards* that may be identified with an importation and the specificity of each *disease*, detection and *surveillance* systems, exposure scenarios and types and amounts of data and information.

2) Both *qualitative risk assessment* and *quantitative risk assessment* methods are valid.

3) The *risk assessment* should be based on the best available information that is in accord with current scientific thinking. The assessment should be well-documented and supported with references to the scientific literature and other sources, including expert opinion.

4) Consistency in *risk assessment* methods should be encouraged and *transparency* is essential in order to ensure fairness and rationality, consistency in decision making and ease of understanding by all the interested parties. Transparency means the comprehensive documentation of all data, information, assumptions, methods, results, discussion and conclusions used in the *risk analysis*.

5) *Risk assessments* should document the uncertainties, the assumptions made, and the effect of these on the final *risk* estimate.

6) *Risk* increases with increasing volume of *commodity* imported.

7) The *risk assessment* should be amenable to updating when additional information becomes available.

[…]

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Annex 37

WORK PROGRAMME FOR
THE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

EU comment
The EU thanks the OIE and supports the future work programme of the Code Commission.
In line with previous EU comments, we very much welcome the prospect of a deep review of the avian influenza chapter. That review should be very high on the OIE's list of priorities, and an ad hoc group of experts should be convened before the end of the year so as to start this essential work. Indeed, the latest worldwide avian influenza episode has again led to severe disruptions of international trade, which in part are due to the non-implementation of the existing OIE standards by OIE member countries. This applies in particular to zoning following disease outbreaks. The recent experience has however also illustrated the urgent need to revise certain key concepts in the avian influenza Code chapter. The EU would thus favour a clear distinction between the recommendations for infection with high vs. low pathogenicity avian influenza viruses and between commercial vs. non-commercial poultry, as well as a review of the process for regaining country or zone freedom including clear recommendations on the use of zoning and other risk mitigating measures taking into account the specificities of the respective viruses involved. We look forward to actively participating in this essential work and will make available to the OIE the scientific opinions of the European Food Safety Authority as soon as they become available. Furthermore, we reiterate our offer for technical support and expertise for the relevant ad hoc group of experts.
In addition, we would like to recall previous comments regarding the long-standing work on the Code chapter on BSE. We regret the apparent delay in the revision of this chapter and request that high priority is given to this topic so as to continue this important work and present a revised draft chapter for member country comments as soon as possible. As stated in previous EU comments, this revision should inter alia address the following: a risk based and proportionate surveillance, including for regaining a higher status; a revised system of surveillance points targets taking into account concerns of countries with small cattle populations; clear guidance ensuring an effective feed ban; and targeted recommendations for atypical BSE.
Finally, the EU recalls its previous requests for a revision of the OIE Code chapter on Scrapie, taking into account the recently revised Scrapie Manual chapter and the genetic resistance of sheep. In particular, the EU would support replacing the concept of scrapie freedom with that of negligible scrapie risk; clarifying how continued surveillance should be designed once freedom (or negligible risk) status is reached; and clarifying the seven-year rule for scrapie free (or negligible risk) countries or zones.

Subject	**Issue (By priority order, reason for new work)**	**Status and Action (Start date, # of rounds for comments)**
Restructuring of the Code	1) Work with AAHSC towards harmonisation, as appropriate, of the horizontal parts of the *Codes,* notably Glossary, User's Guide and Section 4 on disease control and Section 6 on Veterinary Public Health (Member Countries comments)	Ongoing

Subject	Issue (By priority order, reason for new work)	Status and Action (Start date, # of rounds for comments)
	2) Work with BSC for accurate disease description and diagnostic in the *Manual* and case definitions in the *Code* and names of diseases and country and zone disease status (Member Countries comments)	Ongoing
	3) Revision and formatting of chapters (articles numbering, tables and figures) (Member Countries comments and to improve consistency)	Ongoing
	4) Revision of the Users' guide to address the precedence of chapters (Member Countries comments)	Preliminary discussion
Glossary	1) Global revision of glossary for consistency throughout the Code (Member Countries comments and to improve consistency)	Ongoing and proposed some editorial changes & deletions sent for comments (FEB 2016 / 3rd)
	2) Vaccination, zone, free zone, infected zone, containment zone, protection zone (Member Countries comments and to improve consistency)	Revised definitions for comments in parallel with revision of CH 4.3. and new CH 4.X. on vaccination sent for comments (FEB 2016 / 3rd)
	3) Pathogenic agent, disease, infection and infestation (To improve consistency)	New and revised definitions sent for comments (SEP 2016 / 2nd)
Horizontal issues not yet in the Code **Section 4 Disease control**	1) New CH on vaccination (Member Countries comments and implications for status recognition)	Revised CH sent for comments (SEP 2016 / 2nd)
	2) New CH on management of outbreaks of the listed diseases (Member Countries comments and part of restructuring of Section 4)	Preliminary discussion
	3) New introductory CH in Section 4 (Part of restructuring of Section 4)	Draft new CH sent for comments (FEB 2017 / 1st)
	4) New CH on zoning application (Member Countries comments)	Preliminary discussion

