EUROPEAN UNION

Brussels
SANTE G2/MMK/ise (2017) 6739531

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 2017 meeting of the OIE Terrestrial Animal Health Standards Commission, for consideration at its next meeting in February 2018;
- the comments of the EU on the report of the September 2017 meeting of the OIE Aquatic Animal Health Standards Commission, for consideration at its next meeting in February 2018;
- 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 2017.

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

Yours sincerely,

Dr Olev Kalda CVO and OIE Delegate Estonia	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.

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Organisation Mondiale de la Santé Animale
World Organisation for Animal Health
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Annex 1

Original: English

September 2017

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

Paris, 18–29 September 2017

EU comment

The EU would like to commend the OIE for its work and thank in particular the Code Commission for having taken into consideration EU comments on the Terrestrial Code submitted previously.

A number of general comments on this report of the September 2017 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 once again its continued commitment to participate in the work of the OIE and to offer all technical support needed by the Code Commission and OIE ad hoc groups for future work on the Terrestrial Code.

The OIE Terrestrial Animal Health Standards Commission (the Code Commission) met at OIE Headquarters in Paris from 18–29 September 2017. The list of participants is attached as **Annex 1**.

EU comment

The EU notes that Annex 1 is not appended to the report.

Furthermore, we note that certain *ad hoc* group meeting reports are not appended to this report either, even though the report refers to them and in one case even encourages Member Countries review them (Items 6.2. and 6.3.).

The Code Commission thanked the following Member Countries for providing comments: Argentina, Australia, Brazil, Canada, Chile, China, Japan, Mexico, New Caledonia, New Zealand, Norway, Singapore, Switzerland, South Africa, Taipei China, Thailand, USA, the Member States of European Union (EU) and the African Union Interafrican Bureau for Animal Resources (AU-IBAR) on behalf of African Member Countries of the OIE. Comments were also received from the Global Alliance of Pet Food Associations (GAPFA), International Coalition for Animal Welfare (ICFAW) and the International Poultry Council (IPC).

The Code Commission reviewed Member Country comments, which were submitted on time and supported by a rationale, and amended relevant chapters of the OIE *Terrestrial Animal Health Code* (the *Terrestrial Code*) where appropriate. The amendments are presented in the usual manner by '<u>double underline</u>' and '~~strikethrough~~' and the chapters are annexed to this report. In Annexes 8, 10, 11, 12, 14, 15, 17, 18, 19, 20, 21, 22 and 23, amendments proposed at this meeting are highlighted with a coloured background to distinguish them from those proposed previously.

The Code Commission considered all Member Country comments supported by a rationale and documented its responses. However, because of the large volume of work, the Code Commission was not able to draft a detailed explanation of the reasons for accepting or not each of the comments received and focused its explanations on the major ones.

The Code Commission encourages Member Countries to refer to previous reports when preparing comments on

longstanding issues. The Code Commission also draws the attention of Member Countries to those instances where the Scientific Commission for Animal Diseases (the Scientific Commission), the Biological Standards Commission, a Working Group or an *ad hoc* Group has addressed specific Member Countries comments or questions and proposed answers or amendments. In such cases the rationale is described in the Scientific Commission's, Biological Standards Commission's, Working Group's or *ad hoc* Group's reports and Member Countries are encouraged to review its report together with those of the Scientific Commission, Biological Standards Commission, Working Groups and *ad hoc* Groups. These reports are readily available on the OIE website.

Member Countries should note that texts in **Part A** of this report are submitted for comments and proposed for adoption at the 86th General Session in May 2018. Texts in **Part B** are submitted for comments. The reports of meetings of *ad hoc* Groups and other related documents are attached for information in **Part C**.

Comments on **Parts A** and **B** of the report must reach OIE Headquarters **by 9 January 2018** for them to be considered at the February 2018 meeting of the Code Commission. Comments received after the due date will not be submitted to the Code Commission for its consideration.

Member Countries' attention is drawn to the one page questionnaire on Veterinary Paraprofessionals Competency in **Annex 36** and are requested to provide their responses to the OIE Headquarters **by 9 January 2018.**

All comments and responses to the questionnaire and related documents should be sent to the OIE Standards Department at: standards.dept@oie.int.

The Code Commission again strongly encourages Member Countries to participate in the development of the OIE's international standards by submitting comments on this report, and prepare to participate in the process of adoption at the General Session. Comments should be submitted as Word files rather than pdf files because pdf files are difficult to incorporate into the Code Commission's working documents. Comments should be submitted as specific proposed text changes, supported by a structured rationale or by published scientific references. Proposed deletions should be indicated in '~~strikethrough~~' and proposed additions with 'double underline'. Member Countries should not use the automatic 'track-changes' function provided by word processing software as such changes are lost in the process of collating Member Countries' submissions into the Code Commission's working documents. Member Countries are also requested **not** to reproduce the full text of a chapter as this makes it easy to miss comments while preparing the working documents.

EU comment

The EU in general notes that the annexes to this report do not reproduce the full text of chapters being amended, but only those articles to which changes are proposed. This makes the commenting process more cumbersome, as often other articles need to be taken into account, and cross-references may be necessary. Indeed, it is important for commenting member countries to consider the entire chapter so as to understand the implications of changes proposed to individual articles. This may lead to confusion and is not in line with OIE's commitment to transparency; therefore, the EU suggests reverting to the well-established practice of presenting the entire text of a chapter in the annexes of the Code Commission's report.

Item No.	Texts for Member Countries' comments and proposed for adoption in May 2018	Part A: Annex No.
4.1	User's guide	Annex 3
4.2	Criteria applied by the OIE for assessing the safety of commodities (Chapter 2.2.)	Annex 4
4.3	Chapter on prevention and control of *Salmonella* in commercial pig production systems (Chapter 6.13.)	Annex 5
4.7	Infection with lumpy skin disease virus (Articles 11.9.4., 11.9.5., 11.9.6. and 11.9.15.)	Annex 6
4.8	Infection with African swine fever virus (Articles 15.1.1bis., 15.1.2., and 15.1.22.)	Annex 7

5.1	Glossary	Annex 8
5.1′	Proposed deletion of Glossary definition of 'transparency' and consequential changes to chapter on import risk analysis (Articles 2.1.1 and 2.1.3.)	Annex 9
5.4	Zoning and compartmentalisation (Chapter 4.3.)	Annex 10
5.5	Collection and processing of *in vitro* derived embryos from livestock and equids (Chapter 4.8.)	Annex 11
5.6	New chapter on vaccination (Chapter 4.X.)	Annex 12
5.8	New chapter on introduction to recommendations for veterinary public health (Chapter 6.X.)	Annex 13
5.9	The role of the veterinary services in food safety (Chapter 6.1.)	Annex 14
5.10	Harmonisation of national antimicrobial resistance surveillance and monitoring programmes (Chapter 6.7.)	Annex 15
5.11	Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals (Articles 6.8.1. and 6.8.1bis.)	Annex 16
5.12	Introduction to the recommendations for animal welfare (Article 7.1.1.)	Annex 17
5.12′	New article on guiding principles for the use of animal-based measures (Article 7.1.X.)	Annex 18
5.13	Animal welfare and pig production systems (Chapter 7.X.)	Annex 19
5.14	Infection with bluetongue virus (Chapter 8.3.)	Annex 20
5.15	Infection with *Brucella abortus*, *B. melitensis* and *B. suis* (Article 8.4.10.)	Annex 21
5.17	Infection with rinderpest virus (Article 8.15.2.)	Annex 22
5.18	Infection with *Burkholderia mallei* (Glanders) (Chapter 12.10.)	Annex 23

Item No.	**Texts for Member Countries' comments**	**Part B: Annex No.**
5.2	Animal health surveillance (Chapter 1.4.) (including proposed new definition of 'early warning system')	Annex 24
5.7	New chapter on management of outbreaks of listed diseases (Chapter 4.Y.)	Annex 25
6.1	New chapter on introduction to recommendations for disease prevention and control (Chapter 4.Z.)	Annex 26
6.2	New chapter on the slaughter and killing of commercially farmed reptiles for their skins and meat (Chapter 7.Y.)	Annex 27
6.3	New chapter on animal welfare and laying hen production systems (Chapter 7.Z)	Annex 28
6.4	New chapter on infection with *Trypanosoma evansi* (non equine surra) (Chapter 8.X.)	Annex 29
6.5	Draft revised chapter on infection with *Trypanozoon* in equids (Chapter 12.3.)	Annex 30
6.6	Chapter 11.12. on infection with *Theileria annulata*, *T. orientalis* and *T. parva (bovidae)*	Annex 31
6.6′	New chapter on infection with *theileria lestoquardi*, *T. luwenshuni* and *T. uilenbergi* (small ruminants) (Chapter 14.X.)	Annex 32
7.2	Work programme	Annex 33
7.4.1	Questionnaire on Veterinary paraprofessionals competency	Annex 36
Item No.	**Texts for Member Countries' information**	**Part C: Annex No.**

5.13	Report of the *ad hoc* Group on Animal Welfare and Pig Production Systems (August 2017)	Annex 34
6.5	Report of the *ad hoc* Group on Equine Trypanosomoses (June 2016)	Annex 35
7.4.1	Report of the *ad hoc* Group on Veterinary Paraprofessionals (August 2017)	Annex 36

1. Meeting with the Director General

The Code Commission met with Dr Monique Eloit, Director General, on 25 September 2017. Dr Eloit welcomed the Code Commission members and thanked them for their support and commitment to achieving OIE objectives.

The Director General noted the procedure for nomination for election to the OIE Specialist Commissions and that the Evaluation Guide and the composition of the Evaluation Committee had been provided to the Council for its endorsement. The Director General also noted the ongoing work to develop standard operating procedures for the disease status recognition process and the revision of the related questionnaires.

The Director General also informed the Code Commission that the Standards Department had several new staff who would be working specifically on the Observatory on the implementation of standards project and while the project was still in the design phase, it would be useful in the future to gather feedback from the Members of the Code Commission on issues related to the implementation of OIE standards by OIE Member Countries. In response, the President noted that the Code Commission was also making efforts to improve the guidance provided in its reports, along with rationale supporting its proposed changes to chapters and that it would look forward to being engaged in further discussion on the Observatory.

2. Adoption of the agenda

The adopted agenda of the meeting is attached as **Annex 2**.

3. Cooperation with other Specialist Commissions

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

The President of the Code Commission met with the President of the Aquatic Animal Health Standards Commission (Aquatic Animals Commission). The Presidents discussed issues of mutual interest in the *Terrestrial* and *Aquatic Codes* to facilitate harmonisation of relevant chapters in the two *Code*s when under review by the respective Commissions.

Issues discussed included:

- Harmonisation of the User's Guides for the *Terrestrial* and *Aquatic Codes*, where appropriate.
- Development of draft Guidelines for the application of listing criteria.
- Proposed changes to the Glossary for definitions of 'biosecurity' and 'biosecurity plan' in the *Aquatic Code*, which are necessary for the new draft chapter on Biosecurity in Aquaculture Establishments in Section 4. The Code Commission expressed an interest in this work and the new chapter on biosecurity, noting that it would add this to its work programme.
- The President of the Code Commission noted that it was continuing with the proposed deletion of the definition of disease from the Glossary, but will retain the definitions for listed disease, emerging disease and notifiable disease.
- Revision to Chapter1.4. on surveillance in both *Codes*.
- Concerning the chapters on zoning and compartmentalisation, the President of the Aquatic Animals Commission noted its plan to develop a new chapter on the application of zoning. The President of the Code Commission noted that the general chapter of the *Terrestrial Code* on zoning and compartmentalisation was in the process of revision and would need first to be adopted before going further.

- Concerning the Code Commissions' proposed new chapter on management of outbreaks of listed diseases, the President of the Aquatic Animals Commission noted its plans for a different approach, which will include the development of two new chapters, one on emergency disease preparedness and one on outbreak disease management.

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

The meeting schedule did not allow for joint meetings with either the Biological or Scientific Commissions. However, there was consultation on several key items of work that was coordinated through the Secretariats.

The Scientific Commission provided advice to the Code Commission in response to Member Country comments on several chapters under consideration at this meeting, including both horizontal and listed disease-specific chapters. It also provided suggestions for proposed amendments on its own initiative.

The Biological Commission provided advice to the Code Commission in response to Member Country comments and in response to specific questions.

4 Examination of Member Country comments at the 85th General Session

EU comment

The EU queries whether its comments on the PRRS chapter, more specifically regarding the recommendations on semen, submitted in writing prior to and referred to orally during the OIE General Session of May 2017 (see extract of the Final Report of the General Session below), will be addressed by the Code Commission.

The EU comments of May 2017 are available here (see p. 129-138):

https://ec.europa.eu/food/sites/food/files/safety/docs/ia_standards_oie_eu_position_tahsc-report_201705.pdf

Extract from paragraph 266 of the Final Report of the 85th OIE General Session:

"[...]

Switzerland and Norway supported the adoption of the chapter but raised a concern that the testing regime in relation to semen collection centres is not sufficient to prevent the introduction of the virus through semen from countries that are not free, and asked the OIE to consider the article for semen in a future revision.

[...]

Denmark, speaking on behalf of the 28 Member States of the EU, emphasised that the ad hoc Group considered that meat should be safe when it is derived from pigs that have passed ante- and post-mortem inspection, and therefore fresh meat should be included in the safe commodities definition. Denmark also mentioned that no PRRS risk is associated with fresh meat and therefore should not create unjustified barriers to trade. Denmark also supported Norway and Switzerland's position.

[...]".

4.1. User's guide

The following Member Country made comments at the 85th General Session: Thailand .

During the adoption of the two new chapters on *Salmonella*, a Member Country requested that a sentence be added to the purpose and scope of both Chapters 6.12. and 6.13. that would read: 'This

chapter is not intended to be used to elaborate conditions for trade'. In response, the President noted that the issue would better be addressed in the User's Guide.

The Code Commission confirmed that these chapters are not intended to provide recommendations on trade measures but on the way Veterinary Services could eliminate or control food safety hazards. In response to the concerns of that Member Country, the Code Commission amended the paragraph relating to Chapter 6.4. in Section C point 4 of the User's guide to clarify that the chapters in Section 6 provide 'recommendations for some specific on-farm prevention and control plans for the unlisted foodborne pathogen *Salmonella* as part of the Veterinary Services mission to avoid, eliminate or control food safety hazards in animal production'.

At the request of the OIE Headquarters, the Code Commission added a new sentence to the introduction of the User's guide to indicate that all chapters now include the dates of first adoption and last revision. This will assist Member Countries to ensure that they use the latest version of the chapters when implementing them. In regards to the date of adoption and date of revision, the OIE Headquarters noted it had made every effort to ensure the accuracy of the information based on its historical records.

The revised User's guide is attached as **Annex 3** for comments and is proposed for adoption at the 86th General Session in May 2018.

EU comment

The EU in general supports the proposed changes to the User's guide. Comments are inserted in the text of Annex 3.

4.2. Criteria applied by the OIE for assessing the safety of commodities (Chapter 2.2.)

The following Member Countries made comments at the 85th General Session: the United States on behalf of the OIE Members of the Region of the Americas, Australia and AU-IBAR.

The Code Commission considered Member Countries comments on the text adopted in May 2017, especially about the inconsistency between Articles 2.2.1. and 2.2.2., the reference to GMP, and proposed amendments to Article 2.2.1.

In response to Member Countries comments on the use of the term 'should' throughout this chapter, the Code Commission recalled that the intent of the chapter is to describe criteria and the way in which these criteria are to be applied when drafting lists of safe commodities rather than recommendations on treatments. The Code Commission modified the fourth paragraph of Article 2.2.1. to clarify that its intention is to indicate that this is a prerequisite to applying the criteria mentioned in Article 2.2.2. The Code Commission also modified Article 2.2.2. to include some recommendations for those who use this chapter and, finally, a clear cross reference between Articles 2.2.1. and 2.2.2 was made. In conclusion, the Code Commission noted that the chapter on how to apply the criteria is directed at *ad hoc* Groups and the Specialist Commissions.

The revised Chapter 2.2. is attached as **Annex 4** for comments and is proposed for adoption at the 86th General Session in May 2018.

EU comment

The EU supports the proposed changes to this chapter.

4.3. Chapter on prevention and control of *Salmonella* in commercial pig production systems (Chapter 6.13.)

The following Member Countries made comments at the 85th General Session: Australia, Costa Rica on behalf of OIE Members of the Americas, Thailand and USA.

In examining a Member Country comment made during the 85th General Session indicating that infection with *Salmonella* in pigs is not an OIE listed disease, the Code Commission recalled that this is a public health issue and noted that these concerns had been addressed by the modification it proposed to the User's guide (see above).

In reference to Member Country's requests to clarify the use of the term "commercial" specifically to exclude backyard and family pigs in the chapter, the Code Commission reiterated its view that narrowing the scope of this chapter would have consequences for other chapters related to pigs and

that it was not appropriate. The Code Commission noted that the aim of this chapter is to solve problems in the production and commercialisation of meat for consumption. For the purposes of the chapter, the term 'commercial pig production systems' is intended to mean production of pigs and pig meat that are put on the market. Therefore, the Code Commission proposed to amend the definition as follows: '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 commercially traded pigs or pig meat.' The scope would hence be positively limited to the products that are commercially traded.

The revised Chapter 6.13. is attached as **Annex 5** for Member Country comments and is proposed for adoption at the 86th General Session in May 2018.

EU comment

The EU in general supports the proposed changes to this chapter. Comments are inserted in the text of Annex 5.

4.4. Welfare of working equids (Chapter 7.12.)

The following Member Countries made comments at the 85th General Session: Uruguay on behalf of the OIE Members of the Region of the Americas, Thailand and EU.

The Code Commission considered Member Country comments that were sent before, and expressed at, the General Session and the reiteration of a comment from the USA on Article 7.12.12.

In response to a Member Country's repeated request to include horses used in hippotherapy in the scope of this chapter, the Code Commission reiterated its previous advice that this category of animals is similar to horses that are used in leisure activities and sport and as such is out of the scope of the chapter. Working equids are those that are used primarily in traction and transportation, e.g. horse drawn carts and carriages.

In relation to a proposal from Member Countries to add 'sweating' to the indicators of heat stress, the Code Commission noted that 'sweating' per se is not an indicator. In regards to the reference provided by those Member Countries to support their proposal, it noted the reference cited was insufficient to enable it to verify the applicability of it. However, the Code Commission considered that excessive sweating could be an indicator of heat stress and proposed to add a criterion 'excessive sweating'.

The Code Commission discussed the comment made on behalf of the Americas during the 85th General Session to consider the deletion of an input-based measure on the recommendation on the maximum working hours for working equids. The Code Commission recalled that the President of the Code Commission had requested the Delegates of that Region to provide information to support this proposal, but as such information had not been submitted it could not make any modification to the article. The Code Commission requested the Headquarters to contact the Member Countries and request that they provide relevant scientific information to support their proposal. It also encouraged the Headquarters to look for relevant scientific information so the issue could be considered further at its next meeting.

The article will be reconsidered by the Code Commission in light of new information when it is provided.

4.5. Infection with *Mycobacterium tuberculosis* complex (Chapter 8.11.)

The following Member Country made comments at the 85th General Session: Australia.

In examining the Member Country comment challenging the scientific expertise and assessment in reference to the epidemiological link for animal-to-human or animal-to-animal transmission of *M. tuberculosis* infection, the Code Commission noted that establishing the public health burden of *M. tuberculosis* is obvious even if it is difficult to prove the actual transmission between animals and humans. It is completely reasonable to assume that whenever cattle are found to be a reservoir in a

country where humans are infected at the same time, assumptions are made that there is a link and it is appropriate to control the disease in animals.

However, the Code Commission considered that more analysis and discussion is needed with the Scientific and Biological Commissions on whether *M. tuberculosis* and *M. caprae* should be included in the OIE listed diseases. In this regard, the Code Commission requested the OIE Headquarters to seek expert advice in order to assess the two pathogenic agents (*M. caprae* and *M. tuberculosis*) against the OIE criteria for listing. The Code Commission noted that it is important that the scientific references used be cited when this assessment is undertaken and the information should be available for the Code, Scientific and Biological Commissions to consider at their meetings in February 2018.

EU comment

The EU notes that according to the paragraph above, the Code Commission considers that *M. caprae* and M. *tuberculosis* are currently not OIE listed diseases, and that expert advice should be sought in order to assess whether these two pathogens meet the listing criteria of Chapter 1.2.

Indeed, in Chapter 1.3., only "Bovine tuberculosis" is currently listed within the category of cattle diseases, and the OIE list was not amended in May 2017 when the new Chapter 8.11. entitled "Infection with *Mycobacterium tuberculosis* complex" was adopted.

This has created an obvious inconsistency between Chapter 8.11. and the OIE list of diseases that urgently needs to be addressed. Indeed, this results from the definition for the purposes of the Code in Chapter 8.11. of *M. tuberculosis* complex as including *M. caprae* and *M. tuberculosis* in conjunction with the case definition included in its Article 8.11.1. on the one hand and the OIE list of diseases of Chapter 1.3. that does not contain these two pathogens on the other.

It is thus unclear whether occurrence of infection with these two non-listed pathogens is notifiable according to Chapter 1.1., and in what species. The EU is of the opinion that this uncertainty needs to be solved without delay, at the next OIE General Session in May 2018, preferably by updating Chapter 1.3. accordingly.

In response to a former Member Country comment on herd freedom and surveillance in goats and camelids, the Code Commission agreed that existing scientific information shows that it would be possible to formulate a practicable system for determining herd or flock freedom. This would need a testing regime to be included in the *Terrestrial Manual*, but the Biological Standards Commission had indicated previously that there was currently not enough information available to do this. However, the Code Commission noted that there is a need for joint discussion on the complexity of the issue and that literature previously provided by a Member Country showed that the sensitivity and specificity of testing in goats and camelids is no worse than in cattle. The Code Commission urged the Headquarters to work with the Biological Standards Commission on the revision of the chapter of the *Manual* on tuberculosis and the possible inclusion of tests on camelids and goats so that surveillance and testing could be addressed in the Code.

The following scientific information was provided to the Code Commission:

- legislation supporting Argentina's National Plan for Eradication of Bovine Tuberculosis (Resolución SENASA 128/2012): http://servicios.infoleg.gob.ar/infolegInternet/anexos/195000-199999/195314/texact.htm

- A study of tuberculosis in goats in New Zealand considered the sensitivity of the tuberculin test to be 80%. Sanson R.L. (1998). Tuberculosis in goats. Surveillance. Vol.15, No.2; 7–8.
- A review article in the OIE's *Scientific and Technical Review* reports sensitivity of the tuberculin test in goats to be 100%, 38%, >95% and 87% in various studies. The same article

cites sensitivity of the Bovigam test in goats as 100%, 83.7% and 87.2%. These sensitivities are, with one exception, adequate for most purposes.

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

4.6. Infection with avian influenza viruses (Chapter 10.4.)

The following Member Countries made comments at the 85th General Session or submitted written comments to the OIE: Australia, Latvia on behalf of the OIE Members of the European Region, France on behalf of the EU, Thailand on behalf of ASEAN, and the International Poultry Council (IPC).

The Code Commission noted in the report of its February 2017 meeting that there is a need for further revision of this chapter to take into account the following:

– differences among Member Countries in terms of notification to the OIE,

– differing needs when responding to either low pathogenic AI (LPAI) or highly pathogenic AI (HPAI) outbreaks and when recovering free status,

– impacts of unjustified barriers to trade being implemented by some Member Countries, and

– need to include articles on safe commodities and to expand those on surveillance.

OIE Headquarters introduced the discussion paper that it had prepared in response to the request from the Code Commission at its February 2017 meeting. The paper noted that the AI chapter had been comprehensively revised and adopted by the World Assembly in May 2005. This revision was proposed in order to provide clear notification criteria, as well as definitions for free status, conditions for status recovery, and commodity-specific risk-based mitigating measures, which would provide safety when trading and encouraging transparent reporting. This new text was aimed at encouraging rapid and transparent reporting of AI by Member Countries, as well as giving clear recommendations on how to avoid unjustified trade disruptions resulting from these reports.

After considering concerns about problems in trade raised by Member Countries at the General Session in May 2017 and in correspondence, the paper notes that there are strong indications that this chapter has been ineffective in fulfilling its objectives in terms of disease control and resumption or continuation of trade. In addition, the chapter is unclear about the difference between health measures for low and highly pathogenic AI viruses and lacks sufficient detail to guide Member Countries in the implementation of zoning and compartmentalisation. To date, the disease continues to affect large parts of the world with high impacts, while the number of trade issues related to AI outbreaks remains relatively high compared to other diseases of concern. These issues appear to be related to non-implementation of existing OIE standards by some Member Countries, either because of disregard for their obligations or difficulties in abiding by standards that cannot be adapted easily to their situation.

In this regard, the Code Commission has received several requests from Member Countries to update the AI chapter to ensure that the requirements are still relevant to the most recent scientific findings. This revision is more important in today's environment because many countries worldwide are experiencing unprecedented HPAI events, which threaten animal health, public health, food security, agricultural productivity, farming community livelihoods and global trade, and the number of circulating subtypes are continually increasing.

The Code Commission thanked the OIE Headquarters for the paper and the high priority that had been given to this issue. It broadly agreed with the definition of the problems outlined in the discussion paper. The Code Commission focussed its discussion on the draft Terms of Reference for the proposed *ad hoc* Group and on its management and membership.

Given the breadth of the issues to be discussed, observers from the Code, Scientific and Biological Standards Commissions should be included in the *ad hoc* Group. Membership of the group needs to include a balance of representation to cover the broad range of issues including risk managers (e.g.

CVO), reference laboratory, OFFLU, industry and the Working Group on Wildlife. OIE Headquarters noted that it would aim to hold the first meeting before the end of the year so that the report could be considered by the Specialist Commissions in February 2018.

The Code Commission reviewed the draft Terms of Reference of the *ad hoc* Group and made several comments and proposals for further consideration by the OIE Headquarters.

The Code Commission further noted that a key point for the *ad hoc* Group was the need to review the virus dynamics of AI introduction via wild birds with respect to critical number of wild birds and presence of water bodies required for AI virus amplification. In addition, the *ad hoc* Group needs to propose effective biosecurity measures to be implemented by poultry farmers to prevent the introduction of AI virus from wild birds into poultry. The Code Commission stressed that another important task to be carried out by the *ad hoc* Group is to propose risk-mitigating measures for trading some commodities safely from countries or zones not free from AI.

OIE Headquarters noted that in line with its efforts to provide greater transparency to the work of *ad hoc* Groups it was intending to put Terms of Reference for these groups on its website along with the reports. The Terms of Reference for the revision of the chapter on avian influenza, together with the revised discussion paper will be put on its website in October 2017.

4.7. Infection with lumpy skin disease virus (Chapter 11.9.)

The following Member Countries made comments at the 85th General Session: EU.

The President of the Code Commission reminded the Delegates that this chapter had been adopted as a matter of urgency because of the crisis in Europe and the Middle East. Member Countries had raised a question concerning the inclusion of 'which are not a consequence of vaccination' in the definition of a case. The Code Commission agreed with the explanation provided by the Scientific Commission that currently it is not possible to differentiate vaccine-induced antibodies from those induced by natural infection. Furthermore, the presence of antibodies does not ensure complete protection. Consequently, the case definition was not modified.

In relation to the comment of a Member Country on inconsistencies between point 2) of Article 11.9.3. and Article 11.9.15., the Code Commission proposed to modify the text in Article 11.9.15. on the General principles of surveillance, to increase the clarity of the chapter with respect to clinical signs.

The Code Commission agreed with a Member Country proposal to modify Article 11.9.4. and proposed some additional modifications to improve the clarity of the text.

The Code Commission agreed with the proposal of a Member Country to delete the term 'domestic' throughout the chapter, as both *Bos indicus* and *Bos taurus* are domestic animals. In response to Member Countries noting that Article 11.9.5. did not explicitly exclude the importation of seropositive animals from a free country or zone, the Code Commission clarified that while there is prohibition on vaccination in a free country or zone, there is no prohibition on the importation of vaccinated animals into that free country. Article 11.9.6. states that when imported from an infected country, animals should be vaccinated.

The revised Articles 11.9.4., 11.9.5., 11.9.6. and 11.9.15. are attached as **Annex 6** for Member Country comments and are proposed for adoption at the 86th General Session in May 2018.

EU comment

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

4.8. Infection with African swine fever virus (Chapter 15.1.)

The following Member Countries made comments at the 85th General Session or submitted written comments to the OIE: Australia, China, Korea and USA.

The Code Commission considered the Member Country comments proposing a change to the definition of 'domestic pigs' (i.e. 'excluding backyard farms and family pig farms for own use') in Article 15.1.2. The Code Commission did not agree with the rationale for excluding backyard and

family pigs from the case definition because not only there is no clear distinction between the different types of production but also backyard operations play a significant role in the epidemiology of the disease. Backyard farms are a significant pathway for the infection of larger units. Indeed, backyard and family-farmed pigs and their products are commercialized locally and present a high risk to other domestic populations. That is one of the reasons why the chapter allows for the distinction of status of free compartments, which should be protected from the rest of the pigs by appropriate biosecurity. Regarding 'captive wild pigs', the Code Commission noted that in some regions, some wild pigs are kept and fed for the production of meat and should be considered 'captive wild' in accordance with the glossary definition. In that case, they should be considered together with domestic pig populations because of the risk they represent. In other regions, some wild pigs may be kept in large parks or ranches but are not fed or under direct human supervision and cannot be considered 'captive wild' in accordance with the glossary definition, but rather 'wild pigs'.

The President of the Code Commission recalled the discussion during the 85th General Session, in which Member Countries proposed to delete the last paragraph of Article 15.1.2. on safe trade of pig commodities despite the notification of cases in wildlife. The Code Commission agreed to delete the paragraph, since it is one of the purposes of the chapter that pig commodities can be safely traded from countries complying with the relevant provisions of the Code, even if they notify an infection with ASFV in wild or feral pigs or African wild suids.

Furthermore, the Code Commission proposed a new Article 15.1.1bis. on safe commodities, including canned meat and gelatine. In considering the inclusion of canned meat in the new article, the Code Commission referred to the Codex definition of canned food (CX/RCP-23/1979 Code of hygienic practice for low and acidified low acid canned foods), which means commercially sterile food in hermetically sealed containers. The Code Commission also considered these amendments responded to the question of another Member Country concerning the title of the point on safe commodities in other chapters.

The revised Articles 15.1.1bis., 15.1.2. and 15.1.22. are attached as **Annex 7** for Member Country comments and are proposed for adoption at the 86th General Session in May 2018.

EU comment

The EU cannot support the proposed changes to this chapter as presented. Important comments are inserted in the text of Annex 7 that should be taken into account.

5. Texts circulated for Member Country comments at the February 2017 Code Commission meeting

5.1. Glossary

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

The Code Commission considered Member Country comments and proposed the following amendments and observations on proposed changes to the Glossary.

Compartment – In line with the proposal to remove the term "disease" from the Glossary, the words "*infection* and *infestation*" were included in the definition. The Code Commission considered it was not necessary to include "defined by the Veterinary Authority" after the words "animal *subpopulation*" as it is the responsibility of industry to define the *subpopulation* while the *Veterinary Authority* approves its status. It did not agree with a proposal to delete the words "for the purpose of international trade or disease prevention and control in a country or zone", as, in fact, this was included at the request of Member Countries in order to convey the intention that compartments were not only for trade but also for disease prevention and control.

Containment zone – In response to a request to replace 'movement control, biosecurity and sanitary measures' with the term 'biocontainment measures' the Code Commission did not consider that it was appropriate or necessary to replace defined terms with 'biocontainment measures' which was used in a different context and is not defined in the *Code* or *Manual*.

Disease– In considering Member Country comments, the Code Commission agreed that the consequential changes as a result of the deletion of the definition of 'disease' required throughout the *Code* will be extensive. It noted that it would make relevant changes as it reviews chapters and,

where appropriate, either the term 'infection and infestation' would replace 'disease' or the term 'disease' would be retained and unitalicised. It agreed that consideration should be given to harmonising the *Aquatic Code* at the same time, and noted that the Presidents of the two Commissions had been discussing this for some time and that OIE Headquarters would look at how to manage this once the decision was taken to delete the definition. It further noted that the word 'disease' would not disappear from the *Code* entirely, and references to disease-specific chapters would be replaced with *listed disease*-specific chapters and that the definitions of *notifiable disease* and *emerging disease* would remain. In response to a proposal to include the term *infestation* within the definition of *infection*, it did not agree with the rationale provided as there are *Code* chapters that referred only to '*infestation* with', and the distinction is still relevant (see Item 5.2.).

EU comment

The EU thanks the Code Commission for addressing our previous comments. We note that also the Glossary definitions of "notifiable disease" and "emerging disease" will need to be amended as a consequence of deleting the definition of "disease".

Furthermore, the EU suggests working on the necessary amendments of Chapter 1.3., as these will be significant and important.

Finally, we suggest keeping the general term "disease free country or zone", as amending it to "free country or zone" could lead to confusion (i.e. it would be unclear what the country or zone is free from).

Free zone – The Code Commission did not consider it was necessary to include 'defined by the veterinary authority', since it is already included in the definition of zone.

Infected zone – The Code Commission included the words 'defined as such' in order to avoid confusion with provisions to determine the health status of a *zone* in other relevant chapters of the *Code*, especially some listed disease-specific chapters.

Protection zone – The Code Commission noted that in the report of its February 2017 meeting (Annex 21) two definitions for protection zone had mistakenly been included; the second option presented was the proposed amended definition. The Code Commission agreed to change 'adjacent' to 'neighbouring' as it more accurately reflects how the *Code* deals with *protection zones* and their wider application. In response to a proposal to replace 'pathogenic agent' with '*infection* and *infestation*' the Code Commission disagreed as 'the entry' refers to the entry of a pathogenic agent. With respect to a proposal to replace *biosecurity* with 'biocontainment', the Code Commission considered that it was not appropriate or necessary to replace defined terms that are relevant and well understood. Further, with respect to the request to include 'free' before 'zone', the Code Commission agreed with the Scientific Commission that this was not appropriate, as '*protection zone*' does not, by definition, necessarily mean be free.

EU comment

The EU thanks the OIE for having accepted its previous comment to replace "adjacent" with "neighbouring". As indicated by the Code Commission also elsewhere in this report, we support the use of the term "neighbouring" throughout the Code (e.g. in the chapter on Bluetongue), and would suggest these editorial amendments be systematically made once the above chapter is adopted by the World Assembly.

Vaccination – The Code Commission agreed to replace 'several' with 'more' for consistency with the definition of *compartment* and because 'one or more' is more appropriate, as 'several' means two or more.

Zone/~~region~~ – The Code Commission noted that the proposal to delete the words 'population of' and to only refer to 'animal subpopulations' changed the intent of the *Code* in that a *zone*, which is based on geographical data, could include a whole animal population in a country or only a subpopulation.

Transparency – The Code Commission noted there were no comments on the proposed deletion of the definition of 'transparency' in the glossary, and that relevant content of this definition would be included in Chapter 2.1. (see below).

The revised definitions are attached in **Annex 8** for Member Country comments and are proposed for adoption at the 86th General Session in May 2018.

EU comment

The EU thanks the OIE and in general supports the proposed changes to the Glossary. Comments are inserted in the text of Annex 8.

NB: With respect to new or revised definitions being proposed because of a new or revised chapter, these definitions will be included with the chapter in the relevant annex. This will assist Member Countries in their review of the chapters and preparation of their comments.

Revision of Article 2.1.1. (Consequence of the deletion of the definition of "transparency")

At its February 2017 meeting, the Code Commission noted in its review of the Glossary that "transparency" appears in one chapter only, Chapter 2.1. Its placement in the Glossary arose because originally risk analysis was addressed in two chapters. These were later merged into a single chapter, but "transparency" remained in the Glossary. Noting this, the Code Commission removed the italics from the word "transparency" in Article 2.1.1., and consequently revised point 4) of Article 2.1.3., inserting the sentence defining transparency that was deleted from the Glossary, to read:

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

During this meeting, the Code Commission re-examined the proposal and considered that the amendments proposed to Article 2.1.3. were clear and there was no need for further amendment. It recalled that it had included the first sentence only because the meaning of the second sentence is clearly conveyed in the rest of the article.

The revised Articles 2.1.1. and 2.1.3. are attached in **Annex 9** for Member Country comments and are proposed for adoption at the 86th General Session in May 2018.

EU comment

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

5.2. Animal health surveillance (Chapter 1.4.) and review of the *ad hoc* Group report (June 2017)

The Code Commission commended the *ad hoc* Group for its work on revising the chapter. Regarding the *ad hoc* Group proposal to revise the definition of 'infection' to include 'infestation', the Code Commission did not agree as not only this would involve a large body of work to update all the related chapters, but also the International Epidemiological Association[1] dictionary contained separate definitions for these terms. The Code Commission agreed with the proposal of the *ad hoc* Group to replace the term 'early detection system' with 'early warning system' (Article 1.4.8.) and amended the definition in the Glossary accordingly. For consistency with the approach taken in other chapters the term 'disease' was replaced with '*infection* and *infestation*' where appropriate, the term 'disease-specific chapters' was revised to read '*listed* disease-specific chapters' and 'non-infected' was changed to 'uninfected' as this is correct English.

[1] http://irea.ir/files/site1/pages/dictionary.pdf

The Code Commission proceeded to review the chapter article by article and proposed the following amendments:

Article 1.4.3. Surveillance systems

Point 1, b): The Code Commission included timing in the subheading for clarity, added a new sentence and bullets on the factors to be taken into consideration when determining the timing and duration of surveillance. As it is not only the epidemiology of the disease which determines the surveillance activities but it is also important to identify how and when samples should be taken, and the frequency of collection when designing the system.

Point 1, d): Epidemiological units – The *ad hoc* Group considered the definition provided in the Glossary, which considers only a group of animals as epidemiological units. Whilst the Group agreed that, most often, epidemiological units consist of a group of animals, it pointed out that, in some circumstances, epidemiological units may consist of individual animals (one animal holding, wildlife, etc.). The Code Commission considered the proposal of the *ad hoc* Group, which was supported by the Scientific Commission, and agreed to consider the possibility of revising the definition at its February 2018 meeting.

EU comment

The EU supports the need to update the Glossary definition of "epidemiological unit" to include the possibility that it can consist of just one animal. This is relevant for example in the case of horses. Reference is made to the EU comment in Annex 23 (chapter on glanders).

Article 1.4.4. Surveillance methods – the Code Commission proposed several editorial amendments to this article to improve the clarity and to ensure consistency with other chapters of the *Code*, including the deletion of the term 'animal identification system', as traceability goes beyond the definition used in the Glossary, and replacing 'likelihood and consequence of disease' with 'risk of introduction of the *infection*', since 'risk' is the result of the likelihood and consequences of a hazard.

Article 1.4.5. Considerations in survey design – the Code Commission proposed amendments to clarify the language and to better define the considerations in the design of surveys.

Article 1.4.6. Surveillance to demonstrate freedom from a disease or infection – the Code Commission included a new point to address requirements to declare a compartment free from infection or infestation and proposed changes to improve clarity and for consistency with the Glossary and other chapters of the *Code*.

Since the proposed revised chapter is significantly different from the current chapter, the proposed revision is provided as clean text.

The draft revised Chapter 1.4. and draft revised definition of 'early warning system' are attached as **Annex 24** and are proposed for Member Country comments.

EU comment

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

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

Comments were received from Australia, Chile, New Caledonia, New Zealand, USA and EU.

The OIE Headquarters advised the Code Commission that the Scientific Commission had considered and addressed the Member Country comments on the questionnaires related to official recognition at its recent meeting. However, although all Member Countries comments had been addressed by the Scientific Commission, the Code Commission, after having reviewed one of them, considered that they still required some significant editing to improve the context and add clarity to the language. Given the size of this task, and taking into consideration the comments from Member Countries at the General Session, the Code Commission decided it was not possible to review all the

questionnaires thoroughly at this meeting. The OIE Headquarters proposed that it would undertake further work between now and the Scientific and Code Commissions' meetings of February 2018, with the assistance of Professor MacDiarmid. The Code Commission could then circulate them for further Member Country comments after its February meeting with the possibility of proposing them for adoption in May 2018. The Code Commission also requested that the OIE prepare the questionnaires as a separate chapter for each disease because, in its opinion, Chapter 1.6. should only cover the procedures and that this would facilitate any future revisions of the questionnaires in a more efficient and effective manner.

EU comment

The EU recalls its previous comment, especially as regards the need to review the changes proposed based on a track changes version of the questionnaires. Linked to that, the timeline proposed, with possible adoption of the questionnaires in May 2018, seems overly ambitious.

5.4. Zoning and compartmentalisation (Chapter 4.3.)

Comments were received from Australia, Canada, Chile, Mexico, New Caledonia, New Zealand, South Africa and EU.

The Code Commission noted the general comment of a Member Country in support of the chapter and the expanded concept of a containment zone. In regards to another Member Country comment in relation to the definitions of 'free zone', 'infected zone' and 'protection zone' in the chapter, it noted these terms in the chapter and in the Glossary would be aligned and adopted at the same time. With respect to the use of 'disease, infection and infestation', 'cases' and 'outbreaks', the Code Commission noted it would make appropriate amendments to harmonise their use throughout the *Code*.

Article 4.3.1. Introduction

In response to a Member Country comment on paragraph 8 and proposals to make the text clearer, the Code Commission considered that there was no need to include reference to zones being defined on a geographical basis as this was adequately covered in the rest of the chapter. It proposed minor amendments to improve the readability.

Article 4.3.2. General considerations

In responding to Member Country comments, the Code Commission proposed to add reference to movement control and official control programmes in the first paragraph and where appropriate vaccination, treatment and protection against vectors in the fourth paragraph. In response to a Member Country comment on the last paragraph on certification, the Code Commission agreed with the opinion of the Scientific Commission that certification may not always be required, although some form of paperwork would generally be required, so proposed to add 'when necessary' to clarify this point. It also added reference to vaccination in the list of systems to be audited.

EU comment

The EU notes that despite being mentioned in the paragraph above, reference to movement control was not added in the first paragraph of Article 4.3.2. (See also EU comments in Annex 5).

Article 4.3.3. Principles for defining and establishing a zone or compartment

In responding to Member Countries comments on the legal boundaries in point 1, the Code Commission disagreed with a proposal to replace 'legal' with 'administrative' as this was inconsistent with the language used in other parts of the *Code* and that in its view 'administrative boundaries' would be covered by 'legal boundaries'. In response to the same Member Countries comments on point 4) on the need to include the concept of movement controls, the Code Commission agreed with the opinion of the Scientific Commission that individual animal identification is not compulsory and that movement control is already included in the text (as well as

in point 3)). The Code Commission amended the point by deleting 'animal' and inserting 'commodities' for consistency with the first sentence and because the definition of commodity in the Glossary includes live animals. In responding to a proposal to include records of cleansing and disinfection in point 5) the Code Commission noted this was covered by 'and any other criteria' so was considered unnecessary and reminded the Member Countries that 'cleaning' is covered in the definition of 'disinfection'.

The Code Commission proposed other editorial amendments for consistency with other chapters in the *Code* including deleting 'disease' where it appears before 'risk' as disease is included in the definition of risk in the Glossary.

Article 4.3.4. Free zone

The Code Commission agreed with the opinion of the Scientific Commission in response to a Member Country proposal to include vector surveillance in the second paragraph. The Commissions agreed that the presence of competent vector is a factor to take into consideration in surveillance and that the absence of the competent vector may be evidence of the absence of the transmission of the disease.

Article 4.3.5. Infected zone

The Code Commission noted the opinion of the Scientific Commission about the definition of infected zone and noted it had proposed amendments to the definition in the Glossary, which were also included in this article. The Code Commission made other editorial amendments for consistency with other chapters in the *Code* including deleting 'disease' and replacing it with 'infection or infestation' as appropriate.

Article 4.3.6. Protection zone

The Code Commission considered the comments of Member Countries and clarified that because of an oversight there were two proposals of definition included in the Glossary in its February 2017 report and that the first proposal for the definition should not have been included. It disagreed with a comment stating that the establishment of a protection zone does not guarantee that the introduction of the pathogenic agent is prevented. In response to a request to delete the second 'vehicles' before 'for transportation' in point 4, the Code Commission noted that the definition of *vehicles/vessels* contained in the Glossary specifically referenced live animals and did not include commodities, and it amended the point to read 'used for transport' to clarify the intent of this point. The Code Commission further noted that any time the status of the protection zone changes, the status should be determined in accordance with the relevant listed disease-specific chapters.

The Code Commission considered the proposal from the Scientific Commission to include provisions in the *Code* to enable countries to establish a temporary preventive zone, as a containment zone, in response to a sudden increased risk. The two main purposes are to avoid trade barriers for those countries that may decide to implement vaccination to manage that risk, while retaining their status as free countries or zones and to protect the status of the rest of the free country or zone in case of introduction of a pathogenic agent. The Code Commission had a broad discussion, including with the OIE Headquarters Status Department, on the concept of « temporary preventive » zone and agreed on the need to include the concept within the article on protection zone. It considered this could be addressed by inserting new paragraphs at the end of the article. The new paragraphs provide for the establishment of a temporary *protection zone* in the event of an emergency, such as a sudden increased *risk* to a free country or *zone*. A paragraph was included in order to clarify that in such a situation, measures implemented in a *protection zone* established within a free country or *zone* will not affect the status of the rest of the free country or *zone*. However, some of the measures, such as *vaccination*, may make it necessary to distinguish the status of the *protection zone* from the rest of the country or *zone*.

The Code Commission noted that, by definition, temporary implied for a limited period of time. Therefore, it included a paragraph to clarify that a temporary protection zone should be established for a defined period, and that at the end of that period either it has to be permanently distinguished from the rest of the country or zone or it has to be disestablished.

It also wanted to ensure that Member Countries were clear in their understanding of the consequences of a case of an infection or infestation being detected in the temporary *protection zone*. It added a further paragraph to clarify that providing the zone was established at least two incubation periods before the occurrence this would not affect the status of the rest of the country or zone. It further clarified, without it being needed in the article, that should a case occur before two incubation periods have lapsed since the establishment of the zone, the status of the country or zone would be suspended until that zone becomes a containment zone.

Article 4.3.7. Containment zone

In examining Member Country comments on this article, the Code Commission noted, in agreement with the Scientific Commission, that if sufficiently justified, it may be possible to have more than one containment zone provided that the outbreaks in different containment zones are not epidemiologically linked. Hence, the Code Commission reiterated its February 2017 report explanation that there is a need for a reference to 'all epidemiologically linked' outbreaks being in one containment zone. The Code Commission further agreed with the comment that it may not always be possible to identify the definitive epidemiological link and for it to be the main criteria in defining the number of containment zones. The design of the containment zone or zones depends on the Veterinary Services' strategy to manage outbreaks while facilitating safe trade. The containment zones for diseases with official status must be recognised by the Scientific Commission, and countries should provide the OIE with evidence to justify the establishment and the maintenance of the zone. For other diseases, countries should provide evidence to their trading partners.

The Code Commission considered Member Country comments on periods needed for the effective establishment of a containment zone, and noted that listed disease-specific chapters refer to two incubation periods. It agreed with the Scientific Commission that point b) of this article allows countries to recover free status outside of the containment zone promptly despite continuous outbreaks in the containment zone. In this situation a country should demonstrate that the protection zone around the containment zone remains free despite the event that triggered the creation of the containment zone. Two incubation periods would be needed to ensure time for appropriate implementation of measures, such as movement control between the zone where outbreaks are occurring and the protection zone, are effective. The Code Commission also modified the point to clarify that the period begun from the disposal of the last detected case.

Article 4.3.8. Bilateral recognition by trading countries:

In examining Member Country comments on this article, the Code Commission noted that editorial amendments proposed to align the text with the SPS Agreement were unnecessary and reiterated its previous advice that the *Code* does not paraphrase articles of the SPS Agreement. It further noted that in respect to the need to demonstrate that an importing country's requirements were being met, this was also not appropriate as the chapter was about the implementation of zoning and compartmentalisation and not meeting importing country requirements.

The Code Commission, in concluding its examination of this chapter, noted that its adoption in May 2018 would allow completion of work on listed disease-specific chapters that are dependent on the acceptance by Member Countries of the concepts outlined in this chapter.

The revised draft Chapter 4.3. is attached as **Annex 10** for Member Country comments and is proposed for adoption at the 86th General Session in May 2018.

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 10.

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

Comments were received from Chile, New Caledonia, New Zealand, Switzerland, USA and EU.

The Code Commission noted comments in support of the proposed revised chapter. In examining Member Country comments, it proposed the following amendments to the chapter.

Article 4.8.3. Conditions applicable to the processing laboratories

The Code Commission added a new point to include the need for laboratories to use appropriate facilities to handle and process embryos for export. The justification for the inclusion of the additional requirements was provided by the OIE Collaborating Centre (and references provided by the Member Country) and in line with the recommendations in the *Manual of the International Embryo Transfer Society* (IETS).

Article 4.8.4. Conditions applicable to donor animals – The Code Commission agreed with a proposal to replace 'Veterinary Authority' with 'Veterinary Services' for consistency with the rest of the chapter. It noted the concerns expressed about the batch collection and agreed this should be addressed in future revisions of the chapter.

The Code Commission noted that it had requested advice from the OIE Collaborating Centre on whether the list of diseases for donor animals should be reviewed in point 2 of this article. In response, the OIE Collaborating Centre expressed the opinion that the individual status of the donor, whenever it can be ascertained, should take priority over the status of the herd or flock of origin. The Code Commission expressed its appreciation for the advice provided by the Collaborating Centre, noting in particular that the specialised expertise provided in the Manual of the IETS should be the reference for this chapter. It further noted the cross reference with Article 4.7.4. at the beginning of the article, which provides conditions for donors. This point will be discussed again in the February meeting when looking at the issue of the batch collection.

Article 4.8.5. Optional tests and treatments

In response to Member Countries comments, and in accordance with the scientific justification provided in chapter 5 of the Manual of the IETS, the Code Commission added a new point 4 to read 'a pool of the last three washes from the 10 washes performed on the embryos.' The Code Commission did not agree with the proposal to include reference to 'in the case of livestock' in point 1) cross-referencing to Chapter 4.5. and 4.6. as the words 'as appropriate' were clear enough to avoid any confusion as to which species were included.

Article 4.8.7. Conditions applicable to the storage and transport of oocytes and embryos

In considering a Member Country comment on point 2) b), the Code Commission agreed there was a need for further clarity and amended the point to indicate that the liquid nitrogen should not have been used previously in order to avoid cross contamination of the oocytes and embryos during storage.

The revised draft Chapter 4.8.is attached as **Annex 11** for Member Country comments and is proposed for adoption at the 86th General Session in May 2018.

EU comment

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

5.6. New chapter on vaccination (Chapter 4.X.)

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

The Code Commission noted that the comments of Member Countries indicated there was a lot of support for the content of the chapter. In addition to this chapter on vaccination programmes, a Member Country recommended the development of recommendations for the approval of veterinary medicines, such as vaccines to ensure they are effective and safe to use in a disease control programme. In response to this question, the Biological Standards Commission advised that the recommendations in the *Terrestrial Manual* cover diagnostics and vaccines but not veterinary

medicines. Chapter 1.1.8. of the *Terrestrial Manual* gives comprehensive guidelines on the manufacture of vaccines, and Chapter 3.7.2. gives minimum requirements for the production and quality control of vaccines. While the Biological Standards Commission recognises that this does not cover the scope of veterinary medicines, its mandate does not include approval of these products. It further noted that the question of expanding the mandate of the Biological Standards Commission is one for Member Countries. On the other hand, the Code Commission noted that there are OIE Standards on the use of veterinary antimicrobials in the Terrestrial Code (Chapters 6.7. to 6.10.) and the Aquatic Code (6.1. to 6.5.), and there are OIE Standards on the organisation of the control of veterinary medicines in Chapters 3.2. and 3.4. (Article 3.4.11.). Moreover, the OIE has an agreement with the VICH, referenced in Chapter 6.9.: 'Member Countries are encouraged to apply the existing guidelines established by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH).'

EU comment

With reference to the discussion in the paragraph above, the EU is of the opinion that the approval of veterinary products, including vaccines, is not only beyond the mandate of the OIE but also far beyond its technical and human resource capacities.

In response to a proposal from the same Member Country to replace the phrase 'marketing authorisation' with 'relevant approvals' throughout the chapter, the Code Commission agreed with the proposal of the Biological Standards Commission to refer to 'relevant regulatory approvals' because some countries may not use the term 'marketing authorisation' when approving vaccines according to national legislation. The term 'marketing authorisation' has been replaced with 'relevant regulatory approvals' throughout the chapter.

EU comment

The EU supports the proposal above. Indeed, as this is a recurring issue not only relevant for this Code chapter, we would encourage the OIE to use the term "relevant regulatory approvals" throughout the Code and also the Manual.

The Code Commission reviewed the draft chapter and in response to Member Country comments proposed some additional amendments.

Article 4.X.1 Objective and introduction

In response to a Member Country proposal to only reference vaccination carried out as part of an official control programme, the Code Commission did not agree to narrow the scope, as the objective is to provide guidance for all types of vaccination control programmes, not just those under official control. Further, in respect to the proposal by the same Member Country to include reference to infestations, the Code Commission noted that vaccination against infestations is not yet available. In response to another proposal to replace 'implementation' with 'use' the Code Commission made the proposed change as the guidance is broader than implementation. In point 4, 'and quality control' was added for clarity.

Article 4.X.2 Definitions

Vaccination programme

The Code Commission agreed with a proposal to include 'prevention or' to harmonise the text with Article 4.X.1. and to clarify that the definition of vaccination programme includes both disease prevention and control.

Emergency vaccination

While recognising that a clear timeline for vaccination is desirable, the Code Commission agreed with the Scientific Commission that it was not always possible to estimate the time to end an emergency vaccination programme and therefore did not accept the proposal to include 'with a defined start and end date' in the definition.

In response to a proposal from a Member Country to include a new definition of vaccination campaign, the Code Commission concurred with the view of the Scientific Commission and the *ad hoc* Group that had extensively discussed the terminology at its first meeting. The *ad hoc* Group considered the draft definition and emphasised that the vaccination programme should involve a structured plan to apply vaccines with the specific purpose of disease control or eradication. The *ad hoc* Group did not consider it necessary to provide a definition for 'vaccination campaign' as it is considered part of a vaccination programme.

Article 4.X.3. Vaccination programmes

The Code Commission replaced disease with *infection* where appropriate throughout the chapter.

In the chapeau, in response to a Member Country comment, the Code Commission proposed adding a new point to clarify the need for close collaboration with other public health authorities when developing vaccination programmes against zoonoses.

Point 1). The Code Commission proposed to replace 'adjacent' with 'neighbouring' as the term was more appropriate to the intent of the chapter and also more generally throughout the *Code*. In regards to the sentence 'prevent the introduction of a pathogenic agent from an infected adjacent country or zone,' and a proposal from a Member Country to delete this reference, the Code Commission disagreed in principle with the rationale that vaccination by itself does not prevent the introduction of an infection. If successful, vaccination can indeed prevent introduction, with PPR being a good example of vaccination preventing infection.

Point 2) a). The Code Commission proposed deleting 'disease' for consistency with editorial amendments being proposed to other chapters.

Point 2) b). In response to a Member Country proposal to include reference to emergency vaccination that is applied to boost immunity, the Code Commission agreed that this is the case and proposed replacing 'is applied' with 'revaccination' as it was a more appropriate term in this context.

Point 2) d). In response to a Member Country comment, the Code Commission amended the point to read 'introduction of a pathogenic agent or emergence of a disease' for clarity, as the introduction of a pathogenic agent and emergence of disease are different concepts.

Article 4.X.4. Launching a vaccination programme

Point 3). In response to the same Member Country comment on point 2) b), the Code Commission proposed to add reference to the introduction of a pathogenic agent and emergence of disease, for clarity and consistency with point 2) d).

In response to a Member Country comment on the inclusion of reference to the need for an animal identification system to differentiate vaccinated from unvaccinated subpopulations, the Code Commission agreed to include a new point 7 bis).

Point 8). The Code Commission considered the proposal of a Member Country to add a new point on the safety and efficacy of available vaccines and reworded point 8) by deleting 'an appropriate' and replacing it with 'safe and effective' and placing the reference to 'availability of human, financial, and material resources' into a new point 8 bis).

Article 4.X.5. Vaccination strategies

Ring vaccination - In response to a Member Country comment that the inclusion of how to conduct the process of ring vaccination was too prescriptive, the Code Commission agreed with the Scientific Commission that the strategy to follow when implementing ring vaccination could vary depending on the circumstances and deleted the last sentence.

Barrier vaccination – The Code Commission replaced 'disease' with 'infection' for consistency.

Article 4.X.6. Choice of vaccine

In responding to a proposal to include reference to the availability of diagnostic tests to monitor for vaccine-induced antibodies, the Code Commission and the Scientific Commission disagreed with the Member Country and considered that the point was not relevant, as the availability of a diagnostic test does not influence the availability or cost of the vaccine and, in any case, this was covered in point b) biological characteristics. The Code Commission also proposed to change 'antibodies' to 'immunity'.

In response to a Member Country comment on the need to include reference to 'stability in ambient conditions' under point 2, the Code Commission and the Scientific Commission noted this was covered by thermostability under point b) biological characteristics.

The Code Commission agreed with a Member Country on the need to include specific reference to 'age of animals' in point b) biological characteristics – 'suitability of vaccine formulation for species in the target population', as the age of the animal could be an important factor in determining the appropriate dose depending on the formulation of the vaccine.

In response to a request to include 'target species', the Code Commission and the Scientific Commission both agreed that this was adequately covered in point c) side effects, and that there was no justification to include it in point b) biological characteristics.

Point c) side effects, in responding to a Member Country comment proposing the addition of three new points to cover reversion to virulence, risk of vaccine pressure selecting new resistant strains of the disease agent, and risk of vaccination masking future outbreaks, the Code Commission agreed with the Scientific Commission that reversion to virulence is covered by the added text and that the other two points are more related to the vaccination programme, and not directly linked to the vaccine characteristics. To address the Member Country concerns, the Code Commission proposed to amend the point on transmission of live strains by splitting it and creating a new point on reversion of attenuated strains to virulence.

Article 4.X.7. Other critical elements of a vaccination programme

Legal basis – The Code Commission noted in response to a question from a Member Country that the adverse effects referred to were those experienced by the animals, rather than humans. The Code Commission considered that the inclusion of a specific reference to 'accidental damage caused by vaccination' was unnecessary, as this would be covered by 'adverse effects'. In regards to other Member Country comments about the legal basis for the vaccination programme, the Code Commission revised the text to take these into account and for clarity.

Stakeholder involvement – In response to Member Country comments on the need for clarity in what is meant by good governance by the Veterinary Services, the Code Commission reworded the text to show that it is the responsibility of the Veterinary Services to demonstrate good governance of the *vaccination* programme.

Timing of vaccination campaigns

The Code Commission proposed several editorial amendments to this point to address a Member Country comment in relation to a need for a definition of vaccination campaign and other Member Country comments in relation to storage facilities and animal identification systems.

Auditing of vaccination campaigns

The Code Commission proposed several editorial amendments to this point to address Member Country comments in relation to the need to increase the flexibility in the way audit is applied and the timing and duration of the campaign.

Article 4.X.8. Logistics of vaccination

For consistency, the Code Commission replaced 'marketing authorisation' with 'relevant regulatory approval' and in response to Member Country comments added a new point 1 bis) Procurement of equipment and consumables, to cover the procurement of all necessary equipment and consumables which are also an important part of the logistics of vaccination. Subsequently it also added reference to other consumables such as ampoules, vials and bottles under 'disposition'.

In response to a Member Country comment on the need to ensure the safety and welfare of vaccination teams, the Code Commission considered this was already covered in point g); however, for clarity it added a point g bis) specifically referencing safety of the vaccination teams distinct from the safety and welfare of the animals.

Point 5 animal identification, the Code Commission agreed with a proposal to replace 'carried out' with 'implemented' as it was clearer.

Article 4.X.9. Evaluation and monitoring of a vaccination programme

In examining Member Country comments on this article, the Code Commission agreed with the Scientific Commission that monitoring and evaluation should not only be applied to systematic vaccination but also to emergency vaccination, that the term 'side effects' was broad and includes adverse reactions and that the reduction of clinical signs is covered by 'reduction of the impact' covered in point 4.

Article 4.X.10. Exit strategy of a vaccination programme

In considering Member Country comments, the Code Commission proposed several editorial amendments for consistency with changes proposed to previous articles including adding reference to '*pathogenic agent'*.

Article 4.X.11. Impact on disease status and management of vaccinated animals

In response to a Member Country comment proposing to include reference to 'absence of cases needing to be accurately demonstrated through documented surveillance' the Code Commission agreed with the Scientific Commission that this is a default requirement in the listed disease-specific chapters of the *Code* and that surveillance in accordance with Chapter 1.4. should be implemented. Therefore, including a reference here would be a duplication of that guidance.

The revised draft Chapter 4.X. is attached as **Annex 12** for Member Country comments and is proposed for adoption at the 86th General Session in May 2018.

EU comment

The EU thanks the OIE and in general supports this new chapter. Comments are inserted in the text of Annex 12.

5.7. New chapter on official control of emerging and listed disease (Chapter 4.Y)

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

The Code Commission expressed disappointment that developing Member Countries had not commented on the draft chapter. It also expressed concern that this lack of comment could be interpreted to mean that developing Member Countries do not see this draft chapter as being relevant to them. The Code Commission calls on all Member Countries to review and comment on this draft chapter, meant to provide general guidance relevant to any OIE Member Country.

In examining comments from Member Countries and the advice from the Scientific Commission, the Code Commission had a general discussion on whether the scope of the chapter should be restricted to management of listed diseases under official control by the *Veterinary Services*. Noting the *Code* deals with emerging and listed diseases except in some circumstances, the Code Commission revised the title of the chapter to 'Official Control of Emerging and Listed Diseases'. This change was proposed to emphasise that the recommendations apply to official control programmes and are not intended to impose anything on countries that do not have such

programmes. The Code Commission noted that the new title reflected defined terms in the Glossary, which will facilitate its implementation.

The Code Commission analysed all Member Countries comments and introduced several modifications to the draft text to improve its clarity and consistency and to reflect the new title and scope of the draft chapter and with other chapters of the *Code*.

Article 4.Y.1. Introduction

The Code Commission considered a Member Country comment on the reference to the results of risk analysis. It agreed to its deletion, noting it is more appropriate to reference this elsewhere in the article and so included it in the fourth paragraph. In response to other Member Country comments, the text of the article was modified to clarify the scope and to highlight that the measures can vary from a rapid response to a new hazard to management of outbreaks to long-term control of an endemic infection or infestation in accordance with the likely impact of the disease. The article was also modified to include the need for responses to be adapted according to the epidemiology of the disease, the need for cooperation with other relevant stakeholders and authorities, and the need for plans to include an exit strategy.

Article 4.Y.2. Legal Framework and regulatory environment

The Code Commission did not agree with the proposal to delete reference to veterinary legislation in point 2) but included 'or other relevant legal framework' to address the different approaches that may apply in some countries, such as coordination with other authorities, that may not be addressed in veterinary legislation.

In examining a Member Country proposal to modify point 3) to include policy and regulations the Code Commission agreed that it adds clarity and confirms the variety of approaches used by different countries through both regulatory and non-regulatory approaches.

The Code Commission also modified the second bullet point under point 3) by separating it into two bullet points for clarity.

The Code Commission did not agree with the proposal of a Member Country to replace 'disinsection' by 'disinfestation', as the first is broader and its use in this article is consistent with concepts included in Chapter 4.13.

Article 4.Y.3. Preparedness

In examining a Member Country proposal to modify the third paragraph of point 1), on risk analysis, the Code Commission partially agreed with the proposal and amended the paragraph for clarity and to highlight the need to review the risk analysis in light of new scientific evidence.

Article 4.Y.4. Early detection system (Surveillance and early warning systems)

The Code Commission had an extensive discussion on the use of the term 'early warning system' and noted the proposal of the *ad hoc* Group on surveillance that the term 'early detection system' be replaced with 'early warning system' in the revised Chapter 1.4. on surveillance. To take into account the change to 'early warning system' the Code Commission amended the title of the article to 'Surveillance and early warning systems' and agreed to use 'early warning system' throughout the chapter.

