Ref. Ares(2017)97069 - 09/01/2017

EUROPEAN UNION

Brussels
SANTE G2/MMK/dj Ares (2016)7383625

Subject: **EU comments on the OIE Terrestrial and Aquatic Codes and Manuals**

Dear Director General,

Please find here attached:

- the comments of the EU on the report of the September 2016 meeting of the OIE Terrestrial Animal Health Standards Commission, for consideration at its next meeting in February 2017;

- the comments of the EU on the report of the September 2016 meeting of the OIE Aquatic Animal Health Standards Commission, for consideration at its next meeting in February 2017;

- the comments of the EU on the draft chapters of the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*, submitted for Member comments in October 2016.

We trust you will find this useful and thank you for your continued good 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

Annexes: 3

Copy: All Directors / Chief Veterinary Officers of the EU 28 and Iceland, Liechtenstein, Norway, Switzerland, and Albania, the former Yugoslav Republic of Macedonia, Montenegro, Serbia and Turkey.

Dr Monique Eloit
Director General
World Organisation for Animal Health (OIE)
12, rue de Prony
FR-75017 Paris

Commission européenne/Europese Commissie, 1049 Bruxelles/Brussel, BELGIQUE/BELGIË - Tel. +32 22991111
Office: B232 03/085 - Tel. direct line (32 2) 295.31.43 Fax: (32-2) 295.31.44

Electronically signed on 02/12/2016 14:39 (UTC+01) in accordance with article 4.2 (Validity of electronic documents) of Commission Decision 2004/563

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Annex 1

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

Original: English
September 2016

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

Paris, 5–16 September 2016

EU comments

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 September 2016 meeting of the Code Commission are inserted in the text below, while specific comments are inserted in the text of the respective annexes to the report.

The EU would like to stress 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.

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

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

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

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

proposed amendments. In such cases the rationale for such amendments is described in the Scientific Commission's or *ad hoc* Group's report, and the Code Commission encourages Member Countries to review its report together with those of the Scientific Commission and *ad hoc* Groups.

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

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

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

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

A. MEETING WITH THE DIRECTOR GENERAL

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

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

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

B. ADOPTION OF THE AGENDA

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

C. MEETING WITH THE AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

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

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– proposed revisions to glossary definitions of '*zone/region*', '*infected zone*', '*free zone*', '*containment zone*' and '*protection zone*' in the *Terrestrial Code*;

– planned global revision to the glossary of the *Terrestrial Code* by the Code Commission;

– proposed new procedures that could be used when undertaking an assessment of a disease against the criteria for listing;

– proposed drafting of a new chapter on the slaughter and killing of farmed reptiles for skins and meat in the *Terrestrial Code*;

– proposed restructuring of Section 4 of the *Aquatic* and *Terrestrial Codes*;

– update on the revised draft new chapter on criteria for assessing the safety of commodities (Chapter 2.X.).

D. MEETING WITH THE BIOLOGICAL STANDARDS COMMISSION

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

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

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

EU comment

The EU thanks the OIE for having attended to our previous comment re. the spelling of FMD. While we would prefer following the ICTV spelling (with two hyphens) for both the name of the disease and the name of the virus, we can accept leaving the spelling as it is in the *Code* and *Manual* for now. We would however encourage the OIE to consistently stick to that spelling in all of its publications, including on the OIE website where both alternatives can be found.

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

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

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

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

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EU comment

The EU thanks the OIE Code and Biological Standards Commissions for having discussed the points that we raised in relation to bluetongue in previous comments. In this connection we would like to inform the OIE that the European Food Safety Authority (EFSA) is working on a mandate from the European Commission on bluetongue, the outputs of which are expected to become available end of January and end of June 2017. A copy of the EFSA mandate as available on the EFSA website is attached for information. We will be happy to share the scientific opinions of EFSA with the OIE once they are published.

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

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

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

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

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

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

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

Item 1 General comments of OIE Member Countries

General comments were received from Australia and New Zealand.

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

Item No.	Texts for Member Countries' comments and proposed for adoption in May 2017	Part A: Annex No.
2	Glossary Part A, A′ and A″	Annex 4
2	Glossary Part B and B′	Annex 5
4	Criteria for the inclusion of diseases, infections and infestations in the OIE list (Article 1.2.1.)	Annex 6
5	Disease listed by the OIE (the Preamble of Chapter 1.3.)	Annex 7

UNOFFICIAL VERSION

7	Draft new chapter on criteria for assessing the safety of commodities (Chapter 2.X.)	Annex 8
10	OIE procedures relevant to the Agreement on the Application of Sanitary and Phytosanitary Measures on the World Trade Organisation (Chapter 5.3.)	Annex 9
12 a)	Draft new chapter on prevention, detection and control of *Salmonella* in cattle (Chapter 6.X.)	Annex 10
12 b)	Draft new chapter on prevention, detection and control of *Salmonella* in pigs (Chapter 6.Y.)	Annex 11
13 f)	Animal welfare and dairy cattle production systems (Article 7.11.6.)	Annex 12
13 g)	Welfare of working equids (Chapter 7.12.)	Annex 13
16	Draft new chapter on infection with *Mycobacterium tuberculosis* complex (Chapter 8.X.)	Annex 14
17	Infection with Avian influenza viruses (Article 10.4.25.)	Annex 15
18	Infection with Lumpy skin disease (Chapter 11.11.)	Annex 16
21 b)	Infection with *Burkholderia mallei* (Glanders) (Chapter 12.10.)	Annex 17
19	Infection with African swine fever virus (Chapter 15.1.)	Annex 18
20	Draft new chapter on infection with porcine reproductive and respiratory syndrome virus (Chapter 15.X.)	Annex 19
21 a)	High health status subpopulation (Article 4.16.3.)	Annex 20
Item No.	**Texts for Member Countries' comments**	**Part B: Annex No.**
2	Glossary Part B	Annex 5
8 a)	Zoning and compartmentalisation (Chapter 4.3.)	Annex 21
Item No.	**Texts for Member Countries' comments**	**Part B: Annex No.**
8 b)	Draft new chapter on vaccination (Chapter 4.X.)	Annex 22
9 b)	Collection and processing of *in vitro* derived embryos from livestock and equids (Chapter 4.8.)	Annex 23
9 c)	Somatic cell nuclear transfer in production livestock and horses (Article 4.11.4.)	Annex 24
11 b)	Harmonisation of national antimicrobial resistance surveillance and monitoring programmes (Chapter 6.7.)	Annex 25
13 b)	Draft new article on guiding principles on the use of animal based measures (Article 7.1.X.)	Annex 26
13 h)	Draft new chapter on animal welfare and pig production systems (Chapter 7.X.)	Annex 27
14	Infection with bluetongue virus (Chapter 8.3.)	Annex 28
22	Work programme	Annex 29
Item No.	**Annexes for Member Countries' information:**	**Part C: Annex No.**
13 a)	The report of the Animal Welfare Working Group	Annex 30
13 k)	The report of the ad hoc Group on Animal Welfare and Pig Production Systems	Annex 31

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Item 2 Glossary

EU comment

The EU notes that Item 2 of this report is very confusing, as it jumps between the various parts of Annexes 4 and 5. A more systematic approach (starting with part A of Annex 4 and ending with part B' of Annex 5) would have been preferred.

a) OIE Standard and OIE Guideline

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

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

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

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

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

Containment zone

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

Free zone

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

Infected zone

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

Protection zone

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

Zone/Region

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

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

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

EU comment

The EU thanks the OIE and in general supports the proposed changes to the glossary presented in this part B of Annex 5. Comments are inserted in the text of that part of Annex 5.

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

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

Pathogenic agent

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

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

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

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

EU comment

While in general supporting the proposed new definition of "pathogenic agent", the EU disagrees with the procedure suggested in the paragraph above. Indeed, there is no such thing as "minor amendments" to the OIE Code, especially as regards the use of the terms mentioned in the paragraph above.

As a matter of principle, the EU strongly opposes "silent" changes to the Code, i.e. without prior circulation to member countries for comments. In case mistakes are to be corrected, member countries should at least be informed beforehand of any changes foreseen, as done for example in this report for the glossary (Annex 4 part A'').

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

d) Overall revision of the Glossary

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

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

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

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

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

Proposed deletions

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

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

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

EU comment

The EU supports the proposed deletions of glossary definitions presented in part A' of Annex 4.

Proposed amendments related to the revision of chapters

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

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

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

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

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

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

EU comment

The EU thanks the OIE and in general supports the proposed changes to the glossary presented in part A of Annex 4. Comments are inserted in the text of that part of Annex 4.

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

EU comment

The EU in general supports the proposed changes to the glossary presented in this part B' of Annex 5. However, comments are inserted in the text of that part of Annex 5.

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

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

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

EU comment

The EU supports the proposed editorial amendments to the glossary presented in part A'' of Annex 4.

The editorial amendments are described in the following table.

Glossary terms	Rationale for and description of the change
ANIMAL HANDLER	**Editorial** The word 'and/' have been deleted because of possible confusion and for correct syntax.
ANIMAL IDENTIFICATION SYSTEM	**Editorial** The unnecessary symbols such as parentheses around plural s and a slash (/) have been deleted for correct syntax.
ANIMAL WELFARE	**Editorial** The unnecessary symbol, a slash (/), has been deleted and replaced with 'and', for correct syntax.
FLOCK	**Editorial** The words 'For the purpose of the *Terrestrial Code*' has been deleted because it is an error, these words already appear at the beginning of the glossary.
HERD	**Editorial** For the same reason as above.
INCUBATION PERIOD	**Editorial** The word 'which' has been replaced with 'that' to correct grammar. (English version only)
INTERNATIONAL VETERINARY CERTIFICATE	**Editorial** A slash (/) and the word 'or' have been deleted for correct syntax. The word 'which' has been replaced with 'that' to correct grammar. (English version only)
KILLING	**Editorial** The word 'which' has been replaced with 'that' to correct grammar. (English version only)

UNOFFICIAL VERSION

OFFICIAL VETERINARIAN	**Editorial** The word 'and/' and a slash (/) have been deleted for correct syntax.
QUARANTINE STATION	**Editorial** The unnecessary symbols such as parentheses around plural s have been deleted. At the last sentence, the word 'and' has been replaced with 'or' to improve clarity and for correct syntax.
RESPONSIBLE DOG OWNERSHIP	**Editorial** The words '(as defined above)' have been deleted because it was an error due to previous versions.
SAFE COMMODITY	**Editorial** The word 'which' has been replaced with 'that' to correct grammar. (English version only)
SLAUGHTER	**Editorial** For the same reason as above.
STUNNING	**Editorial** For the same reason as above.

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

Comments were received from Australia and EU.

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

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

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

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

Comments were received from EU.

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

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

EU comment

The EU thanks the OIE and supports the proposed change to this article.

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

Comments were received from Australia, Colombia and EU.

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

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

EU comment

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

Item 6 Animal health surveillance (Chapter 1.4.)

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

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

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

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

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

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

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

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

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

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

EU comment

The EU in general supports the proposed changes to this draft new chapter. Comments are inserted in the text of Annex 8.

Item 8 Disease prevention and control

a) Zoning and compartmentalisation (Chapter 4.3.)

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

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

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

UNOFFICIAL VERSION

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

UNOFFICIAL VERSION

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

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

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

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 21.

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

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

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

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

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

EU comment

The EU in general supports the proposed draft new chapter. Comments are inserted in the text of Annex 22.

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

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

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

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

Item 9 Semen and embryos

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

A comment was received from Australia.

The Code Commission noted that in the past, in relation to the report of its September 2014 meeting, some other Member Countries also commented about inconsistencies between this chapter and disease-specific chapters in both the *Code* and the *Manual*. While noting the effort made by Headquarters to correct these inconsistencies, the Code Commission considered that it is difficult to keep updated cross-references from this chapter to disease-specific chapters. The Code Commission discussed the value of this chapter in addition to Chapter 4.5. and disease-

UNOFFICIAL VERSION

specific chapters, and discussed two options: (1) developing a single complete chapter that includes detailed testing requirements without cross references and (2) simplifying the existing chapter by including only general conditions applicable to semen collection and handling.

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

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

Comments were received from Australia and the IETS.

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

The Code Commission changed the order of 'embryo' and 'oocyte' in the title, for consistency, and removed the reference to 'rinderpest' in Article 4.8.6. point 2, as this disease has already been eradicated globally. The Code Commission also made some editorial modifications, including some relating to the existing definitions of *slaughterhouse/abattoir* and *shipment* and the proposed definition of 'pathogenic agent'.

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

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

EU comment

The EU in general supports the proposed changes to this chapter. Comments are inserted in the text of Annex 23.

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

A comment was received from New Zealand.

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

> "Risks themselves are neither 'qualitative' nor 'quantitative'; it is the assessments which are one or the other. The glossary definition of 'qualitative risk assessment' is "an assessment where the outputs on the likelihood of the outcome or the magnitude of the consequences are expressed in qualitative terms such as 'high', 'medium', 'low' or 'negligible'". This contradicts the statement in 2. above that such descriptors are 'semi-quantitative'.
>
> Chapter 2.1. of the *Code* nowhere mentions 'semi-quantitative risk assessment'. The OIE publication Handbook on Import Risk Analysis for Animals and Animal Products: Volume 1 Introduction and Qualitative Risk Analysis (second edition, 2010. World Organisation for Animal Health, Paris. Pages 36-37.) states:
>
> [...] all risk analyses inevitably include a degree of subjectivity. Nevertheless, because many people find numbers seductive and reassuring, some analysts use so-called semi-quantitative methods in the mistaken view that they are somehow more 'objective' than strictly qualitative techniques. [...] However, a number of significant problems may arise

UNOFFICIAL VERSION

from adopting a semi-quantitative approach in an import risk analysis. It is sometimes employed as a means of combining various qualitative estimates, by assigning numbers to them, to produce a summary measure or to prioritise risks. The numbers may be in the form of probability ranges or scores, which may be weighted before being combined by addition, multiplication or similar mathematical operations. The numbers, ranges, weights and methods of combination chosen are usually quite arbitrary, and need careful justification to ensure transparency.

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

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

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

EU comment

The EU supports the proposed changes to this article.

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

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

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

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

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

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

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

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

UNOFFICIAL VERSION

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

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

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

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

EU comment

The EU thanks the OIE and in general supports the proposed changes to this chapter. A comment is inserted in the text of Annex 9.

Item 11 Veterinary public health

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

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

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

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

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

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

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

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

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

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

UNOFFICIAL VERSION

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

– Impact on animal health and welfare;

– Implication of antimicrobial resistance in the pathogen for therapeutic options in veterinary practice;

– Impact on food security and on production (economic importance of associated diseases);

– Bacterial diseases responsible for the majority of veterinary antimicrobial usage (stratified by usage of different classes or their importance);

– Existence of validated susceptibility testing methodologies for the pathogen.

The Table of suggested veterinary pathogens in Article 6 *a)* of Chapter 6.7. of the *Terrestrial Code* was developed by the Group reflecting the above considerations. Some veterinary pathogens, such as *Brachyspira* spp. and *Histophilus somni* (formerly *Haemophilus somnus*), were not included in the table, even though they are considered important, because they are fastidious and technically difficult to test and there is no internationally agreed standard methodology for testing them. Validation of susceptibility testing methodologies should be encouraged for these veterinary pathogens. The Code Commission did not accept a Member Country comment to amend point *b)i)* as it considered it clear as written. However, the Code Commission did accept the proposal to amend the second paragraph to allow consideration of private laboratories and to reflect current practices in sampling and surveillance for *Campylobacter*."

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

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

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

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

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 25.

Item 12 Veterinary public health: zoonoses and food safety

a) Draft new chapter on prevention, detection and control of *Salmonella* in cattle (Chapter 6.X.)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

UNOFFICIAL VERSION

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

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

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

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

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

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

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

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

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

EU comment

The EU thanks the OIE and in general supports the proposed changes to this draft new chapter. Comments are inserted in the text of Annex 10.

b) Draft new chapter on prevention, detection and control of *Salmonella* in pigs (Chapter 6.Y.)

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

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

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

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

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

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

UNOFFICIAL VERSION

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

EU comment

The EU thanks the OIE and in general supports the proposed changes to this draft new chapter. Comments are inserted in the text of Annex 11.

Item 13 Animal welfare

a) Report of Animal Welfare Working Group (AWWG)

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

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

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

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

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

EU comment

The EU thanks the OIE for its work and for drafting a new article on this important issue. The EU can in general agree to the proposed text of the article. We do however have a few comments on certain principle issues as indicated in the text of Annex 26.

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

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

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

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

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

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

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

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

Comments were received from Australia and EU.

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

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

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

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

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

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

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

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

EU comment

The EU thanks the OIE for its work. The EU can agree to the amendment proposed for this article of the chapter.

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g) Welfare of working equids (Chapter 7.12.)

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

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

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

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

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

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

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

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

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

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

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

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

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

UNOFFICIAL VERSION

EU comment

The EU thanks the OIE for its work and for taking many of the EU comments into account. The EU can in general agree to the changes made in this modified chapter but does have two comments as indicated in the text of Annex 13.

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

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

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

EU comment

The EU thanks the OIE for its work on this new draft chapter. It is consistent with the other OIE animal welfare chapters but also addresses those issues that are specific for pigs in a clear and simple manner. The EU does however have a number of comments as indicated in the text of Annex 27.

Item 14 Infection with bluetongue virus (Chapter 8.3.)

A comment was received from Australia.

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

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

– the strains of bluetongue virus, and concluded that it was not possible to explicitly exclude non-pathogenic strains from the case definition, as there are currently no means to differentiate between pathogenic and non-pathogenic;

– the vaccine strains, and concluded that the case definition should include them if found in a non-vaccinated animal or an animal that was vaccinated against another strain or with an inactivated vaccine.

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

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

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

The Code Commission noted that it had already removed 'seasonally free country' from other chapters, which only refer to 'seasonally free zones', the zone covering possibly the entire territory of a country. After the completion of the first round of harmonisation on vector-borne disease chapters, it noted that there are still some inconsistencies among the chapters. The Code Commission also noted

UNOFFICIAL VERSION

an inconsistency in Article 8.3.7. regarding the importation from zones seasonally free from *bluetongue* and made modifications to point 5 in order to fix the inconsistency. If adopted, this modification will also apply to Chapter 8.7.

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

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

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

EU comment

Referring to its general comment on the procedures for amending the Code (see item 2 above), the EU strongly opposes "silent" changes to the Code, i.e. without prior circulation to member countries for comments. This includes analogous follow-up changes in other chapters, as indicated in the paragraphs above. These should duly be brought to the attention of member countries and adopted by the World Assembly.

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

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

EU comment

The EU cannot support some of the proposed changes to this chapter. Important comments are inserted in the text of Annex 28.

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

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

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

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

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

UNOFFICIAL VERSION

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

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

> ″After reviewing the *ad hoc* Group report and consultation with the Scientific Commission, the Code Commission concluded it currently had insufficient information to include New World camelids in the list of susceptible species. It asked Headquarters and both the Laboratories Commission and the Scientific Commission to re-evaluate the significance of infection with M. tuberculosis complex in New World camelids along with the available diagnostic and risk management tools to determine whether they should be included in the case definition or not.
>
> Member Countries' observations that compliance with the provisions of Article 8.X.14. point 1 requires that goats are kept in a herd that has been subjected to a testing regime, were referred to the Laboratories Commission and the Scientific Commission to support further consideration of the development of such a testing regime to demonstrate herd freedom from infection with *M. tuberculosis* complex in goats.″

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

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

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

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

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

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

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

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

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

UNOFFICIAL VERSION

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

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

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

EU comment

The EU thanks the OIE and in general supports the proposed changes to this draft new chapter. A comment is inserted in the text of Annex 14.

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

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

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

– Plain or pure egg yolk: temperature 60°C, time 288 seconds – inserted as a new line;

– Dried egg white: temperature 54.4°C, time changed to 50.4 hours;

– Dried egg white: temperature changed to 51.7°C, time changed to 73.2 hours.

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

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

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

EU comment

The EU supports the proposed changes to this article.

In addition, we would encourage the OIE to do further work on this chapter in the near future, especially as regards country and zone status, recovery of status and international trade recommendations.

Item 18 Lumpy skin disease (Chapter 11.11.)

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

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

UNOFFICIAL VERSION

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

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

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

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

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

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

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

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

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

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 16.

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

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

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

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

UNOFFICIAL VERSION

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

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

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

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

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

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

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

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

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

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

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

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

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

In response to a Member Country's comments on Article 15.1.5. points 2 and 3, the Code Commission did not agree to add supplementary requirements, as in the requirement for free status,

UNOFFICIAL VERSION

the separation of animals in terms of biosecurity is already included, and free zones or compartments should only import animals according to the relevant conditions of the chapter.

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

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

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

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

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

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

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

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

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

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

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

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

UNOFFICIAL VERSION

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

In response to a Member Countries' request for clarification on the use of the term 'flagging' in Article 15.1.27., the Code Commission provided the following reference: "CO_2 flagging - an improved method for the collection of questing ticks". Gherman CM, A Mihalca AD, Dumitrache MO, Györke A, Oroian I, Sandor M and Cozma V (2012). Parasit Vectors. 2012 Jun 21; 5:125. doi: 10.1186/1756-3305-5-125.

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

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 18.

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

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

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

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

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

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

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

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

UNOFFICIAL VERSION

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

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

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

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

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

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

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

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

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

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

UNOFFICIAL VERSION

EU comment

The EU thanks the OIE and in general supports the proposed changes to this draft new chapter. Comments are inserted in the text of Annex 19.

Item 21 Equine diseases

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

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

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

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

EU comment

The EU supports the proposed changes to this article.

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

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

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

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

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

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

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

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

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

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

UNOFFICIAL VERSION

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

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

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

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

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

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

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

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

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

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

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

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

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

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 17.

G. OTHER ISSUES

Item 22 Update of the Code Commission's work programme

UNOFFICIAL VERSION

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

EU comment

The EU thanks the OIE and supports the future work programme of the Code Commission.

Item 23 Other issues

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

A comment was received from New Zealand.

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

EU comment

The EU would like to inform the OIE that the European Food Safety Authority (EFSA) is working on a mandate from the European Commission on chronic wasting disease, the outputs of which are expected to become available end of 2016 and end of 2017, respectively. A copy of the EFSA mandate as available on the EFSA website is attached for information. We will be happy to share the scientific opinions of EFSA with the OIE once they are published.

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

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

c) Dates of next meetings

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

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Annexes/…

UNOFFICIAL VERSION

Annex 4

GLOSSARY (PART A–AMENDMENTS)

EU comment

The EU thanks the OIE and in general supports the proposed changes to the glossary presented in this part A of Annex 4. Comments are inserted in the text below.

ANIMAL HEALTH STATUS

means the status of a country or a *zone* 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]

EU comment

The EU agrees with the proposal to place the word "animal" in square brackets in the terms related to "wildlife" defined in the glossary. We note however that the explanation given in the introduction of the report (last paragraph of p. 7) suggests the word "animal" be replaced by the word "species", whereas this is not done in this part A of Annex 4. Furthermore, "species" would not be the correct term when referring e.g. to "birds" or "ruminants". Therefore, the term "taxon" is suggested as alternative.

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 ~~a~~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*.

EU comment

UNOFFICIAL VERSION

As explained in the EU comments on the proposed amended definition of disease (see EU comment to Annex 5), there is a "dilemma" in the proposed definitions of "pathogenic agent" and "disease". This could be solved by amending the above proposed new definition of "pathogenic agent" by replacing the word "disease" by the word "pathology". Indeed, the term "pathogenic agent" should rather be linked to "pathology" than to "disease" (which according to the proposed amended definition can include sub-clinical infections), as a pathological manifestation can be either clinical or sub-clinical.

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.

UNOFFICIAL VERSION

Annex 4 (contd)

GLOSSARY (PART A—DELETIONS)

EU comment

The EU supports the proposed deletions of glossary definitions presented in this part A' of Annex 4.

~~***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.~~

— Text deleted.

UNOFFICIAL VERSION

Annex 4 (contd)

GLOSSARY (PART A—EDITORIAL)

EU comment

The EU supports the proposed editorial amendments to the glossary presented in this part A" of Annex 4.

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

UNOFFICIAL VERSION

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.

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.

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— Text deleted.

UNOFFICIAL VERSION

Annex 5

GLOSSARY (PART B)

EU comment

The EU thanks the OIE and in general supports the proposed changes to the glossary presented in this part B of Annex 5. Comments are inserted in the text below.

CONTAINMENT ZONE

means an *infected* ~~defined~~ *zone* ~~around and~~ in a previously free country or *zone*, ~~in~~ which ~~are~~ ~~included~~ includes ~~including~~ all ~~*epidemiological units*~~ suspected or and confirmed *outbreaks* ~~to be infected *establishments*, taking into account the epidemiological factors and results of investigations,~~ and where movement control, *biosecurity* and *sanitary measures* ~~have been~~ are applied to prevent the spread of, and to eradicate, the ~~*infection*~~ *disease* ~~are applied~~.

EU comment

The EU suggests inserting the words "defined within" and delete "in" before the words "a previously free country or zone" (for the sentence to read "means an infected zone defined within a previously free country or zone, [...]"). This would clarify both that the zone is well defined, and is within the previously free country or zone.

Furthermore, the EU does not support replacing the word "infection" with "disease" (see EU comment on the definition of "disease" in Part B' of this Annex 5 for rationale).

It is not clear what is meant by "suspected *outbreaks*". To avoid any confusion, it would be easier to say the following: "[...] zone, which ~~includes~~ contains all susceptible animals in which the infection is suspected and ~~or~~ confirmed ~~outbreaks~~, and where [...]"

In addition, the aim of setting up a containment zone could be emphasised by replacing the words "to prevent the spread of, and to eradicate, the disease" by "with the aim of *eradication*". Indeed, the concept of eradication encompasses prevention of spread.

Finally, "movement control" should be plural ("movement controls") (syntax).

FREE ZONE

means a *zone* in which the absence of a specific ~~the~~ *disease~~, infection~~ or infestation* ~~under consideration~~ in an animal *population* has been demonstrated ~~by~~ in accordance with the relevant requirements ~~specified in~~ of the *Terrestrial Code* ~~for free status being met~~. ~~Within the *zone* and at its borders, appropriate *official veterinary control* is effectively applied for *animals* and animal products, and their transportation.~~

EU comment

The EU does not support deleting the words ", infection or infestation" (see EU comment on the definition of "disease" in Part B' of this Annex 5 for rationale).

INFECTED ZONE

~~means, if not otherwise defined in the specific disease chapter of the *Terrestrial Code*, a *zone* in which a *disease, infection* or *infestation* has been diagnosed.~~

means, a *zone* either in which a *disease* has been diagnosed, or that does not meet *disease* freedom provisions of the relevant chapters of the *Terrestrial Code*.

EU comment

UNOFFICIAL VERSION

The comma after "means" should be removed (syntax).

Furthermore, the word "diagnosed" should be replaced by the word "confirmed". Indeed, "confirmed" is more appropriate as it will require the identification of a pathogen(s), whereas "diagnosed" could have been done on clinical signs.

Finally, since this would usually refer to one specific disease, the word "chapters" in the second half of the sentence should be used in singular.

For more clarity, the sentence could thus be reworded as follows:

"means, a *zone* either in which a disease has been confirmeddiagnosed, or one that does not meet the disease freedom provisions of the relevant chapters of the Terrestrial Code."

PROTECTION ZONE

means a *zone* established to protect the health status of animals in a free country or *free zone*, from those in the entry or spread of a pathogen from an adjacent country or *zone* of a different *animal health status*, using *biosecurity* and *sanitary measures* based on the epidemiology of the *disease* under consideration to prevent spread of the causative pathogenic agent into a free country or *free zone*. These measures that may include, but are not limited to, *vaccination*, movement control and an intensified degree of *surveillance*.

EU comment

In the second line of the definition above, the EU suggests replacing the word pathogen by "*Pathogenic agent*". Indeed, this would be consistent with the new definition of "*Pathogenic agent* " proposed in Part A of Annex 4.

ZONE/REGION

means a clearly defined part of a territory of a country containing an animal *population* or *subpopulation* with a distinct specific health status with respect to a specific *disease, infection or infestation*. for which required *surveillance*, control and *biosecurity* measures have been applied for the purpose of *international trade*.

EU comment

The EU does not support deleting the words ", infection or infestation" (see EU comment on the definition of "disease" in Part B' of this Annex 5 for rationale).

Furthermore, the word "clearly" is superfluous and should be deleted. Indeed, it is enough to say that the zone is defined. However, it should be stated who defines the zone, and that this should be documented. The EU therefore suggests adding the following sentence (in analogy with the corresponding proposal of the Aquatic Animals Commission):

"Such zones are documented by the Veterinary Authority."

UNOFFICIAL VERSION

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— Text deleted.

Annex 5 (contd)

GLOSSARY (PART B')

EU comment

The EU in general supports the proposed changes to the glossary presented in this part B' of Annex 5. However, comments are inserted in the text below.

COMPARTMENT

means an animal *subpopulation* contained in one or more *establishments* under a common *biosecurity* management system with a ~~distinct~~ specific health status with respect to a ~~specific~~ *disease* or ~~specific~~ *diseases* for which required *surveillance*, control and *biosecurity* ~~measures~~ have been applied for the purpose of *disease* prevention and control or *international trade*.

EU comment

While in principle supporting the proposed changes to the definition of compartment above, the EU notes that "disease control" would apply only for a zone, not for a compartment. Indeed, the word "control" implies that the disease could be present in a compartment, which would go against the purpose of compartmentalisation where management, biosecurity and surveillance practices are used to prevent the introduction of a disease in the compartment with a view to attain a distinct health status to facilitate trade. This should therefore be addressed in the avbove definition. (Reference is also made to the EU comment on Article 4.3.1. in Annex 21).

DISEASE

means ~~the~~ a clinical or non-clinical ~~pathological manifestation of~~ *infection* or *infestation*.

EU comment

The EU does not agree with the amendment of the definition of disease as proposed. Indeed, that change would result in the equipollence of the definitions of "disease" and "infection". This would be in contradiction with classical concepts of epidemiology, whereby an infection with a pathogenic agent not always leads to disease (i.e., clinical signs or pathological manifestation).

Furthermore, the definition as proposed would be far too wide. Indeed, even when considering the proposed amendment of the definition of "infection" (restricting it to pathogenic agents) and the proposed new definition of "pathogenic agent" (organism that causes [...] a disease), "disease" would precisely include all infections with non-pathogenic organisms (including commensals, saprophytes and the gut microbiome), as these would meet the definition of a pathogenic agent (i.e., including organisms that cause non-clinical disease). This can hardly be the intention of the OIE.

In addition, as a consequence, the whole OIE Code would need to be revised, starting with the title of Chapter 1.3. which as it now stands would become tautological. This significant task would need to be done concurrently, i.e. the amendment of the definition and all consequent changes throughout the Code would need to be done at the same time.

UNOFFICIAL VERSION

Consequently, the EU does not support replacing the word "infection" with "disease" nor the deletion of "infection and infestation" in the amended definitions of Part B of this Annex 5 (see EU comments there).

A possible solution would be to restrict the new definition of "pathogenic agent" to real pathogens, e.g. by inserting the word "pathogenic" before the word "organism". Another option would be to replace the word "disease" by "pathology" in that definition (see the EU comment on the proposed new definition in part A of Annex 4). This would solve the dilemma of non-pathogenic organisms causing non-clinical disease being included.

VACCINATION

means the ~~successful immunisation~~ administration of a vaccine, ~~susceptible *animals* through the administration~~ in accordance with the manufacturer's instructions and the *Terrestrial Manual*, ~~where~~ when relevant, ~~of a vaccine comprising antigens appropriate to the~~ inducing immunity in an *animal* or group of *animals* against one or several *diseases* ~~to be controlled~~.

EU comment

The EU in general supports the proposed amendments to the definition of vaccination. However, from the wording ("administration of a vaccine [...] inducing immunity [...]") it remains unclear whether only "successful" acts of vaccination are to be covered by the definition (i.e., administration of vaccine that indeed induces immunity), and thus "unsuccessful" ones are excluded (e.g., immunocompromised animals in which the administered vaccine does not induce immunity). The definition should preferably be more explicit on this.

Indeed, "vaccination" per se has nothing to do with the outcome of the injection, it is simply the act of administration of the vaccine. That is why "vaccination coverage" only refers to the percentage of animals from the total that were administered the vaccine. However, in order to assess the "success" of the vaccination, it is necessary to check for post-vaccination immunity which checks the effect of the vaccination. This will show whether the cold chain worked or whether there are immune-supressed animals or whether the antigen used in the vaccine had sufficient match with the circulating field strain etc.

Furthermore, the EU suggests inserting the words "or national legislation" after the words "the *Terrestrial Manual* ". Indeed, national legislation sometimes prescribes a different vaccination schedule than the manufacturer.

In addition, the EU suggests replacing the word "diseases" at the end of the definition by "*pathogenic agents*" (consistency with the new definition proposed in Part A of Annex 4).

Finally, the EU suggests adding the words "or antigenic variants of the target pathogen" after the words "against one or several diseases". Indeed, vaccination is not only to control diseases, but also to prevent (prophylactic vaccination) or simply to protect an individual animal against possible risks, in which case the health status of the country (for example infected with rabies) is not at all affected.

UNOFFICIAL VERSION

Annex 6

CHAPTER 1.2.

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

EU comment

The EU thanks the OIE and supports the proposed change to this 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*.

[Article 1.2.2.]

- Text deleted.

UNOFFICIAL VERSION

Annex 7

CHAPTER 1.3.

DISEASES, INFECTIONS AND INFESTATIONS LISTED BY THE OIE

EU comment

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

[Article 1.3.1.]

[…]

[Article 1.3.9.]

- Text deleted.

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Annex 8

CHAPTER 2.X.

CRITERIA APPLIED BY THE OIE FOR ASSESSING THE SAFETY OF COMMODITIES

EU comment

The EU in general supports the proposed changes to this draft new chapter. Comments are inserted in the text below.

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. 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.

EU comment

Use of the reference to Article X.X.2. in the paragraph above might lead to confusion, as there is no Article X.X.2. in the Terrestrial Code. It would be preferable to use a clear reference instead, i.e. by replacing the words "Article X.X.2." by the words "the second article", or to explain what is meant by "X.X.2.".

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~~ ~~dose~~ 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*.

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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:

EU comment

Use of the word "normally" in the paragraph above could give rise to misunderstandings or uncertainties. Indeed, it could be understood that the treatment would usually be applied to the commodity, but that there could be exceptions. It would however be important to clearly state that the treatment should always be applied. One option could be to simply deleted the word "normally".

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 9

CHAPTER 5.3.

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

EU comment

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

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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.~~

~~In order to~~ 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 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 determining 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.

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 be ~~satisfied~~ assured that its *animal ~~health status~~* and human health 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* present, border security and internal movement controls.

EU comment

The EU reiterates its previous comments that for linguistic and clarity reasons, the word "its" before "animal and human health" be deleted in the paragraph above. Alternatively, the word "status" should be reinserted and placed after "human health".

Indeed, a country's health status can be protected, or health in general (in that country), but not "its health", as a country does not have health.

~~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 establishing~~ 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

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concurrently.

Sanitary measures are ~~those~~ described in ~~each~~ the *disease*-specific chapter of the *Terrestrial Code* ~~which are used for managing~~ to manage *risk*s ~~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 ~~specified *disease* *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*;

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;

UNOFFICIAL VERSION

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;

UNOFFICIAL VERSION

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) requests ~~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*.

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:

UNOFFICIAL VERSION

Annex 9 (contd)

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;

UNOFFICIAL VERSION

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.

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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— Text deleted.

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Annex 10

DRAFT CHAPTER 6.X.

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

EU comment

The EU thanks the OIE and in general supports the proposed changes to this draft new chapter. Comments are inserted in the text below.

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Article 6.X.1.

Introduction

Nontyphoidal salmonellosis is one of the most common 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 depending on the region. ~~For example,~~ In ~~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 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 may vary considerably within and between farms, countries and regions. It is important for *Veterinary Authorities* and ~~the~~ producers to consider serotypes of *Salmonella*, their occurrence and the *disease* burden in cattle and human populations ~~if~~ when they develop~~ing~~ and implement~~ing~~ strategies for the prevention and control of *Salmonella* in commercial cattle production systems.

Article 6.X.2.

Definitions

For the purposes of this chapter:

Commercial cattle 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 for the production of *meat* ~~and *meat products*~~ or *milk* ~~and *milk products*~~.

Intensive cattle production systems: means commercial systems ~~where~~ in which cattle 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 production systems: means commercial systems ~~where~~ in which cattle have the freedom to roam outdoors, and where the cattle 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.

~~**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~~ provide<u>s</u> recommendations for the prevention and control of *Salmonella* in <u>commercial</u> cattle <u>production systems</u> in order to reduce the burden of *disease* in cattle and the *risk* of human illness through food-borne contamination as well as human *infections* resulting from direct or indirect contact with <u>infected</u> cattle ~~(e.g. via faeces or abortion material)~~.

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

EU comment

There seems to be a serious issue concerning the use of the term "cattle" in the OIE Code. Indeed, the term is used in most of the disease specific chapters of Section 11, and many other parts of the Code, however is often not defined at all or sometimes defined with a varying list of species for the purpose of a particular chapter (for example, the list of species in Article 8.4.1. [Brucellosis] includes *B. frontalis* in addition to all the species mentioned in the paragraph above, while Article 11.4.1. [BSE] only includes *B. taurus* and *B. indicus* in the definition of "cattle"). Yet other chapters do not use the term "cattle" at all but speak only of "bovids" (for example Chapter 11.7. on CBPP).

The EU, while in principle not disagreeing with the proposed change to the paragraph above, would suggest the OIE review the use of the term "cattle" throughout the Code, both for clarity and consistency. Furthermore, there also seems to be a translation issue with that term, as it is not translated consistently in the French and Spanish versions of the Code. Perhaps a uniform glossary definition of that term would be a possible solution.

This chapter should be read in conjunction with the Codex Alimentarius Code of Hygienic Practice for Meat (CAC/RCP 58-2005)<u>,</u> ~~and the Codex Alimentarius~~ Code of Hygienic Practice for Milk and Milk Products (CAC/RCP 57-2004)<u>, Code of Practice 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 ~~under development~~), and the OIE/FAO Guide to Good Farming Practices for Animal Production Food Safety</u>.

Article 6.X.4.

Objectives of prevention and control measures

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

EU comment

The EU thanks the OIE for having taken our previous comment on the paragraph above into account. However, for reasons of clarity and better understanding, we suggest amending the second sentence above as follows:

"~~These~~ <u>Preventive</u> measures <u>for those serotypes</u> will also contribute to the reduction of other serotypes <u>of *Salmonella*</u>."

~~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;~~

UNOFFICIAL VERSION

~~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 production systems may:

1) reduce the prevalence and ~~concentration~~ 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 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 or contaminated material or water.

EU comment

Even if only indirectly linked to cattle, an important cause of human salmonellosis are vegetables contaminated with *Salmonella* from contaminated irrigation water. The EU therefore suggests adding the words "including water for irrigation" at the end of point 4) above.

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

EU comment

The EU does not support the paragraph above as proposed, and suggests amending it as follows:

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

Indeed, good farming practices should always be taken into account, while HACCP is more difficult to implement at primary production and should therefore only be recommended where appropriate.

Articles 6.X.5. to 6.X.~~14~~16. provide recommendations for the prevention and control of *Salmonella* in commercial cattle 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 to assist with the prevention and control of *Salmonella*. A *biosecurity* ~~management~~ *plan* should be developed according to the commercial cattle production systems employed ~~e.g. intensive or extensive~~.

EU comment

The first sentence could benefit from being strengthened in order to even further stress the importance of biosecurity to prevent and control *Salmonella*. The EU therefore suggests the following wording:

UNOFFICIAL VERSION

"Biosecurity ~~is intended to assist with~~ has a major role in prevention and control of *Salmonella*."

The applicability of the measures, described below, will vary according to the type of commercial cattle production system.

When including *Salmonella* as part of a *biosecurity* ~~management~~ *plan* ~~it is recommended that~~ the following should be addressed:

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

2) veterinary supervision of cattle health;

3) management of the introduction and mixing of cattle;

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

5) maintenance of records including data on cattle health, production, movements, feeding, 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;

8) minimising the entry of *wild* birds into cattle buildings and feed stores;

9) cleaning and *disinfection* procedures for buildings in which cattle are handled or housed in accordance with Chapter 4.13.; ~~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. All visible organic material should be removed before *disinfection*.~~

~~When chemical disinfectants are used, the effective concentration and contact time for *Salmonella* should be considered and the choice of disinfectant should take into account the cleaning process. Surfaces should be allowed to dry after *disinfection*. Disinfectants should be used 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 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.

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

Location and design of cattle establishment

When making decisions on the location and design of cattle *establishments,* it is recommended that ~~mitigation~~ reduction of the ~~*risk*~~ likelihood of transfer of pathogens, 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 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*;

UNOFFICIAL VERSION

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

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

64) cattle handling and movements to minimise stress and spread of *Salmonella* ~~*infection*~~;

75) separation of cattle according to likelihood of ~~different~~ *infection* with, or susceptibility to, *Salmonella* ~~*risk status*~~;

86) restriction of entry of domestic animals, ~~*wild*~~ birds, rodents, flies and other relevant *wildlife*.

In extensive cattle 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

EU comment

In line with the *Salmonella* chapter for pigs, we suggest inserting the following as the first sentence in this article:

"Introduction of cattle into a herd is an important risk factor for introducing *Salmonella*, especially from infected farms or from farms of unknown status in moderate and high prevalence regions.".

To minimise the ~~*risk*~~ likelihood of introducing *Salmonella* through cattle introductions~~, it is recommended that~~:

UNOFFICIAL VERSION

1) ~~There be~~ good communication within the cattle 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;

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 should be sourced directly from *herds* of origin because live animal markets or other places where cattle from multiple properties are mixed for resale may increase the ~~*risk*~~ likelihood of spread of *Salmonella* and other ~~*infections*~~ infectious agents among cattle~~.~~;

~~5~~4) newly introduced cattle should be kept separate from the rest of the *herd* for a suitable period before mixing with other cattle, 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 should be considered to inform subsequent control measures, for example, when introducing cattle of unknown status.

Article 6.X.8.

On farm cattle management

To ~~minimise~~ reduce the ~~*risk*~~ likelihood of transferring *Salmonella* among cattle~~, it is recommended that~~:

1) cattle with suspected salmonellosis or otherwise sick should be separated from healthy cattle~~.~~;

2) care of healthy cattle should be carried out prior to care of cattle with suspected salmonellosis~~.~~;

3) priority should be given to the hygienic management of calving areas, for example keeping perinatal cattle separated from sick cattle and maintaining a clean environment~~.~~;

4) cattle 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 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 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. 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 and feed ingredients should be transported, ~~and~~ stored and fed in a hygienic manner that minimises contamination by manure and access by domestic animals, ~~wild~~ birds, rodents and ~~other~~ *wildlife*.