Annex 37 (contd)

Subject	Issue (By priority order, reason for new work)	Status and Action (Start date, # of rounds for comments)

Horizontal issues not yet in the Code **Section 6 Veterinary Public Health**	1) New introductory CH in Section 6 (APFSWG proposal)	Draft new CH sent for comments (FEB 2017)
	2) New CH on *Salmonella* in bovines (In conjunction with Codex's work on *Salmonella* spp. in cattle & pigs)	Proposed for adoption in 2017 (FEB 2015 / 4th)
	2bis) New CH on *Salmonella* in pigs (In conjunctionwith Codex's work on *Salmonella* spp. in cattle & pigs)	Proposed for adoption in 2017 (SEP 2014 / 4th)
	3) Control of Shiga toxin-producing *E. coli* (STEC) in food-producing animals (Member Countries comments)	Preliminary discussion pending FAO/WHO expert consultation
Horizontal issues not yet in the Code **Section 7 Animal Welfare**	1) New CH on AW and pig production systems (Member Countries comments)	Revised CH sent for comments (SEP 2016 / 2nd)
	2) New CH on slaughter and killing methods of farmed reptiles (Member Countries comments)	Draft new CH reviewed and sent back to HQs for revision (SEP 2016)
	3) New CH on AW and laying hen production systems (Member Countries comments)	Draft new CH reviewed and sent back to HQs for revision (FEB 2017)
The Code texts on horizontal issues in need of revision: **Section 1 Notification**	1) Revision of CH 1.4. on Animal Health Surveillance (Member Countries comments and implications for status recognition)	1st and 2nd revision prepared by TAHSC and pending AHG (FEB 2016 / 1st)
	2) CH 1.6. on Status: revision and reorganisation (Member Countries comments and implications for status recognition)	Revised questionnaires sent for comments and other articles pending HQs review (FEB 2017 / 1st)
	3) CH 1.3. on listed diseases: assess CWD & WNF against the criteria (Member Countries comments)	Pending SCAD advice on CWD Pending HQs advice on WNF
The Code texts on horizontal issues in need of revision: **Section 2 Risk analysis**	1) New CH on criteria for assessing safe commodities (Member Countries comments)	Proposed for adoption in 2017 (SEP 2015 / 4th)
The Code texts on horizontal issues in need of revision: **Section 3 Veterinary Services**	1) Revision of CHs of Section 3 in the light of the return of experience of the PVS Pathway	Pending discussion at PVS think tank

Annex 37 (contd)

Subject	Issue (By priority order, reason for new work)	Status and Action (Start date, # of rounds for comments)
The Code texts on horizontal issues in need of revision: **Section 4 Disease control**	1) Revision of CH 4.3. on zoning (Member Countries comments and implications for status recognition)	Revised CH sent for comments (FEB 2016 / 3rd)
	2) Revision of CH 4.13. on disinfection (Member Countries comments)	Preliminary discussion
	3) Revision of CH 4.6. on semen collection (Member Countries comments and trade implications)	Pending experts advice
	4) Revision of CHs 4.7. and 4.8. on embryos (Member Countreis comments and trade implications)	Pending experts advice
	5) Revision of CH 4.16. on HHP (To reflect the recent publication of "the OIE handbook for management of HHP horses")	Proposed for adoption in 2017 (SEP 2016 / 2nd)
The Code texts on horizontal issues in need of revision: **Section 5 Trade measures**	1) Revision of CH 5.3. on SPS agreement (Outdated CH and trade implications)	Proposed for adoption in 2017 (SEP 2015 / 4th)
	2) Revision of CH 5.12. on Model certificates for competition horses (Member Countries comments)	Preliminary discussion and pending revision of CHs on horse diseases
The Code texts on horizontal issues in need of revision: **Section 6 Veterinary Health**	1) Revision of CH 6.1. on the role of VS in food safety (Planned work by TAHSC)	Revised CH sent for comments (FEB 2016 / 2nd)
	2) Revision of CH 6.2. on meat inspection (Planned work by TAHSC)	Pending AHG report
	3) Revision of CH 6.7. on AMR surveillance and monitoring programme (Member Countries comments and to align with Codex work on AMR)	Revised CH sent for comments (Sep 2015 / 3rd)
	4) Revision of Article 6.8.1. on monitoring of AMR in food producing animals (In conjunction with Codex work on AMR)	Report of AHG on AMR sent for comments (FEB 2017)