Taking into consideration the revised chapter on surveillance (Chapter 1.4) the Code Commission deleted points 2) to 6) of the article as these concepts are more appropriately addressed in the surveillance chapter. The deletion simplifies the article and will allow for the inclusion of these concepts in Chapter 1.4.

Article 4.Y.5. General considerations when managing an outbreak

The Code Commission modified the first paragraph to specify and clarify that it applies to diseases subject to an official control programme. In response to Member Country proposal to change 'disinsection' to 'disinfestation' the Code Commission did not agree with the rationale provided and clarified that the point addresses the need for disinfection and, if relevant, disinsection.

The Code Commission agreed with a Member Country comment to address the control of movement of people and agreed it is an important factor to be considered to stop the spread of infection and added a new indent in point 2.

The Code Commission agreed in principle with the general comment of a Member Country that there was a need to add a reference to 'incident command system' and included the need for close coordination through intersectoral mechanisms, such as an incident command system, in a new paragraph.

Article 4.Y.6. Culling and disposal

In response to Member Country proposals to modify the first paragraph to correct the overly definitive expression that animals always are the greatest source of infection, and to highlight the risk of pathogenic agents surviving in the environment, the Code Commission amended the paragraph accordingly to address both issues and to add clarity to the text.

The Code Commission agreed with a Member Country comment that employing and adapting strategies is equally applicable to killing and disposal of animals and animal products as it is to culling and so modified the second paragraph accordingly.

The Code Commission amended the title of point 1) Stamping-out by adding 'policy' for clarity. In response to Member Country comments the Code Commission reordered and amended the paragraphs for a more logical flow and to clarify that the application of a stamping-out policy should take into consideration an assessment of the associated risks, particularly when it is to be applied to animals present on an affected establishment.

The Code Commission agreed with a Member Country to include eggs in the list of commodities to be destroyed or processed to inactivate the pathogenic agent.

The Code Commission and the Scientific Commission agreed with a Member Country comment that the design of a test and cull strategy is dependent on the performance characteristics of the diagnostic tests available. The Code Commission modified point 2) by including a new sentence on the application of different test and cull strategies based on the epidemiology of the infection or infestation and that the design of the strategy should take into account the specificity and sensitivity of diagnostic tests.

Article 4.Y.7. Movement control

The Code Commission agreed with a Member Country on the need for movement restrictions on animal products as well as animals, people and vehicles. In regards to the erection of physical barriers, the Code Commission agreed to replace 'should' with 'may' as it is not always necessary to put up physical barriers to restrict movement. The Code Commission also amended the paragraph to include the need to review measures on the basis of a risk assessment.

Article 4.Y.8. Biosecurity

In examining Member Country comments, the Code Commission agreed with proposals to modify paragraphs one and two to include the potential for anything to act as a fomite, in the first one, and to indicate that the use of disinfection is not always part of the management of all infections or infestations in the second one.

Article 4.Y.10. Zoning

The Code Commission proposed editorial amendments including reference to 'slaughter' and to clarify the use of zones in response to outbreaks of emerging or listed diseases.

Article 4.Y.11. Specific post-control surveillance

The Code Commission proposed minor editorial amendments for consistency with the rest of the chapter.

The revised new Chapter 4.Y. and the proposed definition of 'early warning system' are attached as **Annex 25** for Member Country comments**.**

EU comment

The EU thanks the OIE and in general supports this new chapter. Comments are inserted in the text of Annex 25.

5.8. New chapter on introduction to recommendations for veterinary public health (Chapter 6.X.)

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

Article 6.X.1.

The Code Commission considered Member Country comments on the introductory paragraph and amended it for consistency with the WHO definition of veterinary public health[2] and proposed minor editorial amendments for clarity.

In response to other Member Country comments on the rest of the chapter, the Code Commission proposed minor editorial amendments and included references to improvement of animal welfare, contributions to biomedical research, food security and the need for veterinary education to take into account the role of *Veterinary Services* in public health at national, regional and global level in the development of veterinary public health capabilities.

The revised draft Chapter 6.X.is attached as **Annex 13** for Member Country comments and is proposed for adoption at the 86th General Session in May 2018.

EU comment

The EU thanks the OIE and in general supports this new chapter. One comment is inserted in the text of Annex 13.

5.9. The role of the veterinary services in food safety (Chapter 6.1.)

Comments were received from Australia, Canada, China, New Caledonia, New Zealand, Switzerland, USA and EU.

The Code Commission examined the particularly large number of Member Country comments on this chapter and made the following amendments.

Article 6.1.1. The Code Commission agreed with several proposals to change 'actors' to 'personnel' as the term was more readily understood at the international level and included reference to 'foodborne' and 'hygiene' to clarify the training of veterinarians in relation to food safety. For further clarity, the Code Commission merged the first and second paragraphs

Article 6.1.3. Point 1). The Code Commission agreed with a Member Country proposal to include 'storage' in the list at the end of the first paragraph for completeness. It also partially agreed with a proposal to include 'hazards and associated risks' but did not agree to include 'competent authorities, which comprise' as it considered that the definition in the Glossary was sufficient and that in the case of a food safety incident Veterinary Services were often not the only competent

[2] http://apps.who.int/iris/bitstream/10665/42460/1/WHO_TRS_907.pdf Joint FAO/WHO Expert Committee on Veterinary Public Health as "a component of public health activities devoted to the application of professional veterinary skills, knowledge and resources to the protection and improvement of human health"

authority involved. It also agreed to reinstate a sentence highlighting the effectiveness of control of hazards throughout the food chain.

Point 2). The Code Commission agreed with a proposal to change 'risk assessment' to 'risk analysis; it agreed to reinstate the proposed deletion of 'prevention, detection and control of foodborne hazards' and included an example at the end of the paragraph to highlight the role in 'providing information on the occurrence of *infections* on the farm prior to dispatch of animals for slaughter may allow more targeted, risk-based inspection at the *slaughterhouse/abattoir.'* In response to a Member Country comment that the inclusion of responsibilities for consumers seemed a bit strong, the Code Commission noted that consumers have a role to play in that it is their responsibility to follow storage and preparation instructions in order to ensure food safety.

Point 3). The Code Commission disagreed with the need to include 'relevant' before 'Competent Authorities' as countries may have multiple competent authorities when it comes to food safety and, in general, a food business operator will only be required to inform a single competent authority.

Point 4). The Code Commission did not agree with Member Country proposals to amend this point as it considered it is clear that preventive actions may be part of the corrective action plan. The Code Commission agreed in part with a proposal to include reference to the use of 'third party providers to implement controls' and added a new paragraph to address this proposal, noting that this aligned with Codex guidelines.

Article 6.1.4. The Code Commission made several proposed changes to this article to address Member Country comments, in particular in point 3, to clarify that Veterinary Services play a key role in the investigation of and response to foodborne disease outbreaks which may be attributable to or involve animal products.

The revised draft Chapter 6.1. is attached as **Annex 14a** (in track changes) and **Annex 14b** (clean) respectively for Member Country comments and is proposed for adoption at the 86th General Session in May 2018.

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 14a.

5.10. Harmonisation of national antimicrobial resistance surveillance and monitoring programmes (Chapter 6.7.) and review of the report of the *ad hoc* Group on AMR (August 2017)

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

The OIE *ad hoc* Group on Antimicrobial Resistance met from 29 to 31 August 2017. The tasks of the *ad hoc* Group included revision of Member Country comments received on Chapter 6.7. Harmonisation of national antimicrobial resistance surveillance and monitoring programmes and on the proposed definitions for possible inclusion in Chapter 6.8. of the *Terrestrial Code*: therapeutic use, preventative use and growth promotion.

The Code Commission considered the advice provided by the *ad hoc* Group on Member Country proposals and thanked it for its work. In reviewing the chapter, the Code Commission proposed the following amendments:

Article 6.7.2. In response to a Member Country comment that the chapter was about surveillance and monitoring, the Code Commission added 'monitoring' where appropriate for consistency.

Article 6.7.3. Point 1), in response to a Member Country comment on the inclusion of 'trends', the Code Commission noted that surveillance of antimicrobial resistance and monitoring the trends in prevalence was more appropriate language and amended the first paragraph accordingly. In response to the same Member Country comment that animal feed and the environment should not be considered critical to animal health and safety, the Code Commission agreed with the opinion of the

ad hoc Group that feed is one of a number of possible sources of resistant bacteria and the purpose of the chapter is not to provide a comprehensive list of sources which might be monitored, but to provide an indication of those types of monitoring which might be appropriate to the national situation. The Code Commission agreed with the proposal of the Scientific Commission to delete animal feed and environment and to add a sentence at the end of the paragraph to indicate these should be considered according to national priorities.

Point 3). In response to a Member Country comment noting the definitions of herds and flocks are identical in the Glossary, the Code Commission noted that this was the case but that the terms were applied differently according to Member Countries and, for this reason, it was necessary to include both terms in the *Code*.

Point 4). In response to a Member Country proposal to add 'where available' the Code Commission noted that the introduction to this paragraph contains the term "may include" which already implies that inclusion of this item is optional.

Point 6). In response to a Member Country proposal to delete this point, the Code Commission agreed with the *ad hoc* Group that the purpose of the chapter was not to provide a comprehensive list of all possible sources of exposure, but to indicate the types of surveillance and monitoring which may be considered depending on national priorities. In response to another Member Country proposal to delete 'feed ingredients', as the word 'feed' covers feed ingredients, the Code Commission did not agree, but instead noted it would consider whether there was a need to include a definition of feed ingredient in the Glossary because in Chapters 6.3. the definitions of feed and feed ingredients are different.

Article 6.7.4. The Code Commission proposed several amendments to take into consideration Member Country comments, except in response to a proposal to amend the title of Table 1; it agreed with the *ad hoc* Group that the proposed changes did not reflect the content of Table 1. The Code Commission also noted that the *ad hoc* Group agreed to add additional rows to Table 1 to cover lower expected prevalence of 1% and 5%. However, as the *ad hoc* Group did not offer specific figures to include in the table, the Code Commission was unable to make the proposed change and invited the *ad hoc* Group to address this oversight at its next meeting.

Table 2. The Code Commission noted the opinion of the *ad hoc* Group and revised the order of the points in the paragraphs preceding the table. In response to a proposal to include 'animal origin' before 'food' in point c), the Code Commission did not consider this was necessary as it was clear that it applied to food of animal origin. In response to another Member Country comment proposing to add 'While it is difficult to collect' in point 4) the Code Commission disagreed with the proposal as it was unnecessary and inconsistent with the intent and purpose of the *Code*.

In regards to a Member Country comment on the outputs for carcass and food products, the Code Commission agreed with the *ad hoc* Group that the outputs for 'abattoir' and 'processing' and 'packing' could be clearer and amended the outputs of each to read 'prevalence of resistant bacteria after carcass dressing (processing), representative of the hygiene of the process and the contamination during slaughter (processing and handling)'.

Article 6.7.5. The Code Commission considered the comment of a Member Country and a proposal from the *ad hoc* Group and amended point iv) accordingly.

Table 3. The *ad hoc* Group considered a Member Country proposal to add *Salmonella* and *Campylobacter* under the poultry pathogens listed in the Table but did not support this. The Code Commission noted however that Table 3 focuses on animal pathogens and because *Salmonella* is relevant in cattle, pigs as well as poultry, it included *salmonella spp.* as an enteric pathogen for poultry.

In response to a Member Country comment on point a) *Salmonella,* the Code Commission noted the proposal of the *ad hoc* Group to address this comment, inserted the revised text, and reordered the wording for consistency with previous amendments. In response to another Member Country comment on the low prevalence of *Salmonella,* the Code Commission considered this comment had been addressed by the amendments proposed. In response to a Member Country proposal to replace

'phage typing' with 'genetic based tests' the *ad hoc* Group proposed alternate wording which the Code Commission largely accepted.

The revised draft Chapter 6.7. is attached as **Annex 15** for Member Country comments and is proposed for adoption at the 86th General Session in May 2018.

EU comment

The EU in general supports the proposed changes to this chapter. Comments are inserted in the text of Annex 15.

5.11. Definitions for inclusion in Chapter 6.8. Monitoring the quantities and usage patterns of antimicrobial agents in food-producing animals and review of the report of the ad hoc Group on AMR (August 2017)

Comments were received from Australia, Japan, New Caledonia, New Zealand, Singapore, USA, EU and the International Poultry Council.

The Code Commission recalled that proposed definitions of 'therapeutic use', 'preventative use' and 'growth promotion' had been circulated in its last report for Member Country comments at the request of the Director General of the OIE. The Member Country comments received were reviewed by the *ad hoc* Group on Antimicrobial Resistance at its meeting in August 2017. The *ad hoc* Group proposed further amendments to the definitions in order to reconcile the many Member Country comments and presented revised definitions for consideration of the Code Commission.

These revised definitions included additional definitions of 'treatment', 'control' and 'prevention' in order to clarify the definition of therapeutic use. While the Code Commission appreciated the work of the *ad hoc* Group, it considered that the definitions as presented were overly duplicative and that the structure of the text did not fit within the *Code*. The Code Commission revised the structure and content of the definitions to take into account Member Country comments and to improve clarity.

In revising the definitions, the Code Commission noted that the inclusion of the text 'The Veterinary Medicinal Products (VMP) containing antimicrobial agents should only be used on the prescription of a veterinarian or other suitably trained person authorised to prescribe VMP containing antimicrobial agents in accordance with national legislation and under the supervision of a veterinarian', whilst important, was not appropriate in this chapter about monitoring usage, and was already covered in Chapter 6.9. on responsible and prudent use of antimicrobial agents in veterinary medicine.

The Code Commission considered the structure of Article 6.1.8. and agreed with the proposal presented by the OIE Headquarters to have separate articles for purpose and definitions. The Code Commission revised the purpose for clarity and amended the definitions in the proposed new Article 6.8.1bis.

In reviewing Member Country comments, the Code Commission noted the opinion of the *ad hoc* Group on a proposal to include a new definition of medically important antimicrobial drugs, and shared the opinion that the concept relates to human health and lies within the remit of WHO and was not appropriate or necessary to include in this chapter. The Code Commission considered that in reviewing the definitions it had followed the rationale of the *ad hoc* Group, reduced duplication and improved the clarity of the text and that the definitions now provided a clear distinction between therapeutic and nontherapeutic use.

The draft revised Article 6.8.1 and new Article 6.8.1bis (including the definitions) are attached at **Annex 16** for Member Country comments and are proposed for adoption at the 86th General Session in May 2018.

EU comment

The EU in general supports the proposed changes to this chapter. However, important comments are inserted in the text of Annex 16.

5.12. Introduction to the recommendations for animal welfare (Chapter 7.1.) (including proposed amendment of definition of 'animal welfare' and a new article on guiding principles for the use of animal-based measures)

Definition

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

The Code Commission recalled that the proposal to modify the definition of animal welfare was developed by the OIE Animal Welfare Working Group (AWWG) during the 4th Global Conference on Animal Welfare (December 2016). The Code Commission considered that the modification would provide a more precise definition in the Glossary and that the descriptive text fits more appropriately in Chapter 7.1. Introduction to the recommendations for animal welfare, and in particular in Article 7.1.1. General principles.

In examining comments from Member Countries and an organisation proposing to retain the current definition, the Code Commission did not agree, because the details of the factors involved in the animal welfare concept are retained in the modified Article 7.1.1.

The Code Commission agreed with the proposal of some Members Countries to replace 'well-being' with 'physical and psychological state', as the latter is an integral part of the concept of 'well-being' and will allow a better translation in French and Spanish.

The revised definition of animal welfare is attached as **Annex 17,** and is proposed for Member Country comments.

EU comment

The EU thanks the OIE for its work on the revised definition of animal welfare. The EU can generally agree with the proposed changes and has a specific comment that is inserted in the text of Annex 17.

Chapter 7.1. Article 7.1.1. General considerations

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

The Code Commission took note of the general comments of Member Countries and reiterated its response to comments on the definition. The Code Commission also pointed out that '*animal welfare*' is used throughout the *Code*, not just in Section 7.

In response to a comment from a Member Country and an organisation to keep the title of the article as 'Definition', the Code Commission did not agree as this article not only deals with the definition of animal welfare but also with some general consideration regarding good animal welfare and how to promote it.

In response to a Member Country proposal to amend the first and second paragraphs of the article, the Code Commission modified these in order to be consistent with the proposed new definition in the Glossary.

The Code Commission agreed with a Member Country proposal to delete the parenthesis around 'as indicated by scientific evidence', as the following articles, in particular Articles 7.1.2. and 7.1.3., provide sufficient information to support the statement.

The Code Commission agreed partially with some Member Country proposal to add more descriptive elements to achieve good animal welfare and included the term 'enjoy', in its legal meaning, to emphasise the need for some required conditions to achieve good animal welfare. The Code Commission did not agree with a Member Country to add text in relation to the state of the animals, as in this paragraph the intention is to include the recommendation to allow the animals to develop good animal welfare.

The Code Commission noted and thanked a Member Country for its comment on Article 7.1.3. Nevertheless, the Code Commission would like to have agreement on the current modifications before reviewing and revising the remaining articles in this chapter.

The revised Article 7.1.1. is attached as **Annex 17** for Member Country comments and is proposed for adoption at the 86th General Session in May 2018.

EU comment

The EU thanks the OIE for its work on the revised Article 7.1.1. and revised definition of animal welfare in the Glossary, and for taking some EU comments into account. The EU can generally agree with the proposed changes. Comments are inserted in the text of Annex 17.

New article on guiding principles on the use of animal-based measures (Article 7.1.X.)

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

The Code Commission considered the Member Countries comments and edited the first item to emphasise that animal welfare should be evaluated using positive outcomes-based criteria while, nevertheless, recognising the necessity of having some specific recommendations on conditions.

Considering that some comments of the Members Countries were contradictory, the Code Commission developed a new proposal to clarify the meaning of the first sentence of Article 7.1.X.

The Code Commission did not agree with a Member Country proposal to use the term 'five domains' instead of 'five freedoms' as the latter is still part of the guiding principles for animal welfare, and are mentioned in Article 7.1.2. However, the Code Commission commented that it could be considered further in the next review of the chapter.

The Code Commission did not agree with Member Country comments and decided to keep 'criteria' in point 2), as the rationale was not clear enough to support the proposed change.

In examining Member Country comments on point 2), the Code Commission did not agree to delete the word 'ideally' as this means 'preferably' while not excluding other possibilities. However, the Code commission changed the sentence to 'ideally comprising animal-based measures' according to the suggestion of another Member Country, to improve clarity. In this point, the Code Commission's intention was to keep the emphasis that the main recommendation of the OIE is to base the assessment of animal welfare on animal-based criteria, and not only on the measures applied. Finally, the Code Commission accepted the comment of a Member Country to use 'criteria' with 'or measurables' between brackets to harmonise the terminology with other chapters.

The Code Commission did not agree with a Member Country comment on point 4), that users should establish targets and thresholds, or with the rationale that the OIE should not establish them, as in some cases it is necessary to provide the guidance on targets on the thresholds. The Code Commission did not agree with a Member Country suggestion to replace 'In addition' with 'When compared' as the meanings are different. However, considering these comments, and to improve the logic and clarity, the Code Commission opted to place point 4) before point 3) and consequently renumbered the points.

The Code Commission agreed partially with a Member Country comment on point 4) that proposed replacing 'Competent Authorities' with 'other relevant bodies'. However, the Code Commission decided to keep both for clarity.

The Code Commission agreed with a proposal of some Member Countries and an organisation to include a sentence explaining what should be done in case of a failure in the measurements of the outcomes. However, for clarity, it emphasised that however the outcome is measured, if it is unsatisfactory, the user should consider what might be changed, including management of resources,

to improve the outcome in the future. The Code Commission proposed to add the sentence as a new bullet point 6).

The new Article 7.1.X. is attached as **Annex 18** and is proposed for adoption at the 86th General Session in May 2018.

EU comment

The EU thanks the OIE for its work on the revised draft article and for taking EU comments into account. The EU can agree with the proposed changes and welcomes that the draft article covers both resource and outcome based measures.

5.13. Animal Welfare and pig production systems (Chapter 7.X.) and review of the report of the *ad hoc* Group (August 2017)

Comments were received from Australia, Canada, China, Japan, New Caledonia, New Zealand, , Norway, Mexico, Switzerland, USA, EU and ICFAW.

The Code Commission noted that the *ad hoc* Group on Animal Welfare and Pig Production Systems met at OIE Headquarters from 29 – 31 August 2017 in order to review Member Country comments on the revised draft Chapter 7.X. The Code Commission commended the *ad hoc* Group for its revised draft chapter. It invited Member Countries to review the report of the *ad hoc* Group for more extensive responses to Member Country comments.

The Code Commission reviewed the draft chapter together with the Member County comments and proposed some modifications in addition to those proposed by the *ad hoc* Group, to ensure consistency with other chapters and where appropriate address comments it considered required more detailed revision. The rationale for specific proposals is given below.

Article 7.X.1. In respect to the definition of 'pig production systems', the Code Commission modified the article to take into consideration the revised definition for commercial systems used in Chapter 6.13. on prevention and control of *Salmonella* in commercial pig production systems and to align the other definitions with proposed changes to the definition of animal welfare. The Code Commission agreed with the modifications proposed by the *ad hoc* Group to address Member Country comments on the use of 'biological functioning' as it considered the use of 'physical and psychological' was more appropriate and in line with the revised definition of animal welfare.

Article 7.X.4. For clarity, the Code Commission deleted references to 'health' proposed for inclusion by the *ad hoc* Group in a number of points, as it did not consider this was relevant. The Code Commission agreed with the *ad hoc* Group not to include a table proposed by a Member Country, noting that the information was designed to be used at the national level to show the relationship between animal-based measures and normal and abnormal behaviours.

Point 6). The Code Commission disagreed with the *ad hoc* Group's decision to include 'sunburn' as a type of skin discoloration as it was considered too specific. In the same point, the Code Commission inserted the words 'painful or potentially painful' to indicate that not all the procedures used in the management of pigs are painful and agreed to reinstate the reference to 'human safety'.

The Code Commission did not accept a recommendation by the *ad hoc* Group to include a definition of the term 'suffering' in the Glossary because it considered this was unnecessary as the definition in the Oxford English Dictionary is sufficiently clear.

Article 7.X.5. The Code Commission disagreed with the addition of the last sentence in the third paragraph, as all the recommendations included in this chapter are intended to ameliorate the animal welfare of the pigs, and therefore proposed to delete it.

For consistency with the wording of the proposed new Article 7.1.X., 'outcome-based criteria' was replaced by 'animal-based criteria' throughout the draft chapter.

Article 7.X.8. The Code Commission considered the recommendations in the article relating to painful procedures and proposed to delete the reference to the use of anaesthesia or analgesia from the second paragraph, as this was adequately covered in the general recommendations. In regards to the proposal by an organisation to include recommendations related to tail docking, the Code Commission agreed with the *ad hoc* Group that there is broad general agreement that tail docking should be avoided and this was adequately covered in the existing text.

Article 7.X.9. The Code Commission added reference to 'emaciation' in the animal-based criteria and deleted reference to 'in piglets' as it was unnecessary and proposed to reinstate reference to 'pigs should be fed a diet with sufficient fibrous feedstuffs' as this was an important consideration.

Article 7.X.13. The Code Commission agreed with the comprehensive rationale provided by the *ad hoc* Group in relation to the proposal by some Member Countries and an organisation for the use of 'stalls and crates'. The *ad hoc* Group noted as follows:

> 'In relation to Member Countries recommendation to discourage the use of stalls and crates, the *ad hoc* Group did not agree to add the proposed new paragraph, as loose housing for pregnant sows is already included in Article 7.X12. Furthermore, the group did not find enough convincing scientific evidence that the mortality rate of live born piglets could be kept as low as in crate farrowing and lactation systems. Until this problem is solved, the group did not consider it appropriate to recommend loose housing systems for farrowing sows and gilts.
>
> The *ad hoc* Group recognised that large comparative studies in Europe (Weber et al., 2007; Kilbride et al., 2012) show that crushing is higher in loose pens and mortality due to other causes (e.g. stillborn) was higher in farrowing crates.
>
> While the group however, did acknowledge the evidence that piglets reared in farrowing crates may be deprived of some benefits relating to social development (e.g., piglets reared in loose farrowing and lactation systems show more play behaviour and less injurious behaviour, such as nibbling, sucking or chewing another piglet (Oostindjer et al., 2011; Singh et al., 2017)), higher live-born piglet mortality in loose farrowing and lactation systems (e.g., Weber et al., 2007; Kilbride et al., 2012; Cronin et al., 2014) is a serious concern. Since the majority of pre-weaning piglet mortalities occur within the first 2–3 days postpartum and are mainly caused by crushing, Johnson and Marchant-Forde (2009) concluded that farrowing crates can safeguard piglet survival and welfare during nest occupation in the farrowing phase, especially limiting early pre-weaning mortality.'

Article 7.X.14. The Code Commission agreed with the *ad hoc* Group not to accept the proposal by a Member Country to include text to support phasing out of fully slatted floor systems, as it did not consider the scientific references provided sufficient evidence to differentiate between partially and fully slatted floors in terms of foot and leg injuries and the ability to provide enrichment. The *ad hoc* Group could not find other references that could support the phasing out of fully slatted floors.

Article 7.X.16. In response to a Member Country comment relating to cold stress, the Code Commission agreed with the *ad hoc* Group's position not to include the phrase 'skin discoloration of more than 10% of the skin' after 'piloerection', as the *ad hoc* Group could not find support for this in the 'Welfare Quality Assessment Protocol for Pigs, 2009', where other parameters such as huddling or shivering are used for the assessment of cold stress.

Article 7.X.18. The Code Commission agreed with the proposed deletion of the paragraph which provided a recommendation on the minimum intensity of light, as the *ad hoc* Group could not find enough supportive evidence. Nevertheless, the Code Commission indicated that Member Countries should carefully consider the recommendation on the adequate photoperiod suitable for pigs and also the necessary light intensity to conduct inspections. The Code Commission agreed with the *ad hoc* Group on a Member Country proposal to add a new article related to Regulatory Assessment Procedures, but considered the addition was out of the scope, even if it was considered relevant and was not only relevant to animal welfare but also to animal health standards. Nevertheless, the Code

Commission agreed with the recommendation of the *ad hoc Group* that the OIE Headquarters should consider this proposal further in the next revision of the chapter.

Article 7.X.19. The Code Commission noted that the *ad hoc* Group had proposed new text in order to resolve conflicting Member Country comments and that it had also proposed to delete the second paragraph of this article for consistency with the previous articles on housing and space allowance, as it was agreed not to recommend specific housing or farrowing systems because the current literature is not conclusive.

The Code Commission broadly agreed with the proposals made by the *ad hoc* Group to address Member Country comments on the remaining articles and commended the *ad hoc* Group for its thorough review of the chapter and in addressing Member Country comments.

The report of the *ad hoc* Group is attached as **Annex 34** for Member Countries' information.

The new Chapter 7.X. is attached as **Annex 19** for Member Country comments and is proposed for adoption at the 86th General Session in May 2018.

EU comment

The EU thanks the OIE for its work on the revision of the draft chapter and for taking most of the EU comments into account. The EU can in general agree with the proposed changes. However, the EU has relevant comments inserted in the text of Annex 19.

5.14 Infection with bluetongue virus (Chapter 8.3.)

Comments were received from Australia, Canada, Mexico, New Zealand, South Africa, Switzerland, Taipei China, USA, EU and AU-IBAR.

In examining Member Country comments on the revised chapter, the Code Commission proposed a number of editorial amendments for consistency with amendments to the Glossary and for consistency with other chapters of the *Code*.

The Code Commission agreed with the opinion of the Scientific Commission on a Member Country proposal to include recommendations for the declaration of seasonal vector-free period and should criteria be developed they should be included in Chapter 1.5. Surveillance for arthropod vectors. The Code Commission noted this should be discussed further between the two Commissions.

Article 8.3.1. General provisions

In response to a general proposal by a Member Country to amend the first paragraph to include reference to other susceptible herbivores of epidemiological significance, the Code Commission noted that the case definition is restricted to some relevant species for purposes of notification but surveillance can cover more species. For this reason in Article 8.3.16. (and not Articles 8.3.14. or 8.3.15.) there is reference to species relevant 'within the country or zone'. The Code Commission further noted it would examine this together with the Scientific Commission a future meeting.

In response to Member Countries comments on point 3) on inclusion of 'virulent, revertant or reassortant', the Code Commission agreed with the opinion of the Scientific Commission that the presence of a virus in unvaccinated animals is considered an infection as per the case definition, whether or not the virus is a vaccine strain that has reverted to virulence or reassorted, therefore there was no need to amend this point. The Code Commission noted that it is indeed possible that an infection with clinical signs could result from a live BTV vaccine.

The Code Commission agreed with a Member Country that the terms 'detected' and 'identified' were used inconsistently in the chapter and proposed changes throughout in order to correct this.

Article 8.3.2. Safe commodities

In response to a Member Country proposal to delete point 5), and another Member Country comment on the categorisation of embryos as a risk of transmission, the Code Commission did not agree with the rationale provided, and noted that the authority for the *Code* when considering the safety of embryos is the expertise of the IETS and its Manual and the recommendations in this article are in line with that advice.

Article 8.3.4. Country or zone seasonally free from bluetongue

The Code Commission agreed with a Member Country proposal to include a cross reference to surveillance in accordance with Articles 8.3.14. to 8.3.17. The Code Commission also drew the Member Countries' attention to the report of its February 2017 meeting with regards to the use of 'seasonally free' as referring to the season as being free and proposed no further changes.

Article 8.3.6. Recommendations for importation from countries or zones free from bluetongue

In responding to Member Country comments, the Code Commission agreed with the opinion of the Scientific Commission and merged several points under point 5), and proposed editorial changes for clarity. It agreed with the proposal of a Member Country to delete point a) and reminded another Member Country that the definition of *vaccinated* in the Glossary means 'were subject to vaccination'.

Article 8.3.7. Recommendations for importation from zones seasonally free from bluetongue (added country to the subheading)

The Code Commission examined Member Country comments and amended the article for consistency with Article 8.3.6. and included reference to Article 8.3.13., point 2). In response to a proposal to amend point 6), the Code Commission noted that, by definition, a seasonally free zone is within an infected country. It further noted other Member Country comments had either been addressed in the amendments to the previous article or rationale provided against previous articles for not accepting them.

Article 8.3.8. Recommendations for importation from countries or zones infected with BTV

The Code Commission amended point 5) for consistency with the two previous articles and in response to a Member Country comment included reference to Article 8.3.8. in points 2), 3) and 4). The Code Commission did not agree with the same Member Country proposal to amend point 5) to include reference to 'vaccination with a vaccine approved by the exporting country' (see definition in the Glossary). In response to a proposal to include 'a protective level of antibodies' in point 6), the Code Commission noted the opinion of the Biological Standards Commission that a protective level of antibodies for BTV has not been established but the detection of antibodies to a particular serotype is indicative of infection with that serotype. Animals thus exposed may be considered protected against that serotype.

Article 8.3.9. Recommendations for importation from countries or zones free or seasonally free from bluetongue

The Code Commission considered Member Country comments and proposed minor changes to this article adding reference to 'country' where appropriate. The Code Commission also noted it should examine the option of exporting semen from vaccinated animals in a future revision of the chapter and requested the OIE Headquarters to seek expert advice as to whether it was appropriate to include the same conditions for importation of semen as was applicable to the importation of live animals.

Article 8.3.10. Recommendations for importation from countries or zones infected with BTV

In response to a proposal from a Member Country to include 'were protected from attacks from *Culicoides'*, the Code Commission considered it was unnecessary in point b) as the recommendation included the requirement the animals be kept in a vector-protected establishment and this was considered sufficient. The same applies to Article 8.3.12.

Article 8.3.11. Recommendations for importation from countries or zones seasonally free from bluetongue

The Code Commission noted with respect to proposed alternate text for *in vivo*-derived embryos that this was already covered in Article 8.3.2. and did not need to be repeated.

Article 8.3.12 Recommendations for importation from countries or zones infected with BTV

To improve clarity, the Code Commission included reference to Articles 8.3.13. and 8.3.10., as proposed by a Member Country.

Article 8.3.15. General conditions for surveillance

In response to a Member Country proposal to include reference to camelids and other susceptible herbivores, the Code Commission did not agree as the case definition provided adequate clarity with reference to camelids. In responding to another Member Country suggestion to add 'using all of the five strategies below', the Code Commission agreed with the opinion of the Scientific Commission that it may not always be appropriate to use all five strategies. Depending on the epidemiological situation, it is up to Member Countries to decide on the most suitable strategy.

In response to the same Member Country comment on point 5), vector surveillance relating to over-winter and seasonal freedom and that more specific recommendations on criteria for the definition of the Seasonal Vector Free Period (SVFP) should be included in the article, the Scientific Commission and the Code Commission agreed that new scientific evidence related to over-winter and seasonal freedom could be taken into account in a future revision of the chapter and that SVFP should be considered for inclusion in Chapter 1.5. surveillance for arthropod vectors.

The revised draft Chapter 8.3. is attached as **Annex 20** for Member Country comments and is proposed for adoption at the 86th General Session in May 2018.

EU comment

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

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

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

The Code Commission considered Member Country comments on the exclusion of castrated males from testing and, for clarity, a slight modification was proposed; namely adding 'i.e.'. The Code Commission noted that the wording 'except castrated males' takes into account the fact that castrated males are not sexually mature.

The revised Article 8.4.10. is attached as **Annex 21** for Member Country comments and is proposed for adoption at the 86th General Session in May 2018.

EU comment

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

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

Comments were received from Australia, Canada, China Japan, New Caledonia, New Zealand, Singapore, South Africa, Switzerland, Taipei China, Thailand, USA, EU and AU-IBAR.

The Code Commission noted that the comments from Member Countries had been reviewed by the Scientific Commission. However, in light of the proposed changes to Chapter 4.3. zoning and compartmentalisation and specifically with regards to the concept of a temporary preventive *protection* zone, the Code Commission decided it would wait until its February 2018 meeting to review this chapter, with the possibility of including the concept of temporary preventive *protection*

zone to address problems in maintaining FMD free status, and its implications for international trade.

5.17. Infection with rinderpest virus (Article 8.15.2.)

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

The Code Commission examined Member Country comments on the proposed revised article and in response to comments on diagnostic material encoding live virus, it agreed with the opinion of the Scientific Commission that the term may not be sufficiently clear and, at the suggestion of the Biological Standards Commission, clarified the term to read 'laboratory-generated material containing live virus'.

Point 2). In response to the same Member Country comment concerning the reference 'either as plasmids or incorporated into other recombinant viruses,' the Code Commission sought the advice of the Scientific and Biological Standards Commissions. Having confirmed that this is not effective at the present time, the Code Commission decided to keep the reference (deleting 'other') as a precaution, because of the likelihood of future developments.

In response to another Member Country comment concerning the time and temperature reference, the Code Commission amended this to read 'to at least 56°C for at least two hours' for clarity. Other Member Country comments were difficult to reconcile, as the countries did not provide sufficient rationale to support their proposals.

Point 3). The Scientific Commission proposed to amend the point to address a Member Country question on whether it was intended that the point left room to vaccinate animals with recombinant DNA sequences or antigens derived from recombinant RP sequences. The Code Commission agreed with the proposal of the Scientific Commission to amend the point to clarify that the intention is to ban any form of vaccination against rinderpest.

The revised Article 8.15.1. is attached as **Annex 22** for Member Country comments and is proposed for adoption at the 86th General Session in May 2018.

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 22.

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

No new comments were received as the chapter was initially proposed (in September 2016) for comments and adoption at the General Session in May 2017. However, at its February 2017 meeting the Code Commission decided not to put it forward for adoption until the chapter on glanders in the *Terrestrial Manual* had been reviewed. Further, it was waiting advice from experts on surveillance. The Code Commission noted that the review of the chapter in the *Manual* has now been completed and also that the Biological Standards Commission and Scientific Commission, as well as other experts, had encouraged Member Countries to use the same antigen when testing to avoid disputes over test results.

The Code Commission replaced the term 'glanders' with *infection* with *B. mallei* throughout the chapter for consistency with other recently adopted listed disease-specific chapters and proposed other editorial changes to reflect changes or proposed changes to Glossary definitions.

Article 12.10.1. General provisions

In examining Member Country comments, the Code Commission agreed with a proposal to include goats in the first paragraph, but noted that this had no consequence for the case definition and that the infection was not notifiable in goats. In regards to the same Member Country proposal to change 'significant' to 'rare', it agreed this was appropriate.

Article 12.10.2. Country or zone free from infection with *B. mallei*

Point 3), in response to a Member Country proposal to maintain the previous proposal for a 12 month period of surveillance, the Code Commission agreed with the opinion of the Scientific Commission that two incubation periods is the approach generally followed in the *Code.* The Code Commission further noted that for a disease where clinical signs are not obvious and there are difficulties in surveillance and reliability of tests, 12 months was appropriate.

Point 4), in response to the same Member Country proposal to delete reference to 'and their germplasm', the Code Commission agreed with the opinion of the Scientific Commission that germplasm may not, *per se*, be a safe commodity and retained it. The Code Commission further noted that there was a need to continue to work on semen and embryos in this chapter.

Article 12.10.3. Recovery of free status

The Code Commission noted, in response to Member Country comments on a proposal to change 'standstill' to 'prohibition', the Oxford English Dictionary definition of standstill, namely 'a situation or condition in which there is no movement or activity at all', was appropriate as the intent of this point was to stop all movement or activity. With regards to references to 'infected establishments', the Code Commission recalled previous discussions on the use of this term and noted it was not the establishment that became infected; rather the establishment was affected when infected animals were detected. Therefore, it amended the term to read 'affected establishments' for clarity and consistency with other chapters. The Code Commission reinstated '12 months' for the same reason as given in point 3) and deleted the word 'increased' as it was superfluous. In respect to its decision to reinstate the 12 months, the Code Commission further noted that the incubation period of this disease is variable and horses often travelled long distances on frequent occasions and therefore the period for surveillance had to err on the side of caution.

Article 12.10.4. Recommendations for importation of equids from countries or zones free from infection with *B. mallei*

In response to a Member Country proposal to clarify the intent of this article, the Code Commission amended point 2 b) to make it clear that if the animals have been imported into a free country from a country not free and then re-exported, the previous importation must be in accordance with Article 12.10.5.

Article 12.10.5. Recommendations for importation of equids from countries or zones not free from infection with *B. mallei*

In response to a Member Country comment on the time during which the samples should be taken, the Code Commission agreed with the opinion of the Scientific Commission that the samples should be taken between 21 to 30 days apart and amended the text accordingly. In response to another Member Country on consistency with other chapters, the Code Commission added 'tests for infection with *B. mallei'*.

Article 12.10.6. Recommendations for the importation of equine semen

In response to Member Country comments, the Code Commission considered an opinion of the Scientific Commission. However, after reviewing the literature referred to in the Scientific Commission's September 2016 report, it concluded that the risk is related to the collection of semen from animals with cutaneous lesions rather than to the semen itself and proposed to add text to point b) to address this issue. It further clarified that the recommendations related to the day of collection and amended the article for clarity. The Code Commission did not delete references to Articles 4.6.5. to 4.6.7. as, although Chapter 4.6. is applicable to processing of bovine, small ruminant and porcine semen only, Articles 4.6.5 to 4.6.7. could be applied to all types of semen. However, the Code Commission noted the request of the Member Country to consider this in a future review of Chapter 4.6.

Article 12.10.7. Recommendations for the importation of *in vivo*-derived equine embryos

The Code Commission agreed with the opinion of the Scientific Commission on a request from a Member Country to delete point 1 a) and b) and point 3), that there was still a risk of infection during collection and therefore retained the recommendations.

Article 12.10.8. General principles for surveillance

The Code Commission reminded Member Countries that the recommendations in this section reflected what was in practice already being done by many countries and that it was no more prescriptive than necessary. The Code Commission proposed editorial amendments to harmonise the text with Chapter 1.4. on surveillance and to address Member Country comments.

Article 12.10.9. Surveillance strategies

In examining Member Country comments on this article, the Code Commission noted that a large portion of the text was redundant as it paraphrased language from epidemiology textbooks and was therefore unnecessary. In addressing Member Country comments, the Code Commission took into account advice from the Scientific Commission to clarify questions on serologically positive and malleinisation and included a reference to animal identification and harmonised the text with other chapters.

The Code Commission acknowledged that there is a need for more information on surveillance but that it was difficult to be more precise because of the nature of this disease. It also requested the OIE Headquarters to request the Biological Standards Commission to consider recommending a single antigen only in the *Manual*, as this would assist Member Countries to avoid trade disputes over test results.

The revised Chapter 12.10. is attached as **Annex 23** for Member Country comments and is proposed for adoption at the 86th General Session in May 2018.

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 23.

5.19. Infection with classical swine fever virus (Chapter 15.2.)

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

In examining Member Country comments, the Code Commission considered the advice provided by the Scientific Commission and proposed substantial changes to the chapter to address inconsistencies and to harmonise the chapter with the recently adopted Chapter 15.1. Infection with African swine fever virus. Considering the number of changes proposed to the chapter, the Code Commission requested the OIE Headquarters refer the revised text back to the Scientific Commission for further consideration at its February 2018 meeting. The Code Commission also noted the need for the revised chapter to be discussed at a proposed joint meeting between the two Commissions in February 2018.

The revised Chapter 15.2. is not attached to this report but will be circulated again for Member Country comments after the February 2018 meetings of the Code and Scientific Commissions.

6. New amendments or new chapters proposed for inclusion in the *Terrestrial Code*

6.1. Draft introductory chapter Section 4 4.Z. introduction to recommendations for disease prevention and control

The Code Commission recalled that the chapters in this section describe the measures and tools that should be used to assist Member Countries manage and control animal diseases. It also recalled that, as was the case with some other sections of the *Code*, this section lacked an introductory chapter. The Code Commission thus drafted one. It finally proposed to change the title of Section 4 to reflect its content.

The draft new Chapter 4.Z. is attached at **Annex 26** for Member Country comments.

EU comment

The EU in general supports the proposed change to the title of Section 4 and the proposed new Chapter 4.Z. Comments are inserted in the text of Annex 26.

6.2. New chapter on the slaughter and killing of commercially farmed reptiles for their skins and meat (Chapter 7.Y.) and review of the report of the *ad hoc* Group (August 2017)

The Code Commission considered the report of the *ad hoc* Group that met at OIE Headquarters in August 2017, and commended it on its work, in particular that it had taken into account the Code Commission's request to restructure the chapter and to harmonise it with other animal welfare chapters in the *Code*.

The Code Commission noted the proposed modification to the title, to include 'other products', to better align with the scope of the chapter but did not agree with the proposal to include 'commercial' in the title, as it considered that this would cause confusion. The Code Commission proposed to amend the title to 'Killing of reptiles for their skins, meat and other products' for clarity.

In examining the rest of the articles of the draft chapter, the Code Commission proposed some modifications to add clarity and for consistency with the other animal welfare chapters of the *Code*, notably Chapter 7.1. The Code Commission invited Member Countries to review the report of the *ad hoc* Group for more details on the development of this draft.

The new Chapter 7.Y. is attached as **Annex 27** for Member Country comments.

EU comment

The EU thanks the OIE for preparing this draft chapter and encourages the work of the OIE in this area. The EU welcomes the outcome-based approach of this draft chapter and appreciates that the conditions for killing of reptiles can be very different. Comments are inserted in the text of Annex 27.

6.3. New chapter on animal welfare and laying hen production systems (Chapter 7.X) and review of the report of the *ad hoc* Group (November 2016)

The Code Commission recalled that it had reviewed the report of the *ad hoc* Group that met in Paris in November 2016, at its February 2017 meeting. The Code Commission had requested that the draft chapter proposed by the *ad hoc* Group should be restructured specifically to arrange the articles and bullets in a logical order, as used in other chapters. The OIE Headquarters had undertaken the restructuring of the document and conducted further electronic consultations with members of the *ad hoc* Group and the Code Commission in order to refine the text.

The Code Commission reviewed the restructured draft chapter and modified it accordingly for accuracy, clarity and consistency.

The proposed new Chapter 7.X is attached as **Annex 28** for Member Country comments.

EU comment

The EU thanks the OIE for drafting this draft chapter and initiating its work in this important area. The EU asks the OIE to consider its comments for further development of the text. Comments are inserted in the text of Annex 28.

6.4. New Chapter on infection with trypanosome evansi (non-equine surra) (Chapter 8.X.) and review of the report of the *ad hoc* Group on equine trypanosomoses (June 2016)

The Code Commission recalled that an *ad hoc* Group on equine trypanosomoses had met in Paris from 14 to 16 June 2016. The *ad hoc* Group noted that both dourine and surra were listed diseases.

However, recommendations for trade in live susceptible animals and their products were currently only provided in Chapter 12.3. infection with trypanozoon in equids (dourine). Member Countries had expressed a need for trade standards applicable to non-equine surra and in response to this request the *ad hoc* Group developed a draft new chapter that was reviewed by the Scientific Commission before being forwarded to the Code Commission for consideration.

The Code Commission revised the chapter provided by the *ad hoc* Group, included hair in the list of safe commodities, included appropriate cross-references to Chapter 12.3. and agreed with the opinion of the Scientific Commission that the recommendations in Article 8.X.4. on recovery of free status proposed by the *ad hoc* Group were not applicable in the context of this chapter but were only applicable to Chapter 12.3. and amended the article accordingly.

The proposed new Chapter 8.X. is attached as **Annex 29** for Member Country comments.

EU comment

The EU cannot at this stage support this draft new chapter. Comments are inserted in the text of Annex 29.

6.5. Draft revised Chapter on infection with trypanozoon in equids (Chapter 12.3.) and review of the report of the *ad hoc* Group on equine trypanosomoses (June 2016)

The Code Commission recalled that an *ad hoc* Group on equine trypanosomoses had met in Paris from 14 to 16 June 2016 to revise the current *Code* Chapter 12.3. on dourine to encompass all infections with Trypanozoon in equids. The Code Commission revised the chapter provided by the *ad hoc* Group, which had also been reviewed by the Scientific Commission, and proposed editorial changes for consistency with other listed disease-specific chapters in the Code.

The report of the *ad hoc* Group on equine trypanosomoses is attached at **Annex 35** for information.

The proposed draft revised Chapter 12.3. is attached as **Annex 30** for Member Country comments

EU comment

The EU in cannot at this stage support the proposed changes to this chapter. Comments are inserted in the text of Annex 30.

6.6. New Chapter on Theileriosis and review of the report of the *ad hoc* Group on Theileriosis (February 2017)

The Code Commission thanked the *ad hoc* Group for its work on the revision of Chapter 11.12. infection with *Theileria* spp. in ruminants. In discussing the outcomes of the *ad hoc* Group, the Code Commission noted the expansion of the range of host species covered in the chapter. Whilst the *ad hoc* Group had agreed that small ruminant *theileriosis* should be covered by the same chapter, and that only certain species of pathogenic agent met the criteria for listing, the Code Commission considered this would be problematic in the future, as this was the first time that notification requirement differs by pathogen species and by host species within a single chapter. In order to prevent problems in the future, the Code Commission decided it was more appropriate to have two separate chapters.

The two chapters are presented as draft revised Chapter 11.12. Infection with *Theileria annulata, T. orientalis and T. parva* (bovidae) and new Chapter 14.X. Infection with *Theileria lestoquardi, T. luwenshuni* and *T. uilenbergi (small ruminants).*

a) Draft revised Chapter on Infection with *Theileria annulata, T. orientalis and T. parva* (bovidae) (Chapter 11.12.)

In line with its decision to amend the scope of the chapter to cover only bovidae, the Code Commission deleted references to sheep and goats and any corresponding recommendations. It proposed further editorial modifications for consistency with other chapters of the Code.

The Code Commission also noted that the *ad hoc* Group had reviewed the list of susceptible species and acknowledged that, while camels and some wild ruminants could be infected with *Theileria* spp., they are not considered to play a significant role in the epidemiology of the disease as related to trade. The Code Commission agreed with the decision to include bovines and water buffaloes in the case definition, and included wild ruminants as susceptible animals and included them in the article relating to recommendations for the importation of trophies.

The proposed draft revised Chapter 11.12. is attached as **Annex 31** for Member Country comments

The EU in general supports the proposed changes to this chapter. Comments are inserted in the text of Annex 31.

b) New Chapter 14.X. Infection with *Theileria lestoquardi, T. luwenshuni* and *T. uilenbergi* (small ruminants).

In line with its decision to amend the scope of the chapter to cover only small ruminants (sheep and goats) the Code Commission deleted references to bovines and water buffalo and any corresponding recommendations. It proposed further editorial modifications for consistency with other chapters of the *Code*.

The proposed new Chapter 14.X. is attached as **Annex 32** for Member Country comments

EU comment

Comments are inserted in the text of Annex 32.

7. Other issues

7.1. General comments of Member Countries on the texts circulated after the Code Commission's February 2017 meeting

Comments were received from the EU and AU-IBAR.

The Code Commission considered general comments and, where appropriate, reflected them in its work programme and in the relevant agenda items. In regards to specific comments relating to the questionnaires for official recognition by the OIE (Chapter 1.6.) and the burden this large volume of annexes had placed on Member Countries, it noted it had taken these concerns into account during its discussion of the specific agenda item (see Item 5.3.). The Code Commission did however note that when there is a thorough revision of a chapter, which included structural and text changes it would provide clean text in order to facilitate thorough review of the complete text by the Member Countries, as well as to facilitate its own work when reconciling the comments with the revised chapter. This was the case with Chapter 1.6.

In response to another Member Country comment on the use of the term 'bovid' in the Code, the Code Commission noted that it would use 'bovine' throughout to replace 'cattle' and 'bovid' as relevant chapters are reviewed, and at which time it would need to consider which species were covered by the term 'bovine' as this will vary depending on the purpose of the chapter and the epidemiology of the disease.

7.2. Update of the Code Commission's work programme

The Code Commission updated its work programme taking into account the priorities discussed at the General Session, the work of other Specialist Commissions and Member Country comments. The following new items were included in the work programme.

- New chapter on Tsetse transmitted trypanosomiases
- New chapter on biosecurity
- Revision of Chapters 5.4. to 5.7. (discussion see below)
- Revision Chapter 5.10. to include a model certificate for pet food (discussion see below)

- Revision of Chapter 7.7 on stray dog population control (pending the outcomes of a proposed ad hoc Group on rabies).

Chapter 1.3. diseases, infections and infestations listed by the OIE: assessment of chronic wasting disease (CWD) and West Nile fever (WNF) against the criteria for listing disease

The Code Commission noted that the Scientific Commission considered that there were still significant gaps in the understanding of the epidemiology of CWD that may impede the ability to make an informed decision. However, the Code Commission noted the EFSA opinion and epidemiological information previously provided by a Member Country and requested OIE Headquarters ask the relevant Collaborating Centre to assess CWD against the listing criteria of Chapter 1.2. of the *Terrestrial Code* and provide advice back to the Specialist Commissions on what, if any, gaps there are in the scientific evidence, and if not to advise on its listing or not.

In regards to listing of WNF, the Code Commission, considering the fact that horses are dead-end hosts, questioned whether it was appropriate for the disease to remain listed in Section 8, multiple species disease category or be moved to Section 10 aves disease category. Consequently, the Code Commission requested that the OIE Headquarters gathered expert advice, not necessarily from specialists in the disease, to decide on where to place it in the *Code*, or to delist WNF based on the listing criteria.

New work on quarantine stations – proposal from Brazil

In response to a request from a Member Country on the need for guidance for Member countries on the establishment and management of quarantine stations, the Code Commission noted the chapters in Section 5 of the *Terrestrial Animal Health Code* already express some recommendations in relation to the import and quarantine of animals and the measures that are applicable on arrival. Nevertheless, the Code Commission acknowledged that the chapters in this section are old and may not be adequate to support countries in managing the risk of the introduction of disease through the importation of live animals. It noted the interaction between these chapters with recommendations in the disease specific chapters in Volume II of the *Code*, which are constantly evolving through updates endorsed by the World Assembly. Periodic review of the horizontal chapters of Volume I is important to ensure ongoing alignment and coherence between Volumes I and II of the *Code*.

In order to respond more adequately to the concerns raised, the Code Commission included review of these chapters on its work programme and requested the OIE to consider establishing an *ad hoc* Group to revise Section 5, specifically Chapters 5.4. to 5.7. The *ad hoc* Group Terms of Reference should include: providing recommendations relating to control at border (not just with neighbouring countries), especially for the importation of live animals; considering whether there is a need for additional detailed guidance on the use of quarantine stations (both at departure in the exporting country or at arrival in the importing country); and align the chapters with the relevant listed disease-specific chapters as necessary.

Request to restart work on a standard for pet food - proposal from Global Alliance of Pet Food Associations (GAPFA),

The Code Commission considered a request from an organisation, with which the OIE has a cooperation agreement, to restart work on the development of an international standard for pet food. The organisation expressed its continued interest in facilitating the development of consensus-based guidance for the global pet food industry, to better support the health and wellbeing of pets and to help the eradication of disease from foodborne pathogens.

The Code Commission noted that previous attempts had been halted due to a lack of consensus and that a draft chapter could not be progressed due to a lack of support by Member Countries and the industries' reluctance to provide detailed information on manufacturing processes to inactive certain pathogens. In considering this request the Code Commission noted that the problem is not specifically about the safety of pet food, but rather a lack of recognition that heat treatment can inactivate pathogens of concern and that in order to avoid the contentious issues encountered last time the development of a model certificate for pet food should be explored. This work would require input from the industry and a willingness from them to provide detailed scientific evidence

on specific heat treatments. A model certificate could then be developed in Section 5 of the *Code*, and modifications could be proposed in the relevant listed disease-specific chapters.

In light of the Code Commission's full work programme and noting the OIE budget constraints with regards to the establishment of *ad hoc* Groups, it requested the OIE Headquarters to write to the organisation and seek its views on the possible development of a model certificate for pet food in international trade, such a certificate could include recommendations on minimum treatment required for inactivation of pathogens of concern.

The Code Commission added this item to its work programme but noted it was a relatively low priority.

The updated work programme is attached as **Annex 33** for Member Countries' information and comments.

EU comment

The EU thanks the Code Commission for having taken its previous comments into consideration, and in general supports the proposed revised work programme.

Comments are inserted in the text of Annex 33.

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

The Code Commission noted the Member Country comments in relation to the editorial amendments proposed to the 2017 Edition of the *Code*, and the OIE Headquarters advised that the comments related to typographical errors had all been resolved in the 2017 Edition before it was published. The Code Commission requested the OIE Headquarters analyse the remaining issues and make proposals for addressing them at its February 2018 meeting in preparation for the publication of the 2018 edition.

7.4. Other Business

7.4.1. Report of the *ad hoc* Group on Veterinary Paraprofessionals

The OIE *ad hoc* Group on Veterinary Paraprofessionals met from 31 July to 2 August 2017 at the OIE Headquarters in Paris, France.

OIE Headquarters provided the background to the work of the current *ad hoc* Group, recalling the activity of a previous *ad hoc* Group on the role of private veterinarians and veterinary paraprofessionals (VPPs) in the provision of animal health services, which was convened in 2003 and led to adoption of changes in the *Code* on Veterinary Services with regard to the role of VPPs, including a definition of VPPs being included in the Glossary in 2004. The later work of the *ad hoc* Group on veterinary education was also noted with regard to the development of competencies of graduating veterinarians, as well as a core curriculum for the training of veterinarians and that this work had served as a model for the creation and activities of the current *ad hoc* Group on VPPs.

The Code Commission welcomed the work of the current *ad hoc* Group which is divided into two parts – first the development of expected competencies for VPPs working in three tracks, namely laboratory diagnosis, animal health and veterinary public health, followed by the development of core curricula for the three tracks. The OIE noted that the competencies are identified as basic or advanced, indicating that basic competencies would be covered in a core curriculum but advanced competencies would require additional training.

The Code Commission thanked the OIE for the update on the work of the *ad hoc* Group and the OIE for its support to this work. It further noted that at this stage the work of the *ad hoc* Group did not imply any revision of the *Code* was required at this time. However, in order to seek the views of Member Countries on the draft Veterinary Paraprofessionals Competency document, it agreed to append the report of the *ad hoc* Group as an annex to its report and to

invite Member Countries to submit their comments to the OIE Headquarters, including their responses to the one page questionnaire that accompanies the Competency Document.

The report of the *ad hoc* Group and questionnaire are attached as **Annex 36** for Member Countries' comments. Responses to the questionnaire should reach the OIE Headquarters no later than 9 January 2018.

EU comment

Comments are inserted in the text of Annex 36.

7.4.2. Invasive hornet (*Vespa velutina*)

OIE Headquarters introduced a scientific review of *Vespa velutina nigrithorax,* the aim of this paper being to provide an assessment of *Vespa velutina nigrithorax* against the OIE criteria for listing a disease, infection or infestation. The Scientific Commission proposed that the Code Commission consider the inclusion of *Vespa velutina nigrithorax* in the OIE List of diseases, as was done with *Aethina tumida* (small hive beetle).

The Code Commission noted the concerns and the issues raised in the paper. However, it was of the opinion that *Vespa velutina nigrithorax* is an invasive species, rather than a disease or a parasite of animals. Therefore, the issue was considered to be outside the mandate of the *Code*. The Code Commission also noted that at the national level this type of issue was not in the remit of the Veterinary Services but more likely to be within the competence of a national environment authority. The Code Commission further recalled that listing of diseases was a way to provide guidance to Member Countries for the control of those diseases, and considered that since the hornet was quite widespread and that control measures had not proven to be successful anywhere, although in one country the bees had adapted and developed some resistance, it should not even be a candidate for listing.

However, the Code Commission agreed there was a need for further research involving both veterinary services and environmental agencies. It recommended that the OIE should continue to work on this issue unless the Member Countries indicated that this was outside the mandate of the OIE.

EU comment

The EU concurs with the Code Commission in that the Asian hornet is an invasive alien species rather than a disease or parasite, as well as with the other comments of the Code Commission. Indeed, in the EU, *Vespa velutina nigrithorax* is included in the list of invasive alien species of Union concern under the relevant EU environment legislation (Regulation (EU) 1143/2014 on invasive alien species, http://ec.europa.eu/environment/nature/invasivealien/index_en.htm). In our opinion, the Asian hornet is a predator of honey bees and other insects, and predators should in general not be considered for inclusion in the OIE list of diseases. Thus, the EU considers this issue outside of the mandate of the OIE.

7.4.3. Chapter 5.8. International Transfer and laboratory containment of animal pathogens

An *ad hoc* Group was held from 17 to 19 July 2017 on transport of biological materials. The *ad hoc* Group identified the need to update the *Terrestrial Animal Health Code* Chapter 5.8 entitled "International transfer and laboratory containment of animal pathogens", especially with respect to the international requirements for transfer of animal pathogens due to CITES and the Nagoya Protocol.

The Code Commission noted the recommendation from the *ad hoc* Group, but did not consider that it was necessary to include a revision of the chapter to include reference to a need for a CITES permit to accompany pathogens from animals. Specifically in relation to the inclusion of biodiversity issues in the work programmes of the Specialist Commissions, this should only apply if it is clearly linked to animal health or wildlife. In this regard, the

Code Commission was of the view that the OIE Headquarters should seek an exemption from the Nagoya Protocol in order to avoid future requests of this nature.

EU comment

The EU notes that the above issues would best be covered by the OIE Manual and the Biological Standards Commission (BSC).

In addition, we note that the Code Chapter 5.8. is seriously outdated. Indeed, it still refers to the classification of pathogens into four categories in accordance with the risk they pose to both human and animal health, and refers to the Manual for more information. However, that concept was abandoned a few years ago by the BSC and is no longer included in the Manual. Furthermore, Code Chapter 5.8. specifically refers to Manual Chapter 1.1.2. as regards guidance on the laboratory containment of animal pathogenic agents and on the import conditions applicable to them, however the structure of the Manual has been revised and the numbering of chapters has changed.

The EU would thus either support an update of this chapter, or preferably its deletion from the Code and transfer to the Manual.

7.5. Date of next meetings

The Code Commission agreed that the dates for its next meetings would be tentatively, **12–23 February 2018** in order to facilitate a joint meeting with the Scientific Commission in preparation for the 86th General Session of the World Assembly of OIE Delegates.

…/Annexes

Annex 3

USER'S GUIDE

EU comment

The EU in general supports the proposed changes to the User's guide. Comments are inserted in the text below.

A. Introduction

1) The OIE *Terrestrial Animal Health Code* (hereafter referred to as the *Terrestrial Code*) establishes standards for the improvement of terrestrial animal health and welfare and veterinary public health worldwide. The purpose of this guide is to advise the Veterinary Authorities of OIE Member Countries on how to use the *Terrestrial Code*.

2) Veterinary Authorities should use the standards in the *Terrestrial Code* to set up measures providing for early detection, internal reporting, notification and control of pathogenic agents, including zoonotic ones, in terrestrial animals (mammals, birds and bees) and preventing their spread via international trade in animals and animal products, while avoiding unjustified sanitary barriers to trade.

EU comment

Please include "reptiles" in the parenthesis of point 2) above, as the Glossary definition of "animal" was amended accordingly in May 2016.

3) The OIE standards are based on the most recent scientific and technical information. Correctly applied, they protect animal health and welfare and veterinary public health during production and trade in animals and animal products, and in the use of animals.

4) The absence of chapters, articles or recommendations on particular aetiological agents or commodities does not preclude the application of appropriate sanitary measures by the Veterinary Authorities, provided they are based on risk analyses conducted in accordance with the *Terrestrial Code*.

5) The complete text of the *Terrestrial Code* is available on the OIE Web site and individual chapters may be downloaded from: http://www.oie.int.

6) The year that a chapter was first adopted and the year of its last revision are noted at the end of each chapter.

B. *Terrestrial Code* content

1) 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. The reader should be aware of the definitions given in the Glossary when reading and using the *Terrestrial Code*. Defined terms appear in italics. In the on-line version of the *Terrestrial Code*, a hyperlink leads to the relevant definition.

2) The term '(under study)' is found in some rare instances, with reference to an article or part of an article. This means that this part of the text has not been adopted by the World Assembly of OIE Delegates and the particular provisions are thus not part of the *Terrestrial Code*.

3) The standards in the chapters of Section 1 are designed for the implementation of measures for the diagnosis, surveillance and notification of pathogenic agents. The standards include procedures for notification to the OIE, tests for international trade, and procedures for the assessment of the health status of a country, zone or compartment.

4) The standards in Section 2 are designed to guide the importing country in conducting import risk analysis in the absence of OIE recommendations on particular aetiological agents or commodities. The importing country should also use these standards to justify import measures which are more stringent than existing OIE standards.

5) The standards in the chapters of Section 3 are designed for the establishment, maintenance and evaluation of Veterinary Services, including veterinary legislation and communication. These standards are intended to assist the Veterinary Services of Member Countries to meet their objectives of improving terrestrial animal health and welfare and veterinary public health, as well as to establish and maintain confidence in their international veterinary certificates.

6) The standards in the chapters of Section 4 are designed for the implementation of measures for the prevention and control of pathogenic agents. Measures in this section include animal identification, traceability, zoning, compartmentalisation, disposal of dead animals, disinfection, disinsection and general hygiene precautions. Some chapters address the specific sanitary measures to be applied for the collection and processing of semen and embryos of animals.

7) The standards in the chapters of Section 5 are designed for the implementation of general sanitary measures for trade. They address veterinary certification and the measures applicable by the exporting, transit and importing countries. A range of model veterinary certificates is provided to facilitate consistent documentation in international trade.

8) The standards in the chapters of Section 6 are designed for the implementation of preventive measures in animal production systems. These measures are intended to assist Member Countries in meeting their veterinary public health objectives. They include ante- and post-mortem inspection, control of hazards in feed, biosecurity at the animal production level, and the control of antimicrobial resistance in animals.

EU comment

The EU would suggest clearly stating in the paragraph above that the chapters of Section 6 (e.g. the Salmonella chapters) do not represent guidelines for trade but rather recommendations to encourage member countries who wish to prevent certain infections including zoonosis. (Reference is made to the EU comment in Annex 5.)

9) The standards in the chapters of Section 7 are designed for the implementation of animal welfare measures. The standards cover production, transport, and slaughter or killing, as well as the animal welfare aspects of stray dog population control and the use of animals in research and education.

10) The standards in each of the chapters of Sections 8 to 15 are designed to prevent the aetiological agents of OIE listed diseases, infections or infestations from being introduced into an importing country. The standards take into account the nature of the traded commodity, the animal health status of the exporting country, zone or compartment, and the risk reduction measures applicable to each commodity.