EU comment

UNOFFICIAL VERSION

The EU suggests deleting the words "where practical" in point 2) above. Indeed, feed should always be handled in a way so as to minimize contamination.

~~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 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 new-born 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 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 to *Salmonella*. Management of potentially stressful situations, such as mixing of groups of cattle, 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. ~~*Antimicrobial agents* can be used for treatment of clinical salmonellosis and when administered, it should be in accordance with Chapter 6.9.~~ Furthermore ~~However~~, *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.

Article 6.X.~~11~~12.

Transportation

~~Hygienic maintenance of *vehicles* is recommended~~ *Vehicles* should be properly cleaned and disinfected after transportation of animals.

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.

UNOFFICIAL VERSION

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.

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~~.

EU comment

The EU queries the scientific rationale for suggesting "washing the live animals to reduce contamination of meat at slaughter". Indeed, this recommendation needs to be backed by scientific publications that clearly show the benefit of washing of live animals and the link to reduced meat contamination.

Article 6.X.~~13~~15.

Surveillance ~~in cattle~~ for *Salmonella* in commercial cattle 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, slurry samples, or caecal or lymph node~~s~~ samples collected post-mortem can also be useful for microbiological testing. Some types 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 ~~by means of serological testing~~.

Article 6.X.~~14~~16.

Prevention and control in low prevalence regions

In regions where *Salmonella infection* of cattle 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.

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— Text deleted.

UNOFFICIAL VERSION

Annex 11

DRAFT CHAPTER 6.Y.

PREVENTION AND CONTROL OF SALMONELLA IN COMMERCIAL PIG PRODUCTION SYSTEMS ~~PIG HERDS~~

EU comment

The EU thanks the OIE and in general supports the proposed changes to this draft new chapter. Comments are inserted in the text below.

In general, the chapter seems to be missing an important part on weaning policy, since this is a critical period for *Salmonella* growth and spread. The EU therefore suggests adding recommendations on weaning in a new Article 6.Y.8bis (see EU comment below).

Article 6.Y.1.

Introduction

Nontyphoidal salmonellosis is one of the most common food-borne 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. ~~For example, in~~ In some countries *S.* Infantis and *S.* Choleraesuis may ~~also~~ 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 ~~the~~ producers to consider ~~the sero~~types 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~~.

EU comment

For reasons of consistency with draft Chapter 6.X., the EU requests that the word "serotypes" be used in the 2nd line of the paragraph above, as this is the term commonly used for *Salmonella*.

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.

UNOFFICIAL VERSION

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 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 ~~under development~~) ~~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.~~

UNOFFICIAL VERSION

Article 6.Y.~~5~~4.

~~Prevention~~ Objectives of prevention and control measures

~~It is recommended that~~ Prevention ~~prevention~~ and control measures ~~be focused~~ 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.

EU comment

The EU thanks the OIE for having taken our previous comment on the paragraph above into account. However, for reasons of clarity and better understanding, we suggest amending the second sentence above as follows:

"~~These~~ Preventive measures for those serotypes will also contribute to the reduction of other serotypes of *Salmonella*."

Prevention and control measures in commercial pig production systems may:

1) reduce the prevalence and ~~concentration~~ 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 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 material or water.

EU comment

Even if only indirectly linked to pigs, an important cause of human salmonellosis are vegetables contaminated with *Salmonella* from contaminated irrigation water. The EU therefore suggests adding the words "including water for irrigation" at the end of point 3) above.

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

EU comment

The EU does not support the paragraph above as proposed, and suggests amending it as follows:

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

Indeed, good farming practices should always be taken into account, while HACCP is more difficult to implement at primary production and should therefore only be recommended where appropriate.

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*~~.

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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 to assist with the prevention and control of *Salmonella*. The choice of specific measures will vary according to the type of commercial pig production system.

EU comment

The first sentence could benefit from being strengthened in order to even further stress the importance of biosecurity to prevent and control *Salmonella*. The EU therefore suggests the following wording:

"Biosecurity ~~is intended to assist with~~ has a major role in prevention and control of *Salmonella*."

Furthermore, for reasons of consistency with the *Salmonella* chapter for cattle and in order to stress the importance of applying a biosecurity plan against *Salmonella* and applicable to the type of pig production, the EU suggests inserting the following sentence between the two sentences of the paragraph above:

"A biosecurity plan against salmonella should be developed according to the commercial pig production systems employed".

When including *Salmonella* as part of a *biosecurity* ~~management~~ *plan*, ~~it is recommended that~~ 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~~.~~;

5~~3~~) maintenance of records including data on pig health, production, movements, 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 *wild* birds into pig ~~houses and~~ buildings and feed stores~~.~~;

9~~7~~) cleaning and *disinfection* procedures for buildings in which pigs are handled or housed in accordance with Chapter 4.13.; ~~including feeding systems, drinkers, floor, walls, aisles, walkways, partitions between pens, and ventilation ducting. 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~~

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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.

119) Controlled access of persons and *vehicles* entering the *establishment*. control and hygienic procedures for entry and movement of persons and *vehicles*;

1210) *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*;

1412) 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 animals are suspected or known to be infected.

Article 6.Y.76.

Facility Location and design of pig establishments

When making decisions on the location and design of pig *establishments*, it is recommended that reduction of the likelihood of transfer of pathogens, 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, persons personnel, domestic animals, birds, rodents, flies and *wildlife*.

It is recommended that the 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*;

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

43) 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 controlled 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*;

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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~~, it is recommended that~~:

EU comment

The EU does not agree with deleting the words "an important" in the first sentence of the paragraph above. Indeed, as a quantitative risk assessment concluded that in both breeder and slaughter pigs, infected incoming pigs and *Salmonella*-contaminated feed are the two major sources of *Salmonella*, we request that the words "one of the most important" be inserted before "risk factor" instead.

References:

Wierup M and Widell S: *Estimation of costs for control of Salmonella in high-risk feed materials and compound feed*. Infect Ecol Epidemiol. 2014 Jun 12;4.

European Food Safety Authority: Scientific opinion on a quantitative microbiological risk assessment of Salmonella in slaughter and breeder pigs. EFSA J 2010; 8: 1547.

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) ~~the introduction of~~ new genetic material should be introduced through the use of semen whenever ~~possible~~ 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) ~~where~~ 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*~~, 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' 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.

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EU comment

Post weaning diarrhoea can be caused by *Salmonella* and may result in pig diseases as well as further dissemination of *Salmonella* in a herd. It seems therefore appropriate to add a specific article on preventive measures for this critical period. The following Article 6.Y.8bis is therefore proposed:

Article 6.Y.8bis.

(Post-)weaning strategy

The post-weaning period is a critical period that may result in disease, multiplication and dissemination of *Salmonella* within a herd. The following recommendations can be considered:

1. Stress at weaning should be minimised by keeping piglets from the same sow together where possible, by ensuring a comfortable climate (temperature, air flow), easy and sufficient access to water and by an appropriate stocking density;

2. Age and weight at weaning should be considered and preferably increased in case of recurrent infections;

3. An appropriate feeding strategy should be considered, starting before weaning. This may include a gradual approach in changing the nutritional content of the diet and consideration of the use of feed additives (e.g. acids), the type of feed (meal/pellets, wet/dry), appropriate feeding practices, etc.

4. The preventive use of antimicrobial agents should be discouraged to avoid antimicrobial resistance. Environmental effects should be considered before using certain products.

Article 6.Y.~~8~~9.

Feed and feed composition

1. Feed and feed ingredients

Feed and feed ingredients can be sources of *Salmonella* ~~*infection*~~ for pigs. This is especially important in *herds*, countries or regions of low prevalence. To minimise the spread of *Salmonella* through feed~~, it is recommended that~~:

a) feed and feed ingredients should be produced, handled, stored, transported and distributed in accordance with Chapter 6.3.;

b) ~~where practical~~ when practicable, feed and feed ingredients should be transported, stored and fed in a hygienic manner that minimises contamination by manure and access by domestic animals, birds, rodents and *wildlife*;

EU comment

The EU suggests deleting the words "when practicable" in point b) above. Indeed, feed should always be handled in a way so as to minimize contamination.

c) when practicable, feeds should be treated with heat, or with *approved* bactericidal or bacteriostatic treatments ~~e.g.~~ 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.~~

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~~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* ~~it is recommended that~~ 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 ~~most~~ 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.

Article 6.Y.~~9~~10.

Water

~~For the effective control~~ Drinking water ~~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~~

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~~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.~~

~~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. ~~*Antimicrobial agents* can be used for treatment of clinical salmonellosis and when administered, it should be in accordance with Chapter 6.9.~~ Furthermore ~~However~~, *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.

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~~*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

~~Hygienic maintenance of *vehicles* is recommended.~~ *Vehicles* should be properly cleaned and disinfected after transportation of animals.

When transporting animals from multiple *establishments*, ~~it is recommended that~~ 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 ~~by means of serological testing~~.

UNOFFICIAL VERSION

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 types 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. ~~, by pooling~~ 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 types of *Salmonella* such as *S.* Choleraesuis can be difficult to detect using microbiological methods.

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, ~~or~~ 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.

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Annex 12

CHAPTER 7.11.

ANIMAL WELFARE AND DAIRY CATTLE PRODUCTION SYSTEMS

EU comment

The EU thanks the OIE for its work. The EU can agree to the amendment proposed for this article of the chapter.

[Article 7.11.1.]

[Article 7.11.2.]

[Article 7.11.3.]

[Article 7.11.4.]

[Article 7.11.5.]

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.

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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.

UNOFFICIAL VERSION

Annex 13

DRAFT CHAPTER 7.12.

WELFARE OF WORKING EQUIDS

EU comment

The EU thanks the OIE for its work and for taking many of the EU comments into account. The EU can in general agree to the changes made in this modified chapter but does have two comments as indicated below.

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.

EU comment

The EU would also like to exclude horses used in therapy from the 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, equine-assisted therapy, research or kept solely for the production of meat or biopharmaceuticals are excluded."

Rationale:

It should be quite clear from the text which category of equids that are covered by the provisions of this chapter.

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.

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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

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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");

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– locomotive stereotypies: stable walking, weaving;

– abnormal vocalisation, agitation and defaecation.

EU comment

The EU would also propose the following rewording of this point:

"- abnormal vocalisation, agitation or ~~and~~ defaecation."

Justification:

The listed behaviours will not necessarily all appear at the same time.

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*.

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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

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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.

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.

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.

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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.

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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

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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 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.

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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.

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— Text deleted.

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Annex 14

DRAFT CHAPTER 8.X.

INFECTION WITH *MYCOBACTERIUM TUBERCULOSIS* COMPLEX

EU comment

The EU thanks the OIE and in general supports the proposed changes to this draft new chapter. A comment is inserted in the text below.

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 (*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).*

EU comment

The EU suggests deleting the word "domestic" in point 4 above, as it is superfluous. Indeed, the first sentence of the paragraph above states "'animals' means domestic and captive wild animal populations of the following categories". Therefore, repeating the word "domestic" before llamas is confusing.

The EU reiterates its previous comment that it is very important to continue work to define appropriate testing regimes for both New World camelids and goats, and to further evaluate the application of new diagnostic techniques to these species which, if infected, may pose a risk in international trade.

In this regard, the EU would like to point out a document on the diagnosis of tuberculosis in camelids produced by the European Union Reference Laboratory for

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tuberculosis, available on the internet at https://www.visavet.es/bovinetuberculosis/data/wd/SANCO-7034-2013_Diagnosis_of_tuberculosis_in_camelids.pdf

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*.

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*;

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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.

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*

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provided that measures ~~have been implemented~~ intended to prevent transmission of *infection* with *M. tuberculosis* complex to cervids have been implemented.

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 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 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;

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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 *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 ~~c) i) or ii);~~. ~~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 ~~or for at least six months prior to shipment~~ 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.

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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:

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.

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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.

UNOFFICIAL VERSION

Annex 15

CHAPTER 10.4.

INFECTION WITH AVIAN INFLUENZA VIRUSES

EU comment

The EU supports the proposed changes to this article.

[Article 10.4.1.]

[…]

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.

[…]

[Article 10.4.33.]

- Text deleted.

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Annex 16

CHAPTER 11.11.

INFECTION WITH LUMPY SKIN DISEASE VIRUS

EU comment

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

Article 11.11.1.

General provisions

Lumpy skin disease (LSD) susceptible animals are cattle (*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 ~~(*Bos indicus* and *B. taurus*)~~ and water buffaloes ~~*(Bubalus bubalis)*~~ with lumpy skin disease virus (LSDV).

EU comment

The EU in general suggests clarifying what species are meant by the term "cattle", as this seems not to be consistent across the OIE Code. Reference is made to our comment on Chapter 6.X. (Annex 10).

The following defines *infection* with LSDV:

1) LSDV has been isolated from a sample from cattle or water buffaloes; or

2) antigen or nucleic acid specific to LSDV, excluding vaccine strains, has been identified in a sample from cattle or water buffaloes 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 or water buffaloes that either show clinical signs consistent with LSD, or are epidemiologically linked to a suspected or confirmed *case*.

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~~;~~.

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~~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 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) the country or *zone* has prohibited *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 of *infection* with LSDV in the country or *zone* for at least three years; or

3) the country or *zone* has prohibited *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 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 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) 14 months after 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 a *stamping-out policy* has been applied and during which period clinical *surveillance* alone has been conducted in accordance with Article 11.11.14.;

   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

The EU understands that serological surveillance as referred to in this Article would be done to substantiate absence of infection in unvaccinated animals only, as mentioned in point 3) of Article 11.11.14. In case of high vaccination coverage in the country / zone concerned, these would essentially be unvaccinated calves above the age of 6 months (to avoid detecting maternal antibodies). On the other hand, serological tests on vaccinated animals would be an indicator of success of the vaccination programme.

Article 11.11.4.

Recommendations for importation from countries or zones free from LSD

For domestic cattle and water buffaloes

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the

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animals:

1) showed no clinical sign of LSD on the day of shipment;

2) come from a country or *zone* free from LSD.

Article 11.11.5.

Recommendations for importation from countries or zones not free from LSD

For domestic cattle 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 60 days 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.

Article 11.11.6.

Recommendations for importation from countries or zones free from LSD

For semen of cattle 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 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*;

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OR

iii) were subjected to a serological test to detect antibodies specific to LSDV, with negative results, at least every 14 days throughout the collection period and one test 14 days after the final collection for this consignment; and

EU comment

Serological tests every 14 days are unpractical, given the unavailability of commercial ELISAs and the fact that in-house tests would need to be performed under Safety Level 3 conditions. The EU therefore suggests replacing "at least every 14 days throughout the collection period" by "at least every 28 days throughout the collection period" in point iii) above, which would be in line with serological testing intervals for other diseases.

iv) were subjected to agent detection by PCR conducted on blood samples collected at commencement and conclusion of, and at least every 14 days during, semen collection for this consignment, with negative results; and

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 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 Articles 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 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*;

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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

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 Articles 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 11.11.12.

Recommendations for importation of meal and flour from blood, meat other than skeletal muscle, or bones from cattle and water buffaloes

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) these products have been 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 11.11.13.

Recommendations for importation of hides of cattle and water buffaloes

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 ~~had~~ have been; ~~processed to ensure the destruction of LSDV, in premises controlled and~~

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~~approved by the *Veterinary Authority* of the *exporting country*.~~

a) derived from animals which have undergone ante- and post-mortem inspection in accordance with Chapter 6.2. with favourable results;

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.

Article 11.11.14.

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 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 *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* 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 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 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 susceptible unvaccinated animals.

EU comment

Due to possible interference of maternal antibodies, the EU suggests adding a sentence at the end of the paragraph above to also exclude young unvaccinated animals (under 6 months old) from serological surveillance in case the dam was vaccinated.

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

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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*.

— Text deleted.

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Annex 17

CHAPTER 12.10.

INFECTION WITH *BURKHOLDERIA MALLEI* (GLANDERS)

EU comment

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

Taking into account the proposed change to the designation of the disease and the title of this chapter, the EU suggests changing the corresponding entry in the list of diseases in Chapter 1.3. (i.e., replacing "glanders" by "infection with *Burkholderia mallei*" in Article 1.3.4.).

Article 12.10.1.

General provisions

~~Most glanders susceptible animals are equids.~~ Equids are the major hosts and reservoirs of glanders although s~~S~~cientific data are not available ~~for~~ on the occurrence of *infection* in zebras. Camelids and various carnivores including bears, canids and felids can also be infected but play no significant ~~epidemiological~~ role in the epidemiology of the *disease*. Glanders is a significant and potentially fatal zoonotic disease~~ with fatal outcome if not treated in a timely manner~~.

EU comment

Equids cannot be the host and reservoirs of glanders, but only of *Burkholderia mallei*. The EU therefore suggests amending the paragraph above as follows:

"Equids are the major hosts and reservoirs of ~~glanders~~ *Burkholderia mallei* although [...]".

Furthermore, it is well known that goats are sometimes infected with *B. mallei* as well. The EU therefore suggests inserting ", goats"after "Camelids".

Finally, the EU suggests amending the last sentence of the paragraph above as follows:

"Glanders is a rare but ~~significant and~~ potentially fatal zoonotic disease".

Indeed, while being a significant i.e. potentially fatal zoonosis when human infections do occur, recent experience shows that human cases are extremely rare. This should be reflected in the text.

For the purposes of the *Terrestrial Code*, glanders is defined as an *infection* of equids with *Burkholderia mallei* ~~in an equid~~ with or without the presence of clinical signs.

EU comment

For reasons of consistency with other disease specific chapters and established Code format, the EU suggests replacing the word "glanders" by the words "*infection* with *B. mallei*" in the paragraph above, and throughout the chapter as appropriate.

~~The chapter deals not only with the occurrence of clinical signs caused by *B. mallei*, but also with the presence of *infection* with *B. mallei* in the absence of clinical signs.~~

The following defines the occurrence of ~~an~~ *infection* with *B. mallei*:

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1) *B. mallei* has been isolated from a sample from an equid; or

2) antigen or genetic material specific to *B. mallei* has been identified in a sample from an equid showing clinical or pathological signs consistent with glanders, or epidemiologically linked to a confirmed or suspected *outbreak* of glanders, or giving cause for suspicion of previous contact with *B. mallei*; or

3) antibodies specific to *B. mallei* have been identified by a testing regime appropriate to the species in a sample from an equid showing clinical or pathological signs consistent with glanders, or epidemiologically linked to a confirmed or suspected *outbreak* of glanders, or giving cause for suspicion of previous contact with *B. mallei.*

For the purposes of the *Terrestrial Code*, the *infective period* of *B. mallei* in equids is lifelong and the *incubation period* is six months.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

Article 12.10.2.

Country or zone free from infection with *B. mallei* ~~infection~~

A country or a *zone* that does not comply with the point 1 *a)* of Article 1.4.6. may be considered free from *infection* with *B. mallei* when:

1) ~~glanders~~ *infection* with *B. mallei* ~~is~~ has been a *notifiable disease* in the entire country for at least the past three years;

2) ~~either:~~

   ~~a)~~ there has been no *case* ~~*outbreak* and no evidence~~ of *infection* with *B. mallei* ~~in equids~~ during the past three years~~. following the destruction of the last *case*; or~~

3~~b~~) ~~no evidence of *infection* with *B. mallei* has been found during the past six months following the destruction of the last *case*; and there is~~ a *surveillance* programme ~~in place demonstrating the absence of *infection*~~ in accordance with Article 12.10.8. has demonstrated no evidence of *infection* with *B. mallei* in the past ~~12~~ six months;

~~AND~~

4~~3~~) imports of equids and their germplasm into the country or *zone* are carried out in accordance with this chapter.

Article 12.10.3.

Recovery of free status

When a *case* is detected in a previously free country or *zone*, freedom from *infection* with *B. mallei* can be regained after the following:

1) a standstill of movements of equids and their germplasm from *establishments* ~~affected~~ infected or suspected of being ~~affected~~ infected has been imposed until the destruction of the last *case*;

EU comment

The EU would prefer replacing the term "standstill" with the term "prohibition" in point 1 above. Indeed, a standstill of equids (i.e. a complete freezing of all movements) will be difficult to implement, especially before the diagnosis is laboratory confirmed. Furthermore, depending on when the germplasm was collected (which could be years before the infection), there is no need for a standstill but rather for a control of movements.

2) an epidemiological investigation (trace-back, trace-forward), including ~~investigations~~ to determine the likely source of the *outbreak,* ~~have~~ has been carried out;

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3) a *stamping-out policy,* which includes at least the destruction of all infected equids and cleansing and *disinfection* of the ~~affected~~ infected *establishments,* has been applied;

EU comment

To avoid confusion, the term "infected *establishments*" in point 3 above should not be used. Indeed, whereas an "infected zone" is defined, it is unclear what exactly an "infected *establishment*" would be. The EU thus suggests the following alternative:

"[...] cleansing and *disinfection* of the *establishments* accommodating infected animals".

4) increased *surveillance* in accordance with Article 12.10.8. has been carried out and has demonstrated ~~not detected any~~ no evidence of *infection* in the six months after ~~*stamping-out*~~ *disinfection* of the last infected *establishment* and during that period measures have been in place to control the movement of equids.

EU comment

The EU reiterates its previous comment asking to delete the word "increased" from point 4 above. We think that this is very relevant, and note that no explanation is given in the introduction to the report on why that comment was not taken into account.

Indeed, as surveillance is to be carried out in accordance with Article 12.10.8., the use of the word "increased" is superfluous and confusing. For example, it is not used in the context of gaining free status (Article 12.10.2. point 3), and it is not clear what should be "increased" when carrying out surveillance for recovery of free status. Furthermore, the term "increased surveillance" is used nowhere in the Code; other similar articles on recovery of free status simply refer to "surveillance in accordance with Article X.Y.Z.". The introduction of this term here would thus be inconsistent with other disease specific chapters and could lead to confusion.

~~5) measures are in place to control the movement of equids to prevent the spread of *B. mallei.*~~

When the measures above are not carried out, Article 12.10.2. applies.

Article 12.10.4.

Recommendations for importation of equids from countries or zones free from infection with *B. mallei* ~~infection~~

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the equid:

1) showed no clinical signs of ~~glanders~~ *infection* with *B. mallei* on the day of shipment;

2) either:

a) was kept for six months prior to shipment, or since birth, in a ~~the *exporting* *country*~~ or *zone* free from *infection* with *B. mallei*; or

EU comment

For reasons of clarity and consistency with other chapters, the EU suggests inserting the words "at least" before "six months" in point 2 a) above.

b) was ~~imported in accordance with Article 12.10.5.~~ kept in an *establishment* in the *exporting country* for at least 30 days and then ~~was~~ subjected to a ~~prescribed~~ test with negative result ~~on a sample taken during the 10 days prior to shipment~~.

EU comment

For clarity reasons, the EU suggests rephrasing point 2 b) above as follows:

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"was kept in an establishment in the exporting country for at least 30 days and ~~then~~ subjected with a negative result to a test for *B. mallei* carried out on a sample taken after that period ~~with negative result~~".

Indeed, it is the date of sampling that is relevant, not the date of testing.

Article 12.10.5.

Recommendations for importation of equids from countries or zones ~~considered infected~~ not free from infection with *B. mallei*

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the equid:

1) showed no clinical signs of ~~glanders~~ *infection* with *B. mallei* on the day of shipment;

2) was kept for six months prior to shipment, or since birth, in an *establishment* where no *case* of ~~glanders~~ *infection* with *B. mallei* was reported during the ~~six~~ 12 months prior to shipment;

EU comment

For reasons of clarity and consistency with other chapters, the EU suggests inserting the words "at least" before "six months" in point 2 above.

3) was isolated and subjected to two ~~a prescribed~~ tests, with negative results on ~~a~~ samples taken ~~during the~~ 30 days apart with the second sample taken within 10 days prior to shipment.

EU comment

For clarity reasons, the EU suggests rephrasing point 3 above as follows:

"was isolated, and during isolation was subjected to ~~two~~ tests for glanders~~,~~ carried out with negative results on samples taken on two occasions at least 30 days apart, ~~with~~ the second ~~sample~~ of which taken ~~within~~ during the 10 days prior to shipment."

Article 12.10.6.

Recommendations for the importation of equine semen

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

1) the donor males ~~animals~~:

   a) showed no clinical signs of ~~glanders~~ *infection* with *B. mallei* on the day of collection; ~~and for the following 21 days;~~

   b) were examined clinically for signs of orchitis, with negative results;~~were kept continuously:~~

EU comment

For clarity reasons, the EU suggests rephrasing point b above as follows:

"were examined ~~clinically~~ for clinical signs of [...]."

   ~~i) either for a period of at least 21 days prior to, and for until at least 21 days after, the collection in a country or a *zone* free from *infection* with *B. mallei*, or~~

   ~~ii) for at least six months prior to the collection of the semen and during the collection in an *establishment* or *artificial insemination centre* free from *infection* with *B. mallei* and were subjected to a prescribed test, with a negative result on a sample taken between 21 and 30 days before the collection, or in the case of frozen semen between 21 and 30 days after the collection;~~

2) the semen was collected, processed and stored in accordance with the relevant recommendations in Chapter 4.5. and in Articles 4.6.5. to 4.6.7.

EU comment

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The EU supports the new references to Articles 4.6.5. to 4.6.7. in the point above, as these contain rather generic recommendation, even if Chapter 4.6. in principle only relates to bovine, small ruminant and porcine semen. We would however encourage the OIE to revise that chapter in the future to include also equids.

Article 12.10.7.

Recommendations for the importation of *in vivo* derived equine embryos

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

1) the donor females ~~animals:~~

   ~~a)~~ showed no clinical signs of ~~glanders~~ *infection* with *B. mallei* on the day of collection ~~and for the following 21 days~~;

   ~~b) were kept continuously:~~

      ~~i) either for a period of at least 21 days before, and for until at least 21 days after, the day of collection of the embryos in a country or a *zone* free from *infection* with *B. mallei*, or~~

      ~~ii) for at least six months prior to the collection and during the collection in an *establishment* free from *infection* with *B. mallei* and were subjected to a prescribed test, with a negative result on a sample taken between 21 and 30 days before the collection, or in the case of frozen embryos, between 21 and 30 days after the collection;~~

2) the embryos were collected, processed and stored in accordance with the relevant recommendations in Chapters 4.7. and 4.9.~~, as relevant~~;

3) the semen used for embryo production ~~to fertilise the oocytes~~ complies with ~~the recommendations in~~ Article 12.10.6.

Article 12.10.8.

General Principles of surveillance

~~The purpose of *surveillance* is to determine the status of a country or a *zone* with respect to *infection* with *B. mallei*.~~

~~*Surveillance* should be carried out in accordance with Chapter 1.4.~~

~~Populations of *captive wild*, *feral* and *wild* equids should be included in the *surveillance* programme, for example through testing of roadkill or equids or culled as part of population control measures.~~

~~Clinical *surveillance* aims at detecting signs of glanders by close physical examination of susceptible animals. Clinical inspection is an important component of *surveillance* contributing to the desired level of confidence of detection of *disease*, if so long as a sufficiently large number of clinically susceptible animals is examined. Laboratory investigations should be conducted on all suspected *cases*.~~

~~Systematic pathological *surveillance* is an effective approach for glanders and should be conducted on dead equids on farm, at *slaughterhouses/abattoirs* and establishments for the disposal of carcasses of equids. Suspicious pathological findings should be confirmed by agent identification and isolates should be typed.~~

~~When conducting serological *surveillance* repeated testing of the equine population is necessary to reach an acceptable level of confidence.~~

~~Clinical examination and laboratory testing should be applied to clarify the status of suspects detected by either of these complementary diagnostic approaches. Laboratory testing and necropsy may contribute to confirm clinical suspicion, while clinical examination may contribute to confirmation of positive serology.~~

This article and Article 12.10.9. provide recommendations for *surveillance* for glanders and are complementary to Chapter 1.4. The impact and epidemiology of glanders vary in different regions of the world. The *surveillance* strategies employed for determining glanders status should be adapted to the respective epidemiological situation.

UNOFFICIAL VERSION

The *surveillance* programme should be designed to demonstrate that susceptible populations in a country or *zone* show no evidence of *infection* with *B. mallei* or to detect its introduction into a free population. If *B. mallei* is known to be present, *surveillance* should allow the estimation of the *prevalence* and the determination of the distribution of the *infection*.

EU comment

It is unclear what is meant by "susceptible populations" in the paragraph above – does this include humans and camelids etc.? Indeed, glanders is defined as *B. mallei* infection in equids (Article 12.10.1.), so the susceptible populations in the surveillance programme should preferably be specified. The EU thus suggests replacing "susceptible populations" by "equids".

A *surveillance* system in accordance with Chapter 1.4 should be under the responsibility of the *Veterinary Authority* and should have in place:

a) a formal and ongoing system for detecting and investigating *outbreaks* of *disease*;

EU comment

It is unclear why the term "disease" is used in point a) above. Indeed, infections should be detected and investigated as well. The EU therefore suggests deleting the words "of disease".

Furthermore, slaughterhouse findings should be mentioned as well.

b) a procedure for the rapid collection and transport of samples from suspected *cases* to a *laboratory* with appropriate testing capability for glanders diagnosis;

EU comment

As point b) above deals with laboratory testing, instead of "glanders" (i.e. the disease), the reference should be "infection with *B. mallei*".

c) a system for recording, managing and analysing diagnostic, epidemiological and surveillance data;

d) established links with an OIE Reference Laboratory in case of need for confirmatory testing.

EU comment

Point d) above seems excessive. Indeed, as surveillance must be carried out at almost all time, even if the country is free of glanders, is it really necessary to have "established links" with an OIE Reference laboratory? Is it not sufficient if the link is established only in case the disease cannot be confirmed? This should not be a requirement but a recommendation.

Furthermore, the EU suggests adding a point on animal identification and registration, which should be done in accordance with Chapter 4.2.

The glanders *surveillance* programme should include an *early detection system* for reporting suspected *cases*. Diagnosticians and those with regular contact with susceptible or infected equids should report promptly any suspicion of glanders 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 awareness programmes. Personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in glanders, epidemiological evaluation and control as part of their contingency plan.

EU comment

The wording regarding "susceptible or infected equids" should be revised. Indeed, all equids are susceptible, and if an equid has regular contact with infected equids, there is no need to report a suspicion because that equid is likely already infected, i.e. there is a

UNOFFICIAL VERSION

need for confirmation. The EU suggests requiring that people handling equids should report suspicions.

Furthermore, the wording of the last sentence of the paragraph above should be revised, as it suggests that the personnel responsible for surveillance have a contingency plan (e.g. by amending as follows: "[...] as part of ~~their~~ the country's contingency plan).

The *Veterinary Authority* should implement, when relevant, regular and frequent clinical inspections and random or targeted serological surveys and laboratory testing of high-risk groups or those adjacent to a country or *zone* infected with *B. mallei*. An effective *surveillance* system is likely to identify suspected *cases* that require follow-up investigation to confirm or exclude that the cause of the condition is *B. mallei*. All suspected *cases* of *infection* with *B. mallei* should be investigated immediately and samples should be taken and submitted to a *laboratory*. This requires that sampling kits and other equipment be available to those responsible for the *surveillance*. Details of the occurrence of suspected *cases* and how they were investigated and dealt with should be documented. This should include the results of diagnostic testing and the control measures to which the equids concerned were subjected during the investigation (quarantine, movement control).

Susceptible *captive wild*, *feral* and *wild* equine populations should be included in the *surveillance* programme.

EU comment

The word "Susceptible" should be deleted, as all equids are susceptible.

Surveillance should address not only the occurrence of clinical signs caused by *B. mallei*, but also evidence of *infection* with *B. mallei* in the absence of clinical signs.

Article 12.10.9.

Surveillance strategies

The strategy employed may be based on clinical investigation, or randomised or targeted sampling at an acceptable level of statistical confidence. If glanders is present, it is usually at a very low *prevalence*. If an increased likelihood of *infection* in particular geographical locations or *subpopulations* can be identified, targeted sampling is appropriate.

EU comment

In the paragraph above, the EU suggests inserting the words "for surveillance" after the words "The strategy employed", and the words "and testing" after the words "or targeted sampling" (clarity).

To detect *infection* or to determine the distribution and estimate the *prevalence* of *infection* either at the level of the entire population or within targeted *subpopulations,* the design of the sampling strategy and frequency of testing should incorporate epidemiologically appropriate design *prevalence* for the selected populations. The sample size selected for testing should be statistically relevant to detect the presence of *infection* if it were to occur at a predetermined minimum rate. The design *prevalence* and confidence level should be consistent with the objectives of the *surveillance* and the epidemiological situation.

To substantiate freedom from *infection* in a country or *zone*, *surveillance* should be conducted in accordance with the relevant provisions of Chapter 1.4. Irrespective of the approach selected, the sensitivity and specificity of the diagnostic tests employed should be considered in the design and in the interpretation of the results obtained. The occurrence of false positive reactions has to be considered and the rate at which these false positives are likely to occur should be calculated in advance. Every positive result should be investigated to determine whether it is indicative of *infection* or not. This involves supplementary tests, trace-back and trace-forward, and inspection of individual *animals* and *herds* for clinical signs. Laboratory results should be interpreted in the context of the epidemiological situation.

EU comment

In the paragraph above, the EU suggests inserting the words "during surveillance" after the words "of the results obtained", and replacing the word "calculated" by the word "estimated" (clarity).

UNOFFICIAL VERSION

Furthermore, the EU suggests inserting the words "<u>, including in cohort animals,</u>" after "This involves supplementary tests", as well as the word "<u>contact</u>" after the words "and inspection of individual".

Finally, the EU queries the difference between "herds" (used in the second last sentence of the paragraph above) and "epidemiological units" (used in the paragraph below).

Methods should include clinical *surveillance* and laboratory testing. They should always be applied in series to clarify the status of suspected *cases* of glanders detected by either of these complementary diagnostic approaches. Agent identification should be carried out on any equid positive or showing clinical signs. Any *epidemiological unit* within which suspected *cases* are detected should be considered infected until contrary evidence is produced.

EU comment

In the paragraph above, it is not clear what "positive" refers to (in the context of "on any equid positive or showing clinical signs"). Would this be positive in a serology assay?

1. Clinical surveillance

   Clinical *surveillance* aims at detecting clinical signs by close physical examination of equids. However, clinical *surveillance* is of limited use only as asymptomatic carrier animals are the main reservoir of the *disease*.

EU comment

In point 1 above, for reasons of clarity, the EU suggests moving the word "only" for the sentence to read as follows:

"[...] However, clinical surveillance is <u>only</u> of limited use ~~only~~ as asymptomatic [...]".

2. Pathological and bacteriological surveillance

   Systematic pathological *surveillance* is an effective approach for the detection of glanders and should be conducted on dead equids on farms, at *slaughterhouses/abattoirs* and facilities for the disposal of carcasses of equids. Suspicious pathological findings should be confirmed by agent identification and isolates should be characterised.

3. Serological surveillance

   Serological *surveillance* for glanders is the preferred strategy. Repeated testing of the equid population with recommended tests is necessary to reach an acceptable level of confidence.

EU comment

The EU suggests deleting the words "to reach an acceptable level of confidence", as they do not add anything meaningful.

Furthermore, it should be specified that a condition for serological surveillance and repeated testing to be acceptable is that all animals are individually identified and registered.

4. Malleinisation

   Frequently used as a *surveillance* method, malleinisation demonstrates hypersensitivity to antigens of *B. mallei*. However, this method has shortcomings that should be considered when interpreting results.

UNOFFICIAL VERSION

Annex 18

CHAPTER 15.1.

INFECTION WITH AFRICAN SWINE FEVER VIRUS

EU comment

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

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 *infection* with ASFV:

EU comment

The EU suggests inserting the words "the occurrence of" before the words "infection with ASFV" in the sentence above. Indeed, it is the occurrence of infection that is defined below, and not infection per se. (This comment would be valid also for other disease-specific chapters.)

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 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

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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 purpose of the *Terrestrial Code*, the *incubation period* in *Sus scrofa* ~~is~~ shall be ~~15~~ 19 days.

EU comment

The EU does not agree with changing the incubation period from 15 to 19 days in the Code chapter.

While it is true that the Manual states that "*The incubation period in nature is usually 4 to 19 days*", this does not seem relevant for the purposes of the Code.

Indeed, the Manual describes the maximum range of incubation period as determined in experimental scientific studies, which not necessarily corresponds to common natural situations. Practical experience however shows that the incubation period in the field in general is much shorter than 15 days.

Thus, the incubation period of 15 days as defined for the purposes of the Code already includes a significant safety margin, which has proven to be adequate to safeguard international trade for many years. This has been certified by ASF experts, and also the members of the OIE ad hoc group on ASF suggested keeping the incubation period at 15 days.

Therefore, there is no reason to change the incubation period in the Code, and there should certainly be no automatic transfer to the Code of the maximum incubation period described in the Manual (NB most disease-specific chapters of the Manual do not even describe the incubation period.)

For these reasons, the EU requests that the incubation period be reverted to 15 days in line with the proposal of the ad hoc group.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

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 Articles 15.1.22. 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

UNOFFICIAL VERSION

ASF spread including taking into account the presence of *Ornithodoros* ticks where relevant;

7) 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 protected from *Ornithodoros* ticks where relevant.

Commodities of domestic or *captive wild* pigs can be traded safely ~~according to~~ 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 ~~demonstrates~~ 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.

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 ~~demonstrates~~ 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.~~

UNOFFICIAL VERSION

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* have originated outside the *containment zone* unless these *commodities* 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.

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 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~~

EU comment

The EU supports the amendment proposed above. However it should be clarified that this should also apply not only in cases where ticks are suspected to be involved, but also when it is actually known that ticks are involved in the epidemiology of ASF. Thus, the EU suggests inserting the words "known or" before the words "suspected to be".

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

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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.

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;

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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.

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) 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:

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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) fertilisation was achieved with semen meeting the conditions referred to in Articles 15.1.7. or Article 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

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 a~~n 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 Article 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 ~~considered infected with~~ 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~~

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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.~~

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 Articles 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~~

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~~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 Article 15.1.3 point 1 or 2 and have been processed in a facility approved by the *Veterinary Authority* for export purposes; or

2~~1~~) originated from ~~domestic or *captive wild* pigs suids~~ 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~~2~~) 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.

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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;

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 ~~(under study)~~

   ~~*a)* if salted, *Meat* should be cured with salt and dried for a minimum of six months.; or~~

   ~~*b)* if not salted, *meat* should be cured and dried for a minimum of 12 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 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

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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 ~~prepared from 30 ml commercial formalin per litre of water~~.

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 ~~Chapter~~ 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 ~~production~~ 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.

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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 ~~*outbreaks*~~ *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*;

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– 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.

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.

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Annex 18 (contd)

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 w*ild* and *feral* suid 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.

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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 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 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.

— Text deleted.

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Annex 19

CHAPTER 15.X.

INFECTION WITH PORCINE REPRODUCTIVE AND RESPIRATORY SYNDROME VIRUS

Article 15.X.1.

EU comment

The EU thanks the OIE and in general supports the proposed changes to this draft new chapter. Comments are inserted in the text below.

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 *infection* with PRRSV:

1) a strain of PRRSV has been isolated from samples from a domestic or *captive wild* pig;

EU comment

For reasons of consistency with other disease-specific chapters of the Code, the EU suggests deleting the words "a strain of", and replacing the word "samples" by "a sample" in point 1) above.

Furthermore, from the wording of point 1 above it seems that the isolation of a live vaccine virus strain would need to be considered as falling under the case definition, which would not be adequate. Perhaps this could be solved by inserting the words "that is not the consequence of vaccination" after "PRRSV" in point 1) above, which would be consistent with the wording of point 2) below. Alternatively, "isolation of a live PRRSV vaccine strain" could be added to point 3) below.

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 samples from a domestic or *captive wild* pig epidemiologically linked to a confirmed or suspected *outbreak* of PRRS, or giving cause for suspicion of previous association or contact with PRRSV, with or without clinical signs consistent with PRRS;

OR

3) antigen or ribonucleic acid specific to a PRRSV vaccine strain has been detected in samples from a domestic or *captive wild* pig that is unvaccinated, or has been vaccinated with an inactivated vaccine, or with a different vaccine strain;

EU comment

The EU does not support the new point 3) above as proposed. As explained in the EU comment on the corresponding point in the chapter on bluetongue (see Annex 28), live attenuated vaccine virus naturally transmitted to an unvaccinated animal without causing any clinical disease or other harm should not be included in the case definition.

In analogy to the suggestion in the bluetongue chapter, we therefore suggest the following amendments to point 3) above:

"3) antigen or ribonucleic acid specific to a virulent revertant or reassortant of a PRRSV live vaccine strain has been detected in samples from a domestic or captive wild pig that was not vaccinated with that live vaccine strain ~~is unvaccinated, or has been vaccinated with an inactivated vaccine, or with a different vaccine strain~~ and showing clinical signs consistent with PRRS, or epidemiologically linked to a suspected or confirmed case;"

OR

~~4~~3) ~~virus specific~~ antibodies specific ~~against~~ to PRRSV that are not 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.

EU comment

The EU queries whether the new insertion in point 4) above is adequate. Indeed, maternally derived immunity could also be considered as being the consequence of vaccination, as the immunity of the dam could be the result of vaccination. If that were not the case, maternally derived immunity should give rise to suspicion that should initiate further investigations.

~~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.~~

~~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.~~ *Commodities* of domestic or *captive wild* pigs can be traded safely ~~according to~~ 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.

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;

4) *meat-and-bone meal*;

~~5) blood by-products;~~

5~~6~~) *casings*;

6) gelatine.

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Article 15.X.3.

Country, zone or compartment free from PRRS

A country, *zone* or *compartment* may be considered free from PRRS when:

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.~~15~~13~~13~~12. to 15.X.~~18~~16~~16~~15. 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) no ~~evidence of~~ *infection* with PRRSV has been found in domestic and *captive wild* pigs during the past 12 months;

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;

~~7~~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.~~14~~12~~12~~11.

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.~~15~~13~~13~~12. to 15.X.~~18~~16~~16~~15. 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

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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;

EU comment

The insertion of the requirement above seems logical at first sight, however it appears to put into question the assurance provided by isolation and double serological testing as required according to point 4) below. The EU is of the opinion that point 1) above is not necessary and should be deleted.

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 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.

EU comment

The EU suggests prescribing the required isolation period in point 4) above, i.e. 28 days as per pre-isolation prior to entry in AI centre. A clear recommendation indeed seems necessary in order to avoid any possible disproportionate duration of pre-export isolation set up by importing countries.

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.~~9~~8.

Recommendations for importation from countries, zones or compartments free from PRRS

For semen of domestic and captive wild pigs

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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.~~10~~9.

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 ~~either:~~

   ~~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 and were ~~serologically tested~~ subjected to a serological test with negative results on 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 ~~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, a statistically representative sample of all donor males is subjected ~~are all boars are subjected~~, ~~at least every month,~~ to a serological test for *infection* with PRRSV with negative results~~, at least every month~~. The sampling scheme should be designed to ensure that all donor males ~~should be~~ 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 ~~pigs~~ 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, on serum samples taken ~~seronegative for PRRS~~ on the day of collection;

EU comment

For reasons of clarity, the EU suggests inserting the words "with negative results" after the words "serological and virological examinations" in point ii) above.