Annex 37 (contd)

Subject	Issue (By priority order, reason for new work)	Status and Action (Start date, # of rounds for comments)
The Code texts on horizontal issues in need of revision: **Section 7 Animal welfare**	1) Revision of CH 7.5. on slaughter and CH 7.6. on killing of animals for disease control purposes (Member Countries comments)	Revised CHs to be referred to experts for further advice (FEB 2015 / 3rd)
	2) Revision of CH 7.12. on AW of working equids (Member Countries comments)	Proposed for adoption in 2017 (SEP 2016 / 2nd)
	3) Revision of Article 7.11.6. on AW and cattle production systems (Member Countreis comments)	Proposed for adoption in 2017 (SEP 2016 / 2nd)
	4) Revision of CH 7.1. on introduction to recommendations on AW (AWWG proposals)	Draft new Article 7.1.X. on guiding principle on the use of animal-based measures and revision of Article 7.1.1. (definition of AW) sent for comments (FEB 2017 / 1st)
Diseases issues not yet in the Code	1) New CH 15.X. on PRRS (Member Countries comments, listed disease without chapter)	Proposed for adoption in 2017 (FEB 2014 / 4th)
	2) New CH on Surra and revision of CH on Dourine (Non-tsetse transmitted Trypanosomosis) (Member Countries comments)	Review at SEP 2017 meeting
	3) New CH on Crimean Congo hemorrhagic fever (Member Countries comments, listed disease without chapter)	Preliminary discussion
The Code texts on diseases in need of revision: **Sections 8 to 15**	1) Revision of CH 15.1. on ASF (Member Countries comments)	Proposed for adoption in 2017 (FEB 2015 / 5th)
	2) New CH 8.X. on tuberculosis to merge CHs 11.5. & CH 11.6. (taking the example of new CH on *Brucella*)	Proposed for adoption in 2017 (SEP 2015 / 4th)
	3) Revision of CH 11.11. on lumpy skin disease (Member Countries comments and animal health concern)	Proposed for adoption in 2017 (FEB 2016 / 3rd)
	4) Revision of CH 10.4. on AI (Member Countries comments and trade implications)	Pending revision by experts
	5) Revision of CH 12.10. on glanders (outdated CH and trade implications)	Pending review of new scientific evidence (SEP 2014 / 3rd)
	6) Revision of CH 11.4. on BSE (Member Countries comments and trade implications)	HQs evaluation and possible AHG (FEB 2015 / 1st)

Annex 37 (contd)

Subject	Issue (By priority order, reason for new work)	Status and Action (Start date, # of rounds for comments)
	7) Revision of CH 8.8. on FMD (Member Countries comments and implications for status recognition)	Revised CH sent for comments (SEP 2015 / 2nd)
	8) Revision of CH 8.13. on Rabies (Member Countries comments)	Pending AHG
	9) Revision of CH 11.12. on Theileriosis (outdated CH)	Discussion of AHG report in September 2017
	10) Revision of CH 8.3. on Bluetongue (Member Countries comments)	Revised CH sent for comments (SEP 2016 / 2nd)
	11) Revision of CH 15.2. on CSF (Member Countries comments and implications for status recognition)	Revised CH sent for comments (FEB 2017 / 1st)
	12) Revision of CH 14.8. on scrapie (Member Countries comments)	Pending experts opinion on Member Countries comments
	13) Revision of CH 10.5. on avian mycoplasmosis (Member Countries comments and trade implications)	Pending experts' opinion
	14) Revision of CH 11.7. on CBPP (Implications for status recognition)	Pending review of AHG report at SEP 2017 TAHSC meeting
	15) Revision of Article 8.15.2. on rinderpest (Member Countries comments and proposal by JAC)	Revised article sent for comments (FEB 2017 / 1st)

List of abbreviations	
AAHSC	Aquatic Animal Health Standards Commission
AHG	*ad hoc* Group
AI	Avian influenza
APFSWG	Animal Production Food Safety Working Group
ASF	African Swine Fever
AW	Animal Welfare
AWWG	Animal Welfare Working Group
BSC	Biological Standards Commission
BSE	Bovine Spongiform Encephalopathy
CBPP	Contagious bovine pleuropneumonia
CH	Chapters
CSF	Classical swine fever
CWD	Chronic Wasting Disease
FMD	Foot and mouth disease
HQs	Headquarters
JAC	FAO-OIE Rinderpest Joint Advisory Committee
PRRS	Porcine reproductive and respiratory syndrome
PVS	Performance of Veterinary Service
TAHSC	Terrestrial Animal Health Standards Commission
WNF	West Nile fever