These standards assume that the agent is either not present in the importing country or is the subject of a control or eradication programme. Sections 8 to 15 each relate to the host species of the pathogenic agent: multiple species or single species of Apidae, Aves, Bovidae, Equidae, Leporidae, Caprinae and Suidae. Some chapters include specific measures to prevent and control the infections of global concern. Although the OIE aims to include a chapter for each OIE listed disease, not all OIE listed diseases have been covered yet by a specific chapter. This is work in progress, depending on available scientific knowledge and the priorities set by the World Assembly.

C. Specific issues

1. Notification

Chapter 1.1. describes Member Countries' obligations under OIE Organic Statutes. Listed and emerging diseases, as prescribed in Chapter 1.1., are compulsorily notifiable. Member Countries are encouraged to also provide information to the OIE on other animal health events of epidemiological significance.

Chapter 1.2. describes the criteria for the inclusion of ~~a disease,~~ an infection or infestation in the OIE List and Chapter 1.3. gives the current list. Diseases are divided into nine categories based on the host species of the aetiological agents.

EU comment

It seems premature to propose the change in the paragraph above. Indeed, the definition of "disease" was not yet deleted from the Glossary, and consequential changes should not be anticipated in other chapters. In addition, the consequential changes in Chapter

1.3. will be important and should be proposed and adopted at the same time, to avoid confusion and contradictions. The EU further notes that the above change is not being proposed in the other paragraphs in this User's guide that refer to "disease, infection or infestation".

2. Diagnostic tests and vaccines

It is recommended that specified diagnostic tests and vaccines in *Terrestrial Code* chapters be used with a reference to the relevant section in the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (hereafter referred to as the *Terrestrial Manual*). Experts responsible for facilities used for disease diagnosis and vaccine production should be fully conversant with the standards in the *Terrestrial Manual*.

3. Freedom from a disease, infection or infestation

Article 1.4.6. provides general principles for declaring a country or zone free from a disease, infection or infestation. This article applies when there are no specific requirements in the listed disease-specific chapter.

4 Prevention and control

Chapters 4.3. and 4.4. describe the measures that should be implemented to establish zones and compartments. Zoning and compartmentalisation should be considered as tools to control diseases and to facilitate safe trade.

Chapters 4.5. to 4.11. describe the measures which should be implemented during collection and processing of semen and embryos of animals, including micromanipulation and cloning, in order to prevent animal health risks, especially when trading these commodities. Although the measures relate principally to OIE listed diseases or infections, general standards apply to all infectious disease risks. Moreover, in Chapter 4.7. diseases that are not listed are marked as such but are included for the information of Member Countries.

Chapter 4.14. addresses the specific issue of the control of bee diseases and some of its trade implications. This chapter should be read in conjunction with the specific bee disease chapters in Section 9.

Chapter 6.4. is designed for the implementation of general biosecurity measures in intensive poultry production. Chapters 6.5., 6.12. and 6.13. ~~is an example of a~~ provide recommendations for some specific on-farm prevention and control plans for the ~~non-~~unlisted food-borne pathogen *Salmonella* ~~in poultry~~ as part of the Veterinary Services mission to avoid, eliminate or control food safety hazards in animal production.

Chapter 6.11. deals specifically with the zoonotic risk associated with the movements of non-human primates and gives standards for certification, transportation and import conditions for these animals.

5. Trade requirements

Animal health measures related to international trade should be based on OIE standards. A Member Country may authorise the importation of animals or animal products into its territory under conditions different from those recommended by the *Terrestrial Code*. To scientifically justify more stringent measures, the importing country should conduct a risk analysis in accordance with OIE standards, as described in Chapter 2.1. Members of the WTO should refer to the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).

Chapters 5.1. to 5.3. describe the obligations and ethical responsibilities of importing and exporting countries in international trade. Veterinary Authorities and all veterinarians directly involved in international trade should be familiar with these chapters. Chapter 5.3. also describes the OIE informal procedure for dispute mediation.

The OIE aims to include an article listing the commodities that are considered safe for trade without the need for risk mitigation measures specifically directed against a particular listed disease, infection or infestation, regardless of the status of the country or zone of origin for the agent in question, at the beginning of each listed disease-specific chapter in Sections 8 to 15. This is work in progress and some chapters do not yet contain articles listing safe commodities. When a list of safe commodities is present in a chapter, importing countries should not apply trade restrictions to such commodities with respect to the agent in question.

6. International veterinary certificates

An international veterinary certificate is an official document that the Veterinary Authority of an exporting country issues in accordance with Chapters 5.1. and 5.2. It lists animal health requirements and, where appropriate, public health requirements for the exported commodity. The quality of the exporting country's Veterinary Services is essential in providing assurances to trading partners regarding the safety of exported animals and products. This includes the Veterinary Services' ethical approach to the provision of veterinary certificates and their history in meeting their notification obligations.

International veterinary certificates underpin international trade and provide assurances to the importing country regarding the health status of the animals and products imported. The measures prescribed should take into account the health status of both exporting and importing countries, and zones or compartments within them, and be based upon the standards in the *Terrestrial Code*.

The following steps should be taken when drafting international veterinary certificates:

a) identify the diseases, infections or infestations from which the importing country is justified in seeking protection because of its own health status. Importing countries should not impose measures in regards to diseases that occur in their own territory but are not subject to official control programmes;

b) for commodities capable of transmitting these diseases, infections or infestations through international trade, the importing country should apply the relevant articles in the listed disease-specific chapters. The application of the articles should be adapted to the disease status of the country, zone or compartment of origin. Such status should be established according to Article 1.4.6. except when articles of the relevant listed disease chapter specify otherwise;

c) when preparing international veterinary certificates, the importing country should endeavour to use terms and expressions in accordance with the definitions given in the Glossary. International veterinary certificates should be kept as simple as possible and should be clearly worded, to avoid misunderstanding of the importing country's requirements;

d) Chapters 5.10. to 5.13. provide, as further guidance to Member Countries, model certificates that should be used as a baseline.

7. Guidance notes for importers and exporters

It is recommended that Veterinary Authorities prepare 'guidance notes' to assist importers and exporters understand trade requirements. These notes should identify and explain the trade conditions, including the measures to be applied before and after export and during transport and unloading, and the relevant legal obligations and operational procedures. The guidance notes should advise on all details to be included in the health certification accompanying the consignment to its destination. Exporters should also be reminded of the International Air Transport Association rules governing air transport of animals and animal products.

Annex 4

CHAPTER 2.2.

CRITERIA APPLIED BY THE OIE FOR ASSESSING THE SAFETY OF COMMODITIES

EU comment

The EU supports the proposed changes to this chapter.

Article 2.2.1.

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, the second article lists *commodities* that can be traded from a country or *zone* regardless of its status with respect to the specific *listed disease*. The criteria for their inclusion in the list of *safe commodities* are based on the absence of the pathogenic agent in the traded *commodity*, either due to its absence in the tissues from which the *commodity* is derived or to its inactivation by the processing or treatment that the *animal* products have undergone.

The assessment of the safety of the *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 pathogenic agent of concern are considered.

For the criteria in Article 2.2.2. to be applied, ~~It~~ it is 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 2.2.2.

Criteria

For an *animal* product to be considered a *safe commodity* for *international trade*~~,~~ as described in the User's guide and Article 2.2.1., 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 in an amount able to cause *infection* in a human or *animal* by a natural exposure route. This evidence is based on the known distribution of the pathogenic agent in an infected *animal*, whether or not it shows clinical signs of disease.

OR

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

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

   or

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

   or

   c) biological (e.g. fermentation);

   or

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

_____

Annex 5

CHAPTER 6.13.

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

EU comment
The EU in general supports the proposed changes to this chapter.
The EU notes a possible contradiction between the explanations given in the report of the Code Commission meeting under Item 4.3. and the amendment proposed to the definition of "Commercial pig production systems" in Article 6.13.2.
Indeed, while this chapter is not to apply to international trade since *Salmonella* in pigs is not included in the OIE list of diseases, the scope is limited to commercially traded pigs and pig meat. A suggestion to that effect is inserted in the text below.
Furthermore, we would support clearly stating in the User´s Guide that this type of chapter does not represent guidelines for trade but rather recommendations to member countries who wish to prevent certain infections including zoonosis.

Article 6.13.1.

Introduction

Nontyphoidal salmonellosis is one of the most common foodborne bacterial diseases in the world with *Salmonella* Enteritidis and *S.* Typhimurium (including monophasic variants) being the predominant serotypes identified in humans in most countries. *S*. Enteritidis is primarily associated with *poultry* while *S*. Typhimurium may be present in many mammalian and avian hosts. These serotypes and several others occur at variable prevalence in pigs depending on the region. In some countries *S*. Infantis and *S*. Choleraesuis may cause salmonellosis in humans.

Salmonella infection in pigs is mostly subclinical, although clinical disease such as enteritis and septicaemia in weaned pigs may occur. Subclinical *infection,* including a carrier state, can be of variable duration and can play an important role in the spread of *Salmonella* within and between *herds* and pose a public health *risk*.

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

Article 6.13.2.

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 commercially traded pigs or pig *meat*.

EU comment
To solve the issue explained in the general comment above, the EU suggests slightly amending the definition as follows:

"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 with the intention ~~for the production~~ of commercially ~~traded~~ producing and placing on the market of pigs or pig meat."

Article 6.13.3.

Purpose and scope

This chapter provides recommendations for the prevention and control of *Salmonella* in commercial pig production systems, including outdoor pig production systems, where practicable, in order to reduce the burden of *infection* in pigs and the *risk* of human illness through foodborne contamination as well as human *infections* resulting from direct or indirect contact with infected pigs.

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

[…]

Article 6.13.16.

Outdoor pig production

For outdoor pigs in commercial production systems, in addition to ~~Where practicable,~~ the prevention and control measures described in Articles 6.13.5. to 6.13.15., ~~should also be applied to outdoor pigs in commercial pig production systems to reduce *Salmonella infection*.~~ In addition, 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 designed to minimise attraction of, or access by, *wild* birds;

3) the location of other outdoor pig *herds* and the concentration and behaviour of *wild* birds in the area be considered.

EU comment

We suggest wild animals are covered as well as wild birds in paragraphs 2) and 3) of the article above. Indeed, the intention here is to deal with potential cross-contamination to outdoor kept pigs and whilst in Europe these will be fenced in that will not be the case everywhere. Wild animals other than birds could also bring in infection.

The EU therefore suggests replacing the word "birds" after "*wild*" in both paragraphs 2) and 3) by the word "*animals*" (it is important to italicise the word "animals" to refer to the Glossary definition, which includes mammals and birds).

Annex 6

CHAPTER 11.9.

INFECTION WITH LUMPY SKIN DISEASE VIRUS

EU comment

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

[...]

Article 11.9.4.

Recovery of free status

1) When a *case* of LSD occurs in a country or *zone* previously free from LSD, one of the following waiting periods is applicable to regain free status:

a) when a *stamping-out policy* has been applied:

i) 14 months after the *slaughter* or *killing* of the last *case*, or after the last *vaccination* if emergency *vaccination* has been used, whichever occurred last, and during which period clinical, virological and serological *surveillance* ~~has been~~ conducted in accordance with Article 11.9.15. has demonstrated no occurrence of *infection* with LSDV;

ii) 26 months after the *slaughter* or *killing* of the last *case*, or after the last *vaccination* if emergency *vaccination* has been used, whichever occurred last, and during which period clinical *surveillance* alone ~~has been~~ conducted in accordance with Article 11.9.15. has demonstrated no occurrence of *infection* with LSDV;

b) when a *stamping-out policy* is not applied, Article 11.9.3. 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 11.9.15. has demonstrated no occurrence of *infection* with LSDV.

Article 11.9.5.

Recommendations for importation from countries or zones free from LSD

For ~~domestic~~ bovines and water buffaloes

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

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

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

Article 11.9.6.

Recommendations for importation from countries or zones not free from LSD

For ~~domestic~~ bovines and water buffaloes

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

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

2) were kept since birth, or for the past 60 days prior to shipment, in an *epidemiological unit* where no *case* of LSD occurred during that period;

3) were vaccinated against LSD according to manufacturer's instructions between 60 days and one year prior to shipment;

4) were demonstrated to have antibodies at least 30 days after *vaccination*;

5) were kept in a *quarantine station* for the 28 days prior to shipment during which time they were subjected to an agent identification test with negative results.

[...]

Article 11.9.15.

Surveillance

1. General principles of surveillance

A Member Country should justify the *surveillance* strategy chosen as being adequate to detect the presence of *infection* with LSDV, even in the absence of clinical signs, given the prevailing epidemiological situation, in accordance with Chapter 1.4. and Chapter 1.5. and under the responsibility of the *Veterinary Authority*.

The *Veterinary Services* should implement programmes to raise awareness among farmers and workers who have day-to-day contact with livestock, as well as *veterinary paraprofessionals*, *veterinarians* and diagnosticians, who should report promptly any suspicion of LSD.

In particular Member Countries should have in place:

a) a formal and ongoing system for detecting and investigating *cases*;

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

c) a system for recording, managing and analysing diagnostic and *surveillance* data.

2. Clinical surveillance

Clinical *surveillance* is essential for detecting cases of infection with LSDV and requires the physical examination of susceptible animals.

Surveillance based on clinical inspection provides a high level of confidence of detection of disease if a sufficient number of clinically susceptible animals is examined regularly at an appropriate frequency and investigations are recorded and quantified. Clinical examination and *laboratory* testing should be pre-planned and applied using appropriate types of samples to clarify the status of suspected *cases*.

3. Virological and serological surveillance

An active programme of *surveillance* 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 bovines and water buffaloes may be used to detect presence of *infection* with LSDV in naturally infected animals.

The study population used for a serological survey should be representative of the population at risk in the country or *zone* and should be restricted to susceptible unvaccinated animals. Identification of vaccinated animals may minimise interference with serological *surveillance* and assist with recovery of free status.

4. Surveillance in high-risk areas

Disease-specific enhanced *surveillance* in a free country or *zone* should be carried out over an appropriate distance from the border with an infected country or *zone*, based upon geography, climate, history of infection and other relevant factors. The *surveillance* should be carried out over a distance of at least 20 kilometres from the border with that country or *zone*, but a lesser distance could be acceptable if there are relevant ecological or geographical features likely to interrupt the transmission of LSDV. A country or *zone* free from LSD may be protected from an adjacent infected country or *zone* by a *protection zone*.

Annex 7

CHAPTER 15.1.

INFECTION WITH AFRICAN SWINE FEVER VIRUS

EU comment

The EU cannot support the proposed changes to this chapter as presented. Important comments are inserted in the text below that should be taken into account.

[...]

Article 15.1.1bis.

Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any ASF related conditions, regardless of the ASF status of the *exporting country* or *zone*:

1) canned *meat*;

2) gelatine.

EU comment

While the EU could in general support a new article on safe commodities in this chapter, including for canned meat and gelatine, we have serious concerns as regards the proposed text.

Indeed, referring simply to "canned meat" and "gelatine", without any additional information, could lead to misunderstandings and confusion. We query why and based on what scientific grounds the specific reference to "hermetically sealed container with a Fo value of 3.00 or more" should be dismissed. That wording from the current Article 15.1.22. should rather be included in this new article on safe commodities, as it was shown to be effective in inactivating ASFV.

Also for gelatine, many different production standards and treatments are possible. Therefore, similar to canned meat, the minimum treatment needs to be defined.

In general, in our opinion it is not sufficient to refer in general to Codex standards solely in the Code Commission's report, which are not part of the OIE standards; such references to specific Codex standards should rather be included in the text of the chapter in order to be valid and relevant.

In addition, the general reference to "standard processing or treatment applied to produce the commodity to be traded" in Chapter 2.2. on *Criteria applied by the OIE for assessing the safety of commodities* is not sufficient for commodities such as canned meat or gelatine, as treatments can vary significantly (e.g. as regards temperature/time combinations). Thus, there is no such thing as a "standard" processing or treatment for those commodities. Furthermore, as the tenacity of pathogens differs wildly, it is necessary to define the processing / treatment in individual disease specific chapters so as to ensure reliable inactivation of the pathogen and thus safety of a given commodity.

Article 15.1.2.

General criteria for the determination of the ASF status of a country, zone or compartment

1) ASF is a *notifiable disease* in the entire 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 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 the species of *wild* and *feral* pigs and African *wild* suids present, their distribution and habitat in the country or *zone*;

5) for domestic and *captive wild* pigs, an appropriate *surveillance* programme in accordance with Articles15.1.27. to 15.1.30. and 15.1.32. 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 15.1.31., considering the presence of natural and artificial boundaries, the ecology of the *wild* and *feral* pig and African *wild* suid populations and an assessment of the likelihood of ASF spread including taking into account the presence of *Ornithodoros* ticks where relevant;

7) the domestic and *captive wild* pig populations are separated by appropriate *biosecurity*, effectively implemented and supervised, from the *wild* and *feral* pig and African *wild* suid populations, based on the assessed likelihood of spread within the *wild* and *feral* pig and African *wild* suid populations, and *surveillance* in accordance with Article 15.1.31.; they are also protected from *Ornithodoros* ticks where relevant.

~~*Commodities* of domestic or *captive wild* pigs can be traded safely in accordance with the relevant articles of this chapter from countries complying with the provisions of this article, even if they notify *infection* with ASFV in *wild* or *feral* pigs or African *wild* suids.~~

EU comment

The EU does not support the deletion of the sentence above, as it is consistent with the intent and spirit of this chapter, as adopted at the OIE General Session in May 2017. Indeed, a country notifying infection only in wildlife can be considered as a "free country" according to point 3) of Article 15.1.3., and trade recommendations pertaining to "free countries" are to be applied also for in that case. Deletion of this sentence could therefore cause confusion and lead to incorrect interpretation and implementation of the recommendations of the chapter, and ultimately unjustified trade restrictions.

However we understand that this sentence is not well placed in the article on criteria for determining country, zone or compartment freedom, as it is not directly linked to those criteria. As it is a more general statement helping member countries to correctly interpret the chapter, similar to a sentence already included for example in Chapter 10.4. on avian influenza (in the article on general provisions, i.e. point 8 of Article 10.4.1.), we would suggest moving the sentence to Article 15.1.1. "General provisions", or at the end of Article 15.1.3. "Country or zone free from ASF".

Furthermore, for clarity reasons and in order to assist member countries in correctly interpreting and implementing this Code chapter, the EU suggests specifying in the articles providing recommendations for importation from free countries, zones or compartments that these apply to importation from countries or zones fulfilling the conditions of either point 1, 2 or 3 of Article 15.1.3.

Indeed, the recommendations for trade in commodities of wild or feral pigs (e.g. Article

15.1.15.; point 1 of 15.1.19.) already stipulate that these can only be traded under either point 1 (historical freedom) or point 2 (freedom in all suids) of the definition of "Country or Zone free from ASF" in Article 15.1.3.

The same type of clarification should also be included in the recommendations for importation from countries, zones or compartments free from ASF (i.e. in Articles 15.1.7., 15.1.9., 15.1.11 and 15.1.13., as well as in point 1 of 15.1.17., 15.1.18 and 15.1.20., and in point 2 of 15.1.19.), as follows:

"[...] kept in a country, zone or compartment free from ASF in accordance with either point 1), point 2) or point 3) of Article 15.1.3. [...]"; and

" [...] originated from domestic or captive wild pigs in a country, zone or compartment free from ASF in accordance with either point 1), point 2) or point 3) of Article 15.1.3. [...]".

Moreover, we note an inconsistency between point 1 (historical freedom) and points 2 and 3 of Article 15.1.3. Indeed, the provision that "pigs and pig commodities are imported in accordance with Articles 15.1.7 to 15.1.20" as contained in both points 2 (c) and 3 (c) of Article 15.1.3 is missing from the "historical freedom" option and should be included also there.

Finally, the EU is in general concerned about the possible misinterpretation that the recommendations for importation from "countries or zones not free from ASF" will also apply to countries or zones notifying infection with ASF only in wild or feral pigs. It should be clear(er) that for a country or zone to be defined as "not free from ASF" the infection must have been confirmed in domestic or captive pigs, regardless of the status of infection in wild/feral pigs. To that effect, a new article titled "ASF infected country or zone" should thus be drafted and included in this chapter, on the basis of infection being present in domestic/captive pigs only. Consequently, the relevant titles in the recommendations for import (i.e. Articles 15.1.8., 15.1.10., 15.1.12. and 15.1.14.) should be changed to "Recommendations for importation from countries or zones infected with ASF".

All in all, the amendments suggested above will increase transparency and address inconsistencies, hopefully contributing to correct interpretation and better implementation of this important chapter in international trade.

[...]

Article 15.1.22.

Procedures for the inactivation of ASFV in meat

For the inactivation of ASFV in *meat*, one of the following procedures should be used:

1. Heat treatment

   Meat should be subjected to ~~one of the following:~~

   ~~*a)* heat treatment in a hermetically sealed container with a Fo value of 3.00 or more; or~~

   ~~*b)*~~ heat treatment for at least 30 minutes at a minimum temperature of 70°C, which should be reached throughout the *meat*.

2. Dry cured pig meat

Meat should be cured with salt and dried for a minimum of six months.

[...]

_____

Annex 8

GLOSSARY

EU comment

The EU thanks the OIE and in general supports the proposed changes to the Glossary. 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 *animal health status* with respect to ~~a specific~~ one ~~disease~~ or more ~~specific diseases~~ *infections* or *infestations* for which required *surveillance*, ~~control and~~ *biosecurity* and control measures have been applied for the purpose of *international trade* or disease prevention and control in a country or *zone* ~~*international trade*~~.

CONTAINMENT ZONE

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

EU comment

The EU notes some differences between the wording of the definition above, and the first paragraph of Article 4.3.7. in Annex 10. Indeed, whereas the definition above refers to "all suspected or confirmed cases", Art. 4.3.7. refers to "all epidemiologically linked outbreaks". In order to avoid confusion, the wording should preferably be harmonized, and the notion of "epidemiologically linked" be included in the definition. The latter is especially important as otherwise more than one containment zone within one country or zone would not be possible.

~~***DISEASE***~~

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

EU comment

Reference is made to the general EU comments inserted in the text of the report.

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.~~

INFECTED ZONE

means a *zone* either in which an *infection* or *infestation* has been confirmed, or one that ~~does not meet the provisions for freedom of~~ is defined as such in the relevant chapters of the *Terrestrial Code.*

EU comment

The EU is hesitant as regards the proposed amendment above. Indeed, in many disease specific chapters, there currently is no definition of what is an infected country or zone.

Therefore, the previous automatic categorisation as infected in case the freedom provisions are not met will no longer apply. The consequences for each disease specific chapter should be assessed before the change is adopted, as they could indeed be significant. Consequential amendments should carefully be planned in the work program of the Code Commission and adopted at the same time as the change in the definition.

PROTECTION ZONE

means a *zone* where specific *biosecurity* and *sanitary measures* are implemented to prevent the entry of a pathogenic agent into a free country or *zone* from an ~~adjacent~~ neighbouring country or *zone* of a different *animal health status*.

~~***TRANSPARENCY***~~

~~means the comprehensive documentation of all data, information, assumptions, methods, results, discussion and conclusions used in the *risk analysis*. Conclusions should be supported by an objective and logical discussion and the document should be fully referenced.~~

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~~ with the intention of inducing immunity in an *animal* or group of *animals* against one or ~~several~~ more pathogenic agents ~~disease to be controlled~~.

EU comment

The EU suggests inserting the word "appropriate" before "vaccine" in the above definition ([…] administration of an appropriate vaccine, […]). Indeed, the notion of appropriateness of the vaccine with a view to the pathogenic agent(s) against which an immune response is to be elicited seems to be missing from the definition. This would be especially relevant for e.g. Foot-and-Mouth disease, where matching of the vaccine strain(s) with the circulating virus(es) is of particular relevance.

ZONE~~/REGION~~

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

Annex 9

CHAPTER 2.1.

IMPORT RISK ANALYSIS

EU comment

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

Article 2.1.1.

Introduction

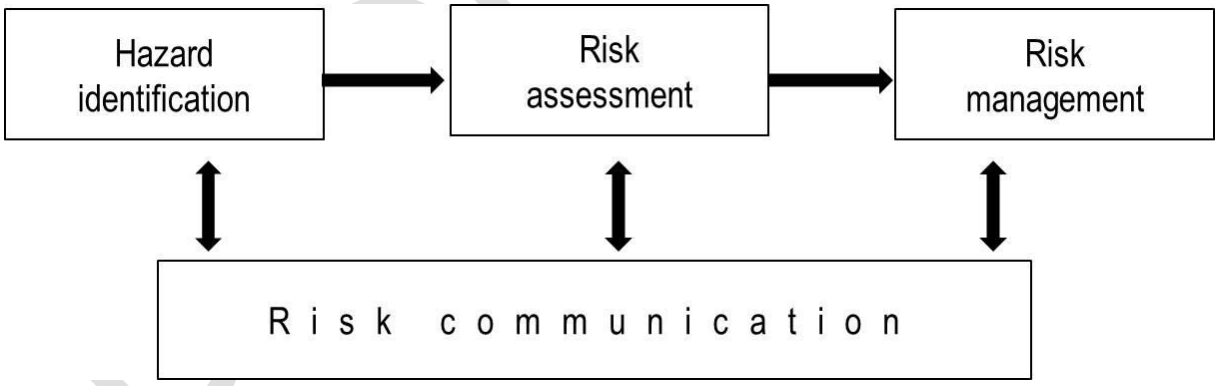
The importation of *animals* and animal products involves a degree of *disease risk* to the *importing country*. This *risk* may be represented by one or several *diseases* or *infections*.

The principal aim of import *risk analysis* is to provide *importing countries* with an objective and defensible method of assessing the *disease risks* associated with the importation of *animals*, animal products, animal genetic material, feedstuffs, biological products and *pathological material*. The analysis should be transparent. This is necessary so that the *exporting country* is provided with clear reasons for the imposition of import conditions or refusal to import.

Transparency is also essential because data are often uncertain or incomplete and, without full documentation, the distinction between facts and the analyst's value judgements may blur.

This chapter provides recommendations and principles for conducting transparent, objective and defensible *risk analyses* for *international trade*. The components of *risk analysis* are *hazard* identification, *risk assessment*, *risk management* and *risk communication* (Figure 1).

Fig. 1. The four components of risk analysis



The *risk assessment* is the component of the analysis which estimates the *risks* associated with a *hazard*. *Risk assessments* may be qualitative or quantitative. For many *diseases*, particularly for those *diseases* listed in this *Terrestrial Code* where there are well developed internationally agreed standards, there is broad agreement concerning the likely *risks*. In such cases it is more likely that a qualitative assessment is all that is required. Qualitative assessment does not require mathematical modelling skills to carry out and so is often the type of assessment used for routine decision making. No single method of import *risk assessment* has proven applicable in all situations, and different methods may be appropriate in different circumstances.

The process of import *risk analysis* usually needs to take into consideration the results of an evaluation of *Veterinary Services*, zoning, compartmentalisation and *surveillance* systems in place for monitoring of animal health in the *exporting country*. These are described in separate chapters in the *Terrestrial Code*.

[Article 2.1.2.]

Annex 9 (contd)

Article 2.1.3.

Principles of risk assessment

1) *Risk assessment* should be flexible to deal with the complexity of real life situations. No single method is applicable in all cases. *Risk assessment* should be able to accommodate the variety of animal *commodities*, the multiple *hazards* that may be identified with an importation and the specificity of each *disease*, detection and *surveillance* systems, exposure scenarios and types and amounts of data and information.

2) Both *qualitative risk assessment* and *quantitative risk assessment* methods are valid.

3) The *risk assessment* should be based on the best available information that is in accord with current scientific thinking. The assessment should be well-documented and supported with references to the scientific literature and other sources, including expert opinion.

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

5) *Risk assessments* should document the uncertainties, the assumptions made, and the effect of these on the final *risk* estimate.

6) *Risk* increases with increasing volume of *commodity* imported.

7) The *risk assessment* should be amenable to updating when additional information becomes available.

[…]

Annex 10

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.

As a more general comment, we suggest that this chapter should much more emphasise that any zone must be designed in a way that it can be controlled and enforced during all the time it is established. Indeed, sometimes zones are proposed that are completely artificial and cannot be controlled. In this sense it is very important that this chapter refers also to legal (i.e. administrative) boundaries.

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 purposes of *international trade* or disease prevention or control. *Subpopulations* may be separated by natural or artificial geographical barriers or~~, in certain situations,~~ by the application of appropriate *biosecurity* management.

EU comment

The EU suggests replacing the words "of this" with "of achieving this goal" (style).

~~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~~ appropriate management, including *biosecurity plans*, play important roles in the application of both concepts.

~~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~~ Cc~~C~~ompartmentalisation 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. To facilitate disease control and the continuation of trade following a disease *outbreak* in a previously free country or *zone*, 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*.~~

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*, on ~~and~~ ~~the~~ *animal identification* and *animal traceability* and on *official control programmes* ~~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.~~

EU comment

The EU notes that further to its previous comment, the Code Commission proposes, in the report under Item 5.4., to add a reference to movement control (and to official control programmes) in the paragraph above. However, while the reference to official control programmes was added, the reference to movement control is missing. Indeed, that reference is important to complement the reference to animal identification and traceability which are on their own are meaningless in this context, and should be mentioned explicitly (even if in theory covered by "official control programmes").

The procedures used to establish and maintain the ~~distinct~~ specific *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*.

EU comment

With regards to the reference to "epidemiology of the disease" in the paragraph above, the EU would like to point out that since zoning is about livestock, epidemiology is only one of the many aspects to be considered. At least as important is the functionality of any zoning which takes into account the value chain, i.e. access to markets, slaughterhouses, holdings that form part of the production chain (piglets from weaners to fattening farms to finishing farms), pastures, and access to germinal products or

breeding animals. In the case of working animals also the area where the animals are used for work should be considered, and not only the area where they are kept.

In addition, depending on the disease, a zone should have a certain minimum size to remain self-sustainable and to accommodate the above elements, but also to remain meaningful (for example the 2000 km² in EU legislation).

Finally, for reasons of consistency, the word "disease" should be replaced by "infection" (to read "… on the epidemiology of the infection, …").

Biosecurity and *surveillance* are essential components of zoning and compartmentalisation, and should be developed through active cooperation between industry and *Veterinary Services*.

The authority, organisation and infrastructure of the *Veterinary Services*, including *laboratories*, should be ~~clearly documented~~ established and should operate 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 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 *surveillance*, ~~and~~ diagnosis and, when appropriate, *vaccination*, treatment and protection against *vectors*.

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*~~.

EU comment

The EU suggests inserting the words "and materials" after "and their products", to cover also things like used straw, manure etc. which are not considered "animal products".

In this context, we note that there is no Glossary definition of "animal products", which would indeed be useful to have.

The *Veterinary Services* should provide movement certification, when necessary, and carry out documented periodic inspections of facilities, *biosecurity*, records and *surveillance* procedures. *Veterinary Services* should conduct or audit *surveillance*, reporting, *vaccination* and *laboratory* diagnostic examinations.

EU comment

The EU notes that in the paragraph above, reference is made to surveillance conducted or audited by the Veterinary Services, whereas the paragraph below refers to industry's responsibility to conducting surveillance, however there is no link between the two. Perhaps it would be useful to either specify in the paragraph above or below that the VS audit the surveillance performed by industry.

Furthermore, we suggest inserting "when relevant" before "vaccination" in the paragraph above, as vaccination is not always performed in a zone or compartment.

~~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, in consultation with the *Veterinary Services* if appropriate, the application of *biosecurity*, documenting and recording movements of *commodities* and personnel, managing quality assurance schemes, documenting the implementation of corrective actions, conducting *surveillance*, rapid reporting and maintenance of records in a readily accessible form.

~~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.

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.~~

~~*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 operators through official channels.

3~~5~~) *Animals* and *herds~~/~~* or *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~~ specific *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 EU queries what is meant by "epidemiological separation" in point 3) above. Indeed, it is not clear what is meant by that.

Moreover, in case of a compartment, it should not be the Veterinary Authority to document in detail the measures taken to ensure identification of the subpopulation; the role of industry should also be mentioned. Perhaps the words "to be" could be inserted before "taken".

Furthermore, for reasons of consistency, the word "disease" should be replaced by "infection" (to read "… on the epidemiology of the infection, …").

4~~6~~) Relevant ~~*animals*~~ *commodities* 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*~~,~~ or *flock* ~~lot~~ or individual animal level. Relevant ~~animal~~ movements of *commodities* 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*.

EU comment

The EU suggests inserting the words "For certain species" in the last sentence of the paragraph above, as this requirement would not apply to poultry for example.

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 *commodities* ~~animal movement controls~~, the plan should include *herd* or *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.

EU Comments

The role of Veterinary Services should be made clear. The EU therefore suggests adding the following sentence to the paragraph above:

"The Veterinary Services should carry out documented periodic inspections and verification audits of facilities biosecurity records and surveillance procedures of a compartment."

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 *infection* or *infestation* in an animal population has been demonstrated in accordance with the relevant requirements of the *Terrestrial Code*.

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 may require past or ongoing pathogen-specific and *vector 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. and the relevant chapters of the *Terrestrial Code*.

EU comment

Surveillance should also cover the demographics of the animal population, i.e. possible absence of susceptible species from the zone. This could be mentioned in the paragraph above.

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 *infection* or *infestation*, and principles determined for its definition and establishment are respected, the *zone* maintains its free status.

Article 4.3.5.

Infected zone

An *infected zone* is one either in which an *infection* or *infestation* has been confirmed, or that ~~does not meet~~ is defined as such in ~~the provisions for freedom of~~ the relevant chapters of the *Terrestrial Code.*

EU comment

For clarity and consistency, the EU suggests inserting the words "listed disease-specific"

before "chapters" in the paragraph above. Furthermore, reference is made to the EU comments on the Glossary definition of "infected zone".

An *infected zone* in which an *infection* or *infestation* has been confirmed may be:

1) a *zone* of a country where the ~~disease, *infection* or *infestation*~~ is present and has not yet been eradicated, while other *zones* of the country may be free; or

2) a *zone* of a previously free country or *zone*, in which the ~~disease, *infection* or *infestation*~~ 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 an ~~disease~~ *outbreak* in a previously *free zone*, Member Countries should follow the recommendations in the relevant 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* by preventing the introduction of a pathogenic agent of a specific *infection* or *infestation* from ~~adjacent~~ neighbouring countries or *zones* of different *animal health status* to that animal *population*. A *protection zone* can be established within or outside the *free zone* or within the free country.

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 the ~~adjacent~~ neighbouring infected countries or *zones*.

EU comment

In the paragraph above, for reasons of consistency, the word "disease" should be replaced by "infection" (to read "… the epidemiology of the infection under consideration …").

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) *vaccination* of all or at risk susceptible *animals*;

2) testing or *vaccination* of *animals* moved;

3) specific procedures for sample handling, dispatching and testing;

4) enhanced *biosecurity* including *disinfection* procedures for *vehicles*/*vessels*~~,~~ and vehicles used for transportation of animal products ~~*commodities*~~, feed or fodder, and possible compulsory routes for their movements within, to or from the *zone*;

EU comment

In point 4) above, the EU suggests inserting the words "and disinsection" after "disinfection", as this would be relevant in case of vector borne diseases.

Referring to the EU comment above, we note that a Glossary definition of "animal product" would also be useful in connection with point 4) above.

5) specific *surveillance* of susceptible *wildlife* and relevant *vectors*;

6) awareness campaigns aimed at the public or targeted at breeders, traders, hunters or *veterinarians*.

Anytime the status of the *protection zone* changes, the status should be determined in accordance with the relevant *listed disease*-specific chapters.

In the event of an emergency, such as a sudden increased *risk* to a free country or *zone*, a temporary *protection zone* may be established in a free country or *zone*. In such a situation, ~~M~~measures~~, such as *vaccination*,~~ implemented in that ~~a *protection* zone established in a free country or *zone*~~ will not affect the status of ~~the rest of~~ the free country or *zone*. However, ~~even if~~ some of ~~such~~ the measures, such as *vaccination*, may make it necessary to distinguish the status of the *protection zone* from the rest of the country or *zone*.

A temporary *protection zone* should be established for a defined period at the end of which either it is permanently distinguished from the rest of the country or *zone* or it is disestablished.

In the event of an occurrence, in a temporary *protection zone*, of a *case* of an *infection* or *infestation* for which it was established, this will not affect the status of the rest of the country or *zone*, provided that the *zone* was established at least two incubation periods before the occurrence.

EU comment

The paragraph above implies that in the case of an outbreak, the temporary protection zone would become an infected zone that is distinct from the rest of the country or zone which would retain its free status provided the temporary protection zone was established at least 2 incubation periods before the outbreak. This latter requirement (2 incubation periods) is equivalent to the time needed to establish a containment zone, and the temporary prevention zone could thus become something similar to a containment zone. However in order to work (i.e. to preserve the status of the rest of the country or zone), this would necessitate the same type of movement controls in both cases (i.e. movement restrictions during the 2 incubation periods prior to the outbreak in the temporary protection zone, just as would be the case for a containment zone). For reasons of clarify, this should preferably be mentioned explicitly in the text.

Furthermore, it should be clarified in the text what would happen to the temporary protection zone in such a case, i.e. would it become an infected zone or could it be turned into a containment zone (in which further outbreaks may or may not occur). The Code Commission report (under Item 5.3.) seems to suggest the latter (i.e. that the temporary protection zone would become a containment zone), however this is not entirely clear from the text and should preferably be clarified in order to prevent confusion and different interpretation by trading partners.

Article 4.3.7.

Containment zone

In the event of *outbreaks* in a country or *zone* previously free from a disease, a *containment zone*, which includes all epidemiologically linked *outbreaks* may be established to minimise the impact on the rest of the country or *zone*.

EU comment

With reference to the explanations provided by the Code Commission in its report, the EU suggests explicitly mentioning in the paragraph above that it is possible to establish more than one containment zone in a country or zone. Indeed, from experience, this would be important for clarity and acceptance by trading partners.

Furthermore, reference is made to the EU comment on the Glossary definition of "containment zone".

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*.

EU comment

Please insert the word "either" before "from inside or outside the containment zone" to

make this statement clearer.

Establishment of a *containment zone* should be based on a rapid response, prepared in a contingency plan, and that includes:

EU comment

Please replace the word "that" for "which" before "includes" at the end of the sentence above to make this statement clearer.

1) appropriate control of movement of *animals* and other *commodities* upon declaration of suspicion of the specified disease;

EU comment

Please insert the words "within the containment zone" after "specified disease" to make this statement clearer.

2) epidemiological investigation (trace-back, trace-forward) after confirmation of *infection* or *infestation*, demonstrating that the *outbreaks* are epidemiologically related and all contained within the defined boundaries of the *containment zone*;

3) a *stamping-out policy* or another effective emergency control strategy aimed at eradicating the disease;

EU comment

Please insert the words "within the containment zone" after "disease" to make this statement clearer.

4) *animal identification* of the susceptible population within the *containment zone* enabling its recognition as belonging to the *containment zone*;

5) increased passive and targeted *surveillance* in accordance with Chapter 1.4. in the rest of the country or *zone* demonstrating no occurrence of *infection* or *infestation*;

6) *biosecurity* and *sanitary measures*, including ongoing *surveillance* and control of the movement of *animals* and other *commodities* within and from the *containment zone*, consistent with the *listed disease*-specific chapter, when there is one, to prevent spread of the *infection* or *infestation* from the *containment zone* to the rest of the country or *zone*.

EU comment

The EU suggests inserting the word "other" before "sanitary measures" in the paragraph above. Indeed, biosecurity is also a sanitary measure.

For the effective establishment of a *containment zone*, it is necessary to demonstrate that either:

EU comment

The sentence above is not entirely clear. Perhaps the intended meaning could be clarified further by amending the wording as follows:

"A containment zone can be considered as effectively established if the following can be demonstrated:

EITHER".

Alternative:

"The establishment of a containment zone can be considered as effective if the following can be demonstrated:

EITHER"

a) there have been no new *cases* in the *containment zone* within a minimum of two *incubation periods* from the disposal of the last detected *case*.

EU comment

The EU would like to reiterate a previous general comment regarding the differences in the way the above provision is handled in individual disease specific chapters. Indeed, sometimes reference is made to cleaning and disinfection, and sometimes to the disposal of the last animal killed, etc., when specifying from when the recovery time starts counting after a stamping-out policy has been applied. The EU would prefer a consistent approach throughout the Code.

OR

b) the *containment zone* comprises an *infected zone* where *cases* may continue to occur and a *protection zone*, where no *outbreaks* have occurred for at least two *incubation periods*~~.~~ after the control measures above are in place, and that separates the *infected zone* from the rest of the country or *zone*.

The free status of the areas outside the *containment zone* is suspended pending the effective establishment of the *containment zone*. Once the *containment zone* has been established, the areas outside the *containment zone* regain free status.

EU comment

Again, with reference to the explanations provided by the Code Commission in its report, the EU suggests explicitly mentioning in the paragraph above the difference between diseases with an official status granted by the OIE and other listed diseases as regards recognition of containment zones.

The free status of the *containment zone* should be regained in accordance with the relevant *listed disease*-specific chapters or, if there are none, with Article 1.4.6.

Article 4.3.8.

Bilateral recognition by trading countries

While the OIE has procedures for official recognition of status for a number of ~~diseases or~~ *infections* (refer to Chapter 1.6.), for other ~~diseases,~~ *infections* or *infestations*, countries may recognise each other's status through a bilateral process. 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 specific *animal health status* for ~~the~~ a 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*.

In accordance with Chapter 5.3., 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* is able to ~~certifies~~ demonstrate~~s~~ that this is the case.

Annex 11

CHAPTER 4.8.

COLLECTION AND PROCESSING OF OOCYTES AND *IN VITRO* PRODUCED EMBRYOS ~~/OOCYTES~~ FROM LIVESTOCK AND HORSES

EU comment

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

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.

Annex 11 (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~~ where oocytes ~~which~~ that 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.

5) The processing laboratory should have and use appropriate facilities to handle and process embryos for export, in accordance with the recommendations in the Manual of the International Embryo Transfer Society (IETS).

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~~)~~[1].

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 or slicing techniques. 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 *slaughterhouse*/*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.

Additionally:

1) The *Veterinary* ~~*Authority*~~ *Services* 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.

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.

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~~.~~;

4) a pool of the last three washes from the 10 washes performed on 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.

Annex 11 (contd)

Additionally:

1) Semen used to fertilise oocytes *in vitro* should have been collected and processed in accordance with Chapter 4.5. and 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] of the IETS 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 of the IETS[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 of the IETS[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*;

   b) the health status of the *herds* or *flocks* and the donors from which the ovaries~~,~~ ~~/~~ oocytes~~,~~ ~~/~~ ~~or~~ embryos or semen for fertilisation of oocytes 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 of the IETS[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 of the IETS[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 of the IETS[1].

b) The frozen oocytes and embryos should ~~if possible, depending on the species,~~ be frozen in ~~fresh~~ liquid nitrogen that has not been used previously ~~or other cryoprotectant and~~ then stored in ~~fresh cryoprotectant~~ liquid phase nitrogen that has not been used previously 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 of the IETS[1].

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 of the IETS[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.

Annex 11 (contd)

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.

Annex 12

DRAFT CHAPTER 4.X.

VACCINATION

EU comment

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

Article 4.X.1.

Introduction and objectives

~~In general,~~ *Vaccination* is intended to prevent and control ~~and prevent~~ the occurrence of a disease and reduce the transmission of the pathogenic agent. ~~For the purpose of disease control~~ Ideally, 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*.

The objective of this chapter is to provide guidance to *Veterinary Authorities* for the successful ~~implementation~~ use of *vaccination* in support of disease prevention and control programmes. The recommendations in this chapter may be refined by the specific approaches described in the *listed disease*-specific chapters of the *Terrestrial Code*. Furthermore, the recommendations in this chapter may also be used for any diseases for which a vaccine exists.

EU comment

The EU suggests deleting the word "successful" in the paragraph above, which seems superfluous. Indeed, guidance is provided by this chapter whether or not use of vaccination will be successful or not.

The *vaccination* strategy applied depends on biological, 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.~~

~~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 *listed disease*-specific chapters of the *Terrestrial Code*;

4) the relevant general and specific recommendations for ~~principles of~~ veterinary vaccine production and quality control in ~~Chapter 1.1.8. of~~ the *Terrestrial Manual.*

EU comment

As point 4) above is relevant only for countries that have a domestic production of vaccines, the words "<u>, if applicable for the Member Country concerned</u>" should be inserted after "Terrestrial Manual".

~~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*.~~

~~Standards for vaccines are described in the *Terrestrial Manual*.~~

Article 4.X.2.

Definitions

For the purposes 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 prevention or 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.

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.

Article 4.X.3.

Vaccination programmes

The objectives and strategy 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~~ *infection* , its impact and zoonotic potential, 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. When appropriate, a regional approach to harmonise *vaccination* programmes is recommended.

Veterinary Authorities should liaise with public health authorities when developing *vaccination* programmes against zoonoses.

EU comment

The EU suggests replacing the word "developing" with "dealing with" in the sentence above, as cooperation with public health authorities should not be limited to the development phase of the vaccination campaign.

Furthermore, the words "when relevant" should be added the end of the sentence, as this will not be relevant for all zoonotic diseases.

Vaccination programmes may include systematic *vaccination* and emergency *vaccination*.

1) Systematic *vaccination* in infected countries aims to reduce the incidence, prevalence or impact of a disease with the objective of prevention, control and possible eradication. In ~~disease~~ free countries or *zones*, the objective of systematic *vaccination* is to prevent the introduction of a pathogenic agent from an infected ~~adjacent~~ neighbouring country or *zone*, or to limit the impact in the case of ~~an~~ the introduction of that pathogenic agent ~~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 ~~disease~~ free country or *zone*;

b) an *outbreak* in a country or *zone* that applies systematic *vaccination*, but when ~~vaccines are~~ revaccination is 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 of a pathogenic agent or emergence of a disease in a free country or *zone*.

Vaccination programmes should ~~consider other~~ be integrated with other ongoing animal health related activities involving the target population. This can improve the efficiency of the programme and reduce the cost by ~~sharing~~ optimisation of resources.

Article 4.X.4.

Launching a vaccination programme

When deciding whether to initiate a *vaccination* programme the *Veterinary Authority* should consider, among others, the following:

EU comment

The EU suggests adding a point below regarding the existence of a vaccine. Indeed, sometimes a vaccine does not exist for a particular disease, or it is not available for all susceptible animal species, or does not have the regulatory approval to be used in a given country.

1) the epidemiology of the ~~disease~~ *infection*;

1bis) the probability that the disease cannot be rapidly contained by means other than *vaccination*;

2) the ~~an increased~~ *incidence* of an existing disease;

3) the ~~an increased~~ likelihood of introduction of a pathogenic agent or emergence of a disease;

3bis) the zoonotic potential of the disease;

4) the density of the exposed susceptible animal~~s~~ *population*;

5) the ~~an insufficient~~ level of population immunity;

6) the *risk* of exposure of specific *subpopulations* of susceptible animals;

7) the suitability of a *vaccination* programme as an alternative to or an adjunct to other disease control measures such as a *stamping-out policy;*

7bis) the existence of an *animal identification system* to differentiate vaccinated from unvaccinated *subpopulations*;

EU comment

The EU agrees with the insertion of the new point above. However, this will not be feasible for wildlife. We thus suggest adding consideration for biological marker systems for wildlife vaccines (such as tetracycline in oral rabies vaccine baits for foxes and other carnivores).

8) the availability of ~~an appropriate~~ a safe and effective vaccine ~~and human, financial, and material resources~~;

8bis) the availability of human, financial, and material resources;

9) the cost-benefit analysis ~~considerations~~ of the *vaccination* programme, including the impact on trade.

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*.

2) **Ring vaccination:** *vaccination* ~~primarily~~ of all susceptible animals in a delineated area surrounding the location ~~*establishments*~~ where an *outbreak* has occurred. ~~To prevent outward spread of disease, *vaccination* should be applied from the outer limit boundary of the area inwards.~~

3) **Barrier vaccination:** *vaccination* in an area along the border of an infected country or *zone* to prevent the spread of ~~disease~~ *infection* into or from a neighbouring country or *zone*.

4) **Targeted vaccination:** v*accination* of a *subpopulation* of susceptible animals~~ defined by a greater likelihood of exposure or severity of the consequences~~.

Article 4.X.6~~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 is a critical element that depends on ~~different~~ several factors including:

EU comment

The EU suggests inserting the following sentence between the two sentences above:

"If only one vaccine is available, balance benefit / risk of use of this vacine according to data available (quality, safety and efficacy) should be considered."

Indeed, it could be useful to introduce the benefit / risk analysis of use of a vaccine for which some information is missing, particularly in case of emergency situations.

1. Availability and cost

   a) availability of the vaccine including marketing authorisation and ~~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.

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;
- onset of immunity;
- shelf-life and expiry date;
- thermostability;
- duration of the effective immunity;
- number of doses required to achieve effective immunity;
- ability to be monitored for vaccine-induced ~~antibodies~~ immunity;
- effect on the ability to differentiate infected from vaccinated animals, at the individual or group level;
- suitability of vaccine formulation for species and age of animals in the target population;
- safety for the users, the consumers and the environment.

c) Side effects

- adverse reactions;
- transmission of live vaccine strains ~~or reversion of attenuated strains to virulent.~~;
- reversion of attenuated strains to virulence.

EU comment

The EU notes that the transmission of live vaccines is not always negative, and should thus not be regarded as a side effect.

Article 4.X.7~~6~~.

Other critical elements of a vaccination programme

In addition to the choice of vaccine, the *vaccination* programme should include the following other critical elements. ~~and~~ The *vaccination* programme should be communicated to all stakeholders.

1. Legal basis

There should be a legal basis for the *vaccination* programme, including for possible compulsory compliance and for compensation of animal owners for possible adverse reactions in their animals. ~~The legal basis for a *vaccination* campaign, including a legal obligation for the *vaccination* and compensation for farmers for possible side effects, should be in place.~~

EU comment

Please delete the word "for" before "compensation" to clarify that the word "possible" refers to both "compliance" and "adverse reactions". Indeed, it is important that both elements are not compulsory.

Furthermore, there should also be a legal basis for mandatory reporting of vaccine adverse effects. This could be mentioned in the paragraph above.

2. 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~~ *infection* 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.

3~~2~~. Vaccination coverage

~~In practical terms, it~~ It may be difficult to immunise the entire target population. The *vaccination* programme should define the minimum *vaccination* coverage necessary to achieve ~~for the minimum~~ a sufficient population immunity ~~required to achieve~~ to fulfil the objectives of the programme. The minimum *population* immunity required will vary according to the epidemiology of the disease, density of susceptible animals, efficacy of the vaccine and geographical factors.

Measuring population immunity during the monitoring of the *vaccination* programme may assist ~~to~~ in identifying subsets of the target *population* that have not been adequately immunised.

4~~3~~. Stakeholder involvement

Veterinary Services ~~The *vaccination* programme~~ should demonstrate good governance of the *vaccination* programme by ~~the *Veterinary Services* and by~~ clearly identifying the involvement of different stakeholders including other ~~government agencies~~ governmental organisations, ~~farmers~~ animal owners, 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.

5~~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.

6~~5~~. Actions and timeline

The *vaccination* programme should describe the responsibilities, expected deliverables and timeline for each activity.

7~~6~~. Timing of vaccination campaigns

The *vaccination* programme should describe the periodicity of ~~the~~ any *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~~ a *vaccination* campaign ~~is~~ should be to achieve the ~~necessary~~ *vaccination* coverage necessary to attain or maintain ~~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.

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;

a~~b~~i) vaccine storage facilities and delivery systems;

b) accessibility of the target population;

c) animal handling facilities;

d) animal body condition and physiological state;

e) geographical factors;

f) climate conditions;

fbis) *vector* activity;

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.

8~~7~~. Auditing of ~~the~~ vaccination campaigns

The *vaccination* programme should include periodic auditing of all the participants in ~~the~~ any *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.

Indicators related to auditing of ~~the~~ a *vaccination* campaign may include:

a) proportion of the targeted *population* of *animals* and *herds* vaccinated within the defined timeframe;

b) number of vaccine doses used compared with number of animals vaccinated;

bbis) number of animals vaccinated compared to census figures for the relevant animal *population*;

c) number of reports of breaches of the cold chain;

d) performance of vaccinator teams ~~in respect of~~ in complying with the standard operating procedures;

e) timing and ~~length~~ duration 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.

Article 4.X.8.

Logistics of vaccination

Vaccination campaigns should be planned in detail and well in advance considering the following elements:

1. Procurement of vaccine

The vaccine selected for use in a *vaccination* programme should have been ~~be~~ subjected to the ~~registration marketing authorisation~~ relevant regulatory approval procedure of the country, which is congruent with the recommendation of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary ~~Medical~~ Medicinal Products (VICH).

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 ~~marketing authorisation~~ relevant regulatory approval ~~registration~~ should be obtained.

Vaccine banks, established in accordance with Chapter 1.1.10. of the *Terrestrial Manual*, facilitate the timely procurement of vaccines.

1~~bis~~. Procurement of equipment and consumables

In addition to the vaccine itself, the planning of the *vaccination* campaigns should include the procurement of all necessary equipment and consumables.

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 the establishment of s~~Standard operating procedures should be established to:

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;

e~~bis~~) determine the disposition of partially used or unused containers (ampoules, vials, bottles, etc.) of vaccine;

EU comment

The EU suggests slightly rewording the added parenthesis above to read "(such as ampoules, vials and bottles~~, etc.~~)" (for consistency with established Code style in other chapters).

e~~ter~~) implement *biosecurity* to ensure *vaccination* teams do not transmit the pathogenic agent between *establishments*;

f) identify vaccinated animals;

g) ensure the safety and welfare of animals and *vaccination* teams;

g~~bis~~) ensure the safety of *vaccination* teams;

EU comment

The EU suggests clearly separating the safety and welfare of animals on the one hand (covered in point g), and the safety of vaccination teams (covered in point gbis). Thus, for clarity reasons, the words "and vaccination team" at the end of point g) should be deleted.

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.

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 the places where *vaccination* is carried out ~~sites~~.

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.

EU comment

Please insert the word "the" before "public" in the point above (style).

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-~~unvaccinated 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~~ implemented 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.

EU comment

In the paragraph above, enhanced biosecurity could also be added, as this may be useful especially in view of preparation for cessation of vaccination.

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~~ A *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 during the campaign 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;

3) frequency and severity of ~~adverse reactions~~ side effects;

4) reduction of *incidence*, ~~or~~ *prevalence* or impact of the disease.

If the objectives and targets of the *vaccination* programme are not achieved, the reasons for this should be identified and addressed.

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 of the pathogenic agent or emergence of the disease;

3) reduction of the incidence, ~~or~~ prevalence or impact of the disease to a level where alternative measures such as a *stamping-out policy* may be ~~sufficient~~ more appropriate to achieve disease control;

4) inability of the programme to meet the desired objectives;

5) adverse public reaction to the *vaccination* programme~~.~~;

6) a revised cost-benefit analysis leads to decision to cease the *vaccination* programme.

EU comment

Another point that could be added above is a disrupture in vaccine supply or insufficient vaccine availability at some stage during the 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.

Article 4.X.11.

Impact on disease status and management of vaccinated animals

Vaccination has proved its capacity to help prevent, control and eradicate several 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 last statement in the paragraph above is not particularly helpful, as it does not seem to encourage international trade.

Indeed, unjustified trade barriers are often owed to importing countries not implementing recommendations of disease-specific chapters of the OIE Code, that include specific trade recommendations for vaccinated animals or their products.

A reference to those disease-specific guidelines should be included here, along with an encouragement of Member Countries to implement them in their international trade policies.

When appropriate, *vaccination* programmes should include provisions for the management of vaccinated animals such as '*vaccination* to live' or 'suppressive *vaccination*' policies. *Listed* ~~D~~*disease*-specific chapters of the *Terrestrial Code* provide additional recommendations on the management of vaccinated animals.

~~Disease f~~Free countries or *zones* applying systematic or emergency *vaccination* in response to an ~~change in the~~ increased *risk* of occurrence of a disease should inform trading partners and the OIE, as appropriate. In the absence of *cases* and unless otherwise specified in the relevant *listed* *disease*-specific chapters, *vaccination* of animals does not affect the ~~disease~~ status of the country or *zone*~~,~~ and should not disrupt trade.

Annex 13

CHAPTER 6.X.

INTRODUCTION TO RECOMMENDATIONS FOR VETERINARY PUBLIC HEALTH

EU comment

The EU thanks the OIE and in general supports this new chapter. One comment is inserted in the text below.

Article 6.X.1.

Veterinary public health is a component of public health that focuses on the application of veterinary science and that includes all actions directly or indirectly linked with *animals*, their products and by-products, so long as they contribute to the protection and improvement of the physical, mental and social well-being of humans.

Veterinary science has a rich history of contributions to public health, especially with regard to the provision of safe and adequate food, the prevention, control and eradication of zoonoses, the improvement of *animal welfare* and contributing to biomedical research.

Veterinary Services play a key role in preventing, mitigating and controlling *risks* to public health at the origin or source~~s~~ of *infection*. In particular, *Veterinary Services* contribute to public health in several areas such as food security, food safety (with respect to foodborne diseases as well as residues and pollutants), control of zoonoses and responses to natural disasters and bioterrorism.

Furthermore, a number of anthropogenic factors influence the occurrence of *emerging diseases*. These factors include among others population growth and eating habits and their consequences such as increasing food demand and intensification of production systems; increased movements and trade of *animals* and their products and derived products; the use and misuse of *antimicrobial agents* generating resistance; the disruption of ecosystems; ~~and~~ climate change~~, among others~~.

EU comment

The EU suggests inserting the word "zoonotic" before "emerging diseases" in the paragraph above. Indeed, "emerging disease" is defined in the Glossary as a disease occurring in an animal, and only those animal diseases that have an impact on public health should be referred to here.

In this context, *Veterinary Services* are integrated into the “One Health” approach to the prevention of contagious diseases and preservation of the integrity of ecosystems for the benefit of human health, the health of ~~and~~ domestic *animals* and *wildlife,* ~~animal health, including domestic *animals* and *wildlife,*~~ and biodiversity.

Veterinary training and education should take into account the role of *Veterinary Services* in public health at national, regional and global level in the development of ~~these~~ veterinary public health capabilities ~~in the local, regional and global context~~.

Annex 14a

CHAPTER 6.1.

THE ROLE OF ~~THE~~ VETERINARY SERVICES IN FOOD SAFETY SYSTEMS

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 6.1.1.

Introduction

Veterinarians are trained in both animal health (including foodborne zoonoses) and food ~~safety~~ hygiene, which makes them uniquely equipped to play a central role in ensuring food safety, especially the safety of food of animal origin.

Close cooperation and effective communication between all ~~actors~~ participants in a food safety system, including *veterinarians*, other relevant professionals and stakeholders, is critical for the effective operation of the ~~food safety~~ system. ~~Food safety systems are now considerably different from those of earlier years and this provides a wider role for the *Veterinary Services*. The characteristics of these systems are global,~~ Indeed, ~~T~~the global, regional, national and local implications of food safety systems, ~~in reach,~~ especially in relation to the globalisation of the food supply, ~~which requires a greate~~r demands a high level of engagement and collaboration between *Competent Authorities* responsible for animal health, food safety and public health, in line with the One Health approach. This provides a wider role and greater responsibilities for *Veterinary Services*. ~~There is a particular emphasis on risk-based food safety systems where implementation is a responsibility shared with a wide range of actors along with assurance of non-food safety requirements that are of high importance to consumers.~~Food safety activities performed by *Veterinary Services* should be integrated to the greatest extent possible with the activities of all other responsible ~~public~~ agencies throughout the food chain.

~~The education and training of *veterinarians*, which includes both *animal* health (including *zoonoses*) and food safety components, makes them uniquely equipped to play a central role in ensuring food safety, especially the safety of foods of *animal* origin. In addition to *veterinarians*, other professionals are involved in ensuring an integrated food safety system throughout the food chain.~~

Article 6.1.2.

Purpose and scope

The purpose of this chapter is to provide guidance to Member Countries on the role and responsibilities of ~~the~~ *Veterinary Services* in food safety systems.

This chapter should be read in conjunction with Chapter~~s~~ 4.1., Chapter 4.2., and relevant chapters of Sections 6 and 7.

~~The OIE and Codex Alimentarius Commission, through the development and implementation of standards and guidelines, contribute to improving food safety and human health by reducing risks that may arise at the farm and any subsequent stages in the food production continuum. Therefore, this~~This chapter should also be read in conjunction with the Codex Alimentarius Principles and Guidelines for National Food Control Systems (CAC/GL 82-2013), General Principles of Food Hygiene (CAC/RCP 1-1969), Code of Hygienic Practice for Meat (CAC/RCP 58-2005), Code of Practice on Good Animal Feeding (CAC/RCP 54-2004), ~~and~~ Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes Associated with the Use of Veterinary Drugs in Food Producing Animals (CAC/GL 71-2009), and other relevant Codex texts ~~on hygienic practices, food import and export certification systems and antimicrobial resistance~~.

Annex 14 (contd)

Article 6.1.3.

Characteristics of a food safety system

1. ~~Farm-to-plate approach~~ Food chain approach

Food safety is best assured by an integrated, multidisciplinary approach~~, considering~~ that considers the ~~whole~~ entire food chain. ~~Everyone in the food chain, such as food business operators, the *Veterinary Services* and consumers, has a responsibility to ensure that food is safe.~~ A ~~modern~~ food safety system should take into account the complexity of food production and the ~~increased~~ globalisation of the food supply, and should be risk-based. ~~The application of traceability systems and sharing of food chain information will enhance the effectiveness of a food safety system. The food safety system~~ It should ~~include consideration of~~ consider *hazards* and potential ~~risks~~ associated *risks* at ~~with~~ each ~~component~~ stage of the food chain, ~~namely~~ i.e. primary production, transport, processing, storage and distribution, and integrate *risk management* responses to such *risks* at the most appropriate points along ~~these~~ ~~throughout~~ the food chain ~~continuum~~. The prevention, detection, and control of foodborne *hazards* throughout the food chain is generally more effective in reducing or eliminating the *risk* of unwanted health effects than relying on controls of the final product. The application of traceability systems and sharing food chain information enhance the effectiveness of a food safety system. Everyone involved in the food chain, including food business operators, *Veterinary Services* and consumers, has a responsibility to ensure that food is safe.

2. Risk-based food safety systems

Risk-based food safety systems include measures based on good practices (such as good agricultural practice ~~Good Agricultural Practice~~, good hygienic practice ~~Good Hygienic Practice~~), hazard analysis and critical control points (HACCP) principles and *risk analysis* ~~assessment~~. The design and application of a risk-based food safety system depends ~~this risk-based approach depend~~ on the availability of adequate scientific information and effective utilisation of the technical resources of food business operators and *Competent Authorities*. ~~and technical resources of the *Competent Authority*. Monitoring and review are essential to evaluate the performance of a risk-based food safety system.~~ Monitoring food safety outcomes and reviewing control measures are essential to ensure the effective performance of a risk-based food safety system. For example, providing information on the occurrence of *infections* on the farm prior to dispatch of animals for *slaughter* may allow more targeted, risk-based inspection at the *slaughterhouse/abattoir*.

~~For international trade, a risk-based approach to food safety systems contributes to the determination of equivalence between trading partners.~~

3. ~~Primary r~~Responsibilities of food business operators for food safety

Food business operators, including feed producers, farmers, processors, wholesalers, distributors, importers, exporters and retailers, have primary responsibility for ensuring the safety of their products and should be able to demonstrate that they comply with relevant food safety regulatory requirements. ~~The food~~ Food business operators have a responsibility to inform the *Competent Authority* in their country of any non-compliance associated with their product and take action to manage the *risk* e.g. the withdrawal of the product.

4. Responsibilities of the relevant Competent Authorities ~~Competent Authority~~

~~Each Member Country should establish its objectives for *animal* health and public health protection, through consultation with stakeholders (especially livestock producers, processors and consumers) in accordance with the social, economic, cultural, religious and political contexts of the country. Based on these objectives and the analysis of scientific information, the~~ *Competent Authorities* ~~*Authority* has~~ are responsible for developing ~~the responsibility to develop national legislation and~~ policies, legislation and regulations relevant to food safety. ~~The *Competent Authority*~~ They should also take steps to ~~raise awareness of these both~~ communicate these within ~~the~~ their country and ~~to~~ with trading partners.