      ~~*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.

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Article 15.X.~~11~~10.

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.~~9~~8. or 15.X.~~10~~9.

Article 15.X.~~12~~11.

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 ~~of the embryos~~;

   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 Articles 15.X.~~9~~8. or 15.X.~~10~~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*:~~

~~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:~~

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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.1513<u>12</u>.

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 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:

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– 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.~~16~~13.

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.

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.~~17~~15~~15~~14.

Surveillance strategies

1. Introduction

   The objective of ~~the~~ *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* 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.~~

   ~~In some circumstances such as clinical *disease* investigations and in high risk populations, virological *surveillance* may provide advantage through earlier detection.~~

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Annex 19 (contd)

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 ~~at~~ 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.~~1816~~15.

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*;

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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.

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Annex 20

CHAPTER 4.16.

HIGH HEALTH STATUS HORSE SUBPOPULATION

EU comment

The EU supports the proposed changes to this article.

[Article 4.16.1.]

[…]

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.

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Annex 21

CHAPTER 4.3.

ZONING AND COMPARTMENTALISATION

EU comment

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

Article 4.3.1.

Introduction

~~For the purposes of the *Terrestrial Code*, 'zoning' and 'regionalisation' have the same meaning.~~

The purpose of this chapter is to provide recommendations on the principles of zoning and compartmentalisation to Member Countries wishing to establish and maintain different *subpopulations* with specific health status within their territory. These principles should be applied in accordance with the relevant chapters of the *Terrestrial Code*. This chapter also outlines a process by which trading partners may recognise such *subpopulations*.

Establishing and maintaining a *disease*-free status throughout the country should be the final goal for Member Countries. However, given the difficulty of this ~~of establishing and maintaining a *disease* free status for an entire territory, especially for *diseases*, the entry of which is difficult to control through measures at national boundaries~~, there may be benefits to a Member Country in establishing and maintaining a *subpopulation* with a ~~distinct~~ specific health status within its territory for the purpose of *disease* control or *international trade*. *Subpopulations* may be separated by natural or artificial geographical barriers or~~, in certain situations,~~ by the application of appropriate management.

EU comment

The EU in principle agrees with replacing "distinct" with "specific" in the paragraph above. However, we note that this has not been done throughout the chapter. Indeed, "distinct health status" and "distinct animal health status" are still used several times in this chapter. The wording should preferably be consistent throughout the chapter.

Furthermore, while in principle agreeing with the insertion of "for the purpose of disease control or international trade" in the paragraph above, the EU notes that the purpose "disease control" would apply only for a zone, not for a compartment. Indeed, the word "control" implies that the disease could be present in a compartment, which would go against the purpose of compartmentalisation where management, biosecurity and surveillance practices are used to prevent the introduction of a disease in the compartment with a view to attain a distinct health status to facilitate trade. This should therefore be clarified somewhere in this chapter.

Finally, the EU suggests including the concept of disease prevention in the paragraph above, as this is an important aspect of zoning.

~~Zoning and compartmentalisation are procedures implemented by a Member Country under the provisions of this chapter with a view to defining *subpopulations* of distinct health status within its territory for the purpose of *disease* control and/or *international trade*.~~ While zoning applies to an animal *subpopulation* defined primarily on a geographical basis ~~(using natural, artificial or legal boundaries)~~, compartmentalisation applies to an animal *subpopulation* defined primarily by management and husbandry practices related to *biosecurity*. In practice, spatial considerations and good management, including *biosecurity plans*, play important roles in the application of both concepts.

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~~A particular application of the concept of zoning is the establishment of a *containment zone*. In the event of limited *outbreaks* of a specified *disease* within an otherwise free country or *zone*, a single *containment zone*, which includes all *cases*, can be established for the purpose of minimizing the impact on the entire country or *zone*.~~

~~This chapter is to assist Member Countries wishing to establish and maintain different *subpopulations* within their territory using the principles of compartmentalisation and zoning. These principles should be applied in accordance with the measures recommended in the relevant *disease* chapter(s). This chapter also outlines a process through which trading partners may recognise such *subpopulations*. This process is best implemented by trading partners through establishing parameters and gaining agreement on the necessary measures prior to *outbreaks* of *disease*.~~

~~Before trade in *animals* or their products may occur, an *importing country* needs to be satisfied that its *animal health status* will be appropriately protected. In most cases, the import regulations developed will rely in part on judgements made about the effectiveness of sanitary procedures undertaken by the *exporting country*, both at its borders and within its territory.~~

~~As well as contributing to the safety of *international trade*, zoning and compartmentalisation may assist *disease* control or eradication within a Member Country's territory.~~ Zoning may encourage the more efficient use of resources within certain parts of a country and compartmentalisation may allow the functional separation of a *subpopulation* from other domestic ~~*animals*~~ or *wild animals* through *biosecurity* ~~measures~~, which a *zone* ~~(through geographical separation)~~ would not achieve through geographical separation. In a country where a *disease* is endemic, establishment of *free zones* may assist in the progressive control and eradication of the *disease*. Following a *disease outbreak* in a previously free country or *zone*, to facilitate *disease* control and the continuation of trade, the use of zoning may allow a Member Country to limit the extension of the *disease* to a defined restricted area, while preserving the status of the remaining territory. ~~the~~ For the same reasons, the use of compartmentalisation may allow a Member Country to take advantage of epidemiological links among *subpopulations* or common practices relating to *biosecurity*, despite diverse geographical locations~~, to facilitate *disease* control and/or the continuation of trade~~.

A Member Country may thus have more than one *zone* or *compartment* within its territory.

~~Zoning and compartmentalisation cannot be applied to all *diseases* but separate requirements will be developed for each *disease* for which the application of zoning or compartmentalisation is considered appropriate.~~

~~To regain free status following a *disease outbreak* in a *zone* or *compartment*, Member Countries should follow the recommendations in the relevant *disease* chapter in the *Terrestrial Code*.~~

~~The purpose of this chapter is to provide recommendations on the principles of zoning and compartmentalisation to Member Countries wishing to establish and maintain different *subpopulations* within their territory. These principles should be applied in accordance with the relevant chapters of the *Terrestrial Code*. This chapter also outlines a process by which trading partners may recognise such *subpopulations*.~~

Article 4.3.2.

General considerations

The *Veterinary Services* of ~~an *exporting*~~ a Member ~~country~~ Country ~~which~~ that is establishing a *zone* or *compartment* within its territory ~~for *international trade* purposes~~ should clearly define the *subpopulation* in accordance with the recommendations in the relevant chapters ~~in~~ of the *Terrestrial Code*, including those on *surveillance*, and the *identification* and *traceability* of ~~live~~ *animals*. ~~The *Veterinary Services* of an *exporting country* should be able to explain to the *Veterinary Services* of an *importing country* the basis for claiming a distinct *animal health status* for the given *zone* or *compartment* under consideration.~~

The procedures used to establish and maintain the distinct *animal health status* of a *zone* or *compartment* ~~will~~ depend on the epidemiology of the *disease*, including ~~in particular~~ the presence and role of *vectors* and susceptible *wildlife* ~~species,~~ and environmental factors, as well as on the application of *biosecurity* and *sanitary measures*.

Biosecurity and *surveillance* are essential components of zoning and compartmentalisation, and ~~the arrangements~~ should be developed through active cooperation of industry and *Veterinary Services*.

The authority, organisation and infrastructure of the *Veterinary Services*, including *laboratories*, should be clearly documented in accordance with ~~the~~ Chapters 3.1. and 3.2. ~~on the evaluation of *Veterinary Services* of the *Terrestrial Code*~~, to provide confidence in the integrity of the *zone* or *compartment*. The final authority ~~of~~ over the *zone* or *compartment*, for the purposes of domestic and *international trade*, lies with the *Veterinary Authority*. The *Veterinary Authority* should conduct an assessment of the resources needed and available to establish and

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maintain a *zone* or *compartment*. These include the human and financial resources and the technical capability of the *Veterinary Services* (and of the relevant industry and production system (especially in the case of a *compartment*), including for *disease surveillance* and diagnosis.

EU comment

The EU wonders whether the term "documented" in the first sentence of the paragraph above is appropriate. Indeed, while documenting the organisation and infrastructure of the Veterinary Services is certainly important (e.g. for contingency plans), these need to first of all be well established (e.g. in national law or a decree etc.) and also operational. The EU therefore suggests amending the sentence as follows:

"The authority, organisation and infrastructure of the Veterinary Services, including laboratories, should be ~~clearly documented~~ established and operate in accordance with the principles and criteria of Chapters 3.1. and 3.2. [...]"

In the context of maintaining the *animal health status* of a *population* or *subpopulation* of a country, *zone* or *compartment*, ~~references to 'import', 'importation' and 'imported animals/ products' found in the *Terrestrial Code* apply both to~~ importations into ~~a~~ the country as well as ~~and to the~~ movements of *animals* and their products into the *zones* ~~and~~ or *compartments*. ~~Such movements~~ should be the subject of appropriate *sanitary measures* and *biosecurity* ~~to preserve the *animal health status* of the country, *zone/* or *compartment*~~.

The *Veterinary Services* should provide movement certification, and carry out documented periodic inspections of facilities, *biosecurity*, records and *surveillance* procedures. *Veterinary Services* should conduct or audit *surveillance*, reporting and *laboratory* diagnostic examinations.

~~The *exporting country* should be able to demonstrate, through detailed documentation provided to the *importing country*, that it has implemented the recommendations in the *Terrestrial Code* for establishing and maintaining such a *zone* or *compartment*.~~

~~An *importing country* should recognise the existence of this *zone* or *compartment* when the appropriate measures recommended in the *Terrestrial Code* are applied and the *Veterinary Authority* of the *exporting country* certifies that this is the case.~~

~~The *exporting country* should conduct an assessment of the resources needed and available to establish and maintain a *zone* or *compartment* for *international trade* purposes. These include the human and financial resources, and the technical capability of the *Veterinary Services* (and of the relevant industry and production system, in the case of a *compartment*) including *disease surveillance* and diagnosis.~~

~~*Biosecurity* and *surveillance* are essential components of zoning and compartmentalisation, and the arrangements should be developed through cooperation of industry and *Veterinary Services*.~~

~~Industry's responsibilities include the application of *biosecurity* measures, documenting and recording movements of *animals* and personnel, quality assurance schemes, monitoring the efficacy of the measures, documenting corrective actions, conducting *surveillance*, rapid reporting and maintenance of records in a readily accessible form.~~

Industry's responsibilities include the application of *biosecurity*, documenting and recording movements of *animals* and personnel, quality assurance schemes, documenting corrective actions, conducting *surveillance*, rapid reporting and maintenance of records in a readily accessible form.

EU comment

The EU suggests inserting the words "and their products" after "movements of animals" in the paragraph above. Indeed, products such as meat, milk, hatching eggs and germinal products should be included here, but perhaps also manure and dead animals.

~~The *Veterinary Services* should provide movement certification, and carry out documented periodic inspections of facilities, *biosecurity* measures, records and *surveillance* procedures. *Veterinary Services* should conduct or audit *surveillance*, reporting and *laboratory* diagnostic examinations.~~

Article 4.3.3.

UNOFFICIAL VERSION

Principles for defining and establishing a zone or compartment~~, including protection and containment zones~~

~~In conjunction with the above considerations, the~~ The following principles ~~should~~ apply when Member Countries define a *zone* or a *compartment*.

1) The extent of a *zone* and its geographical limits should be established by the *Veterinary Authority* on the basis of natural, artificial ~~and/~~or legal boundaries, and made public through official channels.

~~2) A *protection zone* may be established to preserve the health status of *animals* in a free country or *zone*, from adjacent countries or *zones* of different *animal health status*. Measures should be implemented based on the epidemiology of the *disease* under consideration to prevent introduction of the pathogenic agent and to ensure early detection.~~

~~These measures should include intensified movement control and *surveillance* and may include:~~

~~*a)* *animal identification* and *animal traceability* to ensure that *animals* in the *protection zone* are clearly distinguishable from other populations;~~

~~*b)* *vaccination* of all or at risk susceptible *animals*;~~

~~*c)* testing and/or *vaccination* of *animals* moved;~~

~~*d)* specific procedures for sample handling, sending and testing;~~

~~*e)* enhanced *biosecurity* including cleansing – *disinfection* procedures for transport means, and possible compulsory routes;~~

~~*f)* specific *surveillance* of susceptible *wildlife* species and relevant *vectors*;~~

~~*g)* awareness campaigns to the public or targeted at breeders, traders, hunters, *veterinarians*.~~

~~The application of these measures can be in the entire free *zone* or in a defined area within and/or outside the free *zone*.~~

~~3) In the event of limited *outbreaks* in a country or *zone* previously free of a *disease*, a *containment zone* may be established for the purposes of trade. Establishment of a *containment zone* should be based on a rapid response including:~~

~~*a)* Appropriate standstill of movement of *animals* and other *commodities* upon notification of suspicion of the specified *disease* and the demonstration that the *outbreaks* are contained within this zone through epidemiological investigation (trace back, trace forward) after confirmation of *infection*. The primary *outbreak* has been identified and investigations on the likely source of the *outbreak* have been carried out and all *cases* shown to be epidemiologically linked.~~

~~*b)* A *stamping out policy* or another effective control strategy aimed at eradicating the *disease* should be applied and the susceptible animal population within the *containment zones* should be clearly identifiable as belonging to the *containment zone*. Increased passive and targeted *surveillance* in accordance with Chapter 1.4. in the rest of the country or *zone* should be carried out and has not detected any evidence of *infection*.~~

~~*c)* Measures consistent with the *disease* specific chapter should be in place to prevent spread of the *infection* from the *containment zone* to the rest of the country or *zone*, including ongoing *surveillance* in the *containment zone*.~~

~~*d)* For the effective establishment of a *containment zone*, it is necessary to demonstrate that there have been no new *cases* in the *containment zone* within a minimum of two *incubation periods* from the last detected *case*.~~

~~*e)* The free status of the areas outside the *containment zone* would be suspended pending the establishment of the *containment zone*. The free status of these areas could be reinstated, once the *containment zone* is clearly established, irrespective of the provisions of the *disease* specific chapter.~~

UNOFFICIAL VERSION

~~f)~~ ~~The *containment zone* should be managed in such a way that it can be demonstrated that *commodities* for *international trade* can be shown to have originated outside the *containment zone*.~~

~~g)~~ ~~The recovery of the free status of the *containment zone* should follow the provisions of the *disease* specific chapter.~~

2~~4~~) The factors defining a *compartment* should be established by the *Veterinary Authority* on the basis of relevant criteria such as management and husbandry practices related to *biosecurity*, and ~~made public~~ communicated to the relevant industry through official channels.

EU comment

The EU suggests replacing the term "industry" with "operators". Indeed, the operators of the compartments should be the target, not the entire industry.

3~~5~~) *Animals* and *herds/flocks* belonging to ~~such~~ *subpopulations* of *zones* or *compartments* ~~need to~~ should be recognisable as such through a clear epidemiological separation from other *animals* and all ~~things~~ factors presenting a *disease risk*. ~~For a *zone* or *compartment*, the~~ The *Veterinary Authority* should document in detail the measures taken to ensure the identification of the *subpopulation* and the establishment and maintenance of its health status through a *biosecurity plan*. The measures used to establish and maintain the distinct *animal health status* of a *zone* or *compartment* should be appropriate to the particular circumstances, and ~~will~~ depend on the epidemiology of the *disease*, environmental factors, the health status of *animals* in adjacent areas, applicable *biosecurity* ~~measures~~ (including movement controls, use of natural, ~~and~~ artificial or legal boundaries, ~~the~~ spatial separation of *animals*, control of fomites, and commercial management and husbandry practices), and *surveillance*.

EU comment

The word "and" before "commercial management" in point 3 above should be deleted (syntax).

4~~6~~) Relevant *animals* and animal products within the *zone* or *compartment* should be identified in such a way that their movements are traceable. Depending on the system of production, identification may be done at the *herd/~~,~~ flock* ~~lot~~ or individual animal level. Relevant animal movements into and out of the *zone* or *compartment* should be well documented and controlled. The existence of ~~a valid~~ an *animal identification system* is a prerequisite to assess the integrity of the *zone* or *compartment*.

5~~7~~) For a *compartment*, the *biosecurity plan* should describe the partnership between the relevant industry and the *Veterinary Authority*, and their respective responsibilities. It should also describe the ~~routine~~ standard operating procedures to provide clear evidence that the *surveillance* conducted, the ~~live~~ *animal identification* and *traceability* system, and the management practices are adequate to meet the definition of the *compartment*. In addition to information on controls of movements of relevant *animals* and animal products ~~animal movement controls~~, the plan should include *herd/~~,~~ flock* production records, feed sources, *surveillance* results, birth and *death* records, visitor logbook, morbidity and mortality history, medications, *vaccinations*, documentation of training of relevant personnel and any other criteria necessary for evaluation of *risk management*. The information required may vary in accordance with the species and *diseases* under consideration. The *biosecurity plan* should also describe how the measures will be audited to ensure that the *risks* are regularly ~~re-assessed~~ reassessed and the measures adjusted accordingly.

Articles 4.3.4. to 4.3.7. describe different types of *zones* that can be established by Member Countries. However, other types of *zones* may be established for the purposes of *disease* control or trade.

Article 4.3.4.

Free zone

A *free zone* is one in which the absence of a specific *disease~~, infection or infestation~~* in an animal population has been demonstrated ~~by *surveillance*~~ in accordance with the relevant requirements of the *Terrestrial Code*.

EU comment

The EU does not support deleting the words ", infection or infestation" (see EU comment on the definition of "disease" in Part B' of Annex 5 for rationale).

UNOFFICIAL VERSION

In conjunction with Articles 4.3.2. and 4.3.3., and depending on the prevailing epidemiological situation, the attainment or maintenance of free status ~~demonstration~~ may require past or ongoing pathogen-specific *surveillance*, as well as appropriate *biosecurity* and *sanitary measures*, within the *zone* and at its borders. The *surveillance* should be conducted in accordance with Chapter 1.4. ~~or~~ and the relevant *disease*-specific chapters of the *Terrestrial Code*.

The free status can apply to one or more susceptible animal species populations, domestic or wild.

So long as an ongoing *surveillance* demonstrates there is no occurrence of the specific *disease~~, infection or infestation~~*, the *zone* ~~keeps~~ maintains its free status.

EU comment

The EU does not support deleting the words ", infection or infestation" (see EU comment on the definition of "disease" in Part B' of Annex 5 for rationale).

Article 4.3.5.

Infected zone

An *infected zone* is one either in which a *disease~~, infection~~* or *infestation* ~~either~~ has been diagnosed, or that does not meet *disease* freedom provisions of the relevant chapters of the *Terrestrial Code*~~, the absence of which cannot be demonstrated. In the latter case, the *disease* specific chapter of the *Terrestrial Code* contains an article describing the conditions for free and infected status.~~

EU comment

The EU does not support deleting the words ", infection or infestation" (see EU comment on the definition of "disease" in Part B' of Annex 5 for rationale).

An *infected zone* may be:

– a *zone* of a country where the *disease* has been present ~~for a long period~~ and has not yet been eradicated, while other *zones* of the country ~~have been~~ are free;

– a *zone* of a previously free country or *zone* ~~previously free~~, in which the *disease* has been introduced or reintroduced, while the rest of the country or *zone* remains unaffected.

To gain free status in an *infected zone*, or regain free status following a *disease outbreak* in a previously *free zone*, Member Countries should follow the recommendations in the relevant ~~*disease*-specific~~ chapters of the *Terrestrial Code*.

Article 4.3.6.

Protection zone

A *protection zone* may be established to preserve the *animal health status* of an *animal population* in a free country or a *free zone* from introduction of a pathogenic agent of a specific *disease~~, infection or infestation~~* from adjacent countries or *zones* of different animal health status. A *protection zone* can be established within or outside the *free zone* or within the free country.

EU comment

The first sentence of the paragraph above reads a bit awkward ("A protection zone [...] established <u>to preserve</u> the [...] status [...] <u>from introduction</u> of a pathogenic agent [...]). The EU suggests rephrasing the sentence as follows:

"A protection zone may be established to preserve the animal health status of an animal population in a free country or a free zone ~~from~~ <u>by preventing the</u> introduction of a pathogenic agent of a specific disease [...]".

UNOFFICIAL VERSION

Furthermore, the EU does not support deleting the words ", infection or infestation" (see EU comment on the definition of "disease" in Part B' of Annex 5 for rationale).

Biosecurity and *sanitary measures* should be implemented in the *protection zone* based on the animal management systems, the epidemiology of the *disease* under consideration and the epidemiological situation prevailing in ~~an~~ the adjacent infected ~~country or *zone*~~ countries or *zones*.

These measures should include intensified movement control and *surveillance* and specific *animal identification* and *animal traceability* to ensure that *animals* in the *protection zone* are clearly distinguishable from other populations, and may also include:

~~1)~~ ~~specific *animal identification* and *animal traceability* to ensure that *animals* in the *protection zone* are clearly distinguishable from other populations;~~

1~~2~~) *vaccination* of all or at risk susceptible *animals*;

2~~3~~) testing or *vaccination* of *animals* moved;

3~~4~~) specific procedures for sample handling, dispatching and testing;

4~~5~~) enhanced *biosecurity* including *disinfection* procedures for *vehicles*/*vessels*, vehicles for transportation of feed or fodder, and possible compulsory routes;

5~~6~~) specific *surveillance* of susceptible *wildlife* and relevant *vectors*;

6~~7~~) awareness campaigns aimed at the public or targeted at breeders, traders, hunters or *veterinarians*.

~~The *protection zone* may be a part of an *infected zone* or of a *free zone*.~~

Article 4.3.7.

Containment zone

In the event of ~~limited~~ *outbreaks* in a country or *zone* previously free from a *disease*, a *containment zone*, which includes all *outbreaks* may be established to minimise the impact on the rest of the country or *zone* ~~for the purposes of *disease* control or trade~~.

A *containment zone* is an *infected zone* that should be managed in such a way that *commodities* for *international trade* can be shown to have originated from inside or outside the *containment zone*.

Establishment of a *containment zone* should be based on a rapid response, prepared in a contingency plan, including:

1) appropriate control ~~standstill~~ of movement of *animals* and other *commodities* upon notification of suspicion of the specified *disease*;

2) epidemiological investigation (trace-back, trace-forward) after confirmation of *infection*, demonstrating that the *outbreaks* are epidemiologically ~~linked~~ related and all contained within the defined boundaries of the *containment zone*;

3) *stamping-out policy* or another effective emergency control strategy aimed at eradicating the *disease*;

4) clear identification of the susceptible animal population within the *containment zone* enabling its recognition as belonging to the *containment zone*;

EU comment

It is not clear what is meant by "clear identification of the susceptible animal population within the containment zone" – specific / additional ear tags on each animal? What about wild animals?

Furthermore, the word "clear" is not necessary and should be deleted. Indeed, the animals must be identified and registered as belonging to the zone. Therefore, the words "and registration" should be inserted after the word "identification".

UNOFFICIAL VERSION

5) increased passive and targeted *surveillance* in accordance with Chapter 1.4. in the rest of the country or *zone* demonstrating no evidence of *infection*;

6) *biosecurity* and *sanitary measures*, including ongoing *surveillance* and control of the movement of *animals* and *commodities* within and from ~~in~~ the *containment zone*, consistent with the *disease*-specific chapter, when there is one, to prevent spread of the *infection* from the *containment zone* to the rest of the country or *zone*.

For the effective establishment of a *containment zone*, it is necessary to demonstrate that either:

a) there have been no new *cases* in the *containment zone* within a minimum of two *incubation periods* from the last detected *case*.

OR

b) the *containment zone* comprises an *infected zone* where *outbreaks* may continue to occur and a *protection zone*, where no *outbreaks* have occurred, which separates the *infected zone* from the rest of the country or *zone*.

EU comment

In point b) above, the EU suggests replacing the word "outbreaks" by the word "cases", for consistency with the wording of point a) above.

The free status of the areas outside the *containment zone* ~~would be~~ is suspended pending ~~demonstration of the effectiveness~~ effective establishment of the *containment zone*. Once the *containment zone* has been established, the free status of these areas ~~may then be~~ is reinstated~~, irrespective of the provisions of the *disease*-specific chapter~~.

The free status of the *containment zone* should be regained in accordance with Article 1.4.6. or relevant *disease*-specific chapters.

~~The *containment zone* is an infected zone that should be managed in such a way that *commodities* for *international trade* can be shown to have originated from inside or outside the *containment zone*. Well managed, it may allow the rest of the country or *zone* to keep their free status.~~

Article 4.3.8.

Bilateral recognition by trading countries

Trading partners should exchange information allowing the recognition of different *subpopulations* within their respective territories. This recognition process is best implemented through establishing parameters and gaining agreement on the necessary measures prior to *outbreaks* of *disease*.

The *Veterinary Services* of an *exporting country* should be able to explain to the *Veterinary Services* of an *importing country* the basis for claiming a distinct *animal health status* for the given *zone* or *compartment* under consideration.

The *exporting country* should be able to demonstrate, through detailed documentation provided to the *importing country*, that it has implemented the recommendations in the *Terrestrial Code* for establishing and maintaining such a *zone* or *compartment*.

An *importing country* should recognise the existence of this *zone* or *compartment* when the appropriate measures recommended in the *Terrestrial Code* are applied and the *Veterinary Authority* of the *exporting country* certifies that this is the case.

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— Text deleted.

UNOFFICIAL VERSION

Annex 22

DRAFT CHAPTER 4.X.

VACCINATION

EU comment

The EU in general supports the proposed draft new chapter. Comments are inserted in the text below.

Article 4.X.1.

Introduction and objectives

In general, *vaccination* is intended to control and prevent the occurrence of a *disease* and reduce the transmission of the pathogenic agent. For the purpose of *disease* control, vaccines should induce immunity that, ideally, prevents *infection*. However, some vaccines may only prevent clinical signs, or reduce multiplication and shedding of the pathogenic agent. *Vaccination* may contribute to improvement of *animal* and human health, *animal welfare*, agricultural sustainability and to reduction of the use of *antimicrobial agents* in *animals*.

EU comment

The first sentence of the paragraph above seems a bit too general and mixes different concepts. The EU suggests mentioning disease prevention first, then disease control of which reduction of transmission is one element. The following alternative wording is suggested:

"~~In general, v~~ Vaccination is intended to ~~control and~~ prevent the occurrence of a disease or to control a disease and reduce the transmission of the pathogenic agent."

In the second sentence, the EU suggests inserting the words "prevention and" before the word "control". Indeed, sterile protective immunity is also the goal of preventive vaccination.

The *vaccination* strategy applied depends on technical and policy considerations, available resources and the feasibility of implementation. The recommendations in this chapter are intended for all *diseases* for which a vaccine exists.

EU comment

The EU suggests inserting the words "cost-benefit analyses" after "technical and policy considerations" in the above paragraph, as this will also influence the vaccination strategy.

In addition to other *disease* control measures, *vaccination* may be a component of a *disease* control programme. The prerequisites to enable a Member Country to successfully implement *vaccination* include compliance with:

1) the recommendations on *surveillance* in Chapter 1.4.;

2) the relevant provisions in Chapters 3.1. and 3.4.;

3) the recommendations on *vaccination* in the *disease*-specific chapters;

4) the principles of veterinary vaccine production in Chapter 1.1.8. of the *Terrestrial Manual*.

EU comment

UNOFFICIAL VERSION

The EU suggests replacing point 4 above by a general reference to the Terrestrial Manual. Indeed, other chapters of the Manual would be important to comply with as well, such as Chapter 1.1.9.; the Part C (requirements for vaccines) of all disease specific chapters; and Section 3.7. In short, the vaccines used should at least comply with OIE standards as recommended in the Terrestrial Manual.

However, as the numbering of chapters of the Manual can change, there should be only generic reference to the Manual chapters.

The objective of this chapter is to provide guidance to Member Countries for successful implementation of *vaccination* in support of *disease* control programmes. The recommendations in this chapter may be refined by the specific approaches described in the *disease*-specific chapters of the *Terrestrial Code*.

EU comment

In the first sentence of the paragraph above, the EU suggests inserting the words "prevention and" before the word "control". Indeed, vaccination is also implemented preventively.

Furthermore, the EU suggests clarifying the scope of this chapter in the paragraph above, which should be limited to listed diseases and to official government vaccination programmes (as opposed to private schemes).

Finally, the paragraph on objectives should be moved up to beginning of this article.

Standards for vaccines are described in the *Terrestrial Manual*.

Article 4.X.2.

Definitions

For the purpose of this chapter:

Vaccination programme: means a plan to apply *vaccination* to an epidemiologically appropriate proportion of the susceptible animal population for the purpose of *disease* control.

Emergency vaccination: means a *vaccination* programme applied in immediate response to an *outbreak* or increased *risk* of introduction or emergence of a *disease*.

Systematic vaccination: means an ongoing routine *vaccination* programme.

EU comment

The EU queries whether the definition of "emergency vaccination" should be restricted to that applied in response to an outbreak. Indeed, "preventive vaccination" (i.e. applied in response to increased risk of introduction or emergence of a disease) can also take the form of "systematic vaccination", i.e., become an ongoing routine programme. Therefore, "preventive vaccination" could be defined separately (i.e., not part of the definition of "emergency vaccination"). Taking into account the descriptions in Art. 4.X.3., this would indeed make sense.

Vaccination coverage: means the proportion of the target population to which vaccine was administered during a specified timeframe.

Population immunity: means the proportion of the target population effectively immunised at a specific time.

UNOFFICIAL VERSION

Article 4.X.3.

Vaccination programmes

EU comment

In line with the EU comment above asking to limit the scope of this chapter to listed diseases and official government vaccination programmes (as opposed to private schemes), the EU suggests adding the word "Official" to the title of this article (and whenever "vaccination programme(s)" is used throughout this chapter), for it to read as follows:

"Official vaccination programmes".

Indeed, it would be important to clearly distinguish official national or regional vaccination programmes under the responsibility of the Veterinary Authority from the ones organised by e.g. producer organisations representing the private sector, or private practicing veterinarians.

The objectives of a *vaccination* programme should be defined by the *Veterinary Authority* before the implementation of the *vaccination* taking into account the epidemiology of the *disease*, the species affected and their distribution. If these factors indicate that the programme should be expanded beyond national boundaries, the *Veterinary Authority* should liaise with the *Veterinary Authorities* of neighbouring countries.

EU comment

The EU suggests adding the following at the end of the paragraph above:

"[...] with a view to agreeing on and implementing a common disease control strategy".

When appropriate, a regional approach to harmonise *vaccination* programmes is recommended.

EU comment

In the sentence above, the EU suggests inserting the words "disease control encompassing" after "a regional approach to". Indeed, the harmonised vaccination programmes should be embedded in a regionally coordinated disease control strategy.

Vaccination programmes may include systematic *vaccination* and emergency *vaccination*.

1) Systematic *vaccination* in infected countries aims to reduce the incidence of a *disease* with the objective of control and possible eradication. In *disease* free countries or *zones*, the objective of systematic *vaccination* is to limit the impact in the case of an introduction of *disease* .

2) Emergency *vaccination* provides an adjunct to the application of other essential *biosecurity* and *disease* control measures and may be applied to control *outbreaks*. Emergency *vaccination* may be used in response to:

   a) an *outbreak* in a free country or *zone*;

   b) an *outbreak* in a country or *zone* that applies systematic *vaccination*, but when vaccines are applied to boost existing immunity;

   c) an outbreak in a country or *zone* that applies systematic *vaccination*, but when the vaccine employed does not provide protection against the strain of the pathogenic agent involved in the *outbreak;*

   d) a change in the *risk* of introduction or emergence of *disease* in a free country or *zone*.

Vaccination programmes should consider other ongoing animal health related activities involving the target population. This can improve the efficiency of the programme and reduce the cost by sharing resources.

Article 4.X.4.

UNOFFICIAL VERSION

Launching a vaccination programme

When deciding whether to initiate a *vaccination* programme the *Veterinary Authority* should consider the following:

EU comment

The list below should not be considered exhaustive, as many other factors could be relevant, depending on the disease, its epidemiology and the geographical / climatic conditions of the country concerned. Therefore, the EU suggests inserting the words "among others" after "should consider" in the sentence above.

1) the probability that the *disease* cannot be rapidly contained;

EU comment

For clarity reasons, please add the words "by other means than vaccination" at the end of point 1 above.

2) an increased *incidence* of an existing *disease*;

3) an increased likelihood of introduction or emergence of a *disease*;

4) the density of susceptible animals;

5) an insufficient level of population immunity;

6) the *risk* of exposure of specific *subpopulations* of susceptible animals;

7) the suitability of *vaccination* as an alternative to or an adjunct to other *disease* control measures such as a *stamping-out policy;*

8) the availability of resources;

9) cost-benefit considerations of *vaccination*, including the impact on trade.

EU comment

The EU suggests adding a point to the list above in relation to vectors. Indeed, for vector-borne diseases, the occurrence of competent vectors, their density / abundance, the seasonality etc. should also be considered.

Furthermore, a point should be added in relation to zoonotic diseases and their likely impact on public health.

Another point could be added in relation to the capacity of the country to conduct post-vaccination surveillance, and thus its ability to detect silent pathogen circulation under the radar when the vaccination coverage / population immunity is inadequate or wanes with time.

As also wildlife or other domestic species not targeted by the vaccination programme (e.g. small ruminants in FMD) can play an important epidemiological role, these should also be considered in a separate point.

In addition, the availability of live, inactivated, vectored, or marker vaccines and corresponding DIVA tests could be added as well.

Further points could be added on the following issues:

- risk analysis ('risk taken when vaccinating' versus 'risk taken when not vaccinating', taking into account the risk-benefit ratio of the vaccine under consideration;

UNOFFICIAL VERSION

- the epidemiological situation ('endemic' versus 'circumscribed');

- whether the target animals are identified and registered vs. the investment needed to ensure this in view of the vaccination programme (for follow-up and certification purposes, and to avoid unnecessary re-injections;

- reduction of exposure of neighbouring countries or zones.

Finally, trade considerations and legal restrictions (e.g. legal provisions with regard to a certain disease such as free status) should also be considered.

Article 4.X.5.

Vaccination strategies

Different *vaccination* strategies may be applied alone or in combination, taking into account the epidemiological and geographical characteristics of occurrence of the *disease*. The following strategies may be applied:

1) **Blanket vaccination:** *vaccination* of all susceptible animals in an area or an entire country or *zone*.

EU comment

In point 1 above, it is not clear what the difference is between an area and a zone. Perhaps it is not necessary to make that distinction, which may give rise to confusion.

2) **Ring vaccination:** *vaccination* primarily of all susceptible animals in a delineated area surrounding the *establishments* where an *outbreak* has occurred. To prevent outward spread of *disease*, *vaccination* should be applied from the outer boundary of the area inwards.

EU comment

Perhaps "establishments" is not the appropriate term to be used in point 2 above. Indeed, one could think of a village or common grazing land. Thus, perhaps the term "epidemiological unit" should be used here instead.

3) **Barrier vaccination:** *vaccination* in an area along the border of an infected country or *zone* to prevent the spread of *disease* into or from a neighbouring country or *zone*.

EU comment

The concept of "protection zone" could be mentioned in point 3 above, as the "area along the border" could correspond to a protection zone.

4) **Targeted vaccination:** v*accination* of a *subpopulation* of susceptible animals defined by a greater likelihood of exposure or severity of the consequences.

EU comment

The words "<u>of the disease</u>" should be added at the end of point 4 above (clarity).

Furthermore, the words "<u>, or feasibility</u>" should be added at the end of point 4). Indeed, vaccination of wildlife will usually be more difficult to achieve or may not be possible at all, meaning that even if wildlife is affected by a particular disease and plays a role in its epidemiology, one must sometimes settle for vaccination of domestic animals only.

Article 4.X.6.

Critical elements of a vaccination programme

In addition to the choice of vaccine, the *vaccination* programme should include the following critical elements and be communicated to all stakeholders.

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EU comment

The choice of the vaccine (if a choice is indeed available) is the first critical element of any vaccination programme. Vaccines are often efficient tools, but they have nevertheless their limits (specific indications, side effects, galenic form restricting its use to specific subpopulations (wildlife versus domestic animals), etc. A cross-reference to Article 4.X.7. could also be considered.

1. Target population

The *vaccination* programme should define the animal population to be vaccinated and the geographical area where the target population is located.

The target population may include the entire susceptible population or an epidemiological relevant *subpopulation* depending on the likelihood of exposure, the consequences of the *disease*, the role of the different *subpopulations* in the epidemiology of the *disease* and the resources available. The target population may include *wildlife*.

Factors to consider in determining the target population may include species, age, maternal immunity, sex, production types, geographical distribution as well as the number of *animals* and *herds*. These factors should be reviewed and updated regularly.

2. Vaccination coverage

In practical terms, it may be difficult to immunise the entire target population. The *vaccination* programme should define the minimum *vaccination* coverage necessary for the minimum population immunity required to achieve the objectives of the programme. The minimum population immunity required will vary according to the epidemiology of the *disease*, density of susceptible animals and geographical factors.

EU comment

The words ", virulence of the pathogen" could be inserted after "epidemiology of the disease" in the paragraph above, as the minimum population immunity required varies also according to the virulence of the pathogen.

Measuring population immunity during the monitoring of the *vaccination* programme may assist to identify subsets of the target population that have not been adequately immunised.

3. Stakeholder involvement

The *vaccination* programme should demonstrate good governance by the *Veterinary Services* and clearly identify the involvement of different stakeholders including other government agencies, farmers, farmer organisations, private sector veterinarians, non-governmental organisations*, veterinary paraprofessionals*, local government authorities and vaccine suppliers. Stakeholder acceptance of *vaccination* is crucial for the success of the *vaccination* programme. Different stakeholders should preferably be involved in the planning and implementation of *vaccination*, the awareness campaigns, the monitoring of *vaccination*, the production and delivery of vaccines and the financing of the *vaccination* programme.

EU comment

It is not clear what is meant by "The vaccination programme should demonstrate good governance by the Veterinary Services".

Furthermore, the term "government agencies" is too specific and may not be relevant for all countries depending on their government structures. It should thus be replaced by "government authorities" or "public authorities" or "national competent authorities".

4. Resources

Vaccination programmes may often span several years. To achieve the desired objective, human, financial and material resources should be available throughout the estimated duration of the *vaccination* programme.

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5. Actions and timeline

The *vaccination* programme should describe the responsibilities, expected deliverables and timeline for each activity.

6. Timing of vaccination campaigns

The *vaccination* programme should describe the periodicity of the *vaccination* campaigns. Depending on the *disease* and type of vaccine, animals may be vaccinated once or several times during their lifetime.

The objective of the *vaccination* campaign is to achieve the necessary *vaccination* coverage and the minimum population immunity in the target population within a defined timeframe. The *vaccination* campaign should be implemented in such a manner as to ensure that the majority of the target population is immunised within as short a time as possible. The *vaccination* programme should include a detailed description of the implementation of the *vaccination* campaigns, including frequency and starting and ending dates of each campaign.

EU comment

As the objective could also be to maintain the population immunity, the EU suggests amending the first sentence of the paragraph above as follows:

"The objective of the vaccination campaign is to achieve the necessary vaccination coverage, ~~and~~ the minimum population immunity in the target population within a defined timeframe, or to maintain the population immunity.".

The frequency, timing and duration of the *vaccination* campaigns should be determined taking into consideration the following factors:

a) vaccine characteristics and manufacturer's directions for use;

b) accessibility of the target population;

c) animal handling facilities;

d) animal body condition and physiological state;

e) geographical factors;

f) climate conditions;

g) awareness, acceptance and engagement of stakeholders;

h) types of production systems and animal movement patterns;

i) timing of agricultural, social or cultural activities;

j) availability of resources.

EU comment

A further point could be added to the list above regarding vector activity or seasonality. Indeed, this would be relevant for certain vector-borne diseases.

In addition, a point on availability of authorised vaccines could also be added.

7. Auditing of the vaccination campaigns

The *vaccination* programme should include periodic auditing of the *vaccination* campaigns. Auditing ensures that all components of the system function and provide verifiable documentation of procedures. Auditing may detect deviations of procedures from those documented in the programme.

EU comment

For reasons of clarity, we suggest amending the first sentence sa follows:

UNOFFICIAL VERSION

"The vaccination programme should include periodic auditing of all the actors involved in the vaccination campaigns."

Indeed, it is the actors involved in the vaccination campaign that are audited.

Indicators related to the *vaccination* campaign include:

a) proportion of *animals* and *herds* vaccinated within the defined timeframe;

b) number of vaccine doses used compared with number of animals vaccinated;

c) number of reports of breaches of the cold chain;

d) performance of vaccinator teams in respect of the standard operating procedures;

e) timing and length of the campaign;

f) overall cost and cost per individual animal vaccinated.

To enable auditing of the *vaccination* programme, a recording system should be in place to measure the indicators above.

EU comment

It should be mentioned in the point above that a serological post vaccination monitoring should preferably be part of this auditing system.

Furthermore, for reasons of clarity, the word "auditing" should be replaced by "measuring the effective conduct" in the last sentence.

Article 4.X.7.

Choice of vaccine

Depending on the *disease*, several vaccines may be available. To achieve the objectives of the *vaccination* programme, the choice of a vaccine depends on different factors including:

1. Availability and cost

a) availability of the vaccine in adequate quantities at the time required;

b) capacity of the providers to supply the vaccine for the duration of the *vaccination* campaign and to respond to increased needs;

c) flexibility in the number of doses per vial to match the structure of the target population;

d) a comparison of the costs of vaccines that meet the technical specifications established in the *vaccination* programme.

EU comment

A further point to be added above is the legal status of a given vaccine, i.e., marketing authorisation in the target country. Indeed, this could have an effect on "availability".

2. Vaccine characteristics

a) Physical characteristics

– route and ease of administration;

– volume of dose;

– type of adjuvant and other components.

b) Biological characteristics

– immunity against circulating strains;

– live, inactivated or biotechnology-derived vaccines;

– number of strains and pathogens included in the vaccine;

– potency of the vaccine;

UNOFFICIAL VERSION

- onset of immunity;
- shelf-life and expiry date;
- thermostability;
- duration of the effective immunity;
- number of doses required to achieve effective immunity;
- effect on the ability to differentiate infected from vaccinated animals, at the individual or group level;
- suitability of vaccine formulation for species in the target population;
- safety for the environment.

EU comment

A further point to be added above is "safety for the consumer". Indeed, this is important for food producing animals (i.e., residues in milk, meat etc.), and usually part of the marketing authorisation procedure.

c) Side effects

- adverse reactions;

EU comment

The point above could be supplemented as follows:

"adverse reactions (frequency, duration and intensity of e.g. vaccine reaction, vaccine complication, vaccinial disease, vaccine failure)".

- transmission of live vaccine strains.

EU comment

The point above could be reworded as follows:

"for live vaccines, spread of the vaccine strain to non-vaccinated animals and persistent circulation of vaccine strains with or without reversion to virulence".