Competent Authorities should collaborate with other responsible agencies to ensure that roles and responsibilities for food safety systems, including responses to foodborne disease *outbreaks*, are addressed in a coordinated manner.

~~The *Competent Authority* should ensure~~ The relevant *Competent Authorities* should verify that the control systems used by food business operators are appropriate, validated, and effective, and operated in such a way that the regulatory requirements ~~standards~~ are met. This ~~should be verified~~ can be achieved through activities such as inspection and audit. In the event of noncompliance, appropriate corrective actions and sanctions should be applied.

When the *Competent Authority* delegates some control responsibilites to a third party, it should assess and regulary reassess that third party's competency.

~~5. Animal and public health roles of the Veterinary Services~~

~~At the national level the activities of the *Competent Authority* serve both public and *animal* health objectives. In the case of food safety, this duality of roles provides an opportunity for the *Veterinary Services* to perform complementary activities throughout the food chain in coordination with other relevant agencies. It is important that this duality of functions is recognised, and relevant public health and *animal* health activities are integrated.~~

Article 6.1.4.

The ~~role~~ roles and responsibilities of ~~the~~ Veterinary Services in a food safety system

1. Roles and responsibilities ~~Responsibilities~~ of ~~the~~ Veterinary Services

~~The~~ *Veterinary Authorities* ~~*Authority*~~ or other *Competent Authorities* ~~*Authority*~~ should provide an appropriate institutional environment to allow ~~the~~ *Veterinary Services* to implement the necessary policies and standards, and ensure adequate resources for them to carry out their tasks in a sustainable manner. ~~Within the~~ *Veterinary Services* ~~there~~ should ~~be~~ have a clear chain of command and ~~well documented assignment of~~ respective roles and responsibilities should be clearly defined and well documented. ~~and chain of command. In developing policies and national standards for food safety, the *Veterinary Authority* or other *Competent Authority* should collaborate with other responsible agencies to ensure that food safety risks are addressed in a coordinated manner.~~

~~In order for *Veterinary Services* to make the best possible contribution to food safety, it is important that the education and training of *veterinarians* and *veterinary para-professionals* meet appropriate levels of competence and that there are national programmes for ongoing professional development.~~

~~The~~ *Veterinary Services* should ~~be responsible for, or involved in,~~ be fully involved in the design and implementation of ~~national control programmes of~~ a risk-based food safety system appropriate to their mandate and organisational structure at the national level. ~~Implementation includes verification, audit, assurance and certification.~~ In the implementation of food safety systems for food~~s~~ of animal origin, ~~the~~ *Veterinary Services* should retain responsibility for verification and audit and facilitate a flexible approach to operational activities.

~~Where food safety activities are delegated outside of the *Veterinary Services*, the~~ *Veterinary Services* should retain overall responsibility for the delivery and performance of any activities ~~that they~~ delegated to third party providers. ~~competency standards and performance of the delegated activities.~~

~~In addition to *veterinarians*, several other professional groups are involved in ensuring food safety throughout the food chain, including analysts, epidemiologists, food technologists, human and environmental health professionals, microbiologists and toxicologists. Irrespective of the roles assigned to the different professional groups and stakeholders by the administrative system in the country, close cooperation and effective communication between all involved is imperative to achieve the best results from the combined resources.~~

~~In view of the competencies within the *Veterinary Services*, they~~ Where relevant, ~~the~~ *Veterinary Services* should contribute to other food safety related activities, such as investigations of foodborne disease *outbreaks*, food ~~defence~~ defense, disaster management, and identifying emerging *risks*. In addition, *Veterinary Services* should contribute to the development and management of coordinated *surveillance* and control programmes for foodborne pathogens of public health importance.

Annex 14 (contd)

In order for *Veterinary Services* to make the best possible contribution to ensuring food safety, the education and training of *veterinarians* and *veterinary paraprofessionals* should include appropriate training in food safety systems and ongoing professional development.

2. Activities of Veterinary Services throughout the food chain

~~The *Veterinary Services* have a significant role to play throughout the food safety system.~~ Depending on the ~~role and~~ responsibilities of the *Competent Authority*, the responsibilities of the *Veterinary Services* may be limited to the first part of the food chain (from farm to *slaughterhouse/abattoir* and associated premises for further processing) while in other cases the *Veterinary Services* may be responsible for the whole food chain.

a) Primary production

Through their presence on farms and ~~appropriate~~ collaboration with farmers, *Veterinary Services* play a key role in ensuring that *animals* are kept under good sanitary and hygienic conditions, and in *biosecurity* and ~~in the~~ early detection, *surveillance* and treatment of animal diseases, including conditions of public health significance. ~~The *Veterinary Services* advise on animal husbandry practices, *biosecurity* and interventions that limit the transmission of animal diseases, including foodborne *zoonoses*.~~

EU comment

The sentence above as amended seems weird and is rather long. Indeed, "animals kept […] in biosecurity" doesn't seem right. We suggest amending the sentence as follows:

"Through their presence on farms and collaboration with farmers, Veterinary Services play a key role:

- in ensuring that animals are kept under good sanitary and hygienic conditions,

- that good ~~and in~~ biosecurity practices are followed,

- and that early detection, surveillance and treatment of animal diseases, including conditions of public health significance, are ensured."

~~Because of the importance of traceability throughout the food chain, the verification by the *Veterinary Services* of *animal identification* is an important function.~~

In regard to food safety, ~~The~~ *Veterinary Services* ~~assist~~ provide guidance to farmers on practices that ~~how to~~ prevent or minimise physical and chemical hazards (~~e.g. for example,~~ mycotoxins, environmental contaminants ~~drug~~ and pesticide residues~~, mycotoxins and environmental contaminants~~) in primary production, including ~~through~~ animal feed.

EU comment

The EU suggests deleting the words "In regard to food safety" from the paragraph above. Indeed, while the first paragraph of point 2a) above seems to refer to biological hazards, the second one refers to chemical and physical ones, while both (i.e. also biological hazards) are related to food safety (not only the second one).

~~Producers' organisations, particularly those with veterinary advisers, are in a good position to provide awareness and training as they are regularly in contact with farmers and are well placed to understand their priorities. Technical support from the *Veterinary Services* is important and both private *veterinarians* and employees of the *Veterinary Authority* can assist. The~~ *Veterinary Services* play a central role in ensuring the responsible and prudent use of ~~biological products and~~ *veterinary medicinal products* ~~drugs~~, including *antimicrobial agents* in accordance with Chapter 6.9. in animal husbandry. This helps to minimise the ~~*risk*~~ likelihood of noncompliant levels of veterinary drug residues ~~developing antimicrobial resistance and unsafe levels of veterinary drug residues~~ in food~~s~~ of animal origin and the development of antimicrobial resistance.

Veterinary Services also play an important role in ensuring traceability throughout the food chain by verifying *animal identification* in accordance with Chapters 4.1. and 4.2.

b) ~~Processing~~ Slaughter, processing and distribution

Activities at the *slaughterhouse/abattoir* should be designed and implemented according to an integrated, risk-based approach in accordance with Chapter 6.2. ~~The~~ *Veterinary Services* have an essential role in ensuring that these activities, including meat inspection, minimise ~~processing (including meat inspection) and distribution minimises~~ foodborne *risks* to public health. This may be provided by supervision and verification of process control and direct involvement in operational activities such as ante-~~mortem~~ and post-mortem inspection. *Slaughterhouse/abattoir* inspection of live *animals* ~~(ante-mortem)~~ and their carcasses ~~(post-mortem)~~ plays a key role both in ~~both~~ the *surveillance* network for animal diseases and zoonoses, and in ensuring the safety and suitability of *meat* and by-products for their intended uses. Control or reduction of biological *hazards* of public health and animal health importance by ante- and post-mortem meat inspection is a core responsibility of ~~the~~ *Veterinary Services*. ~~and they should have primary responsibility for the development and effective implementation of relevant inspection programmes. Chapter 6.2. provides recommendations for the control of biological hazards of *animal* health and public health importance through ante- and post-mortem meat inspection.~~

The *Veterinary Services* may be responsible for overseeing the control measures during processing and distribution of food of animal origin. ~~The *Veterinary Services* also~~ They also play an important role in raising the awareness of food producers, processors and distributors regarding ~~other stakeholders of the~~ measures required to assure food safety.

~~*Veterinarians* provide essential inputs in terms of scientific information, risk assessment, validation of control measures, and monitoring and review of public health outcomes, in the design and implementation of a risk-based food safety system.~~

~~*Veterinarians* have an important role in ensuring food safety in various parts of the food chain, for example through the application of HACCP based controls and other quality assurance systems during food processing and distribution.~~

c) Assurance schemes and certification of food of animal origin ~~animal products~~ for international trade

~~The *Veterinary Services* have an important role in providing public health assurance for products of *animal* origin. When assurance is required for *animal* products *international trade* assurance may take the form of certification of consignments. In which case, the *Veterinary Services* ensure that *international veterinary certificates* comply with *animal* health and food safety standards. Certification of *animal* products in relation to *animal diseases*, including foodborne *zoonoses*, and *meat* hygiene should be the responsibility of the *Veterinary Services*. Certification may be provided by other professionals in connection with food processing and hygiene (e.g. pasteurisation of *milk products*).~~

Veterinary Services have an ~~essential~~ important role in overseeing assurance schemes and an essential role in certifying that food of animal origin complies with animal health and food safety standards.

Other *Competent Authorities* may also be involved in providing assurances and certification of food of animal origin (for example, pasteurisation of *milk products*) for *international trade*.

3. Foodborne disease outbreaks

~~Most reported *outbreaks* of foodborne disease in humans are due to contamination of foods with zoonotic agents during primary production or processing. The~~ *Veterinary Services* play a key role in the investigation of, and response to, ~~such~~ foodborne disease *outbreaks* which may be attributable to or involve animal products, ~~throughout the food chain and in formulating and~~ including the implementation of ~~implementing~~ control measures ~~as appropriate once the source of the *outbreak* has been identified~~. This work should be carried out in close collaboration with ~~human and environmental~~ public health professionals, analysts, epidemiologists, food producers, processors and traders and any others involved.

~~The *Veterinary Services* can play a leading role in development and application of new epidemiological and diagnostic tools to better attribute outbreaks of foodborne diseases to specific *animal* reservoirs.~~

~~In the view~~ Because of the global nature of the food trade, ~~the~~ *Veterinary Services* should work with other national agencies in reporting to international emergency foodborne disease networks, such as the

International Network of Food Safety Authorities (INFOSAN), and in utilising such information for preparedness.

~~4.~~ ~~Animal and public health roles of the Veterinary Services~~

~~This complementary role of the *Veterinary Services* is clearly illustrated in relation to inspection and monitoring at the *slaughterhouse*, for both *animal* health and public health hazards.~~

~~The *Veterinary Services* contribute to the development and management of coordinated *surveillance* and control programmes related to foodborne pathogens of public health importance, such as *Salmonella* and *Trichinella*.~~

Annex 15

CHAPTER 6.7.

HARMONISATION OF NATIONAL ANTIMICROBIAL RESISTANCE SURVEILLANCE AND MONITORING PROGRAMMES

EU comment

The EU 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, and the

~~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.

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.). The OIE encourages ~~C~~cooperation between all Member Countries conducting antimicrobial resistance surveillance and monitoring ~~should be encouraged~~.

Surveillance and monitoring of antimicrobial resistance is necessary to:

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.

General aspects ~~The development~~ of antimicrobial resistance surveillance and monitoring programmes

~~1. General aspects~~

Surveillance of antimicrobial resistance and ~~at targeted intervals or ongoing~~ monitoring of the prevalence of, and trends in, 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. Animal feed and the environment should also be considered according to national priorities.

EU comment

The EU does not agree with the downgrading of the importance of surveillance/monitoring of antimicrobial resistance in the environment.

Indeed, there is growing evidence and increasing concern that the environment plays an important role in the emergence and spread of AMR. Given that humans and animals are inseparably linked through the environment, addressing the environmental aspects of AMR has become one of the priorities under the One Health approach. This is also clearly recognised in the 2017 *new EU One Health Action Plan against Antimicrobial Resistance* (https://ec.europa.eu/health/amr/action_eu_en).

Important knowledge gaps in this area are also due to the lack of harmonised environmental monitoring. It should be noted that the 2016 EU *Council conclusions on the next steps under a One Health approach to combat AMR* (http://www.consilium.europa.eu/en/press/press-releases/2016/06/17/epsco-conclusions-antimicrobial-resistance/) call for aligning surveillance on AMR in humans, food, animals and the environment at EU level.

In addition, according to the 2015 WHO *Global Action Plan on Antimicrobial Resistance*, the following is stated as one of the particularly important gaps in knowledge that need to be filled: "Understanding how resistance develops and spreads, including how resistance circulates within and between humans and animals and through food, water and the environment, is important for the development of new tools, policies and regulations to counter antimicrobial resistance" (see point 32, http://www.wpro.who.int/entity/drug_resistance/resources/global_action_plan_eng.pdf)

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And also the 2016 OIE *Strategy on Antimicrobial Resistance and the Prudent Use of Antimicrobials* states the following: "The OIE Strategy on Antimicrobial Resistance is aligned with the WHO Global Action Plan and recognizes the importance of a "One Health" approach – involving human and animal health, agricultural and environmental needs." (see http://www.oie.int/fileadmin/Home/eng/Media_Center/docs/pdf/PortailAMR/EN_OIE-AMRstrategy.pdf).

The EU therefore suggests maintaining the environment in the Article 6.7.3. as a critical part of animal health and food safety strategies, for consistency with these important priorities.

Surveillance or ~~M~~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:

1~~a~~) statistically based surveys;

2~~b~~) sampling and testing of food-producing animals on the farm, at live animal markets or at *slaughter*;

3~~c~~) an organised sentinel programme, for example targeted sampling of food-producing animals, *herds*, *flocks*, and *vectors* (e.g. birds, rodents);

4d) analysis of veterinary practice and diagnostic *laboratory* records;

5e) sampling and testing of products of animal origin intended for human consumption.;

6) sampling and testing of feed ingredients or feed.

Article 6.7.4.

Sampling

12. Sampling strategies

a) Sampling should be conducted on a statistical basis. The sampling strategy should ensure:

– 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 method such as targeted, systematic random, non-random;

– type of sample (e.g. such as faecal, faeces, caeca, carcass, food product);

– sample size.

23. Sample size

The sample size should be large enough to allow detection or determine prevalence of, or trends in, existing and emerging antimicrobial resistance phenotypes.

The sample should avoid bias and provide a be representative sample of the animal *population*, process, product or other unit of interest whilst taking into account the expected prevalence of the bacteria in the sample type, the expected prevalence of the resistance phenotype and the desired level of precision and confidence.

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

Sample size estimates for prevalence of antimicrobial resistance in a large population are provided in Table 1 below.

Table 1. Sample size estimates for prevalence in a large population

	90% Level of confidence			95% Level of confidence		
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

Expected prevalence	90% Level of confidence			95% Level of confidence		
	Desired precision			Desired precision		
	10%	5%	1%	10%	5%	1%
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

34. Sample sources (Table 2)

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*.~~

a~~b~~) Food-producing animals

Categories of food-producing animals considered for sampling should be relevant to the country's production system. Resource allocation should be guided by production volume of the food-producing animal species and the *prevalence* of resistant bacteria.

b~~c~~) Food

Member Countries should consider including products of animal origin intended for human consumption, produced locally or imported, in surveillance and monitoring programmes, as foodborne transmission is considered to be an important route for the transfer of antimicrobial resistance.

c) 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*.

EU comment

In line with our comment above regarding the importance of surveillance/monitoring of antimicrobial resistance in the environment, the EU suggests adding a new point to the Article above on the environment as a further possible sample source, as follows:

"d) Member Countries should consider including the environment (in and around places where animals are housed or handled, i.e. feed, litter, water, soil, holding pen floor, truck or crate swabs, dust) in surveillance and monitoring programmes, as the environment of animals is considered an important route for transfer of antimicrobial resistance.".

45. Type of sample to be collected (Table 2)

While it is difficult to collect ~~F~~feed samples representative of the batch 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

As stated in the report under item 5.10., the words "While it is difficult to collect" should be deleted, otherwise the sentence does not make sense. The EU supports that deletion.

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*).

~~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	Prevalence of resistant bacteria after carcass dressing, representative of the ~~H~~hygiene~~,~~ of the process and the contamination during slaughter	
Processing, packing	Food products	Prevalence of resistant bacteria after processing, representative of the ~~H~~hygiene~~,~~ of the process and the 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	

EU comment

The EU suggests including a line in Table 2 above on the environment as a sampling source, as follows:

"Stable / Dust / Prevalence of resistant bacteria originating from the animals kept".

Article 6.7.5.

Bacteria subjected to surveillance and monitoring

~~6.~~ ~~Bacterial isolates~~

The following categories of bacteria ~~could~~ may be included in surveillance and monitoring programmes ~~monitored~~:

1~~a~~) Animal bacterial pathogens relevant to the countries' priorities

a) Surveillance and 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) - provide data ~~guide~~ for veterinarians ~~in~~ to inform their ~~prescribing~~ treatment decisions~~.~~;

- provide information for epidemiological studies and trend analysis.

b) 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.

c) 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, such as vaccines and Good Agricultural Practices.

The table below, derived using the above criteria, lists suggested animal bacterial pathogens for inclusion in a surveillance or 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 pathogens**
Cattle	*Pasteurella multocida*	*Escherichia coli*	*Staphylococcus aureus*	
	Mannheimia haemolytica	*Salmonella* spp.	*Streptococcus* spp.	
Pigs	*Actinobacillus pleuropneumoniae*	*Escherichia coli*		*Streptococcus suis*
		Salmonella spp.		
Poultry		*Salmonella* spp.		*Escherichia coli*

2~~b~~) Zoonotic bacteria

a~~i~~) *Salmonella*

Salmonella should be sampled from ~~animal feed,~~ food-producing animals, ~~and~~ animal-derived food products and animal feed. For the purpose of consistency and harmonisation, ~~feed samples should preferably be taken at the feed mill and~~ animal samples should ~~be~~ preferably be taken at the

slaughterhouse/abattoir from healthy *animals* and feed samples should preferably be taken at the feed mill.

Surveillance and monitoring programmes may also include bacterial isolates originating from other sources obtained from designated ~~national~~ *laboratories* ~~originating from other sources~~.

EU comment

In consistence with our comments above, the EU suggests referring also to sampling of the environment in the sentence above, as follows:

"Surveillance and monitoring programmes may also include sampling of the environment at places where animals are housed or handled (i.e. dust) or bacterial isolates [...]".

Isolation and identification of bacteria and bacterial strains should follow nationally or internationally standardised procedures.

Serovars of public health importance such as *S.* Typhimurium and *S.* Enteritidis should be included in surveillance and monitoring programmes. The inclusion of other relevant serovars will depend on the epidemiological situation in each country.

All *Salmonella* isolates should be characterised by serotyped and, where appropriate, ~~phage-typed according to standard~~ genotypic methods used at ~~the nationally~~ designated *laboratories*. ~~For those countries that have the capabilities, *Salmonella* could be genotyped using genetic finger-printing methods.~~

b~~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.

c~~iii~~) Other bacteria that are pathogenic for humans ~~emerging bacterial pathogens~~

Other ~~emerging~~ bacterial ~~that are pathogens~~ pathogenic for humans such as methicillin-resistant *Staphylococcus aureus* (MRSA)~~,~~ and *Listeria monocytogenes* ~~or others which are pathogenic to humans~~, may be included in resistance surveillance and monitoring programmes.

3~~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.

EU comment

The EU suggests inserting a reference to sampling of the environment in the sentence above, as follows:

"[…] may be sampled from animal feed, food- producing animals, their environment and products of [...]".

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~~.

Article 6.7.6.

~~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.

Article 6.7.7.

~~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 surveillance and monitoring purposes~~. However~~, recognising that 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~~.

Article 6.7.8.

~~9.~~ **Recording, storage and interpretation of data**

1~~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.

2~~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.

3~~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 surveillance and monitoring programmes) is envisaged. Results should be collected in a suitable national database~~. They should be~~ and recorded quantitatively:

a~~i~~) as distributions of MICs in micrograms per millilitre;

b~~ii~~) or inhibition zone diameters in millimetres.

4~~d~~) The information to be recorded should include, where possible, the following aspects:

a~~i~~) sampling programme;

b~~ii~~) sampling date;

c~~iii~~) animal species and production type;

d~~iv~~) type of sample;

e~~v~~) purpose of sampling;

f~~vi~~) type of antimicrobial susceptibility testing method used;

g~~vii~~) geographical origin (geographical information system data where available) of *herd*, *flock* or *animal*;

h~~vii~~) *animal* factors ~~(e.g.~~ such as age, condition, health status, identification, sex~~).~~;

i) exposure of *animals* to *antimicrobial agents*;

j) bacterial isolation rate.

5e) The reporting of *laboratory* data should include the following information:

a) i) identity of *laboratory*,

b) ii) isolation date,

c) iii) reporting date,

d) iv) bacterial species,

and, where relevant, other typing characteristics, such as:

e) v) serotype or serovar,

f) vi) phage type,

g) vi) antimicrobial susceptibility result or resistance phenotype,

h) vii) genotype.

6f) ~~The proportion of isolates regarded as resistant should be reported,~~ The number of isolates regarded as resistant should be reported as a proportion of the number of isolates tested, including the defined interpretive criteria used.

7g) 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.

8h) The bacterial isolation methods, antimicrobial susceptibility testing methods, standards and guidelines used should be recorded.

9i) For surveillance and monitoring 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.

10j) Ideally, data should be collected at the individual isolate level~~.~~. This will allow ~~allowing~~ antimicrobial resistance patterns to be recorded over time ~~to be recorded~~, along with relevant data on usage of *antimicrobial agents* and management practices.

Article 6.7.9.

~~10.~~ **Reference laboratory and annual reports**

1a) Member Countries should designate a national reference centre that assumes the responsibility to:

a) i) coordinate the activities related to the antimicrobial resistance surveillance and monitoring programmes;

b) ii) coordinate and collect information from participating ~~surveillance~~ laboratories within the country;

c) iii) produce an annual report on the antimicrobial resistance situation in the country.

2b) The national reference centre should have access to the:

a) i) raw data;

b) ii) complete results of quality assurance and inter-laboratory calibration activities;

c) iii) inter-laboratory proficiency testing results;

d) iv) information on the structure of the surveillance or monitoring system;

e~~v~~*)* information on the chosen laboratory methods.

Annex 16

CHAPTER 6.8.

MONITORING OF THE QUANTITIES AND USAGE PATTERNS OF ANTIMICROBIAL AGENTS USED IN FOOD-PRODUCING ANIMALS

Article 6.8.1.

EU comment

The EU in general supports the proposed changes to this chapter. However, important comments are inserted in the text below.

~~**Definition and**~~ **P~~p~~urpose**

~~For the purpose of this chapter, therapeutic use of *antimicrobial agents* means the administration of *antimicrobial agents* to *animals* for treating and controlling infectious diseases.~~

The purpose of the~~se~~ recommendations in this chapter is to describe an approach to the monitoring of the quantities of *antimicrobial agents* used in food-producing animals.

In order to evaluate antimicrobial exposure in food-producing animals, quantitative information should be collected to monitor usage patterns by animal species, *antimicrobial agents* or class of *antimicrobial agents*, route of administration and type of use: ~~(~~therapeutic (to treat, control or prevent) or nontherapeutic (including growth promotion) ~~and route of administration~~.

EU comment

The EU supports that a clear distinction is made between "to treat, control or prevent" on the one side and other uses of antimicrobial agents including growth promotion on the other. In order to avoid confusion with the terms "therapeutic" and "treatment", the EU suggests replacing the term "therapeutic" with "infectious disease-related", and consequently the term "nontherapeutic" with "not related to infectious diseases", throughout this chapter and the OIE Codes.

Furthermore, the EU queries what uses besides growth promotion are included in "nontherapeutic" use.

Article 6.8.1bis.

Definitions

EU comment

The EU can in principle agree that treatment, control and prevention of infectious diseases be grouped together (under "infectious disease-related use of antimicrobial agents" as explained in the EU comment above).

However, we note that the definitions of these latter three terms proposed below differ from the ones recently agreed by the G7 CVO Forum (available here: http://www.salute.gov.it/imgs/C_17_notizie_3118_listaFile_itemName_0_file.pdf). In addition, yet another set of definitions of these same terms is also being discussed in the ongoing process of revising the *Codex Code of Practice to Minimise and Contain*

Antimicrobial Resistance **(CAC/RCP 61-2005).**

Furthermore, as regards growth promotion, a new definition is proposed here below, while the G7 CVO Forum agreed to maintain the definition from the cited Codex Code, and the current draft of its revised version also maintains it.

In order to avoid confusion, the EU would advocate striving for maximum consistency and clarity at international level, by consolidating and aligning as much as possible the wording of these definitions in all of the above fora.

The EU therefore suggests, as a preferred option:

- adapting the recently agreed G7 CVO Forum definitions to define treatment, control/metaphylaxis and prevention/prophylaxis in the present Code Chapter 6.8. (note that the EU is proposing the same also as regards the revised Codex Code);

- using the current Codex Alimentarius definition for growth promotion.

Nevertheless, in case the above cannot be accommodated, some specific comments are provided below as regards individual proposed definitions for consideration by the OIE.

For the purposes of the *Terrestrial Code*,

Therapeutic use of antimicrobial agents means the administration of an *antimicrobial agent* to an individual or a group of *animals* to treat, control or prevent *infection* or disease:

EU comment

In the point above, the EU suggests replacing the word "Therapeutic" with "Infectious disease-related" (see EU comment above).

Furthermore, the EU notes that in the above definition, the wording "to treat, control or prevent infection or disease" is technically not fully accurate/complete as, strictly speaking, infection *per se* is not "treated" (disease is) and therefore the definition should generally refer to "infectious disease". We would thus suggest amending the wording as follows:

"[...] to treat, control or prevent ~~infection or~~ infectious disease".

Indeed, this would leave it to the definitions of "control" and "prevention" below to put "infection" in the right context.

This comment is valid also for the definition of "nontherapeutic" use below.

– to treat means to administer an *antimicrobial agent* to an individual or a group of *animals* showing clinical signs of an infectious disease;

– to control means to administer an *antimicrobial agent* to a group of *animals* containing sick *animals* and healthy *animals* (presumed to be infected), to minimise or resolve clinical signs and to prevent further spread of the disease;

EU comment

The EU does not agree with the proposed definition of "to control" above. Indeed, in our opinion the administration of antimicrobial agents for "control" purposes refers only to the healthy animals in the group, while clinically sick animals in the same group would be covered by "treatment". Reference is made to the wording of the relevant G7 CVO Forum definition, where that distinction is made.

Furthermore, the EU suggests introducing here also the synonym for "control", i.e. metaphylaxis, which is a term commonly used in the EU and is also used in the relevant

G7 CVO Forum definition.

– to prevent means to administer, using an appropriate dose and for a limited, defined duration, an *antimicrobial agent* to an individual or a group of *animals* at risk of developing a specific *infection* or in a specific situation where disease is likely to occur if the drug is not administered.

EU comment

In the proposed definition of "to prevent" above, the wording "using an appropriate dose and for a limited, defined duration" introduces conditions for preventive use which are not the purpose of a definition, nor are appropriate in this chapter which is about monitoring of usage (similar as for provisions on prescription proposed by the *ad hoc* group, which were rejected by the Code Commission for these same reasons).

Indeed, while we agree on the need to set such conditions for use in the OIE Code, it is preferable to have pure definitions here and provide conditions/restrictions for control and preventive use separately, in Chapter 6.9. *Responsible and prudent use of antimicrobial agents in veterinary medicine* (which could then be referenced here).

Hence, the EU suggests including concrete principles for preventive / prophylactic use and control / metaphylactic use in Chapter 6.9., along the following lines:

"Responsible and prudent preventive / prophylactic use of antimicrobials should be limited to exceptional cases, only when the risk of bacterial disease is high and consequences are severe and should be based on veterinarian oversight (or by other suitably trained and authorised person in accordance with national legislation). This use should not be systematic, nor routine, nor applied to compensate for poor hygiene or inadequate animal husbandry/plant production practices, and it should be prescribed only for a limited duration to cover the period of risk. It should always be based on epidemiological and clinical knowledge, with documented justification. When considering preventive use in populations, it should be focused on subsets at highest risk. Preventive use of antibiotics should be limited to individual animals only. Preventive use should always represent a very small proportion of total infectious disease-related use.

Responsible and prudent control / metaphylactic use should not be systematic, nor routine, nor applied to compensate for poor hygiene or inadequate animal husbandry/plant production practices. The decision to administer antimicrobials metaphylactically should be based on the diagnosis and prescribed by or on the order of a veterinarian or other suitably trained person authorised in accordance with national legislation, with documented justification. It should be based on epidemiological and clinical knowledge, and understanding of risk factors associated with the group, and in accordance with pre-established criteria (where available) for initiation of administration of antimicrobials."

The above two paragraphs are taken from the recent EU comments on Codex Circular Letter CL 2017/83-AMR (Proposed draft revision of the *Code of practice to minimize and contain antimicrobial resistance* CAC/RCP 61-2005), included as new General Principles 18 and 19 (see https://ec.europa.eu/food/sites/food/files/safety/docs/codex_tfamr_05_agenda-item-04.pdf). These two principles are to a large extent also included in the G7 CVO Forum document referenced above.

However, we note that the scope of and the terms used in both the Codex and G7 context ("antimicrobials"; "antibiotics"; "plant production"; "populations") do not fully concur with those of the OIE Code. Indeed, for instance Section 6 of the OIE Code only

uses the term "Antimicrobial agent", the Glossary definition of which is wide (i.e. substances targeting all micro-organisms), while the term "antibiotic" (with a narrower scope, targeting bacteria only) is not used in that section nor defined in the Code's Glossary.

The EU would therefore invite the OIE, when revising Chapter 6.9. to include these principles on responsible and prudent preventive and control use, to on the one hand adapt these principles to the OIE context, and on the other hand, for the sake of harmonisation as far as possible of international standards in this field, to include additional definitions in Chapter 6.9. to cater for the differences between "antimicrobial agents"/"antimicrobials" and "antibiotics".

Furthermore, the wording "at risk of developing a specific infection" in the proposed definition of "to prevent" above is technically not fully accurate as, strictly speaking, infection is acquired rather than developed (the latter applies to disease). The EU thus suggests amending the wording as follows:

"[…] at risk of ~~developing~~ acquiring a specific infection […]".

Finally, the EU suggests introducing here also the synonym for "prevention", i.e. prophylaxis, which is a term commonly used in the EU and is also used in the relevant G7 CVO Forum definition.

Nontherapeutic use of antimicrobial agents means the administration of *antimicrobial agents* to *animals* for any purpose other than to treat, control or prevent *infection* or disease; it includes growth promotion.

EU comment

In the point above, the EU suggests replacing the word "Nontherapeutic" with "Not related to infectious diseases" (see EU comment above).

Growth promotion means the administration of *antimicrobial agents* to *animals* in their feed or water to increase the rate of weight gain or the efficiency of feed utilisation.

[…]

Annex 17

CHAPTER 7.1.

INTRODUCTION TO THE RECOMMENDATIONS FOR ANIMAL WELFARE

EU comment

The EU thanks the OIE for its work on the revised Article 7.1.1. and revised definition of animal welfare in the Glossary, and for taking some EU comments into account. The EU can generally agree with the proposed changes and has a specific comment.

Furthermore when referring globally to the definition of animal welfare, the EU encourages the OIE to promote and highlight the key elements, contained in the previous definition and now included in the draft "General considerations", as important explanatory and complementary part of the newly proposed draft animal welfare definition.

Article 7.1.1.

~~**Definition**~~ **General considerations**

Animal welfare means the physical and psychological state ~~of well-being~~ of ~~how~~ an animal ~~is coping with~~ in relation to the conditions in which it lives and dies.

EU comment

In the above sentence, the EU asks the OIE to consider replacing the text as follows:

"psychological" with "mental and affective", as to read the text as follows: "the physical and, ~~psychological~~ mental and affective state".

Justification

Clarity, based on recent scientific evidence.

A recent paper by professor Mellor refers to 'Five Domains', in particular to four physical domains (nutrition, environment, health, behaviour) and a 5th affective domain, the mental state. After animal welfare is assessed, their anticipated affective consequences are assigned to the 'mental' domain; this means that the 'affective domain/mental state' encompasses positive and negative states, reciprocal to the four physical domains.

If there is agreement that 'domains' can be replaced by 'states' then the preferred option would be 'physical and, mental and affective states', as to have a more comprehensive definition, including nutrition, environment, health, behaviour and mental state. Furthermore, this would make clear that we are referring to the overarching domain feature, rather than a narrower body/mind feature.

References

B. Nicks (1)* & M. Vandenheede 2014). Animal health and welfare: equivalent or complementary? Rev. sci. tech. Off. int. Epiz., 2014, 33 (1), 97-101.

Mellor and Beausoleil, 2015. Extending the five domains model for animal welfare assessment to incorporate positive welfare states. Animal Welfare 2015, 24: 241-253, doi 10.71

Assessing affective states http://horback.faculty.ucdavis.edu/assessing-affective-states/

Animal Welfare for youth http://msue.anr.msu.edu/news/animal_welfare_for_youth_part_6_affective_states

An animal ~~is in a good state of~~ enjoys good welfare if ~~(as indicated by scientific evidence)~~ it is healthy, comfortable, well nourished, safe, it is not suffering from unpleasant states such as pain, fear and distress and it is able to express ~~innate~~ behaviours that are important for its physical and psychological state ~~well-being. and if it is not suffering from unpleasant states such as pain, fear, and distress~~.

EU comment

In the above sentence, the EU asks the OIE to consider replacing the text "psychological" with "mental and affective", as to read the text as follows:

"[...] it is not suffering from unpleasant states such as pain, fear and distress and it is able to express ~~innate~~ behaviours that are important for its physical and ~~psychological~~ mental and affective state".

Justification

See previous comment

Good *animal welfare* requires disease prevention and appropriate veterinary ~~treatment~~ care, shelter, management and nutrition, a stimulating environment, humane handling and humane *slaughter* or *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.

EU comment

When referring globally to the definition of animal welfare, the EU encourages the OIE to promote also the 2 above paragraphs as containing key elements which are complementary and explanatory of the newly proposed draft animal welfare definition.

Justification

See general comment above.

[…]

Annex 17 (contd)

GLOSSARY

EU comment

The EU thanks the OIE for its work on the revised definition of animal welfare. The EU can generally agree with the proposed changes and has a specific comment.

[. . .]

ANIMAL WELFARE

means the physical and psychological state ~~of well-being~~ of ~~how~~ an *animal* ~~is coping with~~ in relation to the conditions in which it lives and dies. ~~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/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.~~

EU comment

In the above sentence, the EU asks the OIE to consider replacing the text as follow:

"psychological" with "mental and affective", as to read the text as follow: "the physical and, ~~psychological~~ mental and affective state".

Justification

Clarity, based on recent scientific evidence.

A recent paper by professor Mellor refers to 'Five Domains', in particular to four physical domains (nutrition, environment, health, behaviour) and a 5th affective domain, the mental state. After animal welfare is assessed, their anticipated affective consequences are assigned to the 'mental' domain; this means that the 'affective domain/mental state' encompasses positive and negative states, reciprocal to the four physical domains.

If there is agreement that 'domains' can be replaced by 'states' then the preferred option would be 'physical and, mental and affective states', as to have a more comprehensive definition, including nutrition, environment, health, behaviour and mental state. Furthermore, this would make clear that we are referring to the overarching domain feature, rather than a narrower body/mind feature.

References

B. Nicks (1)* & M. Vandenheede 2014). Animal health and welfare: equivalent or complementary? Rev. sci. tech. Off. int. Epiz., 2014, 33 (1), 97-101.

Mellor and Beausoleil, 2015. Extending the five domains model for animal welfare assessment to incorporate positive welfare states. Animal Welfare 2015, 24: 241-253, doi 10.71

Assessing affective states http://horback.faculty.ucdavis.edu/assessing-affective-states/

Animal Welfare for youth http://msue.anr.msu.edu/news/animal_welfare_for_youth_part_6_affective_states

[...]

Annex 18

CHAPTER 7.1.

INTRODUCTION TO THE RECOMMENDATIONS FOR ANIMAL WELFARE

[...]

EU comment

The EU thanks the OIE for its work on the revised draft article and for taking EU comments into account. The EU can agree with the proposed changes and welcomes that the draft article covers both resource and outcome based measures.

Article 7.1.X.

Guiding principles for the use of measures to assess animal welfare

1) For the OIE *animal welfare* standards to be applicable globally, they should ~~put more~~ emphasise ~~on~~ favourable ~~good~~ outcomes for the animals, although, in some circumstances, it may be necessary to recommend ~~than on~~ specific conditions of the animals' environment and management. Outcomes are generally measured by assessing animals' enjoyment of the "five freedoms" decribed in Article 7.1.2.

2) For each principle listed in Article 7.1.4., the most relevant criteria (or measurables), ideally comprising animal-based measures, should be included in the standard. Any given animal-based measure may be linked to more than one principle.

~~3)~~ ~~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. Outcomes can be measured by an assessment of individuals or animal groups, or a representative sample of those, using data from establishments, transport or slaughterhouses/abattoirs.~~

3~~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 relevant science and experience of experts. To guide users, *Competent Authorities* and other relevant bodies should collect data that can be used to set relevant target values.

4~~5~~) In addition to animal-based measures, resource-based measures and management-based measures should be defined on the basis of science and expert experience showing that a welfare outcome is clearly linked to a resource or to a management procedure.

5) 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. Outcomes can be measured by an assessment of individuals or animal groups, or a representative sample of those, using data from establishments, transport or *slaughterhouses/abattoirs*.

6) Whatever the basis of the measure, if outcomes are unsatisfactory, users should consider what changes to resources or management are necessary to improve outcomes.

Annex 19

DRAFT CHAPTER 7.X.

ANIMAL WELFARE AND PIG PRODUCTION SYSTEMS

EU comment

The EU thanks the OIE for its work on the revision of the draft chapter and for taking most of the EU comments into account. The EU can in general agree with the proposed changes. However, the EU has relevant comments inserted in text below.

Article 7.X.1.

Definitions

~~'Pig production systems' are defined as all commercial~~ 'Commercial pig production systems' means those systems in which the purpose of the operation includes some or all of the breeding, rearing and management of pigs (*Sus scrofa*) ~~intended~~ for the production of commercially traded pigs or pig *meat*.

For the purposes 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 of handlers, and animal management practices, such as best practice in housing and husbandry and implementation of welfare protocols and audits, all have an impact on *animal welfare*. At the *animal handler* level this requires a range of well-developed husbandry skills and knowledge of how to care for animals.

For the purposes of this chapter, 'environmental enrichment' means increasing the complexity (e.g. foraging opportunities, social housing) of the animal's environment to foster the expression of normal behavior, provide cognitive stimulation and reduce the expression of abnormal behaviour ~~and provide cognitive stimulation~~. The ~~endpoint~~ aim of providing enrichment should be to improve the ~~biological functioning~~ physical and psychological state of the animal (Newberry, 1995, Mellor, 2015 and 2016).

For the purposes of this chapter 'stereotypy' is a repetitive behaviour induced by frustration, repeated attempts to cope or central nervous system dysfunction. It is expressed as a sequence of abnormal behaviours~~, repetitive and unvarying behaviours~~ which have no obvious purpose or function. ~~caused by known factors such as frustration, coping attempts~~. Permanent ~~or~~ dysfunction of the central nervous system in response to stressful conditions may mean that developed stereotypies may not resolve despite later changes to the environment or other treatment. Some stereotypies commonly observed in pigs include sham chewing, stone chewing, tongue rolling, teeth grinding, bar biting and floor licking (NFACC, 2014; Tuyttens, 2007; Mason ~~and Latham,~~ 20084).

For the purposes of this chapter 'apathy' means that the animal ceases to respond to stimuli that would normally elicit a response (Wood-Gush and Vestergaard, 1989). Furthermore, apathetic behaviour has been described as an abnormal or maladaptive behaviour, indicated by reduced activity, lack of interest or concern (i.e. indifference) and lack of feeling or emotion (impassiveness).

For the purposes of this chapter 'agonistic behaviour' is a continuum of behaviours expressed in conflict situations, and includes offence, defence and submissive or escape components. The behaviours involved may include contact, such as biting and pushing, or non-contact, such as threats in the form of body postures and gestures. Aggressive behaviour is a component of agonistic behaviour (Petherick and Blackshaw, 1987).

Article 7.X.2.

Scope

This chapter addresses the welfare aspects of commercial domestic 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 systems

   These are systems in which pigs are kept indoors, and are fully dependent on humans to provide for basic animal needs such as food feed 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 systems

   These are systems in which pigs live outdoors with shelter or shade, have some autonomy over access to shelter or shade, and but may be fully dependent on humans to provide for basic animal needs such as food feed and water. They Pigs are typically confined in paddocks or pastures according to their production stage. The animals may be kept in groups or individually.

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 (or measurables), 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 tools to monitor the efficiency of design and management, given that both of these can affect *animal welfare.*

EU comment

The EU proposes OIE to include the text "resources provided" in the second last sentence of the paragraph above, as to read as follow:

"Consideration should be given also to the resources provided and to the design of the systems".

Justification

Both resources provided and design of the system influence the welfare of pigs. Furthermore, this proposed text is in consistency with the draft Chapter on animal welfare and laying hens production systems under development.

1. Behaviour

   Certain behaviours could indicate an *animal welfare* and health problem. These include changes of in feed and water intake, altered locomotory behaviour and or posture, altered lying time, postures and patterns, altered respiratory rate and panting, coughing, shivering and huddling, certain vocalisations, and increased agonistic behaviours (including aggression), and stereotypic, apathetic or other abnormal behaviours (e.g. tail biting).

   Certain behaviours are indicators of good *animal welfare*. These may include positive social and play behaviour.

EU comment

In the above sentence, the EU would like to suggest removal of the word "may" and replace this with "These include, for example, …." as to read:

"Certain behaviours are indicators of good *animal welfare*. These ~~may~~ include for example positive social and play behaviour."
Justification
It is well documented that positive social and play behaviour are indicators of good animal welfare.
References
Reimert, Inonge, et al. "Emotional states and emotional contagion in pigs after exposure to a positive and negative treatment." Applied Animal Behaviour Science (2017).

~~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.~~

2. Morbidity rates

Rates of i~~I~~nfectious and metabolic diseases, lameness, ~~peri-partum~~ peripartum 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~~ at the *herd* level. Understanding the aetiology of the disease or syndrome is important for detecting potential *animal welfare* problems. Mastitis and metritis, leg and hoof problems, shoulder ulcers in sows, skin lesions, respiratory and digestive diseases, and reproductive diseases are also particularly important animal health problems for pigs. Scoring systems, such as for body condition, lameness and injuries, and information gathered at the *slaugtherhouse/abattoir*, can provide additional information.

Both clinical and *post mortem* pathologic 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* at the *herd* level ~~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 weight loss, are indicators of poor *animal welfare* and health.

~~In mature animals, b~~Body condition outside an acceptable range or large variation amongst individual animals in the group may be an indicator of compromised *animal welfare*~~,~~ and health, and reproductive efficiency in mature animals.

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 efficiency, compared with the targets expected for a particular breed or hybrid, can indicate *animal welfare* problems (Hemsworth *et al.*, 1981, 1986, 1989, 1994, Munsterjelm *et al.*, 2006).

Examples may include:

– low conception rates,

– high abortion rates,

– metritis and mastitis,

– ~~low~~ small litter size (total born),

– 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 *animal welfare* include:

– body condition outside an acceptable range,

– presence of ectoparasites,

– abnormal texture or hair loss,

– excessive soiling with faeces ~~in indoor systems~~,

– ~~reddish~~ skin discolouration,

– swellings, injuries or lesions,

– discharges (e.g. from nose or eyes, including tear staining) (Telkänranta *et al.*, 2016).

– feet and leg abnormalities,

– abnormal posture (e.g. rounded back, head low),

– emaciation or dehydration ~~(in piglets)~~.

7. Handling response

Improper handling or lack of human contact can result in fear and distress in pigs. Fear of humans may be an indicator of poor *animal welfare* ~~and health~~. Indicators may include:

– evidence of poor human-animal relationship, such as marked avoidance of handlers and abnormal or excessive vocalisation ~~disturbed behaviour~~ when being moved or when *animal handlers* interact with pigs ~~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~~ cause lameness and ~~to~~ gait abnormalities. Pigs that are lame or have gait abnormalities may have difficulty reaching ~~food~~ feed and water and may experience pain and distress. 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

Some painful or potentially painful 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 or environmental requirements ~~and improve human safety~~ and improve human safety or ~~and~~ safeguard *animal welfare*.

However, if these procedures are not performed properly, *animal welfare* and health can be unnecessarily compromised.

Indicators of ~~such~~ problems associated with these procedures could include:

– post-procedure *infection* and swelling,

– post-procedure lameness,

– behaviour indicating pain, fear, distress or suffering (Mellor and Patterson-Kane, 2009) ~~and distress~~,

– increased 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. 276. provide recommendations for measures applied to pigs.

Each recommendation in Article 7.X.6. to 7.X.24. includes a list of relevant animal ~~outcome~~-based criteria (or measurables) derived from Article 7.X.4.

This does not exclude other criteria being used where or when appropriate.

~~Article 7.X.6.~~

~~**Housing**~~

~~When new facilities are planned or existing facilities are modified, professional advice on design in regards to welfare and health of animals 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.~~

~~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.~~

~~Pigs should not be tethered as part of their normal housing systems.~~

~~Good outcomes in the welfare and health of animals can be achieved in a range of housing systems. The design and management of the system are critical for achieving that.~~

~~Pigs are social animals and prefer living in groups, therefore housing systems where pregnant sows and gilts can be kept in groups are recommended.~~

~~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.~~

Article 7.X.67.

Training of ~~P~~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~~ Animal-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.

Article 7.X. 7~~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~~ feed 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, sick or injured pigs and those showing abnormal behaviours such as ~~tail-nibbling and~~ tail biting.

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.

Annex 19 (contd)

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 when other methods fail ~~in extreme circumstances~~ and provided that the animal can move freely and is able to move away from the handling aid. The use of electric ~~prods~~ goads should be avoided (see also point 3 of Article 7.3.8.), and ~~in any case~~ should not be repeatedly used on the same animal, and not be used in sensitive areas including the udder, face, eyes, nose, ears or ~~ano-genital~~ anogenital region.

Exposure of pigs to sudden movement, loud noises or changes in visual contrasts should be minimised where possible to prevent stress and fear reactions. Pigs should not be improperly or aggressively handled ~~aggressively~~ (e.g. kicked, thrown, dropped, 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.

Pigs should be restrained only for as long as necessary and only appropriate, well-maintained restraint devices should be used.

Well designed and maintained handling facilities assists proper handling.

~~Outcome-~~ Animal ~~-~~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.8~~9~~.

Painful procedures

Some procedures such as surgical castration, tail docking, teeth clipping or grinding, tusk trimming, identification, and nose ringing ~~are~~ may be ~~commonly~~ performed in pigs. These procedures should only be performed when necessary to facilitate management, ~~to~~ meet market or environmental requirements ~~and improve human safety,~~ improve human safety or ~~and~~ safeguard *animal welfare*.

These procedures are painful or have the potential to cause pain. They ~~and thus~~ should be performed ~~only when necessary and~~ in such a way as to minimise any pain ~~and~~, distress or suffering to the animal~~, e.g. using anaesthesia, or analgesia or both under the recommendation or supervision of a *veterinarian*~~.

Options for enhancing *animal welfare* in relation to these procedures include the internationally recognised 'three Rs' ~~which involves~~: replacement (e.g. using entire males or immunocastrated males ~~vs.~~ rather than castrated males), reduction (e.g. tail docking and teeth clipping only when necessary) and refinement (e.g. providing analgesia or anaesthesia under the recommendation or supervision of a *veterinarian*) (Bonastre *et al.*, 2016 and Hansson *et al.*, 2011).

Ovariectomy should not be performed without anaesthesia and prolonged analgesia. An immunological product that reversibly and effectively suppresses ovarian function in pigs is available. Immunological prevention of oestrus should be encouraged to avoid ovariectomy (Dalmau *et al.*, 2015).

~~Outcome-~~ Animal ~~-~~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.

Article 7.X.9~~10~~.

Feeding and provision of water~~ing 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, genetics, size and physiological state of the pigs (e.g. pregnancy, lactation, growth), and their state of health, growth rate, previous feeding levels and level of activity and exercise.

All pigs should receive adequate ~~quantities~~ quantity and quality of feed and nutrients each day to enable each pig to:

– maintain good health;

– meet its physiological ~~and behavioural~~ requirements ~~demands;~~ and,

EU comment

The EU suggests OIE retaining the original wording in the above bullet point, as follow:

"- meet its physiological and behavioural requirements"

Justification

Not all pigs in all systems can forage but there are alternatives, i.e. oral (manipulative) behaviours such as manipulation of pen components which is an indicator of immediate postprandial satiety, which can satisfy behaviour.

References

REF De Leeuw, J. A., et al. "Effects of dietary fibre on behaviour and satiety in pigs." Proceedings of the Nutrition Society 67.4 (2008): 334-342.

– meet its requirements for foraging (Bergeron *et al.*, 2008, Brouns *et al.*, 1994, Ramonet *et al.*, 1999, Robert *et al.*, 1993 and 1997).

– ~~avoid metabolic and nutritional disorders.~~

Feed and water should be provided in such a way as to prevent ~~undue~~ excessive or injurious 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 (Herskin *et al.*, 2016).

All pigs should have access to an adequate supply of ~~palatable~~ drinkable 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~~ Animal-based criteria (or measurables): changes in body weight and body condition, physical appearance (emaciation, dehydration ~~in piglets~~), behaviour (agonistic behaviour at feeding and watering places and abnormal behaviour such as tail biting), mortality and culling rates, and morbidity rates ~~(gastric ulcers)~~.

Article 7.X.10~~11~~.

Environmental enrichment

Animals should be provided with an environment that provides complexity, manipulability and cognitive stimulation (e.g. foraging opportunities, social housing) to foster normal behaviour (e.g. rooting, ~~and~~ biting~~/~~ foraging or chewing materials other than feedstuffs), reduce abnormal behaviour (e.g. tail, ear, leg and flank biting and apathetic behaviour) and improve their ~~well-being~~ physical and psychological state ~~biological function~~ (Dudnik *et al.*, 2006; Elmore *et al.*, 201; Newberry, 1995; Van de Weerd *et al.*, 2006; Wittaker *et al.*, 1999).

Pigs should be provided with multiple forms of enrichment that aim to improve their 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 explore and look for feed (edible materials), bite (chewable materials), root (investigable materials) and manipulate ~~(manipulable~~ materials~~)~~ (Bracke *et al.*, 2006)~~:~~. ~~a~~Novelty is another aspect that is important in maintaining interest in the provided material~~(s)~~ (Trickett *et al.*, 2009; Abou-Ismaila and Mendl, 2016; Tarou and Bradshaw 2007);

– social enrichment ~~which~~ that involves either keeping pigs in groups or individually with visual, olfactory and auditory contact with other pigs;

– positive human contact (such as regular direct physical contact associated with positive events, which may include feed, pats, rubs, scratching and talking when the opportunity arises) (Hemsworth and Coleman, 2011; Hemsworth and Coleman, 1994).

~~Outcome~~ Animal~~-~~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.11~~12~~.

Prevention of abnormal behaviour

In pig production there ~~are~~ is a number of abnormal behaviours that can be prevented or minimised with appropriate 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 r~~Recommendations ~~to~~ Management procedures that may reduce the~~ir~~ occurrence of some of these behavioural problems 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~~ minerals (Fraser, 1987) or essential ~~amino acids~~ 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), general health, thermal comfort and air quality.

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 for resources, including feed and water ~~in accessing the feeding area~~ (Bench *et al.*, 2013; Leeb *et al.*, 2001; Rizvi *et al.*, 1998).

~~Outcome~~ Animal~~-~~based criteria (or measurables): 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.12~~6~~.

Housing (including outdoor production systems)

When new facilities to accommodate pigs are planned or existing facilities are modified, professional advice on design in regards to welfare and health of animals 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~~ and stress for pigs. Facilities should ~~to~~ allow for the safe, efficient and humane management and movement of pigs. In systems where pigs could be exposed to adverse weather conditions they should have access to shelter to avoid thermal stress and sunburn.

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, and water and ~~food~~ feed ~~must~~ should be within reach.

Pigs should not be tethered as part of their normal housing systems.

Good outcomes in the welfare and health of animals can be achieved in a range of housing systems. The design and management of the system are critical for achieving ~~that~~ these outcomes.

~~Pigs~~ Sows and gilts, like other pigs, are social animals and prefer living in groups (Stolba and Wood-Gush, 1989; Newberry and Wood-Gush, 1988; Gonyou, 2001), therefore ~~housing systems where~~ pregnant sows and gilts should preferably be housed ~~can be kept~~ in groups ~~are recommended~~ (Anil *et al.*, 2005; Barnett *et al.*, 2001; Boyle *et al.*, 2002; Broom *et al.*, 1995; Karlen *et al.*, 2007; Marchant and Broom, 1996; McGlone *et al.*, 2004; AVMA, 2015). ~~Sows and gilts can be successfully mixed early after breeding, without any reproduction consequences (Spoolder *et al.*, 2009).~~

EU comment

The EU would like to reiterate part of its previous comment and asks the OIE to include the following text at the end of the last sentence above, as to read:

"[...] therefore pregnant sows and gilts should preferably be housed in groups, with sufficient space to perform normal social behaviour."

Justification

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.

Furthermore, this brings the text in line with OIE introductory chapter 7.1.5 "Social grouping of animals should be managed to allow positive social behaviour and minimise injury, distress and chronic fear".

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.

EU comment

The EU would like to retain the last sentence of the above paragraph, currently proposed for deletion, and proposes to replace the word "breeding" with "service":

"Sows and gilts can be successfully mixed early after service ~~breeding~~, without any reproduction consequences (Spoolder *et al.*, 2009)."

Justification

Scientific research showing that mixing pregnant sows within a few days of insemination, can result in equivalent or better reproductive performance than later mixing was produced.

The same term should be used in the entire draft chapter for consistency and clarity.

References

Report of the Scientific Veterinary Committee "The Welfare of Intensively Kept Pigs" 30.09.1997
https://ec.europa.eu/food/sites/food/files/animals/docs/aw_arch_1997_intensively_kept_pigs_en.pdf

~~Outcome~~ Animal-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.

Article 7.X.13.

Space allowance

Space allowance should be managed taking into account different areas for lying, standing, ~~and~~ feeding and elimination. ~~Crowding~~ Stocking density should not adversely affect normal behaviour of pigs and durations of time spent lying.

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 to affect pig welfare (Marchant–Forde, 2009; Verdon, 2015). All pigs should be able to lie down ~~rest~~ simultaneously~~,~~ and ~~each animal lie down,~~ to 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.

   Group housing systems should provide sufficent space and opportunities to avoid or escape from potential aggressors.

EU comment

Given its importance, the EU asks the OIE to consider including the following sentence at the end of the above paragraph:

"Group housing systems of pigs should be encouraged compared to other systems, causing health and welfare problems (for example gestation stalls)."

Justification

Pigs are highly social animals and it is important for their welfare that they are kept in groups as much as possible so that they have the possibility to express natural and social behaviour. Farrowing crates and stalls 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 stalls or farrowing 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.

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.

Edwards, S.A. 1992: Scientific perspective on loose housing systems for sow. Pig Veterinary Journal 28, pp. 40-51

Marchant, J.N., Rudd, A.R., Broom, D.M. (1997): The effects of housing on heart rate of gestating sows during specific behaviours. Appl. Anim. Behav. Sci., 55, 67-78.

Marchant, J.N. and Broom, D.M. (1996): Effects of dry sow housing conditions on muscle weight and bone strength, Animal Science, 62, 105-113.

Rhodes, R.T., Appleby, M.C., Chinn, K., Douglas, L., Firkins, L.D., Houpt, K.A., Irwin, C., McGlone, J.J., Sundberg, P., Tokach, L., Wills, R.W. (2005): A comprehensive review of housing for pregnant sows. J. Am. Vet. Med. Assoc., 227, 1580-1590.

Schenck, E.L., McMunn, K.A., Rosenstein, D.S., Stroshine, R.L., Nielsen, B.D., Richert, B.T., Marchant-Forde, J.N., Lay, D.C. (2008): Exercising stall-housed gestating gilts: Effects on lameness, the musculo-skeletal system, production, and behavior. J. Anim. Sci. 2008, 86, 3166-3180.

Li, Y.Z. and Gonyou, H.W. (2007): Effects of stall width and sow size on behavior of gestating sows. Canadian Journal of Animal Science, 87, 129-138.

Report of the Scientific Veterinary Committee "The Welfare of Intensively Kept Pigs" 30.09.1997 https://ec.europa.eu/food/sites/food/files/animals/docs/aw_arch_1997_intensively_kept_pigs_en.pdf

Barnett, J. L., Winfield, C. G., Cronin, G. M., Hemsworth, P. H., & Dewar, A. M. (1985). The effect of individual and group housing on behavioural and physiological responses related to the welfare of pregnant pigs. *Applied Animal Behaviour Science, 14*(2), 149-161.

Barnett, J. L., Hemsworth, P. H., Cronin, G. M., Jongman, E. C., & Hutson, G. D. (2001). A review of the welfare issues for sows and piglets in relation to housing. *Australian journal of agricultural research, 52*(1), 1-28.

If abnormally aggressive behaviour is seen, corrective measures should be taken, such as increasing space allowance and providing barriers where possible or individually housing the aggressive pig.

In outdoor systems where pigs have some autonomy over diet selection, stocking density should be matched to the available feed supply.

~~Outcome~~ Animal ~~-~~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. excessive presence of faeces on the skin).

2. Individual pens

Pigs should only be housed in individual pens if necessary. In individual pens, pigs ~~must~~should be provided with sufficient space so that they can stand up, turn around and lie comfortably in a natural position, and that provides separate areas for ~~separation of~~ ~~dunging~~ elimination, lying and eating ~~areas~~.

~~Outcome~~ Animal ~~-~~based criteria (or measurables): increasing abnormal behaviour (stereotypies), morbidity, mortality and culling rates, and physical appearance (e.g. excessive presence of faeces on the skin, injuries).

3. Stalls and ~~(~~crates~~)~~

Feeding, insemination and gestation ~~and insemination~~ stalls and farrowing crates ~~Stalls~~ should ~~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 or crate,
- stand up ~~without~~ in their natural stance without contact with ~~touching~~ the top bars,
- stand ~~in a stall~~ without simultaneously touching both ends of the stall or crate,
- lie comfortably on their sides without disturbing neighbouring pigs or being injured by another pig.

EU comment

Given its importance, the EU would like to reiterate its previous comment and asks the OIE to consider including above the following sentence.

"**When sows or gilts are kept in gestation stalls, it is recommended to keep them only up to a maximum of 4 weeks/28 days after service.**"

Justification

Sows and gilts can succesfully be mixed into groups directly after service, without any reproduction consequences. The use of stalls can and should be limited to a restricted amount of days at most. The scientific references reported below highlight that confining sows in stalls for the first four weeks of pregnancy is not necessary to prevent stress that could disrupt implantation of the embryos. Well-managed mixing of sows before, or within a few days of insemination, can result in equivalent or better reproductive performance than later mixing.

Reference

Report of the Scientific Veterinary Committee "The Welfare of Intensively Kept Pigs" 30.09.1997
https://ec.europa.eu/food/sites/food/files/animals/docs/aw_arch_1997_intensively_kept_pigs_en.pdf

Anil, L., Anil, S.S., Deen, J., Baidoo, S.K., Wheaton, J.E. (2005): Evaluation of well-being, productivity, and longevity of pregnant sows housed in groups in pens with an electronic sow feeder or separately in gestation stalls. Am. J. Vet. Res., 66, 1630-1638.

Marchant, J.N., Rudd, A.R., Broom, D.M. (1997): The effects of housing on heart rate of gestating sows during specific behaviours. Appl. Anim. Behav. Sci., 55, 67-78.

Marchant, J.N. and Broom, D.M. (1996): Effects of dry sow housing conditions on muscle weight and bone strength, Animal Science, 62, 105-113.

Rhodes, R.T., Appleby, M.C., Chinn, K., Douglas, L., Firkins, L.D., Houpt, K.A., Irwin, C., McGlone, J.J., Sundberg, P., Tokach, L., Wills, R.W. (2005): A comprehensive review of housing for pregnant sows. J. Am. Vet. Med. Assoc., 227, 1580-1590.

Schenck, E.L., McMunn, K.A., Rosenstein, D.S., Stroshine, R.L., Nielsen, B.D., Richert, B.T., Marchant-Forde, J.N., Lay, D.C. (2008): Exercising stall-housed gestating gilts: Effects on lameness, the musculo-skeletal system, production, and behavior. J. Anim. Sci. 2008, 86, 3166-3180.

Li, Y.Z. and Gonyou, H.W. (2007): Effects of stall width and sow size on behavior of gestating sows. Canadian Journal of Animal Science, 87, 129-138.

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.

However, as in the Scientific Report of EFSA (2007) it is mentioned that if grouping takes place 1-2 weeks after mating, higher re-mating percentages and smaller litter have been found in sows kept in large dynamic groups without bedding compared to sows that have been tethered until testing four weeks after mating (Arey and Edwards, 1998, Te Brake and Bressers, 1990), a maximum period of sows and gilts in gestation stalls of 4 weeks after service could be acceptable as a maximum in the international context.

Seddon Y and Brown J. 2016. Managing sows in groups from weaning: are there advantages? Centered on Swine, Winter. Prairie Swine Center, Inc.

Parsons TD. 2013. Lessons learned from a decade of transitioning sow farms from stalls to pens. Advances in Pork Production 24:91-100.

Peet-Schwering, CMC van der, Hoofs AIJ, Soede NM, Spoolder HAM, Vereijken P (2009). Groepshuisvesting van zeugen tijdens de vroege dracht. [Group housing of sows during early gestation]. Rapport 283. Wageningen UR Livestock Research, Lelystad. http://edepot.wur.nl/51275 (Abstract and summary in English, rest in Dutch

Van Wettere, W.H.E.J., Pain, S.J., Stott, P.G., Hughes, P.E., 2008. Mixing gilts in early pregnancy does not affect embryo survival. Animal Reproduction Science 104, 382–388

Cassar G, Kirkwood RN, Seguin MJ, Widowski TM, Farzan A, Zanella AJ, Friendship, M. Influence of stage of gestation at grouping and presence of boars on farrowing rate and litter size of group-housed sows. Journal of Swine Health and Production. 2008:16:81-85.

~~Outcome~~ Animal ~~-~~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).

Article 7.X.14.

Flooring, bedding, resting surfaces

In all production systems pigs need a well-drained, dry and comfortable place to rest.

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.

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.

Slope~~s~~ of the floor ~~pens~~ should allow water to drain and not pool ~~in the pens~~.

In outdoor systems, pigs should be rotated between paddocks or pastures to ensure good hygiene and minimise risk of diseases.

If bedding or rubber matting 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~~ Animal ~~-~~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 and abnormal behaviour. Dust, toxins, ~~micro-organisms~~ microorganisms and noxious gases, including ammonia, hydrogen sulphide, and methane caused by decomposing animal waste, can be problematic in indoor systems ~~due to decomposing animal waste~~ (Drummond *et al.*, 1980).

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~~ concentration in enclosed housing should not exceed 25 ppm. A useful indicator is that if air quality at the level of the pigs is unpleasant for humans it is ~~also~~ most likely ~~to be~~ a problem for pigs.

EU comment

The EU would like to suggest including the following words in the first sentence of the above paragraph:

"Proper ventilation, without draughts, is important [...]"

Justification

Whilst thermal comfort and ventilation are covered in different parts of the chapter there is no mention of the need to avoid draughts.

As highligthed by the EFSA scientific opinion mentioned below (pg 24,30 44, 96), temperature and draughts may affect tail-biting incidence, and may result in altered lying behaviour, panting (too hot) or shivering (too cold) (e.g. Scott et al., 2009). Poor air quality, such as increased levels of ammonia and dust, results in respiratory problems like coughing and sneezing (Scott et al., 2007). Additional references reported below highlight the effects of draughts.

References

Managing pig health, Muirhead, Alexander and Carr et al, 2013

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

Spoolder HA, Aarnink AA, Vermeer HM, van Riel J and Edwards SA, 2012. Effect of increasing temperature on space requirements of group housed finishing pigs. Applied Animal Behaviour Science,138, 229-239.

Ducreux E, Aloui B, Robin P, Dourmad J, Courboulay V and Meunier-Salaün M, 2002. Ambient temperature influences the choice made by pigs for certain types of floor. Proceedings of the Multifactorial approach to assess pig welfare EFSA Journal 2012;12(5):3702 51 34émes Journées de la Recherche Porcine, sous l'égide de l'Association Françcaise de Zootechnie, Paris, France, 5-7 février 2002, 211-216.

Scheepens, C. J. M., Hessing, M. J. C., Laarakker, E., Schouten, W. G. P., & Tielen, M. J. M. (1991). Influences of intermittent daily draught on the behaviour of weaned pigs. Applied Animal Behaviour Science, 31(1-2), 69-82.

Scheepens, C. J. M., Tielen, M. J. M., & Hessing, M. J. C. (1991). Influence of daily intermittent draught on the health status of weaned pigs. Livestock Production Science, 29(2-3), 241-254.

Hessing, M. J. C., & Tielen, M. J. M. (1994). The effect of climatic environment and relocating and mixing on health status and productivity of pigs. Animal Science, 59(1), 131-139.

Scheepens, C. J. M., Hessing, M. J. C., Hensen, E. J., & Henricks, P. A. J. (1994). Effect of climatic stress on the immunological reactivity of weaned pigs. Veterinary Quarterly, 16(3), 137-143.

~~Outcome~~ Animal ~~-~~based criteria (or measurables): morbidity, mortality and culling rates, physical appearance (excessive soiling and tear staining), behaviour (especially respiratory rate, ~~or~~ coughing and tail biting), change in body weight and body condition.

Article 7.X.16.

Thermal environment

Although pigs can adapt to ~~different~~ a range of thermal environments, particularly if appropriate breeds and housing 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 discomfort, as well as 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, ventilation rates, stocking density, shade and wallow availability in outdoor systems~~,~~ and animal factors including breed, age and body condition (Heitman and Hughes, 1949; Quiniou and Noblet, 1999).

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 too 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, water-based cooling systems (dripping or misting), and provision of cooling systems as appropriate for the local conditions.

~~Outcome~~ Animal ~~-~~based criteria (or measurables): behaviour (feed and water intake, respiratory rate, panting, lying postures and patterns, agonistic behaviour), physical appearance (presence of faeces on the skin, sunburn), morbidity, mortality and culling rates, and reproductive efficiency.

2. Cold stress

Protection from cold should be provided when ~~these~~ conditions are likely ~~create a serious risk to the~~ to compromise ~~to~~ the welfare of pigs, particularly in neonates and young pigs and others that are physiologically compromised (e.g. ill animals). ~~This~~ Protection can be provided by insulation, extra bedding, heat mats or lamps and natural or man-made shelters in outdoor systems (Blecha and Kelley, 1981).

~~Outcome~~ Animal ~~-~~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 able to cope with a range of adaptable to different levels and types of noise. However, e~~Exposure of pigs to sudden or loud noises should be ~~minimised~~ avoided ~~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 suggests the OIE including the words "prolonged" and "increased aggression" in the first sentence of the above paragraph and modifying it as follow:

"Exposure of pigs to prolonged, sudden or loud noises should be ~~minimised~~ avoided ~~where possible~~ to prevent increased aggression, stress and fear".

Justification

Pigs exposed to mechanical noise (ventilation) of 80db for a prolonged period showed increased aggression and less submissive responses to aggression compared with pigs exposed to 40db.

References

Parker, M. O., O'Connor, E. A., McLeman, M. A., Demmers, T. G. M., Lowe, J. C., Owen, R. C., ... & Abeyesinghe, S. M. (2010). The impact of chronic environmental

stressors on growing pigs, Sus scrofa (Part 2): social behaviour. *animal*, *4*(11), 1910-1921.

~~Outcome~~ Animal ~~-~~based criteria (or measurables): behaviour (e.g. fleeing and abnormal or excessive vocalisation), physical appearance (e.g. injuries), reproductive efficiency, changes in body weight and body condition.

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~~ should 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.

~~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 would like to retain the above sentence in the following modified version:

"Light instensitity of at least 40 lux should used to avoid increased aggression."

Justification

Light intensities of less than 40 lux can increase aggression

References

O'Connor, E. A., Parker, M. O., McLeman, M. A., Demmers, T. G., Lowe, J. C., Cui, L., ... & Abeyesinghe, S. M. (2010). The impact of chronic environmental stressors on growing pigs, Sus scrofa (Part 1): stress physiology, production and play behaviour. *animal*, *4*(11), 1899-1909.

Martelli, G., Boccuzzi, R., Grandi, M., Mazzone, G., Zaghini, G., & Sardi, L. (2010). The effects of two different light intensities on the production and behavioural traits of Italian heavy pigs. *Berliner und Munchener tierarztliche Wochenschrift*, *123*(11-12), 457-462.

Artificial light sources should be located so as not to cause discomfort to the pigs.

~~Outcome~~ Animal ~~-~~based criteria (or measurables): 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~~ available to sows and gilts where possible for at least one day prior to ~~some days before~~ farrowing (Yun *et al.*, 2014, Lawrence *et al.*, 1994 and Jarvis *et al.*, 1998). Sows and gilts should be observed frequently around their expected farrowing times. As some sows and gilts need assistance during farrowing, there should be sufficient space and competent staff.

~~When new buildings are planned, loose housing systems for farrowing sows and gilts should be considered. (Baxter *et al.*, 2012; Cronin *et al.*, 2014; KilBride *et al.*, 2012; Morrison *et al.*, 2013; Weber, 2007).~~

~~Outcome~~ Animal ~~-~~based criteria (or measurables): mortality and culling rates (piglets and sows), morbidity rates (metritis and mastitis), behaviour (~~stereotypies~~ restlessness and savaging), reproductive efficiency, physical appearance (injuries).

Article 7.X.20.

Weaning

Weaning ~~can be~~ is a stressful time for sows and piglets and good management is required. Problems associated with weaning are generally related to the piglets' size and physiological maturity. ~~Early weaning systems require good management and nutrition of the piglets.~~

Weaned piglets should be moved into clean and disinfected housing separate from where sows are kept, in order to minimise the transmission of diseases to the piglets.

~~An average~~ Piglets should be weaned~~ing age of~~ at three weeks or older, unless otherwise recommended by a *veterinarian* for disease control puposes ~~is recommended~~ (Hameister *et al.*, 2010; Smith *et al.*, 2010; Gonyou *et al.*, 1998; Worobec *et al.*, 1999). Early weaning systems require good management and nutrition of the piglets.

Delaying weaning to the age of four weeks or more may produce benefits such as improved gut immunity,less diarrhoea and less use of *antimicrobial agents* (EFSA, 2007; Hameister *et al.*, 2010; McLamb *et al.*, 2013; Smith *et al.*, 2010; Gonyou *et al.*, 1998, Bailey *et al.*, 2001).

EU comment

The EU would like to propose modifying the beginning of the first sentence of the above paragraph as follow:

"~~Delaying~~ weaning at ~~to the age of~~ four weeks of age or more may produce benefits […]"

Justification

The European Food Safety Authority recommended that piglets should not be weaned before four weeks of age.

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.

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 and appropriate diet is important. The area that piglets are weaned into should be clean, ~~and~~ dry and warm.

All newly weaned pigs should be monitored during the first two weeks after weaning for any signs of ill-health or abnormal stress.

~~Outcome~~ Animal-based criteria (or measurables): mortality and culling rates (piglets), morbidity rates (respiratory disease, 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 a~~ Animals should be observed after mixing and interventions applied if the aggression is intense or prolonged, and pigs become injured ~~supervised~~.

Measures to prevent excessive fighting and injuries can include (Arey and Edwards, 1998, Verdon *et al.*, 2015):

– providing additional space and a non-slippery floor,

– feeding before mixing,

– feeding on the floor in the mixing area,

– ~~provision of~~ providing straw or other suitable enrichment materials in the mixing area,

– providing opportunities to escape and to hide from other pigs, such as visual barriers,

– mixing previously familiarised animals whenever possible,

– mixing young animals ~~should be mixed~~ as soon after weaning as possible,

– avoiding the addition of ~~adding~~ one or small number of animals to a large established group.

~~Outcome~~ Animal~~-~~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

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). Including social effects into breeding programmes may also reduce negative social interactions and increase positive ones and may have major positive effects on group-housed animals. (Rodenburg *et al.*, 2010)

~~Outcome~~ Animal~~-~~based criteria (or measurables): physical appearance, behaviour (e.g. maternal and agonistic behaviour), changes in body weight and body condition, handling response, reproductive efficiency, lameness, and morbidity, mortality and culling rates.

Article 7.X.23.

Protection from predators and pests

In outdoor and combination systems pigs should be protected from predators.

Where practicable, ~~P~~pigs should also be protected from pests such as excessive numbers of flies and mosquitoes.

~~Outcome~~ Animal~~-~~based criteria (or measurables): 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 pathogenic agents including:

– ~~pigs, including~~ introductions to the *herd*, especially from different sources,

– ~~young~~ semen ~~coming from different sources~~,

– other domestic animals, *wildlife*, and pests,

– people, including sanitation practices,

– equipment, including vehicles, tools and facilities,

– ~~*vehicles*,~~

– ~~air,~~

– air, water ~~supply~~, ~~semen,~~ feed and bedding,

– waste, including manure, ~~waste~~ garbage 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~~ welfare and health of ~~the~~ pigs in the *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*~~, when appropriate~~. This programme should include *biosecurity* and quarantine protocols, the acclimatisation of replacements, *vaccinations*, and good colostrum management, 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) and ~~fly~~ insect control, 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*, pain, distress or suffering ~~or distress~~, such as coughing, abortion, diarrhoea, changes in locomotory behaviour or 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 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*, pain, distress or suffering ~~or distress~~, they should seek advice from those having training and experience, such as *veterinarians* or other qualified advisers, as appropriate.

~~Non-ambulatory~~ Nonambulatory pigs should not be transported or moved unless absolutely necessary for treatment, recovery, or diagnosis. Such movements should be done carefully using methods that avoid dragging the animal or lifting it in a way that might cause further pain, suffering or exacerbate injuries.

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, is not feasible 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~~ Animal ~~-~~based criteria (or measurables): 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 a~~n emergency~~ disease outbreak, consistent with national programmes and recommendations of *Veterinary Services* as appropriate.

Article 7.X.25.

~~Emergency~~ Contingency plans

Where the failure of power, water ~~and~~ or feed supply systems could compromise *animal welfare,* pig producers should have contingency plans in place ~~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.

EU comment

The EU would like to propose modifying the first sentence of the above paragraph as follow:

"Preventive measures for emergencies should be input-based rather than outcome-based, such as checking and testing regularly electricity installations and devices to avoid for example fires ~~Contingency plans should be documented and communicated to all responsible parties.~~ Alarms and back-up systems should be checked regularly. Contingency plans should be documented and communicated to all responsible parties."

Justification

Fires may often be a problem. Experience shows that 'short circuit' of electrical equipment is common risk for and cause of barn fires and that preventive checks and tests on these installations and devices could prevent the barn fires. Barn fires almost always lead to high mortality of animals.

References

Bokma-Bakker, M., Bokma, S., Ellen, H., Hagen, R., Ruijven, C. (2017) Evaluatie Actieplan Stalbranden 2012-2016, Wageningen Livestock Research Rapport 1035.

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.

Procedures for humane *killing* ~~procedures for~~ of sick or injured pigs should be part of the disaster management plan and should follow the recommendations of Chapter 7.6. of the *Terrestrial Code* ~~should be part of the disaster management plan~~.

Reference to ~~emergency~~ contingency plans can also be found in Article 7.X.25.

Article 7.X.27.

~~Euthanasia (Humane killing)~~

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.

The decision to kill an animal humanely and the procedure itself should be undertaken by a competent person.

For a description of acceptable methods for humane *killing* of pigs see Chapter 7.6.

The *establishment* should have documented procedures and the necessary equipment for on-farm humane *killing*. Staff should be trained in humane *killing* procedures appropriate for each class of pig.

Reasons for humane *killing* may include:

– severe emaciation, weak pigs that are ~~non-ambulatory~~ nonambulatory or at risk of becoming ~~non-ambulatory~~ nonambulatory,

– severely injured or ~~non-ambulatory~~ nonambulatory pigs that will not stand up, refuse to eat or drink, or have not responded to ~~therapy~~ treatment,

– rapid deterioration of a medical condition for which ~~therapies have~~ treatment has been unsuccessful,

– ~~severe, debilitating pain,~~ severe pain that cannot be alleviated,

– ~~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.~~

Scientific references

Abou-Ismaila, U.A. and Mendl, M.T. (2016). The effects of enrichment novelty versus complexity in cages of group-housed rats (Rattus norvegicus). Applied Animal Behaviour Science 180, 130-139.

Algers, B., and Jensen, P. (1991). Teat stimulation and milk production during early lactation in sows: effect of continuous noise. Canadian Journal of Animal Science 71: 51-60.

Anil L., Anil S.S., Deen J., Baidoo S.K. & Wheaton J.E. (2005) Evaluation of well-being, productivity, and longevity of pregnant sows housed in groups in pens with an electronic sow feeder or separately in gestation stalls. American Journal of Veterinary Research 66:1630-1638.

Anil, L., S. S. Anil, and J. Deen. (2002). Relationship between postural behaviour and gestation stall dimensions in relation to sow size. *Appl Anim Behav Sci* 77:173–181.

Arey, D.S., Edwards, S.A. 1998. Factors influencing aggression between sows after mixing and the consequences for welfare and production. Livestock Production Science, 56: 61-70.

AVMA, (2015. Welfare implications of gestation sow housing. https://www.avma.org/KB/Resources/LiteratureReviews/Pages/Welfare-Implications-of-Gestation-Sow-Housing.aspx

Bailey M, Vega-Lopez MA, Rothkötter HJ, et al. (2001). Enteric immunity and gut health. In: Varley MA and Wiseman J (eds.), The Weaner Pig: Nutrition and Management (Wallingford, U.K.: CABI Publishing, pp. 207-222).

Barnett J.L., P.H. Hemsworth, G.M. Cronin, E.C. Jongman, and G.D. Hutson (2001). A review of the welfare issues for sows and piglets in relation to housing. Australian Journal of Agricultural Research 52, 1-28.

Baxter, E.M., Lawrence, A.B. and Edwards, S.A. (2012), 'Alternative farrowing accommodation: welfare and economic aspects of existing farrowing and lactation systems for pigs'. Animal (2012), 6, 96–117.

Bench, C. J., F. C. Rioja-Lang, S. M. Hayne, and H. W. Gonyou. 2013. Group gestation housing with individual feeding—I: How feeding regime, resource allocation, and genetic factors affect sow welfare. Livest. Sci. 152(2):208–217.

Bergeron R., Bolduc J., Ramonet Y., Meunier-Salaün M.C. & Robert S. (2000) Feeding motivation and stereotypies in pregnant sows fed increasing levels of fibre and/or food. Applied Animal Behaviour Science 70:27-40.

Bergeron, R., Badnell-Waters, A.J., Lambton, S. and Mason, G. (2008). Stereotypic oral behaviour in captive ungulates: foraging, diet and gastrointestinal function. In "Stereotypic Animal Behaviour: Fundamentals and Applications to Welfare", edited by G. Mason and J. Rushen. CABI, Wallingford, Oxfordshire, UK, pp. 19-57.

Blecha, Frank and Kelley, Keith W. . 1981. Cold Stress Reduces the Acquisition of Colostral Immunoglobulin in Piglets. Journal of Animal science, 52: 594-600.

Bonastre C, Mitjana O, Tejedor MT, Calavia M, Yuste AG, Úbeda JL and Falceto MV. 2016. Acute physiological responses to castration-related pain in piglets: the effect of two local anesthetics with or without meloxicam. Animal 10(9):1474-81.

Boyle, L.A., Leonard, F.C., Lynch, P.B. and Brophy, P. (2002). Effect of gestation housing on behaviour and skin lesions of sows in farrowing crates. Applied Animal Behaviour Science 76, 119–134;

Bracke, M.B.M., Zonderland, J. J., Lenskens, P., Schouten, W. G.P., Vermeer. H, Spoolder, H.A.M., Hendriks, H.J.M., Hopster, H. 2006. Formalised review of environmental enrichment for pigs in relation to political decision making. Applied Animal Behaviour Science 98: 165-182.

Broom, D.M., Mendl, M.T. and Zanella, A.J. (1995). A comparison of the welfare of sows in different housing conditions. Animal Science 61, 369-385.

Brouns, F., Edwards, S.A. and English, P.R. (1994). Effect of dietary fi bre and feeding system on activity and oral behaviour of group housed gilts. Appl. Anim. Behav. Sci . , 39,, 215–23.

Cronin, G.M., Rault, J-L. and Glatz, P.c. (2014). Lessons learned from past experience with intensive livestock management systems. Rev. sci. tech. Off. int. Epiz., 2014, 33 (1), 139-151.

Dalmau A, Velarde A, Rodríguez P et al. 2015. Use of an anti-GnRF vaccine to suppress estrus in crossbred Iberian female pigs. Theriogenology 84(3):342-347.

Drummond, John G.; Curtis, Stanley E.; Simon, Joseph; Norton, Horace W. 1980. Effects of Aerial Ammonia on Growth and Health of Young Pigs1. Journal of Animal Science, 50: 1085-1091.

Annex 19 (contd)

Dudnik, S., Simonse, H., Marks, I., de Jonge, F.H., and Spruijt, B.M., 2006. Announcing the arrival of enrichment increases play behaviour and reduces weaning-stress-induced behaviours of piglets directly after weaning. Applied Animal Behaviour Science, 101: 86-101.

EFSA, (2007), 'Scientific report on the risks associated with tail biting in pigsand possible means to reduce the need for tail docking considering the different housing and husbandry systems'. Annex EFSA J., 611, 1–13 (Question no. EFSA-Q-2006-013, 1–98).

EFSA, (2007) Panel for Animal Health and Welfare. 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.

Ekkel, E.D., Spoolder, H.A.M., Hulsegge, I. and Hopster, H. (2003) Lying characteristics as determinants for space requirements in pigs. *Applied Animal Behaviour Science*. 80, 19-30.

Elmore, M.R.P., Garner, J.P., Johnson, A.K., Kirkden, R.D., Richert, B.T.and Pajor, E.A. .2011. Getting around social status: Motivation and enrichment use of dominant and subordinate sows in a group setting. Applied Animal Behaviour Science, 133, (3-4), 154-163.

Fàbrega, E., Puigvert, X., Soler, J., Tibau, J., Dalmau, A.. 2013. Effect of on farm mixing and slaughter strategy on behaviour, welfare and productivity in Duroc finished entire male pigs. Applied Animal Behaviour Science, 143: 31-39.

Fraser, D, 1987. Mineral-deficient diets and the pig's attraction to blood: implications for tail-biting. Can J An Sci, 67: 909-918.

Gonyou HW, Beltranena E, Whittington DL, and Patience JF. 1998. The behaviour of pigs weaned at 12 and 21 days of age from weaning to market. Canadian Journal of Animal Science 78:517-523.

Gonyou, H.W., Brumm, M.C., Bush, E., Deen, J., Edwards, S.A., Fangman, T., McGlone, J.J., Meunier-Salaun, M., Morrison, R.B., Spoolder, H., Sundberg, P.L. and Johnson, A.K. (2006) Application of broken-line analysis to assess floor space requirements of nursery and grower-finisher pigs expressed on an allometric basis. *Journal if Animal Science.* 84, 229-235.

Gonyou, H.W. 2001. The social behaviour of pigs. In Social behaviour of farm animals, Eds L.J. Keeling and H.W. Gonyou. CABI International, Oxon, UK, p. 147.

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.

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 53:34.

Hedde, R.D., Lindsey, T.O., Parish, R.C., Daniels, H.D., Morgenthien, E.A., Lewis, H.B. Effect of diet particle size and feeding H2 receptors antagonists on gastric ulcers in swine. J Anim Sci. 1985;61(1):179-185.

Heitman, H. and Hughes, E.H. 1949. The effects of air temperature and relative humidity on the physiological well-being of swine. Journal of Animal Science, 8:171-181.

Hemsworth, P.H. and Coleman, G.J. (2011). Human-Livestock Interactions: the Stockperson and the Productivity and Welfare of Farmed Animals. 2nd Edition. CAB International, Oxon, United Kingdom.

Hemsworth, P.H. and Coleman, G.J. (1994). Improving the attitude and behaviour of stockpersons towards pigs and the consequences on the behaviour and reproductive performance of commercial pigs. Applied Animal Behaviour Science 39, 349-362.

Herskin, MS, Jensen, HE, Jespersen, A, Forkman, B, Jensen, MB, Canibe, N and Pedersen, LJ, 2016. Impact of the amount of straw provided to pigs kept in intensive production conditions on the occurrence and severity of gastric ulceration at slaughter. Res. Vet. Sci. 104, 200-206.

Jarvis , S. , Lawrence , A. B. , McLean , K. A. , Chirnside , J. , Deans , L. A. , Calvert , S. K. (1998), ' The effect of environment on plasma cortisol and beta-endorphin in the parturient pig and the involvement of endogenous opioids '. Anim. Reprod. Sci. , 52 , 139–51 .

Karlen, G.A.M., Hemsworth, P.H., Gonyou, H.W., Fabrega, E., Strom, A.D. and Smits, R.J. (2007). The welfare of gestating sows in conventional stalls and large groups on deep litter. Applied Animal Behaviour Science, 105, 87-101.

KilBride, A.L., Mendl, M., Statham, P., Held S., Harris, M., Cooper, S. and Green, L.E. (2012), 'A cohort study of preweaning piglet mortality and farrowing accommodation on 112 commercial pig farms in England'. Preventive Vet. Med., 104, 281–291.

Kilbride AL, Gillman CE, and Green LE. 2008. Prevalence of foot lesions, limb lesions and abnormal locomotion in pigs on commercial farms in Britain and risks associated with flooring. The Pig Journal 61:62-68.

KilBride AL, Gillman CE, Green LE. 2009. A cross-sectional study of the prevalence of lameness in finishing pigs, gilts and pregnant sows and associations with limb lesions and floor types on commercial farms in England. Animal Welfare 18:215-224.

Lawrence , A. B. , Petherick , J. C. , McLean , K. A. , Deans , L. A. , Chirnside , J. , Vaughan , A. , Clutton , E. and Terlouw , E. M. C. (1994), ' The effect of environment on behaviour, plasma cortisol and prolactin in parturient sows '. Appl. Anim. Behav. Sci. , 39 , 313–30.

Leeb B., Leeb Ch., Troxler J. & Schuh M. (2001) Skin lesions and callosities in group-housed pregnant sows: animal-related welfare indicators. Acta Agriculturae Scandinavica, Section A, Animal Science 51:82-87.

~~Mason, G.J. and N.R. Latham (2004). Can't stop, won't stop: is stereotypy a reliable animal welfare indicator? Anim. Welf. 13, S57-69.~~

Mason, G. (2008). Stereotypic behaviour in captive animals: fundamentals and implications for welfare and beyond. In "Stereotypic Animal Behaviour: Fundamentals and Applications to Welfare", edited by G. Mason and J. Rushen. CABI, Wallingford, Oxfordshire, UK, pp 325-357.

Marchant-Forde, J. N. (editor) (2009a), The Welfare of Pigs. Ed. J.N. Marchant-Forde, Springer Science and Business Media, New York City, USA.

Marchant, J.N. and Broom, D.M. (1996) Effects of dry sow housing conditions on muscle weight and bone strength. Journal of Animal Science 63, 105–113.

Martelli, G., Scalabrin, M., Scipioni, R., and Sardi, L. (2005). The effects of the duration of teh artificial photoperiod on the growth paramenters and behaviour of heavy pigs. Veterinary Research Communications 29: 367-369.

McGlone, J.J., von Borell, E.H., Deen, J., Johnson, K., Levis, D.G., Meunier-Salaun, M., Morrow, J., Reeves, D., Salak-Johnson, J.L. and Sundberg, P.L. (2004). Compilation of the scientific literature comparing housing systems for gestating sows and gilts using measures of physiology, behaviour, performance, and health. The Professional Scientist 20, 105–117

McLamb BL, Gibson AJ, Overman EL, Stahl C and Moeser AJ. 2013. Early weaning stress in pigs impairs innate mucosal immune responses to Enterotoxigenic E. coli challenge and exacerbates intestinal injury and clinical disease. PLoS ONE 8(4): e59838.

Mellor DJ, Patterson-Kane E, Stafford KJ. The Sciences of Animal Welfare. Wiley-Blackwell Publishing, Oxford, UK, 2009.

Mellor DJ, Updating Animal Welfare Thinking: Moving beyond the "Five Freedoms" towards "A Life Worth Living".Animals (Basel). 2016 Mar 14;6(3).

Mellor DJ Positive animal welfare states and encouraging environment-focused and animal-to-animal interactive behaviours. N Z Vet J. 2015 Jan;63(1):9-1

Mills, D.T. and Caplen, G. (2010). Abnormal/abnormality. In The Encyclopaedia of Applied Animal Behaviour and Welfare, 1st ed.; Mills, D.M., Marchant-Forde, J.N., Morton, D.B., Phillips, C.J.C., McGreevy, P.D., Nicol, C.J., Sandoe, P., Swaisgood, R.R., Eds.; CABI Publishing: Wallingford, UK, 2010; pp. 32.

Moore, A.S., Gonyou, H.W., Stookey, J.M., McLaren, D.G., 1994. Effect of group composition and pen size on behaviour, productivity and immune response of growing pigs. Appl. Anim. Behav. Sci. 40, 13–30.

Morrison R.S., Sawyer K.S.B., N.J. Kells, N.J., Johnson, C.B. and Hemsworth, P.H. (2013), 'Stress responses of two-day old piglets to tail docking'. In: Manipulating Pig Production XIV. Proc. 14th Biennial Conf. Aust. Pig Sci. Assoc., Eds. J.R. Pluske and J.M. Pluske, pp.128.

Munsterjelm, C, Valros, A, Heinonen, M, Halli, O, and Peltoniemi, 2006. Welfare index and reproductive performance in the sow. Reprod Dom Anim, 41:494-500.

NFACC (2014). Code of Practice for the Care and Handling of Pigs. http://www.nfacc.ca/pdfs/codes/pig_code_of_practice.pdf. Accessed December 15, 2016.

Newberry, R. C. 1995. Environmental enrichment: Increasing the biological relevance of captive environments. Appl. Anim. Behav. Sci. 44:229–243.

Newberry, R. and Wood-Gush, D. 1988. Development of some behaviour patterns in piglets under semi-natural conditions. Animal Science 46: 103-109.

Annex 19 (contd)

Newton, G. L.; Booram, C. V.; Hale, O. M.; Mullinix, B. G. 1980. Effect of Four Types of Floor Slats on Certain Feet Characteristics and Performance of Swine4. Journal of Animal Science, 50: 7-20.

Ni, J.Q., Vinckier, C., Coenegrachts, J., Hendriks, J.. 1999. Effect of manure on ammonia emission from a fattening pig house with partly slatted floor. Livestock Production Science, 59: 25-31.

Patience JF. Water in swine nutrition. In: Chiba LI, editor. Sustainable swine nutrition. Oxford: Blackwell Publishing Ltd; 2013. p. 3–22.

Petherick, J.C. and Blackshaw, J.K. (1987). A review of the factors affecting aggressive and agonistic behaviour of the domestic pig. Australian Journal of Experimental Agriculture, 27, 605-611.

Quiniou, N. and Noblet. 1999. J. Influence of high temperature of multiparous lactating sows. Journal of Animal Science 77: 2124-2134.

Ramonet, Y., Meunier-Salaun, M.C. and Dourmad, J.Y. (1999). High-fiber diets in pregnant sows: digestive utilization and effects on the behavior of the animals. J. Anim. Sci., 77, 591–9.

Robert, S., Rushen, J. and Farmer, C. (1997), 'Both energy content and bulk of feed affect stereotypic behaviour, heart rate and feeding motivation of female pigs'. Appl. Anim. Behav. Sci., 54, 161–171.

Robert, S., Matte, J.J., Farmer, C., Girard, C.L. and Martineau, G.P. (1993). High-fibre diets for sows: effects on stereotypies and adjunctive drinking. Appl. Anim. Behav. Sci., 37, 297–309.

Rodenburg, T.B. ; Bijma, P. ; Ellen, E.D. ; Bergsma, R. ; Vries, S. de; Bolhuis, J.E. ; Kemp, B. ; Arendonk, J.A.M. van (2010) Breeding amiable animals? Improving farm animal welfare by including social effects in breeding programmes. Animal Welfare 19 (Suppl. 1). - p. 77 – 82.

Rizvi S., Nicol C.J. & Green L.E. (1998) Risk factors for vulva biting in breeding sows in southwest England. Veterinary Record 143:654-658.

Schroder-Petersen, D.L. and Simonsen, H.B. (2001), 'Tail biting in pigs'. Vet. J., 162, 196-210.

Smith F, Clark JE, Overman BL, et al. 2010. Early weaning stress impairs development of mucosal barrier function in the porcine intestine. American Journal of Physiology: Gastrointestinal Liver Physiology 298(3):G352-363.

Stereotypic Animal Behaviour. Fundamentals and Applications to Welfare. Eds. G. Mason and J, Rushen, 2nd Edition, CABI, Wallingford, Oxfordshire, UK.

Stolba, A., Wood-Gush, D.G.M., 1989. The behaviour of pigs in a seni-natural environment. Animal Science 48, 419-425.

Sybesma, W. (editor). (1981). Welfare of pigs. Current topics in Veterinary Medical Animal Science 11. Martinus Nijhoff, The Hague, Netherlands.

Tarou, L.R. and Bashaw, M.J. (2007). Maximizing the effectiveness of environmental enrichment: Suggestions from the experimental analysis of behaviour. Applied Animal Behaviour Science 102, 189–204.

Taylor, N.R., Main, D.C.J., Mendl, M. and Edwards, S.A. (2010), 'Tail-biting: a new perspective'. Vet. J., 186, 137-147.

Taylor, N., Prescott, N., Perry, G., Potter, M., Le Suer, C., and Wathes, C. (2006). Preference of growing pigs for illuminance. Applied Animal Behaviour Science 92:19-31.

Telkänranta, H., Marchant-Forde, J.N. and Valros, A. (2016) 'Tear staining in pigs: a potential tool for welfare assessment on commercial farms', *animal*, 10(2), pp. 318–325. doi: 10.1017/S175173111500172X.

Temple, D., Courboulay, V., Manteca, X., Velarde, A., Dalmau, A.. 2012. The welfare of growing pigs in five different production systems: assessment of feeding and housing. Animal, 6,4: 656-667

Trickett, S.L., Guy, G.H. and Edwards, S.A. (2009). The role of novelty in environmental enrichment for the weaned pig. Applied Animal Behaviour Science 116, 45–51.

Turner, S.P., Ewan, M., Rooke, J.A. and Edwards, S.A. (2000) The effect of space allowance on performance, aggression and immune competence of growing pigs housed on straw deep-litter at different group sizes. *Livestock Production Science*. 66 (1), 47-55.

Turner, S.P., White, I. M. S., Brotherstone, S., Farnworth, M. J., Knap, P. W., Penny, P., Mendl, M. and Lawrence, A. B.. 2006. Heritability of post-mixing aggressiveness in grower-stage pigs and its relationship with production traits. Journal of Animal Science, 82: 615-620.

Tuyttens, F. (2007). Stereotypies. In: Velarde, A. and R. Geers (editors), On farm monitoring of pig welfare. Wageningen Academic Publishers, Wageningen, Netherlands. p.41-42.

Van de Weerd, H.A., Docking, C.M., Day, J.E.L., Breuer, K. and Edwards, S.A. .2006. Effects of species-relevant environmental enrichment on the behaviour and productivity of finishing pigs. Applied Animal Behaviour Science. 99, 230-247.

Verdon, M., Hansen, C.F., Rault, J-L., Jongman, E., Hansen, L.U., Plush, K. and Hemsworth, P.H. (2015), 'Effects of group-housing on sow welfare: A review'. J. Anim. Sci., 93, 1999–2017.

Walker, P.K. and Bilkei, G. (2006), 'Tail-biting in outdoor pig production'. Vet. J., 171, 367–369.

Weber, R., Keil, N.M., Fehr, M. and Horat, R. (2007). Piglet mortality on farms using farrowing systems with or without crates. Animal Welfare 16, 277-279.

Werremann, R.P., and Bazer, F.W. (1985).Influence of environmental temeprature on prolificacy of pigs. Journal of Reproduction and Fertility, 33:199-208.

Wittaker, X., Edwards, S.A. Spoolder, H.A.M., Lawrence, A.B, and Corning, S. (1999). Effects of straw bedding and high fibre diets on the behaviour of floor fed group-housed sows. Applied Animal Behaviour Science. 63, 25-39.

Wood-Gush, D.G.M., Vestergaard, K., 1989. Exploratory behavior and the welfare of intensively kept animals. Journal of Agricultural Ethics 2, 161–169.

Worobec, E. K, Duncan, I.J.H., Widowski, T.M. The Effects of weaning at 7, 14 and 28 days on piglet behaviour. Appl Anim Behav Sci.1999;62:173–182.

Yun, J., Swan, K-M., Farmer, C., Oliviero, C., Peltoniemi, O., Valros, A. (2014). Prepartum nest-building has an impact on postpartum nursing performance and maternal behaviour in early lactating sows. Applied Animal Behaviour Science 160:31-37.

Annex 20

CHAPTER 8.3.

INFECTION WITH BLUETONGUE VIRUS

EU comment

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

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 sample~~s~~ 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 live vaccine strain has been ~~detected~~ identified in a sample from a ruminant or camelid that is unvaccinated, or has been vaccinated with an inactivated vaccine, or with a different live vaccine strain, showing clinical signs consistent with bluetongue, or epidemiologically linked to a suspected or confirmed *case*, or

4~~3~~) 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.

Annex 20 (contd)

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.

Country or zone seasonally free from bluetongue

1) A country or *zone* seasonally free from bluetongue is, respectively, an infected country or a part of an infected country or ~~an *infected* zone~~, for which *surveillance* conducted in accordance with Articles 8.3.14. to 8.3.17. demonstrates no evidence either of transmission of BTV or of adult *Culicoides* for part of a year.

2) 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*.

3) 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:

   a~~1~~) at least 28 days before the earliest date that historical data show transmission of BTV may recommence; or

   b~~2~~) immediately if current climatic data or data from a *surveillance* programme indicate transmission of BTV or an earlier resurgence of activity of adult *Culicoides*.

4) 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*.

Annex 20 (contd)

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;

AND

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;~~

   a~~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.;

   b~~c~~) were identified as having been vaccinated;

   c~~d~~) remained in the free country or *zone* for at least seven days 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* in accordance with point 2 of Article 8.3.13. 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 countries or zones seasonally free from bluetongue

For ruminants and camelids

Annex 20 (contd)

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;

AND

2) were kept during the ~~seasonally~~ free ~~period~~ season in a seasonally free country or *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 country or *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 country or *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:

   a) ~~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~~

   b) ~~were~~ identified as having been vaccinated; ~~and~~

   c) kept during the free season ~~remained~~ in the seasonally free ~~country or~~ *zone* for at least seven days and 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* in accordance with point 2 of Article 8.3.13. 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:

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

AND

2) were protected from attacks from *Culicoides* in accordance with Article 8.3.13. 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 accordance with Article 8.3.13. 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 accordance with Article 8.3.13. 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:

   a) 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.;

   b) identified as having been vaccinated; 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 country or *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;~~

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

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;

Annex 20 (contd)

AND

b) were kept in a *vector*-protected *establishment* in accordance with point 1 of Article 8.3.13. 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~~ seven 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; and

~~*b)*~~ were kept in a country or *zone* free from bluetongue or in a seasonally free country or 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

b) comply with point 1 of Article 8.3.12.*:*

~~*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;

AND

b) were kept in a *vector*-protected *establishment* in accordance with point 1 of Article 8.3.13. for at least 60 days before commencement of, and during, 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;

3) the semen used to fertilise the oocytes complied with Article 8.3.9. or Article 8.3.10.

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.

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

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. bovines ~~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.

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. Bovines ~~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 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. Bovines ~~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*.

Annex 20 (contd)

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 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 bovines ~~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.

Annex 21

CHAPTER 8.4.

INFECTION WITH *BRUCELLA ABORTUS*, *B. MELITENSIS* AND *B.SUIS*

EU comment

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

[…]

Article 8.4.10.

Herd or flock free from infection with *Brucella* in bovids, sheep and goats, camelids or cervids without vaccination

1) To qualify as free from *infection* with *Brucella* without *vaccination*, a *herd* or *flock* of bovids, sheep and goats, camelids or cervids should satisfy the following requirements:

a) the *herd* or *flock* is in a country or *zone* free from *infection* with *Brucella* without *vaccination* in the relevant animal category and is certified free without *vaccination* by the *Veterinary Authority*;

OR

b) the *herd* or *flock* is in a country or *zone* free from *infection* with *Brucella* with *vaccination* in the relevant animal category and is certified free without *vaccination* by the *Veterinary Authority*; and no animal of the *herd* or *flock* has been vaccinated in the past three years;

OR

c) the *herd* or *flock* met the following conditions:

i) *infection* with *Brucella* in animals is a *notifiable disease* in the entire country;

ii) no animal of the relevant category of the *herd* or *flock* has been vaccinated in the past three years;

iii) no *case* has been detected in the *herd* or *flock* for at least the past year;

iv) animals showing clinical signs consistent with *infection* with *Brucella* such as abortions have been subjected to the necessary diagnostic tests with negative results;

v) for at least the past year, there has been no evidence of *infection* with *Brucella* in other *herds* or *flocks* of the same *establishment*, or measures have been implemented to prevent any transmission of the *infection* with *Brucella* from these other *herds* or *flocks*;

vi) two tests have been performed with negative results on all sexually mature animals, i.e. except castrated males, present in the *herd* at the time of testing, the first test being performed not before ~~3~~ three months after the *slaughter* of the last case and the second test at an interval of more than ~~6~~ six and less than 12 months.

2) To maintain the free status, the following conditions should be met:

a) the requirements in points 1*a)* or 1*b)* or 1*c) i)* to *v)* above are met;

b) regular tests, at a frequency depending on the prevalence of *herd* or *flock infection* in the country or *zone*, demonstrate the continuing absence of *infection* with *Brucella*;

c) animals of the relevant category introduced into the *herd* or *flock* are accompanied by a certificate from an *Official Veterinarian* attesting that they come from:

i) a country or *zone* free from *infection* with *Brucella* in the relevant category without *vaccination*;

OR

ii) a country or *zone* free from *infection* with *Brucella* with *vaccination* and the animals of the relevant category have not been vaccinated in the past three years;

OR

iii) a *herd* or *flock* free from *infection* with *Brucella* with or without *vaccination* and that the animals have not been vaccinated in the past three years and were tested for *infection* with *Brucella* within 30 days prior to shipment with negative results; in the case of post-parturient females, the test is carried out at least 30 days after giving birth. This test is not required for sexually immature animals.

[…]

Annex 22

CHAPTER 8.15.

INFECTION WITH RINDERPEST VIRUS

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.

Article 8.15.1.

[…]

Article 8.15.2.

Definitions and general provisions

For the purpose of the *Terrestrial Code*:

1) RPV-containing material means field and laboratory strains of RPV; vaccine strains of RPV including valid and expired vaccine stocks; tissues, sera and other ~~clinical~~ *pathological material* ~~from animals known or suspected to be infected~~; laboratory-generated ~~diagnostic~~ material containing ~~or encoding~~ live virus, recombinant morbilliviruses (segmented or nonsegmented) containing unique RPV nucleic acid or amino acid sequences, and full length genomic material including virus ~~ribonucleic acid (~~RNA~~)~~ and its cDNA copies ~~of virus RNA~~;

EU comment

The EU suggests amending point 1) above as follows:

"[…] sera and other pathological material from infected animals; […]"

Indeed, as "pathological material" is defined in the glossary as "samples obtained from live or dead animals, containing or suspected of containing infectious or parasitic agents, [...]", samples from merely suspect animals would be included in the definition of RPV-containing material, and subject to all the restrictions on storage, handling and shipping that are applied to such material.

However, it is necessary that merely suspect animals not be included, otherwise there will be strong disincentives for Member Countries to consider cases as suspect, since material taken from such animals would immediately become RPV-Containing Materials, even though the likelihood of RPV being present is extremely low, and even if they eventually tested negative. There is a significant benefit to encouraging Member Countries to continue considering rinderpest when faced with a syndromically suspicious case, to maintain awareness and rapid response in the (albeit unlikely) event of a re-occurrence.

2) subgenomic fragments of RPV genome (either as plasmid or incorporated into ~~other~~ recombinant viruses) ~~morbillivirus nucleic acid~~ that ~~are not capable of being~~ cannot be incorporated into ~~in~~ a replicating morbillivirus or morbillivirus-like virus are not considered ~~as~~ to be RPV-containing material~~:~~, neither are sera that have been either heat-treated to at least 56˚C for at least ~~2~~ two hours, or shown to be free from RPV genome sequences by a validated RT-PCR assay;

3) a ban on *vaccination* against rinderpest means a ban on administering any vaccine containing RPV or ~~RPV~~ any components derived from RPV to any *animal*;

4) the *incubation period* for rinderpest shall be 21 days;

5) a *case* is defined as an *animal* infected with RPV whether or not showing clinical signs; and

6) for the purpose of this chapter, 'susceptible *animals*' means domestic, *feral* and *wild* artiodactyls.

[…]

Annex 23

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.

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, goats 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~~ rare but potentially fatal zoonotic disease~~ with fatal outcome if not treated in a timely manner~~.

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.

~~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*:

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.*

EU comment

Given the Glossary definition of "outbreak", which refers to "epidemiological unit" (i.e. a group of animals), the EU suggests using the term "case" instead in points 2) and 3) above. Indeed, an individual horse (i.e. not part of an epidemiological unit, thus not part of an "outbreak") that is infected could transmit the pathogen while travelling, i.e. when mixing with other horses on pasture or in an establishent. Reference is made to the general EU comment in the report (under Item 5.2.).

For the purposes of the *Terrestrial Code*, the *infective period* of *B. mallei* in equids is lifelong and the *incubation period* ~~is~~ shall be 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 ~~six~~ 12 months;

~~AND~~

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

EU comment

The EU notes that the words "either", "or" and "and" have been deleted from the article above. This makes it a bit unclear whether all of the points need to be complied with, or a combination of them or just one. Reference is made for example to the chapter on African horse sickness; Article 12.1.2. is explicit on this, using "either" and "or". This would be preferable also in Article 12.10.2.

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*;

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

EU comment

The EU suggests slightly amending point 2) above as follows:

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

Indeed, tracing is only one element of any epidemiological investigation.

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

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~~ 12 months after ~~*stamping-out*~~ *disinfection* of the last ~~infected~~ affected *establishment* and during that period measures have been in place to control the movement of equids.

~~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* or countries or *zones* free from *infection* with *B. mallei*; or

b) if kept at any time in the past six months in a country or *zone* not free from *infection* with *B. mallei*, was imported in accordance with Article 12.10.5. into a country or *zone* free from *infection* with *B. mallei* ~~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~~.

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;

3) was isolated and subjected to two ~~a prescribed~~ tests for *infection* with *B. mallei*, with negative results on ~~a~~ samples taken ~~during the~~ 21 to 30 days apart with the second sample taken within 10 days prior to shipment.

EU comment

The requirements of "two tests" in point 3) above is misleading, as it could be understood that one needs to carry out two different diagnostic tests, whereas in fact the "two" refers only to the minimum number of samples to be tested. In addition, the

animal must remain isolated after the last sample and the sampling must be linked to the isolation. The EU therefore suggests slightly rewording point 3) as follows:

"3) was isolated for at least the last 30 days prior to shipment and during isolation subjected to ~~two~~ a tests for infection with *B. mallei*, carried out with negative results on two samples taken 21 to 30 days apart with the second sample taken within 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) on the day of collection, 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 and cutaneous lesions of the penis, with negative results; ~~were kept continuously:~~

~~*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.

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*.~~

~~Populations of *captive wild*, *feral* and *wild* equids should be included in the *surveillance* programme, for example through roadkill or 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 a sufficiently large number of clinically susceptible animals is examined.~~

~~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~~ *infection* with *B. mallei* and are complementary to Chapter 1.4. The impact and epidemiology of ~~glanders~~ *infection* with *B. mallei* vary in different regions of the world. The *surveillance* strategies employed ~~for determining glanders status~~ should be adapted to the respective epidemiological situation.

The *surveillance* ~~programme~~ systems should be designed:

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

~~A~~ The *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

The EU suggests deleting the words "of disease", as they do not seem necessary and could cause confusion. Indeed, for consistency with rest of text, infection without clinical signs should also be covered.

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

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

d) ~~established links~~ a procedure for confirmation of inconclusive tests in ~~with~~ an OIE Reference Laboratory ~~in case of need for confirmatory testing~~.

EU comment

For clarity reasons, please replace "incloncluse tests" with "inconclusive test results" in point d) above.

~~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, including private *veterinarians*, *veterinary paraprofessionals* and *animal handlers* should report promptly any suspicion of ~~glanders~~ *infection* with *B. mallei*. ~~to the *Veterinary Authority*~~. The reporting system efficacy should be enhanced ~~under the *Veterinary Authority* should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary paraprofessionals*)~~ by ~~government~~ awareness programmes and *animal identification* of equids. ~~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.~~

The *Veterinary ~~Authority~~ Services* should implement, when relevant and according to the results of former *surveillance*, regular and frequent clinical inspections and ~~random or~~ targeted serological surveys ~~and laboratory testing~~ of high-risk ~~groups~~ *subpopulations* or those ~~adjacent to~~ neighbouring a country or *zone* infected with *B. mallei*.

EU comment

The EU suggests amending the paragreaph above as follows:

"The Veterinary Services should implement, ~~when~~ where relevant and ~~according to~~ taking into acount the results of ~~former~~ previous surveillance, regular and frequent clinical inspections of equidae and targeted serological surveys ~~of high risk~~ on equine subpopulations representing a high risk or ~~those~~ situated in the neighbourhood of ~~neighbouring~~ a country or zone known to be infected with *B. mallei*."

Indeed, clinical inspections cannot be implemented according to results of previous surveillance results, but the planning or design of such inspections must take into account what was the result of a previous surveillance. Furthermore, it is not clear how one can clinically inspect horse populations for glanders, however clinical inspection of a horse for glanders is possible (as indicated in the paragraph on clinical surveillance). Finally, horse subpopulations cannot neighbour a country or zone.

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 or affected *establishments* were subjected during the investigation (quarantine, movement control, euthanasia).

EU comment

In the first sentence of the paragraph above, please insert the words "infection with" before "*B. mallei*" (clarity).

Furthermore, in the second sentence, please replace the word "immediately" with "without delay". Indeed, it may not be feasible (and it is not necessary) to investigate

immediately, e.g. because it is nighttime and there is no light or there is a heavy storm. However what possibly could be done is to immediately arrange the isolation.

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

EU comment

In the first sentence above, please delete the words "Susceptible", as all eqine popultations are susceptible for glanders, and it would be diffucult to distinguish susceptible from non-susceptible ones.

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.

EU comment

The sentence above is redundant and could be deleted (i.e. that principle is already mentioned in Article 12.10.1.). If really needed, it could be moved to the first paragraph of the surveillance article.

Article 12.10.9.

Surveillance strategies

The strategy employed ~~may~~ should be based on ~~clinical investigation, or randomised or targeted sampling at an acceptable level of statistical confidence.~~ the current knowledge of the epidemiological situation, and the expected results of the *surveillance*, such as the demonstration of a supposed free status. The *populations* of equids subject to the *surveillance* can be covered by passive clinical *surveillance*, active investigation of suspected *cases*, or randomised or targeted sampling.

~~If glanders is present, it is usually~~ *Infection* with *B. mallei* usually occurs at a very low *prevalence* and randomised samples should be collected in high numbers. If an increased likelihood of *infection* in particular geographical locations or *subpopulations* can be identified, targeted sampling is appropriate.

~~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.~~ Article 1.4.6. ~~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 relatively high rate of occurrence of false positive reactions to tests for *B. mallei* ~~has to~~ should 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.~~

~~Methods should include c~~Clinical or pathological *surveillance* and laboratory testing are complementary diagnostic approaches that~~. 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 serologically 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

The EU suggests amending the second sentence of the paragraph above as follows:

"Tests for agent identification should be carried out on anz equid serologically positive ~~or~~ and showing clinical signs."

Indeed, as clinical signs of glanders are not always clear, it may not be practical prescribe testing for agent identification of every animal with clinical signs.

1. Clinical surveillance

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

2. Pathological ~~and bacteriological~~ surveillance

Systematic pathological *surveillance* is an effective approach for the detection of ~~glanders~~ *infection* with *B. mallei* and should be conducted on dead equids on farms, at *slaughterhouses/abattoirs* and facilities for the disposal of carcasses of equids. ~~Suspicious p~~Pathological findings indicating possible *infection* with *B. mallei* should be confirmed by agent identification and any isolate~~s~~ should be characterised.

EU comment

We suggest inserting the words "Where possible," at the beginning of the second sentence of the paragraph above. Indeed, while being best practice, agent identification requires containment facilities and technologies that may not be available in every country.

3. Serological surveillance

Serological *surveillance* for ~~glanders~~ *infection* with *B. mallei* is the preferred strategy. *Animal identification* and ~~R~~repeated testing of the ~~equid~~ *population* ~~with recommended tests is~~ are necessary to ~~reach an acceptable level of confidence~~ establish its *infection* status.

4. Malleinisation

Frequently used as a *surveillance* method, malleinisation demonstrates hypersensitivity to antigens of *B. mallei*. However, this method has shortcomings, such as low sensitivity, interference with other tests and *animal welfare* concerns ~~that should be considered when interpreting results~~.

Annex 24

CHAPTER 1.4.

ANIMAL HEALTH SURVEILLANCE

EU comment

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

Furthermore, the EU encourages the Code Commission to include in the present chapter elements from points 2) to 6) of Article 4.Y.4. which are proposed to be deleted from draft Chapter 4.Y., as stipulated in the meeting report under Item 5.7.

Article 1.4.1.

Introduction and objectives

1) In general, *surveillance* is aimed at demonstrating the absence of *infection* or *infestation*, determining the presence or distribution of *infection* or *infestation* or detecting as early as possible exotic diseases or *emerging diseases*. Animal health *surveillance* is a tool to monitor disease trends, to facilitate the control of *infection* or *infestation*, to provide data for use in *risk analysis*, for animal or public health purposes, to substantiate the rationale for *sanitary measures* and for providing assurances to trading partners. The type of *surveillance* applied depends on the available data sources and the outputs needed to support decision-making. The general recommendations in this chapter may be applied to all *infections* or *infestations* and all susceptible species (including *wildlife*) and may be refined. *Specific surveillance* is described in some *listed disease*-specific chapters.

2) *Wildlife* may be included in a *surveillance* system because they can serve as reservoirs of *infection* or *infestation* and as indicators of *risk* to humans and domestic *animals*. However, the presence of an *infection* or *infestation* in *wildlife* does not mean it is necessarily present in domestic *animals* in the same country or *zone,* or vice versa. *Surveillance* in *wildlife* presents challenges that may differ significantly from those in *surveillance* in domestic *animals*.

3) Prerequisites to enable a Member Country to provide information for the evaluation of its *animal health status* are:

   a) that the Member Country complies with the provisions of Chapter 3.1. on *Veterinary Services*;

   b) that, where possible, *surveillance* data be complemented by other sources of information, such as scientific publications, research data, animal production data, documented field observations and other data;

   c) that transparency in the planning, execution and results of *surveillance* activities, is in accordance with Chapter 1.1.

4) The objectives of this chapter are to:

   a) provide guidance on the design of a *surveillance* system and the type of output it should generate;

   b) provide recommendations to assess the quality of *surveillance* systems.

Article 1.4.2.

Definitions

The following definitions apply for the purposes of this chapter:

Bias: means a tendency of an estimate to deviate in one direction from a true *population* parameter.

Confidence: means the probability that the type of *surveillance* applied would detect the presence of *infection* or *infestation* if the *population* were infected and is equivalent to the sensitivity of the *surveillance*. Confidence depends on, among other parameters, the assumed prevalence of *infection* or *infestation*.

Probability sampling: means a sampling strategy in which every unit is chosen at random and has a known non-zero probability of inclusion in the sample.

Sample: means the group of elements (sampling units) drawn from a population, on which tests are performed or parameters measured to provide *surveillance* information.

Sampling unit: means the unit that is sampled, either in a random survey or in non-random *surveillance*. This may be an individual *animal* or a group of *animals*, such as an *epidemiological unit*. Together, they comprise the sampling frame.

Sensitivity: means the proportion of infected sampling units that are correctly identified as positive.

EU comment:

The EU proposes to insert the words "<u>or infested</u>" after "infected" to comply with the scope of diseases in the Code.

Specificity: means the proportion of uninfected sampling units that are correctly identified as negative.

EU comment:

The EU proposes to insert the words "<u>or uninfested</u>" after "uninfected" to comply with the scope of diseases in the Code.

Study population: means the *population* from which *surveillance* data are derived. This may be the same as the target population or a subset of it.

Surveillance system: means the use of one or more *surveillance* components to generate information on the health status of animal populations.

Survey: means a component of a *surveillance* system to systematically collect information with a predefined goal on a sample of a defined population group, within a defined period.

Target population: means the population to which conclusions are to be inferred.

Test: means a procedure used to classify a unit as either positive, negative or suspect with respect to an *infection* or *infestation*.

Article 1.4.3.

Surveillance systems

In designing, implementing and assessing a surveillance system, the following components should be addressed in addition to the quality of *Veterinary Services*.

1. <u>Design of surveillance system</u>

   a) Populations

   Surveillance should take into account all animal species susceptible to the *infection* or *infestation* in a country, *zone* or *compartment*. The *surveillance* activity may cover all individuals in the *population* or only some of them. When *surveillance* is conducted only on a *subpopulation*, inferences to the target population should be justified based on the epidemiology of the *infection* or *infestation*.

   Definitions of appropriate *populations* should be based on the specific recommendations of the relevant chapters of the *Terrestrial Code*.

EU comment

The EU suggests inserting the words "listed disease-specific" before "chapters", as this is where the specific recommendations are.

b) Timing and Temporal validity of surveillance data

The timing and duration of *surveillance* should be determined taking into consideration factors such as:

– objectives of the *surveillance*;

– epidemiology (e.g. *vectors*, transmission pathways, seasonality);

EU comment:

The EU suggests adding the words "and biology" after "epidemiology" to complete the enumeration of relevant aspects.

– husbandry practices and production systems;

– accessibility of target population;

– geographical factors;

– climate conditions.

Surveillance should be carried out at a frequency that reflects the epidemiology of the *infection* or *infestation* and the *risk* of its introduction and spread.

c) Case definition

Where one exists, the *case* definition in the relevant chapter of the *Terrestrial Code* should be used. If the *Terrestrial Code* does not give a *case* definition, a *case* should be defined using clear criteria for each *infection* or *infestation* under *surveillance*. For *wildlife infection* or *infestation surveillance*, it is essential to correctly identify and report host animal taxonomy, including genus and species.

EU comment

The EU suggests inserting the words "listed disease-specific" before "chapters", as this is where the case definitions are.

d) Epidemiological unit

The relevant *epidemiological unit* for the *surveillance* system should be defined to ensure that it is appropriate to meet the objectives of *surveillance*.

e) Clustering

Infection or *infestation* in a country, *zone* or *compartment* usually clusters rather than being uniformly or randomly distributed through a population. Clustering may occur at a number of different levels (e.g. a cluster of infected *animals* within a *herd or flock*, a cluster of pens in a building, or a cluster of farms in a *compartment*). Clustering should be taken into account in the design of *surveillance* activities and considered in the statistical analysis of *surveillance* data, at least at what is judged to be the most significant level of clustering for the particular animal population and *infection* or *infestation*.

f) Analytical methodologies

Surveillance data should be analysed using appropriate methodologies and at the appropriate organisational level to facilitate effective decision-making, whether it be for planning disease control interventions or demonstrating health status.

Methodologies for the analysis of *surveillance* data should be flexible to deal with the complexity of real life situations. No single method is applicable in all cases. Different methodologies may be used to

accommodate different host species, pathogenic agents, production systems and *surveillance* systems, and types and amounts of data and information available.

The methodology used should be based on the best data sources available. It should also be in accordance with this chapter, fully documented and, whenever possible, supported by reference to scientific literature and other sources, including expert opinion. Sophisticated mathematical or statistical analyses should only be carried out when justified by the objectives of the *surveillance* and the availability and quality of field data.

Consistency in the application of different methodologies should be encouraged. Transparency is essential in order to ensure objectivity and rationality, consistency in decision-making and ease of understanding. The uncertainties, assumptions made, and the effect of these on the final conclusions should be documented.

g) Scope of the surveillance system

When designing the *surveillance* system consideration should be given to the purpose of *surveillance* and how the information it generates will be used, the limitations of the information it will generate, including representativeness of the study population and potential sources of bias as well as the availability of financial, technical, and human resources.

h) Follow up actions

The design of the *surveillance* system should include consideration of what actions will be taken on the basis of the information generated.

2. Implementation of the surveillance system

a) Diagnostic tests

Surveillance involves the detection of *infection* or *infestation* according to appropriate case definitions. Tests used in *surveillance* may range from detailed laboratory examinations to clinical observations and the analysis of production records.

Tests should be chosen in accordance with the relevant chapters of the *Terrestrial Manual.*

i) Sensitivity and specificity: The performance of a test at the *population* level (including field observations) may be described in terms of its sensitivity, specificity and predictive values. Imperfect sensitivity or specificity, as well as prevalence, will have an impact on the conclusions from *surveillance*. Therefore, these parameters should be taken into account in the design of *surveillance* systems and analysis of *surveillance* data.

The sensitivity and specificity values of the tests used should be specified for each species in which they may be used and the method used to estimate these values should be documented in accordance with Chapter 1.1.6. of the *Terrestrial Manual*.

EU comment

As the structure of the Manual and the numbering of its chapters may change, the EU suggests avoiding references to merely the number of a Manual chapter, but rather to its title.

ii) Pooling: Samples from a number of *animals* or *units* may be pooled and subjected to a testing protocol. The results should be interpreted using sensitivity and specificity values that have been determined or estimated for that particular pool size and testing procedure.

b) Data collection and management

The success of a *surveillance* system is dependent on a reliable process for data collection and management. The process may be based on paper or electronic records. Even where data are collected for non-survey purposes (e.g. during disease control interventions, inspections for movement control or during disease eradication schemes), the consistency and quality of data collection and event reporting in a format that facilitates analysis is critical. Factors influencing the quality of collected data include:

– the distribution of, and communication between, those involved in generating and transferring data from the field to a centralised location; this requires effective collaboration among all stakeholders, such as government or non-governmental organisations, and others, particularly for data involving *wildlife*;

– the ability of the data processing system to detect missing, inconsistent or inaccurate data, and to address these problems;

– maintenance of raw data rather than the compilation of summary data;

– minimisation of transcription errors during data processing and communication.

3. Quality assurance

Surveillance systems should be subjected to periodic auditing to ensure that all components function and provide verifiable documentation of procedures and basic checks to detect significant deviations of procedures from those specified in the design, in order to implement appropriate corrective actions.

Article 1.4.4.

Surveillance methods

Surveillance systems routinely use structured random and non-random data, either alone or in combination. A wide variety of *surveillance* sources may be available. These vary in their primary purpose and the type of *surveillance* information they are able to provide.

1. Disease reporting systems

Disease reporting systems are based on reporting of animal health related events to the *Veterinary Authority*. Data derived from disease reporting systems can be used in combination with other data sources to substantiate claims of *animal health status*, to generate data for *risk analysis* or for early warning and response. Effective laboratory support is an important component of any reporting system. Reporting systems relying on laboratory confirmation of suspected clinical *cases* should use tests that have high specificity as described in the *Terrestrial Manual*.

Whenever the responsibility for disease reporting falls outside the scope of the *Veterinary Authority*, for example human *cases* of zoonotic diseases or *infections* or *infestations* in *wildlife*, effective communication and data sharing should be established with the relevant authorities.

Participatory *surveillance* methods may be useful to collect epidemiological data that can support disease reporting systems.

2. Data generated by control programmes and health schemes

While focusing on the control or eradication of specific *infections* or *infestations,* control programmes or health schemes can be used to generate data that can contribute to other *surveillance* objectives.

3. Risk-based methods

Surveillance activities targeting selected *subpopulations* in which an *infection* or *infestation* is more likely to be introduced or found are useful to increase the efficiency of detection and can contribute to freedom claims, disease control activities, and estimation of prevalence. Risk-based methods can be used for both probability and non-probability selection of sampling units and data collection. The effect of the selection (i.e. its impact on probability of detection) should be estimated.

Risk-based methods are useful to optimise the use of *surveillance* resources.

4. Ante-mortem and post-mortem inspection

Inspection of *animals* at *slaughterhouses/abattoirs* may provide valuable *surveillance* data. The sensitivity and specificity of *slaughterhouse/abattoir* inspection for detecting the presence of specified diseases will be influenced by:

a) clinical and pathological signs;

b) the training, experience and number of the inspection staff;

c) the involvement of the *Competent Authority* in the supervision of ante-mortem and post-mortem inspection;

d) the quality of construction of the *slaughterhouse/abattoir*, speed of the slaughter chain, lighting quality, etc.; and

e) independence of the inspection staff.

Slaughterhouse/abattoir inspections are likely to provide good coverage for particular age groups and geographical areas only. *Slaughterhouse/abattoir surveillance* data may only be representative of a particular *subpopulation* (e.g. only *animals* of a particular class and age are likely to be slaughtered for human consumption in significant numbers). Such limitations should be recognised when analysing *surveillance* data.

The usefulness of data generated by *slaughterhouse/abattoir* inspections is dependent on effective *animal traceability* that relates *animals* to their *herd* or *flock* or locality of origin.

EU comment

In the EU, under certain conditions, ante-mortem inspection may be carried out at the holding of provenance. Furthermore, food business operators of slaughterhouses must request, receive, check and act upon food chain information in respect of animals sent to the slaughterhouse, i.e. information from the records of the establishment of origin related to the general hygiene provisions for primary production. The EU suggests including reference to such systems in the paragraph above, as they contribute to ensuring its objectives (relating animals to their herd or flock or locality of origin).

5. Laboratory investigation records

Laboratory investigation records may provide useful data for *surveillance*. Multiple sources of data such as national, accredited, university and private sector *laboratories* should be integrated in order to increase the coverage of the *surveillance* system.

Valid analysis of data from different *laboratories* depends on the existence of standardised diagnostic procedures and standardised methods for data recording and interpretation as well as a mechanism to ensure the traceability of specimens to *herd or flock* or locality of origin.

6. Biological specimen banks

Specimen banks consist of stored specimens, gathered through representative sampling or opportunistic collection. Specimen banks may contribute to retrospective studies, including providing support for claims of historical freedom from *infection* or *infestation*, and may allow certain studies to be conducted more quickly and at lower cost than other approaches.

7. Sentinel units

Sentinel *units* involve the identification and regular testing of one or more *animals* of known health or immune status in a specified geographical location to detect the occurrence of *infection* or *infestation.* Sentinel *units* provide the opportunity to target *surveillance* depending on the risk of introduction, likelihood of *infection* or *infestation,* cost and other practical constraints. Sentinel *units* may provide evidence of freedom from *infection* or *infestation*, or of their distribution.

8. Clinical observations

Clinical observations of *animals* in the field are an important source of *surveillance* data. The sensitivity and specificity of clinical observations are highly dependent on the criteria used to define a suspected *case*. In order to allow comparison of data, the *case* definition should be standardised. Training of potential field observers in the application of the *case* definition and reporting is important. Ideally, both the number of positive observations and the total number of observations should be recorded.

9. Syndromic data

Systematic analysis of health data, including morbidity and mortality rates, production records and other parameters can be used to generate signals that may be indicative of changes in the occurrence of *infection* or *infestation*. Software may offer the prospect of extraction of syndromic data for aggregation and analysis.