Article 4.X.8.

Logistics of vaccination

Vaccination campaigns should be planned in detail and well in advance considering the following elements:

EU comment

The legal basis for a vaccination campaign, including a possible legal obligation for the vaccination and compensation of farmers for possible side effects, should also be in place before a vaccination campaign can start.

1. Procurement of vaccine

The vaccine selected for use in a *vaccination* programme should be subjected to the registration procedure of the country, which is congruent with the recommendation of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medical Products (VICH).

EU comment

The EU suggests replacing the term "registration procedure" in the paragraph above and throughout the text by the term "marketing authorisation procedure", as this is the term used in the legal system of the EU and many other countries. Indeed, vaccines

UNOFFICIAL VERSION

should be subject to a marketing authorisation by the competent authority, not merely to a "registration".

Furthermore, it should be mentioned that the vaccine should preferably be authorised in the country before the start of the vaccination campaign.

For systematic *vaccination* campaigns, the process of procurement of the selected vaccine should be initiated in advance to ensure timely delivery to meet the timeframe of the *vaccination* campaign.

National *disease* contingency plans should provide for emergency *vaccination*. These provisions may allow for simplified procedures to procure vaccine and grant authorisation for temporary use. If *vaccination* is to be used systematically, definitive registration should be obtained.

EU comment

The first sentence of the paragraph above is too prescriptive. Indeed, the choice of reverting to vaccination for a given disease will depend on the epidemiology of that disease and the legal provisions of the country concerned. In addition, for some animal diseases no vaccine is available.

Vaccine banks, established in accordance with Chapter 1.1.10. of the *Terrestrial Manual*, facilitate the timely procurement of vaccines.

EU comment

The word "procurement" in the sentence above should be replaced by "availability", as indeed the procurement is done in advance and thus facilitates / accelerates the availability of the vaccine in a crisis situation.

2. Implementation of the vaccination programme

In addition to the vaccine itself, the planning of the *vaccination* campaigns should include the procurement of all necessary equipment and consumables as well as standard operating procedures to:

EU comment

The EU suggests inserting the words "<u>the establishment of</u>" before the words "standard operating procedures", as indeed the latter are not procured.

a) implement the communication plan;

b) establish, maintain and monitor the fixed and mobile components of the cold chain;

c) store, transport and administer the vaccine;

d) clean and disinfect equipment and *vehicles,* including heat sterilisation of reusable equipment;

e) dispose of waste;

f) identify vaccinated animals;

g) ensure safety and welfare of animals and *vaccination* teams;

h) record activities of *vaccination* teams;

i) document *vaccinations*.

The availability of appropriate animal handling facilities at the *vaccination* site is essential to ensure effective *vaccination* as well as safety and welfare of *animals* and *vaccination* teams.

3. Human resources

Vaccination should be conducted by appropriately trained and authorised personnel under the supervision of the *Veterinary Authority*. The *vaccination* programme should provide for periodic training sessions including updated written standard operating procedures for field use.

UNOFFICIAL VERSION

The number of *vaccination* teams should be sufficient to implement the *vaccination* campaign within the defined timeframe. The *vaccination* teams should be adequately equipped and have means of transport to reach *vaccination* sites.

EU comment

We suggest inserting the following after "should be adequately equipped":

"(e.g. to ensure maintenance of the cold chain, when relevant)".

4. Public awareness and communication

The *Veterinary Authority* should develop a communication strategy in accordance with Chapter 3.3., which should be directed at all stakeholders and public to ensure awareness and acceptability of the *vaccination* programme, its objectives and potential benefits.

The communication plan may include details on the timing and location of the *vaccination*, target population and other technical aspects that may be relevant for the public to know.

5. Animal identification

Animal identification allows for the differentiation of vaccinated from non-vaccinated animals and is required for the monitoring and certification of *vaccination*.

Identification can range from temporary to permanent identifiers and can be individual or group-based. *Animal identification* should be carried out in accordance with Chapters 4.1. and 4.2.

6. Record keeping and vaccination certificates

Vaccination programmes under the *Veterinary Authority's* responsibility should provide for maintenance of detailed records of the vaccinated population.

Whenever needed, the *Veterinary Services* should consider issuing official certificates of the *vaccination* status of animals or groups of animals.

7. Additional animal health related activities

In addition to *vaccination* against a specific pathogenic agent, *vaccination* programmes may include other animal health-related activities such as *vaccination* against other pathogenic agents, treatments, *surveillance*, *animal identification* and communication.

Including additional animal health-related activities may enhance the acceptability of the *vaccination* programme. These activities should not negatively affect the primary objective of the *vaccination* programme.

Simultaneous *vaccination* against multiple pathogenic agents may be conducted, provided that compatibility has been demonstrated and the efficacy of the immune response against each of the pathogenic agents is not compromised.

Article 4.X.9.

Evaluation and monitoring of a vaccination programme

The *vaccination* programme should provide for outcome-based evaluation and monitoring to assess the achievements of the *vaccination* programme. Evaluation and monitoring should be carried out periodically to enable the timely application of corrective measures and to enhance the sustainability of the *vaccination* programme.

Based on the objectives and targets of the *vaccination* programme, the following outcomes should be assessed:

1) *vaccination* coverage stratified by species, geographical location and type of production system;

2) population immunity measured by testing, stratified by species, geographical location and type of production system;

UNOFFICIAL VERSION

3) frequency and severity of adverse reactions;

4) reduction of *incidence* or *prevalence*.

EU comment

The following additional point could be added as well:

"5) in case the objectives and targets of the vaccination programme are not achieved, reasons for non-compliance and ways to remedy".

Article 4.X.10.

Exit strategy of a vaccination programme

The *vaccination* programme may provide for an exit strategy to cease *vaccination*. The cessation of *vaccination* may apply to the entire target population or to a subset of it, as defined by the *risk* of exposure and as determined by the *Veterinary Authority*.

Criteria to cease *vaccination* may include:

1) eradication of the *disease* in a country or *zone* has been achieved;

2) *risk analysis* demonstrates sufficient reduction of likelihood of introduction or emergence of the *disease;*

3) reduction of the *incidence* or *prevalence* of the *disease* to a level where alternative measures such as *stamping-out* may be sufficient to achieve *disease* control;

4) inability of the programme to meet the desired objectives;

5) adverse public reaction to the *vaccination* programme.

EU comment

The following additional point could be added as well:

"6) new cost-benefit analysis leads to decision to cease vaccination programme".

When the achievement of *disease* free status requires the cessation of *vaccination*, the *Veterinary Authority* should prohibit *vaccination* and take appropriate measures to control remaining vaccine stocks as well as vaccine importation.

The cessation of *vaccination* may require the revision of the contingency plan and enhanced *biosecurity, sanitary measures* and *surveillance* for early detection of *disease*.

EU comment

Import policy / rules might need to be reviewed as well (introduction of animals only from countries or zones with the same sanitary status).

Article 4.X.11.

Impact on disease status and management of vaccinated animals

Vaccination has proved its capacity to help prevent, control and eradicate *diseases* in addition to or as alternative to stamping-out. However, depending on the *disease* and type of vaccine used, *vaccination* may mask underlying *infections*, affect *disease surveillance* and have implications for the movement of vaccinated animals and their products.

EU comment

The first sentence of the paragraph above is too general, especially as regards "alternative to stamping-out". Indeed, while this might be true for some diseases, it is certainly not universal for all animal diseases. Thus, the EU suggests inserting the words "For certain diseases," at the beginning of the paragraph above.

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When appropriate, *vaccination* programmes should include provisions for the management of vaccinated animals such as '*vaccination* to live' or 'suppressive *vaccination*' policies. *Disease*-specific chapters of the *Terrestrial Code* provide additional recommendations on the management of vaccinated animals.

Disease free countries or *zones* applying systematic or emergency *vaccination* in response to a change in the *risk* of occurrence of a *disease* should inform trading partners and the OIE, as appropriate. Unless otherwise specified in the relevant *disease*-specific chapters, *vaccination* of animals does not affect the *disease* status of the country or *zone*, and should not disrupt trade.

EU comment

The second comma in the last sentence of the paragraph above should be deleted, so that the first part of the sentence relates also to the last part. Indeed, as specified in certain disease-specific chapters (e.g., FMD), starting a vaccination programme can indeed lead to a disruption of trade, as it may lead to a different health status of the vaccinated animal population and thus prevent an importing country that is not vaccinating from continuing trade.

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— Text deleted.

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Annex 23

CHAPTER 4.8.

COLLECTION AND PROCESSING OF OOCYTES AND *IN VITRO* PRODUCED EMBRYOS~~/OOCYTES~~ FROM LIVESTOCK AND HORSES

EU comment

The EU in general supports the proposed changes to this chapter. Comments are inserted in the text below.

Article 4.8.1.

Aims of control

Production of embryos *in vitro* involves the collection of oocytes from the ovaries of donors, *in vitro* maturation and fertilisation of the oocytes, then *in vitro* culture to the morula~~/~~ or blastocyst stage at which they are ready for transfer into recipients. The purpose of official sanitary control of *in vitro* produced embryos intended for movement internationally is to ensure that specific pathogenic organisms, which could be associated with such embryos, are controlled and transmission of *infection* to recipient animals and progeny is avoided. The conditions outlined in this chapter are also applicable where the movement of *in vitro* maturing (IVM) oocytes is intended.

Article 4.8.2.

Conditions applicable to the embryo production team

The embryo production team is a group of competent technicians, including at least one *veterinarian*, to perform the collection and processing of ovaries~~/~~ and oocytes and the production and storage of *in vitro* produced embryos. The following conditions should apply:

1) The team should be approved by the *Competent Authority*.

2) The team should be supervised by a team *veterinarian*.

3) The team *veterinarian* is responsible for all team operations which include the hygienic collection of ovaries and oocytes and all other procedures involved in the production of embryos intended for international movement.

4) Team personnel should be adequately trained in the techniques and principles of disease control. High standards of hygiene should be practised to preclude the introduction of *infection*.

5) The production team should have adequate facilities and equipment for:

   a) collecting ovaries ~~and/~~or oocytes;

   b) processing of oocytes and production of embryos at a permanent or mobile laboratory;

   c) storing oocytes ~~and/~~or embryos.

   These facilities need not necessarily be at the same location.

6) The embryo production team should keep a record of its activities, which should be maintained for inspection by the *Veterinary ~~Authority~~ Services* for a period of at least two years after the embryos have been exported.

7) The embryo production team should be subjected to regular inspection at least once a year by an *Official Veterinarian* to ensure compliance with procedures for the sanitary collection and processing of oocytes and the production and storage of embryos.

UNOFFICIAL VERSION

Annex 23 (contd)

Article 4.8.3.

Conditions applicable to the processing laboratories

A processing laboratory used by the embryo production team may be mobile or permanent. It may be contiguous with the oocyte recovery area or at a separate location. It is a facility in which oocytes which have been recovered from ovaries are then matured and fertilised, and where the resulting embryos are further cultured *in vitro*.

Embryos may also be subjected to any required treatments such as washing and storage and quarantine in this laboratory.

Additionally:

1) The laboratory should be under the direct supervision of the team *veterinarian* and regularly inspected by an *Official Veterinarian*.

2) While embryos for export are being produced prior to their storage in ampoules, vials or straws, no oocyte~~/~~ or embryo of a lesser health status should be recovered or processed in the same laboratory.

3) The laboratory should be protected against rodents and insects.

4) The processing laboratory should be constructed with materials which permit its effective cleansing and *disinfection*. This should be done frequently and always before and after each occasion when embryos for export are processed.

EU comment

There is no reference anywhere in this chapter to the need for a laminar flow facility in which to handle/process the oocytes/embryos. The EU suggests that this article is the appropriate place to include this. Alternatively, there could be a cross reference to the IETS manual here.

Article 4.8.4.

Conditions applicable to donor animals

Oocytes for the *in vitro* production of embryos are obtained from donors basically in two different ways: individual collection or batch collection. The recommended conditions for these differ.

Individual collection usually involves the aspiration of oocytes from the ovaries of individual live animals on the farm where the animal resides, or at the laboratory. Occasionally oocytes may also be recovered from individual live donors by aspiration from surgically excised ovaries. When oocytes are recovered from individual live animals, the conditions for these donors should resemble those set out in Article 4.7.4.

In these cases the cleaning and sterilisation of equipment (e.g. ultrasound guided probes) is especially important and should be carried out between each donor in accordance with the recommendations in the Manual of the International Embryo Transfer Society (IETS)[i].

Batch collection involves the removal of ovaries from batches of donors slaughtered at a *slaughterhouse*/*abattoir* ~~(hereafter '*abattoir*')~~; these ovaries are then transported to the processing laboratory where the oocytes are recovered from the ovarian follicles by aspiration. Batch collection has the disadvantage that it is usually impractical to relate the ovaries which are transported to the laboratory to the donors which were slaughtered at the *abattoir*. Nevertheless, it is critical to ensure that only healthy tissues are obtained and that they are removed from the donors and transported to the laboratory in a hygienic manner.

EU comment

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At the end of the first sentence of the paragraph above, the EU suggests adding the words "or slicing technique" so as to complete the list of methods which are available for the collection of oocytes. Indeed, slicing is a well-established method to instrumentally open the follicle and release the oocytes into a buffer filled petri dish.

Additionally:

1) The *Veterinary Authority* should have knowledge of the *herd~~(s)~~* or *flock~~(s)~~* from which the donor animals have been sourced.

2) The donor animals should not originate from *herds* or *flocks* that are subject to veterinary restrictions for foot and mouth disease~~, rinderpest and~~ or peste des petits ruminants, and neither should the removal of any tissue or aspiration of oocytes take place in an *infected zone*, or one that is subject to veterinary restrictions for those *diseases*.

EU comment

While in general supporting the deletion of the reference to rinderpest in the above point, the EU wonders whether other diseases – in addition to FMD and PPR – should be mentioned here. Indeed, further diseases that can be transmitted via the tissues at issue (i.e. ovaries, blood) could be of relevance in this context (including e.g. certain herpesviruses in horses, but also rinderpest, in case it should reoccur). The EU would thus ask the OIE to preferably define such a list, or alternatively refer to a possibly existing IETS list.

3) In the case of oocyte recovery from live donors, post-collection surveillance of the donors and donor *herd~~(s)~~* or *flock~~(s)~~* should be conducted based on the recognised *incubation periods* of the *diseases* of concern to determine retrospectively the health status of donors.

4) In the case of oocyte recovery from batches of ovaries collected from a~~n~~ *slaughterhouse*/*abattoir*, ~~the *abattoir*~~ it should be officially approved and under the supervision of a *veterinarian* whose responsibility is to ensure that ante-~~mortem~~ and post-mortem inspections of potential donor animals are carried out, and to certify them to be free of clinical or pathological signs of the *diseases* listed in point 2.

5) Donor animals slaughtered at a~~n~~ *slaughterhouse*/*abattoir* should not ~~have been~~ be animals designated for compulsory *slaughter* for a *notifiable disease* ~~and~~ or ~~should not~~ be slaughtered at the same time as such animals ~~donors from which ovaries and other tissues will be removed~~.

6) Batches of ovaries and other tissues collected from a~~n~~ *slaughterhouse*/*abattoir* should not be transported to the processing laboratory before confirmation has been obtained that ante- and post-mortem inspection of donors has been ~~satisfactorily completed~~ carried out with favourable results.

7) Equipment for the removal and transport of ovaries and other tissues should be cleaned and sterilised before use and used exclusively ~~used~~ for these purposes.

8) Records of the identities and origins of all donors should be maintained for inspection by the *Veterinary ~~Authority~~ Services* for a period of at least two years after the embryos have been exported. While this may be difficult to achieve in the case of batch collection, it is to be expected that the identities of the *herds* or *flocks* from which the donors originated will be maintained.

Article 4.8.5.

Optional tests and treatments

A supplementary approach for ensuring that *in vitro* produced embryos do not transmit *disease* is by testing various materials to confirm the absence of pathogenic ~~organisms~~ agents listed in point 2 of Article 4.8.4.

EU comment

The OIE Manual does not usually prescribe tests that can be used on the matrices/material mentioned in points 1) to 3) below for the various pathogenic agents of

UNOFFICIAL VERSION

concern. The EU proposes that if IETS or any other OIE reference laboratory has validated any such tests, then this could be usefully incorporated into the OIE Manual. Same comment applies to Article 4.8.6.3.b) below.

Tests may also be used to assess whether quality control procedures being applied in the processing laboratory are of an acceptable standard.

Tests may be carried out on the following materials:

1) non-viable oocytes~~/~~ or embryos from any stage of the *in vitro* production line from batches intended for export;

2) samples of *in vitro* maturation medium taken prior to mixing the oocytes with semen for the fertilisation process;

3) samples of embryo culture medium taken immediately prior to embryo storage.

EU comment

In order to complete the list of options for testing, the EU suggests adding a 4th point as follows:

"4) a pool of at least three washes of the washing medium used for the oocytes/the embryos".

These samples should be stored at 4°C and tested within 24 hours. If this is not possible, then the samples should be stored frozen at minus 70°C or lower.

Additionally:

1) Semen used to fertilise oocytes *in vitro* should meet the health requirements ~~and standards set out~~ in Chapter 4.6. as appropriate to the species.

   When the donor of the semen used to fertilise the oocytes is dead, and when the health status of the semen donor concerning a particular infectious *disease* or *diseases* of concern was not known at the time of semen collection, additional tests on the spare embryos may be required to verify that these infectious *diseases* were not transmitted.

   An alternative may be to test an aliquot of semen from the same collection date.

2) Any biological product of animal origin, including co-culture cells and media constituents, used in oocyte recovery, maturation, fertilisation, culture, washing and storage should be free ~~of~~ from ~~living pathogens~~ pathogenic agents. Media should be sterilised prior to use by approved methods in accordance with the IETS Manual[1] and handled in such a manner as to ensure that sterility is maintained. Antibiotics should be added to all fluids and media as recommended in the IETS Manual[1].

3) All equipment used to recover, handle, culture, wash, freeze and store oocytes~~/~~ or embryos should be new or cleaned and sterilised prior to use as recommended in the IETS Manual[1].

Article 4.8.6.

Risk management

With regard to disease transmission, transfer of *in vitro* produced embryos is a low risk method for moving animal genetic material although the risk is not quite as low as for *in vivo* derived embryos. It should be noted that categorisation of *diseases*~~/~~ and ~~disease~~ pathogenic agents by the IETS, as described for *in vivo* derived embryos in Article 4.7.14., does not apply in the case of *in vitro* produced embryos. Irrespective of the animal species, there are three phases in the embryo production and transfer process that determine the final level of risk. These are as follows:

1) the first phase comprises the risk potential for ovary, ~~/~~ oocyte~~/~~ or embryo contamination and depends on:

   a) the disease situation in the *exporting country* ~~and/~~or *zone*;

UNOFFICIAL VERSION

b) the health status of the *herds* or *flocks* and the donors from which the ovaries, ~~/~~ oocytes~~/~~ or embryos are collected;

c) the ~~pathogenic~~ characteristics of the ~~specified~~ ~~disease~~ pathogenic agents listed in point 2 of Article 4.8.4.;

2) the second phase covers risk mitigation by the use of internationally accepted procedures for the processing of embryos which are set out in the IETS Manual[1]. These include the following:

a) after the *in vitro* culture period is finished the embryos should be washed at least ~~ten~~ 10 times with at least 100–fold dilutions between each wash, and a fresh pipette should be used for transferring the embryos through each wash;

b) only embryos from the same donor (in the case of individual collection) or from the same batch (in the case of batch collection) should be washed together, and no more than ten embryos should be washed at any one time;

c) *sometimes, for example when inactivation or removal of certain viruses (e.g. bovine herpesvirus-1, or* Aujeszky's disease virus) is required, the standard washing procedure should be modified to include additional washes with the enzyme trypsin, as described in the IETS Manual[1];

d) the *zona pellucida* of each embryo, after washing, should be examined over its entire surface area at not less than 50X magnification to ensure that it is intact and free ~~of~~ from adherent material;

3) the third phase, which is applicable to diseases listed in point 2 of Article 4.8.4. encompasses the risk reductions resulting from:

a) post-collection *surveillance* of the donors and donor *herds* or *flocks* based on the recognised incubation periods of the diseases of concern to determine retrospectively the health status of the donors whilst the embryos are stored (in species where effective storage by cryopreservation is possible) in the *exporting country*. Post-collection *surveillance* of donors is not, of course, possible in the case of batch collection from a~~n~~ *slaughterhouse*/*abattoir*, although surveillance of the *herds* or *flocks* of origin may be possible;

b) testing of oocytes, ~~/~~ embryos, co-culture cells, media and other samples (e.g. blood) (as referred to in Article 4.8.5.) in a *laboratory* for presence of ~~disease~~ pathogenic agents.

Article 4.8.7.

Conditions applicable to the storage and transport of oocytes and embryos

Oocytes and *in vitro* produced embryos can be stored and transported fresh, chilled or frozen.

Fresh embryos may undergo culture in portable incubators during transportation and should arrive at the recipient animal within five days, in time for transfer of the mature blastocysts. Chilled embryos should be transferred within 10 days of chilling.

The *Veterinary Services* should have knowledge of the variety of oocyte and embryo storage systems available and should have procedures in place for the safe and timely inspection and certification of these oocytes and embryos to ensure their viability.

1) Only embryos from the same individual donor or from the same batch collection should be stored together in the same ampoule, vial or straw.

2) For frozen oocytes and embryos

a) Sterile ampoules, vials or straws should be sealed prior to freezing or after vitrification and should be labelled according to the IETS Manual[1].

b) The frozen oocytes and embryos should ~~if possible, depending on the species,~~ be frozen in fresh liquid nitrogen ~~or other cryoprotectant and~~ then stored in ~~fresh cryoprotectant~~ liquid phase nitrogen or in the vapour phase of liquid nitrogen ~~cleaned~~ disinfected containers under strict hygienic conditions at a storage place.

c) Liquid nitrogen containers should be sealed prior to *shipment*.

3) For fresh or chilled oocytes and embryos

a) Sterile ~~Ampoules~~ ampoules, vials or straws should be sealed prior to storing in portable incubators ~~at the time of freezing~~ and should be labelled in accordance with the IETS Manual[1].

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b) The fresh or chilled oocytes and embryos should be stored under strict hygienic conditions in portable incubators disinfected in accordance with the IETS Manual[1] and manufacturer's instructions.

c) Portable incubators should be sealed prior to *shipment*.

~~4) Liquid nitrogen containers should be sealed prior to shipment from the *exporting* country.~~

4~~5~~) Oocytes and embryos ~~Embryos~~ should not be exported until the appropriate veterinary certificates are completed.

Article 4.8.8.

Procedure for micromanipulation

When micromanipulation of the embryos is to be carried out, this should be done after completion of the treatments described in point 2 of Article 4.8.6. and conducted in accordance with Chapter 4.9.

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— Text deleted.

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[i] Manual of the International Embryo Transfer Society.

Annex 24

CHAPTER 4.11.

SOMATIC CELL NUCLEAR TRANSFER IN PRODUCTION LIVESTOCK AND HORSES

EU comment

The EU supports the proposed changes to this 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.

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[Article 4.11.5.]

[…]

[Article 4.11.7.]

- Text deleted.

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Annex 25

CHAPTER 6.7.

HARMONISATION OF NATIONAL ANTIMICROBIAL RESISTANCE SURVEILLANCE AND MONITORING PROGRAMMES

EU comment

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

Article 6.7.1.

Objective

This chapter provides criteria for the:

1) development of national antimicrobial resistance surveillance and monitoring programmes,

2) harmonisation of existing national antimicrobial resistance surveillance and monitoring programmes,

in food producing animals and in products of animal origin intended for human consumption.

EU comment

This chapter doesn't only deal with the surveillance and monitoring of AMR in food producing animals and in products of animal origin intended for human consumption, as stipulated by the sentence above. Indeed, it includes also other products, such as in particular feed and faeces. Even if one considers faeces as a part of "animal" screening, feed for food producing animals still should be mentioned separately also here in the objective, for reasons of coherence.

Therefore, the sentence above should read as follows:

"[...] in food producing animals, in their feed and in products of animal origin intended for human consumption.

Article 6.7.2.

Purpose of surveillance and monitoring

Active (targeted) surveillance and monitoring are core parts of national antimicrobial resistance surveillance programmes. Passive surveillance and monitoring may offer additional information (refer to Chapter 1.4.). Cooperation between all Member Countries conducting antimicrobial resistance surveillance should be encouraged.

EU comment

The EU suggests deleting the word "(targeted)" in the paragraph above. Indeed, while "targeted surveillance" can refer to the process of sampling a specific subset of the population which is considered most likely to have the disease in question, active surveillance is not necessarily targeted (but targeted surveillance will always be active). Therefore, we suggest removing the word "targeted" to avoid any possible confusion.

Surveillance and monitoring of antimicrobial resistance is necessary to:

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1) assess and determine the trends and sources of antimicrobial resistance ~~in bacteria~~;

2) detect the emergence of new antimicrobial resistance mechanisms;

3) provide the data necessary for conducting *risk analyses* as relevant to animal and human health;

4) provide a basis for policy recommendations for animal and human health;

5) provide information for evaluating antimicrobial prescribing practices and, for prudent use recommendations;

6) assess and determine effects of actions to combat antimicrobial resistance.

Article 6.7.3.

The development of antimicrobial resistance surveillance and monitoring programmes

EU comment

The EU notes that this article is rather long and makes up most of the chapter (7 of 8 pages), which makes it difficult to read. The EU in general invites the OIE to draft shorter articles to make the Code more user-friendly.

1. General aspects

Surveillance of antimicrobial resistance at targeted intervals or ongoing monitoring of the prevalence of resistance in bacteria from *animals*, animal feed, food, environment and humans, constitutes a critical part of animal health and food safety strategies aimed at limiting the spread of antimicrobial resistance and optimising the choice of *antimicrobial agents* used in therapy.

EU comment

For the same reasons as explained in the EU comment above, we suggest replacing the term "targeted intervals" by "defined intervals". Indeed, "targeted" could be misunderstood also in this context.

Monitoring of bacteria from products of animal origin intended for human consumption collected at different steps of the food chain, including processing, packing and retailing, should also be considered.

National antimicrobial resistance monitoring and surveillance programmes should be scientifically based and may include the following components:

a) statistically based surveys;

b) sampling and testing of food producing animals on the farm, at live animal markets or at *slaughter*;

c) an organised sentinel programme, for example targeted sampling of food producing animals, *herds*, *flocks*, and *vectors* (e.g. birds, rodents);

d) analysis of veterinary practice and diagnostic *laboratory* records;

e) sampling and testing of products of animal origin intended for human consumption.

EU comment

In order to be consistent with the inclusion of feed as a component in the surveillance programme, the EU suggests adding a point as follows:

"f) sampling and testing of feed ingredients or feed intended for animal consumption."

2. Sampling strategies

a) Sampling should be conducted on a statistical basis. The sampling strategy should ensure:

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– the sample is representative of the population of interest;

– the robustness of the sampling method.

b) The following criteria are to be considered:

– sample source such as food producing animal, food, animal feed;

– animal species;

– category of *animal* within species such as age group, production type;

– health status of the *animals* such as healthy, diseased;

– sample selection such as targeted, systematic random, non-random;

– type of sample ~~(e.g.~~ such as ~~faecal,~~ faeces, carcass, food product~~)~~;

– sample size.

3. Sample size

The sample size should be large enough to allow detection of existing and emerging antimicrobial resistance phenotypes.

EU comment

The EU suggests amending the sentence above as follows:

"The sample size should be large enough to provide a representative sample and should take into account the expected prevalence of the resistance phenotype and the desired level of precision and confidence. ~~allow detection of existing and emerging antimicrobial resistance phenotypes.~~"

Indeed, a large sample size will not ensure that emerging phenotypes will be detected. The aim of the sample size calculation is to ensure that enough samples are collected to be confident that if the same population was randomly sampled again a similar prevalence would be found.

~~Sample size estimates for prevalence of antimicrobial resistance in a large population are provided in Table 1 below.~~

EU comment

The EU wonders why the sentence above is being deleted from point 3. Even if the text is similar to that of the title of Table 1 and thus seems repetitive at first sight, it is rather important as it is the only reference to that table in the text and thus links the table with the article. If deleted, Table 1 will stand alone without being referred to in the text, which will likely lead to confusion. Indeed, it is established Code format to include references to tables in the relevant articles.

If the intention is merely to delete repeated text, perhaps deleting the title of the table (leaving only "Table 1" above the table) is the better option.

This comment is also valid in relation to point 5 and Table 2 below.

Table 1. Sample size estimates for prevalence in a large population

	90% Level of confidence	95% Level of confidence

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Expected prevalence	Desired precision			Desired precision		
	10%	5%	1%	10%	5%	1%
10%	24	97	2,429	35	138	3,445
20%	43	173	4,310	61	246	6,109
30%	57	227	5,650	81	323	8,003
40%	65	260	6,451	92	369	9,135
50%	68	270	6,718	96	384	9,512
60%	65	260	6,451	92	369	9,135
70%	57	227	5,650	81	323	8,003
80%	43	173	4,310	61	246	6,109
90%	24	97	2,429	35	138	3,445

4. Sample sources

Member Countries should examine their livestock production systems on the basis of available information and assess which sources are likely to contribute most to a potential risk to animal and human health.

a) Animal feed

Member Countries should consider including animal feed in surveillance and monitoring programmes as they may become contaminated with antimicrobial resistant bacteria, e.g. *Salmonella*.

b) Food producing animals

Categories of food producing animals considered for sampling should be relevant to the country's production system.

EU comment

The following sentence should be added:

"Resource allocation should be guided by production volume and the prevalence of resistant bacteria".

Indeed, it may be that a population of food producing animals contributes a lot to production without showing crucial prevalence of resistant bacteria (example: dairy cows). This is why a second criterion for sampling should be added to this point b) above.

c) Food

Member Countries should consider including products of animal origin intended for human consumption in surveillance and monitoring programmes as foodborne transmission is considered to be an important route for the transfer of antimicrobial resistance.

EU comment

The EU suggests that something be included in the paragraph above to say that any food sampled should be identified as being imported / not. This has been flagged as an important issue with food samples taken as part of existing EU requirements. Alternatively this point could be mentioned in section 2 b) above.

5. Type of sample to be collected

Feed samples should be collected in amounts sufficient for isolation of resistant bacteria of concern (at least 25 g) and should be linked to pathogen surveillance programmes.

EU comment

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The EU suggests amending the paragraph above as follows:

"Feed samples should be collected in <u>a manner that is representative of the batch and in</u> amounts sufficient for isolation of resistant bacteria of concern (at least 25 g) and should be linked to pathogen surveillance programmes."

Indeed, batches of feed are not homogenous, therefore it is not sufficient to take 25g from one single area. A number of samples need to be taken from different locations so as to be representative of the whole batch. This will vary depending on the size of the batch and the container in which it is stored.

Faecal samples should be collected in amounts sufficient for isolation of the resistant bacteria of concern (at least 5 g from bovine and porcine and whole caeca from *poultry*).

EU comment

The EU suggests adding the following to the sentence above:

" [...] **<u>and should be representative of the herd, flock or population being tested</u>."**

Indeed, as per the previous EU comment there needs to be a reference to the sampling strategy to ensure that samples collected are representative of the herd, flock or population being tested.

Sampling of carcasses at the *slaughterhouse*/*abattoir* provides information on *slaughter* practices, *slaughter* hygiene and the level of microbiological contamination and cross-contamination of *meat*. Further sampling of the product at retail sales level may provide additional information on the overall microbiological contamination from *slaughter* to the consumer.

Existing food processing microbiological monitoring, risk-based management and other food safety programmes may provide useful samples for surveillance and monitoring of resistance in the food chain after *slaughter*.

~~Table 2 provides examples of sampling sources, sample types and monitoring outcomes.~~

Table 2. Examples of sampling sources, sample types and monitoring output

Source	Type	Output	Additional information required or additional stratification
Herd or flock of origin	Faeces or bulk milk	Prevalence of resistant bacteria originating from animal populations (of different production types) Relationship between resistance – and antimicrobial use	Age categories, production types, etc. Antimicrobial use over time
Abattoir	Faeces	Prevalence of resistant bacteria originating from animals at slaughter	
	Caeca or intestines	As above	
	Carcass	Hygiene, contamination during slaughter	
Processing, packing	Food products	Hygiene, contamination during processing and handling	
Point of sale (Retail)	Food products	Prevalence of resistant bacteria originating from food, exposure data for consumers	
Various origins	Animal feed	Prevalence of resistant bacteria originating from animal feed, exposure data for animals	

6. <u>Bacterial isolates</u>

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The following categories of bacteria could be included in surveillance and monitoring programmes ~~monitored~~:

a) Animal bacterial pathogens relevant to the countries' priorities

i) Surveillance and ~~M~~monitoring of antimicrobial resistance in animal bacterial pathogens is important~~, both~~ to:

~~i)~~ — detect emerging resistance that may pose a concern for animal and human health;

~~ii)~~ — detect changes in susceptibility patterns;

~~iii)~~ — provide information for *risk analysis*;

~~iv)~~ — guide *veterinarians* in their ~~prescribing~~ treatment decisions.

EU comment

The EU suggests amending the bullet point above as follows:

"~~guide~~ provide information for *veterinarians* to inform their ~~in their prescribing~~ treatment decisions"

Resistance patterns vary from farm to farm so aggregated national data collected via passive surveillance is unlikely to accurately reflect the patterns of resistance in the specific animals veterinarians may be treating. However it is useful for veterinarians to be aware of the levels of resistance in the wider population. Therefore we there should be less emphasis on using data from passive surveillance as a basis for prescribing.

ii) Information on the occurrence of antimicrobial resistance in animal bacterial pathogens is in general either derived from ~~routine~~ clinical material sent to veterinary diagnostic *laboratories* or from an active monitoring programme. ~~These samples, often derived from severe or recurrent clinical cases including therapy failure, may provide biased information.~~ Although antimicrobial resistance information provided by diagnostic *laboratories* is primarily for treatment purposes, it is also useful for identification of novel resistance patterns and can possibly assist in identifying emerging resistance. However, in order to estimate accurately the prevalence of antimicrobial resistance in the bacterial pathogen, in a larger population of animals, an active sampling programme should be implemented.

iii) To promote a harmonised global approach to the selection of animal bacterial pathogens for inclusion in national surveillance and monitoring programmes, bacteria should be selected using the following criteria:

— impact on animal health and welfare;

— implication of antimicrobial resistance in the bacterial pathogen on therapeutic options in veterinary practice;

— impact on food security and on production (economic importance of associated diseases);

— bacterial diseases responsible for the majority of veterinary antimicrobial usage (stratified by usage of different classes or their importance);

— existence of validated susceptibility testing methodologies for the bacterial pathogen;

— Existence of quality assurance programmes or other pathogen reduction options that are non-antimicrobial (vaccines).

EU comment

The mention of vaccines in parenthesis in the last bullet of point 6.a.iii above seems to limit the scope of pathogen reduction options to vaccines, whereby those are broader, e.g. good management practices, better biosecurity, SPF, etc., and none of these necessarily fall into quality assurance. Therefore, the EU suggests inserting the words "such as" before the "vaccine".

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The table below, derived using the above criteria, lists suggested animal bacterial pathogens for inclusion in a monitoring programme of food-producing animals. This list is not exhaustive and should be adapted according to the situation in the country.

Table 3. Examples of target animal species and animal bacterial pathogens that may be included in resistance surveillance and monitoring programmes

Target animals	Respiratory pathogens	Enteric pathogens	Udder pathogens	Other
Cattle	*Pasteurella multocida*	*Escherichia coli*	*Staphylococcus aureus*	
	Mannheimia haemolytica	*Salmonella* spp.	*Streptococcus* spp.	
Pigs	*Actinobacillus pleuropneumoniae*	*Escherichia coli*		*Streptococcus suis*
		Salmonella spp.		
Poultry				*Escherichia coli*

EU comment

The EU considers that the term "Other" in the fifth column of Table 3 might give the impression that this column is of lesser priority, which is not necessarily the case. For instance, in piglets, *Streptococcus suis* causes meningitis and neurological symptoms and in poultry, some pathogenic *E. coli* may cause omphalitis. Therefore, the term "Other" should be replaced by a more specific wording such as "Other pathogens responsible for serious systemic symptoms".

Furthermore, regarding poultry pathogens, the EU would suggest to include *E. coli* also in the second and third columns (i.e., respiratory and enteric pathogens) as some pathogenic *E. coli* may cause serious diarrhoea and respiratory symptoms in poultry.

b) Zoonotic bacteria

i) Salmonella

Salmonella should be sampled from animal feed, food producing animals and animal derived food products. For the purpose of consistency and harmonisation, samples should be preferably taken at the *slaughterhouse/abattoir*.

EU comment

While agreeing that it is reasonable to collect samples at slaughterhouses, the intention of the second sentence is a bit unclear – is the intention to sample only animals and carcasses at the slaughterhouse, or also other kinds of samples? This would not be meaningful for e.g. feed. In addition, in order to detect *Salmonella*, also environmental sampling in herds is valuable. Therefore, the EU suggests replacing the second sentence of the paragraph above by the following:

"Feed samples should preferably be taken at the feed mill. Animal samples may be collected at farm, but should be preferably taken at the *slaughterhouse/abattoir*.

Surveillance and monitoring programmes may also include bacterial isolates originating from other sources obtained from designated ~~national~~ *laboratories* ~~originating from other sources~~.

Isolation and identification of bacteria and bacterial strains should follow nationally or internationally standardised procedures.

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Serovars of public health importance such as *S.* Typhimurium and *S.* Enteritidis should be included. The inclusion of other relevant serovars will depend on the epidemiological situation in each country.

All *Salmonella* isolates should be serotyped and, where appropriate, phage-typed according to standard methods used at the nationally designated *laboratories*. For those countries that have the capabilities, *Salmonella* could be genotyped using genetic finger-printing methods.

ii) Campylobacter

Campylobacter ~~jejuni and C. coli~~ should be isolated from food producing animals and associated food products ~~(primarily from *poultry*)~~. Isolation and identification of these bacteria should follow nationally or internationally standardised procedures. *Campylobacter* isolates should be identified to the species level.

iii) Other emerging bacterial pathogens

Other emerging bacterial pathogens such as methicillin-resistant *Staphylococcus aureus* (MRSA), *Listeria monocytogenes* or others which are pathogenic to humans, may be included in resistance surveillance and monitoring programmes.

EU comment

The EU suggests replacing the sentence above by the following wording:

"Other ~~emerging bacterial pathogens~~ bacteria which are pathogenic to humans such as methicillin-resistant *Stapphylococcus aureus* (MRSA) or *Listeria moncytogenes* ~~or others which are pathogenic to humans,~~ may be included in resistance surveillance and monitoring programmes."

Indeed, the term "emerging" is not correct in the context of bacterial infections. The proposed wording addresses the issue of human pathogens more clearly.

In addition, this should be reflected in the title as well, which should be amended as follows:

"iii) Other bacteria which are pathogenic to humans ~~emerging bacterial pathogens~~ ".

c) Commensal bacteria

E. coli and *enterococci* (*Enterococcus faecium* and *E. faecalis*) may be sampled from animal feed, food producing animals and products of animal origin intended for human consumption.

These bacteria are commonly used in surveillance and monitoring programmes as indicators, providing information on the potential reservoir of antimicrobial resistance genes, which may be transferred to pathogenic bacteria. It is considered that these bacteria should be isolated from healthy *animals*, preferably at the *slaughterhouse*/*abattoir*, for the purpose of consistency and harmonisation ~~and be monitored for antimicrobial resistance~~.

EU comment

The term "preferably" in the paragraph above should be replaced by "e.g.", and consequently the proposed insertion "for the purpose of consistency and harmonisation" should be deleted.

Indeed, while it may be practical to collect samples at slaughter, it is difficult to relate the observed resistance to antimicrobial use on farm.

7. Storage of bacterial strains

If possible, isolates should be preserved at least until reporting is completed. Preferably, appropriate isolates should be permanently stored. Bacterial strain collections, established by storage of all isolates from certain years, will provide the possibility of conducting retrospective studies.

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8. Antimicrobial susceptibility testing

Clinically important *antimicrobial agents* or classes used in human and veterinary medicine should be included in antimicrobial resistance surveillance programmes. Member Countries should refer to the OIE list of *antimicrobials* of veterinary importance for monitoring purposes. However, the number of tested *antimicrobial agents* may have to be limited according to financial resources.

Appropriately validated antimicrobial susceptibility testing methods should be used in accordance with ~~Guideline~~ Chapter 3.1. of the *Terrestrial Manual*, concerning laboratory methodologies for bacterial antimicrobial susceptibility testing. Antimicrobial susceptibility data should be reported not only qualitatively (susceptible or resistant), but also quantitatively (minimum inhibitory concentrations [MICs] or inhibition zone diameters)~~, rather than qualitatively~~.

9. Recording, storage and interpretation of data

a) Because of the volume and complexity of the information to be stored and the need to keep these data available for an undetermined period of time, careful consideration should be given to database design.

b) The storage of raw (primary, non-interpreted) data is essential to allow the evaluation in response to various kinds of questions, including those arising in the future.

c) Consideration should be given to the technical requirements of computer systems when an exchange of data between different systems (comparability or compatibility of automatic recording of laboratory data and transfer of these data between and within resistance monitoring programmes) is envisaged. Results should be collected in a suitable national database. They should be recorded quantitatively:

i) as distributions of MICs in micrograms per millilitre;

ii) or inhibition zone diameters in millimetres.

d) The information to be recorded should include, where possible, the following aspects:

i) sampling programme;

ii) sampling date;

iii) animal species and production type;

iv) type of sample;

v) purpose of sampling;

vi) type of antimicrobial susceptibility testing method used;

vii) geographical origin (geographical information system data where available) of *herd*, *flock* or *animal*;

viii) *animal* factors ~~(e.g.~~ such as age, condition, health status, identification, sex~~).~~;

ix) exposure of *animals* to *antimicrobial agents*;

x) bacterial recovery rate.

EU comment

The EU queries what exactly is meant by "bacterial recovery rate", as this is unclear even to experts.

e) The reporting of *laboratory* data should include the following information:

i) identity of *laboratory*,

ii) isolation date,

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iii) reporting date,

iv) bacterial species,

and, where relevant, other typing characteristics, such as:

v) serotype or serovar,

vi) phage type,

vii) antimicrobial susceptibility result or resistance phenotype,

viii) genotype.

f) The proportion of isolates regarded as resistant should be reported, including the defined interpretive criteria used.

g) In the clinical setting, breakpoints are used to categorise bacterial strains as susceptible, intermediate or resistant. These clinical breakpoints may be elaborated on a national basis and may vary between Member Countries.

h) The antimicrobial susceptibility testing standards and guidelines used should be recorded.

i) For surveillance purposes, use of the microbiological breakpoint (also referred to as epidemiological cut-off point), which is based on the distribution of MICs or inhibition zone diameters of the specific bacterial species tested, is preferred. When using microbiological breakpoints, only the bacterial population with acquired resistance that clearly deviates from the distribution of the normal susceptible population will be designated as resistant.

j) Ideally, data should be collected at the individual isolate level, allowing antimicrobial resistance patterns to be recorded.