10. Other data sources

a) Wildlife data

Specimens for *surveillance* from *wildlife* may be available from sources such as hunters and trappers, road-kills, *wild animal meat* markets, sanitary inspection of hunted *animals*, morbidity and mortality observations by the general public, *wildlife* rehabilitation centres, *wildlife* biologists and *wildlife* agency field personnel, farmers and other landholders, naturalists and conservationists. *Wildlife* data such as census data, trends over time, and reproductive success can be used in a manner similar to farm production records for epidemiological purposes.

b) Public health data

For zoonotic diseases public health data may be an indicator of a potential change in the *animal health status*. The *Veterinary Authority* should coordinate with human health authorities and share data for integration into *specific surveillance* systems.

c) Environmental data

Relevant environmental data such as rainfall, temperature, extreme climatic events, presence and abundance of potential *vectors* as described in Chapter 1.5., should also be integrated into the *surveillance* system.

d) Additional supporting data such as:

i) data on the epidemiology of the *infection* or *infestation*, including host *population* distribution;

ii) data on animal movements, including transhumance and natural *wildlife* migrations;

iii) trading patterns for *animals* and animal products;

iv) national animal health regulations, including information on compliance and effectiveness;

v) history of imports of potentially infected material;

vi) *biosecurity* in place; and

vii) the *risk* of introduction of *infection* or *infestation*.

Article 1.4.5.

Considerations in survey design

In addition to the principles in Article 1.4.3., the following should be considered when planning, implementing and analysing surveys.

1. Types of surveys

Surveys may be conducted on the entire target *population* (i.e. a census) or on a sample.

Surveys conducted in order to document freedom from *infection* or *infestation* should be conducted using probability-based sampling methods so that data from the study *population* can be extrapolated to the target *population* in a statistically valid manner.

EU comment

The EU notes that the term "conducted" is used twice in the sentence above, which does not read well. We therefore suggest replacing the second one with "carried out" or "performed".

The sources of data should be fully described and should include a detailed description of the sampling strategy used for the selection of *units* for testing. Also, consideration should be given to any biases that may be inherent in the survey design.

2. Survey design

The target and study *populations* should first be clearly defined. Depending on the design of the survey, appropriate sampling *units* should be defined for each stage.

The design of the survey will depend on the knowledge of the size, structure and distribution of the *population*, the epidemiology of the *infection* or *infestation* and the resources available.

Data on the size, structure and distribution of *wildlife* populations often do not exist. However, they should be estimated to the extent possible before the survey is designed. Expert opinion can be sought in the gathering and interpretation of such *population* data. Historical *population* data should be updated since these may not reflect current *populations*.

3. Sampling

a) Objective

The objective of probability sampling from a *population* is to select a subset of units that is representative of the *population* of interest with respect to the objective of the study, taking into account practical constraints imposed by different environments and production systems.

When selecting *epidemiological units* within a *population*, probability sampling, such as a simple random selection, should be used. Where probability sampling is not feasible, non-probability based methods may be applied and should provide the best practical chance of generating a sample that is representative of the target *population*. The objective of non-probability based sampling is to maximise the likelihood of detection of the *infection* or *infestation*. However, this type of sampling will not be representative of the study and target *population*.

The sampling method used at all stages should be fully documented.

b) Sample size

In surveys conducted to demonstrate the presence or absence of an *infection* or *infestation* the method used to calculate sample size depends on the size of the *population*, the design of the survey, the expected prevalence, the level of confidence desired of the survey results and the performance of the tests used.

In addition, for surveys designed to estimate a parameter (e.g. prevalence) consideration should be given to the desired precision of the estimate.

c) A sample may be selected by either:

i) probability-based sampling methods, such as:

– simple random selection;

– cluster sampling;

– stratified sampling;

– systematic sampling; or

ii) non-probability-based sampling methods, depending on:

– convenience;

– expert choice;

– quota;

– *risk*.

Article 1.4.6.

Surveillance to demonstrate freedom from an infection or infestation

This article provides general principles for declaring freedom from an *infection* or *infestation*, including for the recognition of historical freedom.

1. Demonstration of freedom

A *surveillance* system to demonstrate freedom from an *infection* and *infestation* should meet the following, in addition to the general principles outlined in Article 1.4.3.

Freedom implies the absence of the pathogenic agent in the country, *zone* or *compartment*. Scientific methods cannot provide absolute certainty of this absence. Therefore, demonstrating freedom involves providing sufficient evidence to demonstrate (to a level of confidence acceptable to Member Countries) that *infection or infestation* with a specified pathogenic agent, if present, is present in less than a specified proportion of the *population*.

EU comment

The first sentence of the paragraph above is too broad and should be specified further, e.g. by inserting the notion of pathogen circulation in the target population. Indeed, the pathogenic agent may be physically present in the country or zone, e.g. in a laboratory freezer or in live animals in a research facility, a quarantine station or zoo, which should not influence the status of the country or zone as free in domestic or wild animals.

Alternatively, the above situations could explicitly be described as exceptions that would not affect the status of the country.

However, finding evidence of *infection* or *infestation* at any prevalence in the target *population* automatically invalidates any freedom claim unless otherwise stated in the relevant chapter of the *Terrestrial Code*. The implications for the status of domestic *animals* of *infection* or *infestation* present in *wildlife* in the same country or *zone* should be assessed in each situation, as indicated in the relevant chapter of the *Terrestrial Code*.

EU comment

For consistency, the EU suggests inserting the words "<u>listed disease-specific</u>" before "chapter" in the paragraph above (twice), and throughout this chapter where relevant.

Evidence from probability-based and non-probability risk-based data sources, as stated before, may increase the level of confidence or be able to detect a lower prevalence with the same level of confidence as structured surveys.

2. Requirements to declare a country or a zone free from an infection or infestation

a) Prerequisites, unless otherwise specified in the relevant chapter of the *Terrestrial Code*:

i) the *infection* or *infestation* has been a *notifiable disease*;

ii) an *early warning system* has been in place for all relevant species;

iii) measures to prevent the introduction of the *infection* or *infestation* have been in place;

iv) no *vaccination* against the disease has been carried out;

v) the *infection* or *infestation* is not known to be established in *wildlife* within the country or *zone*.

b) Historical freedom: unless otherwise specified in the relevant chapter of the *Terrestrial Code*, a country or *zone* may be considered free without formally applying a pathogen-specific *surveillance* programme when:

i) the prerequisites listed in a) are complied with for at least the past 10 years;

ii) the pathogenic agent is likely to produce identifiable clinical or pathological signs in susceptible animals;

iii) for at least 25 years there has been no occurrence of *infection* or *infestation* or eradication has been achieved for the same length of time.

c) Where historical freedom cannot be achieved:

EU comment

In point c) above, the term "achieved" should be replaced with "demonstrated". Indeed whereas freedom can be actively achieved when a disease was eradicated, historical freedom is not achieved but rather asserted.

i) the prerequisites listed in a) are complied with;

EU comment

The EU notes that the current version of the chapter requires that these prerequisites are complied with for the past 10 years. We would prefer that this requirement not be omitted. Indeed, if not specified in the disease-specific chapter, or if no such chapter exists for a given disease, then this article will apply by default, and should thus include a time requirement; however 10 years indeed seems a bit long.

ii) pathogen-specific *surveillance* has been applied as described in this chapter and in the relevant chapter of the *Terrestrial Code,* if it exists, and has not detected any occurrence of the *infection* or *infestation*.

EU comment

The comment above regarding a time requirement is valid also here. The number of years would depend inter alia on the epidemiology of the disease and would need to be adapted accordingly on a case by case basis. However, a default number of years (e.g. 3 or 4 years) should be mentioned here.

3. Requirements to declare a compartment free from infection or infestation

a) The prerequisites listed in 2.a) i) to iv) are complied with;

EU comment

The prerequisites referred to in point a) above include a ban on vaccination, however the FMD chapter for example foresees the possibility of a free compartment with vaccination. Therefore, for clarity reasons a disclaimer should be added also here (e.g. "unless otherwise specified in the relevant chapter of the Terrestrial Code").

b) ongoing pathogen-specific *surveillance* has been applied as described in this chapter and in the relevant chapter of the *Terrestrial Code,* if they exist, and has not detected any occurrence of the *infection* or *infestation*.

EU comment

Please replace the words "if they exist" with "if it exists", for clarity and consistency with the wording of point 2c)ii) above.

4. Recommendations for the maintenance of freedom from infection or infestation

Unless otherwise specified in the relevant chapter of the *Terrestrial Code*, a country or *zone* that has achieved freedom in accordance with the provisions of the *Terrestrial Code* may maintain its free status provided that:

a) the *infection* or *infestation* is a *notifiable disease*;

b) an *early warning system* is in place for all relevant species;

c) measures to prevent the introduction of the *infection* or *infestation* are in place;

d) *surveillance* adapted to the likelihood of occurrence of *infection* or *infestation* is carried out. *Specific surveillance* may not need to be carried out if supported by a *risk assessment* addressing all identified pathways for introduction of the pathogenic agent and provided it is likely to produce identifiable clinical or pathological signs in susceptible *animals*;

EU comment

For reasons of clarity, please replace the word "it" before "is likely to produce" with "the pathogenic agent". Indeed, it is not clear what the word "it" refers to (it could be the specific surveillance)

e) *vaccination* against the disease is not applied;

f) the *infection* or *infestation* is not known to be established in *wildlife*. It can be difficult to collect sufficient epidemiological data to prove absence of *infection* or *infestation* in *wild animal* populations. In such circumstances, a range of supporting evidence should be used to make this assessment.

Article 1.4.7.

Surveillance considerations in support of disease control programmes

Surveillance is an important component in disease control programmes and can be used to determine the distribution and occurrence of *infection* or *infestation* or of other relevant health-related events. It can be used to assess progress and aid in decision-making in the control or eradication of selected *infections* or *infestations*.

Surveillance used to assess progress in control or eradication of selected *infections* or *infestations* should be designed to collect data about a number of variables such as:

1) prevalence or incidence of *infection* or *infestation*;
2) morbidity and mortality;
3) frequency of *risk* factors and their quantification;
4) frequency distribution of results of the laboratory tests;
5) post-vaccination monitoring results;
6) frequency distribution of *infection* or *infestation* in *wildlife*.

The spatial and temporal distribution of these variables and other data such as *wildlife*, public health and environmental data as described in point 10) of Article 1.4.4. can be useful in the assessment of disease control programmes.

Article 1.4.8.

Early warning systems

An *early warning system* is essential for the timely detection, identification and reporting of occurrence, incursion or emergence of *infections* or *infestations*, and should include the following:

EU comment

As regards the paragraph above, reference is made to the EU comment on the draft Glossary definition of "early warning system" at the end of this document, which is valid also here.

1) appropriate coverage of target *animal* populations by the *Veterinary Services*;

2) effective disease investigation and reporting;

3) *laboratories* capable of diagnosing and differentiating relevant *infections* or *infestations*;

4) training and awareness programmes for *veterinarians*, *veterinary paraprofessionals*, livestock owners or keepers and others involved in handling *animals* from the farm to the *slaughterhouse/abattoir*, for detecting and reporting unusual animal health incidents;

5) a legal obligation by relevant stakeholders to report suspected *cases* or *cases* of *notifiable diseases* or *emerging diseases* to the *Veterinary Authority*;

EU comment

Perhaps it would be useful to specify or give examples of what are the relevant stakeholders in this context (e.g. private laboratories should be included).

6) effective systems of communication between the *Veterinary Authority* and relevant stakeholders;

7) a national chain of command.

Early warning systems are an essential component of emergency preparedness.

Article 1.4.9.

Combination and interpretation of surveillance results

Depending on the objective of *surveillance*, the combination of multiple sources of data may provide an indication of the overall sensitivity of the system and may increase the confidence in the results. The methodology used to combine the evidence from multiple data sources should be scientifically valid, and fully documented, including references to published material.

Surveillance information gathered from the same country, *zone* or *compartment* at different times may provide cumulative evidence of *animal health status*. Repeated surveys may be analysed to provide a cumulative level of confidence. However, the combination of data collected over time from multiple sources may be able to achieve an equivalent level of confidence.

Analysis of *surveillance* information gathered intermittently or continuously over time should, where possible, incorporate the time of collection of the information to take the decreased value of older information into account. The sensitivity and specificity of tests used and completeness of data from each source should also be taken into account for the final overall confidence level estimation.

In assessing the efficiency of the *surveillance* system based on multiple sources, the *Veterinary Authority* should consider the relative contribution of each component to the overall sensitivity, while considering the primary objective of each *surveillance* component.

Results from *animal* health *surveillance* systems are subject to one or more potential biases. When assessing the results, care should be taken to identify potential biases that can inadvertently lead to an over-estimate or an under-estimate of the parameters of interest.

Annex 24 (contd)

GLOSSARY

[...]

EARLY WARNING SYSTEM

means a system for the timely detection, identification and reporting of an incursion or emergence of diseases, *infections* or *infestations* in a country, *zone* or *compartment*.

EU comment
The EU in general supports the proposed new definition above.
However, we would suggest that the definition includes the word "characterisation", because "identification" alone implies that we know what the disease or threat is, while some diseases might be new.
Furthermore, the notion of communication could be added to the definition, as not only disease reporting should be part of the system, but also wider communication with stakeholders and the public.
In addition, for consistency in connection with the proposed deletion of the Glossary definition of "disease", the word "diseases" could be deleted form the proposed definition above.
The EU thus suggests that the definition be amended as follows:
"means a system for the timely detection, characterisation or identification and reporting of an incursion or emergence of ~~diseases,~~ infections or infestations in a country, zone or compartment and the communication of the findings to relevant stakeholders."
Finally, we presume the existing Glossary definition of "Early detection system" will be deleted, and the term replaced with "early warning system" throughout the Code.

[...]

Annex 25

CHAPTER 4.Y.

OFFICIAL CONTROL ~~MANAGEMENT~~ OF ~~OUTBREAKS OF~~ EMERGING AND LISTED DISEASES

EU comment

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

As regards the title, the EU suggests mentioning listed diseases first, and then emerging diseases, to keep the same order as elsewhere in the Code (e.g. in Chapter 1.1., and also in the first sentence of Article 4.Y.1.). That order should then be consistently used throughout this chapter (e.g. 2nd paragraph of Article 4.Y.1.).

Article 4.Y.1.

Introduction

When a~~n OIE~~ *listed disease* or *emerging disease* occurs in a Member ~~c~~Country, *Veterinary Services* should implement ~~a response~~ control measures proportionate to the likely impact of the disease ~~and as a result of a *risk analysis*~~, in order to minimise its spread and consequences and, if possible, eradicate it. These measures can vary from rapid response to a new *hazard* and management of *outbreaks*, to long-term control of an endemic *infection* or *infestation*.

The purpose of this chapter is to provide recommendations to prepare, develop and implement *official control programmes* ~~plans~~ in response to occurrence ~~*outbreaks*~~ of *emerging* or *listed diseases*, including zoonoses. It is not aimed at giving ready-made fit-for-all solutions, but rather at outlining principles to follow when combating animal diseases through organised control programmes ~~plans~~.

The *Veterinary Authority* should determine which diseases to establish *official control programmes* against and at which regulatory level, according to an evaluation of the actual or likely impact of the disease. Disease control programmes ~~plans~~ should be prepared in advance by the *Veterinary Authority* and *Veterinary Services* in close collaboration with the relevant stakeholders and other authorities, as appropriate ~~disposing of the necessary regulatory, technical and financial tools~~.

~~Control plans~~ They should be justified by rationales developed through *risk analysis* and ~~considering~~ taking into account animal health, public health~~,~~ and socio-economic, *animal welfare* and environmental aspects. They should be supported by relevant cost-benefit analysis and include the necessary regulatory, technical and financial tools.

Official control programmes ~~Control plans~~ should be developed with the aim of achieving defined measurable objectives, in response to a situation in which ~~purely~~ private action ~~alone~~ is not sufficient. Depending on the prevailing epidemiological, environmental and socio-economic situation, the goal may vary from the reduction of impact to the eradication of a given ~~disease~~ *infection* or *infestation*.

In any case, the components of plans for management of *outbreaks* are an early ~~*detection*~~ warning system ~~(including a warning procedure),~~ ~~and~~ rapid response and ~~quick and~~ effective action, possibly followed by long-term measures. Plans should always include an exit strategy. Learning from past *outbreaks* and reviewing the response sequence are critical for adaptation to evolving epidemiological situations and for better performance in future situations. Plans should be tested regularly to ensure that they are fit-for-purpose, practical, feasible and well-understood and that ~~field~~ staff are trained and other stakeholders are fully aware of their respective roles and responsibilities ~~in implementing the response~~. This is especially important for diseases that are not present in the Member Country.

EU comment

The EU suggests deleting the words "In any case" at the beginning of the paragraph above, as it is superfluous.

Furthermore, an exit strategy may not always be necessary or appropriate, e.g. in case of diseases like anthrax for which control measures are necessary but eradication is not possible or likely even in the long-term (except if one possible exit strategy would be to have no exit strategy).

Finally, not only learning from past experience should be mentioned, but also leaning from experience of others (e.g. VS of neighouring countries, neighbouring regions). For this reasons, it would be useful mentioning cross-border simulation exercises among neighbouring countries, especially in case of transboundary animal diseases.

Article 4.Y.2.

Legal framework and regulatory environment

1) In order to be able to effectively control *emerging diseases* and *listed diseases*, the *Veterinary Authority* should ensure that:

   – the *Veterinary Services* comply with the principles of Chapter 3.1., especially the services dealing with the prevention and control of contagious animal diseases, including zoonoses;

EU comment

The EU suggests replacing the word "contagious" with "infectious" in the indent above, and throughout this chapter where appropriate. Indeed, vector borne diseases would otherwise not be covered.

   – the *veterinary legislation* complies with the principles of Chapter 3.4.

2) In particular, in order for the *Veterinary Services* to be the most effective when combatting animal disease *outbreaks*, the following should be addressed in the *veterinary legislation* or other relevant legal framework:

   – legal powers and structure of command and responsibilities, including responsible officials with defined powers; especially a right of entry to *establishments* or other related enterprises such as live *animal* markets, *slaughterhouses/abattoirs* and animal products processing plants, for regulated purposes of *surveillance* and disease control actions, with the possibility of obliging owners to assist;

   – sources of financing for epidemiological enquiries, laboratory diagnostic, disinfectants, insecticides, vaccines and other critical supplies;

   – sources of financing and compensation policy for livestock and property that may be destroyed as part of disease control programmes;

EU comment

The EU suggests inserting the words ", products of animal origin" before "and property", as depending on the situation also seminal products or food and other commodities of animal origin will need to be destroyed.

   – coordination with other authorities, especially law enforcement and public health authorities.

3) Furthermore, the specific regulations, policies, or guidance on disease control activities ~~policies~~ should include the following:

   – *risk analysis* to identify and prioritise ~~potential *disease*~~ *risks*, including a regularly updated list of

notifiable diseases;

– definitions and procedures for the reporting and management of a suspected *case*~~,~~ or confirmed *case*~~,~~ of an *emerging disease* or a *listed disease*;

– procedures for the management of ~~infected~~ *establishments*~~,~~ directly or indirectly affected by the disease ~~infected *establishment*, contact *establishment*~~;

– definitions and procedures for the declaration and management of *infected zones* and other *zones*, such as *free zones*, *protection zones*, *containment zones*, or less specific ones such as *zones* of intensified *surveillance*;

– procedures for the collection, transport and testing of animal samples;

– procedures for *animal identification* and the management of *animal identification systems* ~~the identification of *animals*~~;

– procedures for the restrictions of movements, including possible standstill or compulsory veterinary certification, of relevant *animals* and animal products within, to, or from given *zones* or *establishments* or other related enterprises;

EU comment

It is important to mention in the indent above also restrictions for equipment and vehicles etc. that may be contaminated and contribute to the spread of the pathogenic agent.

– procedures for the destruction or *slaughter* and safe disposal or processing of infected or potentially infected *animals*, including relevant *wildlife*, and contaminated or potentially contaminated products and materials;

EU comment

As the procedures described in the indent above will be quite different for animals and animal products on the one hand and products and materials on the other, the EU suggests covering products and materials (incl. animal feed, farm equipment, vehicles etc.) in a separate indent.

– procedures for compensation for the owners of *animals* or animal products, including defined standards and means of implementing such compensation;

– procedures for cleaning, *disinfection* and disinsection of *establishments* and related premises, *vehicles* or equipment;

– procedures for the compulsory emergency *vaccination* or treatment of *animals*, as relevant, and for any other necessary disease control actions.

Article 4.Y.3.

Preparedness

Rapid and effective response to a new occurrence or emergence of contagious diseases is dependent on the level of preparedness. The *Veterinary Authority* should integrate preparedness planning and practice as one of its core functions. ~~Rapid, effective response to a new occurrence or emergence of contagious diseases is dependent on the level of preparedness.~~

Preparedness should be justified by *risk analysis*, should be planned, and should include training, capacity building and simulation exercises.

1. Risk analysis

Risk analysis, including import *risk analysis*, in accordance with Chapter 2.1., should be used to determine

which diseases require preparedness planning and to what extent.

A *risk analysis* identifies the pathogenic agents that present the greatest *risk* and for which preparedness is most important and therefore helps to prioritise the range of disease threats and categorise the consequent actions. It also helps to define the best strategies and control options.

The *risk analysis* should be reviewed ~~updated~~ regularly to detect changes (e.g. new pathogenic agents, or changes in distribution and virulence of pathogenic agents previously identified as presenting the major *risk* and changes in possible pathways) and be updated accordingly, taking into account the latest scientific findings.

2. Planning

Four kinds of plans, describing what governmental or local authorities and all stakeholders should do, comprise any comprehensive preparedness and response system:

a) a preparedness plan, which outlines what should be done before an *outbreak* of an *emerging disease* or a *notifiable disease* occurs;

b) a response or contingency plan, which details what should be done in the event of an occurrence of an *emerging disease* or *notifiable disease*, beginning from the point when a suspected *case* is reported;

c) a comprehensive set of instructions for ~~field~~ staff and other stakeholders on how to undertake specific tasks required by the response or contingency plan;

d) a recovery plan for the safe restoration of normal activities, possibly including procedures and practices modified in light of the experience gained during the management of the *outbreak*.

3. Simulation exercises

The *Veterinary Services* and all stakeholders should be made aware of the sequence of measures to be taken in the framework of a contingency plan through the organisation of simulation exercises, mobilising a sufficient number of staff and stakeholders to evaluate the level of preparedness and fill possible gaps in the plan or in staff capacity.

Article 4.Y.4.

Surveillance and ~~E~~early warning ~~detection~~ system

~~1)~~ Depending on the priorities identified by the *Veterinary Authority*, *Veterinary Services* should implement adequate *surveillance* for *listed diseases* in accordance with Chapter 1.4. or *listed disease*-specific chapters, in order to detect suspected *cases* and either rule them out or confirm them. The *surveillance* should be adapted to the epidemiological and environmental situation. Early warning systems should be in place for *infections* or *infestations* for which a rapid response is desired, and should comply with the relevant articles of Chapter 1.4. *Vector surveillance* should be conducted in accordance with Chapter 1.5.

EU comment

In order to avoid confusion, the EU suggests replacing "or" with "and" before "listed disease specific chapters", as it is necessary to implement both. This would also be consistent with the third paragraph of Article 4.Y.12.

Furthermore, the EU encourages the Code Commission to include the elements from points 2) to 6) below in the draft revised Chapter 1.4., as stipulated in the meeting report under Item 5.7.

~~2)~~ ~~In order to implement adequate *surveillance*, the *Veterinary Authority* should have access to good diagnostic capacity. This means that the *veterinarians* and other relevant personnel of the *Veterinary Services* have adequate knowledge of the *disease*, its clinical and pathological manifestation and its epidemiology, and that laboratories approved for the testing of animal samples for the relevant *diseases* are available.~~

~~3)~~ ~~Suspected *cases* of *notifiable diseases* should be reported without delay to the *Veterinary Authority*, ideally with the following information:~~

- ~~the *disease* or pathogenic agent suspected, with brief descriptions of clinical signs or lesions observed, or laboratory test results as relevant;~~

- ~~the date when the signs were first noticed at the initial site and any subsequent sites;~~

- ~~the names and addresses or geographical locations of suspected infected *establishments* or premises;~~

- ~~the animal species affected, including possible human cases, and the approximate numbers of sick and dead *animals*;~~

- ~~initial actions taken, including *biosecurity* and precautionary movement restrictions of *animals*, products, staff, vehicles and equipment;~~

4) ~~Immediately following the report of a suspected *case*, investigation should be conducted by the *Veterinary Services*, taking into account the following:~~

   - ~~*biosecurity* to be observed when entering and leaving the *establishment*, premises or locality;~~

   - ~~clinical examinations to be undertaken (number and types of *animals*);~~

   - ~~samples to be taken from *animals* showing signs or not (number and types of *animals*), with specified sampling and sample handling equipment and sample handling procedures, including for the safety of the investigator and animal owners;~~

   - ~~procedure for submitting samples for testing;~~

   - ~~size of the affected *establishment*, premises or locality and possible entry pathways;~~

   - ~~investigation of the approximate numbers of similar or possibly susceptible *animals* in the *establishment* and its surroundings;~~

   - ~~details of any recent movements of possibly susceptible *animals* or *vehicles* or people to or from the affected *establishments*, premises or locality;~~

   - ~~any other relevant epidemiological information, such as presence of the suspected *disease* in *wildlife* or abnormal *vector* activity;~~

~~A procedure should be in place for reporting findings to the *Veterinary Authority* and for record keeping.~~

5) ~~All suspected *case* investigations should provide a result, either positive or negative. Criteria should be established in advance for a *case* definition. Confirmation can be made on clinical and post-mortem grounds, epidemiological information, laboratory test results or a combination of these, in accordance with relevant articles of the *Terrestrial Code* or *Terrestrial Manual*. Strong suspicion based on supportive, but not definitive, findings should lead to the implementation of local control measures as a precaution. When a *case* is confirmed, full *sanitary measures* should be implemented as planned.~~

6) ~~When a *case* of a *listed disease* is detected, *notification* shall be made to the OIE in accordance with Chapter 1.1.~~

Article 4.Y.5.

General considerations when managing an outbreak

Upon confirmation of ~~Once~~ an *outbreak* of an *emerging disease* or a *notifiable disease* that is subject to an *official control programme* ~~is confirmed~~ effective *risk management* depends on the application of a combination of measures that are operating at the same time or consecutively, aimed at:

1) eliminating the source of pathogenic agent, through:

   - the *killing* or *slaughter* of *animals* infected or suspected of being infected, and safe disposal of dead *animals* and potentially contaminated products;

   - the cleaning, *disinfection* and, if relevant, disinsection of premises and equipment;

2) stopping the spread of *infection*, through:

- movement restrictions on *animals*, *vehicles*, ~~and~~ equipment and people, as appropriate;
- *biosecurity*;
- *vaccination*, treatment or culling of *animals* at risk;
- communication and public awareness.

Different strategies may be chosen depending on the epidemiological, environmental, economic and social situation. The *Veterinary Authority* should assess the situation beforehand and at the time of the *outbreak* detection. For example, the wider the spread of the disease and the more locations affected at the beginning of the implementation of the measures, the less likely it will be that culling as a main eradication tool will be effective, and the more likely it will be that other control tools such as *vaccination* or treatment, either in conjunction with culling or alone, will be needed. The involvement of *vectors* or *wildlife* will also have a major influence on the control strategy and different options chosen.

EU comment

An important element seems to be missing in the paragraph above, i.e. the objective of the control strategy (e.g. complete eradication or not), which again will depend on a lot of factors.

In any case, the management plan should consider the costs of the measures in relation to the benefits expected, and should at least integrate the compensation of owners for losses incurred by the measures.

In case of highly contagious or high impact disease events, the management plan should be closely coordinated through an inter-sectoral mechanism such as an incident command system.

Article 4.Y.6.

Culling and disposal of dead animals and animal products

EU comment

A Glossary definition of "animal products" should be considered, as it is unclear what exactly is meant and covered by this term.

Living infected *animals* can be ~~are~~ the greatest source of pathogenic agents. These *animals* may directly transmit the pathogenic agent to other *animals*. They may ~~and~~ also cause ~~lead to~~ indirect *infection* through the contamination of fomites, including breeding and handling equipment, bedding, feed, *vehicles*, and people's clothing and footwear, or the contamination of the environment. Although carcasses may remain contaminated for a period after death, active shedding of the pathogenic agent effectively ceases when the *animal* is killed or slaughtered. Thus, culling of *animals* is often a ~~the~~ preferred strategy for the control of contagious diseases.

Veterinary Services should adapt any strategy for culling, *killing* or disposal of *animals* and their products ~~strategy~~ to the transmission pathways of the pathogenic agent. A ~~S~~*stamping-out policy* is ~~should be~~ the preferred strategy for highly contagious diseases and for situations where the country or *zone* was formerly free or freedom was impending, while other strategies, such as test and cull, are better suited to less contagious diseases and situations where the disease is endemic.

EU comment

The word "formerly" before "free" should preferably be replaced with "previously", as that is the term used in relevant articles of listed disease specific chapters.

For control measures, including destruction of *animals* or products, to be most effective, *animal identification* and *animal traceability* should be in place, in accordance with Chapters 4.1. and 4.2.

EU comment

In the paragraph above, the EU suggests adding the words "as well as vaccination" after "or products", as animal identification and traceability is also essential when using vaccination for disease control.

The *slaughter* or *killing* of *animals* should be performed in accordance with Chapters 7.5. or 7.6., respectively.

The disposal of dead *animals* and their potentially contaminated products should be performed in accordance with Chapter 4.12.

1. Stamping-out policy

A ~~S~~s*tamping-out policy* consists primarily ~~in~~ of the *killing* of all the *animals* ~~affected~~ infected or suspected of being ~~affected~~ infected, including those ~~which~~ that have been directly or indirectly exposed to the causal pathogenic agent. This strategy is used for the most contagious diseases.

A ~~S~~s*tamping-out policy* can be limited to the affected *establishments* and, where appropriate, other *establishments* found to be epidemiologically linked with an affected *establishment*, or be broadened to include all *establishments* of a defined *zone*, when pre-emptive depopulation can be used to stop the transmission of a fast spreading pathogenic agent.

A stamping-out policy can be applied to all the animal species present on an affected *establishment*, or to all susceptible species, or only to the same species as the infected *animals*, based on the assessment of associated *risks*.

Killing should preferably be performed on site, and the carcasses disposed of on site or transported directly and safely to a rendering plant or other dedicated site for destruction. If to be killed outside of the *establishment* or slaughtered, the *animals* should be transported directly to a dedicated *approved* rendering plant or *slaughterhouse/abattoir* respectively, without any possible direct or indirect contacts with other *animals*. Slaughtered *animals* and their products should be processed separately from others.

EU comment

The first sentence of the paragraph above gives the impression that the preferred option for carcass disposal is disposal on site (i.e. on the farm). This should clearly no longer be the case nowadays, as is reflected by the recent changes in the Glossary definition of Stamping-out policy, where the order of possible disposal options in point b) was changed accordingly (i.e. mentioning rendering first). Therefore, the EU suggests following the same rationale also here, by mentioning rendering first, and disposal on site last, as follows:

"… , and the carcasses ~~disposed of on site or~~ transported directly and safely to a rendering plant or other dedicated site for destruction, or disposed of on site by burning or burial".

~~Stamping-out can be applied to all the animal species present on affected premises, or to all susceptible species, or only to the same species as the affected *animals*.~~

Products originating from killed or slaughtered *animals*, ~~(~~ranging from carcasses, *meat*, *milk*, eggs or genetic material to hair, wool, feathers or manure, ~~slurry)~~ should be destroyed or processed in a way that inactivates the pathogenic agent. The inactivating process should be carried out in accordance with the relevant articles of the *listed disease*-specific chapters.

Stamping-out procedures systematically include the cleaning and *disinfection* of *establishments* and *vehicles* used for the transport of *animals*, carcasses or products, as well as of any equipment and material that has been in direct or indirect contact with the *animals*. The procedures may include disinsection or *disinfestation* in the case of *vector*-borne disease or parasitic *infestation*. These procedures should be conducted in accordance with the relevant articles of Chapter 4.13.

EU comment

The EU reiterates its previous comments on the need to harmonise the timing of the different elements of the stamping-out policy (killing – disposal – cleaning and disinfection), i.e. when should the waiting period for the recovery of the free status start?

2. Test and cull

This strategy consists primarily of finding the ~~proven~~ infected *animals* in order to remove them from the population and either *slaughter* or kill and dispose of them. This strategy is ~~It should be~~ used for less contagious or slow-spreading diseases. *Veterinary Services* may apply different test and cull strategies based on the epidemiology of the *infection* or *infestation* or on the characteristics of available diagnostic tests. In particular, the design of test and cull strategy will depend on the sensitivity and specificity of the tests.

Apart from the selection of *animals* to be culled, the same principles apply as for *stamping-out* in terms of processing, treatment and disposal of dead or slaughtered *animals* and their products.

Article 4.Y.7.

Movement control

Disease spread due to the movement of live *animals*, animal products and contaminated material should be controlled by movement restrictions that are adequately enforced.

These restrictions can be applied to one or more animal species and their associated products, and to people, *vehicles* and equipment. They may vary from pre-movement certification to total standstill, and be limited to one or more *establishments*, or cover specific *zones*, or the entire country. The restrictions can include the complete isolation of individual *animals* or group of *animals*, and specific rules applied to movements, such as protection from *vectors*.

Specific rules covering movement controls should apply to each of any defined *zones*. Physical barriers ~~should~~ may be installed as needed, to ensure the effective application of movement restrictions.

Movement controls should be in place until the end of other disease control operations, ~~e.g.~~ such as a *stamping-out policy*, and after *surveillance* and a revised *risk assessment* ~~has~~ have demonstrated they are no longer needed.

Veterinary Services should coordinate their movement control actions with other relevant authorities such as local authorities, law enforcement agencies and communication media, as well as with neighbouring countries in the case of transboundary animal diseases.

EU comment

It is not clear what is meant by "communication media" in the context of the paragraph above.

Furthermore, we suggest adding "<u>, especially when outbreaks occur close to national borders</u>" at the end of the paragraph above. Indeed, these are the situations when coordination among neighbouring countries is most crucial.

Article 4.Y.8.

Biosecurity

In order to avoid the spread of the pathogenic agent outside of the affected *establishments* or *infected zones*, and in addition to the management measures described in Articles 4.Y.5. to 4.Y.7., *biosecurity* should be applied, in particular measures to avoid the contamination of people's clothes and shoes, of equipment, of *vehicles*, ~~and~~ of the environment or anything capable of acting as a fomite.

When *disinfection* is applied, ~~S~~specific disinfectant solutions should be used for footbaths or disinfectant baths for *vehicles*' wheels~~.~~ ~~s~~Single use material and clothes or material and clothes that can be effectively cleaned and disinfected should be used for the handling of *animals* and animal products~~.~~ ~~p~~Protection of premises from *wildlife*

should be ensured~~;~~. ~~w~~Wastes, waste-water and other effluents should be collected and treated appropriately.

EU comment

In the paragraph above, the words "<u>, pests, birds and domestic animals like pets</u>" should be inserted after "from wildlife", as also this should be ensured to avoid spread of the pathogenic agent. Perhaps vector protection should also be mentioned in this context.

Article 4.Y.9.

Vaccination and treatment

EU comment

We note that while the title of Article 4.Y.9. mentions also treatment, the text below deals with vaccination only. The words "and treatment" should thus either be deleted from the title, or specific text added regarding treatment.

Vaccination in response to a contagious disease *outbreak* should be conducted in accordance with Chapter 4.X.

Vaccination in response to an *outbreak* requires previous planning to identify potential sources of vaccine, including vaccine banks, and to plan the possible strategies for application, such as emergency *vaccination* or ring *vaccination*.

The properties of the vaccines should be well understood, especially the level of protection against *infection* or disease and the possibility to differentiate the immune response produced by the vaccine from that produced by *infection* with the pathogenic agent.

EU comment

In the paragraph above, the word "produced" (used twice) should be replaced with "<u>elicited</u>", as this is the correct term generally used in this context.

Although *vaccination* may hide ongoing *infection* or agent transmission, it can be used to decrease the shedding of the pathogenic agent, hence reduce the reproductive rate of the *infection*. In particular, when stamping-out is not feasible, *vaccination* can be used to reduce the circulation of the *infection* until levels are low enough for a test and cull strategy.

Whenever *vaccination* is to be used as a tool to control *outbreaks* or spread of disease, the control plan should include an exit strategy, i.e. when and how to stop the *vaccination* or whether *vaccination* should become routine.

Article 4.Y.10.

Zoning

The *Veterinary Authority* should use the tool of zoning in accordance with Chapter 4.3.

The use of zoning for disease control is inherently linked with measures of *killing* <u>or *slaughter*</u>, movement control, *vaccination* and *surveillance*, which apply differently according to the *zones*. In particular, efforts should be concentrated on those parts of a territory affected by the disease, to prevent the spread of the pathogenic agent and to preserve the status of the parts of the territory not affected by the disease.

EU comment

In the paragraph above, the words "<u>and eradication</u>" should be inserted after "The use of zoning for disease control", and the notion of eradication should also be added at the end of the paragraph as one of the possible objectives of zoning.

Zones <u>established</u> ~~defined~~ <u>in response to *outbreaks* of *emerging diseases* or *listed diseases*</u> ~~may be~~ <u>are usually</u>

infected zones, *protection zones*~~,~~ and *containment zones*~~,~~. However, ~~or~~ other types of *zones*, ~~e.g.~~ such as *zones* of intensified *surveillance*~~,~~ or *zones* of intensified *vaccination* can also be used.

EU comment

In the article above, it would be important to mention that the zoning used for outbreak control and eradication needs to be adapted and reshaped periodically to take into account the evolution of the disease in the affected zones.

Article 4.Y.11.

Communication in outbreak management

For the best implementation of disease control measures, *Veterinary Services* should ensure good communication with all concerned stakeholders, including the general public. This should be carried out, among others, through awareness campaigns targeted at breeders, *veterinarians*, *veterinary paraprofessionals*, local authorities, consumers and general public.

EU comment

In the paragraph above, the words "and the media" should be inserted after "the general public", as depending on the magnitude of the outbreak and its consequences for the country's economy and the general public, this will also be crucial.

Veterinary Services should communicate before, during and after *outbreaks*, in accordance with Chapter 3.3.

Article 4.Y.12.

Specific post-control surveillance

Specific *surveillance* should be applied in order to monitor the effectiveness of the *official control programme* ~~plan~~, and assess the status of the remaining *animal populations* in the different *zones* established by the *Veterinary Services*.

The results of this *surveillance* should be used to reassess the measures applied, including reshaping of the *zones* and re-evaluation of the culling or *vaccination* strategies, and for the eventual recovery of free status, if possible.

This *surveillance* should be conducted in accordance with Chapter 1.4. and with the relevant articles of the *listed disease*-specific chapters.

Article 4.Y.13.

Further outbreak investigation, monitoring, evaluation and review

In order to gather information required for any management information system, *Veterinary Services* should conduct an in-depth epidemiological investigation of each *outbreak* to build up a detailed first-hand, field-based knowledge of how the disease is transmitted, and inform further disease control plans. This requires staff who have been trained in the way to conduct it and the use of the standardised data collection forms.

Information gathered and experience gained should be used to monitor, evaluate and review ~~disease~~ *official control programmes* ~~plans~~.

Annex 26

SECTION 4.

~~GENERAL RECOMMENDATIONS:~~ DISEASE PREVENTION AND CONTROL

CHAPTER 4.Z.

INTRODUCTION TO RECOMMENDATIONS FOR DISEASE PREVENTION AND CONTROL

EU comment

The EU in general supports the proposed change to the title of Section 4 and the proposed new Chapter 4.Z. Comments are inserted in the text below.

Article 4.Z.1.

Effective prevention and control of contagious animal diseases, including zoonoses, is a central mandate of the *Veterinary Services* of each Member Country.

EU comment

The EU suggests replacing the word "contagious" with "infectious" throughout this chapter. Indeed, vector borne diseases would otherwise not be covered.

Furthermore, in order not to diminish the other important mandates of Veterinary Services, the words "a central mandate" could be replaced with "one of the central mandates".

From the extensive experience in combatting contagious animal diseases, *Veterinary Services* around the world, supported by significant progress in veterinary science, have developed and improved a number of tools to prevent, control and sometimes eradicate them.

EU comment

The word "sometimes" should be deleted, as this restriction is confusing. Indeed, even if not possible for all diseases, and not always done when possible due to budget or other considerations, eradication of animal diseases is essentially possible and has been done for many diseases in many countries all around the world. As an alternative, the term could be replaced with "even".

The following chapters of this section describe these tools and the different aspects of disease prevention and control to be implemented by the *Veterinary Services*.

To prevent effectively introduction and transmission of contagious animal diseases while minimising potential negative impacts of *sanitary measures*, *Veterinary Services* should consider devising a set of measures selected from the recommendations described in this section, taking into account various factors including their impact on trade, public health and environment. In parallel with disease-specific measures, *Veterinary Services* should take into account relevant commodity-based *sanitary measures*.

EU comment

For clarity reasons, the EU suggests slightly rephrasing the first sentence of the paragraph above, as follows:

"To effectively prevent ~~effectively~~ the introduction …".

Furthermore, the EU suggests inserting the word "listed" before "disease-specific" in the paragraph above, for consistency with other chapters in connection with the proposed deletion of the Glossary definition of "disease".

Finally, the EU queries a clarification on what is meant by "commodity-based sanitary measures" in the last sentence of the paragraph above. Indeed, it is not clear whether this would apply to international trade, and should preferably be specified that it does not.

Furthermore, although the general principles covering the measures described in this section are applicable to multiple diseases, *Veterinary Services* should adapt them to their circumstances, because characteristics of the pathogenic agents and the situations in which they occur are different disease by disease and country by country. To this end, recommendations in this section should be read in conjunction with *listed disease*-specific recommendations in Sections 8 to 15.

Veterinary Services should ensure that any prevention and control programme be proportionate to the *risk*, practical and feasible within the national context and be based on *risk analysis*.

EU comment

The paragraph above is very important. Indeed, it must be clear what recommendations are solely addressed to the Veterinary Services of Member Countries as guidance, to allow for flexible adaptation at national level in line with local situations and priorities, and would thus not necessarily be relevant for or applicable in international trade. Such a clarification could be included in this introduction chapter, and should preferably also be added to the User's guide as regards all the chapters of Section 4.

Furthermore, the EU suggests adding the notion of "cost-benefit analysis" in the paragraph above, as budgetary constraints make it necessary to prioritise interventions taking into account economic realities.

Prerequisites for devising such programmes may include:

– quality *Veterinary Services* including legislative framework and *laboratory* capacity;

– appropriate education to secure *veterinarians* and *veterinary paraprofessionals*;

– close link with research institutions;

– effective awareness of private stakeholders;

EU comment

The words "and active cooperation with" should be added after "awareness of" in the indent above. Indeed, private stakeholders should not only be aware of the programmes, they should be actively involved.

– public-private partnerships;

– regional cooperation among *Veterinary Authorities* on transboundary animal diseases.

Annex 27

CHAPTER 7.Y.

KILLING OF REPTILES FOR THEIR SKINS, MEAT AND OTHER PRODUCTS

EU comment

The EU thanks the OIE for preparing this draft chapter and encourages the work of the OIE in this area. The EU welcomes the outcome-based approach of this draft chapter and appreciates that the conditions for killing of reptiles can be very different.

Article 7.Y.1.

Scope

The recommendations in this chapter address the need to ensure the welfare of chelonians, crocodilians, lacertilians and ophidians, during the process of *killing* them for their skins, *meat* and other products.

Article 7.Y.2.

Definitions

For the purpose of this chapter:

EU comment

The EU suggests the OIE explaining at the beginning of Article 7.Y.2 that the existing definition of stunning and restrain in the Glossary and in chapter 7.5 need to be adapted to reptiles, given the specific characteristics and differences of these animals.

Justification

To highlight that possible differences in the definition of stunning and restrain proposed in this draft chapter depend on the specific characteristic of reptiles, and to clarify consistency with the other chapters of the Code.

Restraint: means any acceptable physical or chemical method of reducing, or eliminating, voluntary or reactive movement of the reptile, to facilitate efficient *stunning* or *killing*.

Stunning: means the procedure that causes immediate unconsciousness until the animal is dead, or causes the absence of pain, distress and suffering until the onset of unconsciousness, according to the outcomes defined in this chapter for the species covered.

EU comment

The EU suggests the OIE replacing the word "animal" with the word "reptile" in the above definition and in the entire draft chapter.

Justification

As to ensure clarity and consistency in the entire draft chapter, as explained in the above comment.

Unconsciousness: means the state of unawareness caused by temporary or permanent disruption of brain function.

Pithing: means a method carried out by inserting a rod or probe through the foramen magnum (or the hole from a penetrative captive bolt or gunshot), into the brain to ensure thorough brain destruction.

Article 7.Y.3.

General considerations

EU comment

The EU would encourage the OIE to include at that beginning of Article 7.Y.3 a general sentence highlighting that reptiles' species can be very different.

Justification

Such general sentence would highlight the importance of the general considerations and recommendations contained in this draft chapter.

1. Animal Welfare Plan

Facilities in which reptiles are killed should have an *animal welfare* plan and associated procedures. The purpose of such a plan should be to maintain good *animal welfare* at all stages of handling of animals until their *death*.

The *animal welfare* plan should contain standard operating procedures for each step of animal handling to ensure that it is properly implemented, based on relevant indicators shown in Article 7.Y.5. It should also include corrective actions to address specific risks, for example, power failures or other circumstances that could negatively affect the welfare of animals.

2. Competency and training of the personnel

Animal handlers should be competent in handling and moving reptiles, as well as understanding relevant behaviours of these animals and the underlying *animal welfare* and technical principles necessary to carry out their tasks.

EU comment

The EU suggests amending the above paragraph as follows:

"Animal handlers should be competent in care, handling and moving, stunning and monitoring effective stun, and kill of reptiles, as well as understanding relevant behaviours of these animals and the underlying animal welfare and technical principles necessary to carry out their tasks."

Justification

Staff should also be trained to restrain, stun and kill live reptiles as well as to identify signs of good and effective stunning and killing. As the killing process involves either prior stunning followed by a killing method or an instantaneous method of killing, it is important to ensure that the animal handers are competent in monitoring effective stun and kill of reptiles.

There should be sufficient number of personnel, who should be competent and familiar with the recommendations outlined in this chapter and their application within the national context.

The manager of the facility should ensure that personnel are competent and carry out their tasks in accordance with the guiding principles for *animal welfare* in Article 7.1.2.

Competence may be gained through formal training or practical experience. This competence should be verified by the *Competent Authority* or an independent body accredited by it.

3. Source of animals

Animals should be acquired legally in accordance with national jurisdictions and international treaties, including the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES).

Relevant documentation related to the source of the animals should accompany the animals.

If animals captured in the wild are to be used, capture and transport techniques should be humane and give due regard to human and animal health, welfare and safety.

4. Behaviour

Handling and *killing* methods should take into account specific reptile behaviours such as:

– reptiles are sensitive to and will respond to visual and tactile stimuli as well as noise and vibrations;

– the restraint and handling of reptiles can be difficult because of their agility and strength;

– reptiles can inflict significant bite wounds to handlers and wound infection or envenomation are not uncommon;

– low body temperatures may result in slow movements, torpor and reduced responsiveness that should not be regarded as indicators of quiescence or unconsciousness;

– absence of vocalisation is common or normal in reptiles, even in highly traumatic situations.

Article 7.Y.4.

Selection of a killing process

In the case of reptiles, the *killing* process may involve a stunning and a subsequent *killing* step or a direct *killing* method.

EU comment

The EU suggests amending the paragraph as follows:

"In the case of reptiles, the killing process ~~may involve a stunning and a subsequent killing step or a direct killing method~~ should involve either prior stunning followed by a killing method or an instantaneous method of killing."

Justification

Clarification of the sentence.

Criteria which may influence the choice of methods used in the process include:

– level of knowledge and skill required to perform the procedure effectively;

– safety of the operator;

– compatibility with processing requirements and animal product purpose;

– in the case of the use of drugs, the drug availability, licensing and use requirements, possible human abuse, and implications for other product uses such as consumption by animals or humans;

– ability to maintain equipment in proper working order;

– cost of the method;

EU comment

The EU suggests the OIE deleting the above bullet point "~~cost of method~~".

Justification

The criteria listed in this draft article are "animal welfare" criteria. The cost of the method is not a welfare criterion.

The *killing* process used should:

– avoid excitement, fear and stress to the animal;

– be appropriate for the species, size, age and health of the animal;

– be reliable and reproducible;

– ensure that any stunning used is in accordance with Article 7.Y.2.; and

– include the use of a *killing* method if the stunning method does not result in death of the animal during unconsciousness.

Article 7.Y.5.

Criteria (or measurables) for the outcome of the stunning and killing of reptiles

The following animal-based criteria (or measurables) can be useful indicators of *animal welfare*. The use of these criteria and their appropriate thresholds should be adapted to the different methods used to stun and kill reptiles. These criteria can be considered as tools to monitor the impact of the method and management used, given that both of these can affect *animal welfare*.

Criteria to measure the effectiveness of stunning and killing methods

Whilst multiple criteria are preferable for the establishment of unconsciousness or *death*, the presence of any of the following criteria should be regarded as sufficient to establish suspicion of consciousness:

– pupillary response to light;

– pupillary response to objects or movement;

– eye movement in response to objects or movement;

– blink or nictitating membrane responses to touch or contact of the cornea;

– spontaneous eyelid opening or closing;

– intentional defensive responses;

– tongue movement.

In addition to the absence of all the criteria above, *death* may be inferred by confirming permanent cessation of the following:

– response to somatic stimuli applied to the head, indicating brain activity;

– respiration;

EU comment

The EU suggests the OIE amending the above bullet point as follow:

"- respiration, except for chelonians resistant to anoxia; and".

Justification

Chelonians are resistant to anoxia. Furthermore, permanent cessation of both respiration and cardiac activity should be present in order to confirm death.

References

Nilsson GE1, Lutz PL., 2004 Anoxia tolerant brains. J Cereb Blood Flow Metab. 2004 May;24(5):475-86.

Donald C Jackson, 2002. Hibernating without oxygen: physiological adaptations of the painted turtle J Physiol. 2002 Sep 15; 543(Pt 3): 731–737.

Storey KB, 2007 Anoxia tolerance in turtles: metabolic regulation and gene expression Comp Biochem Physiol A Mol Integr Physiol. 2007 Jun;147(2):263-76. Epub 2006 Sep 6.

Krivoruchko A1, Storey KB, 2015. Turtle anoxia tolerance: Biochemistry and gene regulation. Biochim Biophys Acta. 2015 Jun;1850(6):1188-96. doi: 10.1016/j.bbagen.2015.02.001. Epub 2015 Feb 7.

– cardiac activity (while presence of a heartbeat does not necessarily mean that an animal is alive, permanent cessation of a heartbeat indicates death).

Article 7.Y.6.

Physical restraint

Physical restraint is often required in the process of *stunning* and *killing* of reptiles. Special considerations for the restraint of reptiles are needed due to the physical and behavioural characteristics of this taxonomic group.

Annex 27 (contd)

Recommendations for effective physical restraint in relation to animal welfare

The method of restraint should:

– avoid injuries due to excessive pressure applied by equipment or personnel;

– be applied rapidly to avoid excessive or prolonged struggling of the animal;

– exclude features that may cause pain or injury;

– not hoist or suspend animals by the feet, legs, tail or head;

– not restrain only one area of the body (e.g. head or neck) leaving the rest able to move excessively;

– ensure animals can breathe freely through the nostrils where the mouth is restrained;

– adequately support the animal's body when moving it;

– avoid taping or binding the legs or feet of the animals as the sole method of restraint, and where required, the method should not cause injuries or pain;

– not break legs, cut limb tendons or blind animals in order to immobilise them;

– not sever the spinal cord to immobilise animals.

EU comment

The EU suggests adding the following sentence:

"- not lifting, pulling or probing sensitive body parts."

Justification

This is a common requirement for all species.

Animal-based criteria (or measurables): excessive struggling, excessive movements, trauma and injuries.

Article 7.Y.7.

Introduction to stunning and killing methods

Stunning may be used to facilitate the *killing* of reptiles. *Stunning* methods may result in the *death* of the animal following unconsciousness, or may require an additional *killing* step.

If *stunning* is used, the method should:

– be appropriate for the species, size, age and health of the animal;

– be reliable and reproducible;

– avoid excitement, fear and stress to the animal;

– avoid or minimise restraint in accordance with Article 7.Y.6.;

– result in the immediate onset of unconsciousness or the absence of pain, distress and suffering until the onset of unconsciousness that lasts until the animal is dead;

– be followed by a killing method if stunning does not result in death of the animal during unconsciousness.

The equipment used should be maintained and operated properly in accordance with the manufacturer's recommendations, in particular with regard to the species and size of the animal. The maintenance of the equipment is the responsibility of the management of the facility, and should be under the supervision of the *Competent Authority* or accredited delegated body. If the primary method of *stunning* fails to produce unconsciousness as described in Article 7.Y.5., a back-up *stunning* or *killing* method should be used immediately (Articles 7.Y.8. to 7.Y.15.).

EU comment

The EU suggests OIE amending the first phrase of the above paragraph as follows:

"The equipment used should be maintained and operated properly and in accordance with the manufacturer's recommendations, in particular with regard to the species and size of the animal."

Justification

Equipment that is self-made or does not come with manufacturer's recommendations should be maintained and operated properly anyway.

Animal-based criteria (or measurables): immediate onset of unconsciousness or *death* as described in Article 7.Y.5.

Article 7.Y.8.

Electrical stunning (for crocodilians only)

Electrical stunning is the application of an electric current through electrodes for the purpose of causing immediate unconsciousness that lasts until death.

EU comment

The EU kindly asks the OIE to clarify whether this article refers to head only electrical stunning. If this is the case, the EU suggests the OIE including the word "head" before "electrical stunning" in the title of draft article 7.Y.8 and in the above sentence.

Justification

Head only is a different method than head to body. From the description in the section, the text appears to relate only to head only and this should be made very clear in the title and introductory paragraph, given the differences

Recommendations for effective use in relation to *animal welfare*:

– the equipment and the procedure for its application should be approved by the *Competent Authority* an accredited designated authority;

EU comment

The EU suggests OIE including the word "or" in the above bullet point as follow:

"- [...] should be approved by the Competent Authority <u>or</u> an accredited designed authority".

Justification

Clarity

– apparatus should deliver sufficient current through the brain;

– the equipment should be scientifically validated, tested and calibrated prior to use and maintained according to a set protocol;

– minimum electrical parameters (current, voltage and frequency) should be applied;

– minimum stun duration should be achieved;

EU comment

The EU suggests the OIE amending the above bullet point as follows:

"- minimum stun duration <u>of current's exposure</u> should be achieved;"

Justification

Clarity. The "stun duration" might be confused with the time between loss and recovery of consciousness following the stun.

– animals should be killed in accordance to Articles 7.Y.9. to 7.Y.15. without delay following confirmation of effective stunning to avoid recovery of consciousness.

EU comment

The EU suggests adding the additional following bullet points:

"- animals should be effectively restrained;

- equipment should be selected to suit the type and size of animal;

- equipment should be cleaned, maintained and stored, following manufacturer's recommendations."

Justification

Restraining may be required for precise placement of electrodes. Equipment and electrodes needs to fit the animals' dimensions. Equipment used for electrical stunning needs cleaning and maintenance (electrodes, for example, may require regular cleaning and sharpening). Furthermore, this inclusion is in consistency with Articles 7.Y.10, 7.Y.11, 7.Y.12 and 7.Y.15.

Animal-based criteria (or measurables): immediate onset of unconsciousness as described in Article 7.Y.5.

Article 7.Y.9.

Penetrative captive bolt

The aim of this method is to produce a state of unconsciousness and cause severe damage to the brain by the impact and penetration of a captive bolt using a mechanical device. The force of impact and the physical damage caused by the passage of the bolt should result in immediate unconsciousness and death. If death does not occur following the passage of the penetrative bolt, then an additional killing method in accordance with Articles 7.Y.9. to 7.Y.15. should be used immediately to ensure death.

EU comment

The EU suggests OIE amending the last phrase of the above paragraph as follows:

"If death does not reliably occur following the passage of the penetrative bolt, then an additional killing method in accordance with Articles 7.Y.9. to 7.Y.15. should be used immediately to ensure death."

Justification

When a stunning method is used that may or may not result in death during unconsciousness, the immediate use of an additional killing method should be mandatory, in order to avoid any possible recovery of consciousness.

Recommendations for the effective use in relation to *animal welfare*:

– animals should be effectively restrained;

– the device should be correctly positioned on the head to result in the penetration of the brain by the bolt;

– the bolt should be of appropriate mass, length, diameter and shape;

– cartridge or compressed air specifications should be determined to deliver the correct bolt velocity;

– equipment and charge should be selected to suit the type and size of animal;

– equipment should be cleaned, maintained and stored, following manufacturer's recommendations.

Animal-based criteria (or measurables): immediate onset of unconsciousness and *death* as described in Article 7.Y.5.

EU comment

The EU suggests amending the above sentence as follow:

"Animal-based criteria (or measurables): immediate onset of unconsciousness and <u>or</u> death as described in Article 7.Y.5."

Justification

Criteria for death are only applicable if the captive bolt is not followed by an additional killing method (compare 7.Y.10).

Article 7.Y.10.

Non-penetrative captive bolt

The non-penetrative captive bolt method is sometimes called 'concussive stunning', although concussion is the underlying principle for both penetrative and non-penetrative methods. The concussion may result in both unconsciousness and *death*. If *death* does not occur following the application of the percussive blow, then an additional *killing* method in accordance with Articles 7.Y.9. to 7.Y.15. should be used immediately to assure *death*.

EU comment

The EU suggests OIE adding the following sentence at the end of the above paragraph:

"- <u>non penetrative captive bolt is not appropriate for large reptiles (such as large crocodilians)</u>".

Justification

Non penetrative captive bolt does not consistently produce concussion and animals are not rendered unconscious.

References

Zoo Animal and Wildlife Immobilization and Anesthesia edited by Gary West, Darryl Heard, Nigel Caulkett (this only recommends penetrative bolt for crocodilians)

Recommendations for an effective use in relation to *animal welfare*:

– animals should be effectively restrained;

– the device should be correctly positioned on the head to allow optimum transfer of energy to the brain;

– the bolt should be of appropriate mass, diameter and shape;

– cartridge or compressed air specifications should be determined to deliver the correct bolt velocity;

– equipment and charge should be selected to suit the type and size of animal;

– equipment should be cleaned, maintained and stored, preferably following manufacturer's recommendations.

EU comment

The EU suggests OIE deleting the word "~~preferably~~" in the above bullet point.

Justification

Consistency with draft Article 7.Y.9.

Outcome-based criteria (or measurable): immediate onset of unconsciousness or death as described in Article 7.Y.5.

Article 7.Y.11.

Percussive blow to the head

A percussive blow to the head to induce cerebral concussion can be achieved manually. A concussive state is normally associated with a sudden loss of consciousness with associated loss of reflexes. Inducing unconsciousness requires the transfer of sufficient energy into the brain to disrupt normal neural function. If the severity of the blow is sufficient then it will result in the *death* of the animal. If *death* does not occur following the application of the percussive blow, then an additional *killing* method in accordance with Articles 7.Y.9. to 7.Y.15. should be used immediately to ensure *death*.

Recommendations for effective use in relation to *animal welfare*:

– animals should be effectively restrained;

– the blow should be correctly applied to result in optimum transfer of energy to the brain;

– the tool should be of appropriate size and weight, and the blow of sufficient force to induce concussion;

– equipment and method should be selected to suit the type and size of animal.

EU comment

The EU suggests OIE including the following additional bullet points:

"<u>- maximum animal live-weight and/or</u>

- maximum number of animals stunned/killed per person and day"

Justification

Achieving a successful stun/kill with percussive blow may be difficult above a certain live-weight. A person may become exhausted after a certain amount of stuns/kills during a single shift, leading to a reduced precision and force of manual blows.

Animal-based criteria (or measurables): immediate onset of unconsciousness or *death* as described in Article 7.Y.5.

Article 7.Y.12.

Gunshot

An effective gunshot, where the projectile enters the brain, can cause immediate unconsciousness and *death*. A gunshot to the heart or neck does not immediately render an animal unconscious and therefore should not be used. If *death* does not occur following the gunshot, then an additional *killing* method in accordance with Articles 7.Y.9. to 7.Y.15. should be used immediately to ensure *death*.

Manual restraint of the animal should not be used due to safety concerns for humans in the line of fire.

Recommendations for effective use in relation to *animal welfare*:

– ensure accurate targeting of the brain;

– select firearm and projectile suitable for the type and size of animal;

– equipment should be cleaned and stored following manufacturer's recommendations.

Animal-based criteria (or measurables): immediate onset of unconsciousness or *death* as described in Article 7.Y.5.

Article 7.Y.13.

Pithing

Pithing is a method carried out by inserting a rod or probe through the foramen magnum or shot hole from a penetrative captive bolt or gunshot, into the brain to ensure thorough brain destruction. After insertion of the rod or probe it should be promptly turned four to six times in a centrifugal motion to ensure destruction of the brain tissue.

EU comment

The EU suggests amending the paragraph as follows:

"Pithing is a killing method carried out by inserting a rod or probe through the foramen magnum or shot hole from a penetrative captive bolt or gunshot, into the brain to ensure thorough brain destruction. After insertion of the rod or probe it should be promptly turned four to six times in a centrifugal motion to ensure destruction of the brain tissue."

Justification

For clarification sake.

Recommendations for effective use in relation to *animal welfare*:

– should only be used in unconscious animals;

– movement of the pithing implement should ensure maximum destruction of brain tissue.

Animal-based criteria (or measurables): confirmation of *death* as described in Article 7.Y.5.

Article 7.Y.14.

Decapitation or spinal cord severance

Decapitation involves cutting the neck of the animal, between the skull and the first cervical vertebra using a sharp instrument (guillotine, axe or blade) leading to severance of the head. For some reptile species, this method is not anatomically feasible. For severance of the spinal cord, complete separation of the head from the neck is not necessary. Some reptiles may remain conscious for over an hour after decapitation or spinal cord severance, which makes this method acceptable only in stunned and unconscious animals and when followed by immediate destruction of the brain by pithing or percussive blow.

EU comment

The EU suggests amending the paragraph as follows:

"Decapitation is a killing method which involves cutting the neck of the animal, between the skull and the first cervical vertebra using a sharp instrument (guillotine, axe or blade) leading to severance of the head."

Justification

For clarification sake.

Recommendations for effective use in relation to *animal welfare*:

– should only be used on unconscious animals;

– should always be followed immediately by physical intervention to destroy the brain, i.e. immediate crushing of the brain or pithing.

Animal-based criteria (or measurables): confirmation of death as described in Article 7.Y.5.

Article 7.Y.15.

Chemical agents

There are a number of acceptable chemical agents that can be used for the restraint or *killing* of reptiles. The use of these agents for either restraint or *killing* should be supervised by *veterinarians* or *veterinary paraprofessionals* in accordance with the requirements of the *Competent Authority*. If *death* does not occur following administration of the agent, then an additional *killing* method in accordance with Articles 7.Y.9. to 7.Y.15. should be used immediately to ensure *death*.

EU comment

The EU suggests the OIE including the following sentence at the end of the above paragraph:

"The efficacy of the chemical agent will vary according to the temperatures of reptiles."

Justification

It is important to highlight that the efficacy of these agents depend on the temperature and therefore may vary.

Recommendations for effective use in relation to *animal welfare*:

– ensure proper physical restraint is used for administration;

– ensure chemicals and dosage used are appropriate for the animal;

– ensure the route of administration is appropriate for the animal;

Animal-based criteria (or measurables): confirmation of *death* as described in Article 7.Y.5.

Article 7.Y.16.

Methods that are unacceptable for stunning and killing reptiles

Due to particular anatomical and physiological characteristics of reptiles the use of any method other than those described in Articles 7.Y.9. to Article 7.Y15., are considered inappropriate and unacceptable. Some examples of unacceptable methods are:

– exsanguination,

EU comment

The EU suggests amending the bullet point above as follows:

"- exsanguination <u>without prior stunning</u>"

Justification

Some methods (like exanguination) might be suitable for killing after prior stunning.

– freezing or cooling,

– heating or boiling,

– suffocation or drowning,

– inflation using compressed gas or liquid,

– live evisceration or skinning,

– constriction bands to induce cardiac arrest,

– inhaled carbon dioxide (CO_2), carbon monoxide (CO) or nitrogen (N),

– paralytic agent drugs.

References

American Veterinary Medical Association website. AVMA guidelines for the euthanasia of animals. Available at: https://www.avma.org/KB/Policies/Documents/ euthanasia.pdf. Accessed July 29, 2013.

American Veterinary Medical Association website. AVMA guidelines for the humane slaughter of animals:2016 edition. Available at: https://www.avma.org/KB/Resources/Reference/AnimalWelfare/Documents/Humane-Slaughter-Guidelines.pdf. Accessed December 22, 2016.

Arena, P.C.,, Warwick, C. & Duvall, D. (1994) Rattlesnake round-ups. In: Gutzwiller, K. & Knight, R. (Eds.) Wildlife and Recreationists, Island Press, Kansas.

Arena, P.C. & Warwick, C. (1995) Miscellaneous factors affecting health and welfare. In: Warwick, C., Frye, F.L. & Murphy (Eds.) Health and Welfare of Captive Reptiles, Chapman & Hall/Kluwer, London and New York.

Close, B., Bannister, K., Baumans, V., Bernoth, E.M., Bromage, N., Bunyan, J., Erhardt, W., Flecknell, P., Gregory, N., Hackbarth, H., Morton, D. and Warwick, C. (1996) Recommendations for euthanasia of experimental animals. Part 2. Laboratory Animals, 31:1-32.

Close, B., Bannister, K., Baumans, V., Bernoth, E.M., Bromage, N., Bunyan, J., Erhardt, W., Flecknell, P., Gregory, N., Hackbarth, H., Morton, D. and Warwick, C. (1996) Recommendations for euthanasia of experimental animals. Part 1. Laboratory Animals, 30:293-316.

Close, B., Bannister, K., Baumans, V., Bernoth, E.M., Bromage, N., Bunyan, J., Erhardt, W., Flecknell, P., Gregory, N., Hackbarth, H., Morton, D. and Warwick, C. (1996) Recommendations for euthanasia of experimental animals. Part 2. Laboratory Animals, 31:1-32.

Close, B., Bannister, K., Baumans, V., Bernoth, E.M., Bromage, N., Bunyan, J., Erhardt, W., Flecknell, P., Gregory, N., Hackbarth, H., Morton, D. and Warwick, C. (1996) Recommendations for euthanasia of experimental animals. Part 1. Laboratory Animals, 30:293-316.

Cooper, J.E., Ewbank, R., Platt, C. & Warwick, C. (1989a) Euthanasia of amphibians and reptiles, Universities Federation for Animal Welfare/World Society for the Protection of Animals, 35 pp.

Cooper, J.E., Ewbank, R., Platt, C. & Warwick, C. (1986) Euthanasia of reptiles and amphibians. Vet. Rec., Nov. 8.

Jasan Payne-James (2003) Forensic Medicine: Clinical and Pathological Aspects https://books.google.co.uk/books?isbn=1841100269

Nevarez, J.G., Strain, G.M., da Cunha, A. F., Beaufrere, H. (2014) Evaluation of four methods for inducing death during slaughter of American alligators (Alligator mississippiensis). American Journal of Veterinary Research, 75(6), 536-543.

Mader, D. R. (2006) Reptile Medicine and Surgery (Second Edition). ISBN: 978-0-7216-9327-9

Swiss Confederation Federal Veterinary Office website. Analysis on humane killing methods for reptiles in the skin trade.

Warwick, C. (1986) A decapitacao dos repteis constitutium metodo cruel paca a sua occisao. Rev. Port. Cienc. Veter., LXXXl:84-5.

Warwick, C. (1986) Euthanasia of reptiles, New Zealand Vet. J., 34:12.

Warwick, C. (1985) Euthanasia of reptiles, J. Am. Vet. Med. Assoc., 187:1081.

Warwick, C. (1985) Euthanasia of reptiles: decapitation-an inhumane method of slaughter. Notes from Northern Ohio Association of Herpetologists, 8:11-12.

Warwick, C. (1990b). Crocodilian slaughter methods, with special reference to spinal cord severance. Texas J. Sci., 42:191-8.

Warwick, C. (1990e) Observations on collection, transport, storage and slaughter of western diamondback rattleophideans (Crotalus atrox). Herpetopathologia, 2:31-7.

Warwick, C. (1985) Euthanasia of reptiles: decapitation-an inhumane method of slaughter. Notes from Northern Ohio Association of Herpetologists, 8:11-12.

Warwick, C. (2010) Evaluation of two documents regarding the supply sale and slaughter of turtles associated with Tesco plc in China.

Warwick, C. (2016) Crocodilian stunning and slaughter in Vietnam. Report to PETA, 4pp.

Annex 28

CHAPTER 7.Z.

ANIMAL WELFARE AND LAYING HEN PRODUCTION SYSTEMS

EU comment

The EU thanks the OIE for drafting this draft chapter and initiating its work in this important area. The EU asks the OIE to consider its comments for further development of the text.

As general comment and as this draft chapter covers both laying hens and pullets, the EU would like to encourage the OIE to mention pullet in the title, and to clearly specify which measurable and recommendations apply to the laying hens and which to pullets, and thus avoiding as much as possible using the words "birds", "chickens" and "chicks". Furthermore, the EU asks the OIE to clarify and further develop the explanation of outdoor and indoor systems.

Specific comments are included in the text below.

When new draft chapters or chapters substantially reviewed are circulated to member countries for comments, the EU would encourage the OIE to share also the reports of the related *ad hoc* group meetings as background information.

Article 7.Z.1.

Definitions

For the purpose of this chapter:

Laying hens (hens): means sexually mature female birds of the species *Gallus gallus domesticus* kept for the commercial production of eggs for human consumption. Laying hens kept in village or backyard *flocks* are excluded.

EU comment

The EU asks OIE to consider including the following amendment in the first sentence of the above paragraph:

"commercial production of eggs intended for human consumption".

Justification

Clarity

The EU also suggests OIE deleting the following last sentence in the above paragraph and moving it to Article 7.z.2, as second sentence.

"~~Laying hens kept in village or *backyard* flocks are excluded~~."

Furthermore, the EU suggests the OIE better clarifying the meaning and differences between hens "kept in village" or "backyard flocks".

Justification

The proposed modification increases the clarity of the draft article. Furthermore, the above sentence refers more to the scope of the draft chapter rather than to the definition of laying hens.

End-of-lay hens: means laying hens at the end of their productive lives.

Layer pullets (pullets): means female birds of the species *Gallus gallus domesticus* raised for commercial layer production purposes from hatch until the onset of sexual maturity.

Article 7.Z.2.

Scope

This chapter covers the production period from the arrival of *day-old birds* on the pullet-rearing farm to the removal of hens from the laying production facilities.

EU comment

The EU suggests OIE including in the above sentence the words "end-of lay" before hens as to read:

"removal of <u>end-of-lay</u> hens…"

Justification

To clarify that the draft chapter covers the entire production cycle of a hen. Hens indeed may be moved/transported from one layer farm to another to continue their production.

Furthermore, the EU suggests the OIE moving from Art 7.z.1 to the end of the above paragraph the following sentence:

"<u>Laying hens kept in village or backyard flocks are excluded.</u>"

Justification

See previous comment

Commercial production systems involve the confinement of birds, the application of *biosecurity* and trade in the eggs or pullets. These recommendations cover pullets or hens kept in cage or non-cage systems, whether indoors or outdoors.

EU comment

In the first sentence above, the EU suggests OIE deleting "the" as follow:

"biosecurity and trade in ~~the~~ eggs…".

Justification

Grammar

Furthermore, the EU asks OIE to consider including the following sentence at the end of the above paragraph:

"<u>Only systems which allow providing for nesting areas, litter, perches and other recommendations given in this draft chapter, should be encouraged.</u>"

Justification

Housing systems for hens differ in the possibilities for hens to show species specific behaviors such as foraging, dust-bathing, perching and building or selecting a suitable nest. If hens cannot perform such high priority behaviors, this may result in

significant frustration, or deprivation or injury, which is detrimental to their welfare.

EFSA Scientific Opinion on the welfare aspects of various systems of keeping laying hens http://www.efsa.europa.eu/en/efsajournal/pub/197

Commercial pullet or hen production systems include:

1. Indoor systems

   Pullets or hens are completely confined in a poultry house, with or without environmental control.

EU comment

In the sentence above, the EU suggests OIE replacing 'with or without environmental control' by 'in a controlled environment', as to read:

"..in a poultry house, ~~with or without environmental control~~ with a controlled environment".

The same comment would apply for Outdoor systems in point 2.

Justification

Also the basics production for laying hens under the control of a man in a building mean they are required to have some form of lighting regime, ventilation, method of delivering feed and water, control over noise levels and etc., as well as outdoor – shelter from adverse weather, predators, feed and water, access to the outside etc.

2. Outdoor systems

   Pullets or hens are kept in premises with or without environmental control that include a designated outdoor area.

EU comment

The EU suggests the OIE clarifying and further developing the explanation of outdoor and indoor systems.

Justification

It is not clear if, for example, indoor systems include systems having verandas or outdoor spaces, or only systems where hens at all time are kept inside the buildings. Likewise, it is not clear what is intended for outdoors.

A more developed explanation would facilitate the understanding and applicability of the chapter.

This chapter should be read in conjunction with Chapters 6.5., 7.1., 7.2., 7.3., 7.4., 7.5. and 7.6.

Article 7.Z.3.

Criteria or measurables for the welfare of pullets or hens

The welfare of pullets or hens should be assessed using outcome-based measurables. Consideration should also be given to the resources provided and the design of the system. Outcome-based measurables, specifically animal-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 pullets or hens are managed, also taking into account the strain of bird concerned.

Criteria that can be measured in the farm setting include body and plumage condition, egg shell condition, mortality and morbidity rates, etc. The age at which abnormalities of these criteria are observed can help to determine the origin.

EU comment

The EU suggests OIE including at the end of the first sentence of the above paragraph also the following criteria:

"and morbidity rate, bone and foot problems, etc."

Justification

Keel bone problems can occur at the start of lay. Relevant information could be lost by assessing only at the end.

Furthermore, the EU suggests OIE modifying the last sentence above by including the following text:

"Together with other factors such birds strain, behaviour and environment, the age at which abnormalities of these criteria are observed can help to determine the origin."

Justification
Age is not the only factor that could provide an indication; the presentation of the problem (e.g. head vs neck feather loss), the environment the pullets or hens are kept in (e.g. litter quality), pullet or hen management (e.g. frequency & quality of inspection), strain etc can all have a significant impact.
Sci. Ref: e.g Welfare Quality Guide & AssureWel

Other conditions such as bone and foot problems, disease, *infection* or *infestation* can also be assessed at depopulation or during routine sampling. It is recommended that values for welfare measurables be determined with reference to appropriate national, sectorial or regional standards for pullets or hens.

EU comment

The EU suggests modifying the first sentence of the above paragraph as follow:

"be assessed at depopulation ~~or~~ and during routine sampling"

Justification
The fact that assessment takes place during one period of production does not rule out the need for monitoring at other times.

Furthermore, the EU suggests the OIE replacing the term "values" by "thresholds" in the second sentence of the above paragraph as to read:

"that ~~values~~ thresholds for welfare measurable"

Justification

Without monitoring the level of the problem (e.g. at farm / sector / regional level) it is impossible to know what the extent of the problem is; it could be useful to have reference thresholds.

References
http://www.grandin.com/importance.measurement.improve.welfare.html
http://www.assurewel.org/

The following outcome-based criteria and measurables are useful indicators of pullet or hen welfare:

1. Behaviour

The presence or absence of certain chicken behaviours could indicate an animal welfare problem, including fear, pain or sickness. In addition, chickens have evolved behaviours that they are highly motivated to perform and a good understanding of normal chicken behaviour [Nicol, 2015], including their social interactions [Estevez *et al.*, 2007; Rodríguez-Aurrekoetxea, A. and Estevez, I., 2014], is required. Some behaviours may not be uniquely indicative of one type of problem; they may be exhibited for a variety of reasons.

a) Dust bathing

Dust bathing is an intricate body maintenance behaviour. During dust bathing, birds work loose material, such as litter, through their feathers. This behaviour helps remove dirt and parasites, which contributes to maintaining plumage condition, which in turn helps to maintain body temperature and protect against skin injury. Reduced dust bathing behaviour in the *flock* may indicate problems with litter or range quality, such as the litter or ground being wet or not friable [Olson and Keeling, 2005; Van Liere and Bokma, 1987]

EU comment

The EU suggests amending the above paragraph as follow:

"Dust bathing is an intricate body maintenance behaviour. During dust bathing, pullets and hens work loose material, such as litter, through their feathers in a defined sequence. This behaviour helps remove dirt and parasites, which contributes to maintaining plumage condition, which in turn helps to maintain body temperature and protect against skin injury. Reduced dust bathing behaviour in the *flock* or individuals performing incomplete dust bathing sequences may indicate problems with litter or range quality, such as the litter or ground being wet or not friable [Olson and Keeling, 2005; Van Liere and Bokma, 1987], or crowding / insufficient resource or a litter layer that is too shallow. Completion of a full sequence of dust bathing is an indication of good welfare; in the absence of a full sequence of dust-bathing behaviour, the motivation to dust bathe remains [Nicol et al., 2017]."

Justification

The proposed text highlights what is perceived by hens as a satisfactory dust bathing. Furthermore litter conditions depend on the type of material, depth, friability, and moisture as well as housing, technical equipment, and management.

References

https://www.ncbi.nlm.nih.gov/pubmed/20634510
http://agriculture.vic.gov.au/agriculture/animal-health-and-welfare/animal-welfare/farmed-bird-welfare-science-review

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5144664/

Report on the welfare of laying hens in colony systems, 1991, Farm Animal Welfare Council.

b) Fear behaviour

Fearful pullets and hens show high reactivity to various stimuli [Jones R. B., 1987; Zeltner and Hirt,2008]. Fearfulness can lead to injury when the birds pile on top of, and sometimes suffocate, one another. Fearful birds may be less productive [Barnett J. *et al.*, 1992]. Methods have been developed for evaluating fearfulness while *animal handlers* walk through the poultry house or bird area [Jones, 1996; Forkman, 2007].

EU comment

The EU suggests OIE including after the second sentence of the above paragraph the following new text:

"Fearful reactions can also lead to pullets and hens coming into hard contact with furniture of the house leading to broken bones and skin injuries"

Justification

Fearful reactions can increase risk of injuries.

The EU also suggests OIE including the following text at the end of the third sentence above, as follow:

"Fearful pullets and hens may be less productive Barnett J. et al., 1992] and more prone to injurious feather pecking behavior."

Justification

High fearfulness in the rearing period is associated with high levels of feather damage in the laying period; measures to reduce fearfulness are associated with reduced injurious feather pecking.

References

http://www.sciencedirect.com/science/article/pii/S0168159114002159

Furthermore, the EU suggests OIE to modify the last sentence of the above paragraph as follow:

"Methods have been developed for evaluating fearfulness such as while *animal handlers* walk through the house or area where pullets or hens are kept".

Justification

Several methods are available to evaluate fearfulness.

c) Feeding and drinking behaviour

Reduced feeding or drinking can indicate management problems, including inadequate spaces or inappropriate placement of feeders or drinkers, dietary imbalance, poor water quality, or feed contamination. Feeding and drinking are often depressed when birds are ill, and intake may also be reduced during periods of heat stress and increased during cold stress [Garner et al, 2012; Thogerson et al, 2009a; Thogerson et al, 2009b].

EU comment

The EU suggests OIE replacing "reduced" with "changes in" and to add the word "behavior" in the first sentence above, as to read:

"~~Reduced~~ Changes in feeding or drinking behaviour"

Furthermore, the EU suggests including at the end of the paragraph above the following sentence:

"Displacement of pullets or hens at feeders /or drinkers could indicate competition for these resources."

Justification
Not necessarily only a reduction on these elements means abnormal behaviour.

d) Foraging activity

Foraging is the act of searching for food, typically by walking and pecking or scratching the litter substrate; reduced foraging activity could suggest problems with litter quality or the presence of conditions that decrease bird movement [Appleby et al, 2004; Lay et al, 2011; Weeks and Nicol, 2006].

e) Injurious feather pecking and cannibalism

Injurious feather pecking can result in significant feather loss and may lead to cannibalism. Cannibalism is the tearing of the flesh of another bird, and can result in severe injury. These behaviours can have multifactorial causes [Hartcher, 2016; Estevez, 2015; Nicol *et al.*, 2013; Rodenburg, 2013; Lambton, 2013].

f) Locomotion and comfort behaviours

Locomotion and comfort behaviours are important for body and plumage development and maintenance, and may include walking, leaping, turning, stretching legs and wings, wing flapping, feather ruffling and tail wagging [Dawkins and Hardie, 2007].

Opportunities to display these behaviours are influenced by housing system and space [Widowski *et al.*, 2016; Lay, 2011].

EU comment

The EU asks the OIE to consider amending the following sentence as follows:

"Opportunities to display these behaviours are influenced by housing system ,~~and,~~ space and light level [Widowski *et al.*, 2016; Lay, 2011]. A reduction in displaying these behaviours can also be an indication of welfare and health problems."

Justification

Sufficient light stimulates hens to perform their behaviours.

References

O'Connor, E. A., Parker, M. O., Davey, E. L., Grist, H., Owen, R. C., Szladovits, B., Demmers, T. G. M., Wathes, C. M. and Abeyesinghe, S. M. (2011) Effect of low light and high noise on behavioural activity, physiological indicators of stress and production in laying hens. *British Poultry Science, 52*(6), pp. 666-674.

g) Nesting

Nesting is a natural and highly motivated behaviour that includes nest site selection, nest formation and egg laying [Cooper and Albentosa, 2003; Weeks and Nicol, 2006; Cronin *et al.*, 2012; Yue and Duncan, 2003]. Uneven nest box utilisation and egg laying outside the nests may be indicative of problems with environmental or social behavioural factors [Cronin *et al.*, 2012; Cooper and Appleby, 1996; Gunnarsson *et al.*, 1999].

EU comment

The EU suggests the OIE including at the end of the last sentence above the following text:

"including nest box design, cleanliness and level of provision (of nests)."

Justification

It is important to clarify that environmental factors may also be closely related to the actual nest box.

h) Perching

Perching is a natural and highly motivated behaviour. Birds seek elevation during the day; the motivation to seek elevation is particularly strong at night when pullets and hens select a site for resting or sleeping [EFSA, 2015]. Reduced perching behaviour in the flock may indicate problems with environmental factors, injuries and pullet rearing experience [Janczak and Riber, 2015; Gunnarsson *et al.*, 1999].

i) Social behaviour

Chickens are a highly social species, engaging in synchronised behaviour [Olsson *et al.*, 2002; Olsson and Keeling, 2005]. Benefits include social learning, protection from predators [Newberry *et al*., 2001], help in thermoregulation and plumage maintenance. Problems in social behaviour can be assessed using scoring systems for measuring the degree of aggression damage and competition for resources [Estevez, 2002].

j) Spatial distribution

Uneven spatial distribution of the birds may indicate thermal discomfort or uneven availability of resources, such as light, food or water, shelter, comfortable resting locations. [Rodríguez-Aurrekoetxea and Estevez, 2016; Cornetto and Estevez, 2001].

k) Thermoregulatory behaviour

Prolonged or excessive panting and wing spreading are observed during heat stress [Mack, 2013; Lara and Rostagno, 2013]. Indicators of cold stress include feather ruffling, rigid posture, trembling, huddling and piling on top of each other and distress vocalisations.

EU comment

The EU suggests the OIE deleting the following text in the above sentence:

~~"piling on top of each"~~

Justification
Piling on top of each other reflects more the problem of smothering, which has no thermoregulatory causation.

References
Bright, A. and Johnson, E. A. (2011) Smothering in commercial free-range laying hens: a preliminary investigation. Veterinary Record, 168(19).

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l) Vocalisation

Vocalisation can indicate emotional states, both positive and negative. A good understanding of *flock* vocalisations is useful for good animal care [Zimmerman *et al.*, 2000; Bright, 2008; Koshiba et al., 2013].

2. Body condition

Poor body condition is reflective of poor welfare outcomes for individual birds. At *flock* level, uneven body condition may be an indicator of potential welfare problems. Body condition can be evaluated using on-farm sampling methods for body weight or body condition scores [Gregory and Robins, 1998; Craig and Muir, 1996, Elson and Croxall, 2006; Keeling et al, 2003].

EU Comment

The EU suggests OIE modifying the second sentence of the above paragraph as follow:

"indicator of potential ~~welfare~~ problems with health, housing or management"

Jusitifcation
Clarity and useful to provide some examples.

Furthermore, the EU suggests OIE including the following text at the end of the above paragraph:

"Body condition may be masked by good feather cover and the assessment of this should not be performed visually."

Justification
To provide guidance

3. Eye conditions

Conjunctivitis can indicate the presence of irritants such as dust and ammonia. High ammonia levels can also cause corneal burns and eventual blindness. Abnormal eye development can be associated with low light intensity [Jenkins *et al.*, 1979; Lewis and Gous, 2009; Prescott *et al.*, 2003]

4. Foot problems

Hyperkeratosis and bumblefoot are painful conditions associated with inappropriate flooring [Lay *et al.*, 2001; Abrahamsson and Tauson, 1995; Abrahamsson and Tauson, 1997).

EU Comment

The EU suggests OIE including the following text at the end of the above sentence:

", poorly designed perches and poorly maintained litter."

Justification
To provide guidance

References
https://www.european-poultry-science.com/Foot-pad-health-in-Lohmann-Selected-Leghorn-and-Lohmann-Brown-laying-hens-kept-in-different-housing-systems-with-modified-perch-design,QUIEPTQyMTg0NjEmTUlEPTE2MTAxNA.html

Excessive claw growth, broken claws and toe injuries affect locomotion and may be associated with pain [EFSA, 2005].

Contact dermatitis affects skin surfaces that have prolonged contact with wet litter or other wet flooring surfaces [Tauson and Abrahamson, 1996].

Foot problems are usually manifested as blackened skin progressing to erosion and fibrosis on the lower surface of the footpads and at the back of the hocks. If severe, the foot and hock lesions may contribute to locomotion problems and lead to secondary *infections.* Scoring systems for foot problems have been developed [Blatchford *et al.*, 2016].

5. Incidence of diseases, infections, metabolic disorders and infestations

Ill-health, regardless of the cause, is a welfare concern, and may be exacerbated by poor environmental or husbandry management.

EU Comment

The EU suggests OIE including the following text at the end of the above paragraph:

"Red mites infestations cause anaemia and higher mortality in laying hens. Red mites are also known to be vector of several bacterial and viral pathogens, not only to pullets and hens, but also to humans."

Justification
To highlight the impact of red mites infestations in case of poor environment.

References
Sparagano, O., Pavlićević, A., Murano, T., Camarda, A., Sahibi, H., Kilpinen, O., Mul, M., van Emous, R., le Bouquin, S., Hoel, K. and Cafiero, M. (2009) Prevalence and key figures for the poultry red mite Dermanyssus gallinae infections in poultry farm systems. Experimental and Applied Acarology, 48(1-2), pp. 3-10

6. Injury rate and severity

The rate and severity of injuries can indicate welfare problems in the *flock* during production. Injuries include those caused by other birds (e.g. scratches, feather loss or wounding), by environmental conditions, (e.g. fractures and keel bone deformation) and by human intervention (e.g. during handling and catching).

7. Mortality, culling and morbidity rates

Daily, weekly and cumulative mortality, culling and morbidity rates should be within expected ranges. Any unforeseen increase in these rates could reflect an *animal welfare* problem.

8. Performance

Daily, weekly and cumulative performance should be within expected ranges. Any unforeseen decreases in these rates could be reflective of the welfare status of the individual birds or the *flocks*.

a) Pullet growth rate measures average daily mass gain per average pullet and *flock* uniformity.

b) Pullet feed conversion measures the quantity of feed consumed by a *flock* relative to the total live mass produced, expressed as the mass of feed consumed per unit of body mass.

c) Hen feed conversion measures the mass of feed consumed by a *flock* relative to the unit of egg production.

d) Egg production, such as when measured by the number of eggs per hen housed.

e) Egg quality, such as when measured by shell strength and abnormalities.

EU comment

The EU suggests OIE amending the following sentence as follows:

"Egg quality, such as when measured by number of second grade eggs, shell strength and abnormalities, or Haugh units."

Justification

Roberts, J. R. (2004) Factors affecting egg internal quality and egg shell quality in laying hens. Journal of Poultry Science, 41, pp. 161-177.

9. Plumage condition

Evaluation of the plumage condition of pullets and hens provides useful information about aspects of welfare. Feather loss and damage can result from feather pecking behaviour, nutritional problems and abrasions resulting from faults in the housing system [Rodriguez-Aurrekoetxea and Estevez, 2016; Drake *et al.*, 2010]. Plumage dirtiness may be associated with the environment and production system. Plumage scoring systems have been developed for these purposes [Blokhuis, 2007].

EU comment

The EU suggests OIE amending the second last sentence in the paragraph above as follows:

"Plumage dirtiness may be associated with ~~the~~an inappropriate environment and production system.."

Justification

To clarify that it is an inappropriate environment or production system that may cause dirty plumage.

10. Water and feed consumption

Monitoring daily water and feed consumption is a useful tool to indicate disease, *infection* or *infestation* and other welfare conditions, taking into consideration ambient temperature, relative humidity and other related factors. Problems with the water or feed quality and supply can result in wet litter and diarrhoea, dermatitis, dehydration or changes in egg quality, production and body condition.

EU comment

The EU asks the OIE to consider replacing "to" with "which may" in the first sentence above:

"useful tool ~~to~~ which may indicate…"

Justification

Clarity

Article 7.Z.4.

Recommendations

Articles 7.Z.5. to 7.Z.29. provide recommendations for measures applied to pullets and hens.

Each recommendation includes a list of relevant outcome-based measurables derived from Article 7.Z.3. This does not exclude other measures being used when appropriate.

Article 7.Z.5.

Location, construction and equipment of establishments

EU comment

The EU asks the OIE to consider including the following sentence as first sentence of the above paragraph:

"Only systems which allow birds to perform at least their priority behaviours should be encouraged."

Justification

Housing systems for pullets and hens differ in the possibilities for hens to show species

specific behaviours such as foraging, dust-bathing, perching and for hens building or selecting a suitable nest. If pullets and hens cannot perform such high priority behaviours, this may result in significant frustration, or deprivation or injury, which is detrimental to their welfare.

EFSA Scientific Opinion on the welfare aspects of various systems of keeping laying hens http://www.efsa.europa.eu/en/efsajournal/pub/197

The location of pullet and hen *establishments* should be chosen to be safe from the effects of fires and floods and other natural disasters to the extent practicable. In addition *establishments* should be located or designed to avoid or minimise disease risks, exposure of pullets and hens to chemical and physical contaminants, noise and adverse climatic conditions.

Pullet and layer houses, outdoor areas and equipment to which birds have access should be designed after consideration of bird behaviour and maintained to avoid injury or pain to the birds.

Pullet and layer houses should be constructed with materials and electrical and fuel installations that minimise the risk of fire and other hazards.

Producers should have a maintenance programme in place for all equipment, the failure of which could jeopardise bird welfare.

Outcome-based measurables: culling and morbidity, fear behaviour, feeding, drinking and foraging, foot problems, incidence of diseases, *infections* and *infestations*, injury rates and severity, locomotion and comfort behaviours, mortality, performance, plumage condition, social behaviour and spatial distribution, thermoregulatory behaviour, vocalisations.

EU comment

The EU asks the OIE to consider amending the above paragraph as follows:

"Outcome-based measurables: culling and morbidity rates, fear behaviour, feeding~~,~~ and drinking behaviour, ~~and~~ foraging activity, foot problems, incidence of diseases, *infections* and *infestations*, injury rates and severity, locomotion and comfort behaviours, mortality rates, ……."

Justification

To ensure consistency with the terminology used in 7.Z.3. The same comment applies to the rest of the draft chapter.

Article 7.Z.6.

Matching the birds and the housing and production system

Welfare and health considerations should balance any decisions on performance when choosing a layer strain for a particular location, housing and production system. The pullet rearing system should prepare the bird for the layer production system.

EU comment

The EU asks OIE to consider including the following sentences at the end of the above paragraph:

" During the rearing period the pullets should be kept in a system, which prepares them to the situation in the laying (housing system, colour of feeders and drinkers, time of feedings, starting time and ending time of light period, etc.). Furthermore there should be a good provision and management of litter from the first day, to reduce feather pecking in the laying phase."

Justification

Minimising the differences between the rearing and laying environment via a seamless transition is likely to make a flock less prone to injurious feather pecking. Furthermore, factors such as stocking density and feeding strategies during rearing are known to influence feather pecking.

Providing and management of litter from day 1 is important to reduce feather pecking in the laying phase.

References

Van de Weerd, H. A. and Elson, A. (2006) Rearing factors that influence the propensity for injurious feather pecking in laying hens. World's poultry science journal, 62(04), pp. 654-664.

van Niekerk, T., de Jong, I., van Krimpen, M., Reuvekamp, B., de Haas, E. (2013) Effect of UV-light, high fiber feed or litter provision in early rearing on feather pecking in rearing and laying period, Wageningen UR Livestock Research, rapport 671

de Jong, I., Gunnink, H., Rommers J. and van Niekerk, T. (2010) Effect of substrate during early rearing of laying hens on the development of feather pecking behavior, Wageningen UR Livestock Research, rapport 333.

Outcome-based measurables: dust bathing, feeding, drinking, foraging, incidence of *diseases*, injurious feather pecking and cannibalism, injury rate and severity, locomotion and comfort behaviours, mortality, nesting, *infestations*, perching, performance, plumage condition, social behaviour, spatial distribution.

EU comment

The EU asks OIE to consider amending the following paragraph as follow, and to supplement the text in Article 7.Z.3, 1 g) accordingly:

"Outcome-based measurables: dust bathing, feeding, <u>and</u> drinking <u>behaviour</u>, foraging <u>activity</u>, incidence of *diseases* <u>and infestations</u>, injurious feather pecking and cannibalism, injury rate and severity, locomotion and comfort behaviours, mortality <u>rates</u>, nesting, ~~*infestations*~~, perching, <u>number of hens perching in the first night when placed in the layer house,</u> performance, plumage condition, social behaviour, spatial distribution<u>.</u>"

Justification

The number of hens perching in the first night when placed in the layer house is a relevant indicator (low numbers reflect a rearing system that is not matching the layer system). In the entire draft chapter, the outcome-based measurables mentioned should be consistent with those listed in Article 7.Z.3.

Article 7.Z.7.

Stocking density

Pullets and hens should be housed at a stocking density that allows them to have adequate access to resources and to express locomotion and comfort behaviours. The following factors should be taken into account:

EU comment

The EU asks OIE to consider amending the following paragraph as follows:

"Pullets and hens should be housed at a stocking density that allows them to have adequate access to resources <u>without competition</u> and to express specie-specific locomotion and comfort behaviours, <u>at least 750 cm2 per hen as the very minimum.</u> The following factors should be taken into account:"

Justification

Report of the Scientific Veterinary Committee, Animal Welfare Section on the Welfare of Laying Hens, Brussels, 30 October 1996.

Furthermore, the EU suggests including the following sentence at the end of the above paragraph, as follow:

"Furthermore, the group size should be defined in order to allow the expression of behaviors such as nesting, foraging and walking freely. It is particularly important to consider simultaneously group size and stocking densities."

Justification

Considering simultaneously group size and stocking density (in fact the total space available) allows better design of the system and less behavioural restriction.

– management capabilities,

– ambient conditions,

– housing system,

– production system,

EU comment

The EU would like to include above the following new bullet points:

"- usable area within the system,

- needs and availability of resources,"

Justification

It is important to highlight that the space to be considered when calculating stocking densities is the usable rather than the total area. Furthermore stocking density is also linked to the availability of resources. An increase in stocking density would require an increase in resource level which could result in overcrowding.

– litter quality,

– ventilation,

– *biosecurity* strategy,

– genetic strain,

– age and bird mass.

Outcome-based measurables: drinking and foraging, feeding, incidence of diseases *infections* and *infestations*, injury rate and severity, locomotion and comfort behaviours, mortality rate, nesting, perching, performance, plumage condition, social behaviour, spatial distribution.

Article 7.Z.8.

Nutrition

Pullets and hens should always be fed a diet appropriate to their age and genetic strain, which contains adequate nutrients to meet their requirements for good health and welfare.

The form and quality of feed and water should be acceptable to the birds and free from contaminants and microorganisms hazardous to bird health.

The feeding and watering systems should be cleaned regularly to prevent the growth of hazardous microorganisms.

Birds should be provided with adequate access to feed on a daily basis. Water should be continuously available except under veterinary advice. Special provision should be made to enable chicks to access appropriate feed and water.

Outcome-based measurables: aggression, feed and water consumption, foraging behaviour, incidence of disease*, infections* and *infestations*, injurious feather pecking, injury rate and severity, metabolic disorders, mortality rate, performance, vocalisations.

Aerticle 7.Z.9.

Flooring

The flooring for the birds should be easy to clean and disinfect and not cause harm or damage to them.

The slope and design of the floor should allow birds to express normal locomotion and comfort behaviours. The floors should support the birds adequately, prevent injuries and ensure that manure does not contaminate other birds. Changes of flooring types from pullet to layer housing should be avoided.

The provision of loose and dry litter material is desirable to encourage dust bathing and foraging by pullets and hens. When litter is provided it should be managed to minimise any detrimental effects on welfare and health. Litter should be replaced or adequately treated when required to prevent *diseases, infections* and *infestations*.

EU comment

The EU asks the OIE to consider the following amendment of the first and second sentence in the paragraph above:

"The provision of loose and dry litter material ~~is desirable~~ deep enough to allow performing ~~to encourage~~ dust bathing and foraging by pullets and hens, is desirable. ~~When~~ Litter should always be ~~is~~ provided, and it should be maintained in a dry and friable condition ~~managed~~ to minimize any detrimental effects on welfare and health".

Justification

Foraging and probably dust bathing are priority behaviors for laying hens. Scientific evidence shows that litter appropriate for foraging and dust-bathing should be provided in all systems and should be managed in such a way that it is friable and is readily accessible to pullets and hens.

Provision of litter encourages dust bathing behavior. Pullets and hens do not perform complete dust-bathing sequences in the absence of loose dry material. Sham dust-bathing (DB behaviour in the absence of litter) is not a positive welfare outcome.

References

EFSA Scientific Opinion on the welfare aspects of various systems of keeping laying hens http://www.efsa.europa.eu/en/efsajournal/pub/197

Tahamtani, F. M., Brantsæter, M., Nordgreen, J., Sandberg, E., Hansen, T. B., Nødtvedt, A., ... & Janczak, A. M. (2016). Effects of litter provision during early rearing and environmental enrichment during the production phase on feather pecking and feather damage in laying hens. Poultry science, 95(12), 2747-2756

http://agriculture.vic.gov.au/agriculture/animal-health-and-welfare/animal-welfare/farmed-bird-welfare-science-review

https://www.ncbi.nlm.nih.gov/pubmed/20634510

Outcome-based measurables: comfort behaviour, dust bathing, foot problems, foraging, incidence of diseases, *infections* and *infestations*, injury rates and severity, locomotion, performance, plumage condition.

Article 7.Z.10.

Dust bathing areas

When dust bathing areas are offered, they should provide suitable friable materials, designed and positioned to encourage dust bathing, allow synchronised behaviour, prevent undue competition and not cause damage or injuries. Dust bathing areas should be easy to inspect and clean [Lentfer *et al.*, 2011].

EU comment

The EU asks OIE to consider modifying the text at the beginning of the above paragraph as following:

"~~When dust bathing areas are offered, they~~ Dust bathing areas should ~~provide~~ be offered, and they should provide."

Justification

In addition to the comment above on litter, dust bathing areas particularly for indoor pullets and hens on concrete are vital.

References

Vestergaard, K. (1982). Dust-bathing in the domestic fowl—diurnal rhythm and dust deprivation. *Applied Animal Ethology, 8*(5), 487-495.

Van Liere, D.W. and P.R. Wiepkema, 1992: Effects of long-term deprivation of sand on dustbathing behaviour in laying hens. Anim. Behav. 43, 549-558.

Weeks, C. A., & Nicol, C. J. (2006). Behavioural needs, priorities and preferences of laying hens. World's Poultry Science Journal, 62(2), 296-307

Outcome-based measurables: dust bathing, injury rate and severity, plumage condition, spatial distribution.

Article 7.Z.11.

Foraging areas

When foraging areas are offered, they should provide suitable materials, designed and positioned to encourage foraging, allow synchronised behaviour, prevent undue competition and not cause damage or injuries. Foraging areas should be easy to inspect and clean.

EU comment

The EU asks the OIE to consider modifying the text at the beginning of the above paragraph as following:

"~~When foraging areas are offered, they~~ Foraging areas should be offered, and they should provide."

Justification

See the comment above on litter.

Outcome-based measurables: foraging, injurious feather pecking and cannibalism, injury rate and severity, spatial distribution.

Article 7.Z.12.

Nesting areas

When nesting areas are offered, they should be built of suitable materials, designed and positioned to encourage nesting, prevent undue competition and not cause damage or injuries. Nesting areas should be easy to inspect, clean and disinfect.

EU comment

The EU asks the OIE to consider modifying the text at the beginning of the above paragraph as following:

"~~When nesting areas are offered, they~~ Nesting areas should always be provided ~~and~~ in adequate numbers, and they should be built...."

Furthermore, the EU suggests the OIE including the following sentence as second sentence in the above paragraph:

"A suitable substrate should be provided to encourage nesting behaviour; a bare wire floor is unsuitable for nesting."

Justification

Housing systems should provide the possibility for the hens to carry out activities which are behavioral priorities. Hens have a high behavioral priority to lay their eggs in a nest site that is suitable to them and to perform nest building behavior. Nest should be provided and hens' preference is for an enclosed nest and a pre-moulded or mouldable substrate. Hens deprived of nests show higher levels of corticosterone and signs of stress than hens with access.

References

EFSA Scientific Opinion on the welfare aspects of various systems of keeping laying hens http://www.efsa.europa.eu/en/efsajournal/pub/197

Cooper, J. J., & Appleby, M. C. (1995). Nesting behaviour of hens: effects of experience on motivation. Applied Animal Behaviour Science, 42(4), 283-295.

Kruschwitz, A., Zupan, M., Buchwalder, T., & Huber-Eicher, B. (2008). Nest preference of laying hens (Gallus gallus domesticus) and their motivation to exert themselves to gain nest access. Applied animal behaviour science, 112(3), 321-330.

Alm, M., Tauson, R., Holm, L., Wichman, A., Kalliokoski, O., & Wall, H. (2016). Welfare indicators in laying hens in relation to nest exclusion. Poultry science, 95(6), 1238-1247.

Outcome-based measurables: injurious feather pecking and cannibalism, injury rate and severity, nesting, performance, spatial distribution.

EU comment

The EU suggests OIE including the following outcome-based measurable at the end of the above sentence:

"number of floor eggs"

Justification

Eggs outside nests may suggest insufficient space for oviposition in nests. Draft Article 7.Z.3 should be modified for consistency as to include also the proposed measurable.

References

Villanueva, S., Ali, A. B. A., Campbell, D. L. M. and Siegford, J. M. (2017) Nest use and patterns of egg laying and damage by 4 strains of laying hens in an aviary system1. *Poultry Science, 96*(9), pp. 3011-3020.

Article 7.Z.13.

Perches

When perches are offered, they should be built of suitable materials, designed and positioned to encourage perching, to prevent keel bone deformation or foot problems and to maintain stability of the birds during perching. In the absence of designated perches, platforms, grids and slats that are perceived by the birds as elevated and that do not cause damage or injuries, may be a suitable alternative. Perches or their alternatives should be easy to clean and disinfect [Hester, 2014; EFSA, 2015].

EU comment

The EU asks OIE to consider modifying the text at the beginning of the above paragraph as following:

"~~When perches are offered, they~~ Perches should always be provided, and they should be built...."

Furthermore, the EU suggests OIE including at the end of the last sentence the following text:

"Perches or their alternatives should be easy to clean and disinfect and should be positioned to enable safe navigation".

Justification

Housing systems should provide the possibility for the hens to carry out activities which are behavioral priorities. Resting and perching are important aspects of pullet and hen welfare. Perch design and hygiene are important to avoid damage to the foot pad and perch design is also important to minimise keel bone deformation. All pullets and hens should be able to perch at the same time.

Furthermore, detail of how perches could be positioned could be provided where possible. Scientific evidence exist demonstrating work how perches should be positioned to reduce the risk of keel bone problems, pecking and aid navigation.

References

EFSA Scientific Opinion on the welfare aspects of various systems of keeping laying hens http://www.efsa.europa.eu/en/efsajournal/pub/197

EFSA Scientific Opinion Scientific Opinion on welfare aspects of the use of perches for laying hens https://www.efsa.europa.eu/en/efsajournal/pub/4131

Appleby, Michael C., and Barry O. Hughes. "Welfare of laying hens in cages and alternative systems: environmental, physical and behavioural aspects." World's Poultry Science Journal 47.2 (1991): 109-128. This paper states "Foot and claw damage are often a major problem in cages, with lesions, fissures and hyperkeratosis on the feet and with twisted, broken or overgrown claws (Tauson, 1980). These problems are affected by the thickness of the floor wire […]".

On positioning of perches:

https://science.rspca.org.uk/sciencegroup/farmanimals/standards/layinghens

Perch elevation should be carefully considered to minimise injurious feather pecking, cannibalism, keel deformities and fractures.

Outcome-based measurables: foot problems, injurious feather pecking and cannibalism, injury rate and severity, perching, spatial distribution.

EU comment

The EU asks OIE to consider amending the text by the following paragraph:

"Outcome-based measurables: foot problems, keel bone problems, injurious feather pecking and cannibalism, injury rate and severity, perching, spatial distribution."

Justification

Stratmann, A., Fröhlich, E. K. F., Harlander-Matauschek, A., Schrader, L., Toscano, M. J., Würbel, H. and Gebhardt-Henrich, S. G. (2015) Soft Perches in an Aviary System Reduce Incidence of Keel Bone Damage in Laying Hens. Plos One, 10(3), pp. e0122568.

Sandilands, V., Moinard, C. and Sparks, N. H. C. (2009) Providing laying hens with perches: fulfilling behavioural needs but causing injury? British Poultry Science, 50(4), pp. 395-406.

Article 7.Z.14.

Outdoor areas

Pullets can be given access to outdoor areas as soon as they have sufficient feather cover and are old enough to range safely. There should be sufficient appropriately designed exit areas to allow them to leave and re-enter the poultry house freely.

Management of outdoor areas is important. Land and pasture management measures should be taken to reduce the risk of birds becoming infected by pathogenic agents, infested by parasites or being injured. This might include limiting the stocking density or using several pieces of land consecutively in rotation.

Outdoor areas should be located on well-drained ground and managed to minimise swampy conditions and mud. The outdoor area should be able to contain the birds and prevent them escaping. Outdoor areas should allow pullets and hens to feel safe outdoors and be encouraged to optimise utilisation of the range, while mitigating predation and disease risks [Gilani et al, 2014]. Hens should be habituated early to the outdoor area [Rodriguez–Aurrekoetxea and Estevez, 2016]. Outdoor areas should provide shelter for the birds and be free from poisonous plants and contaminants.

EU comment

The EU asks OIE to consider including the following text at the beginning of the above paragraph:

"Outdoor areas should be appropriate to the stocking density of the pullets or hens and be located"

Justification

Stocking densities should be adequate and allow pullets and hens to perform their specie-specific behaviors.

Outcome-based measurables: fear behaviour, foot problems, foraging, incidence of *diseases*, injury rate and severity, locomotion and comfort behaviours, morbidity rate, mortality rate, *infestations*, performance, plumage condition, social behaviour, spatial distribution, thermoregulatory behaviour, vocalisation.

EU comment

The EU asks the OIE to consider including the following text at the end of the above paragraph:

"<u>percentage of pullets and hens that use the outdoor area.</u>"

Justification

This can be a useful out-come based measurable.

Article 7.Z.15.

Thermal environment

Thermal conditions for pullets and hens should be appropriate for their stage of life, and extremes of heat, humidity and cold should be avoided. A heat index can assist in identifying the comfort zones for the pullets and hens at varying temperature and relative humidity levels.

When environmental conditions move outside of these zones, strategies should be used to mitigate the adverse effects on the birds. These may include adjusting air speed, provision of heat or evaporative cooling [Yahav, 2009].

Control of the thermal environment should be monitored frequently enough so that failure of the system will be noticed before it causes a welfare problem.

Outcome-based measurables: morbidity rate, mortality rate, performance, spatial distribution, thermoregulatory behaviours, water and feed consumption.

Article 7.Z.16.

Air quality

Ventilation and manure management can affect air quality. Actions are required to maintain air quality at all times, including the removal of waste gases such as carbon dioxide and ammonia, dust and excess moisture content from the environment.

The ammonia concentration should not routinely exceed 25 ppm at bird level [David *et al.*, 2015; Milles *et al.*, 2006; Olanrewaiu, 2007].

Dust levels should be kept to a minimum [David, 2015]. Where the health and welfare of birds depend on an artificial ventilation system, provision should be made for an appropriate back-up power and alarm system.

Outcome-based measurables: eye conditions, incidence of respiratory diseases, performance.

Article 7.Z.17.

Lighting

There should be an adequate period of continuous light.

The light intensity during the light period should be sufficient and homogeneously distributed for normal development of the birds, for finding feed and water, to stimulate activity, minimise likelihood of feather pecking and cannibalism and to allow adequate inspection [Prescott *et al.*, 2003; Prescott and Wathes, 1999; Green *et al.*, 2000].

There should also be an adequate period of light and darkness during each 24-hour cycle to allow the birds to rest, to reduce stress and to promote circadian rhythms [Malleau et al., 2007].

When changes in lighting are needed, they should be performed in a step-wise fashion, except during induced moulting (if practised) when rapid adjustments to lighting are desired.

EU comment

The EU asks OIE to modify the above sentence as follow:

"they should be performed in a step-wise fashion, ~~except during induced moulting (if~~

~~practised) when rapid adjustments to lighting are desired~~ , e.g. for dusk period to allow pullets or hens to prepare for roosting."

Justification

Induced moulting should not be encouraged from a welfare perspective.

Reference

http://www.animalsandsociety.org/wp-content/uploads/2015/09/207-221-Animal-Welfare-Issues-in-the-Poultry-Industry-Is-There-a-Lesson-to-Be-Learned.pdf

Outcome-based measurables: eye conditions, injurious feather pecking, injury rate and severity, locomotion, nesting perching, performance, spatial distribution.

Article 7.Z.18.

Noise

Pullets and hens are adaptable to different levels and types of noise. However, exposure of birds to unfamiliar noises, particularly those that are sudden or loud, should be minimised wherever possible to prevent stress and fear reactions, such as piling up[Bright and Johnson, 2001]. Ventilation fans, machinery or other indoor or outdoor equipment should be constructed, placed, operated and maintained in such a way that it causes the least possible amount of noise [Chloupek *et al.*, 2009].

EU comment

The EU asks OIE to modify the first sentence of the above paragraph as follow:

"Although pullets and hens are adaptable to different levels and types of noise, ~~However~~, exposure of ~~birds~~ pullets and hens to unfamiliar noises, particularly that are sudden or loud, should be minimised ~~wherever possible~~……"

Justification

There is little evidence with regard to the impacts of noise on hen welfare, however it does impact production. Loud noises should be kept to a minimum to prevent stress at all times.

References

https://www.ncbi.nlm.nih.gov/pubmed/22221232

Location of establishments should, where possible, take into account existing local sources of noise. Strategies should be implemented to habituate the birds to the conditions [Candland *et al.*, 1963; Morris, 2009].

Outcome-based measurables: fear behaviours, injury rate and severity, performance.

Article 7.Z.19.

Prevention and control of injurious feather pecking and cannibalism

Injurious feather pecking and cannibalism are challenges in pullet and hen production.

Management methods that may reduce the risk of occurrence include:

– managing light in rearing and lay [Nicol *et al.*, 2013],

EU comment

The EU suggests OIE replacing "managing light' with "<u>appropriate</u> light <u>levels and distribution</u>" in the above bullet point.

Justification

Improved clarity

– choosing genetic strain [Craig and Muir, 1996; Kjaer and Hocking, 2004],

– influencing age of onset of lay [Green *et al.*, 2010],

– providing foraging materials in rearing and lay [Huber-Eicher and Wechsler, 1998],

EU comment

The EU would suggest OIE including the following bullet point:

"<u>- providing other environmental enrichment materials</u>"

Justification

Dynamic environmental enrichment (EE) may allow expression of natural foraging behavior thus reducing conspecific pecking behaviour and alleviating hen injury. For example the presence of a hay bale is stimulating and may reduce feather pecking while encouraging hens to redirect pecking towards a dynamic and manipulable EE.

References

Daigle, C. L., Rodenburg, T. B., Bolhuis, J. E., Swanson, J. C. and Siegford, J. M. (2014) Use of dynamic and rewarding environmental enrichment to alleviate feather pecking in non-cage laying hens. Applied Animal Behaviour Science, 161(0), pp. 75-85.

Van de Weerd, H. A. and Elson, A. (2006) Rearing factors that influence the propensity for injurious feather pecking in laying hens. World's poultry science journal, 62(04), pp. 654-664.

– adapting diet and form of feed in rearing and lay [Lambton *et al.*, 2010],

– reducing stocking density [Zimmerman et al., 2006],

– reducing group size in rearing and lay [Bilci k and Keeling, 1999],

– providing elevated perches in rearing and lay [Green *et al.*, 2010],

– treating beaks in chicks [Gentle and Hughes, 1997],

EU comment

The EU asks OIE to clarify the bullet point above on treating beaks and in particular to clarify if it refers to beak trimming or infra-red beak treatment of day-old chicks.

If the text refers to infra-red beak trimming, the EU would suggest replacing "treating beaks" with "infra-red beak treatment of day-old chicks".

Justification

Beak trimming is a painful mutilation, which interferes with beak function and sensitivity.Treating beaks"comes with its own welfare concerns and management strategies to deal with the underlying causes of injurious pecking are preferable. It

should also be noted that some methods, e.g. infra-red trimming at day old, is better in terms of welfare than other more traditional methods, i.e. hot blade trimming

https://www.google.co.uk/url?sa=t&rct=j&q=&esrc=s&source=web&cd=4&cad=rja&uact=8&ved=0ahUKEwiruaO7q9jXAhVVFMAKHQofAkYQFgg9MAM&url=https%3A%2F%2Fwww.lf.dk%2F~%2Fmedia%2Flf%2Ffor-medlemmer%2Fsektioner-og-udvalg%2Ferhvervsfjerkraesektionen%2Fkongres-2016%2Fana%25C3%25ABlle-laravoire.pdf%3Fla%3Dda&usg=AOvVaw0G77ueX1ZNKCWd4ZvDJC3K

– minimising fear- related stimuli,

– introducing males [Bestman and Wagenaar, 2003].

EU comment

The EU asks OIE to consider adding the following text:

- Preventing and minimizing parasite infestations (poultry red mite)"

" - During the rearing period, keeping pullets in a system which prepares them to the situation in the laying (housing system, colour of feeders and drinkers, time of feedings, starting time and ending time of light period, etc.)."

Justification

The paper below reviews the knowledge in the scientific literature on the effect of rearing conditions on injurious pecking. Factors such as stocking density and feeding strategies during rearing are known to influence feather pecking. Minimising the differences between the rearing and laying environment via a seamless transition is likely to make a flock less prone to injurious feather pecking. Minimising the differences between the rearing and laying environment via a seamless transition is likely to make a flock less prone to injurious feather pecking.

References

Van de Weerd, H. A. and Elson, A. (2006) Rearing factors that influence the propensity for injurious feather pecking in laying hens. World's poultry science journal, 62(04), pp. 654-664.

Significance and Control of the Poultry Red Mite Dermanyssus gallinae O.A.E. Sparagano,1,∗ D.R. George,1 D.W.J. Harrington, 2 and A. Giangaspero 3 Annu. Rev. Entomol. 2014. 59:447–66 The Annual Review of Entomology is online at ento.annualreviews.org This article's doi:10.1146/annurev-ento-011613-162101

Heerkens, J. L. T., Delezie, E., Kempen, I., Zoons, J., Ampe, B., Rodenburg, T. B. and Tuyttens, F. A. M. (2015) Specific characteristics of the aviary housing system affect plumage condition, mortality and production in laying hens. *Poultry Science, 94*(9), pp. 2008-2017.

Management methods to control the occurrence include the above list, where applicable, and prompt removal of affected birds to a hospital area or euthanasia.

If these management strategies fail, therapeutic beak trimming is the last resort.

EU comment

The EU suggests OIE including at the end of the sentence above the following text:

"beak trimming is the last resort, which should be avoided on mature hens and which should be carried out by trained and competent staff with appropriate and properly maintained equipment. Beak".

Justification

It is important to clarify that staff must be trained and competent. Beak trimming at mature age can cause chronic pain.

References

AVMA literature review https://www.avma.org/KB/Resources/LiteratureReviews/Pages/beak-trimming-bgnd.aspx

Gentle et al., (1997) provided a review of the impact of beak trimming depending on the age of the hens.

Outcome-based measurables: injurious feather peaking and cannibalism, injury rate and severity, mortality rate, plumage condition, vocalisation.

EU comment

The EU would suggests OIE including replacing "peaking" with "pecking" in the above sentence.

Justification

Spelling correction.

Article 7.Z.20.

Moulting

When induced moulting is practised, techniques that do not involve withdrawal of feed should be used. Hens should have access to water at all times. Only hens in good body condition and health should be moulted. During the moulting period, body mass loss should not compromise hen welfare, including welfare during the subsequent laying period. Total mortality during the moult period should not exceed normal variations in *flock* mortality.

EU comment

The EU asks OIE modifying the first sentence of the above paragraph as follow:

"~~When induced moulting is practised~~, Moulting should be discouraged, but if it is practiced, techniques"

Justification

Induced moulting should not be recommended from a welfare perspective.

References

A paper on the suffering entailed in forced moulting is at http://www.animalsandsociety.org/wp-content/uploads/2015/09/207-221-Animal-Welfare-Issues-in-the-Poultry-Industry-Is-There-a-Lesson-to-Be-Learned.pdf

Outcome-based measurables: body condition, feeding and drinking, foraging [Biggs *et al.*, 2004; Saiozkan *et al.*, 2016; Petek and Alpay, 2008], injurious feather pecking and cannibalism, injury rate and severity, morbidity rate, mortality rate, performance, plumage condition, social behaviour.

Article 7.Z.21.

Painful interventions

Painful interventions, such as beak trimming, should not be practised unless absolutely necessary and pain mitigation interventions should be used. Other mutilations (e.g. dubbing and toe trimming) should not be performed in pullets and hens. Pain-free alternatives are preferred. If preventive beak trimming is required, it should be carried out by trained and skilled personnel at the earliest age possible and care should be taken to remove the minimum amount of beak necessary using a method, which minimises pain and controls bleeding. Current methods include infrared treatment or hot blade cutting. [Gentle et al, 1991; Marchand-Forde et al, 2008; Marchand-Forde et al 2010; McKeegan and Philbey, 2012; Freire et al, 2011; Glatz et al, 1998];

EU comment

The EU suggests OIE including the following text at the end of the above paragraph:

"Hot blade cutting should be used only if infrared treatment is not available"

Justification

Hot blade trimming should not be encouraged as first routine method. It requires significant handling and can result in bleeding and infection.

References

Dennis, R. L., Fahey, A. G. and Cheng, H. W. (2009) Infrared beak treatment method compared with conventional hot-blade trimming in laying hens. Poultry Science, 88(1), pp. 38-43.

(BTAG), B. T. A. G. (2015) The Beak Trimming Action Group's Review. in Department for Environment, F. R. A., (ed.): UK government. pp. 40.

https://www.gov.uk/government/publications/beak-trimming-action-group-review

FAWC report (2007)

http://edepot.wur.nl/374964

Beak trimming at a mature age can cause chronic pain. If therapeutic beak trimming is required, at whatever age, it should be carried out by trained and skilled personnel and care should be taken to remove the minimum amount of beak necessary using a method which minimises pain and controls bleeding.

EU comment

The EU suggests OIE modifying the above paragraph as follow:

"Only the tip of the beak should be removed. If therapeutic beak trimming is required in the instance of an outbreak of cannibalism where other methods have failed to deal with the problem, at whatever age,….;"

Justification

Beak trimming should be used only when other methods have failed to deal with cannibalism problems.

Outcome-based measurables: drinking and foraging, feeding, injurious feather pecking and cannibalism, locomotion and comfort behaviours, mortality rate, morbidity rate, performance, plumage condition, vocalisations.

Article 7.Z.22.

Animal health management, preventive medicine and veterinary treatment

Animal handlers responsible for the care of pullets and hens should be aware of the signs of ill-health or distress, such as a change in feed and water intake, reduced production, changes in behaviour, abnormal appearance of feathers, faeces, or other physical features.

EU comment

The EU asks OIE to consider amending as follows:

"*Animal handlers* responsible for the care of pullets and hens should be aware of the signs of ill-health or distress, such as a change in feed and water intake, reduced production, changes in behaviour, abnormal appearance of feathers, faeces incl. faecal structure, or other physical features. Attention should also be paid to other signs of illness, e.g. absence of feather down on the litter.

Justification

Modification of faecal structure could be a sign of intestinal problem.

References

Harlander-Matauschek, A., Piepho, H. P. and Bessei, W. (2006) The Effect of Feather Eating on Feed Passage in Laying Hens. *Poultry Science, 85*(1), pp. 21-25.

If they are not able to identify the causes of disease, ill-health or distress, or to correct these, or if they suspect the presence of a *notifiable disease*, they should seek advice from *veterinarians* or other qualified advisers. Veterinary treatments should be prescribed by a *veterinarian*.

EU comment

The EU asks OIE to consider amending as follows:

"[…] ill-health or distress, ~~or~~ and are not able to correct these […]".

Justification

Clarity as causes of problems should be corrected.

There should be an effective programme for the prevention and treatment of diseases consistent with the programmes established by *Veterinary Services* as appropriate.

Vaccinations and treatments should be administered by personnel skilled in the procedures and with consideration for the welfare of the pullets and hens.

Sick or injured pullets and hens should be placed in a hospital area for observation and treatment or humanely killed in accordance with Chapter 7.6. as soon as possible.

Outcome-based measurables: incidence of diseases, injury rate and severity, metabolic disorders and *infestations*, morbidity rate, mortality rate, performance.

Article 7.Z.23.

Biosecurity

Biosecurity plans should be designed and implemented, commensurate with the best possible bird health status and current disease *risk* (endemic and exotic or transboundary) that is specific to each epidemiological group of pullets and hens and in accordance with relevant recommendations in the *Terrestrial Code*.

These programmes should address the control of the major routes for *infection* and *infestation* such as:

– direct transmission from other *poultry*, domestic *animals* and *wildlife* and humans,

– fomites, such as equipment, facilities and vehicles,

– *vectors* (e.g. arthropods and rodents),

– aerosols,

– water supply,

– feed,

– the practice of partially restocking the house (back filling), due to catastrophe or incomplete *flock* placement, which should only be performed with due consideration to *biosecurity* and in a manner that prevents commingling of *flocks*.

Outcome-based measurables: incidence of diseases, *infestations*, morbidity rate, mortality rate, performance.

Article 7.Z.24.

Humane killing of individual birds or flocks

When individual or groups of birds are killed for diagnostic purposes, depopulation of end-of-lay *flocks* or for purposes of disease control, techniques used should be performed in a humane manner in accordance with Chapter 7.6.

Article 7.Z.25.

Depopulation of pullet and layer facilities

Birds should not be subjected to an excessive period of feed withdrawal prior to the expected depopulation time [Webster, 2003].

Water should be available up to the time of depopulation.

Birds that are not fit for *loading* or transport because they are sick or injured should be humanely killed.

Catching should be carried out by competent *animal handlers* and every attempt should be made to minimise stress, fear reactions and injury. If a bird is injured during catching, it should be humanely killed.

Birds should be handled and placed into the transport *container* according to Article 7.Z.14.

EU comment

The EU suggests OIE checking the above reference to 7.z.14. This draft article does not seem to be related to transport. The reference should probably be with Chapter 7.3.

Justification

Clarity.

Catching should preferably be carried out under dim or blue light to calm the birds.

EU comment

The EU suggests OIE including the following text after the above sentence.

"Ideally pullets and hens should be carried in an upright position, however, where this is not possible they should be carried by both legs, with a maximum of three birds per hand. Distances to modules and crates should be minimised."

Justification

Good practice to prevent pain, injury, suffering and distress.

Catching should be scheduled to minimise the transport time as well as climatic stress during catching, transport and holding.

Stocking density in transport *containers* should comply with Chapters 7.2., 7.3. and 7.4..

Outcome-based measurables: fear behaviour, injury rate and severity, mortality at depopulation and on arrival at the destination, spatial distribution, vocalisation.

Article 7.Z.26.

Emergency plans

Pullet and hen producers should have emergency plans to minimise and mitigate the consequences of natural disasters, disease *outbreaks* and the failure of mechanical equipment. Planning may include the provision of fail-safe alarm devices to detect malfunctions, backup generators, access to maintenance providers, alternative heating or cooling arrangements, ability to store water on farm, access to water cartage services, adequate on-farm storage of feed and alternative feed supply and a plan for managing ventilation emergencies.

EU comments

The EU suggests modifying the above paragraph as follow:

Pullet and hen producers should have emergency plans to minimise and mitigate the consequences of natural disasters, disease *outbreaks* and the failure of mechanical equipment. In environmentally controlled housing, planning ~~may~~ should include the provision of fail-safe alarm devices to detect malfunctions, backup generators, access to maintenance providers and alternative heating or cooling arrangements. In all production systems planning may also include ability to store water on farm, access to water cartage services, adequate on-farm storage of feed and alternative feed supply and a plan for managing ventilation emergencies.

Justification

Clarity.

The emergency plans should be consistent with national programmes established or recommended by *Veterinary Services*. Humane emergency *killing* procedures should be a part of the plan.

Outcome-based measurables: culling, morbidity and mortality rates.

Article 7.Z.27.

EU comment

The EU suggests OIE moving this article on personal competency at the beginning of the chapter as to become Article 7.z.5.

Justification

To be in consistency with the approach of the draft chapter on animal welfare and pig production systems. Training of personnel is indeed important to implement all the recommendations of this draft chapter and should therefore be addressed at the beginning of the document.

Personnel competency

All *animal handlers* responsible for the pullets and hens should have received appropriate training or be able to demonstrate that they are competent to carry out their responsibilities and should have sufficient knowledge of bird behaviour, handling techniques, emergency killing procedures, *biosecurity*, general signs of diseases, and indicators of poor *animal welfare* and procedures for their alleviation.

Outcome-based measurables: fear behaviour, incidence of diseases, locomotion and comfort behaviours, performance, morbidity rate, mortality rate, spatial distribution, vocalisation.

Article 7.Z.28.

Inspection and handling

EU comment

The EU suggests OIE moving this draft article on inspection and handling to the beginning of the chapter as to become Article 7.z.6.

Justification

To be in consistency with the approach of the draft chapter on animal welfare and pig production systems. Inspection and handling is indeed important to implement all the recommendations of this draft chapter and should therefore be addressed at the beginning of the document.

Pullets and hens should be inspected at least daily. Inspection should have three main objectives: to identify sick or injured birds to treat or cull them, to detect and correct any welfare or health problem in the *flock*, and to pick up dead birds.

EU comment

The EU suggests OIE including at the end of the above paragraph the following sentence:

"Records of medical treatment and mortalities found at each inspection should be kept as part of the flock management. Equipment, including feeders and drinkers, ventilation should be checked to ensure they are in good working order."

Justification

Records should be kept of the result of the inspection in order that abnormal fluctuations can be quickly detected. Furthermore, all equipment should be checked routinely to prevent unnecessary suffering, injury or distress.

Inspection should be done in such a way that birds are not unnecessarily disturbed, for example *animal handlers* should move quietly and slowly through the *flock*.