10. Reference laboratory and annual reports

a) Member Countries should designate a national reference centre that assumes the responsibility to:

i) coordinate the activities related to the antimicrobial resistance surveillance and monitoring programmes;

ii) coordinate and collect information from participating surveillance laboratories within the country;

iii) produce an annual report on the antimicrobial resistance situation in the country.

b) The national reference centre should have access to the:

i) raw data;

ii) complete results of quality assurance and inter-laboratory calibration activities;

iii) inter-laboratory proficiency testing results;

iv) information on the structure of the monitoring system;

v) information on the chosen laboratory methods.

EU comment

Assigning coordination in points 10(a)(i) and (ii) to the national reference centre seems a bit too much. Indeed, that should be for the Veterinary Authority while the national reference centre provides technical input for that.

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— Text deleted.

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Annex 26

CHAPTER 7.1.

INTRODUCTION TO THE RECOMMENDATIONS FOR ANIMAL WELFARE

EU comment

The EU thanks the OIE for its work and for drafting a new article on this important issue. The EU can in general agree to the proposed text of the article. We do however have a few comments on certain principle issues as indicated below.

Article 7.1.X.

Guiding principles for the use of animal-based measures

EU comment

The EU would ask OIE to consider the wording in the title of this article:

"Guiding principles for the use of animal-based measurables ~~measures~~"

Justification

Consistency with other chapters where "criteria" or measurable are used

1) For the OIE *animal welfare* standards to be applicable globally, they should emphasise good outcomes for the animals rather than prescribe specific conditions of the animals' environment and management. Outcomes are generally assessed by animal-based measures such as low mortality rate, low prevalence of injuries, ability to move freely, positive human-animal relationship, and a low incidence of aggression and stereotyped behaviour.

EU comment

The EU would ask OIE to consider the following changes to the text of point 1:

"For the OIE *animal welfare* standards to be applicable globally, they should emphasise good outcomes for the animals ~~rather than prescribe specific conditions of the animals' environment and management~~. Outcomes are generally assessed by animal-based measures such as low mortality rate, low prevalence of disease and injuries, ability to move freely, ability to perform natural behaviour, positive human-animal relationship, and a low incidence of aggression and stereotypical~~ed~~ behaviour. Animal based outcomes can be considered as a tool to monitor the impact of the animals' environment and animal management practices. If outcomes are unsatisfactory, producers should consider what changes to resources and/or management are needed to improve outcomes."

Justification

Even though this new article concerns outcome based measures, the use of input values is still pertinent. The new text may be interpreted as if outcomes are more important than inputs, however they are closely related. In fact, for some areas, such as welfare at

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slaughter it is important to have both (i.e. monitoring of birds coming out of waterbaths, subject to particular stunning parameters).

The *assessment* of welfare should take into account both outcomes and animal-based measures. However, when an assessment reveals welfare to be unsatisfactory, an improvement strategy must consider the need for changes to inputs, such as inadequate housing, resources and management.

The relationship between outcomes and inputs is well described in the OIE Chapter on the welfare of dairy cattle. This states that "outcome-based criteria, specifically animal-based criteria, can be useful indicators of animal welfare ... These criteria can be considered as a tool to monitor the impact of design and management, given that both of these can affect animal welfare." Similarly nearly all the principles set out in Article 7.1.4 focus both on resources and the outcomes that each resource should produce. The final two sentences have therefore been included for consistency purposes with other chapters.

The ability to perform natural behaviours and a low prevalence of disease (or ill-health if preferred) should be added to the examples of animal-based measures as they are key indicators of welfare; both are included in the principles listed in Article 7.1.4.

2) For each principle listed in Article 7.1.4., the most relevant measures, ideally animal-based measures, should be included in the standard. Any given animal-based measure may be linked to more than one principle.

3) End-users of the standard should select the most appropriate animal-based measures for their farming system or conditions, from among those listed in the standard.

EU comment

The EU asks the OIE to consider amending this point as follows:

"End-users of the standard should select the most appropriate animal-based measures for their farming system or conditions, from among those listed in the standard or an equivalent when it is supported by scientific evidence."

Justification

It is important to not exclude the possibility of adding other animal based measurables in the future based on developments in science.

4) Standards should, whenever possible, define explicit targets or thresholds that should be met for animal-based measures. Such target values should be based on available science and experience of experts. To guide end-users, *Competent Authorities* should collect data that can be used to set locally relevant target values.

EU comment

The EU asks the OIE to consider amending the second sentence of this point as follows:

"Such target values should be based on relevant available science and experience of experts."

Justification

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Available means that it can be accessed, however it does not necessarily mean that it is up to date. Therefore the word « relevant » is necessary to ensure that the science used is not outdated.

5) In addition to animal-based measures, resource-based measures and management-based measures can be defined on the basis of science and expert experience, in cases where a welfare outcome is clearly linked to a resource such as adequate space, or to a management procedure such as pain mitigation.

EU comment

The EU asks the OIE to consider the changes as indicated below to point 5:

"In addition to animal-based measures, resource-based measures such as adequate space and management-based measures such as pain mitigation can be defined on the basis of science and expert experience, and are equally important as appropriate resources and management are necessary to achieve good outcomes.~~in cases where a welfare outcome is clearly linked to a resource such as adequate space, or to a management procedure such as pain mitigation.~~"

Justification

The existing text seems to suggest that in some cases there is little connection between welfare outcomes and resources or management procedures. This could lead to the assumption that in such cases little attention needs to be given to these inputs. However, in nearly all cases resources, management and stockmanship exert an important influence on the outcomes that are reached.

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— Text deleted.

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Annex 27

DRAFT CHAPTER 7.X.

ANIMAL WELFARE AND PIG PRODUCTION SYSTEMS

EU comment

The EU thanks the OIE for its work on this new draft chapter. It is consistent with the other OIE animal welfare chapters but also addresses those issues that are specific for pigs in a clear and simple manner. The EU does however have a number of comments as indicated in the text below.

Article 7.X.1.

Definitions

Pig production systems are defined as all commercial systems in which the purpose of the operation includes some or all of the breeding, rearing and management of pigs intended for production of *meat*.

For the purpose of this chapter management is defined at the farm management level and at the *animal handler* level. At the level of farm management, human resources management practices including selection and training, and animal management practices, such as best practice in housing and husbandry and implementation of welfare protocol and audits all impact on *animal welfare*.

At the *animal handler* level this requires a range of well-developed husbandry skills and knowledge to care for animals.

For the purpose of this chapter environmental enrichment: means increasing the complexity (e.g. foraging opportunities, social housing, etc.) of the animal's environment to foster the expression of normal behaviour and reduce the expression of abnormal behaviour and provide cognitive stimulation. The endpoint of enrichment should be to improve the biological functioning of the animal (Newberry, 1995).

EU comment

The EU asks the OIE to consider the following amendment of the final sentence in this paragraph:

"The endpoint of enrichment should be to improve the biological functioning and behavioural well-being of the animal."

Justification

As stated in the first sentences of the paragraph enrichment material should be given in order to foster the expression of normal behaviour and reduce the expression of abnormal behaviour whilst also providing cognitive stimulation. These factors relate more to improving the behavioural health and well-being by meeting the behavioural needs of the animal than the biological functioning of the animal. One could argue that behavioural health should be seen as part of biological function. However, this is not clearly understood from the text, nor is this view generally accepted amongst scientists. Furthermore, the current sentence could be interpreted as meaning that only enrichment that improves the biological functioning should be provided, regardless of potential behavioural benefits.

Article 7.X.2.

Scope

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This chapter addresses the welfare aspects of pig production systems. However, *captive wild* pigs are not considered.

Article 7.X.3.

Commercial pig production systems

Commercial pig production systems include:

1. Indoors

   These are systems in which pigs are kept indoors, and are fully dependent on humans to provide for basic animal needs such as food and water. The type of housing depends on the environment, climatic conditions and management system. The animals may be kept in groups or individually.

2. Outdoors

   These are systems in which pigs live outdoors with shelter or shade, have some autonomy over access to shelter or shade, and may be fully dependent on humans to provide for basic animal needs such as food and water. They are typically confined in paddocks according to their production stage.

3. Combination systems

   These are systems in which pigs are managed in any combination of indoor and outdoor production systems, depending on weather or production stage.

Article 7.X.4.

Criteria (or measurables) for the welfare of pigs

The following outcome-based criteria, specifically animal-based criteria, can be useful indicators of *animal welfare*. The use of these indicators and their appropriate thresholds should be adapted to the different situations in which pigs are managed. Consideration should also be given to the design of the systems. These criteria can be considered as a tool to monitor the efficiency of design and management, given that both of these can affect *animal welfare.*

1. Behaviour

   Certain behaviours could indicate an *animal welfare* problem. These include changes of feed and water intake, altered locomotory behaviour and posture, altered lying time, altered respiratory rate and panting, coughing, shivering and huddling, increased agonistic behaviours and stereotypic, apathetic or other abnormal behaviours (e.g. tail biting).

EU comment

The EU asks the OIE to consider altering the above paragraph as follows:

"Certain behaviours could indicate an *animal welfare* problem. These include changes of feed and water intake, altered locomotory behaviour and posture (e.g. due to lameness), altered lying time, altered respiratory rate and panting, coughing, shivering and huddling, certain vocalisations, increased agonistic behaviours (biting and fighting) and stereotypic, apathetic or other abnormal behaviours (e.g. tail biting, ear biting, leg biting, flank biting, vulva biting)."

Justification

These are also other relevant behavioural signs indicating welfare problems.

Scientific references

Broom, D.M., 1988. The scientific assessment of animal welfare. Applied Animal Behaviour Science, 20: 5-19

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Wemelsfelder, F.; Mullen, S., 2014. Applying ethological and health indicators to practical animal welfare assessment Revue Scientifique et Technique-Office International des Epizooties Volume: 33 Issue: 1 Pages: 111-120

Reimert, Inonge; Bolhuis, J. Elizabeth; Kemp, Bas; et al., 2013. Indicators of positive and negative emotions and emotional contagion in pigs.

Physiology & Behaviour Volume: 109 Pages: 42-50

Stereotypy is defined as a sequence of invariant motor acts, which provide no obvious gain or purpose for the animal. Some stereotypies commonly observed in pigs include sham chewing, tongue rolling, teeth grinding, bar biting and floor licking.

EU comment

The EU asks the OIE to consider adding the following sentence:

"Certain behaviours are indicators of good animal welfare. These include low fearfulness of animal handlers (willingness to approach), exploratory behaviour (using the enrichment material provided), positive social behaviour and play behaviour."

Justification

It would be good to also add signs of positive behaviour, as it is now widely accepted that good animal welfare is not simply the absence of negative experiences, but rather is primarily the presence of positive experiences such as pleasure. As we gradually move from focusing solely on the five freedoms towards providing animals with "a life worth living", this should be reflected in the OIE recommendations.

In our opinion, including information on positive welfare indicators would strengthen the text, allowing for more ambitious objectives than simply reducing the level of poor welfare.

Scientific references

Boissy et. al. "Assessment of positive emotions in animals to improve their welfare" Physiology & Behavior, Volume 92 (2007).

AssureWel: Enrichment use – why is it measured? www.assurewel.org/pigs/enrichmentuse

Reimert et. al. "Indicators of positive and negative emotions and emotional contagion in pigs", Physiology & Behavior, Volume 109 (2013) Welfare Quality Pig Protocol (2009)

2. Morbidity rates

Infectious and metabolic diseases, lameness, peri-partum and post-procedural complications, injury and other forms of morbidity, above recognised thresholds, may be direct or indirect indicators of the *animal welfare* status of the whole *herd*. Understanding the aetiology of the disease or syndrome is important for detecting potential *animal welfare* problems. Mastitis and metritis, leg and hoof, and reproductive diseases are also particularly important animal health problems for pigs. Scoring systems, such as for body condition, lameness and injuries, can provide additional information.

EU comment

The EU asks the OIE to consider altering the third and fourth sentences of this paragraph as follows:

"In that respect, ~~M~~mastitis and metritis, leg and hoof problems, gastric ulcers, certain skin lesions (e.g. bitten tails, vulvas, ears) and reproductive diseases are ~~also~~ particularly important animal health problems for pigs. Scoring systems, such as for body condition,

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lameness and injuries, and information gathered at the slaughterhouse, can provide additional information."

Justification

Linguistic

Depending on the system there are other health related issues resulting from behavioural problems or inappropriate management that can be quite common and are important to include here.

Slaughterhouse ante and post mortem conditions can provide valuable information too.

Both clinical examination and pathology should be utilised as indicators of disease, injuries and other problems that may compromise *animal welfare*.

3. Mortality and culling rates

Mortality and culling rates affect the length of productive life and, like morbidity rates, may be direct or indirect indicators of the *animal welfare* status. Depending on the production system, estimates of mortality and culling rates can be obtained by analysing the causes of *death* and culling and their temporal and spatial patterns of occurrence. Mortality and culling rates, and their causes, when known, should be recorded regularly, e.g. daily, and used for monitoring e.g. monthly, annually.

Necropsy is useful in establishing the cause of *death*.

4. Changes in body weight and body condition

In growing animals, body weight changes outside the expected growth rate, especially excessive sudden loss, are indicators of poor *animal welfare* and health.

EU comment

The EU asks the OIE to alter the sentence as follows:

"In growing animals, body weight changes outside the expected growth rate, especially excessive sudden loss of weight, are indicators of poor *animal welfare* and health."

Justification

Linguistic

In mature animals, body condition outside an acceptable range may be an indicator of compromised *animal welfare*, health and reproductive efficiency.

EU comment

The EU asks the OIE to consider altering the sentence as follows:

"~~In mature animals, b~~Body condition outside an acceptable range or great variation amongst individual animals in the group may be an indicator of compromised *animal welfare*, health and reproductive efficiency."

Justification

This point would also apply to weaners or finishing pigs. Likewise it is important to highlight that those pigs that stay behind ('runts') may have a welfare problem.

5. Reproductive efficiency

Reproductive efficiency can be an indicator of *animal welfare* and health status. Future performance of sows or gilts can be affected by under- or over-nutrition at different stages of rearing. Poor reproductive performance, compared with the targets expected for a particular breed or hybrid, can indicate *animal welfare* problems.

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EU comment

The EU asks the OIE to consider altering the text as follows:

"Reproductive efficiency can be an indicator of *animal* ~~*welfare* and~~ health status. Future performance of sows or gilts can be affected by under- or over-nutrition at different stages of rearing. Poor reproductive performance, compared with the targets expected for a particular breed or hybrid, can indicate *animal* *health* ~~*welfare*~~ problems."

Justification

Reproductive efficiency is mainly an effect of "feed and breed". It has in general little to do with overall *animal welfare*. An animal with a poor welfare may still produce offspring as long as for instance feeding is good. Also, very high reproductive rates are hard on the sow and not seldom directly or indirectly linked to impaired welfare.

Examples may include:

- low conception rates,
- high abortion rates,
- metritis and mastitis,
- low litter size,
- low numbers born alive,
- high numbers of stillborns or mummies.

6. Physical appearance

Physical appearance may be an indicator of *animal welfare* and health. Attributes of physical appearance that may indicate compromised welfare include:

- presence of ectoparasites,
- abnormal texture or hair loss,
- excessive soiling with faeces in indoor systems,
- swellings, injuries or lesions,
- discharges (e.g. from nose or eyes),

EU comment

The EU asks the OIE to consider amending this point as follows:

"– discharges (e.g. from nose or eyes, including tear staining),"

Justification

Tear staining or chromodacryorrhea refers to a dark stain below the inner corner of the eye, caused by porphyrin-pigmented secretion from the Harderian gland.

In EFSAs report (2012), tear staining is listed as an indicator of poor welfare due to high levels of ammonia. According to current research, tear staining has not only been shown to be a consistent indicator of stress in rats, but also to correlate with social stress and a barren environment in pigs.

In our opinion, tear staining is a potential tool for on-farm pig welfare assessment on commercial farms, and should be mentioned specifically in this context.

Scientific references:

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H. Telkänranta et. al: "Tear staining in pigs: a potential tool for welfare assessment on commercial farms" Animal (2016), Volume 10, Issue 2.

EFSA Panel on Animal Health and Welfare (AHAW); Scientific Opinion on the use of animal-based measures to assess welfare in pigs. EFSA Journal 2012; 10(1).

- feet and leg abnormalities,
- abnormal posture (e.g. rounded back, head low),
- emaciation or dehydration.

EU comment

The EU asks the OIE to consider an additional point as follows:

"- number (and nature) of interventions or mutilations (such as tail-docking)"

Justification

Many of today's pig husbandry systems routinely perform certain painful procedures such as docking the pigs' tails instead of addressing the environmental factors and management practices that are the main cause of tail-biting. The number of interventions performed is therefore a good measurable.

7. Handling response

Improper handling can result in fear and distress in pigs. Fear of humans may be an indicator of poor *animal welfare* and health. Indicators include:

EU comment

The EU asks the OIE to consider amending the first sentence as follows:

"Improper handling or poor handling facilities can result in fear and distress in pigs."

Justification

Improper handling can increase the risk of the animal slipping and falling, however the handling facilities and flooring also play a significant role. Both animal based indicators and resource based ones are relevant here and this should be emphasised.

Scientific references

Much of Temple Grandin's work refers to the importance of handling facilities – eg Grandin T, 2005 Antemortem Handling & Welfare, in: Meat Science and it's applications. Ed: Hui et al.

- evidence of poor human-animal relationship, such as disturbed behaviour when being moved or when *animal handlers* enter a pen,
- animals slipping or falling during handling,
- injuries sustained during handling, such as bruising, lacerations and fractured legs,
- animals vocalising abnormally or excessively during restraint and handling.

8. Lameness

Pigs are susceptible to a variety of infectious and non-infectious musculoskeletal disorders. These disorders may lead to lameness and to gait abnormalities. Pigs that are lame or have gait abnormalities may have difficulty reaching food and water and may experience pain. Musculoskeletal problems have many causes, including genetic, nutrition, sanitation, floor quality, and other environmental and management factors. There are several gait scoring systems available.

9. Complications from common procedures

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Some procedures such as surgical castration, tail docking, teeth clipping or grinding, tusk trimming, identification, nose ringing and hoof care are commonly performed in pigs to facilitate management, to meet market requirements and improve human safety and *animal welfare*.

EU comment

The EU asks the OIE to consider amending the text so that it reads:

"Some procedures such as surgical castration, tail docking, teeth clipping or grinding, tusk trimming, identification, nose ringing and hoof care are commonly performed in pigs to facilitate management, to meet market requirements or to ~~and~~ improve human safety or ~~and~~ *animal welfare*."

Justification

There are different reasons for carrying out these procedures, but usually not all are relevant at the same time.

However, if these procedures are not performed properly, *animal welfare* and health can be compromised.

Indicators of such problems could include:

EU comment

The EU asks the OIE to consider the following amendment of the text:

"Indicators of ~~such~~ problems associated with these procedures could include:"

Justification

Clarity of text

- post-procedure *infection* and swelling,
- post-procedure lameness,
- behaviour indicating pain, fear and distress,
- morbidity, mortality and culling rates,
- reduced feed and water intake,
- post procedure body condition and weight loss.

Article 7.X.5.

Recommendations

Ensuring good welfare of pigs is contingent on several management factors, including system design, environmental management, and animal management practices which include responsible husbandry and provision of appropriate care. Serious problems can arise in any system if one or more of these elements are lacking.

Articles 7.X.6. to 7.X.X. provide recommendations for measures applied to pigs.

Each recommendation includes a list of relevant outcome-based measurables derived from Article 7.X.4.

This does not exclude other measures being used where or when appropriate.

Article 7.X.6.

Housing

EU comment

The EU asks the OIE to consider replacing housing with accommodation systems:

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"~~Housing~~ Accommodation systems"

Justification:

This chapter applies to indoor and outdoor systems or a combination of them. Outdoor systems may also provide shelter or other physical structures that have the potential to affect the welfare of the pig. This article should therefore apply to all systems.

When new facilities are planned or existing facilities are modified, professional advice on design in regards to *animal welfare* and health should be sought.

Housing systems and their components should be designed, constructed and regularly inspected and maintained in a manner that reduces the risk of injury, *disease* or stress for pigs. Facilities should to allow for the safe, efficient and humane management and movement of pigs.

EU comment

The EU asks the OIE to delete the word "to" in the final sentence of the above paragraph and to insert a new second sentence so that the paragraph reads:

"Accommodation ~~Housing~~ systems and their components should be designed, constructed and regularly inspected and maintained in a manner that reduces the risk of injury, *disease* or stress for pigs. They should also provide for the thermal, social and behavioural needs of the pigs. Facilities should ~~to~~ allow for the safe, efficient and humane management and movement of pigs."

Justification:

Pigs are very sensitive to temperature and thermal comfort is important. In many of today's husbandry systems behavioural problems are prevalent. Also, Chapter 7.1. *Introduction to the recommendations for animal welfare* of the Terrestrial Animal Health Code in its Article 7.1.4., point 4, states that "*The physical environment should allow comfortable resting, safe and comfortable movement including normal postural changes, and the opportunity to perform types of natural behaviour that animals are motivated to perform.*" Furthermore, point 6 of the same article, states «*For housed animals, air quality, temperature and humidity should support good animal health and not be aversive*». It is therefore appropriate to include this aspect here.

Linguistic

There should be a separate area where sick and injured animals can be treated and monitored. When a separated space is provided, this should accommodate all the needs of the animal e.g. recumbent or lame animals or animals with severe wounds may require additional bedding or an alternative floor surface.

EU comment

The EU asks the OIE to consider the following amendment of the text:

"There should be a separate pen or area where sick and injured animals or animals that exhibit abnormal behaviour can be isolated, treated and monitored. Certain animals may need to be kept individually. When a separated space is provided, this should accommodate all the needs of the animal e.g. recumbent or lame animals or animals with severe wounds may require additional bedding or an alternative floor surface."

Justification:

It may be necessary to have some sort of physical barrier to separate the animals and this could be indicated by "pen".

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It is important in order to avoid poor animal welfare that you can remove also those pigs that behave abnormally and may inflict stress and pain on other pigs.

Pigs should not be tethered as part of their normal housing systems.

EU comment

The EU asks the OIE to consider replacing housing with accommodation systems:

"Pigs should not be tethered as part of their normal ~~housing~~ accommodation systems."

Justification:

See above

Good *animal welfare* outcomes can be achieved in a range of housing systems. The design and management of the system are critical for achieving good *animal welfare* and health outcomes.

EU comment

The EU asks the OIE to consider the following amendments:

"Good *animal welfare* outcomes can be achieved in a range of ~~housing~~ accommodation systems. The design and management of the system are critical for achieving good *animal welfare* and health outcomes, including preventing painful husbandry interventions."

Justification:

Many of today's pig husbandry systems routinely dock the pigs' tails instead of addressing the environmental factors and management practices that are the main cause of tail-biting problems. It would therefore be good to highlight that prevention is possible.

Pigs are social animals and prefer living in groups, therefore housing systems where pregnant sows and gilts can be kept in groups are recommended.

EU comment

The EU asks the OIE to consider the following amendment:

"Pigs are social animals and prefer living in groups, therefore ~~housing~~ accommodation systems where all pigs, including pregnant sows and gilts can be kept in groups with sufficient space to perform normal social behaviour are recommended."

Justification:

The recommendation to keep pigs in groups should apply to all pigs.

Sufficient space is an aspect that needs to be taken into account and should be mentioned here. Indeed, providing insufficient space to group housed animals is counter-productive and may dramatically decrease animal welfare.

Scientific references

There are several; an overview related to sows in early pregnancy is provided in:

Spoolder, H.A.M, Geudeke, M.J., Van der Peet-Schwering, C.M.C and Soede, N.M., 2009. Group housing of sows in early pregnancy: a review of success and risk factors. Livestock Science, 125: 1-14.

Outcome-based criteria (or measurables): physical appearance (injuries), behaviour, changes in body weight and body condition, handling response, reproductive efficiency, lameness and morbidity, mortality and culling rates.

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EU comment

The EU asks the OIE to consider the following addition to the list:

"Outcome-based criteria (or measurables): physical appearance (injuries), behaviour, changes in body weight and body condition, handling response, reproductive efficiency, lameness and morbidity, mortality and culling rates and number (and nature) of interventions/mutilations (such as tail-docking)."

Justification:

Many of today's pig husbandry systems routinely dock the pigs' tails instead of addressing the environmental factors and management practices that are the main cause of tail-biting problems. The number of interventions performed is therefore a good measurable.

Article 7.X.7.

Personnel training

Pigs should be cared for by a sufficient number of personnel, who collectively possess the ability, knowledge and competence necessary to maintain the welfare and health of the animals.

All people responsible for pigs should be competent through formal training or practical experience in accordance with their responsibilities. This includes understanding of and skill in animal handling, nutrition, reproductive management techniques, behaviour, *biosecurity*, signs of *disease*, and indicators of poor *animal welfare* such as stress, pain and discomfort, and their alleviation.

Outcome-based criteria (or measurables): handling response, physical appearance, behaviour, changes in body weight, body condition, reproductive efficiency, lameness and morbidity, mortality and culling rates.

EU comment

The EU asks the OIE to consider the following addition to the list:

"Outcome-based criteria (or measurables): handling response, physical appearance, behaviour, changes in body weight, body condition, reproductive efficiency, lameness and morbidity, mortality and culling rates and complications from common [...] procedures […]."

Justification:

If procedures or interventions are not carried out by well-trained staff, complications such as infections may result. Therefore, complications following a procedure or intervention can be a relevant indicator for lack of skill or competence with regard to those procedures or interventions. It is therefore a relevant measurable and is furthermore linked to Article 7.X.4. point 9.

Article 7.X.8.

Handling and inspection

Pigs should be inspected at least once a day when fully dependent on humans to provide for basic needs such as food and water and to identify welfare and health problems.

Some animals should be inspected more frequently, for example, farrowing sows, new born piglets, newly weaned pigs and newly-mixed gilts and sows.

EU comment

The EU asks the OIE to consider expanding on the above examples:

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"Some animals should be inspected more frequently, for example, farrowing sows, new born piglets, newly weaned pigs, ~~and~~ newly-mixed gilts and sows, sick or injured animals and animals that exhibit abnormal behaviour."

Justification:

Animals that are sick, injured or behaving abnormally need a close and regular follow-up. It is important for the welfare of these pigs that they are more frequently inspected.

Pigs identified as sick or injured should be given appropriate treatment at the first available opportunity by competent *animal handlers*. If *animal handlers* are unable to provide appropriate treatment, the services of a *veterinarian* should be sought.

Recommendations on the handling of pigs are also found in Chapter 7.3. In particular handling aids that may cause pain and distress (e.g. electric goads) should be used only in extreme circumstances and provided that the animal can move freely. The use of electric prods should be avoided (see also point 3 of Article 7.3.8.), and in any case should not be used in sensitive areas including the udder, face, eyes, nose or ano-genital region.

EU comment

The EU asks the OIE to consider amending the final sentence of the above paragraph as follows:

"The use of electric prods should be avoided (see also point 3 of Article 7.3.8.), and if used should only be applied to the muscles of the hindquarters. They should in no ~~any~~ case ~~should not~~ be used in sensitive areas including the udder, face, eyes, nose or ano-genital region. Shocks should not be used repeatedly if the animal fails to respond."

Justification:

It is easier to remember one body area to be used and this should then be specified.

If an animal does not respond as desired the first time an electric prod is used, it will only become more stressed if it is used repeatedly.

Exposure of pigs to sudden movement or changes in visual contrasts should be minimised where possible to prevent stress and fear reactions. Pigs should not be handled aggressively (e.g. kicked, walked on top of, held or pulled by one front leg, ears or tail). Pigs that become distressed during handling should be attended to immediately.

EU comment

The EU asks the OIE to consider the following amendment to the final sentence:

"Pigs that become distressed during handling should ~~be attended to~~ immediately be allowed to settle down and become calm."

Justification:

It would be better to state exactly what is to be achieved by the action.

Pigs should be restrained only for as long as necessary and only appropriate, well-maintained restraint devices should be used.

Outcome-based criteria (or measurables): physical appearance, behaviour, changes in body weight and body condition, handling response, reproductive efficiency, lameness and morbidity, mortality and culling rates.

Article 7.X.9.

Painful procedures

Some procedures such as surgical castration, tail docking, teeth clipping or grinding, tusk trimming, identification, and nose ringing are commonly performed in pigs. These procedures should only be performed to facilitate management, to meet market requirements and improve human safety and *animal welfare*.

UNOFFICIAL VERSION

EU comment

The EU asks the OIE to consider amending the final sentence as follows:

"These procedures should only be performed to facilitate management, to meet market requirements or ~~and~~ improve human safety or ~~and~~ *animal welfare*."

Justification

There are different reasons for carrying out these procedures, but usually not all are valid at the same time.

These procedures have the potential to cause pain and thus should be performed in such a way as to minimise any pain and distress to the animal.

EU comment

The EU asks the OIE to consider amending this sentence as follows:

"These procedures are painful or have the potential to cause pain and thus should be performed only when necessary and in such a way as to minimise any pain and distress to the animal."

Justification

The majority of the procedures listed here will always be painful and it is therefore relevant to consider the necessity for performing them.

Scientific reference

Sutherland, M.A. and Tucker, C.B. 2011. The long and short of it: a review of tail docking in farm animals. Applied Animal Behaviour Science, 135(3) pp. 179-191

Options for enhancing *animal welfare* in relation to these procedures include the internationally recognised 'three Rs' which involves replacement (entire or inmunocastrated males vs. castrated males), reduction (tail docking and teeth clipping only when necessary) and refinement (providing analgesia or anaesthesia).

EU comment

The EU strongly supports the inclusion of this paragraph as the majority of the procedures are painful. Furthermore, alternatives to either replace them or reduce the need for them by introducing management measures or addressing environmental aspects of the husbandry system exist. Therefore only when other measures are impractical or have failed should these procedures be performed. Also as a minimum, where the procedure is necessary to carry out it should be performed under anaesthetic and additional prolonged analgesia.

Justification

Routine tail-docking for example is a procedure used to mask behavioural or physiological symptoms due to inadequate environmental conditions or management systems.

Scientific references

Prunier, A., Bonneau, M., von Borell, E.H., Cinotti, S., Gunn, M., Fredriksen, B., Giersing, M., Morton, D.B., Tuyttens, F.A.M., Velarde, A., 2006b. A review of the welfare consequences of surgical castration in piglets and the evaluation of non-surgical methods. Animal Welfare 15, 277-289.

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Backus G, Støier s, Courat M, Bonneau M, Higuera M., 2014. First progress report from the European declaration on alternatives to surgical castration of pigs.

Backus G, van den Broek E, van der Fels B, Heres L, Immink VM, Knol EF, Komelis M, Mathur PK, van der Peet-Schwering C, van Riel JW, Snoek HM, de Smet A, Tacken GML, Valeeva NI, van Wagenberg CPA. Evaluation of producing and marketing entire male pigs.NJAS-Wageningen Journal of Life Sciences. 2016:76:29-41.

Hansson M, Lundeheim N, Nyman G and Johansson G, 2011. Effect of local anaesthesia and/or analgesia on pain responses induced by piglet castration. Acta Veterinaria Scandinavica 2011, 53:34 http://download.springer.com/static/pdf/163/art%253A10.1186%252F1751-0147-53-34.pdf?originUrl=http%3A%2F%2Factavetscand.biomedcentral.com%2Farticle%2F10.1186%2F1751-0147-53-34&token2=exp=1477240380~acl=%2Fstatic%2Fpdf%2F163%2Fart%25253A10.1186%25252F1751-0147-53-34.pdf*~hmac=eb225d30cfcf4375a793b59c7ec47a07c2e88564ef67a888011dc590ba442f13

Farm Animal Welfare Council, 2009. Farm Animal Welfare in Great Britain: Past, Present and Future

Spoolder H, Bracke M, Mueller-Graf C, and Edwards S. Report 2: Preparatory work for the future development of animal based measures for assessing the welfare of weaned, growing and fattening pigs including aspects related to space allowance, floor types, tail biting and need for tail docking. EFSA Supporting Publications. 2011:8:7 DOI: 10.2903/sp.efsa.2011.EN-181.

Outcome-based criteria (or measurables): complications from common procedures, morbidity rates, mortality and culling rates, abnormal behaviour, physical appearance and changes in weight and body condition.

EU comment

The EU asks the OIE to consider the following addition to the list:

Outcome-based criteria (or measurables): complications from common procedures, morbidity rates, mortality and culling rates, abnormal behaviour, physical appearance and changes in weight and body condition and number and nature of interventions or mutilations (such as tail-docking).

Justification:

Many of today's pig husbandry systems routinely dock the pigs' tails or perform teeth-clipping. The number of interventions performed is therefore a good measurable.

Article 7.X.10.

Feeding and watering of animals

The amount of feed and nutrients pigs require in any management system is affected by factors such as climate, the nutritional composition and quality of the diet, the age, gender, size and physiological state of the pigs (e.g. pregnancy, lactation), and their state of health, growth rate, previous feeding levels and level of activity and exercise.

All pigs should receive adequate quantities of feed and nutrients each day to enable each pig to:

– maintain good health;

– meet its physiological demands; and

EU comment

UNOFFICIAL VERSION

The EU asks the OIE to consider the following amendment to the second point:

"- meet its physiological and behavioural demands; and"

Justification:

The feed also needs to cover behavioural needs.

– avoid metabolic and nutritional disorders.

Feed and water should be provided in such a way as to prevent undue competition and injury.

Pigs should be fed a diet with sufficient fibrous feedstuffs in order to reduce as much as possible the occurrence of gastric ulcers (Hedde *et al.*,1985).

EU comment

The EU asks the OIE to consider adding a new second sentence here:

"Pigs should be fed a diet with sufficient fibrous feedstuffs in order to reduce as much as possible the occurrence of digestive problems such as gastric ulcers. or stereotypic behaviour due to hunger. Sows should be given a sufficient quantity of bulky or high-fibre feed in order to prevent hunger."

Justification

Gastric ulcers are not only caused by a lack of fibrous feedstuffs, though there is an aspect related to digestion.

Chronic hunger arises from restricted feeding of gestating sows. This is practised to control the body condition of the sow, who shares the same genetic propensity for rapid weight gain as her offspring, but the lack of feed results in hunger. The European Commission's Scientific Veterinary Committee has said that dry sows are usually hungry throughout much of their lives.

Scientific references

Edwards S. 2014. Feeding behaviour, productivity and welfare of sows. Joint Annual Meeting Symposium, July 22 (Kansas City, Missouri). https://asas.confex.com/asas/jam2014/webprogram/Paper1698.html

Hansen A. 2012. Feed intake in reproducing sows. In: Nutritional Physiology of Pigs – with emphasis on Danish production conditions, Chapter 8. Electronic publication, SEGES, Videncenter for Svineproduktion, Copenhagen, Denmark, 2012. http://vsp.lf.dk/~/media/Files/Laerebog_fysiologi/Chapter%2018.pdf

Appleby, M.C. and Lawrence, A.B., 1987. Food restriction as a cause of stereotypic behaviour in tethered gilts. Animal Production, 45: 103-110

Terlouw, E.M.C., Lawrence, A.B. and Illius, A.W., 1991. Influences of feeding level and physical restriction on development of stereotypies in sows. Animal Behaviour, 42: 981-991

Spoolder, H.A.M., Burbidge, J.A., Lawrence, A.B., Simmins, P.H. and Edwards, S.A., 1995. Provision of straw as a foraging substrate reduces the development of excessive chain and bar manipulation in food restricted sows. Applied Animal Behaviour Science, 43: 249-262

Scientific Veterinary Committee, 1997. The welfare of intensively kept pigs.

UNOFFICIAL VERSION

All pigs should have access to an adequate supply of palatable water at a temperature that does not inhibit drinking and that meets their physiological requirements and is free from contaminants hazardous to pig health (Patience, 2013).

Outcome-based criteria (or measurables): changes in body weight and body condition, agonistic behaviour at feeding and watering places and abnormal behaviour such as tail biting, mortality and culling rates, and morbidity rates (gastric ulcers).

EU comment

The EU asks the OIE to consider the following amendment:

"Outcome-based criteria (or measurables): changes in body weight and body condition, dehydration, agonistic behaviour at feeding and watering places and abnormal behaviour such as tail biting, mortality and culling rates, and morbidity rates (gastric ulcers)."

Justification

Dehydration is listed as an animal-based criteria under 7.X.4 (physical appearance), and it seems relevant to include it here.

Article 7.X.11.

Environmental enrichment

Animals should be provided with an environment that provides complexity and cognitive stimulation (e.g. foraging opportunities, social housing, etc.) to foster normal behaviour, reduce abnormal behaviour and improve biological function.

EU comment

The EU asks the OIE to consider the following amendment of the text:

"Animals should be provided with an environment that provides complexity and cognitive stimulation (e.g. foraging opportunities, social housing, etc.) to foster normal behaviour (especially rooting and biting/chewing), reduce abnormal behaviour (especially tail, ear, leg and flank biting and apathy due to lack of stimulation) and improve biological function."

Justification:

Certain behavioural needs are very strong and if not met will lead to behavioural problems. This should be highlighted here as environmental factors are important in preventing e.g. tail-biting.

Scientific references

Munsterhjelm, C., Peltoniemi, O.A.T., Heinonen, M., Hälli, O., Karhapää, M. and Valros, A., 2009. Experience of moderate bedding affects behaviour of growing pigs. Applied Animal Behaviour Science, 118: 42-53

Bench, C.J. and Gonyou, H.W., 2006. Effect of environmental enrichment and breed line on the incidence of belly nosing in piglets weaned at 7 and 14 days-of-age. Applied Animal Behaviour Science

Beattie, V.E., O'Connell, N.E. and Moss, B.W., 2000. Influence of environmental enrichment on the behaviour, performance and meat quality of domestic pigs. Livestock Production Science, 65: 71-79

UNOFFICIAL VERSION

Horrell, I. and A'Ness, P., 1995. Enrichment satisfying specific behavioural needs in early-weaned pigs. Applied Animal Behaviour Science, 44: 257-281

Pigs should be provided with multiple forms of enrichment that aim to improve the welfare of the animals through the enhancement of their physical and social environments, such as:

– sufficient quantity of suitable materials to enable pigs to fulfil their innate needs to look for feed (edible materials), bite (chewable materials), root (investigable materials) and manipulate (manipulable materials) (Bracke *et al.*, 2006);

EU comment

The EU asks the OIE to consider the following amendment of this first point:

"- sufficient quantity of suitable materials to enable pigs to fulfil their innate needs to forage and explore i.e. to look for feed (i.e. edible materials that have a smell or taste), bite (chewable materials), root (investigable materials […],) and manipulate (~~manipulable~~ change materials […] location, appearance or structure); novelty is another aspect that is very important so as to maintain interest in the provided material(s)."

Justification:

We are strongly supportive of the inclusion of this sentence as provision of enrichment material is essential for the well-being of pigs. However, we would also like to highlight that certain behavioural needs are very strong, such as foraging and exploratory behaviour. The characteristics of suitable enrichment materials have been described in the EFSA opinion issued in 2014 and should be included here.

Scientific references

Weerd, H. van de, Docking, C.M., Day, J.E.L., Avery, P.J. and Edwards, S.A., 2003. A systematic approach towards developing environmental enrichment for pigs. Applied Animal Behaviour Science, 84: 101-118

Bracke, M.B.M, Zonderland, J.J. and Bleumer, E.J.B., 2007. Expert judgement on enrichment materials for pigs validates preliminary RICHPIG model. Applied Animal Behaviour Science, 104: 1-13

Bracke, M.B.M, Zonderland, J.J. and Bleumer, E.J.B., 2007. Expert consultation on weighing factors of criteria for assessing environmental enrichment materials for pigs. Applied Animal Behaviour Science, 104: 14-23

EFSA AHAW Panel (EFSA Panel on Animal Health and Welfare), 2014. Scientific Opinion concerning a multifactorial approach on the use of animal and non-animal-based measures to assess the welfare of pigs. EFSA Journal 2014;12(5):3702, 101 pp. doi:10.2903/j.efsa.2014.3702

– social enrichment which involves either keeping pigs in groups or individually with visual, olfactory and auditory contact with other pigs;

– positive human contact (such as pats, rubs and talking).

Outcome-based criteria (or measurables): physical appearance (injuries), behaviour (stereotypies, tail biting), changes in body weight and body condition, handling response, reproductive efficiency, lameness and morbidity, mortality and culling rates.

Article 7.X.12.

Prevention of abnormal behaviour

UNOFFICIAL VERSION

In pig production there are a number of abnormal behaviours that can be prevented or minimised with management procedures.

Many of these problems are multifactorial and minimising their occurrence requires an examination of the whole environment and of several management factors. However some recommendations to reduce their occurrence include:

1) Oral stereotypies (e.g. bar biting, sham chewing, excessive drinking) in adult pigs can be minimised by providing environmental enrichment and increasing feeding time and satiety by increasing fibre content in the diet or foraging roughage (Robert *et al.*,1997; Bergeron *et al.*, 2000).

2) Tail biting may be reduced by providing an adequate enrichment material and an adequate diet (avoiding deficiencies of sodium or essential amino-acids), and avoiding high stocking densities and competition for feed and water (Walker and Bilkei, 2005). Other factors to consider include animal characteristics (breed, genetics, gender) and social environment (herd size, mixing animals) (Schroder-Petersen and Simonsen, 2001; EFSA, 2007; Taylor *et al.*, 2010).

EU comment

The EU asks the OIE to consider amending the first two sentences and adding more factors in the final sentence:

"Tail biting may be reduced by avoiding unnecessary stressors that agitate the animals, and by providing an adequate enrichment material, cf. Article 7.X.11 […](Zonderland et al., 2008). In this respect prevention includes providing ~~and~~ an adequate diet (avoiding deficiencies of sodium or essential amino-acids), and avoiding high stocking densities and competition for feed and water. Other factors to consider include animal characteristics (breed, genetics, gender), ~~and~~ social environment (herd size, mixing animals) (Schroder-Petersen and Simonsen, 2001; EFSA, 2007; Taylor *et al.*, 2010), general health, thermal comfort and air quality."

Justification

Clarification

Impaired general health, thermal comfort and poor air quality are risk factors to be considered when trying to reduce problems with tail biting.

Scientific references

EFSA AHAW Panel (EFSA Panel on Animal Health and Welfare), 2014. Scientific Opinion concerning a multifactorial approach on the use of animal and non-animal-based measures to assess the welfare of pigs. EFSA Journal 2014;12(5):3702, 101 pp. doi:10.2903/j.efsa.2014.3702

3) Belly nosing and ear sucking may be reduced by increasing the weaning age, and providing feed to piglets prior to weaning to avoid the abrupt change of feed (Marchant-Forde, 2009; Sybesma, 1981; Worobec, 1999).

4) Vulva biting may be reduced by minimising competition in accessing the feeding area (Bench *et al.*, 2013; Leeb *et al.*, 2001; Rizvi *et al.*, 1998).

Outcome-based criteria (or measurable): physical appearance (injuries), behaviour (abnormal behaviour), morbidity rates, mortality and culling rates, reproductive efficiency and changes in body weight and body condition.

Article 7.X.13.

Space allowance

Space allowance should be managed taking into account different areas for lying, standing and feeding. Crowding should not adversely affect normal behaviour of pigs and durations of time spent lying.

UNOFFICIAL VERSION

EU comment

The EU asks the OIE to consider amending the first sentence as follows:

"Space allowance should be managed taking into account different areas for lying, standing, ~~and~~ feeding and elimination behaviour."

Justification

If given the opportunity, pigs maintain a distinct dunging zone.

Scientific references

Stolba, A. and Wood-Gush, D.G.M., 1989. The behaviour of pigs in a semi-natural environment. Animal Production, 48: 419-425

Insufficient and inadequate space allowance may increase stress, the occurrence of injuries and have an adverse effect on growth rate, feed efficiency, reproduction and behaviour such as locomotion, resting, feeding and drinking, agonistic and abnormal behaviour (Gonyou *et al.*, 2006; Ekkel, 2003; Turner, 2000).

1. Group housing

Floor space may interact with a number of factors such as temperature, humidity, floor type and feeding systems (Marchant–Forde, 2009; Verdon, 2015). All pigs should be able to rest simultaneously, and each animal lie down, stand up and move freely. Sufficient space should be provided to enable animals to have access to feed, water, to separate lying and elimination areas and to avoid aggressive animals.

EU comment

The EU asks the OIE to amend the first sentence as follows:

"Floor space requirements may interact with a number of factors such as temperature, humidity, floor type and feeding systems."

Justification:

Linguistic

If abnormal behaviour is seen, corrective measures should be taken, such as increasing space allowance and providing barriers where possible.

EU comment

The EU asks the OIE to consider the following amendments:

"If abnormal behaviour is seen, corrective measures should be taken, such as increasing space allowance, modifying ventilation, providing enrichment material, providing fibrous diets or ~~and~~ providing barriers where possible."

Justification:

The added elements are also known factors in mitigating abnormal behaviour.

In outdoor systems where pigs have autonomy over diet selection, stocking density should be matched to the available feed supply.

Outcome-based criteria (or measurables): reduction or variation in body weight and body condition, increasing agonistic and abnormal behaviour such as tail biting, injuries, morbidity, mortality and culling rates, and physical appearance (e.g. presence of faeces on the skin).

2. Individual pens

Pigs must be provided with sufficient space so that they can stand up, turn around and lie comfortably in a natural position, and that provides for separation of dunging, lying and eating areas.

UNOFFICIAL VERSION

EU comment

The EU asks the OIE to consider the following amendment:

"Pigs should only be housed in individual pens, if necessary. In individual pens pigs must be provided with sufficient space so that they can stand up, turn around and lie comfortably in a natural position, and that provides for separation of dunging, lying and eating areas."

Justification

Pigs are highly social animals and it is important for their welfare and possibility to express natural and social behaviour that they kept in groups as much as possible.

Outcome-based criteria (or measurables): increasing abnormal behaviour (stereotypies), morbidity, mortality and culling rates, and physical appearance (e.g. presence of faeces on the skin, injuries).

3. Stalls (crates)

EU comment

The EU asks the OIE to consider altering the title and adding the following introductory sentence:

"~~Stalls (e~~Crates~~)~~

Systems using crates should be discouraged due to the ensuing health and welfare problems."

Justification

Linguistic: We do not believe that the terms "stalls" and "crates" are synonymous and can be used interchangeably. It is our understanding that this section applies only to farrowing crates or other types of crates. It should therefore be ascertained which terminology is most descriptive and relevant to use. The change of wording would then have to be made throughout this section.

Pigs are highly social animals and it is important for their welfare that they kept in groups as much as possible so that they have the possibility to express natural and social behaviour. Crates limit the pig's possibility for free movement and possibility to express natural/normal behaviour. It is therefore important for the welfare of the pigs that the time they are kept in crates is limited. Furthermore, sows kept in crates where they cannot turn around have reduced bone and muscular strength, reduced cardiovascular fitness and a higher incidence of foot and leg pathologies and stereotypies. Article 7.X.6 states "housing systems where pregnant sows and gilts can be kept in groups are recommended". It would therefore be helpful for Article 7.X.13 to draw attention to the health and welfare problems entailed in the use of crates and to clarify that these systems should discouraged.

Scientific references

EFSA. 2007. Scientific Report on animal health and welfare aspects of different housing and husbandry systems for adult breeding boars, pregnant, farrowing sows and unweaned piglets. European Food Safety Authority. The EFSA Journal 572:1-107. www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/572.pdf.

Mason G and Rushen J. 2006. Stereotypic Animal Behaviour: Fundamentals and Applications to Welfare, 2nd Edition (Wallingford, U.K.: CABI, p. 347).

UNOFFICIAL VERSION

Scientific Veterinary Committee, 1997. The welfare of intensively kept pigs.

Stalls must be sized appropriately to allow pigs to:

– be able to stand up in their natural stance without contact with either side of the stall,

– stand up without touching the top bars,

– stand in a stall without simultaneously touching both ends of the stall,

EU comment

The EU asks the OIE to consider amending this point as follows:

"- stand in a crate ~~stall~~ without simultaneously touching both ends or sides of the crate ~~stall~~,"

Justification

This is an equally restricting situation for the pig.

– lie comfortably on their sides without disturbing neighbouring pigs.

Outcome-based criteria (or measurables): physical appearance (e.g. injuries), increasing abnormal behaviour (stereotypies), reproductive efficiency, lameness and morbidity, mortality and culling rates (e.g. piglets).

EU comment

The EU asks the OIE to consider the following amendments:

"Outcome-based criteria (or measurables): physical appearance (e.g. injuries including shoulder wounds and lameness), increasing abnormal behaviour (stereotypies), reproductive efficiency, lameness and morbidity, mortality and culling rates (e.g. piglets)."

Justification:

The added criteria are also known and relevant for this type of system.

Article 7.X.14.

Flooring, bedding, resting surfaces

In all production systems pigs need a well-drained and comfortable place to rest.

EU comment

The EU asks the OIE to consider the following amendment:

"In all production systems pigs need a well-drained, dry and comfortable place to rest."

Justification

Well-drained is not sufficient as the area needs to be dry for it to be considered comfortable.

Floor management in indoor production systems can have a significant impact on pig welfare (Temple *et al.*, 2012; Newton *et al.*, 1980). 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. Areas with excessive faecal accumulation are not suitable for resting.

EU comment

The EU asks the OIE to consider the following amendment of the final sentence:

"Areas with excessive faecal accumulation are most unsuitable ~~not suitable~~ for resting."

UNOFFICIAL VERSION

Justification

"Not suitable" is inadequate in this context. The pigs need to be provided with a resting area that is both dry and clean.

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, the slat and gap widths should be appropriate to the claw size of the pigs to prevent injuries.

EU comment

The EU asks the OIE to consider adding a new second sentence to this paragraph:

"When new systems are considered those with fully slatted floors should be avoided."

Justification

In housing systems with fully slatted floors it is more difficult to manage appropriately issues that are important to maintain good pig welfare, e.g. the provision of suitable enrichment material.

Slopes of the pens should allow water to drain and not pool in the pens.

EU comment

The EU asks the OIE to amend the first sentence as follows:

"Slopes of the pen's floor should allow water to drain and not pool in the pens."

Justification:

Linguistic

In outdoor systems, pigs should be rotated between paddocks to ensure good hygiene and minimise risk of diseases.

If bedding is provided it should be suitable (e.g. hygienic, non-toxic) and maintained to provide pigs with a clean, dry and comfortable place on which to lie.

Outcome-based criteria (or measurables): physical appearance (e.g. injuries, presence of faeces on the skin, bursitis), lameness and morbidity rates (e.g. respiratory disorders, reproductive tract infections).

Article 7.X.15.

Air quality

Good air quality and ventilation are important for the welfare and health of pigs and reduce the risk of respiratory discomfort and diseases. Dust, micro-organisms and noxious gases, including ammonia, hydrogen sulphide, and methane, can be problematic in indoor systems due to decomposing animal waste (Drummond *et al.*, 1980).

EU comment

The EU asks the OIE to consider the following amendment of the paragraph:

"Good air quality and ventilation are important for the welfare and health of pigs and reduce the risk of respiratory discomfort, ~~and~~ diseases and behavioural abnormalities […]. Dust, micro-organisms, […] toxins and noxious gases, including ammonia, hydrogen sulphide, and methane, can be problematic in indoor systems due to decomposing animal waste."

Justification

UNOFFICIAL VERSION

Bad ventilation is a risk factor as regards tail-biting or other behavioural abnormalities, cf. earlier comment.

For the inclusion of toxins we provide the following scientific references:

Winkel, A., Wouters, I. M., Aarnink, A. J. A., Heederik, D. J. J., & Ogink, N. W. M. (2014). Emissies van endotoxinen uit de veehouderij: een literatuurstudie voor ontwikkeling van een toetsingskader (Rapport 773): Wageningen UR Livestock Research.

Basinas, I., Sigsgaard, T., Kromhout, H., Heederik, D., Wouters, I. M., & Schlunssen, V. (2015). A comprehensive review of levels and determinants of personal exposure to dust and endotoxin in livestock farming. *25*(2), 123-137

The Health Council of the Netherlands. (2010). Endotoxins; Health-based recommended occupational exposure limit. The Hague: Dutch expert Committee on Occupational Safety; a Committee of the Health Council of the Netherlands in cooperation with the Nordic Expert Group for Criteria Documentation of Health Risks from Chemicals

Smit, L. A. M., Wouters, I. M., Heederik, D., & Douwes, J. (2009). Health effects of occupational endotoxin exposure: a review and relevance to veterinary practice. *Tijdschrift voor Diergeneeskunde, 134*(20), 840-846

Lai, H. T. L., Nieuwland, M. G. B., Kemp, B., Aarnink, A. J. A., & Parmentier, H. K. (2009). Effects of dust and airborne dust components on antibody

Air quality is influenced strongly by management and building design in housed systems. Air composition is influenced by stocking density, the size of the pigs, flooring, bedding, waste management, building design and ventilation system (Ni *et al.*, 1999).

Proper ventilation is important for effective heat dissipation in pigs and to prevent the build-up of effluent gases (e.g. ammonia and hydrogen sulphide), including those from manure and dust in the housing unit. The ammonia level in enclosed housing should not exceed 25 ppm. A useful indicator is that if air quality is unpleasant for humans it is also likely to be a problem for pigs.

EU comment

The EU asks the OIE to consider the following amendments:

"Proper ventilation is important for effective heat dissipation in pigs and to prevent the build-up of effluent gases (e.g. ammonia and hydrogen sulphide), including those from manure and dust in the housing unit. The ammonia level in enclosed housing should not exceed 25 ppm. A useful indicator is that if air quality is unpleasant for humans it is ~~also~~ <u>most</u> likely ~~to be~~ a problem for pigs."

Justification

Degree of likelihood is higher.

Outcome-based criteria (or measurables): morbidity, mortality and culling rates, behaviour (especially respiratory rate or coughing), reductions in weight and body condition.

EU comment

The EU asks the OIE to consider the following amendment:

"Outcome-based criteria (or measurables): <u>excessive soiling,</u> morbidity <u>(esp. information on lung lesions gathered at the slaughterhouse)</u>, mortality and culling rates, behaviour (especially respiratory rate or coughing), <u>behavioural abnormalities […], […] tear staining,</u> reductions in weight and body condition."

UNOFFICIAL VERSION

Justification

If the ventilation is insufficient or ammonium levels are too high it can cause unhygienic conditions in the pens and excessive soling will be observed. An inadequate thermal environment, such as drafts, may be a risk factor for tail biting and other behavioural abnormalities. See also previous comment concerning tear staining.

Scientific references

EFSA AHAW Panel (EFSA Panel on Animal Health and Welfare), 2014. Scientific Opinion concerning a multifactorial approach on the use of animal and non-animal-based measures to assess the welfare of pigs. EFSA Journal 2014;12(5):3702, 101 pp. doi:10.2903/j.efsa.2014.3702

Telkanranta, H.; Marchant-Forde, J. N.; Valros, A. 2016. Tear staining in pigs: a potential tool for welfare assessment on commercial farms. Animal, 10 (2): 318-325

DeBoer, S. P.; Garner, J. P.; McCain, R. R.; et al., 2015. An initial investigation into the effects of isolation and enrichment on the welfare of laboratory pigs housed in the PigTurn (R) system, assessed using tear staining, behaviour, physiology and haematology. Animal WelfareVolume: 24 Issue: 1 Pages: 15-27

Article 7.X.16.

Thermal environment

Although pigs can adapt to different thermal environments particularly if appropriate breeds are used for the anticipated conditions, sudden fluctuations in temperature can cause heat or cold stress.

1. Heat stress

Heat stress is a serious problem in pig production. It can cause significant reductions in weight gain and fertility, or sudden death (Werremann and Bazer, 1985).

The risk of heat stress for pigs is influenced by environmental factors including air temperature, relative humidity, wind speed, stocking density, shade and wallow availability in outdoor systems, animal factors including breed, age and body condition (Heitman and Hughes, 1949; Quiniou and Noblet, 1999).

EU comment

The EU asks the OIE to consider the following amendment:

"The risk of heat stress for pigs is influenced by environmental factors including air temperature, relative humidity, wind speed, ventilation rates, stocking density, shade and wallow availability in outdoor systems, animal factors including breed, age and body condition."

Justification

Ventilation is also an equally important factor.

Animal handlers should be aware of the risk that heat stress poses to pigs and of the thresholds in relation to heat and humidity that may require action. If the risk of heat stress reaches very high levels the *animal handlers* should institute an emergency action plan that gives priority to access to additional water and could include provision of shade and wallows in outdoor systems, fans, reduction of stocking density and provision of cooling systems as appropriate for the local conditions.

EU comment

The EU asks the OIE to consider the following amendment of the final sentence:

UNOFFICIAL VERSION

"If the risk of heat stress reaches very high levels the *animal handlers* should institute an emergency action plan that gives priority to access to additional water and could include provision of shade and wallows in outdoor systems, fans, reduction of stocking density and provision of cooling systems (e.g. misting systems) as appropriate for the local conditions."

Justification

Misting systems are a good way to cool down the animals.

Outcome-based criteria (or measurables): behaviour (feed and water intake, respiratory rate, panting, agonistic behaviour), physical appearance (presence of faeces on the skin), morbidity, mortality and culling rates, and reproductive efficiency.

2. Cold stress

Protection from cold should be provided when these conditions are likely to create a serious risk to the welfare of pigs, particularly in neonates and young pigs and others that are physiologically compromised (e.g. ill animals). This could be provided by extra bedding, heat mats or lamps and natural or man-made shelters in outdoor systems (Blecha and Kelley, 1981).

EU comment

The EU asks the OIE to consider the following amendment of the first sentence:

"Protection from cold should be provided when these conditions are likely to create a ~~serious~~ risk to the welfare of pigs, particularly in neonates and young pigs and others that are physiologically compromised (e.g. ill animals)."

Justification

It ought to be enough that there is a risk to the welfare of the animal in order to take action.

Outcome-based criteria (or measurables): morbidity, mortality and culling rates, physical appearance (long hair, piloerection), behaviour (especially abnormal postures, shivering and huddling) and changes in body weight and body condition.

Article 7.X.17.

Noise

Pigs are adaptable to different levels and types of noise. However, exposure of pigs to sudden or loud noises should be minimised where possible to prevent stress and fear reactions. Ventilation fans, feeding machinery or other indoor or outdoor equipment should be constructed, placed, operated and maintained in such a way that they cause the least possible amount of noise (Algers and Jensen, 1991).

EU comment

The EU asks the OIE to consider the following amendment of the first sentence of this paragraph:

"Pigs are to some extent adaptable to different levels and types of noise."

Justification

The adaptation to different levels of noise is limited.

Outcome-based criteria (or measurables): behaviour (e.g. fleeing and vocalisation), physical appearance (e.g. injuries), reproductive efficiency, changes in body weight and body condition.

EU comment

UNOFFICIAL VERSION

The EU asks the OIE to consider the following amendment:

"Outcome-based criteria (or measurables): behaviour (e.g. fear reaction or restlessness, fleeing and vocalisation), physical appearance (e.g. injuries), reproductive efficiency, changes in body weight and body condition."

Justification

These examples are equally relevant reasons for behavioural reactions to loud noise.

Article 7.X.18.

Lighting

Indoor systems should have light levels sufficient to allow all pigs to see one another, to investigate their surroundings visually and to show other normal behaviour patterns and to be seen clearly by staff to allow adequate inspection of the pigs. The lighting regime shall be such as to prevent health and behavioural problems. It should follow a 24-hour rhythm and include sufficient uninterrupted dark and light periods, preferably no less than 6 hours for both.

EU comment

The EU asks the OIE to consider the following amendment of the final sentence:

"It should follow a 24-hour rhythm and include sufficient uninterrupted dark and light periods, preferably no less than 8 ~~6~~ hours for both."

Justification

The suggested period for daylight is very short (only a quarter of a day) and may even affect the reproductive cycle.

A minimum of 40 lux of lighting is recommended for a minimum of 6 hours per day (Martelli *et al.*, 2005; Taylor *et al.*, 2006).

EU comment

The EU asks the OIE to consider the following amendment:

"A minimum of 40 lux of lighting is recommended for a minimum of ~~6~~ 8 hours per day."

Justification

See previous comment. […]

Scientific references:

Taylor, Nina. 30.04.2010. Lighting for Pig Units, Report compiled for BPEX

1997. The welfare of intensively kept pigs. Report of the Scientific Veterinary Committee – Recommendation 25.

Artificial light sources should be located so as not to cause discomfort to the pigs.

Outcome-based criteria (or measurable): behaviour (locomotive behaviour), morbidity rates, reproductive efficiency, physical appearance (injuries) and changes in body weight and body condition.

Article 7.X.19.

Farrowing and lactation

Sows and gilts need time to adjust to their farrowing accommodation before farrowing. Nesting material should be provided where possible some days before farrowing (Yun *et al.*, 2014). Sows should be observed frequently around their expected farrowing times. As some sows and gilts need assistance during farrowing sufficient space and competent staff are needed.

UNOFFICIAL VERSION

EU comment

The EU asks the OIE to consider the following amendment of the second sentence:

"Nesting material should be provided where possible some days before farrowing (Yun *et al.*, 2014) and if necessary be replenished […] so that the animal has enough material to carry out proper nest building behaviour."

Justification

It is unfortunately common that nesting material is only provided (and in low quantities) as the animal is moved to the farrowing unit approximately one week before expected farrowing. As pigs often do not have access to rooting material in many production systems they tend to eat it rapidly. Little, if any, is then left for the actual nest building behaviour. Other reasons why the material needs to be replenished also occur.

EU comment

The EU asks the OIE to consider including a new sentence here:

"Producers should consider the use of loose farrowing systems as in well-designed and well-managed loose systems piglet mortality can be as low as in crates."

Justification

Farrowing crates restrict sows' movements and prevent them from carrying out proper nest building which is an important behavioural need. Loose farrowing systems are better in this respect. It is therefore helpful to draw attention to the development in recent years of loose farrowing systems which can perform as well in terms of piglet mortality as crates while also providing benefits to sow welfare.

Scientific references

Wischner, D., Kemper, N., Krieter, J., 2009a. Nest-building behaviour in sows and consequences for pig husbandry. Livestock Science 124, 1-8.

Weber R, Keil NM, Fehr M and Horat R. 2007. Piglet mortality on farms using farrowing systems with or without crates. Animal Welfare 16(2):277-279.

Baxter EM, Lawrence AB, and Edwards SA. 2012. Alternative farrowing accommodation: welfare and economic aspects of existing farrowing and lactation systems for pigs. Animal 6(1):96-117.

Outcome-based criteria (or measurables): mortality and culling rates (piglets), morbidity rates (metritis and mastitis), behaviour (stereotypies), reproductive efficiency, physical appearance (injuries).

EU comment

The EU asks the OIE to consider including one more example:

"Outcome-based criteria (or measurables): mortality and culling rates (piglets), morbidity rates (metritis and mastitis), behaviour (stereotypies, agitation […]), reproductive efficiency, physical appearance (injuries)."

Justification

In conjunction with farrowing signs of stress is an important measurable.

Article 7.X.20.

UNOFFICIAL VERSION

Weaning

Weaning can be a stressful time for sows and piglets and good management is required. Problems associated with weaning are generally related to the piglet's size and physiological maturity. Early weaning systems require good management and nutrition of the piglets.

EU comment

The EU asks the OIE to consider the following amendment of the first sentence:

"Weaning ~~can be~~ is a stressful time for sows and piglets and good management is required."

Justification

Weaning is always to a certain extent stressful.

An average weaning age of three weeks or older is recommended (Worobec *et al.*, 1999).

EU comment

The EU asks the OIE to consider the following amendment of this sentence and to add a second sentence:

"A~~n~~ ~~average~~ minimum weaning age of three weeks ~~or older~~ is recommended. Piglets should only be weaned once they have become used to another diet."

Justification

The use of "average" would allow some pigs to be weaned at less than three weeks of age. The European Food Safety Authority has recommended that piglets should not be weaned before four weeks of age. To permit some piglets to be weaned at less than three weeks of age would be detrimental to their welfare and their immune systems.

It is important for the welfare and the health of the piglets that they are accustomed to the new diet before they are removed from the sow.

Scientific references

EFSA. 2007. Animal health and welfare aspects of different housing and husbandry systems for adult breeding boars, pregnant, farrowing sows and unweaned piglets. The EFSA Journal 572:1-107.

Hameister, T., Puppe, B., Tuchscherer, M., Kanitz, E., 2010. Effects of weaning age on behavioural and physiological responses of domestic piglets - a review. Berliner und Munchener Tierarztliche Wochenschrift 123, 11-19.

EU comment

The EU asks the OIE to consider including a new paragraph here:

"Delaying weaning until the age of four weeks or older can produce benefits as regards improved intestinal immunity and reduced diarrhoea, less preventive use of antimicrobials and a decrease in weight gain retardation."

Justification

It would be helpful to alert producers to the benefits of later weaning particularly as early weaning is one of the main causes of high levels of routine preventive use of antimicrobials in pig farming.

UNOFFICIAL VERSION

Scientific references

EFSA. 2007. Animal health and welfare aspects of different housing and husbandry systems for adult breeding boars, pregnant, farrowing sows and unweaned piglets. The EFSA Journal 572:1-107.

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Danish Ministry of Agriculture, 2014. http://www.ft.dk/samling/20131/almdel/flf/spm/495/svar/1156714/1401964.pdf

Regardless of age, low weight piglets require additional care and can benefit from being kept in small groups in specialised pens until they are able to be moved to the common nursery area.

Newly weaned pigs are susceptible to disease challenges, so adherence to high-level hygiene protocols is important. It should be ensured that the area that piglets are weaned into is clean and dry.

EU comment

The EU asks the OIE to consider amending both sentences in the above paragraph as follows:

"Newly weaned pigs are susceptible to disease challenges, so adherence to high-level hygiene protocols as well as climate control and proper diet provisions is important. It should be ensured that the area that piglets are weaned into is suitably heated, clean, disinfected and dry."

Justification

The temperature is very important for the welfare of piglets. In many countries heating is vital.

Disinfection is a well-known and recommended practice performed between different groups of animals and is especially important in young animals as they are likely to be more susceptible to disease.

All newly weaned pigs should be monitored during the first two weeks after weaning for any signs of ill-health.

Outcome-based criteria (or measurable): mortality and culling rates (piglets), morbidity rates (respiratory disease,

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diarrhoea), behaviour (belly nosing and ear sucking), physical appearance (injuries) and changes in body weight and body condition.

Article 7.X.21.

Mixing

Mixing of unfamiliar pigs can result in fighting to establish a dominance hierarchy, and therefore mixing should be minimised as much as possible (Moore *et al.*, 1994; Fabrega *et al.*, 2013). When mixing, strategies to reduce aggression and injuries should be implemented and animals should be supervised.

Measures to prevent excessive fighting and injuries could include (Arey and Edwards, 1998):

– providing additional space and a non-slippery floor,

– feeding before mixing,

– feed on the floor in the mixing area,

– provision of straw in the mixing area,

EU comment

The EU asks the OIE to consider amending this point as follows:

"– provision of straw […]or other suitable enrichment materials in the mixing area,"

Justification

For some husbandry systems straw may not be an option and other materials that satisfy the pigs' behavioural needs may have to be used.

– providing opportunities to escape and to hide from other pigs, such as visual barriers,

– mix previously familiarised animals whenever possible,

EU comment

The EU asks the OIE to consider amending this point as follows:

"– mixing only previously familiarised animals whenever possible,"

Justification

Linguistic and to prevent fighting

– young animals should be mixed as soon after weaning as possible,

– avoid adding one or small number of animals to a large established group.

EU comment

The EU asks the OIE to consider including an additional point here:

"- avoid disruption of established groups"

Justification

Disruption of already established groups might lead to poor pig welfare and injuries due to fighting as their way of establishing a new hierarchy.

Outcome-based criteria (or measurables): mortality, morbidity and culling rates, behaviour (agonistic), physical appearance (injuries), changes in body weight and body condition and reproductive efficiency.

Article 7.X.22.

Genetic selection

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Welfare and health considerations should balance any decisions on productivity and growth rate when choosing a breed or hybrid for a particular location or production system.

Selective breeding can improve the welfare of pigs for example by selection to improve maternal behaviour, piglet viability, temperament and resistance to stress and disease and to reduce tail biting and aggressive behaviour (Turner *et al.*, 2006).

Outcome-based criteria (or measurable): physical appearance, behaviour, changes in body weight and body condition, handling response, reproductive efficiency, lameness, and morbidity, mortality and culling rates.

EU comment

The EU asks the OIE to consider amending this paragraph as follows:

"Outcome-based criteria (or measurable): physical appearance, […] behaviour (e.g. good maternal behaviour or low levels of aggression), changes in body weight and body condition, handling response, reproductive efficiency, lameness, and morbidity, […] mortality (piglet and sow) and culling rates."

Justification

Clarification

Article 7.X.23.

Protection from predators

EU comment

The EU asks the OIE to consider changing the title of this article if the below suggestion is taken into account:

"Protection from predators and pests"

In outdoor and combination systems pigs should be protected from predators.

EU comment

The EU asks the OIE to consider adding the following sentence to the paragraph:

"Pigs should also be protected from pests such as excessive numbers of flies and mosquitos."

Justification

In an outdoor environment there are also pests that can adversely affect the animal's well-being, especially when the number of these is high.

Outcome-based criteria (or measurable): morbidity, mortality and culling rates, behaviour, and physical appearance (injuries).

Article 7.X.24.

Biosecurity and animal health

1. Biosecurity and disease prevention

   Biosecurity plans should be designed, implemented and maintained, commensurate with the best possible *herd* health status, available resources and infrastructure, and current disease risk and, for *listed diseases* in accordance with relevant recommendations in the *Terrestrial Code*.

   These *biosecurity plans* should address the control of the major sources and pathways for spread of pathogens:

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– pigs, including introductions to the *herd*,
– young animals coming from different sources,
– other domestic animals, *wildlife*, and pests,
– people, including sanitation practices,
– equipment, tools and facilities,
– *vehicles*,
– air,
– water supply, feed and bedding,
– manure, waste and disposal of dead animals,
– semen.

Outcome-based criteria (or measurables): morbidity, mortality and culling rates, reproductive efficiency, changes in weight and body condition, physical appearance (signs of disease).

a) Animal health management

Animal health management should optimise the physical and behavioural health and welfare of the pig *herd*. It includes the prevention, treatment and control of *diseases* and conditions affecting the *herd* (in particular respiratory, reproductive and enteric diseases).

There should be an effective programme for the prevention and treatment of *diseases* and conditions, formulated in consultation with a *veterinarian*, where appropriate. This programme should include the recording of production data (e.g. number of sows, piglets per sow per year, feed conversion, and body weight at weaning), morbidity, mortality and culling rate and medical treatments. It should be kept up to date by the *animal handler*. Regular monitoring of records aids management and quickly reveals problem areas for intervention.

For parasitic burdens (e.g. endoparasites, ectoparasites and protozoa), a programme should be implemented to monitor, control and treat, as appropriate.

Lameness can be a problem in pigs. *Animal handlers* should monitor the state of feet and legs and take measures to prevent lameness and maintain foot and leg health.

Those responsible for the care of pigs should be aware of early specific signs of *disease* or distress (e.g. coughing, abortion, diarrhoea, changes in locomotory behaviour, apathetic behaviour), and non-specific signs such as reduced feed and water intake, changes in weight and body condition, changes in behaviour or abnormal physical appearance.

Pigs at higher risk of *disease* or distress will require more frequent inspection by *animal handlers*. If *animal handlers* suspect the presence of a *disease* or are not able to correct the causes of *disease* or distress, they should seek advice from those having training and experience, such as *veterinarians* or other qualified advisers, as appropriate.

Non-ambulatory pigs should not be transported or moved unless absolutely necessary for treatment or diagnosis. Such movements should be done carefully using methods that avoid dragging the animal or lifting it in a way that might exacerbate injuries.

EU comment

The EU asks the OIE to consider amending the second sentence of this sentence as follows:

"Such movements should be done carefully using methods that avoid dragging the animal or lifting it in a way that might cause unnecessary pain, suffering or exacerbate injuries."

Justification

UNOFFICIAL VERSION

It is important to have due regard to the welfare of animals, this includes not only injury but also pain and mental suffering. Absence of unnecessary pain, suffering and distress are basic principles of good animal welfare.

Animal handlers should also be competent in assessing fitness to transport, as described in Chapter 7.3.

In case of *disease* or injury, when treatment has failed or recovery is unlikely (e.g. pigs that are unable to stand up, unaided or refuse to eat or drink), the animal should be humanely killed as soon as possible in accordance with Chapter 7.6.

Outcome-based criteria (or measurable): morbidity, mortality and culling rates, reproductive efficiency, behaviour (apathetic behaviour), lameness, physical appearance (injuries) and changes in body weight and body condition.

b) Emergency plans for disease outbreaks

Emergency plans should cover the management of the farm in the event of an emergency disease outbreak, consistent with national programmes and recommendations of *Veterinary Services* as appropriate.

Article 7.X.25.

Emergency plans

Where the failure of power, water and feed supply systems could compromise *animal welfare,* pig producers should have contingency plans to cover the failure of these systems. These plans may include the provision of fail-safe alarms to detect malfunctions, back-up generators, contact information for key service providers, ability to store water on farm, access to water cartage services, adequate on-farm storage of feed and an alternative feed supply.

Preventive measures for emergencies should be input-based rather than outcome-based. Contingency plans should be documented and communicated to all responsible parties. Alarms and back-up systems should be checked regularly.

Article 7.X.26.

Disaster management

Plans should be in place to minimise and mitigate the effect of disasters (e.g. earthquake, fire, flooding, blizzard and hurricane). Such plans may include evacuation procedures, identifying high ground, maintaining emergency feed and water stores, destocking and humane *killing* when necessary.

Humane *killing* procedures for sick or injured pigs should be part of the disaster management plan.

Reference to emergency plans can also be found in Article 7.X.25.

Article 7.X.27.

Euthanasia (Humane killing)

EU comment

The EU asks the OIE to consider altering the title of this article:

"~~Euthanasia (~~Humane killing~~)~~"

Justification

To ensure consistency with other animal welfare chapters. Also, in the wording of the article only the term humane killing is used.

Allowing a sick or injured animal to linger unnecessarily is unacceptable. Therefore, for sick and injured pigs a prompt diagnosis should be made to determine whether the animal should be treated or humanely killed.

UNOFFICIAL VERSION

The decision to kill an animal humanely and the procedure itself should be undertaken by a competent person.

Reasons for humane *killing* may include:

– severe emaciation, weak pigs that are non-ambulatory or at risk of becoming non-ambulatory,
– non-ambulatory pigs that will not stand up, refuse to eat or drink, have not responded to therapy,
– rapid deterioration of a medical condition for which therapies have been unsuccessful,
– severe, debilitating pain,
– compound fracture,
– spinal injury,
– central nervous system *disease*,
– multiple joint *infections* with chronic weight loss,
– piglets that are premature and unlikely to survive, or have a debilitating congenital defect, and
– as part of disaster management response.

For a description of acceptable methods for humane *killing* of pigs see Chapter 7.6.

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Annex 28

CHAPTER 8.3.

INFECTION WITH BLUETONGUE VIRUS

EU comment

The EU cannot support some of the proposed changes to this chapter. Important comments are inserted in the text below.

Article 8.3.1.

General provisions

For the purposes of the *Terrestrial Code*, bluetongue is defined as an *infection* of ruminants and camelids with bluetongue virus (BTV) that is transmitted by *Culicoides vectors*.

The following defines the occurrence of *infection* with BTV:

1) BTV has been isolated from a sample from a ruminant or camelid or a product derived from that ruminant or camelid, or

2) antigen or ribonucleic acid specific to BTV has been identified in a ~~s~~amples from a ruminant or camelid showing clinical signs consistent with bluetongue, or epidemiologically linked to a suspected or confirmed *case*, or

3) antigen or ribonucleic acid specific to a BTV vaccine strain has been detected in a sample from a ruminant or camelid that is unvaccinated, or has been vaccinated with an inactivated vaccine, or with a different vaccine strain, or

EU comment

The EU does not support the new point 3) above as proposed.

Indeed, as indicated in the OIE Manual chapter 2.1.3., there may be limited natural live attenuated vaccine virus transmission between vaccinated and unvaccinated susceptible animals, causing neither clinical disease nor any other problem. Furthermore, antigen or RNA stemming from an inactivated vaccine could be detected in samples from healthy animals recently vaccinated with such vaccine.

These natural occurrences should not be treated the same as natural infections with wild-type virus strains which cause disease, as the consequences for country or zone status and the ensuing trade restrictions would be disproportionate.

However, a live vaccine strain that has reverted to virulence and / or that has reassorted with either wild-type virus or with another vaccine strain and that causes clinical disease could be accepted to be included in the definition of BTV infection.

Therefore, the EU suggests the following alternative wording:

"3) antigen or ribonucleic acid specific to a virulent revertant or reassortant of a BTV live vaccine strain has been detected in a sample from a ruminant or camelid that was not vaccinated with that live vaccine strain ~~is unvaccinated, or has been vaccinated with an inactivated vaccine, or with a different vaccine strain~~ and showing clinical signs consistent with bluetongue, or epidemiologically linked to a suspected or confirmed case, or."

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43) antibodies to structural or nonstructural proteins of BTV that are not a consequence of *vaccination* have been identified in a sample from a ruminant or camelid that either shows clinical signs consistent with bluetongue, or is epidemiologically linked to a suspected or confirmed *case*.

For the purposes of the *Terrestrial Code*, the *infective period* for bluetongue shall be 60 days.

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 8.3.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the BTV status of the ruminant and camelid populations of the *exporting country* or *zone*.

Article 8.3.2.

Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any bluetongue-related conditions regardless of the bluetongue status of the *exporting country*:

1) *milk* and *milk products*;

2) *meat* and *meat products*;

3) hides and skins;

4) wool and fibre;

5) *in vivo* derived bovine embryos collected, processed and stored in accordance with Chapter 4.7.

Article 8.3.3.

Country or zone free from bluetongue

1) Historical freedom as described in Chapter 1.4. does not apply to bluetongue.

2) A country or a *zone* may be considered free from bluetongue when *infection* with BTV is notifiable in the entire country and either:

   a) a *surveillance* programme in accordance with Articles 8.3.14. to 8.3.17. has demonstrated no evidence of *infection* with BTV in the country or *zone* during the past two years; or

   b) an ongoing *surveillance* programme has found no *Culicoides* for at least two years in the country or *zone*.

3) A country or *zone* free from bluetongue in which ongoing *vector surveillance*, performed in accordance with point 5 of Article 8.3.16., has found no *Culicoides* will not lose its free status through the introduction of vaccinated, seropositive or infective ruminants or camelids, or their semen or embryos from infected countries or infected *zones*.

4) A country or *zone* free from bluetongue in which *surveillance* has found evidence that *Culicoides* are present will not lose its free status through the introduction of seropositive or vaccinated ruminants or camelids, or semen or embryos from infected countries or infected *zones*, provided:

   a) an ongoing *surveillance* programme focused on transmission of BTV and a consideration of the epidemiology of *infection* with BTV, in accordance with Articles 8.3.14. to 8.3.17. and Chapter 4.3., has demonstrated no evidence of transmission of BTV in the country or *zone*; or

   b) the ruminants or camelids, their semen and embryos were introduced in accordance with this chapter.

5) A country or *zone* free from bluetongue adjacent to an infected country or infected *zone* should include a *zone* in which *surveillance* is conducted in accordance with Articles 8.3.14. to 8.3.17.

Article 8.3.4.

Zone seasonally free from bluetongue

EU comment

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Notwithstanding the explanation given by the Code Commission that a seasonally free zone could possibly cover the entire territory of a country, the EU would like to reiterate its previous comment in this regard and request that "seasonally free country" be explicitly added in this article. Indeed, speaking only of "seasonally free zone" quite clearly excludes the possibility of a "seasonally free country", and exporting (seasonally free) countries would have difficulties convincing importing countries of the contrary.

A *zone* seasonally free from bluetongue is a part of an infected country or an infected *zone* for which *surveillance* demonstrates no evidence either of transmission of BTV or of adult *Culicoides* for part of a year.

For the application of Articles 8.3.7., 8.3.9. and 8.3.11., the ~~seasonally~~ free ~~period~~ season is taken to commence the day following the last evidence of transmission of BTV (as demonstrated by the *surveillance* programme), and of the cessation of activity of adult *Culicoides*.

For the application of Articles 8.3.7., 8.3.9. and 8.3.11., the ~~seasonally~~ free ~~period~~ season is taken to conclude either:

1) at least 28 days before the earliest date that historical data show transmission of BTV may recommence; or

2) immediately if current climatic data or data from a *surveillance* programme indicate an earlier resurgence of activity of adult *Culicoides*.

A seasonally free *zone* in which ongoing *surveillance* has found no evidence that *Culicoides* are present will not lose its free status through the introduction of vaccinated, seropositive or infective ruminants or camelids, or semen or embryos from infected countries or infected *zones*.

Article 8.3.5.

Country or zone infected with BTV

For the purposes of this chapter, a country or *zone* infected with BTV is one that does not fulfill the requirements to qualify as either free or seasonally free from bluetongue.

Article 8.3.6.

Recommendations for importation from countries or zones free from bluetongue

For ruminants and camelids

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the animals showed no clinical sign of bluetongue on the day of shipment;

2) the animals were kept in a country or *zone* free from bluetongue since birth or for at least 60 days prior to shipment; or

3) the animals were kept in a country or *zone* free from bluetongue for at least 28 days, then were subjected, with negative results, to a serological test to detect antibodies to the BTV group and remained in the free country or *zone* until shipment; or

4) the animals were kept in a free country or *zone* free from bluetongue for at least 14 days, then were subjected, with negative results, to an agent identification test, and remained in the free country or *zone* until shipment; or

5) the animals:

   a) were kept in a country or *zone* free from bluetongue for at least seven days;

   b) were vaccinated, at least 60 days before the introduction into the free country or *zone*, against all serotypes demonstrated to be present in the source population through a *surveillance* programme as described in Articles 8.3.14. to 8.3.17.;

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c) were identified as having been vaccinated;

d) remained in the free country or *zone* until shipment;

AND

6) if the animals were exported from a free *zone* within an infected country, either:

a) did not transit through an infected *zone* during transportation to the *place of shipment*; or

b) were protected from attacks from Culicoides at all times when transiting through an infected zone; or

c) had been vaccinated in accordance with point 5 above.

Article 8.3.7.

Recommendations for importation from zones seasonally free from bluetongue

For ruminants and camelids

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

1) showed no clinical sign of bluetongue on the day of shipment;

2) were kept during the ~~seasonally~~ free ~~period~~ season in a seasonally free *zone* since birth or for at least 60 days prior to shipment; or

3) were kept during the ~~seasonally~~ free ~~period~~ season in a seasonally free *zone* for at least 28 days prior to shipment, and were subjected during the residence period in the *zone* to a serological test to detect antibodies to the BTV group, with negative results, carried out at least 28 days after the commencement of the residence period; or

4) were kept during the ~~seasonally~~ free ~~period~~ season in a seasonally free *zone* for at least 14 days prior to shipment, and were subjected during the residence period in the *zone* to an agent identification test, with negative results, carried out at least 14 days after the commencement of the residence period; or

5) were kept during the ~~seasonally~~ free ~~period~~ season in a seasonally free *zone* and were vaccinated, at least 60 days before ~~the introduction into the free country or *zone*~~ shipment, against all serotypes demonstrated to be present in the source population through a *surveillance* programme in accordance with Articles 8.3.14. to 8.3.17. and were identified as having been vaccinated and remained in the seasonally free ~~country or~~ *zone* until shipment;

AND

6) either:

a) did not transit through an infected *zone* during transportation to the *place of shipment*; or

b) were protected from attacks from *Culicoides* at all times when transiting through an infected *zone*; or

c) were vaccinated in accordance with point 5 above.

Article 8.3.8.

Recommendations for importation from countries or zones infected with BTV

For ruminants and camelids

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

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1) showed no clinical sign of bluetongue on the day of shipment;

2) were protected from attacks from *Culicoides* in a *vector*-protected *establishment* for at least 60 days prior to shipment and during transportation to the *place of shipment*; or

3) were protected from attacks from *Culicoides* in a *vector*-protected *establishment* for at least 28 days prior to shipment and during transportation to the *place of shipment*, and were subjected during that period to a serological test to detect antibodies to the BTV group, with negative results, carried out at least 28 days after introduction into the *vector*-protected *establishment*; or

4) were protected from attacks from *Culicoides* in a *vector*-protected *establishment* for at least 14 days prior to shipment and during transportation to the *place of shipment*, and were subjected during that period to an agent identification test, with negative results, carried out at least 14 days after introduction into the *vector*-protected *establishment*; or

5) were vaccinated, at least 60 days before shipment, against all serotypes demonstrated to be present in the source population through a *surveillance* programme in accordance with Articles 8.3.14. to 8.3.17.; or

6) were demonstrated to have antibodies for at least 60 days prior to dispatch against all serotypes demonstrated to be present in the source population through a *surveillance* programme in accordance with Articles 8.3.14. to 8.3.17.

Article 8.3.9.

Recommendations for importation from countries or zones free or zones seasonally free from bluetongue

For semen of ruminants and camelids

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor males:

   a) showed no clinical sign of bluetongue on the day of collection~~;~~ and

   ~~*b)*~~ were kept in a country or *zone* free from bluetongue or in a seasonally free *zone* during the ~~seasonally~~ free season ~~period~~ for at least 60 days before commencement of, and during, collection of the semen; or

   b~~c~~) comply with point 1 of Article 8.3.10.;~~were subjected to a serological test to detect antibodies to the BTV group, with negative results, between 28 and 60 days after the last collection for this consignment, and, in case of a seasonally free *zone*, at least every 60 days throughout the collection period; or~~

   ~~*d)* were subjected to an agent identification test on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;~~

EU comment

The EU would support the deletion of points c) and d) above. Indeed, there is no need to test donor males from a free country or zone or seasonally free zone if points a) and b) are being complied with.