EU comment

The EU suggests OIE replacing "quietly" with "calmly" in the sentence of the above paragraph.

Justification

The flock is calmer when the inspector is talking.

Hemsworth, P. H. (2009) Impact of human-animal interactions on the health, productivity and welfare of farm animals. in Aland, A. and Madec, F., (eds.) Sustainable Animal Production,Wageningen: Wageningen Academic Publishers. pp. 57-68.

When pullets and hens are handled, particularly when birds are placed into or removed from the house, they should not be injured, unnecessarily frightened or stressed (e.g. should be restrained in an upright posture) [Gregory & Wilkins, 1989; Gross & Siegel, 2007; Kannan & Mench, 1996].

Outcome-based measurables: fear behaviour, injury rate and severity, morbidity rate, mortality rate, performance, spatial distribution, vocalisation.

Article 7.Z.29.

Protection from predators

Pullets and hens should be protected from predators in indoor and outdoor areas.

EU comment

The EU suggests OIE including the following text at the end of the above sentence as follow:

"[...] in indoor and outdoor areas whilst preserving their welfare; for example with well-maintained fences and the provision of overhead cover."

Justification

Predator prevention should not use methods that will cause stress or frighten the pullets or hens. It should neither restrict nor reduce their required space (i.e. by restricting access to specific range or litter areas).It is important to include reference to overhead predators, to ensure provision is made to ensure hens feel safe to range.

References

Gilani et al 2013 https://www.ncbi.nlm.nih.gov/pubmed/14584840

Outcome-based measurables: fear behaviour, mortality, injury rate and severity, locomotion and comfort behaviours, performance, spatial distribution, vocalisation.

References

Abrahamsson P. & Tauson R. (1995) Aviary systems and conventional cages for laying hens. Effects on production, egg quality, health and bird location in three hybrids. Acta Agriculturae Scandinavica Section A Animal Science 45:191-203.

Abrahamsson P. & Tauson R. (1997) Effects of group size on performance health and birds' use of facilities in furnished cages for laying hens. Acta Agriculturae Scandinavica, Section A Animal Science 47:254-260.

Appleby, M. C., J. A. Mench, and B. O. Hughes. 2004. Poultry behaviour and welfare Poultry behaviour and welfare. p x + 276 pp.

Barnett, J, Hemsworth, P., Newman, E. (1992). Fear of humans and its relationships with productivity in laying hens at commercial farms. British Poultry Science 33: 699-710. doi: 10.1080/00071669208417510.

Bestman M.W.P. & Wagenaar J.P. (2003) Farm level factors associated with feather pecking in organic laying hens. Livestock Production Science 80:133-140.

Bilcik, B., L.J. Keeling, 1999: Changes in feather condition in relation to feather pecking and aggressive behaviour in laying hens. British Poultry Science 40, 444-451.

Biggs P. E., Persia, M. E. Koelkebeck, K. W. and., Parsons C. M (2004). Further Evaluation of Nonfeed Removal Methods for Molting Programs , Poultry Science 83:745–752.

Blatchford, R. A., Fulton, R. M. & Mench, J. A. (2016). The utilization of the Welfare Quality® assessment for determining laying hen condition across three housing systems. Poultry Science, 95, 154-163. 10.3382/ps/pev227.

Blokhuis, H. J., Van Niekerk, T. F., Bessei, W., Elson, A., Guemene, D., Kjaer, J. B., Levrino, G. a. M., Nicol, C. J., Tauson, R., Weeks, C. A. & De Weerd, H. a. V. (2007). The LayWel project: welfare implications of changes in production systems for laying hens. Worlds Poultry Science Journal, 63, 101-114. Doi 10.1079/Wps2006132.

Bright, A. (2008). Vocalisation and acoustic parameters of flock noise from feather pecking and non-feather pecking laying flocks. Poultry. Sci. 2008, 49, 241–249.

Bright A. & Johnson E.A. (2011) Smothering in commercial free-range laying hens: A preliminary investigation. Veterinary Record 168:512-513

Candland D.K., Nagy Z.M. & Conklyn D.H. (1963) Emotional behaviour in the domestic chicken (White Leghorn) as a function of age and developmental environment. Journal of Comparative and Physiological Psychology 56:1069-1073.

Chloupek, P., Voslarova, E., Chloupek, J., Bedanova, I. Pistekova, V. & Vecerek, V.. (2009); Stress in Broiler Chickens Due to Acute Noise Exposure ACTA VET. BRNO 2009, 78: 93–98.

Cooper, J. J. & Appleby, M. C. (1996). Individual variation in prelaying behaviour and the incidence of floor eggs. British Poultry Science, 37, 245-253.

Cornetto, T. L., Estevez, I. (2001). Behavior of the domestic fowl in presence of vertical panels. Poultry Science, 80:1455-1462.

Cronin, G.M., Barnett, J.L. and Hemsworth, P.H. (2012). The importance of pre-laying behaviour and nest boxes for laying hen welfare: a review. Animal Production Science 52: 398-405.

Craig J.V. & Muir W.M. (1996) Group selection for adaptation to multiple-hen cages: beak-related mortality, feathering, and body weight responses. Poultry Science 75:294-302.

Drake, K. A., Donnelly, C. A. and Dawkins, M. S. (2010), 'Influence of rearing and lay risk factors on propensity for feather damage in laying hens', Brit. Poultry Sci., 51, 725-733.

Annex 28 (contd)

Dawkins, M. S. and Hardie, H. (2007). Space needs of laying hens Pages 413-416 | Published online: 08 Nov 2007. http://dx.doi.org/10.1080/00071668908417163.

David, B., Mejdell, C., Michel, V., Lund, V. & Moe, R. O. (2015). Air Quality in Alternative Housing Systems may have an Impact on Laying Hen Welfare. Part II-Ammonia. Animals : an open access journal from MDPI, 5, 886-96. 10.3390/ani5030389.

Estevez, I., Andersen, I. L., Nævdal E. (2007). Group size, density and social dynamics in farm animals. Applied Animal Behaviour Science, 103:185-204.

Estevez, I., (2015). Análisis multifactorial del picaje en avicultura. LII Simposio Científico de Avicultura, Málaga, Spain, October 28-30, pp 67-80.

Estevez, I., Newberry, R. C., Keeling, L. J. (2002). Dynamics of aggression in the domestic fowl. Applied Animal Behaviour Science, 76:307-325.

EFSA (2005) The welfare aspects of various systems of keeping laying hens. Report of the Scientific Panel on Animal Health and Welfare. EFSA Journal 197, 1–23. 197.

EFSA, (2015) Scientific Opinion on welfare aspects of the use of perches for laying hens. Panel on Animal Health and Welfare. EFSA Journal: EFSA Journal 2015;13(6):4131 [71 pp.]. doi: 10.2903/j.efsa.2015.4131.

Elson H.A. & Croxall R. (2006) European study on the comparative welfare of laying hens in cage and non-cage systems. Archiv für Geflügelkund 70:194-198.

Freire R., Eastwiir M.A. & Joyce M. (2011) Minor beak trimming in chickens leads to loss of mechanoreception and magnetoreception. Journal of Animal Science 89:1201-1206.

Freire R., Glatz P.C., Hinch G. (2008) Self-administration of an analgesic does not alleviate pain in beak trimmed chickens. Asian-Australasian Journal of Animal Sciences 21:443-448

Forkman B, Boissy, A, Meunier-Salaun M.-C., Canali, E., Jones RB. (2007). A critical review of fear tests used on cattle, pigs, sheep, poultry and horses. Physiology and Behaviour 92: 340-374.

Garner J.P., Kiess A.S., Mench J.A., Newberry R.C. & Hester P.Y. (2012) The effect of cage and house design on egg production and egg weight of White Leghorn hens: an epidemiological study. Poultry Science 91:1522-1535.

Gentle M.J., Hunter L.N. & Waddington D. (1991) The onset of pain related behaviours following partial beak amputation in the chicken. Neuroscience Letters 128:113-116.

Gentle M.J., Hughes B.O., Fox A. & Waddington D. (1997) Behavioural and anatomical consequences of two beak trimming methods in 1- and 10-day-old chicks. British Poultry Science 38:453-463.

Glatz P.C., Lunam C.A., Barnett J.L. & Jongman E.C. (1998) Prevent chronic pain developing in layers subject tobeak-trimming and re-trimming. A report to Rural Industries Research and Development Corporation.

Gilani A.M., Knowles T.G., Nicol, C.J., 2014. Factors affecting ranging behaviour in young and adult laying hens. British Poultry Science 55:127-135.

Green, L.E., Lewis, K., Kimpton A. and Nicol, C.N. (2000). Cross-sectional study of the prevalence of feather pecking in laying hens in alternative systems and its associations with management and disease. Veterinary Record, 147:233-238.

Gregory, N. G. & Robins J. K. (1998) A body condition scoring system for layer hens, New Zealand Journal of Agricultural Research, 41:4, 555-559, DOI: 10.1080/00288233.1998.9513338.

Gregory NG, Wilkins LJ, 1989. Broken bones in domestic fowls handling and processing damage in end of lay battery hens. Br. Poult. Sci. 30:555-562.

Gross WB, Siegel PB, 2007. General principles of stress and welfare. In: Livestock Handling and Transport, T. Grandin (Editor), CAB International, Wallingford, UK, p. 19-29.

Gunnarsson, S., Keeling, L. J. & Svedberg, J. (1999). Effect of rearing factors on the prevalence of floor eggs, cloacal cannibalism and feather pecking in commercial flocks of loose housed laying hens. British Poultry Science, 40, 12-18. Doi 10.1080/00071669987773.

Hartcher K, Wilkinson S, Hemsworth P, Cronin G (2016). Severe feather-pecking in non-cage laying hens and some associated and predisposing factors: a review. World's Poultry Science Journal 72: 103-114. doi: 10.1017/S0043933915002469.

Hester P. (2014). The effect of perches installed in cages on laying hens. World's Poultry Science Journal 2014, 70(2): 27-264.

Huber-Eicher, B. & Wechsler, B. (1998) The effect of quality and availability of foraging matewrials on feather pecking in laying hens. Animal Behaviour 55: 861-873.

Janczak, A. M. & Riber, A. B. (2015). Review of rearing-related factors affecting the welfare of laying hens. Poultry Science, 94, 1454-1469. 10.3382/ps/pev123.

Jenkins, R.L., Ivey, W.D., Mcdaniel, G.R. & Albert, R.A. (1979). A darkness induced eye abnormality in the domestic chicken. Poultry Science, 58: 55–59.

Jones R.B. (1996). Fear and adaptability in poultry: insights, implications and imperatives. Worlds Poult Sci J;52:131–74.

Kannan G, Mench JA, 1996. Influence of different handling methods and crating periods on plasma corticosterone concentrations in broilers. Br. Poult. Sci. 37:21-31.

Keeling L.J., Estevez I., Newberry R.C. & Correia M.G. (2003) Production-related traits of layers reared in different sized flocks: The concept of problematic intermediate group size. Poultry Science 82:1393-1396.

Kjaer J.B. & Hocking P.M. (2004) The genetics of feather pecking and cannibalism. In Perry, G.C. (ed.), Welfare of the Laying Hen (pp. 109-121). Wallingford, UK: CABI.

Koshiba, M., Shirakawa, Y., Mimura, K., Senoo, A., Karino, G., Nakamura, S. (2913) Familiarity perception call elicited under restricted sensory cues in peer-social interactions of the domestic chick. PLoS ONE 8: e58847. doi: 10.1371/journal.pone.0058847.

Lara, L., Rostagno, M. (2013). Impact of Heat Stress on Poultry Production. Animals 2013, 3, 356-369.

Lambton, S.L., Knowles, T.G., Yorke, C. and Nicol, C.J. (2010) The risk factors affecting the development of gentle and sever feather pecking in loose housed laying hens. Applied Animal Behaviour Science 123: 32-42.

Lambton, S. L., Nicol, C. J., Friel, M., Main, D. C. J., Mckinstry, J. L., Sherwin, C. M., Walton, J. & Weeks, C. A. (2013). A bespoke management package can reduce levels of injurious pecking in loose-housed laying hen flocks. Veterinary Record, 172, 423-+. Doi 10.1136/Vr.101067.

Lay, D. C., Fulton, R. M., Hester, P. Y., Karcher, D. M., Kjaer, J. B., Mench, J. A., Mullens, B. A., Newberry, R. C., Nicol, C. J., O'sullivan, N. P. & Porter, R. E. (2011). Hen welfare in different housing systems. Poultry Science, 90, 278-294. DOI 10.3382/ps.2010-00962.

Lentfer, T. L., S. G. Gebhardt-Henrich, E. K. F. Frohlich, and E. von Borell. 2011. Influence of nest site on the behaviour of laying hens. Appl Anim Behav Sci 135: 70-77.

Lewis P.D. & Gous R.M. (2009) Photoperiodic responses of broilers. II. Ocular development, British Poultry Science, 50:6, 667-672.

Mack, L.A.; Felver-Gant, J.N.; Dennis, R.L.; Cheng, H.W. (2013) Genetic variation alter production and behavioral responses following heat stress in 2 strains of laying hens. Poult. Sci., 92, 285–294.

Malleau A.E., Duncan I.J.H. & Widowski T.W. (2007). The importance of rest in young domestic fowl. Applied Animal Behaviour Science 106:52-69.

Annex 28 (contd)

McKeegan D.E.F. & Philbey A.W. (2012) Chronic neurophysiological and anatomical changes associated with infra-red beak treatment and their implications for laying hen welfare. Animal Welfare 21:207-217.

Marchant-Forde R.M., Fahey M.A.G. & Cheng H.W. (2008) Comparative effects of infrared and one-third hot-blade trimming on beak topography, behavior, and growth. Poultry Science 87:1474-1483.

Marchant-Forde, R.M. & Cheng H.W. (2010) Different effects of infrared and one-half hot blade beak trimming on beak topography and growth. Poultry Science 89:2559-2564.

Miles, D.M.; Miller, W.W.; Branton, S.L.; Maslin, W.R.; Lott, B.D. (2006) Ocular responses to ammonia in broiler chickens. Avian Dis., 50, 45–49.

Mejdell, C., David, B., Moe, R. O., Michel, V., Lund, V. & Mejdell, C. 2015. Air Quality in Alternative Housing Systems May Have an Impact on Laying Hen Welfare. Part I-Dust. Animals : an open access journal from MDPI, 5, 495-511. 10.3390/ani5030368.

Morris H.M. (2009) Effects of Early Rearing Environment on Learning Ability and Behavior in Laying Hens. M.Sc. Thesis. Corvallis, Oregon: Oregon State University.

Nicol, C.J. (2015) The behavioural biology of chickens - Wallingford, Oxfordshire, UK ; Boston, MA : CABI, c2015. - vii, 192 p. : ill. ISBN:9781780642505 1780642504

Nicol, C.J., Bestman, M., Gilani, A-M., De Haas, E.N., De Jong, I.C., Lambton, S., Wagenaar, J.P., Weeks, C.A. and Rodenburg, T.B. (2013). The prevention and control of feather pecking in laying hens: application to commercial systems. World Poultry Science Journal 69: 775-787.

Olanrewaju, H.A.; Miller, W.W.; Maslin, W.R.; Thaxton, J.P.; Dozier, W.A., 3rd; Purswell, J.;Branton, S.L. (2007). Interactive effects of ammonia and light intensity on ocular, fear and leg health in broiler chickens. Int. J. Poult. Sci., 6, 762–769.

Olsson, I.A.S. and Keeling, L.J. (2005) Why in earth? Dustbathing behaviour in jungle and domestic fowl reviewed from a Tinbergian and animal welfare perspective. Applied Animal Behaviour Science 93: 259-282.

Petek M. & Alpay F. (2008) Utilization of grain barley and alfalfa meal as alternative moult induction programmes for laying hens: body weight losses and egg production traits , Bulgarian Journal of Veterinary Medicine, 11, No *4: 243−249.*

Prescott N.B., Wathes C.M. & Jarvis, J.R. (2003) Light, vision and the welfare of poultry. Animal Welfare 12:269-288.

Prescott N.B. & Wathes C.M. (1999) Spectral sensitivity of the domestic fowl (Gallus g. domesticus). British Poultry Science 40:332-339.

Rodenburg, T.B., Van Krimpen, M.M., De Jong, I.C., De Haas, E.N. Kops,M.S., Riedstra, B.J. Nordquist, R.E., Wagenaar, J.P. Bestman, M., Nicol, C.J. (2013). The prevention and control of feather pecking in laying hens: identifying the underlying principles. World Poultry Science Journal 69: 361-374.

Rodríguez-Aurrekoetxea, A., Estevez, I. (2014). Aggressiveness in the domestic fowl: Distance versus ´attitude´. Applied Animal Behaviour Science, 153:68–74

Rodríguez-Aurrekoetxea, A., Estevez, I. (2016). Use of space and its impact on the welfare of laying hens in a commercial free-range system. Poultry Science, 95:2503-2513 http://dx.doi.org/10.3382/ps/pew238.

Saiozkan SI, Kara KII and Guclu BK (2016) Applicability of Non-Feed Removal Programs to Induce Molting Instead of the Conventional Feed Withdrawal Method in Brown Laying Hens, Brazilian Journal of Poultry Science 18, No3:535-54.

Tauson, R. and Abrahamson, P. (1996): Foot and keel bone disorders in laying hens Effects of artificial perch material and hybrid. Acta Agric. Scand. Sect. A 46: 239-246.

Thogerson C.M., Hester P.Y., Mench J.A., Newberry R.C., Pajor E.A. & J.P. Garner (2009a) The effect of feeder space allocation on behaviour of Hy-line W-36 hens housed in conventional cages. Poultry Science 88:1544-1552.

Thogerson C.M., Hester P.Y., Mench J.A., Newberry R.C., Okura C.M., Pajor E.A., Talaty P.N. & Garner J.P. (2009b) The effect of feeder space allocation on productivity and physiology of Hy-Line W-36 hens housed in conventional cages. Poultry Science 88:1793-1799.

Van Liere & Bokma, (1987).Dust bathing is a maintenance behaviour that contributes to feather condition by fluffing up the downy feathers and removing stale lipids prior to replacement with fresh lipids through oiling behaviour.

Van Liere D.W. & Bokma S. (1987) Short-term feather maintenance as a function of dustbathing in laying hens. Applied Animal Behaviour Science 18:197-204.

Webster, A. B. (2003). Physiology and behavior of the hen during induced molt. Poult. Sci. 82:992–1002.

Weeks C.A. & Nicol C.J. (2006) Behavioural needs, priorities and preferences of laying hens. World's Poultry Science Journal 62:296-307.

Widowski T, Hemsworth P, Barnett J, Rault J-L (2016). Laying hen welfare I. Social environment and space. World's Poultry Science Journal 72: 333-342. doi: 10.1017/S0043933916000027.

Yahav, S. (2009). Alleviating heat stress in domestic fowl: different strategies. Worlds Poultry Science Journal 65:719-732.

Zeltner, E. and Hirt, H. (2008), ´A note on fear reaction of three different genetic strains of laying hens to a simulated hawk attack in the hen run of a free-range system, Appl. Anim. Behav. Sci., 113, 69-73.

Zimmerman, P.H.; Koene, P.; Van Hooff, J.A. (2000). The vocal expression of feeding motivation and frustration in the domestic layinh hens *Gallus gallus domesticus*. Appl. Anim. Behav. Sci. 2000, 69, 265–273.

Zimmerman, P. H., A. C. Lindberg, S. J. Pope, E. Glen, J. E. Bolhuis, and C. J. Nicol. 2006. The effect of stocking density, flock size and modified management on laying hen behaviour and welfare in a non-cage system. Appl. Anim. Behav. Sci. 101(1–2):111-124.

Annex 29

CHAPTER 8.X.

INFECTION WITH *TRYPANOSOMA EVANSI* (NON EQUINE SURRA)

EU comment

The EU cannot at this stage support this draft new chapter.

Indeed, the EU queries whether equids and other species should really be excluded from this chapter. Indeed, as this is a vector borne disease, and it will be difficult to ensure that the vectors are 100% species specific, it is unclear whether the disease status of a country can really be differentiated by animal species, as was done e.g. in the brucellosis chapter.

Specific comments are inserted in the text below.

Article 8.X.1

General provisions

A wide range of mammals are susceptible to *infection* with *Trypanosoma evansi (T. evansi)*.

For the purposes of this chapter, 'susceptible animals' means camelids, carnivores, animals of the family Bovidae, pigs, cervids, elephants, lagomorphs, rodents and vampire bats.

For the purposes of the *Terrestrial Code, infection* with *T. evansi* is defined as an *infection* of susceptible animals with *T. evansi*.

Infection of equids with the subgenus *Trypanozoon*, including *T. evansi*, is covered by Chapter 12.3.

EU comment

The paragraphs above are confusing. Indeed, merely stating that infection of equids is covered by another chapter does not seem to ensure that equids are excluded from this chapter. Furthermore, while infection is defined for the purposes of the Code (and would need to include equids), susceptible animals is defined for the purposes of this chapter, yet does not include equids.

Mostly mechanically transmitted by biting insects and vampire bats, *T. evansi* may also be transmitted iatrogenically, by contact with mucosal membranes, or by transplacental transmission.

T. evansi can survive for up to 72 hours in *Stomoxys* flies and for up to six hours in tabanids.

The following defines the occurrence of *infection* with *T. evansi*:

1) *T. evansi* has been identified in a sample from a susceptible animal;

OR

2) antibodies to *T. evansi* have been detected in a sample from a susceptible animal showing clinical signs consistent with *infection* with *T. evansi* or epidemiologically linked to a confirmed *case* of *infection* with *T. evansi* in susceptible animals or in equids.

For the purposes of the *Terrestrial Code*, the *incubation period* of *infection* with *T. evansi* shall be six months.

EU comment

The EU queries the background to the proposed incubation period above. Indeed, the OIE technical disease card suggests the incubation period of *T. evansi* in equids and camels is 5-60 days, while the proposed incubation period in this chapter is six months.

(http://www.oie.int/fileadmin/Home/eng/Animal_Health_in_the_World/docs/pdf/Disease_cards/TRYPANO_EVANSI.pdf)

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 *T. evansi* related conditions regardless of the *T. evansi infection* status of the *exporting country*:

1) pasteurised *milk* and *milk products*;

2) hair, wool and fibre;

3) gelatine;

4) horns, hooves and claws;

5) *meat* from susceptible animals that have undergone ante- and post-mortem inspections as described in Chapter 6.2. with favourable results, and *meat products* thereof;

6) hides and skins having undergone standard processing.

EU comment

It is not clear what is meant by "having undergone standard processing" in the indent above. It would be helpful to rather say "Processed hides and skins" and to define that term somewhere in the Code.

Article 8.X.3.

Country or zone free from infection with T. evansi in one or more susceptible animal species

1) A country or *zone* can be considered free from *infection* with *T. evansi* in one or more susceptible animal species if:

a) *infection* with *T. evansi* is a *notifiable disease* in the entire country;

b) a *surveillance* programme is in place in the country or *zone* to detect *infection* with *T. evansi* in accordance with Chapter 1.4.;

c) the relevant conditions of Article 1.4.6. are complied with for the relevant susceptible animal species;

d) no *case* of *infection* with *T. evansi* has occurred in the relevant susceptible animal species for at least two years in the country or *zone*;

e) imported susceptible animals and equids and their *commodities*, except those listed in Articles 8.X.2. and 12.3.2., comply with the requirements in Articles 8.X.5. to 8.X.7. and Articles 12.3.5. to 12.3.8., respectively.

2) A free country or *zone* neighbouring an infected one should conduct adequate *surveillance* in an area of appropriate distance from that country or *zone*.

Article 8.X.4.

Recovery of free status

When an *outbreak* of *infection* with *T. evansi* occurs in a previously free country or *zone*, the country or *zone* may recover its free status once it has implemented *a stamping-out policy* with or without treatment and conditions of Article 8.X.3. are complied with for the relevant susceptible animal species.

EU comment

For clarity reasons, the EU suggests explicitly stating in the article above that recovery of free status would only be possible two years after the stamping-out policy is completed, and that during that time period no cases have occurred.

Alternatively, reference could simply be made to Article 8.X.3.

Article 8.X.5.

Recommendations for importation of susceptible animals

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

1) showed no clinical sign of *infection* with *T. evansi* on the day of shipment;

2) have been kept:

a) since birth or for at least six months prior to shipment in a country or a *zone* free from *infection* with *T. evansi* in all susceptible animals and equids;

OR

b) since birth, or for at least six months prior to shipment in a country or a *zone* free from *infection* with *T. evansi* in the relevant susceptible animal species, were isolated in an *establishment* where no *case* of *infection* with *T. evansi* has occurred in any susceptible animal species or any equid for at least 30 days prior to shipment, were protected from *vectors* during that period and during transportation to the *place of shipment* and were subjected to a test for *T. evansi* within 10 days prior to shipment with negative results;

OR

c) in a country or *zone* not free from *infection* with *T. evansi* in the relevant susceptible animal species, were isolated and protected from *vectors* for at least 30 days prior to shipment and during transportation to the *place of shipment,* and were tested twice with negative results, during that period on samples taken at an interval of 21 to 30 days, with the second sample taken not more than 10 days before shipment.

Article 8.X.6.

Recommendations for importation of camelids, animals of family Bovidae and pigs from an infected country or zone for immediate slaughter

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

1) the animals showed no clinical sign of *infection* with *T. evansi* on the day of the shipment;

2) the animals are permanently identified and transported under the supervision of the *Veterinary Services* in a *vector*-protected *vehicle,* which underwent *disinfection* and disinsection before loading, directly from the *establishment* of origin to the *approved slaughterhouse/abattoir* without coming into contact with other susceptible animals or equids.

Article 8.X.7.

Recommendations for importation of semen of susceptible animals

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

1) the donor males of the relevant susceptible animal species showed no clinical sign of *infection* with *T. evansi* on the day of entry into an *approved* semen collection facility;

2) the donor males of the relevant susceptible animal species have been kept:

a) since birth or for at least six months prior to entry into an *approved* semen collection facility in a country or a *zone* free from *infection* with *T. evansi* in all susceptible animal species, and free from *infection* with *Trypanozoon* in equids;

OR

b) since birth or for at least six months prior to entry into the *approved* semen collection facility in a country or a *zone* free from *infection* with *T. evansi* in the relevant susceptible animal species and were tested for *T. evansi* with negative results within 30 days of entry into the *approved* semen collection facility;

OR

c) in a country or *zone* not free from *infection* with *T. evansi* in the relevant susceptible animal species and:

i) were isolated and protected from *vectors* for at least 30 days in an *establishment* in which no *case* of *infection* with *T. evansi* has occurred for at least the past six months prior to entry into an *approved* semen collection facility;

ii) were tested twice during that period on samples taken with an interval of 21 to 30 days with the second sample taken not more than 10 days prior to entry into the *approved* semen collection facility, with negative results;

iii) were protected from *vectors* at all times while in the *approved* semen collection facility;

3) the semen was collected, processed and stored in accordance with the relevant conditions of Chapters 4.5. and 4.6.

EU comment

Given the incubation period of *T. evansi* in equids and camels is up to 60 days according to the OIE technical disease card, the EU queries whether the 30 day time period in the article above is appropriate. Indeed, testing of donor males seems too early at 30 days against that background.

Annex 30

CHAPTER 12.3.

INFECTION WITH *TRYPANOZOON* IN EQUIDS (DOURINE, EQUINE SURRA)

EU comment

The EU in cannot at this stage support the proposed changes to this chapter.

Indeed, we have some concerns on whether there is enough supporting data for the changes proposed, and – as explained below – whether dourine and equine surra should be included in one single chapter.

Currently, it is not possible to differentiate *Trypanosoma equiperdum* and *T. evansi*, not even at the molecular level. Both parasites use different spectra of intermediate hosts and are transmitted by different routes, i.e. via insects in the case of *T. evansi* and venereal in the case of *T. equiperdum*. Consequently it is impossible to provide the same meaningful recommendations regarding recovery of free status, importation of horses and semen for these very different parasitic infections.

Specific comments are inserted in the text below.

Article 12.3.1.

General provisions

In terms of genetic differentiation, clinical manifestations and diagnostics, it is not possible to differentiate surra (caused by *Trypanosoma evansi*) and dourine (caused by *Trypanosoma equiperdum*) in equids. In addition, *infection* with *Trypanosoma brucei* in equids can cause a disease indistinguishable from the latter two.

For the purposes of the *Terrestrial Code infection* with *Trypanozoon* in equids (dourine, equine surra) is defined as an *infection* of equids with a trypanosome that belongs to the subgenus *Trypanozoon*, either *Trypanosoma evansi, Trypanosoma equiperdum* or *Trypanosoma brucei.*

EU comment

Please insert a comma after "Terrestrial Code" in the paragraph above (typographical).

Infection with *T. evansi* in species other than equids is covered by Chapter 8.X.

Transmission can be vectorial, either mechanical or biological (for *T. brucei*), iatrogenic, venereal, or by contact with mucosal membranes.

The following defines the occurrence of *infection* with *Trypanozoon*:

EU comment

For clarity reasons, please insert the words "in equids" after "*Trypanozoon*" above. Indeed, the 2nd paragraph of this article defines "infection with *Trypanozoon* in equids" for the purposes of the entire Code.

1) the agent has been identified in a sample from an equid;

OR

2) antibodies have been detected in a sample from an equid showing clinical signs consistent with *infection* with *Trypanozoon* or which has an epidemiological link to a confirmed *case* of *infection* with *Trypanozoon* in any animal species.

For the purposes of the *Terrestrial Code,* the *incubation period* of *infection* with *Trypanozoon* in equids shall be 30 days.

EU comment

The EU queries the background to the proposed incubation period above. Indeed, the OIE technical disease card suggests the incubation period of *T. evansi* in equids is 5-60 days, while the proposed incubation period in this chapter is 30 days.

(http://www.oie.int/fileadmin/Home/eng/Animal_Health_in_the_World/docs/pdf/Disease_cards/TRYPANO_EVANSI.pdf)

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

Article 12.3.2.

Safe commodities

When authorising import or transit of the following equine *commodities*, *Veterinary Authorities* should not require *Trypanozoon*-related conditions regardless of the *Trypanozoon infection* status of the *exporting country*:

1) pasteurised *milk* and *milk products*;

2) hair;

3) gelatine;

4) hooves;

5) *meat* from animals that have undergone ante-and post-mortem inspections as described in Chapter 6.2. with favourable results, and *meat products* thereof;

6) hides and skins having undergone standard processing.

EU comment

It is not clear what is meant by "having undergone standard processing" in the indent above. It would be helpful to rather say "Processed hides and skins" and to define that term somewhere in the Code.

Article 12.3.3.

Country or zone free from infection with *Trypanozoon* in equids

A country or *zone* can be considered free from *infection* with *Trypanozoon* in equids if:

1) *infection* with *Trypanozoon* in equids is a *notifiable disease* in the entire country;

2) a *surveillance* programme is in place in the country or *zone* to detect *infection* with *T. evansi* in equids in accordance with Chapter 1.4.;

EU comment

The EU queries why *T. equiperdum* and *T. brucei* are not included in the surveillance programme. This would indeed be relevant for country and zone status.

3) the relevant conditions of Article 1.4.6. are complied with;

4) no *case* of *infection* with *Trypanozoon* in equids has occurred for at least two years in the country or *zone*;

EU comment

Point 4 above will be difficult to demonstrate, i.e. no case of infection for the past two years. Indeed, as the disease is mainly subclinical, we query whether notification of infection with *Trypanozoon* is necessary, and whether it should be "clinical disease should not be reported in the last two years".

5) imported equids and equine *commodities*, except those listed in Article 12.3.2, comply with the requirements in Articles 12.3.5. to 12.3.8.

A free country or *zone* neighbouring an infected one should conduct adequate *surveillance* in an area of appropriate distance from that country or *zone*.

Article 12.3.4.

Recovery of free status

When an *outbreak* of *infection* with *Trypanozoon* occurs in a previously free country or *zone,* the country or *zone* may recover its free status once the following conditions are fulfilled:

1) appropriate *biosecurity* is in place, in particular *vector* protection, breeding restrictions (natural or artificial), and movement restrictions have been imposed on equids in the affected and epidemiologically linked *establishments*;

2) all equids in these *establishments* have been tested for *infection* with *Trypanozoon*;

3) a *stamping-out policy* has been applied, which includes the *slaughter* or *killing* of at least all *cases;*

4) the remaining equids in the *establishments* have not been moved out of the *establishments*, unless for immediate *slaughter*, until all equids in the affected *establishments* have been tested with negative results to agent identification and serological tests on two samples taken at an interval of three to four weeks, the first sample being taken not less than 30 days after the last serologically positive animal has been slaughtered or killed;

5) a *specific surveillance* has been carried out in the six months after measures described in points 1 to 4 have been completed and no *case* of *infection* with *Trypanozoon* in equids has been detected.

When the above conditions cannot be complied with, Article 12.3.3. applies.

EU comment

The article above, especially points 1 and 4, clearly show that it is difficult and probably not appropriate to cover both equine surra and dourine together as regards recovery of country freedom (and more generally in this chapter). Indeed, the epidemiology of these two diseases is very different, i.e. dourine is a venereal disease not transmitted by vectors, whereas surra is a vector borne disease. Thus, depending on which disease has occurred in a previously free country, the control measures and requirements for regaining freedom should be adapted accordingly. For example, in case of dourine, it will not be necessary nor justifiable to take measures against geldings present in affected establishments, leading to difficulties with compliance and thus with regaining of status.

Article 12.3.5.

Recommendations for importation of equids

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

1) showed no clinical sign of *infection* with *Trypanozoon* on the day of shipment;

2) have been kept:

a) since birth or for at least 30 days prior to shipment, in a country or *zone* free from *infection* with *Trypanozoon* in equids and free from *infection* with *T. evansi* in all other species in accordance with Chapter 8.X.;

OR

b) since birth or for at least 30 days prior to shipment, in a country or *zone* free from *infection* with *Trypanozoon* in equids but not free from *infection* with *T. evansi* in all other species according to Chapter 8.X., have been kept for at least 30 days prior to shipment in *establishments* where no *case* of *infection* with *T. evansi* has occurred in any species during that period, were protected from *vectors* during that period and during transportation to the *place of shipment,* and were subjected to a test for *Trypanozoon*, with negative results, within 10 days prior to shipment;

OR

c) in a country or *zone* not free from *infection* with *Trypanozoon* in equids, were isolated and protected from *vectors* for at least 30 days prior to shipment and during transportation to the *place of shipment,* and during that period were tested twice for *Trypanozoon*, with negative results, on samples taken at an interval of 21 to 30 days, the second sample being taken not more than 10 days prior to shipment.

EU comment

Given the incubation period of *T. evansi* in equids is up to 60 days according to the OIE technical disease card, the EU queries whether the 30 day time period in the article above is appropriate.

Article 12.3.6.

Recommendations for the temporary importation of horses for competition purposes

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

1) showed no clinical sign of *infection* with *Trypanozoon* on the day of the shipment;

2) have been kept:

a) since birth, or for at least 30 days prior to shipment in a country or a *zone* free from *infection* with *Trypanozoon* in equids and free from *infection* with *T. evansi* in all other species in accordance with Chapter 8.X.;

OR

b) in a country or a *zone* not free from *infection* with *Trypanozoon* in equids or not free from *infection* with *T. evansi* in all other species according to Chapter 8.X., have been kept for at least 30 days prior to shipment in *establishments* where no *case* of *infection* with *Trypanozoon* has occurred in any species during that period, were protected from *vectors* during that period and during transportation to the *place of shipment*, and were tested for *Trypanozoon* with negative results during the 10 days prior to shipment.

Article 12.3.7.

Recommendations for importation of equids from a country or zone not free from infection with *Trypanozoon* in equids for immediate slaughter

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

1) the animals showed no clinical sign of *infection* with *Trypanozoon* on the day of the shipment;

2) the animals are permanently identified and transported, under the supervision of the *Veterinary Services,* in a *vector*-protected *vehicle*, which underwent *disinfection* and disinsection before loading, directly from the *establishment* of origin to the *place of shipment* without coming into contact with other susceptible species listed in Chapter 8.X.

Article 12.3.8.

Recommendations for importation of semen

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

1) the donor males showed no clinical sign of *infection* with *Trypanozoon* on the day of entry into an *approved* semen collection facility;

2) the donor males:

a) have been kept for at least six months prior to entry into an *approved* semen collection facility in a country or a *zone* free from *infection* with *Trypanozoon* in equids and free from *infection* with *T. evansi* in all other species in accordance with Chapter 8.X.;

OR

b) have been kept for at least six months prior to entry into an *approved* semen collection facility in a country or a *zone* free from *infection* with *Trypanozoon* in equids but not free from *infection* with *T. evansi* in all other species in accordance with Chapter 8.X. and were tested for *Trypanozoon* with negative results, within 30 days of entry into the *approved* semen collection facility;

OR

c) have been kept in a country or a *zone* not free from *infection* with *Trypanozoon* in equids and:

i) were isolated and protected from *vectors* for at least 30 days in an *establishment* in which no *case* of *infection* with *Trypanozoon* has occurred for at least the past six months prior to entry into an *approved* semen collection facility;

ii) were tested twice with negative results during that period on samples taken at an interval of 21 to 30 days, the second sample being taken not more than 10 days prior to entry into the *approved* semen collection facility;

iii) were protected from *vectors* at all times while in the *approved* semen collection facility;

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

EU comment

It is not clear why a residency period of 6 months should be required for stallions in the above article. Indeed, taking into account the incubation period of 30 days as proposed in this draft chapter, or up to 60 days as stated in the OIE technical disease card, this seems excessive, even in case the stallion is not further tested (as foreseen by point 2 a). For example, Articles 12.3.5. and 12.3.6. foresee a residency period of only 30 days, which would equal the proposed incubation period.

Annex 31

CHAPTER 11.12.

INFECTION WITH *THEILERIA ANNULATA, T. ORIENTALIS* AND *T. PARVA*

EU comment

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

As regards the numbering of this chapter, the EU queries why 11.12. is proposed. Indeed, in the 2017 edition of the Code, the current chapter entitled "Theileriosis" is numbered Chapter 11.10.

Article 11.12.1.

General provisions

Animal susceptible to *infection* with *Theileria* are bovines (*Bos indicus*, *B. taurus* and *B. grunniens*), water buffaloes *(Bubalus bubalis)*, African buffaloes *(Syncerus caffer)*, sheep *(Ovis aries)*, goats *(Capra hircus),* camels (*Camel dromedarius* and *C. bactrianus)* and some *wild* ruminants.

EU comment

Please replace the word "Animal" with "Animals" in the paragraph above (typographical error).

Infection with *Theileria* can give rise to disease of variable severity and to *Theileria* transmission. *Theileria* may persist in ruminants for their lifetime. Such animals are considered carriers.

For the purposes of the *Terrestrial Code*, *infection* with *Theileria annulata*, *T. orientalis* and *T. parva* are defined as a tickborne *infection* of bovines and water buffaloes with *T. annulata, T. orientalis* Ikeda, *T. orientalis* Chitose and *T. parva*.

For the purposes of this chapter, *Theileria* means *T. annulata, T. orientalis* Ikeda, *T. orientalis* Chitose and *T. parva.*

The following defines the occurrence of *infection* with *Theileria*:

1) *Theileria* has been identified in a sample from a bovine or water buffalo; or

2) antigen or nucleic acid specific to *Theileria* has been identified in a sample from a bovine or water buffalo showing clinical signs consistent with *infection* with *Theileria*, or epidemiologically linked to a suspected or confirmed *case*, or giving cause for suspicion of previous association with *Theileria*; or

3) antibodies specific to *Theileria* have been detected in a sample from a bovine or water buffalo that either shows clinical signs consistent with *infection* with *Theileria*, or is epidemiologically linked to a suspected or confirmed *case* or giving cause for suspicion of previous association with *Theileria*.

For the purposes of the *Terrestrial Code*, the *incubation period* for *infection* with *Theileria* shall be 35 days.

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

Article 11.12.2.

Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any *Theileria* related conditions regardless of the *Theileria infection* status of the animal population of the *exporting country*:

1) *meat* and *meat products*;

2) *casings*;

3) *milk* and *milk products*;

4) gelatine and collagen;

5) tallow;

6) semen and embryos;

7) hooves and horns;

8) bones.

Article 11.12.3.

Country or zone free from infection with *Theileria*

1) A country or a *zone* may be considered free from *infection* with *Theileria* when the disease is notifiable in the entire country, importation of bovines and water buffaloes and their *commodities* is carried out in accordance with this chapter, and:

   a) the country or *zone* is historically free as described in Article 1.4.6.; or

   b) a *surveillance* programme in accordance with Chapter 1.4. has demonstrated no evidence of *infection* with *Theileria* in the country or *zone* for at least two years; or

   c) an ongoing *surveillance* programme in accordance with Chapter 1.5. has found no tick *vectors* for at least two years in the country or *zone*.

EU comment

The EU queries whether any and all ticks are to be targeted by the surveillance programme, i.e. are they all competent in transmitting the pathogenic agent. Indeed, it will be difficult to demonstrate total absence of ticks in a country or zone for a period of two years.

2) A country or *zone* free from *infection* with *Theileria* in which ongoing *vector surveillance*, performed in accordance with Chapter 1.5., has found no tick *vectors* will not lose its free status through the introduction of vaccinated, test-positive or infected bovines or water buffaloes from infected countries or *zones*.

3) A country or *zone* free from *infection* with *Theileria* will not lose its status as a result of introduction of seropositive or vaccinated bovines, water buffaloes or their *commodities*, provided they were introduced in accordance with this chapter.

Article 11.12.4.

Recommendations for importation from countries or zones free from infection with *Theileria*

For bovines and water buffaloes

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

1) showed no clinical sign of *infection* with *Theileria* on the day of shipment;

2) come from a country or *zone* free from *infection* with *Theileria*.

Article 11.12.5.

Recommendations for importation from countries or zones not free from infection with *Theileria*

For bovines and water buffaloes

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

1) showed no clinical sign of *infection* with *Theileria* and no *infestation* with tick *vectors* on the day of shipment;

2) were kept isolated for at least 35 days prior to shipment, in an e*stablishment* where no *case* of *infection* with *Theileria* has occurred during the preceding two years;

3) were treated with a registered acaricide according to manufacturer's instructions 48 hours prior to entry to the *establishment*, no more than two days after entering the *establishment* and three days prior to shipment;

4) were subjected to serological and agent detection tests with negative results on samples taken on entry to the *establishment* and five days before shipment.

Article 11.12.6.

Recommendations for importation of hides and skins from countries or zones not free from infection with *Theileria*

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the products have been;

1) dry-salted or wet-salted for a period of at least 14 days prior to dispatch; or

2) treated for a period of at least seven days in salt (NaCl) with the addition of 2% sodium carbonate (Na_2CO_3); or

3) dried for a period of at least 42 days at a temperature of at least 20°C; or

4) frozen to at least -20C for at least 48 hours.

Article 11.12.7.

Recommendations for importation of trophies derived from susceptible wild ruminants from countries or zones not free from infection with *Theileria*

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the products have been processed to ensure the destruction of tick *vectors*.

EU comment

The EU suggests deleting the word "wild" from the title of the article above, as trophies from susceptible domestic or feral ruminants should not be excluded.

Annex 32

CHAPTER 14.X.

INFECTION WITH *THEILERIA LESTOQUARDI, T. LUWENSHUNI* AND *T. UILENBERGI*

EU comment

The EU notes that the scope of this new draft chapter is *Theileria* infection in small ruminants. However, according to Chapter 1.3., theileriosis is listed within the category of cattle diseases, in Article 1.3.2. It is thus not clear whether *Theileria lestoquardi, T. luwenshuni* and *T. uilenbergi* infection of small ruminants are included in the OIE list of diseases, infections and infestations. It is also not clear whether these infections have been assessed against the listing criteria of Chapter 1.2. It is thus questionable whether there should be a disease-specific chapter in the Code for these infections. Indeed, according to established OIE Code practice, it is necessary to include these infections on the OIE list first before drafting a listed-disease specific chapter. Chapter 1.3. should thus first be revised accordingly before this chapter is further processed. (As regards priorisation of its work load, reference is made to the EU comments on the Code Commission work programme.)

Further comments are inserted in the text below.

Article 14.X.1.

General provisions

Animal susceptible to *infection* with *Theileria* are bovines (*Bos indicus*, *B. taurus* and *B. grunniens*), water buffaloes *(Bubalus bubalis)*, African buffaloes *(Syncerus caffer)*, sheep *(Ovis aries)*, goats *(Capra hircus),* camels (*Camel dromedarius* and *C. bactrianus*) and some *wild* ruminants.

EU comment

Please replace the word "Animal" with "Animals" in the paragraph above (typographical error).

Infection with *Theileria* can give rise to disease of variable severity and to *Theileria* transmission. *Theileria* may persist in ruminants for their lifetime. Such animals are considered carriers.

For the purposes of the *Terrestrial Code*, *infection* with *Theileria lestoquardi, T. luwenshuni* and *T. uilenbergi* are defined as a tickborne *infection* of sheep and goats with *T. lestoquardi, T. luwenshuni* and *T. uilenbergi*.

For the purposes of this chapter, *Theileria* means *T. lestoquardi, T. luwenshuni* and *T. uilenbergi.*

The following defines the occurrence of *infection* with *Theileria*:

1) *Theileria* has been identified in a sample from a sheep or goat; or

2) antigen or nucleic acid specific to *Theileria* has been identified in a sample from a sheep or goat showing clinical signs consistent with *infection* with *Theileria*, or epidemiologically linked to a suspected or confirmed *case*, or giving cause for suspicion of previous association with *Theileria*; or

3) antibodies specific to *Theileria* have been detected in a sample from a sheep or goat that either shows clinical signs consistent with *Theileria*, or is epidemiologically linked to a suspected or confirmed *case,* or giving cause for suspicion of previous association with *Theileria*.

For the purposes of the *Terrestrial Code*, the *incubation period* for *infection* with *Theileria* shall be 35 days.

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

EU comment

Manual Chapter 2.4.15. on Theileriosis is included in section 2.4. Bovinae, and does not cover the small ruminant *Theileria* species.

Article 14.X.2.

Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any *Theileria* related conditions regardless of the *Theileria infection* status of the animal population of the *exporting country*:

1) *meat* and *meat products*;
2) *casings*;
3) *milk* and *milk products*;
4) gelatine and collagen;
5) tallow;
6) semen and embryos;
7) hooves and horns;
8) bones.

Article 14.X.3.

Country or zone free from infection with *Theileria* in sheep and goats

1) A country or a *zone* may be considered free from *infection* with *Theileria* when the disease is notifiable in the entire country, importation of sheep and goats and their *commodities* is carried out in accordance with this chapter, and:

   a) the country or *zone* is historically free as described in Article 1.4.6.; or

   b) a *surveillance* programme in accordance with Chapter 1.4. has demonstrated no evidence of *infection* with *Theileria* in the country or *zone* for at least two years; or

   c) an ongoing *surveillance* programme in accordance with Chapter 1.5. has found no tick *vectors* for at least two years in the country or *zone*.

EU comment

The EU queries whether any and all ticks are to be targeted by the surveillance programme, i.e. are they all competent in transmitting the pathogenic agent. Indeed, it will be difficult to demonstrate total absence of ticks in a country or zone for a period of two years.

2) A country or *zone* free from *infection* with *Theileria* in which ongoing *vector surveillance*, performed in accordance with Chapter 1.5., has found no tick *vectors* will not lose its free status through the introduction of vaccinated, test-positive or infected sheep and goats from infected countries or *zones*.

3) A country or *zone* free from *infection* with *Theileria* will not lose its status as a result of introduction of seropositive or vaccinated sheep and goats or their *commodities*, provided they were introduced in accordance with this chapter.

Article 14.X.4.

Recommendations for importation from countries or zones free from infection with *Theileria*

For sheep and goats

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

1) showed no clinical sign of *infection* with *Theileria* on the day of shipment;
2) come from a country or *zone* free from *infection* with *Theileria*.

Article 14.X.5.

Recommendations for importation from countries or zones not free from infection with *Theileria*

For sheep and goats

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

1) showed no clinical sign of *infection* with *Theileria* and no *infestation* with tick *vectors* on the day of shipment;

2) were kept isolated for at least 35 days prior to shipment in an e*stablishment* where no *case* of *infection* with *Theileria* has occurred during the preceding two years;

3) were treated with a registered acaricide according to manufacturer's instructions 48 hours prior to entry to the *establishment*, no more than two days after entering the *establishment* and three days prior to shipment;

4) were subjected to serological and agent detection tests with negative results on samples taken on entry to the *establishment* and five days before shipment.

Article 14.X.6.

Recommendations for importation of hides and skins from countries or zones not free from infection with *Theileria*

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

1) dry-salted or wet-salted for a period of at least 14 days prior to dispatch; or

2) treated for a period of at least seven days in salt (NaCl) with the addition of 2% sodium carbonate (Na_2CO_3); or

3) dried for a period of at least 42 days at a temperature of at least 20°C; or

4) frozen to at least -20°C for at least 48 hours.

Article 14.X.7.

Recommendations for importation of wool and fibre of sheep and goats from countries or zones not free from infection with *Theileria*

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the products were subjected to:

1) industrial washing, which consists of the immersion of the wool in a series of baths of water, soap and sodium hydroxide or potassium hydroxide; or

2) industrial scouring, which consists of the immersion of wool in a water-soluble detergent held at 60–70°C.

Article 14.X.8.

Recommendations for importation of trophies derived from susceptible wild ruminants from countries or zones not free from infection with *Theileria*

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the products have been processed to ensure the destruction of tick *vectors*.

EU comment

The EU suggests deleting the word "wild" from the title of the article above, as trophies from susceptible domestic or feral ruminants should not be excluded.

Annex 33

WORK PROGRAMME FOR
THE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

EU comment

The EU thanks the Code Commission for having taken its previous comments into consideration, and in general supports the proposed revised work programme.

We would like to reiterate that for the EU, maximum priority should be given to the revision of the avian influenza chapter and on the finalisation of the review of the BSE chapter. The EU is committed to participate in that work and offers technical support to the Code Commission and the relevant ad hoc groups.

In this regard, we note with appreciation that an ad hoc group on the revision of the avian influenza chapter was convened in December 2017, and very much look forward to reading that group's report along with the February 2018 meeting reports of the Code Commission and Scientific Commission.

With regard to the BSE ad hoc group, we welcome the OIE's intention to convene a meeting in the course of 2018 and insist that priority be given to this work. Two ad hoc groups have already met in 2014 and in 2016 and have made proposals for revising the BSE chapter; however so far the only change made was the addition of a single albeit very important sentence in May 2015. It is therefore urgent that this work be finalised and that a comprehensive revision of the BSE chapter be adopted. The considerable improvement of the BSE epidemiological situation calls for a more balanced approach to BSE, in line with the latest scientific evidence. The BSE surveillance requirements to maintain OIE Member Countries' BSE risk statuses should be updated and adapted to the current situation, and, more generally, the conditions for obtaining and maintaining the BSE risk statuses should be thoroughly reviewed. Furthermore, the chapter should be systematically adapted to cater for the specificities of Atypical BSE. We therefore urge the OIE to convene this group within short delays and for the Code Commission to circulate as soon as possible a draft revision of the BSE chapter of the Code.

Furthermore, we note with some concern that the volume of the work programme keeps increasing, and suggest that this be accompanied by clear priorisation of the work so as to avoid too many ongoing projects at the same time. One way of ensuring this would be to delay work on new chapters (e.g. in sections 3, 4, 5 and 6) until the set of new chapters currently under discussion (e.g. on vaccination, disease control) are finalised and adopted. Work should certainly stop on disease-specific chapters concerning pathogens that are not OIE listed.

Furthermore, reference is made to EU comments elsewhere in the report that pertain to the Code Commission's work programme, i.e. as regards Item 4 (previous EU comments on PRRS chapter); Item 5.1. (consequential amendments of Chapter 1.3.); Item 7.4.3. (revision or deletion of Chapter 5.8.); Annex 10 (Glossary definition of "animal products").

Subject	Issue by priority order (Reason for new work)	Status and Action (Start date, # of rounds for comments)

Subject	Issue by priority order (Reason for new work)	Status and Action (Start date, # of rounds for comments)
Restructuring of the Code	1) Work with AAHSC towards harmonisation, as appropriate, of the horizontal parts of the *Codes,* notably Glossary, User's Guide and Section 4 on disease control and Section 6 on Veterinary Public Health (MCs comments)	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 (MCs comments)	Ongoing
	3) Revision and formatting of chapters (articles numbering, tables and figures) (MCs comments and to improve consistency)	Ongoing
	4) Revision of the Users' guide to address the precedence of chapters (MCs comments)	Preliminary discussion
Glossary	1) Compartment, containment zone, free zone, infected zone, protection zone, vaccination, zone (MCs comments and to improve consistency)	Revised definitions sent for comments and proposed for adoption in 2018 (Feb 2016/4th)
	2) Disease, infection and infestation (To improve consistency)	Deleted and revised definitions sent for comments and proposed for adoption in 2018 (Sep 2016/3rd)
Horizontal issues not yet in the Code **Sec.4. Disease control**	1) New CH on vaccination (MCs comments and implications for status recognition)	Revised new CH sent for comments and proposed for adoption in 2018 (Sep 2016/3rd)
	2) New CH on official control of emerging and listed diseases (MCs comments and part of restructuring of Section 4)	Revised new CH sent for comments (Feb 2017/2nd)
	3) New introductory CH in Section 4 (Part of restructuring of Section 4)	New CH sent for comments (Sep 2017/1st)
	4) New CH on biosecurity	Preliminary discussion
	5) New CH on zoning application (MCs comments)	Preliminary discussion
Horizontal issues not yet in the Code **Sec.6. VPH**	1) New introductory CH in Section 6 (APFSWG proposal)	Revised new CH sent for comments and proposed for adoption in 2018 (Feb 2017/2nd)
	2) Control of Shiga toxin-producing *E. coli* (STEC) in food-producing animals (MCs comments)	Preliminary discussion pending FAO/WHO expert consultation

Subject	Issue by priority order (Reason for new work)	Status and Action (Start date, # of rounds for comments)

Horizontal issues not yet in the Code **Sec.7. AW**	1) New CH on AW and pig production systems (MCs comments)	Revised CH sent for comments and proposed for adoption in 2018 (Sep 2016/3rd)
	2) New CH on slaughter and killing methods of farmed reptiles (MCs comments)	New CH sent for comments (Sep 2017/1st)
	3) New CH on AW and laying hen production systems (MCs comments)	New CH sent for comments (Sep 2017/1st)
Horizontal issues in need of revision: **Sec.1. Notification**	1) Revision of CH 1.4. on Animal Health Surveillance (MCs comments and implications for status recognition)	Revised CH sent for comments (Feb 2016/2nd)
	2) CH 1.6. on Status: revision and reorganisation (MCs comments and implications for status recognition)	Revised questionnaires sent for editing by experts before further review by SCAD and TAHSC (Feb 2017/1st) / Preliminary discussion on Article 1.6.1.
	3) CH 1.3. on listed diseases: assess CWD & WNF against the criteria (MCs comments)	Pending HQs advice on CWD / WNF
Horizontal issues in need of revision: **Sec.2. RA**	1) Revision of Article 2.1.2. (Consequential changes to reflect the proposed deletion of Glossary definition of 'transparency')	Revised article proposed for adoption in 2018 (Feb 2017/2nd)
Horizontal issues in need of revision: **Sec.3. VS**	1) Revision of CHs of Section 3 in the light of the return of experience of the PVS Pathway	Pending outcome of discussion at PVS think tank
Horizontal issues in need of revision: **Sec.4. Disease control**	1) Revision of CH 4.3. on zoning and compartmentalisation (MCs comments and implications for status recognition)	Revised CH sent for comments and proposed for adoption in 2018 (Feb 2016/4th)
	2) Revision of CH 4.8. on collection and processing of *in vitro* produced oocytes or embryos from livestock and horses (MCs comments)	Revised CH sent for comments and proposed for adoption in 2018 (Sep 2016/3rd)
	3) Revision of CH 4.13. on disinfection (MCs comments)	Preliminary discussion
	4) Revision of CH 4.6. on collection and processing of bovine, small ruminant and porcine semen (MCs comments and trade implications)	Pending experts advice
	5) Revision of CH 4.7. collection and processing of in vivo derived embryos from livestock and equids (MCs comments and trade implications)	Pending experts advice
Horizontal issues in need of revision: **Sec.5. Trade measures**	1) Revision of CHs 5.4. to 5.7. on animal health measures applicable at departure, during transit, quarantine stations and on arrival (MCs comments)	Preliminary discussion and pending decision on AHG
	2) Revision of CH 5.12. on model certificates for competition horses (MCs comments)	Preliminary discussion and pending revision of CHs on horse diseases
	3) Revision CH 5.10. to include a model certificate for petfood (NGO comments)	Preliminary discussion

Subject	Issue by priority order (Reason for new work)	Status and Action (Start date, # of rounds for comments)
Horizontal issues in need of revision: **Sec.6. VPH**	1) Revision of CH 6.1. on the role of VS in food safety (Planned work by TAHSC)	Revised CH sent for comments and proposed for adoption in 2018 (Feb 2016/3rd)
	2) Revision of CH 6.7. on AMR surveillance and monitoring programme (MCs comments and to align with Codex work)	Revised CH sent for comments and proposed for adoption in 2018 (Sep 2015/ 4th)
	3) Revision of Article 6.8.1. on monitoring of AMR in food producing animals (In conjunction with Codex work on AMR)	Revised CH sent for comments and proposed for adoption in 2018 (Feb 2017/ 2nd)
	4) Revision of CH 6.2. on meat inspection (Planned work by TAHSC)	Pending AHG report
Horizontal issues in need of revision: **Se.7. AW**	1) Revision of CH 7.5. on slaughter and CH 7.6. on killing of animals for disease control purposes (MCs comments)	Revised CHs to be referred to experts for further advice
	2) Revision of CH 7.12. on AW of working equids (MCs comments)	Pending advice from MCs on Art.7.12.12.
	3) Revision of CH 7.1. on introduction to recommendations on AW (AWWG proposals)	Revised CH sent for comments (Feb 2017 /2nd)
	4) Revision of CH 7.7 on stray dog population control (Experts comments)	Pending work of AHG on rabies
Diseases issues not yet in the Code	1) New CH on non-equine surra and revision of CH on Dourine (Non-tsetse transmitted Trypanosomosis) (MCs comments)	New/revised CHs sent for comments (Sep 2017/1st)
	2) New CH on Tsetse transmitted trypanosomosis (MCs comments)	Pending work of AHG
	3) New CH on Crimean Congo hemorrhagic fever (MCs comments, listed disease without chapter)	Preliminary discussion
Listed disease CHs in need of revision: **Sec. 8 to 15**	1) Revision of CH 10.4. on AI (MCs comments and trade implications)	Pending work of AHG
	2) Revision of CH 12.10. on glanders (outdated CH and trade implications)	Revised CH Sent for comments and proposed for adoption in 2018 (Sep 2014/4th)
	3) Revision of CH 11.4. on BSE (MCs comments and trade implications)	Pending work of AHG (Feb 2015/1st)
	4) Revision of CH 8.8. on FMD (MCs comments and implications for status recognition)	Pending outcome of discussion on zoning (Sep 2015/2nd)
	5) Revision of CH 8.13. on Rabies (MCs comments)	Pending work of AHG
	6) Revision of CH 11.12. on Theileriosis and new CH 14.X. on infection with Theileria in small ruminants (outdated CH)	Revised/new CHs sent for comments (Sep 2017/1st)
	7) Revision of CH 8.3. on Bluetongue (MCs comments)	Revised CH sent for comments and proposed for adoption in 2018 (Sep 2016/3rd)

Subject	Issue by priority order (Reason for new work)	Status and Action (Start date, # of rounds for comments)
Listed disease CHs in need of revision: **Sec. 8 to 15**	8) Revision of CH 15.2. on CSF (MCs comments and implications for status recognition)	Revised CH sent back to HQs for evaluation and SCAD review (Feb 2017/1st)
	9) Revision of CH 14.8. on scrapie (MCs comments)	Pending experts opinion on MCs comments
	10) Revision of CH 10.5. on avian mycoplasmosis (MCs comments and trade implications)	Pending experts' opinion
	11) Revision of CH 11.7. on CBPP (Implications for status recognition)	Pending HQs advice
	12) Revision of Article 8.15.2. on rinderpest (MCs comments and proposal by JAC)	Revised Art. sent for comments and proposed for adoption in 2018 (Feb 2017/2nd)
	13) Revision of listed disease-specific CHs on safe commodity article	Ongoing
	14) Consistency between articles on disease status	Pending SCAD evaluation
Follow-up revision of CHs adopted at 85th GS:	1) Further revision of CH 15.1. on ASF (MCs comments at 85GS)	Revised CH sent for comments and proposed for adoption in 2018 (Sep 2017/1st)
	2) Revision of CH 11.11. on LSD (MCs comments at 85GS)	Revised CH sent for comments and proposed for adoption in 2018 (Sep 2017/1st)
	3) Revision of CH 2.2. on criteria for assessing safety of commodities (MCs comments at 85GS)	Revised CH sent for comments and proposed for adoption in 2018 (Sep 2017/1st)
	4) Revision of CH 6.13. on *Salmonella* in commercial pig production systems (MCs comments at 85GS)	Revised CH sent for comments and proposed for adoption in 2018 (Sep 2017/1st)
	5) Revision of User's guide (MCs comments at 85GS)	Revised User's guide sent for comments and proposed for adoption in 2018 (Sep 2017/1st)
	6) Revision of of CH 8.11. on *M. tuberculosis* complex ((MCs comments at 85GS)	Pending experts advice

List of abbreviations	
AAHSC	Aquatic Animal Health Standards Commission
AHG	*ad hoc* Group
AI	Avian influenza
APFSWG	Animal Production Food Safety Working Group
ASF	African swine fever
AW	Animal Welfare
AWWG	Animal Welfare Working Group
BSC	Biological Standards Commission
BSE	Bovine Spongiform Encephalopathy
CBPP	Contagious bovine pleuropneumonia
CH	Chapters
CSF	Classical swine fever
CWD	Chronic wasting disease
FMD	Foot and mouth disease
HQs	Headquarters
JAC	FAO-OIE Rinderpest Joint Advisory Committee
LSD	Lumpy skin disease
NGO	Non-Governmental Organisation
PVS	Performance of Veterinary Service

RA	Risk Analysis
TAHSC	Terrestrial Animal Health Standards Commission
VPH	Veterinary Public Health
VS	Veterinary Service
WNF	West nile fever

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Annex 36 (contd)

Annex IV

EU comment

The EU commends the OIE for having taken the initiative to embark on this important work on veterinary paraprofessionals, which we fully support. The EU congratulates the *ad hoc* group for the work done so far and encourages the group and the OIE to finalise the work on the draft Veterinary Paraprofessionals Competency Document which will indeed be useful for many OIE Member Countries in need of guidance for developing their competencies and education systems in this important sector.

It is unfortunately not possible to provide detailed answers coordinated at EU level to the questionnaire below within the deadline since the issue is rather complex as it is only partially harmonised at EU level. In general, we kindly suggest the OIE limit the overall number of questionnaires to its Member Countries as much as possible.

1. **For each Track, how well do the VPP Spheres of Activities (SOAs) and Competencies represent the range of Veterinary Paraprofessional (VPP) responsibilities in your country?**

AH/VPH Track

☐	☐	☐	☐	☐
Extremely Well	Very Well	Somewhat	Slightly	Not at All

Laboratory Track

☐	☐	☐	☐	☐
Extremely Well	Very Well	Somewhat	Slightly	Not at All

2. **Please list any additional activities VPPs perform that are not covered by the attached SOA and Competencies:**

AH/VPH Track	**Laboratory Track**

3. **Please identify any SOAs and/or Competencies which are outside the scope of what VPPs do in your country, by SOA and Competency number. (For example: Competency 3 from SOA 1 should be listed as "SOA 1:C3")**

AH/VPH Track	**Laboratory Track**

4. **How can this document assist you to improve the opportunities, quality and performance of VPPs in your country?**

5. **In your opinion, will this document be valuable in improving the Competencies of VPPs in your country?**

☐	☐	☐	☐	☐
Definitely Yes	Probably Yes	I'm Not Sure	Probably Not	Definitely Not

6. **What problems might arise in using this document in your country?**

7. **General comments and suggestions (not covered by the preceding questions):**

Any additional information on existing VPP programs can be provided via email to standards.dept@oie.int