In addition, since the seasonally free zone is free only during that season, it seems necessary to clarify that in the case of a seasonally free zone, the conditions of Article 8.3.9. above apply only during the seasonally free period, and that outside of that period, Article 8.3.10. applies. (This comment is relevant also for Article 8.3.11. on embryos.)

2) the semen was collected, processed and stored in accordance with Chapters 4.5. and 4.6.

Article 8.3.10.

Recommendations for importation from countries or zones infected with BTV

UNOFFICIAL VERSION

For semen of ruminants and camelids

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor males:

   a) showed no clinical sign of bluetongue on the day of collection;

   b) were kept in a *vector*-protected *establishment* for at least 60 days before commencement of, and during, collection of the semen; or

   c) were subjected to a serological test to detect antibodies to the BTV group, with negative results~~, at least every 60 days throughout the collection period and~~ between 28 and 60 days after ~~the final~~ each collection for this consignment; or

   d) were subjected to an agent identification test on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;

2) the semen was collected, processed and stored in accordance with Chapters 4.5. and 4.6.

Article 8.3.11.

Recommendations for importation from countries or zones free or zones seasonally free from bluetongue

For *in vivo* derived embryos of ruminants (other than bovine embryos) and other BTV susceptible herbivores and for *in vitro* produced bovine embryos

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor females:

   a) showed no clinical sign of bluetongue on the day of collection;

   b) were kept in a country or *zone* free from bluetongue or in a seasonally free zone during the ~~seasonally~~ free ~~period~~ season for at least the 60 days prior to, and at the time of, collection of the embryos; or

   c) were subjected to a serological test to detect antibodies to the BTV group, between 28 and 60 days after collection, with negative results; or

   d) were subjected to an agent identification test on a blood sample taken on the day of collection, with negative results;

2) the embryos were collected, processed and stored in accordance with Chapters 4.7., 4.8. and 4.9., as relevant.

Article 8.3.12.

Recommendations for importation from countries or zones infected with BTV

For *in vivo* derived embryos of ruminants (other than bovine embryos) and other BTV susceptible animals and for *in vitro* produced bovine embryos

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor females:

   a) showed no clinical sign of bluetongue on the day of collection;

   b) were kept in a *vector*-protected *establishment* for at least 60 days before commencement of, and during, collection of the embryos; or

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c) were subjected to a serological test to detect antibodies to the BTV group, between 28 and 60 days after collection, with negative results; or

d) were subjected to an agent identification test on a blood sample taken on the day of collection, with negative results;

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 to fertilise the oocytes complied with Article 8.3.9.

Article 8.3.13.

Protecting animals from *Culicoides* attacks

1. Vector-protected establishment or facility

The *establishment* or facility should be approved by the *Veterinary Authority* and the means of protection should at least comprise the following:

a) appropriate physical barriers at entry and exit points, such as double-door entry-exit system;

b) openings of the building are *vector* screened with mesh of appropriate gauge impregnated regularly with an approved insecticide in accordance with manufacturers' instructions;

c) *vector surveillance* and control within and around the building;

d) measures to limit or eliminate breeding sites for *vectors* in the vicinity of the *establishment* or facility;

e) standard operating procedures, including description of back-up and alarm systems, for operation of the *establishment* or facility and transport of animals to the place of *loading*.

2. During transportation

When transporting animals through infected countries or *zones*, *Veterinary Authorities* should require strategies to protect animals from attacks from *Culicoides* during transport, taking into account the local ecology of the *vector*.

a) Transport by road

Risk management strategies may include:

i) treating animals with insect repellents prior to and during transportation;

ii) *loading*, transporting and *unloading* animals at times of low *vector* activity (i.e. bright sunshine, low temperature);

iii) ensuring *vehicles* do not stop en route during dawn or dusk, or overnight, unless the animals are held behind insect proof netting;

iv) darkening the interior of the *vehicle*, for example by covering the roof or sides of *vehicles* with shade cloth;

v) *surveillance* for *vectors* at common stopping and *unloading* points to gain information on seasonal variations;

vi) using historical information or information from appropriately verified and validated bluetongue epidemiological models to identify low risk ports and transport routes.

b) Transport by air

Prior to *loading* the animals, the crates, containers or jet stalls should be sprayed with an insecticide approved in the country of dispatch.

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Crates, containers or jet stalls in which animals are being transported and the cargo hold of the aircraft should be sprayed with an approved insecticide when the doors have been closed and prior to take-off. All possible insect harbourage should be treated. The spray containers should be retained for inspection on arrival.

In addition, during any stopover in countries or *zones* not free from bluetongue, prior to the opening of any aircraft door and until all doors are closed, netting of appropriate gauge impregnated with an approved insecticide should be placed over crates, containers or jet stalls.

Article 8.3.14.

Introduction to surveillance

Articles 8.3.14. to 8.3.17. define the principles and provide guidance on *surveillance* for *infection* with BTV, complementary to Chapter 1.4. and for *vectors* complementary to Chapter 1.5.

Bluetongue is a *vector*-borne *infection* transmitted by various species of *Culicoides* in a range of ecosystems.

The purpose of *surveillance* is the detection of transmission of BTV in a country or *zone* and not determination of the status of an individual animal or *herds*. *Surveillance* deals with the evidence of *infection* with BTV in the presence or absence of clinical signs.

An important component of the epidemiology of bluetongue is the capacity of its *vector*, which provides a measure of *disease risk* that incorporates *vector* competence, abundance, biting rates, survival rates and extrinsic *incubation period*. However, methods and tools for measuring some of these *vector* factors remain to be developed, particularly in a field context. Therefore, *surveillance* for bluetongue should focus on transmission of BTV in domestic ruminants and camelids.

The impact and epidemiology of bluetongue widely differ in different regions of the world and therefore it is not appropriate to provide specific recommendations for all situations. Member Countries should provide scientific data that explain the epidemiology of bluetongue in the country or *zone* concerned and adapt the *surveillance* strategies for defining their status to the local conditions. There is considerable latitude available to Member Countries to justify their status at an acceptable level of confidence.

Surveillance for bluetongue should be in the form of a continuing programme.

Article 8.3.15.

General conditions and methods for surveillance

1) A *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority*. In particular:

   a) a formal and ongoing system for detecting and investigating *outbreaks* of *disease* should be in place;

   b) a procedure should be in place for the rapid collection and transport of samples from suspected *cases* of *infection* with BTV to a *laboratory* for diagnosis;

   c) a system for recording, managing and analysing diagnostic and *surveillance* data should be in place.

2) The bluetongue *surveillance* programme should:

   a) in a free country or *zone* or seasonally free *zone*, have an early warning system which obliges farmers and workers, who have regular contact with domestic ruminants, as well as diagnosticians, to report promptly any suspicion of bluetongue to the *Veterinary Authority*.

   An effective *surveillance* system will periodically identify suspected *cases* that require follow-up and investigation to confirm or exclude whether the cause of the condition is bluetongue. The rate at which such suspected *cases* are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. All suspected *cases* of bluetongue should be investigated immediately and samples should be taken and submitted to a *laboratory*. This requires that sampling kits and other equipment be available for those responsible for *surveillance*;

   AND

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b) conduct random or targeted serological and virological *surveillance* appropriate to the status of the country or *zone*.

Article 8.3.16.

Surveillance strategies

The target population for *surveillance* aimed at identification of *disease* or *infection* should cover susceptible domestic ruminants and camelids, and other susceptible herbivores of epidemiological significance within the country or *zone*. Active and passive *surveillance* for bluetongue should be ongoing as epidemiologically appropriate. *Surveillance* should be composed of random or targeted approaches using virological, serological and clinical methods appropriate for the status of the country or *zone*.

It may be appropriate to focus *surveillance* in an area adjacent to a border of an infected country or infected *zone* for up to 100 kilometres, taking into account relevant ecological or geographical features likely to interrupt the transmission of BTV or the presence in the bordering infected country or infected *zone* of a bluetongue *surveillance* programme (in accordance with Articles 8.3.14. to 8.3.17.) that supports a lesser distance.

A Member Country should justify the *surveillance* strategy chosen as being adequate to detect the presence of *infection* with BTV in accordance with Chapter 1.4. and the prevailing epidemiological situation. It may, for example, be appropriate to target clinical *surveillance* at particular species likely to exhibit clinical signs (e.g. sheep).

Similarly, virological and serological testing may be targeted to species that rarely show clinical signs (e.g. cattle).

In vaccinated populations, serological and virological *surveillance* is necessary to detect the BTV types circulating to ensure that all circulating types are included in the *vaccination* programme.

If a Member Country wishes to declare freedom from bluetongue in a specific *zone*, the design of the *surveillance* strategy should be aimed at the population within the *zone*.

For random surveys, the design of the sampling strategy should incorporate epidemiologically appropriate design prevalence. The sample size selected for testing should be large enough to detect evidence of *infection* if it were to occur at a predetermined minimum rate. The sample size and expected prevalence determine the level of confidence in the results of the survey. The Member Country should justify the choice of design prevalence and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Selection of the design prevalence in particular should be based on the prevailing or historical epidemiological situation.

Irrespective of the survey approach selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the *vaccination* and *infection* history and the different species in the target population.

Irrespective of the testing system employed, *surveillance* system design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There should be an effective procedure for following up positive reactions to ultimately determine with a high level of confidence, whether they are indicative of *infection* or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as those which may be epidemiologically linked to it.

The principles involved in *surveillance* for *disease* or *infection* are technically well defined. The design of *surveillance* programmes to prove the absence of *infection* with and transmission of, BTV should be carefully followed to avoid producing results that are either insufficiently reliable to be accepted by international trading partners, or excessively costly and logistically complicated.

1. Clinical surveillance

Clinical *surveillance* aims to detect clinical signs of bluetongue at the *flock* or *herd* level, particularly during a newly introduced *infection*. In sheep and occasionally goats, clinical signs may include oedema, hyperaemia of mucosal membranes, coronitis and cyanotic tongue.

Suspected *cases* of bluetongue detected by clinical *surveillance* should always be confirmed by *laboratory* testing.

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2. Serological surveillance

An active programme of *surveillance* of host populations to detect evidence of transmission of BTV is essential to establish the bluetongue status of a country or *zone*. Serological testing of ruminants is one of the most effective methods of detecting the presence of BTV. The species tested should reflect the epidemiology of bluetongue. Cattle are usually the most sensitive indicator species. Management variables that may influence likelihood of *infection*, such as the use of insecticides and animal housing, should be considered.

Samples should be examined for antibodies against BTV. Positive test results can have four possible causes:

a) natural *infection*,

b) *vaccination*,

c) maternal antibodies,

d) the lack of specificity of the test.

It may be possible to use sera collected for other survey purposes for bluetongue *surveillance*. However, the principles of survey design described in these recommendations and the requirements for a statistically valid survey for the presence of *infection* with BTV should not be compromised.

The results of random or targeted serological surveys are important in providing reliable evidence that no *infection* with BTV is present in a country or *zone*. It is, therefore, essential that the survey is thoroughly documented. It is critical to interpret the results in light of the movement history of the animals being sampled.

Serological *surveillance* in a free *zone* should target those areas that are at highest risk of transmission of BTV, based on the results of previous *surveillance* and other information. This will usually be towards the boundaries of the free *zone*. In view of the epidemiology of bluetongue, either random or targeted sampling is suitable to select *herds* or animals for testing.

Serological *surveillance* in infected *zones* will identify changes in the boundary of the *zone*, and can also be used to identify the BTV types circulating. In view of the epidemiology of bluetongue, either random or targeted sampling is suitable.

3. Virological surveillance

Isolation and genetic analysis of BTV from a proportion of infected animals provides information on serotype and genetic characteristics of the viruses concerned.

Virological *surveillance* can be conducted:

a) to identify virus transmission in at risk populations,

b) to confirm clinically suspected *cases*,

c) to follow up positive serological results,

d) to better characterise the genotype of circulating virus in a country or *zone*.

4. Sentinel animals

Sentinel animals are a form of targeted *surveillance* with a prospective study design. They are the preferred strategy for bluetongue *surveillance*. They comprise groups of unexposed animals that have not been vaccinated and are managed at fixed locations and sampled regularly to detect new *infections* with BTV.

The primary purpose of a sentinel animal programme is to detect *infections* with BTV occurring at a particular place, for instance sentinel groups may be located on the usual boundaries of infected *zones* to detect changes in distribution of BTV. In addition, sentinel animal programmes allow the timing and dynamics of *infections* to be observed.

A sentinel animal programme should use animals of known source and history of exposure, control management variables such as use of insecticides and animal housing (depending on the epidemiology of

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bluetongue in the area under consideration), and be flexible in its design in terms of sampling frequency and choice of tests.

Care is necessary in choosing the sites for the sentinel groups. The aim is to maximise the chance of detecting transmission of BTV at the geographical location for which the sentinel site acts as a sampling point. The effect of secondary factors that may influence events at each location, such as climate, may also be analysed. To avoid bias, sentinel groups should comprise animals selected to be of similar age and susceptibility to *infection* with BTV. Cattle are the most appropriate sentinels but other domestic ruminant species may be used. The only feature distinguishing groups of sentinels should be their geographical location.

Sera from sentinel animal programmes should be stored methodically in a serum bank to allow retrospective studies to be conducted in the event of new serotypes being isolated.

The frequency of sampling will depend on the reason for choosing the sampling site. In endemic areas, virus isolation will allow monitoring of the serotypes and genotypes of BTV circulating during each time period. The borders between infected and uninfected areas can be defined by serological detection of *infective period*. Monthly sampling intervals are frequently used. Sentinels in declared free *zones* add to confidence that *infection* with BTV is not occurring unobserved. In such cases, sampling prior to and after the possible period of transmission is sufficient.

Definitive information on the presence of BTV in a country or *zone* is provided by isolation and identification of the viruses. If virus isolation is required, sentinels should be sampled at sufficiently frequent intervals to ensure that samples are collected during the period of viraemia.

5. Vector surveillance

BTV is transmitted between ruminant hosts by species of *Culicoides* which vary around the world. It is therefore important to be able to identify potential *vector* species accurately although many such species are closely related and difficult to differentiate with certainty.

Vector surveillance aims to demonstrate the absence of *vectors* or to determine areas of different levels of risk and local details of seasonality by determining the various *vector* species present in an area, their respective seasonal occurrence, and abundance. *Vector surveillance* has particular relevance to potential areas of spread.

Long term *surveillance* can also be used to assess *vector* abatement measures or to confirm continued absence of *vectors*.

The most effective way of gathering this information should take account of the biology and behavioural characteristics of the local *vector* species of *Culicoides* and may include the use of Onderstepoort-type light traps or similar, operated from dusk to dawn in locations adjacent to domestic ruminants, or the use of drop traps over ruminants.

Vector surveillance should be based on scientific sampling techniques. The choice of the number and type of traps to be used and the frequency of their use should take into account the size and ecological characteristics of the area to be surveyed.

The operation of *vector surveillance* sites at the same locations as sentinel animals is advisable.

The use of a *vector surveillance* system to detect the presence of circulating virus is not recommended as a routine procedure as the typically low *vector infection* rates mean that such detections can be rare.

Animal-based *surveillance* strategies are preferred to detect virus transmission.

Article 8.3.17.

Documentation of bluetongue free status

1. Additional surveillance requirements for Member Countries declaring freedom from bluetongue

In addition to the general requirements described above, a Member Country declaring freedom from bluetongue for the entire country or a *zone* should provide evidence for the existence of an effective *surveillance* programme. The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances and should be planned and implemented in accordance with

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general conditions and methods described in this chapter, to demonstrate absence of *infection* with BTV during the preceding 24 months in susceptible domestic ruminant populations. This requires the support of a *laboratory* able to undertake identification of *infection* with BTV through virus detection and antibody tests. This *surveillance* should be targeted to unvaccinated animals. Clinical *surveillance* may be effective in sheep while serological *surveillance* is more appropriate in cattle.

2. Additional requirements for countries or zones that practise vaccination

Vaccination to prevent the transmission of BTV may be part of a disease control programme. The level of *flock* or *herd* immunity required to prevent transmission will depend on the *flock* or *herd* size, composition (e.g. species) and density of the susceptible population. It is therefore impossible to be prescriptive. The vaccine should also comply with the provisions stipulated for BTV vaccines in the *Terrestrial Manual*. Based on the epidemiology of bluetongue in the country or *zone*, it may be decided to vaccinate only certain species or other *subpopulations*.

In countries or *zones* that practise *vaccination*, virological and serological tests should be carried out to ensure the absence of virus transmission. These tests should be performed on unvaccinated subpopulations or on sentinels. The tests should be repeated at appropriate intervals in accordance with the purpose of the *surveillance* programme. For example, longer intervals may be adequate to confirm endemicity, while shorter intervals may allow on-going demonstration of absence of transmission.

— Text deleted.

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Annex 29

FUTURE 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.

As mentioned in the EU comment on the introduction of the report, we would encourage the OIE to thoroughly revise the Code Chapter on Avian Influenza. Especially the recommendations regarding country and zone status, recovery of status and international trade should be reviewed in light of the experience gained in recent years with the implementation of the provisions of the current chapter in international trade. As this is of high economic importance, the EU requests that this revision be given highest priority by all involved OIE fora (i.e., establishment of an ad hoc group, work programmes of the Code Commission and of the Scientific Commission). In this connection, we wish to inform the OIE that the European Food Safety Authority (EFSA) is currently working on mandates from the European Commission, the outputs of which are expected to become available in September 2017. Copies of the EFSA mandates as available on the EFSA website are attached for information. We will be happy to share the scientific opinion of EFSA with the OIE once it is published. Finally, we would like to offer our technical support and expertise and would be grateful if this could be considered when convening the ad hoc group of experts.

Furthermore, the EU would like to reiterate its previous comments regarding the ongoing work to revise the Code chapter on BSE, which should continue to be given high priority so as to present the revised chapter for adoption by the World Assembly as soon as possible.

We would also like to reiterate our previous suggestion to indicate in the printed edition of the Code as well as in the electronic version on OIE's website the year of adoption and / or the year of last amendment of individual Code chapters, as is already the case for the Terrestrial Manual. This would indeed be very useful when working with and making references to the Code.

Finally, in the Code chapter on rabies, we would like to suggest adding guidance for the control of rabies in wildlife, including as regards oral vaccination. Indeed, whereas the current Code chapter includes an article on the control of rabies in dogs, there are no recommendations regarding wildlife. The discussions on the Technical Item on rabies at the recent 27th Conference of the OIE Regional Commission for Europe (Lisbon, September 2016) have however clearly shown that control of rabies in wildlife is crucial in order to progress further towards a rabies free Europe. The EU would therefore highly welcome such guidance in the Code, and is happy to offer all its technical support.

General Topic		
Detailed issue or action (By priority order)	**By whom to be managed**	**Status and further steps**
Restructuring of the *Terrestrial Code*, including harmonisation of the *Terrestrial* and *Aquatic Codes*		

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General Topic		
Detailed issue or action (By priority order)	**By whom to be managed**	**Status and further steps**
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	TAHSC & AAHSC & HQs	Ongoing
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	TAHSC & BSC & HQs	Ongoing
3) Revision and formatting of chapters (articles numbering, tables and figures), especially of Section 7	TAHSC & AWWG &HQs	Ongoing
4) Revision of the Users' guide to address the precedence of chapters	TAHSC & AAHSC &HQs	Preliminary discussion
Glossary		
1) OIE standard, OIE guideline	TAHSC & AAHSC & BSC & SCAD & HQs	To be considered by OIE Council
2) Global revision of glossary for consistency throughout the Code	TAHSC & HQs	Ongoing and proposed some editorial & deletion for MC
3) vaccination	TAHSC & BSC & SCAD & AHG & HQs	Revised definition for MC
4) zone, free zone, infected zone, containment zone, protection zone	TAHSC & SCAD & HQs	Revised definitions for MC
Horizontal issue not yet in the *Terrestrial Code*		
1) CH on vaccination	TAHSC & BSC & SCAD & AHG & HQs	Draft new CH proposed for MC
2) CH on management of outbreaks of the listed diseases	TAHSC & AAHSC & SCAD & HQs	Draft new CH to be discussed in Feb 2017
3) CH on *Salmonella* in pigs and in cattle	TAHSC & APFSWG	reviewed and sent for further MC
4) CH on AW and pig production systems	TAHSC & AWWG	Draft CH (section 7): proposed for MC
5) CH on killing methods for farmed Reptiles	TAHSC & AWWG	Preliminary discussion
***Terrestrial Code* texts on horizontal issues in need of revision: Section 1 Notification**		
1) CH 1.4. on Animal Health Surveillance	TAHSC & SCAD & HQs	Further revision of draft modifications to be discussed in Feb 2017
2) CH 1.3. on listed diseases: assess CWD & WNF against the criteria	TAHSC & HQs	Preliminary discussion
3) CH 1.6. on Status: reorganisation	TAHSC & SCAD & HQs	Ongoing
***Terrestrial Code* texts on horizontal issues in need of revision: Section 2 Risk analysis**		
Draft new CH on criteria for assessing safe commodities	TAHSC	Sent for MC and adoption
***Terrestrial Code* texts on horizontal issues in need of revision: Section 3 Veterinary Services**		

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General Topic		
Detailed issue or action (By priority order)	**By whom to be managed**	**Status and further steps**
Revision of CHs of Section 3 in the light of the return of experience of the PVS Pathway	TAHSC &HQs	Preliminary discussions
***Terrestrial Code* texts on horizontal issues in need of revision: Section 4 Disease control**		
1) CH 4.3. on zoning	TAHSC & SCAD & HQs	New revised version sent for MC
2) CH 4.6. on semen collection	TAHSC &BSC	Pending experts' advice
3) CH 4.7. and 4.8. on embryos	TAHSC & BSC	Pending experts' advice
4) Global restructuring of Section 4	TAHSC & HQs	Ongoing
***Terrestrial Code* texts on horizontal issues in need of revision: Section 5 Trade measures**		
1) CH 5.3. on SPS agreement	TAHSC &HQs	Sent for further MC and adoption
2) CH 5.12. on Model certificates for competition horses	TAHSC & SCAD & HQs	Preliminary discussion
***Terrestrial Code* texts on horizontal issues in need of revision: Section 6 Veterinary Public Health**		
1) New Introductory CH on Section 6	TAHSC & APFSWG	Preliminary discussion
2) Revision of CH 6.1.	TAHSC & APFSWG	Sent to APFSWG
3) Revision of CH 6.2.	TAHSC & APFSWG	Pending WG report
***Terrestrial Code* texts on horizontal issues in need of revision: Section 7 Animal welfare**		
1) CH 7.5. on slaughter CH 7.6. on killing	TAHSC & AWWG	Sent to experts for further advice
2) CH 7.12. on AW of working equids		Proposed for adoption
Diseases issues not yet in the *Terrestrial Code*		
1) New CH 15.X. on PRRS	TAHSC & SCAD	Sent for MC and adoption
2) Non-tsetse transmitted Trypanosomosis (new CH on Surra and revision of CH on Dourine)	TAHSC & SCAD & AHG	Pending AHG
3) Crimean Congo hemorrhagic fever	TAHSC & HQs	Preliminary discussion
***Terrestrial Code* texts on diseases in need of revision: Sections 8 to 15, by priority order**		
1) Revised CH 15.1. on ASF	TAHSC	Sent for further MC and adoption
2) New CH 8.X. on tuberculosis to merge CHs 11.5. & CH 11.6.	TAHSC	Sent for MC and adoption
3) Update CH 11.11. on lumpy skin disease	TAHSC	Sent for MC and adoption
4) Revised CH 12.10. on glanders	TAHSC	Sent for MC and adoption
5) Revised CH 11.4. on BSE	TAHSC & SCAD & BSC & AHG	Pending revision of AHG report
6) Revision CH 8.8. on FMD	TAHSC & SCAD & AHG & HQs	For discussion in Feb 2017
7) Update CH 10.4. on avian influenza viruses	TAHSC & HQs	Pending work on zoning and outbreak management

UNOFFICIAL VERSION

General Topic		
Detailed issue or action (By priority order)	**By whom to be managed**	**Status and further steps**
8) Update CH 10.5. on avian mycoplasmosis	TAHSC & HQs	Pending experts' opinion
9) Update/Revise CH 11.12. on theileriosis	TAHSC & SCAD	Pending AHG
10) Update CH 14.8. on scrapie	TAHSC	Review MC, seek expert opinion

List of abbreviations	
AAHSC	Aquatic Animal Health Standards Commission
AHG	*ad hoc* Group
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
CH	Chapters
CWD	Chronic Wasting Disease
FMD	Foot and mouth disease
HQs	Headquarters
MC	Member Countries' comments
PRRS	Porcine reproductive and respiratory syndrome
PVS	Performance of Veterinary Service
SCAD	Scientific Commission for Animal Diseases
TAHSC	Terrestrial Animal Health Standards Commission
WNF	West Nile fever

UNOFFICIAL VERSION

Annex 29 (contd)

ITEM, ANNEX, CHAPTER NUMBERS AND CURRENT STATUS

Item	Annex	Chapter	Title	Action	To be proposed for Adoption at 85 GS
1	-	-	General comments	-	-
2	4	-	Glossary A and A′	C	O
2	4	-	Glossary A"	I	X
2	5	-	Glossary B and B′	C	X
3	-	1.1.	Notification of diseases, infections and infestations	N	X
4	6	1.2.	Criteria for listing diseases	C	O
5	7	1.3.	Diseases listed by the OIE	C	O
6	-	1.4.	Animal health surveillance	D, E	X
7	8	2.X.	Draft new chapter on criteria for assessing the safety of commodities	C	O
8a	21	4.3.	Zoning and compartmentalisation	C	X
8b	22	4.X.	Draft new chapter on vaccination	C	X
8c	-	4.Y.	Draft new chapter on management of outbreaks of listed diseases	D, E	X
9a	-	4.6.	Collection and processing of bovine, small ruminant and porcine semen	E	X
9b	23	4.8.	Collection and processing of *in vitro* derived embryos from livestock and equids	C	X
9c	24	4.11.	Somatic cell nuclear transfer in production livestock and horses	C	X
10	9	5.3.	OIE procedures relevant to the WTO/SPS Agreement	C	O
11a	-	6.1.	The role of the veterinary services in food safety	D, E	X
11b	25	6.7.	Harmonisation of national antimicrobial resistance surveillance and monitoring programmes	C	X
12a	10	6.X.	Draft new chapter on prevention and control of *Salmonella* in commercial cattle production system	C	O
12b	11	6.Y.	Draft new chapter on prevention and control of *Salmonella* in pig production systems	C	O
13b	26	Art 7.1.X.	Draft article on guiding principles on the use of animal based measures	C	X
13c	-	7.Y.	Draft new chapter on methods of killing farmed reptiles for their skins and meat	D, E	X
13d	-	7.5. & 7.6.	Slaughter of animals/killing of animals for disease control purposes	E	X
13f	12	Art 7.11.6.	Animal welfare and dairy cattle production systems	C	O
13g	13	7.12.	Welfare of working equids	C	O
13h	27	7.X.	Draft new chapter on AW and pig production systems	C	X
14	28	8.3.	Infection with Bluetongue virus	C	X
15	-	8.8.	Infection with Foot and mouth disease virus	D, E	X
16	14	8.X.	Infection with *Mycobacterium tuberculosis* complex	C	O
17	15	Art 10.4.25	Infection with Avian influenza viruses	C	O
18	16	11.11.	Infection with Lumpy skin disease	C	O
19	18	15.1.	Infection with African swine fever virus	C	O
20	19	15.X.	Draft new chapter on Infection with PRRS	C	O
21a	20	Art 4.16.3.	High health status horse subpopulation	C	O
21b	17	12.10.	Infection with *Burkholders mallei* (Glanders)	C	O
22	29	-	Work programme	C	-
23b	-	8.18.	West Nile fever	I	X
13a	30	-	Report of AWWG	I	-
13h	31	-	Report of AHG on AW and pig production systems	I	-

UNOFFICIAL VERSION

C: For Member comments; **E**: under expert consultation (*ad hoc* groups, Specialist Commissions, etc.); **D**: deferred to FEB 2016 meeting; **I**: For Member Country information, **N**: No action; **O**: will be proposed for adoption at 85th General Session; **X**: will not be propose for adoption at 85th General Session.

UNOFFICIAL VERSION

Ref. Ares(2015)1422958 - 31/03/2015

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Deputy Director General for the Food Chain

INCOMING N° 10288
01 APR. 2015
EFSA

Brussels
SANTE/G2/MP/lp (2015) 1458392

Dear Mr Url,

Subject: Request for a scientific opinion on avian influenza

I would like to submit a formal request to EFSA for a scientific opinion on avian influenza with a focus on the currently circulating highly pathogenic avian influenza (HPAI) viruses of H5N8 and possibly other H5 subtypes.

Highly pathogenic avian influenza (HPAI) viruses pose a considerable challenge to risk managers. A series of outbreaks have occurred in 2014 and 2015 involving different viruses, namely HPAI H5N8 in south-east and far-east Asia, North America and the EU requiring immediate response. The EFSA was already requested to deliver a scientific report addressing some specific aspects of the HPAI H5N8 virus.

EU measures to control HPAI are largely based on experience gained and science developed following the HPAI H5N1 epidemic peaking in 2005/06. There is a need to revise and update these measures to face the challenges posed by the new epidemiological situation.

The disease-affected Member States immediately applied control measures as foreseen by Council Directive 2005/94/EC[1] and succeeded in rapidly preventing further virus spread.

The European Commission adopted swiftly certain protective and zoning measures in relation to these HPAI H5N8 outbreaks. However, some principles of avian influenza surveillance in wild birds and in poultry holdings and certain aspects related to biosecurity and confinement of poultry need to be reviewed in the light of the epidemiology of the currently circulating HPAI viruses causing the recent outbreaks.

Low pathogenic avian influenza (LPAI) viruses of the H5 and H7 subtypes have the potential to mutate to HPAI. Therefore, measures to control LPAI outbreaks were included in EU legislation and stamping-out is generally applied in the event of an outbreak. The natural reservoir for all LPAI subtypes in wild birds poses an ongoing risk for LPAI introduction into poultry holdings. Protecting poultry against LPAI infections that is kept in holdings with access to open air access constitutes a specific challenge in terms of biosecurity management and confinement.

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1 OJ L 10, 14.1.2006, p.16.

Mr Bernhard Url
Executive Director
European Food Safety Authority
Via Carlo Magno 1A
I-43126 PARMA

Commission européenne, B-1049 Bruxelles / Europese Commissie, B-1049 Brussel - Belgium. Telephone: (32-2) 299 11 11.
Office :F101 03/078. Telephone: direct line (32-2) 2984256. Fax: (32-2) 2953144.

The European Reference Laboratory for avian influenza (EURL) is a major player not only in the field of avian influenza diagnosis, but also as regards avian influenza epidemiology and surveillance. For the latter the EURL collates and assesses data provided by the Member States to the Commission on surveillance activities for avian influenza in poultry and wild birds. I would therefore suggest involving the EURL that has also expertise on swine influenza viruses.

I am aware that the subject of our request might touch upon the area of the competence of ECDC, so I would also invite EFSA to collaborate with ECDC as appropriate.

In view of the timeliness of this topic, we would request EFSA to provide this opinion by 15 April 2016.

My services remain at your disposal for further information. On this matter, you can contact Maria Pittman of SANTE G2 responsible for this dossier, and Marina Marini, who is the relevant contact point in the Unit in charge of relations with agencies and advisory groups. Their respective phone numbers and e-mail addresses are indicated below.

Yours sincerely,

Ladislav Miko

Contact persons: Ms. M. Marini (02-299.93307), Marina.MARINI@ec.europa.eu
Ms. M. Pittman (02.299.92842), Maria.PITTMAN@ec.europa.eu

Cc.: T. Gumbel, B. Van Goethem, A. Laddomada, R. Vanhoorde, A.-E. Füssel, F. Reviriego (DG SANTE), F. Berthe, A. Gervelmeyer (EFSA).

ANNEX

Commission request for a scientific opinion on avian influenza

- **BACKGROUND**

The occurrence of HPAI outbreaks of the H5N8 subtype in Member States triggered the immediate implementation of control measures according to Council Directive 2005/94/EC[2]. The Commission asked the EFSA to issue a scientific report[3] on the disease situation worldwide and to assess possible virus entry routes into EU poultry holdings with a particular view to the role played by wild migratory birds.

Although there is knowledge about the direct or indirect migration routes from East Asia to Europe, several theories of HPAI H5N8 virus (and possibly other HPAI viruses) entry routes from East Asia into Europe involving infected migratory birds appear plausible. Transmission of HPAI H5N8 virus between different wild bird species at breeding and stopover places seems likely, but needs further assessment. Also the role of other virus entry routes such as through material contaminated by infected wild birds, human activities, movement of vehicles or equipment needs to be further examined for a more complete risk assessment on avian influenza virus introduction into EU poultry holdings.

EU legislation on biosecurity and early detection measures to reduce the risk of HPAI H5N1 introduction into poultry holdings are laid down in Decision 2005/734/EC[4] which sets out the criteria and risk factors to be considered by Member States when defining areas with an increased risk for avian influenza introduction into poultry holdings. The measures are intended to prevent contact between poultry and wild birds as well as separating domestic waterfowl from other poultry species. As the scope of those measures is limited to HPAI H5N1 it is necessary to assess the risk posed by other HPAI viruses and specifically HPAI H5N8 in order to verify if the provisions of Decision 2005/734/EC are suitable when facing further HPAI H5N8 outbreaks. In addition Decision 2006/563/EC[5] also provides for a comprehensive set of protection measures following HPAI H5N1 virus findings in wild birds. The EFSA should assess, if the measures in that Decision are properly addressing risks posed to poultry holdings when HPAI H5N8 and other HPAI viruses are detected in wild birds.

EU wide surveillance programmes for avian influenza in poultry and wild birds are in place since 2003. Directive 2005/94/EC introduced a new legal basis for avian influenza surveillance which is firstly aimed at identifying the circulation of low pathogenic avian influenza (LPAI)[6] viruses in different poultry species before they become widespread in the poultry population. Secondly, it should contribute on the basis of a regularly updated risk assessment, to the current knowledge on the threats posed by wild birds in relation to any influenza virus of avian origin in birds. Following the HPAI H5N1 epidemic in 2006 and subsequent years avian influenza surveillance was reviewed in the light of several EFSA Scientific Opinions, the work of the OIE-FAO OFFLU initiative, the reports of the EU Reference Laboratory (EURL) for avian influenza and the input of the Task Force for Animal Disease surveillance.

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2 OJ L 10, 14.1.2006, p.16.

3 http://www.efsa.europa.eu/en/efsajournal/doc/3941.pdf

4 OJ L 274, 20.10.2005, p. 105.

5 OJ L 222, 15.8.2006, p. 11.

6 LPAI as defined in Directive 2005/94/EC refers to avian influenza viruses of the H5 and H7 subtypes that are not HPAI viruses.

The revised guidelines for avian influenza surveillance laid down in Decision 2010/367/EU[7] follow a risk-based approach. The objectives shall provide for the most suitable surveillance strategy informing competent veterinary authorities on disease prevention and control purposes aimed at protecting poultry and other captive bird holdings from avian influenza infection. Following the current HPAI H5N8 outbreaks it is deemed appropriate to assess, if the EU strategy and guidelines for avian influenza surveillance are still suitable and sufficient considering that active surveillance by laboratory testing of wild birds trapped or hunted is currently not foreseen in the EU approved surveillance programmes.

To this end, alternative surveillance designs based on active sampling of healthy wild birds to study the many different aspects of virus presence and characteristics should be considered within the context of risk management targeted to inform the risk manager in an efficient manner. Therefore some principles of surveillance in wild birds and in poultry holdings need to be revised. In the light of the recent outbreaks it is also necessary that the EFSA studies certain aspects of the epidemiology of HPAI H5N8 virus which are related to biosecurity and confinement of poultry.

Control measures for LPAI outbreaks of the H5 and H7 subtypes were included in Directive 2005/94/EC as those avian influenza viruses have the potential to mutate to HPAI virus with possibly severe consequences for animal health and the poultry industry. The presence of LPAI viruses in the wild bird reservoir poses an ongoing risk for LPAI virus introduction into poultry holdings. A specific challenge for the management of biosecurity measures is to prevent contacts of wild birds with poultry constitutes holdings where poultry is kept in open air runs.

The EFSA is therefore also requested to assess the risks of LPAI virus introduction into poultry holdings taking into account the conditions under which poultry is housed and the appropriate surveillance and biosecurity measures to be applied.

- **TERMS OF REFERENCE**

In view of the above, and in accordance with Article 29 of Regulation (EC) No 178/2002, the Commission asks EFSA for a scientific opinion and to specifically assess:

1. the risks of introduction of HPAI H5N8 and possibly other HPAI viruses considering the possible entry routes into the EU ;

2. the risks posed by HPAI H5N8and possibly other HPAI viruses for public and animal health and specifically with a view to assess the suitability of the provisions on:

    a. biosecurity and early detection measures to reduce the risk of its introduction into poultry holdings laid down in Decision 2005/734/EC;

    b. protection measures in poultry in case of its occurrence in wild birds laid down in Decision 2006/563/EC;

    c. the surveillance strategy, in particular objectives and methodology, laid down in Decision 2010/367/EU.

[7] OJ L 166, 1.7.2010, p. 22.

3. the current situation in the EU and elsewhere as regards the risk of a possible introduction of HPAI(H5N8) virus and possibly other HPAI viruses to EU poultry holdings.

4. the continuous risk posed by LPAI (subtypes H5 and H7) for the introduction from the wild bird reservoir into poultry holdings taking into account risks for holdings where poultry is kept in open air runs and the suitability of surveillance and biosecurity measures aimed at protection of poultry against LPAI infection.

Ref. Ares(2016)2335544 - 19/05/2016

INCOMING N° EL-0015
20 MAG. 2016
EFSA

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Deputy Director-General for Food Safety

Brussels
SANTE/G3/MP/lp (2016) 2881803

Dear Mr Url,

Subject: Request for a scientific opinion on additional issues in relation to EFSA's ongoing mandate on avian influenza

The Commission submitted on 31/3/2015 a formal request to EFSA for a scientific opinion on avian influenza Ares (2015) 1422958. The terms of reference of that mandate focus on highly pathogenic avian influenza (HPAI) viruses of H5N8 and possibly other H5 subtypes that caused outbreaks in poultry during late 2014 and early 2015. In addition, EFSA was asked to assess the specific risks for the introduction of low pathogenic avian influenza (LPAI) of subtypes H5 and H7 into free range farms and the suitability of certain EU prevention and control measures.

The natural reservoir for all LPAI virus subtypes is wild migratory birds posing an ongoing risk for LPAI introduction into poultry holdings. LPAI viruses of the H5 and H7 subtypes have the potential to mutate to HPAI as was demonstrated during large scale HPAI epidemics worldwide (e.g. in the USA, Italy, the Netherlands). Those outbreaks had devastating socio-economic consequences.

Therefore, measures to control LPAI outbreaks were included in EU legislation (Directive 2005/94/EC[1]) and OIE standards and stamping-out may be applied in the event of an outbreak. However, quarantine and further testing of LPAI positive flocks and slaughter for consumption may be applied as an alternative to stamping-out.

Surveillance for avian influenza has been carried out by Member States under co-financed programmes since 2003 and was strengthened by the adoption of Directive 2005/94/EC with new graduated control measures for HPAI and LPAI proportionate to the risks posed by these two categories of viruses. Member States are implementing these measures since mid 2007.

[1] OJ L 10, 14.1.2006, p.16.

Mr Bernhard Url
Executive Director
European Food Safety Authority
Via Carlo Magno 1A
I-43126 PARMA

The entry of the HPAI H5N1 virus into Europe in 2005/2006, constituted an unprecedented event involving HPAI virus transmission mainly via wild migratory birds that became a prominent pathway for HPAI incursions prompting the adoption of a series of very specific control measures.

Member States' experiences during almost a decade show that the EU control measures for avian influenza have worked well so far, but the proportionality of the measures applied for LPAI as compared to HPAI are giving rise for concern, also in view of international trade with frequent imposition of unjustified trade barriers due to LPAI incursions. The measures to control of LPAI outbreaks, the intensity and means of avian influenza surveillance aimed at preventing or reducing HPAI outbreaks should therefore be based on risk assessment.

The new Animal Health Law Regulation (EU) 2016/429[2] and its future delegated and implementing acts offer now the opportunity to review certain disease prevention and control measures.

Following my previous request for a scientific opinion of EFSA on avian influenza Ares (2015) 1422958, as referred to above, I request EFSA to extend the scope of that ongoing mandate by addressing the additional Terms of Reference provided for in the Annex and to issue the scientific opinion by 31 May 2017.

My services remain at your disposal for further information. On this matter, you can contact Maria Pittman of SANTE G3 responsible for this dossier, and Marina Marini, who is the relevant contact point in the Unit in charge of relations with agencies and advisory groups. Their respective phone numbers and e-mail addresses are indicated below.

Yours sincerely,

Vladislav Miko

Mr Bernard Van Goethem
Director
DG Health and Food Safety
for the DDG absent

Contact persons: Ms. M. Marini (02-299.93307), Marina.MARINI@ec.europa.eu
Ms. M. Pittman (02.299.92842), Maria.PITTMAN@ec.europa.eu

Cc: T. Bregeon, B. Van Goethem, M. Seannell, J-F Ryan, A. Gavinelli, A.-E. Fuessel L. Terzi, F. Reviriego Gordejo, M. Marini, B. Logar, (DG SANTE), G. Stancanelli, A. Gervelmeyer, F. Verdonk (EFSA).

[2] OJ L 84, 31.3.2016, p. 1.

ANNEX

Request for a scientific opinion on additional issues in relation to EFSA's ongoing mandate on avian influenza

- **BACKGROUND**

Highly pathogenic avian influenza (HPAI) is a highly contagious viral disease and causes in most bird and poultry species (except in many ducks and geese species) high mortality. Low pathogenic avian influenza viruses mainly cause mild disease and may even remain undetected. Wild migratory birds are the natural reservoir for low pathogenic avian influenza viruses. Low pathogenic avian influenza viruses of the H5 and H7 subtypes (LPAI) have the potential to mutate to HPAI viruses.

Until the adoption of Council Directive 2005/94/EC[3], EU control measures for avian influenza were only directed against HPAI.

Large HPAI epidemics worldwide (USA/Pennsylvania 1983, Italy 1999/2000, the Netherlands 2003) that emerged by mutation from a circulating LPAI virus strain into its highly pathogenic form caused death and killing of more than 60Million poultry with devastating socio-economic consequences. These experiences, supported by science including EFSA (2005[4]) led to the introduction of control measures against LPAI viruses of the H5 and H7 subtypes into EU legislation.

Also the World Animal Health Organisation (OIE) introduced in its Terrestrial Animal Health Code besides the existing recommendations for international trade for HPAI standards for LPAI and developed guidance on surveillance.

The EU control measures for LPAI and HPAI foresee the killing of all poultry on HPAI infected holdings. In case of LPAI infection, poultry may either be killed or be quarantined, further tested and may then go for slaughter under bio-secure conditions. However, recently no Member State has made use of the latter option.

LPAI infected poultry may not show clinical signs. It was therefore necessary to introduce compulsory EU-wide active surveillance programmes in order to detect circulating LPAI virus and in addition circulating HPAI in domestic waterfowl, as these species may not show disease even when infected with HPAI. The programmes are based on sero-surveillance with virological follow- up of positive results and are not aimed at early detection of infection. The surveillance programmes have been refined over the years defining the objectives and enabling targeting risk-based strategies. Passive surveillance and early detection systems are

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[3] OJ L 10, 14.1.2006, p.16.

[4] EFSA AHAW Panel (EFSA Panel on Animal Health and Welfare), 2005. Opinion of the Scientific Panel on Animal Health and Welfare (AHAW) on a request from the Commission related to animal health and welfare aspects of Avian Influenza. doi:10.2903/j.efsa.2005.266.

complementing those active surveillance programmes. The variety of risk factors associated with different poultry species and production systems continue to make meaningful and affordable surveillance a challenge.

Surveillance for avian influenza has been carried out by Member States under co-financed programmes since 2003. Directive 2005/94/EC with new control measures for HPAI and LPAI had to be implemented since mid 2007. During these last 10 years many Member States have made their own experiences with HPAI or LPAI outbreaks or have rehearsed the control measures in the framework of simulation exercises. Also the entry of the HPAI H5N1 virus into Europe in 2005/2006, constituted an unprecedented event involving HPAI virus transmission mainly via wild migratory birds that became a prominent pathway for HPAI incursions prompting the adoption of a series of control measures.

The EU measures for the control of avian influenza have worked well so far, but the proportionality of some measures applied for HPAI and especially for LPAI remains a concern and should be based on risk assessment.

As regards surveillance, the number of LPAI outbreaks in a country is considered to be primarily related to the monitoring intensity and quality of early warning procedures. Countries that have the most elaborate surveillance systems tend to detect more frequently LPAI incursions. This has also consequences for international trade. The OIE's LPAI free status in the Terrestrial Animal Health Code may not properly reflect the real LPAI status of a country considering the heterogeneity of LPAI surveillance systems implemented worldwide ranging from almost non-existing to the well-structured active and passive surveillance programmes implemented in the EU. This must also be seen against the background of the number of countries actually notifying LPAI to the OIE.

A questions remains open as regards at which extent the intensive active and passive surveillance implemented in the EU has effectively lead to preventing or reducing HPAI outbreaks by surveillance and control of LPAI outbreaks.

The new Animal Health Law Regulation (EU) 2016/429[3] and its future delegated and implementing acts offer now the opportunity to review certain disease prevention and control measures.

- **TERMS OF REFERENCE**

In view of the above, and in accordance with Article 29 of Regulation (EC) No 178/2002, the Commission asks EFSA for a scientific opinion and to specifically:

1. assess the different pathways, the most important routes and risk factors for avian influenza viruses (HPAI and LPAI) to enter poultry holdings in the EU including the threat posed by viruses circulating in wild birds;

2. assess the within-flock, within-farm and between-farm transmission characteristics for both LPAI and HPAI viruses;

[3] OJ L, 84, 31.3.2016, p. 1.

3. assess and, if possible, quantify the risk of mutation of a LPAI viruses to HPAI viruses and to identify the factors that influence the mutation frequency of avian influenza viruses in poultry flocks;

4. indicate which avian influenza surveillance tools are most suitable and which factors need to be taken into account for optimising an avian influenza surveillance programme.

Electronically signed on 19/05/2016 16:56 (UTC+02) in accordance with article 4.2 (Validity of electronic documents) of Commission Decision 2004/563

Ref. Ares(2016)969090 - 25/02/2016

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Deputy Director-General for Food Safety

INCOMING N°135291
25 FEB. 2016
EFSA

Brussels
SANTE G3/DD/lp (2016) 46[illegible]185

Dear Dr Url,

Subject: Request for a scientific opinion on Bluetongue

I would like to submit a formal request to EFSA for a scientific opinion on Bluetongue.

Over the past fifteen years Bluetongue (BT) has become widespread across many parts of Europe with affected countries sometimes adopting diverse control policies, particularly as regards vaccination against the disease in order to cope with both the short as well as the long term consequences in animal health, animal production and trade on live animals.

Incidences of BT during that fifteen years period have included unexpected epidemics in areas where it had not appeared for more than ten years (e.g. BTV-4 in the mainland of the Balkan Peninsula in 2014), occurrence of new serotypes, low-impact virus circulation of unclear origin, new serotypes, and disease recurrence (BTV-8 in France in 2015).

In the past, EFSA has produced a number of scientific opinions dealing with various aspects of BT epidemiology, surveillance and control which provided valuable conclusions and recommendations that helped the Commission and the Member States shape the current disease control strategy at the EU level. Nevertheless, an update of that strategy may be necessary in the light of the disease evolution, the current epidemiological situation, the experience gained so far from the implementation of the various BT control policies, the new possible alternative methods to ensure safe trade in live animals from BT restricted zones, and the latest scientific information available. The need to review the overall EU policy on BT has been emphasised repeatedly by national authorities of many Member States.

Furthermore, EFSA has already been made aware of the expected adoption of the Regulation on transmissible animal diseases (Animal Health Law), hereinafter referred to as AHL. While BT is already included in the list of diseases in an Annex to the AHL, this list will need to be reviewed in accordance with a set of criteria provided for in the AHL not later than 2 years before the AHL comes into application, i.e. five years after its entry into force early in 2016.

Dr Bernhard Url
Executive Director
European Food Safety Authority
Via Carlo Magno 1A
43126 Parma
ITALY

Therefore the Commission is in need of scientific advice on the assessment of the significance of BT within the framework of the already known listing and categorisation exercise according to the AHL.

In view of the timelines of these topics, we would request EFSA to provide this opinion by 31 December 2016.

My services remain at your disposal for further information. On this matter, you can contact Dimitrios Dilaveris of SANTE G3 responsible for this dossier, and Marina Marini, who is the relevant contact point in the Unit in charge of relations with agencies and advisory groups. Their respective phone numbers and e-mail addresses are indicated below.

Yours sincerely,

Ladislav Miko

Encl.:

Annex I: General Terms of Reference

Annex II: Specific Terms of Reference on Bluetongue Categorisation in the Framework of the Animal Health Law

Contact persons:

Ms. M. Marini (02.299.93307) Marina.Marini@ec.europa.eu
Mr. D. Dilaveris (02.299.86741) Dimitrios.Dilaveris@ec.europa.eu

C.c.: S. Plecita Ridzikova, B. Van Goethem, M. Scannell, L. Terzi, F. Andriessen, C. Bertrand, A.-E. Fuessel, M. Marini, F. Reviriego Gordejo, B. Logar, (DG SANTE), H. Verhagen, F. Berthe, G. Stancanelli, A. Gervelmeyer (EFSA).

ANNEX I
GENERAL TERMS OF REFERENCE

INTRODUCTION-BACKGROUND INFORMATION

Over the past 15 years BT incursions of a variety of serotypes occurred and on several occasions became widespread across many parts of Europe with affected countries sometimes adopting diverse control policies, particularly as regards vaccination against the disease in order to cope with both the short as well as the long term consequences in animal health, animal production and trade on live animals or their products.

Incidences of BT during this period have included unexpected epidemics in areas where it had not appeared for more than ten years (e.g. BTV-4 in the mainland of the Balkan Peninsula in 2014) but also low-impact circulation of certain serotypes, some of them of unclear origin, incursions of new serotypes, vaccine incidents and disease resurgence (BTV-8 in France in 2015) raising concerns and evidencing new challenges.

The European Commission has repeatedly sought scientific advice on bluetongue (BT) from EFSA in the last decade and in response EFSA has produced a number of scientific opinions dealing with various aspects of BT epidemiology, surveillance and control which provided valuable conclusions and recommendations that helped shape the current disease strategy at the EU level.

Nevertheless, an update appears necessary in the light of the recent disease evolution, the current epidemiological situation, the experience gained so far from the implementation of the various BT control policies and possible alternative methods to ensure safe trade of live animals from BT restricted zones and the latest scientific information available.

The need to review the overall BT policy at EU level is an issue that has been repeatedly emphasised by national authorities of many Member States and the IV International Conference on Bluetongue and related Orbiviruses (Rome, 5-7 November 2014) represents a major milestone for taking stock of the latest state of the art science on BT.

In order to streamline the way forward, the Commission with the Member States have identified a series of issues for which concrete elements of science may provide a good basis for reformulating policies and/or adapting current rules. These are as follows:

1. <u>Safe trade provisions</u>

As regards, provisions for safe trade, in particular from BT restricted areas, the European Commission, on top of those already in place in Commission Regulation (EC) 1266/2007, is keen to explore other options used by the competent authorities of some EU Member Countries in the framework of bilateral trade agreements drafted in accordance with Article 8 of the same Regulation.

Article 8 of Commission Regulation (EC) No 1266/2007 foresees that exemptions from the exit ban are to be based on risk mitigating measures presented in Annex III to the Regulation or on any other appropriate animal health guarantees based on a positive outcome of a risk assessment agreed between the competent authority of the place of origin and the competent authority of the place of destination.

Currently there are such agreements on the movement of live animals concluded between France and Italy of 2015, France and Spain of 2013 and 2015, Italy and Spain of 2012, Spain and Portugal of 2014, France and Luxembourg of 2015 and Italy and Austria of 2016[1].

2. Classification of different BT serotypes

There are indications that more than 25/26 different serotypes of the BT virus have been identified to date. Each of these serotypes, apart from its specific genetic and antigenic features, may also be connected with specific epidemiological and pathogenicity properties. It is necessary to understand whether it is possible to use these properties as a set of standard criteria to divide known BT serotypes in groups, each deserving a distinct treatment as regards surveillance, protection and control measures.

3. BT listing and categorisation in the framework of the AHL

In addition to the classification of the different serotypes, BT merits an assessment as part of the listing and categorisation exercise of animal diseases in the framework of the Animal Health Law in the same manner as it was requested previously for another seven diseases (Ref. SANTE G2/BL/lp (2015) 4940871).

In the light of the above mentioned ongoing procedure the Commission is in need of scientific advice on the assessment of the significance of BT (as an integral disease, or separately for each serotype or group of serotypes, depending on the outcome of the grouping exercise) also within the framework of the listing and categorisation according to the AHL. The criteria, provided for ease of reference in Annex II and Attachments I to IV thereof, shall be used as a basis for this analytical assessment. The risk manager needs an updated scientific advice in order to:

1. assess if the various serotypes or groups of serotypes of BTV cause diseases for which control measures at the EU level are justified;
2. proceed with the profiling of the diseases caused by the serotypes or groups of serotypes of BTV as above in view to their categorisation; and
3. assign listed species to the various serotypes or groups of serotypes of BTV identified as eligible for EU intervention.

TERMS OF REFERENCE

In view of the above, and in accordance with Article 29 of Regulation (EC) No 178/2002, the Commission asks EFSA for a scientific opinion under the following headings:

1. As regards vaccination, eradication and surveillance

1.1 Assess the most suitable duration of a BT vaccination campaign intended to achieve disease freedom in a country or region considering any relevant factors that may affect and influence disease spread, and persistence.

1.2 Assess the probability of BT recurrence in BT affected areas that have regained BT freedom, in particular due to BT virus becoming endemic with low level circulation in these areas and reoccurring "spontaneously" (low-noise circulation in livestock or wildlife, maintenance in vectors or other possible mechanism to be considered).

1.3 Revise and assess the suitability of the provisions on surveillance laid down in Regulation (EC) No 1266/2007 to ensure reliable and robust demonstration of absence

[1] http://ec.europa.eu/food/animal/diseases/controlmeasures/btoctongue_en.htm

of virus transmission in a Member State or epidemiologically relevant area, considering point 1.2 above.

2. **As regards specific options for safe trade that could be used for exemptions from the exit ban applicable to movements of live animals from a restricted zone**

2.1 Assess whether maternal immunity against BT of calves, lambs and kids born to and colostrum fed from vaccinated mothers, constitutes a sufficient guarantee for animals of the above species to be moved safely from a BTV infected to a BTV free country or zone, without a risk for disease spread, with or without the need for any additional pre-movement testing regime and indicate the main parameters that could be used (minimum/maximum age of calves, testing of dams, etc.).

2.2 Assess the minimum age of calves, lambs and kids after which residual colostral antibodies against BTV do not interfere any longer with vaccine immunisation of these animals (in an example of BT bilateral agreement this age limit is set at 90 days).

2.3 Assess the minimum time after completion of the primary vaccination (1-2 doses as indicated by the vaccine manufacturer) for the vaccinated animals to be considered immune to be safely moved from a BT infected to a BT free country or zone (currently set at 60 days in paragraph 5 of Annex III to Regulation (EC) No 1266/2007).

2.4 Assess whether vector protection for 14 days of ruminants below the age of 70 days, combined with a negative PCR test at the end of the 14 days or more, qualify them for a safe movement from a BT restricted to a BT free area.

3. **As regards protection from BTV vectors and vector based provisions for exemption from the exit ban applicable to movements of live animals from a restricted zone**

3.1 Review and update previous opinions as regards vectors ecology (models for distribution/density), in order to have more accurate and applicable criteria for the determination of the seasonally vector-free period.

3.2 Review and update previous opinions as regards over-wintering mechanisms and the duration of the BT viraemia.

3.3 Review and update previous opinions and provide a scientific assessment of the appropriateness of the use of insecticides and repellents against Culicoides as BT competent vectors, including an assessment of their efficacy and recommendations of adequate protocols for their uses, in particular as regards their suitability to protect animals against attacks by vectors performing at least equal to the protection provided by vector-proof establishments – without the need to keep animals in a vector protected facility.

4. **As regards classification and grouping of different BTV serotypes according to their potential impact on animal health**

4.1 Review and update previous opinions providing a short description of existing serotypes in the EU and elsewhere.

4.2 Assess, by using appropriate criteria[2], the feasibility of grouping the currently known BTV serotypes in appropriately defined groups of serotypes sharing similar properties thus creating a number of "BTV serotype groups" separated by significant different levels of impact on animal health (e.g. most serious clinical symptoms in many individuals in large areas, mild symptoms to few individuals within small areas or no symptoms at all in one or more BT susceptible species etc.).

4.3 Review and classify the existing serotypes according to the outcome of the assessment in point 4.2 above and assess whether any of the above serotypes /groups of serotype could be candidates for a partial or total exclusion from the overall BT policy currently in place in the EU, in particular due to their low level of virulence or pathogenicity.

5. Listing and categorisation of BT in the framework of the Animal Health Law.

5.1 Considering the outcome of the assessments and reviews referred to in paragraph 4 above, for each of the aforementioned groups of serotypes, or BT in general as appropriate, assess, following the criteria laid down in Article 7 of the AHL, its eligibility of being listed for Union intervention as laid down in Article 5(3) of the AHL;

5.2 Considering the outcome of the assessments and reviews referred to in paragraph 4 above, for each of the aforementioned groups of serotypes, or for BT in general, if found eligible to be listed for Union intervention, provide:

a) an assessment of its compliance with each of the criteria in Annex IV to the AHL for the purpose of categorisation of diseases in accordance with Article 9 of the AHL;

b) a list of animal species that should be considered candidates for listing in accordance with Article 8 of the AHL.

[2] Such criteria could include: a) Pathogenicity (capacity to produce clinical disease in a large proportion of susceptible animals), b) Epidemiological properties (e.g. spreading potential), c) Laboratory tests characteristics (e.g. genome analysis, antigenic composition, other specific identifiable features etc.)

ANNEX II

SPECIFIC TERMS OF REFERENCE ON BLUETONGUE CATEGORISATION IN THE FRAMEWORK OF THE ANIMAL HEALTH LAW

PART 1: DISEASE SPECIFIC INFORMATION ON BLUETONGUE

Specific international trade standards for Bluetongue are provided for in Chapter 8.3 and in Section 4 (Chapters 4.6. and 4.7.) of the Code, as well as in Chapter 2.1.3. of the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (the Manual).

In the existing EU legislative acts, Bluetongue is referred to in[3]:

- Council Directive 2000/75/EC of 20 November 2000 laying down specific provisions for the control and eradication of bluetongue
- Commission Regulation (EC) No 1266/2007 of 26 October 2007 on implementing rules for Council Directive 2000/75/EC as regards the control, monitoring, surveillance and restrictions on movements of certain animals of susceptible species in relation to bluetongue
- Council Directive 82/894/EEC of 21 December 1982 on the notification of animal diseases within the Community
- Council Directive 2004/68/EC of 26 April 2004 laying down animal health rules for the importation into and transit through the Community of certain live ungulate animals, amending Directives 90/426/EEC and 92/65/EEC and repealing Directive 72/462/EEC
- Council Directive 92/119/EEC of 17 December 1992 introducing general Community measures for the control of certain animal diseases and specific measures relating to swine vesicular disease
- Guidance document SANCO/7068/2012 Rev 3 (October 2012), to assist Member States on the implementation of the criteria for "Vector Protected Establishments" for bluetongue laid down in Annex II of Commission Regulation (EC) No 1266/2007 as amended by Commission Regulation (EC) No 456/2012 of 30 May 2012

[3] Acts – documents more relevant to the tasks of the scientific opinion in subject.

PART 2: ATTACHMENTS ON DISEASE CATEGORISATION IN THE FRAMEWORK OF THE ANIMAL HEALTH LAW

ATTACHMENT I

Assessment criteria

Article 7

Assessment parameters for the listing of diseases

The Commission shall use the following assessment parameters in order to determine whether a disease meets the conditions requiring it to be listed in accordance with Article 5(2):

(a) the disease profile, which shall comprise the following:

(i) the animal species concerned by the disease;

(ii) the morbidity and mortality rates of the disease in animal populations;

(iii) the zoonotic character of the disease;

(iv) the resistance to treatments, including antimicrobial resistance;

(v) the persistence of the disease in an animal population or in the environment;

(vi) the routes and speed of transmission of the disease between animals and, when relevant, between animals and humans;

(vii) the absence or presence and distribution of the disease in the Union, and, where the disease is not present in the Union, the risk of its introduction into the Union;

(viii) the existence of diagnostic and disease control tools;

(b) the impact of the disease on:

(i) agricultural and aquaculture production and other parts of the economy, as regards:

the level of presence of the disease in the Union;

the loss of production due to the disease;

other losses;

(ii) human health, as regards:

transmissibility between animals and humans;

transmissibility between humans;

the severity of human forms of the disease;

the availability of effective prevention or medical treatment in humans;

(iii) animal welfare;

(iv) biodiversity and the environment;

(c) its potential to generate a crisis situation and its potential use in bioterrorism;

(d) the feasibility, availability and effectiveness of the following disease prevention and control measures:

(i) diagnostic tools and capacities;

(ii) vaccination;

(iii) medical treatments;

(iv) biosecurity measures;

(v) restrictions on the movement of animals and products;

(vi) killing of animals;

(vii) disposal of carcasses and other relevant animal by-products;

(e) the impact of disease prevention and control measures, as regards:

(i) the direct and indirect costs for the affected sectors and the economy as a whole;

(ii) their societal acceptance;

(iii) the welfare of affected subpopulations of kept and wild animals;

(iv) the environment and biodiversity.

ATTACHMENT II

Criteria for listing diseases for Union intervention

Article 5
Listing of diseases

....

3. A disease shall be included on the list referred to in point (b) of paragraph 1 of this Article if it has been assessed in accordance with Article 6 and it meets:

(a) all of the following criteria:

(i) scientific evidence indicates that the disease is transmissible;

(ii) animal species are either susceptible to the disease or vectors and reservoirs thereof exist in the Union;

(iii) the disease causes negative effects on animal health or poses a risk to public health due to its zoonotic character;

(iv) diagnostic tools are available for the disease; and

(v) risk-mitigating measures and, where relevant, surveillance of the disease are effective and proportionate to the risks posed by the disease in the Union; and

(b) at least one of the following criteria:

(i) the disease causes or could cause significant negative effects in the Union on animal health, or poses or could pose a significant risk to public health due to its zoonotic character;

(ii) the disease agent has developed resistance to treatments and poses a significant danger to public and/or animal health in the Union;

(iii) the disease causes or could cause a significant negative economic impact affecting agriculture or aquaculture production in the Union;

(iv) the disease has the potential to generate a crisis or the disease agent could be used for the purpose of bioterrorism; or

(v) the disease has or could have a significant negative impact on the environment, including biodiversity, of the Union.

ATTACHMENT III

Criteria for disease categorization

.....

ANNEX IV

Criteria for the application of the disease prevention and control rules referred to in Article 9(1) to diseases listed in accordance with Article 5

The scope of this Annex is to detail the criteria to be considered by the Commission when determining the disease prevention and control rules to be applied to the different categories of diseases listed in accordance with Article 5.

The process of categorisation shall take into account the profile of the disease in question, the level of the impact of that disease on animal and public health, animal welfare and the economy, and the availability, feasibility and effectiveness of the diagnostic tools and different sets of disease prevention and control measures provided for in this Regulation with respect to the disease.

SECTION 1

CRITERIA FOR THE APPLICATION OF THE DISEASE PREVENTION AND CONTROL RULES REFERRED TO IN POINT (A) OF ARTICLE 9(1)

The diseases for which the disease prevention and control rules referred to in point (a) of Article 9(1) apply shall be considered to have the most severe animal health, public health, economic, social or environmental impacts on the Union. Those diseases need to fulfil the following criteria:

(a) the disease in question is:

(i) not present in the territory of the Union;

(ii) present only in exceptional cases (irregular introductions); or

(iii) present in only in a very limited part of the territory of the Union;

and

(b) the disease in question is highly transmissible; in addition to direct and indirect transmission, there may also be possibilities of airborne, waterborne or vector–borne spread. The disease may affect multiple species of kept and wild animals, or a single species of kept animals of economic importance, and may result in high morbidity and significant mortality rates.

In addition to the criteria set out in points (a) and (b), those diseases need to fulfil one or more of the following criteria:

(c) the disease in question has a zoonotic potential with significant consequences for public health, including epidemic or pandemic potential or possible significant threats to food safety;

(d) the disease in question has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals;

(e) the disease in question has a significant impact on one or more of the following:

(i) society, with in particular an impact on labour markets;

(ii) animal welfare, by causing suffering to large numbers of animals;

(iii) the environment, due to the direct impact of the disease or due to the measures taken to control it;

(iv) in the long term, biodiversity or the protection of endangered species or breeds, including the possible disappearance of, or long-term damage to, those species or breeds.

SECTION 2

CRITERIA FOR THE APPLICATION OF THE DISEASE PREVENTION AND CONTROL RULES REFERRED TO IN POINT (B) OF ARTICLE 9(1)

The diseases for which the disease prevention and control rules referred to in point (b) of Article 9(1) apply shall be controlled in all Member States with the goal of eradicating them throughout the Union.

Those diseases need to fulfil the following criteria:

(a) the disease in question is endemic in nature and is present in the whole or part of the Union territory. However, several Member States or zones of the Union are free of the disease; and

(b) the disease is moderately to highly transmissible; in addition to direct and indirect transmission, there may also be possibilities of airborne, waterborne or vector–borne spread. It may affect single or multiple animal species and may result in high morbidity, with in general low mortality.

In addition to the criteria set out in points (a) and (b), those diseases need to fulfil one or more of the following criteria:

(c) the disease in question has a zoonotic potential with significant consequences for public health, including epidemic potential or possible significant threats to food safety;

(d) the disease in question has a significant impact on the economy of the Union causing substantial costs, mainly related to its direct impact on the health and productivity of animals;

(e) the disease has a significant impact on one or more of the following:

(i) society, with in particular an impact on labour markets;

(ii) animal welfare, by causing suffering to large numbers of animals;

(iii) the environment, due to the direct impact of the disease or due to the measures taken to control it;

(iv) in the long term, biodiversity or the protection of endangered species or breeds, including the possible disappearance of, or long-term damage to, those species or breeds.

A disease to which the measures referred to in point (a) of Article 9(1) apply, which has not been successfully and promptly eradicated in a part of the Union, and has, in that part of the Union, obtained an endemic character, may be subject to disease prevention and control measures under point (b) of Article 9(1), in that part of the Union.

SECTION 3

CRITERIA FOR THE APPLICATION OF THE DISEASE PREVENTION AND CONTROL RULES REFERRED TO IN POINT (C) OF ARTICLE 9(1)

The diseases for which the disease prevention and control rules referred to in point (c) of Article 9(1) apply are of relevance to some Member States and measures are needed to prevent them from spreading to parts of the Union that are officially disease-free or that have eradication programmes for the listed disease in question.

Those diseases need to fulfil the following criteria:

(a) in terrestrial animals, the disease in question is endemic in nature and is present in the whole or part of the Union territory; or in aquatic animals, several Member States or zones of the Union are free of the disease; and

(b) (i) in terrestrial animals, the disease in question is moderately to highly transmissible, mainly through direct and indirect transmission. The disease mainly affects multiple

or single animal species, usually does not result in high morbidity, and has a negligible or no mortality rate. Often the most observed effect is production loss;

(ii) in aquatic animals, the disease is moderately to highly transmissible, mainly through direct and indirect transmission. The disease affects multiple or single animal species and may result in high morbidity and usually low mortality. Often the most observed effect is production loss.

In addition to the criteria set out in points (a) and (b), those diseases need to fulfil one or more of the following criteria:

(c) the disease in question has a zoonotic potential with significant consequences for public health, or possible threats to food safety;

(d) the disease in question has a significant impact on the economy of parts of the Union, mainly related to its direct impact on certain types of animal production systems.

(e) the disease in question has a significant impact on one or more of the following:

(i) society, with, in particular, an impact on labour markets;

(ii) animal welfare, by causing suffering to large numbers of animals;

(iii) the environment, due to the direct impact of the disease or of the measures taken to control it;

(iv) in the long term, biodiversity or the protection of endangered species or breeds, including the possible disappearance of, or long-term damage to, those species or breeds.

SECTION 4

CRITERIA FOR THE APPLICATION OF THE DISEASE PREVENTION AND CONTROL RULES REFERRED TO IN POINT (D) OF ARTICLE 9(1)

The disease prevention and control rules referred to in point (d) of Article 9(1) shall apply to diseases that fulfil the criteria set out in Section 1, 2 or 3 and to other diseases fulfilling the criteria set out in Section 5 where the risk posed by the disease in question can be effectively and proportionately mitigated by measures concerning movements of animals and products in order to prevent or limit its occurrence and spread.

SECTION 5

CRITERIA FOR THE APPLICATION OF THE DISEASE PREVENTION AND CONTROL RULES REFERRED TO IN POINT (E) OF ARTICLE 9(1)

The disease prevention and control rules referred to in point (e) of Article 9(1) shall apply to diseases that fulfil the criteria set out in Sections 1, 2 or 3 and to other diseases where surveillance of the disease is necessary for reasons relating to animal health, animal welfare, human health, the economy, society or the environment.

ATTACHMENT IV

Criteria for listing of species

Article 5
Listing of species

....

3. Animal species or groups of animal species shall be added to this list if they are affected or if they pose a risk for the spread of a specific listed disease because:

   (a) they are susceptible for a specific listed disease or scientific evidence indicates that such susceptibility is likely; or

   (b) they are vector species or reservoirs for that disease, or scientific evidence indicates that such role is likely.

Electronically signed on 24/02/2016 16:28 (UTC+01) in accordance with article 4(2) (Validity of electronic documents) of Commission Decision 2004/563

Ref. Ares(2016)2658654 - 08/06/2016

EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Deputy Director General for Food Safety

INCOMING N°442999
13 GIU. 2016
EFSA

Brussels
SANCO/GH/LC/is(2016)

Dear Mr Url,

Subject: Request for a scientific opinion on Chronic Wasting Disease (CWD) in cervids

The former Scientific Steering Committee of the European Commission adopted in 2003 an "*Opinion on Chronic Wasting Disease and tissues that might carry a risk for human and animal feed chains*"[1].

The European Food Safety authority (EFSA) adopted two opinions with regards to EU surveillance on CWD[2], on 2004 and on 2010. CWD was also addressed in the joint EFSA and ECDC (European Centre for Disease Prevention and Control) "*Scientific opinion on any possible epidemiological or molecular association between TSEs in animals and humans*"[3].

On 5 April 2016, Norway notified a first case of CWD in the European Economic Area (EEA), in a wild reindeer. On 25 May 2016, Norway notified a second case of CWD, this time in a wild moose. In view of these detections, EFSA is requested to provide a scientific opinion on CWD in cervids in the EU and EEA in accordance with Article 29 of Regulation (EC) No 178/2002, according to the terms of reference in Annex.

In light of the sensitivity of this emerging issue, I would be grateful if EFSA could deliver its scientific opinion as soon as possible and according to the following schedule:

- EFSA is asked to provide its scientific opinion on the Terms of Reference N° 1 (surveillance), 2 (public health) and 3 (risk mitigation measure) by 31 December 2016;

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[1] http://ec.europa.eu/food/fs/sc/ssc/out323_en.pdf and http://ec.europa.eu/food/fs/sc/ssc/out324_en.pdf
[2] http://www.efsa.europa.eu/en/efsajournal/pub/70 and http://www.efsa.europa.eu/en/efsajournal/pub/1861
[3] http://www.efsa.europa.eu/en/efsajournal/pub/1945

Mr Bernhard Url
Executive Director
European Food Safety Authority
Via Carlo Magno 1/A
I-43126 Parma
Italy
Bernhard.URL@efsa.europa.eu

Commission européenne/Europese Commissie, 1049 Bruxelles/Brussel, BELGIQUE/BELGIË - Tel. +32 22991111
Office: B 232 3/15 - Tel. direct line +32 229 64075 – E-mail: lucio.carrozzo@ec.europa.eu

- EFSA is asked to provide its scientific opinion on the Terms of Reference N° 4 (diagnostic of CWD) and 5 (review of 2010 EFSA opinion) by 31 December 2017.

My services remain at your disposal if you require further information. On this matter, you can contact Lucie Carrouée in DG SANTE G4, who is responsible for this dossier, and Marina Marini in DG SANTE D1, who is the relevant contact point in the Unit in charge of science, stakeholders and enforcement. Their respective phone numbers and e-mail addresses are indicated below.

Yours sincerely,

Ladislav Miko

Encl.: Terms of Reference

Contacts: Lucie Carrouée (lucie.carrouee@ec.europa.eu) Tel.: + (32)2 296.40.75
Marina Marini (marina.marini@ec.europa.eu) Tel.: + (32) 2 299.33.07

C.c.: H. Verhagen, M. Hugas, E. Liebana Criado, G. Stancanelli (EFSA)
B. Van Goethem, F. Andriessen, K. Cernilogar, B. Gautrais, T. Bregeon, L. Terzi, A.-E. Füssel, K. Elliot, A. Ramirez Vela, E. Thévenard, M. Marini, C. Boesinger-Froideveaux, K. De Smet, L. Carrouée (SANTE)

Annex: Terms of Reference

Request for a scientific opinion on chronic wasting disease (CWD) in cervids

1. Background

Previous opinions on zoonotic aspects of CWD and surveillance

The former Scientific Steering Committee of the European Commission (SSC) adopted on 6-7 March 2003 an opinion on CWD and tissues that might carry a risk for human and animal feed chains[4]. In summary it highlighted that a risk of prion transmissions to humans consuming products of CWD affected cervids could not be excluded.

In its scientific opinion of 3 June 2004 on a surveillance programme for CWD in the EU[5], EFSA stressed "a potential risk to consumers if a TSE would be present in European cervids". EFSA further highlighted that "*it might be prudent considering appropriate measures to reduce such a risk, e.g. excluding tissues such as central nervous system (CNS) and lymphoid tissues from the human food chain, which would greatly reduce any potential risk for consumers. However, it is stressed that currently, no data regarding a risk of TSE infections from cervid products for humans are available*".

In its 2010 scientific opinion on possible associations between TSEs in animals and humans[6] , EFSA concluded regarding CWD that, although CWD agents have failed to induce disease in transgenic mice expressing human PrP, experimental transmission to certain non-human primate species has been reported. EFSA also mentioned ongoing experiments to assess the zoonotic potential of CWD strains in primate models.

The SSC Opinion of 6-7 March 2003 also recommended the instigation of a surveillance programme for TSE in cervids in the EU. As a result, the Commission asked EFSA for recommendations concerning such surveillance, and EFSA recommended in its opinion of June 2004 to initiate an EU-wide experimental screening, targeting at-risk groups of animals.

On that basis, a survey on CWD in the EU was launched by Commission Decision 2007/182/EC[7] and implemented between 2007 and 2010. In this framework, more than 13.000 samples were collected from 21 Member States and Norway, mainly from red deer and white-tailed deer (the survey also included 74 samples from reindeer), without any sample found positive to TSE. Therefore, EFSA concluded in 2010[8] that, while occurrences of cases of TSEs in cervids in the EU could not be excluded, especially in remote and presently unsampled geographical areas, there was no cervid TSE epidemic in the EU.

Current measures

The main provisions in the TSE Regulation[9] currently applicable to CWD based on the preceding scientific opinions can be summarised as follows:

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[4] http://ec.europa.eu/food/fs/sc/ssc/out323_en.pdf and http://ec.europa.eu/food/fs/sc/ssc/out324_en.pdf
[5] http://www.efsa.europa.eu/en/efsajournal/pub/70
[6] http://www.efsa.europa.eu/en/efsajournal/pub/1945
[7] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02007D0182-20080812&qid=1460726581882
[8] http://www.efsa.europa.eu/en/efsajournal/pub/1861
[9] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1464098080217&uri=CELEX:02001R0999-20160203

- passive surveillance is mandatory also for cervids, as "*any animal suspected of being infected by a TSE shall be either placed under an official movement restriction until the results of a clinical and epidemiological examination carried out by the competent authority are known, or killed for laboratory examination under official control*" (Article 12(1) of Regulation (EC) No 999/2001);
- on a voluntary basis, Member States may carry out additional TSE surveillance in cervids (Part III of Chapter A of Annex III to Regulation (EC) No 999/2001);
- all parts of the body of a cervid positive for TSE must be sent to disposal as category 1 materials in accordance with the Animal By-Products Regulation[10] (Article 13.1 (a) of Regulation (EC) No 999/2001);
- TSE positive cases in cervids must be notified to the Commission and the Member States (Article 11 of Regulation (EC) No 999/2001);
- in the EU, the feeding to cervids of proteins derived from animals is prohibited, with the exception of milk and milk products, eggs and egg products, hydrolysed proteins from non-ruminants or from ruminant hides and skins, gelatine and collagen from non-ruminants (Article 7 and Annex IV to Regulation (EC) No 999/2001);
- at import into the EU, an attestation is required for meat and meat products from wild and farmed cervids coming from the USA or Canada (Chapter F of Annex IX to Regulation (EC) No 999/2001), confirming that the products:
    - exclude offal and spinal cord,
    - are derived from animals tested for CWD with negative results, and
    - are derived from animals which do not come from a herd (for farmed animals) or a region (for wild animals) where CWD has been confirmed or officially suspected.

In addition, in accordance with Regulation (EU) No 206/2010[11], the import into the EU of live cervids from the USA and Canada is prohibited.

The conditions for imports into the EU of certain animal by-products derived from cervid materials can be summarised as follows:

- the import of unprocessed urine for hunting lures is prohibited when derived from farmed cervids. The import of processed urine from farmed animals is subject to treatment requirements laid down in the ABP Regulations. The import of urine from wild cervids is out of the scope of the EU ABP Regulations.
- the import of petfood containing cervid materials and of products derived from cervids (including PAP) and destined for the manufacturing of petfood is permitted provided that the requirements of the ABP Regulations are met. Raw materials must be derived from cervids slaughtered for human consumption.
- For hides and skins, blood and blood products, animal by-products intended for technical uses, rendered fats, gelatine and collagen, hydrolysed protein, di- and tri-calcium phosphate, fat derivatives, the principle followed in the ABP Regulations can be summarised as follows:

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[10] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1464098179131&uri=CELEX:02009R1069-20130101

[11] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1464098556720&uri=CELEX:32010R0206-20100426

- For raw products: imports are permitted only from third countries that are authorised for the import of fresh meat of cervids[12];
- For processed products derived from cervids: imports are permitted from all third countries listed in the Part 1 of Annex II to Regulation (EC) No 206/2010;
- For fully processed game trophies or hides and skins: imports are permitted from any third countries.

Import data

During the last 10 years, no meat of cervids was imported in EU or EEA countries from the USA. Import data from Canada are in Table 1 (extracted from TRACES).

Table 1

Year	Importing country	Amount (kg)
2006	-	0
2007	FR	368
	CH	2732
2008	FR	17634
	DE	75
2009	FR	2815
	DE	175
	CH	46198
2010	FR	693
	CH	48978
2011	FR	1351
	DE	40
	CH	42878
2012	FR	1357
	CH	1069
2013	BE	2613
	FR	2207
	CH	3363
2014	BE	334
	FR	801

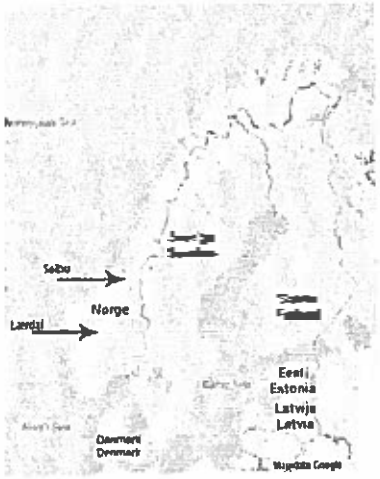
[12] As laid down in Part I of Annex II to Regulation (EC) No 206/2010: Argentina (parts of territory 1, 2, 3, 4), Australia, Botswana (parts 1, 2, 3 and 5), Canada, Chile, Greenland, Iceland, Namibia (part 1), New Caledonia, New Zealand, Russia (part 1), Swaziland (parts 1 and 2), USA, South Africa (part 1).

2015	FR	1261
Total	**BE**	**2947**
	FR	**28488**
	DE	**290**
	CH	**145218**
	All	**176942**

The Norwegian cases

Mid-March 2016, a sick animal was observed during an exercise of identification and registration of wild reindeers by the Norwegian Institute for Nature Research, in the locality of Laerdal (see map below). The animal subsequently died and its carcass was sent to the Norwegian Veterinary Institute for necropsy. The necropsy included testing for TSE. On 4 April 2016, the Norwegian NRL for TSEs confirmed the presence of TSE at ELISA, Western Blotting and Immunohistochemistry. On 7 April 2016, the European Reference laboratory (EURL) for TSE confirmed that the samples received were strongly positive for TSE and were presumptive for CWD. On 27 April 2016, the OIE Reference Laboratory for CWD in Canada (Canadian Food Inspection Agency) confirmed the CWD positive diagnostic, noting that the sample was consistent with CWD in farmed and wild cervids in Canada and reindeer experimentally infected with CWD by the oral route.

On 25 May 2016, a second case of CWD was confirmed in Norway, this time in a wild moose, in the locality of Selbu (see map below). The moose (*Alces alces*) was a young adult and pregnant female, which was killed due to abnormal behavior. The animal was dehydrated, cachectic and had increased urination. It was found in Selbu in South Norway. The Norwegian NRL for TSE performed ELISA and Western Blot, which were both positive.



Following these cases, Norway has expanded its surveillance of cervids for TSEs. Norway's objective is to test those cervids found sick or that died but were not slaughtered for human consumption. In addition, the Norwegian authorities encourage hunters in the two concerned regions to bring heads of animals killed during the hunting season to control points in view of TSE sampling and testing. Furthermore, Norway plans to start a surveillance programme for farmed reindeer, during the slaughter season which starts in September.

Additional information provided by Member States at request of the Commission

United Kingdom informed the Commission on an updated qualitative risk assessment on the risk that CWD is being introduced into Great Britain. The assessment is available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/514401/ara-chronic-wasting-disease.pdf .

The following information has been providing on surveillance after 2010:

Finland:

		2011	2012	2013	2014	2015
Farmed reindeer	Slaughtered					
Rangifer tarandus tarandus	Fallen stock	2	1	4	13	3
Forest reindeer	Found dead					
Rangifer tarandus fennicus						
Moose	Hunted					
Alces alces	Found dead	4	9	3	3	6
White tailed deer	Found dead	1	2	5	3	4
Odocoileus virginianus	Hunted					
Roe deer Capreolus capreolus	Found dead	1	2	2	2	
	slaughtered					
Fallow deer Dama dama	Found dead				1	1
Cervus elaphus	Slaughtered	1				
TOTAL		8	14	14	22	14

Found dead = sick, road kill or found dead

Denmark:

2011	3
2012	2
2013	0
2014	46
2015	25

Poland, Netherland, Lithuania, United Kingdom, Portugal: no TSE test in cervids in the period 2011-2015.

Norway:

Farmed deer				Wild deer					
Year	Fallow d.	Red d.	Reindeer	Moose	Red d.	Musk	Reindeer	Roe deer	Total
2010		2		13	3	4	2	17	41
2011		11	1	11	2		1	12	38
2012	3	6		5	4			3	21
2013	1	4		1				4	10
2014		2		5	2			1	10
2015		3		4	1		3	8	19

Latvia:

2011	0
2012	0
2013	2 (*Alces alces*)
2014	0
2015	2

Sweden: one clinical suspicion in a reindeer in the period 2011-2015

II. Terms of Reference

EFSA is requested to provide a scientific opinion on the following questions:

1) EFSA is asked to provide recommendations on surveillance of cervid populations at country level aimed at detecting CWD and/or estimating the prevalence of CWD in Norway, Sweden, Finland, Iceland, Estonia, Latvia and Poland, which are the EU and EEA countries with reindeer and/or moose populations, depending on the level of prevalence which is wished to be detected.

2) Has new evidence become available with regard to possible public health risks due to the occurrence of CWD in cervids since the publication of the 2010 joint EFSA/ECDC opinion? Does the natural exposure of consumers to cervid products originating from regions where CWD cases are detected represent a risk for public health?

3) EFSA is asked to recommend, if necessary, additional animal health risk-based measures to prevent the introduction of CWD into EU cervid populations and to prevent its spread within the EU?

4) Are the conclusions and recommendations in the EFSA opinion of June 2004 on diagnostic methods for CWD still valid? If not, an update should be provided.

5) EFSA is asked to update the conclusions of the 2010 EFSA opinion on the results of the EU survey on CWD in cervids, as regards the occurrence of CWD in the cervid population in the EU.

Electronically signed on 07/06/2016 15:00 (UTC+02) in accordance with article 4.2 (validity of electronic documents) of Commission Decision 2004/563