

Brussels SANTE G2/MMK/Ili(2018) 6980233

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 2018 meeting of the OIE Terrestrial Animal Health Standards Commission, for consideration at its next meeting in February 2019;
- the comments of the EU on the report of the September 2018 meeting of the OIE Aquatic Animal Health Standards Commission, for consideration at its next meeting in February 2019;
- the comments of the EU on the draft chapters of the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, circulated for Member comments in October 2018, for consideration by the OIE Biological Standards Commission at its next meeting in February 2019.

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

Yours sincerely,

Dr Ulrich Herzog	Dr Bernard Van Goethem
CVO and OIE Delegate	Director for Crisis Management in Food, Animals and Plants
Austria	European Commission, DG Health and Food Safety
Wa Heyee	

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; General Secretariat of the Council of the EU.

Dr Monique Eloit Director General World Organisation for Animal Health (OIE) 12-14, rue de Prony 75017 Paris, France

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



Organisation Mondiale de la Santé Animale World Organisation for Animal Health Ref. Ares(2018)6394899 - 12/12/2018 Organización Mundial de Sanidad Animal

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

Paris, 11-20 September 2018

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 2018 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 11 to 20 September 2018. The list of participants is attached as **Annex 1**.

The Code Commission thanked the following Member Countries for providing comments: Argentina, Australia, Canada, China, Chinese Taipei, Colombia, Costa Rica, Fiji, Guatemala, Japan, Malaysia, New Caledonia, New Zealand, Norway, Singapore, South Africa, Switzerland, Thailand, USA, Americas, 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 Voice of Europe's Poultry Meat Sector (AVEC), European Live Poultry and Hatching Egg Association (ELPHA), the European Serum Product Association (ESPA), the International Coalition for Animal Welfare (ICFAW), International Egg Commission (IEC) and International Poultry Council (IPC). The Code Commission referred comments regarding translation to the OIE Headquarters.

The Code Commission reviewed Member Country comments, which were submitted on time and supported by a rationale, including some comments made by Member Countries during the 86th General Session in May 2018, 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 'double underline' and 'strikethrough' and the chapters are annexed to this report. In Annexes 8, 9, 10, 11, 12, 14, 15 and 17, 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 (the Biological 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 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 <u>Part A</u> of this report are submitted for comments and will be proposed for adoption at the 87th General Session in May 2019. Texts in <u>Part B</u> are submitted for comments only. Comments on <u>Parts A</u> and <u>B</u> of the report must reach OIE Headquarters <u>by 14 January 2019</u> for them to be considered at the February 2019 meeting of the Code Commission. Comments received after the due date will not be submitted to the Code Commission for its consideration. The reports of meetings of *ad hoc* Groups and other related documents are attached for information in <u>Part C</u>.

All comments and related documents should be sent by email 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. Member Countries are also reminded that comments should be submitted as Word files rather than pdf files because pdf files are difficult to incorporate into the working documents of the Code Commission. Comments should be submitted as specific proposed text changes, supported by a structured rationale or by published scientific references. Proposed deletions should be shown using 'strikethrough' and additions using '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 the Code Commission's working documents. Member Countries are also requested not the Code Commission's working documents. Member Countries are also requested not the Code Commission's working documents. Member Countries are also requested not the Code Commission's working documents.

Item No.	Texts proposed for adoption in May 2019	Part A: Annex No.
3.c)	Infection with <i>Chlamydophila abortus</i> (Enzootic abortion of ewes, ovine chlamydiosis) (Chapter 14.4.)	3
4.3	The role of the Veterinary Services in food safety systems (Chaper 6.2.)	4
4.4	Guiding principles for the use of measures to assess animal welfare (Article 7.1.4.)	5
4.5	Animal welfare and pig production systems (Chapter 7.13.)	6
5.1	Glossary Part A ('Early warning system' and 'sanitary measure')	7
5.2	Animal health surveillance (Chapter 1.4.)	8
5.5	Draft new chapter on introduction to recommendations for disease prevention and control (Chapter 4.Z.)	9
5.7	Draft new chapter on killing of reptiles for their skins, meat and other products (Chapter 7.Y)	10
5.8	Infection with rabies virus (Chapter 8.14.)	11
5.10	Infection with African swine fever virus (Articles 15.1.1bis., 15.1.2., 15.1.3., and 15.1.22.)	12
Item No.	Texts for Member Countries comments	Part B: Annex No.
4.3/ 5.10/ 7.1.g)	Glossary Part B ('Competent Authority', 'Veterinary Authority', 'Veterinary Services', 'captive wild [animal]', and 'epidemiological unit')	13
5.3	Procedures for self declaration and for official recognition by the OIE (Chapter 1.6.)	14
5.4	Draft new chapter on official control of listed and emerging diseases (Chapter 4.Y.)	15
5.6	Draft new chapter on animal welfare and laying hen production systems (Chapter 7.Z.)	16
5.11	Infection with classical swine fever virus (Chapter 15.2.)	17

6.2	Veterinary legislation (Chapter 3.4.)	18
6.4	Infection with avian influenza viruses (Chapter 10.4.)	19
7.1.b)	Notification of diseases, infections and infestations, and provision of epidemiological information (Chapter 1.1.)	20
7.1	Work programme	21
Item No.	Texts for Member Countries information	Part C:
		Annex No.
5.6	Report of the <i>ad hoc</i> Group on Animal welfare and laying hen production systems (March 2018)	22
5.6		
	(March 2018) Report of the <i>ad hoc</i> Group on Killing of reptiles for their skins, meat and other	22

1. Welcome and orientation

1.1 Meeting with the Director General

The Code Commission met with Dr Monique Eloit, Director General, on 11 September 2018. Dr Eloit welcomed the Code Commission members and congratulated them on their election or re-election and thanked them for their commitment to the work of this Commission.

The Director General noted that new members bring a diverse range of expertise and experience to what is an important contribution to the standards setting function of the OIE. The Director General acknowledged the Member Countries' requests and high expectations for the OIE standard setting process. Noting the resource and financial constraints faced by the OIE to support *ad hoc* Group meetings, the Director General asked the Code Commission for its active consideration of these constraints in considering its work programme. The Director General drew the attention of the Code Commission members to the framework for the evaluation of the performance of Specialist Commissions which would be introduced at its meeting in 2019 February. Finally the Director General highlighted the importance of good coordination among the Specialist Commissions and their Secretariats and noted the high expectations for the Common Secretariat for which the Standards Department takes a leading role.

The President of the Code Commission thanked the Director General and the Headquarters for the support for the Code Commission's work.

1.2 Induction to the Code Commission work

Noting that this was the first meeting of the newly elected Specialist Commissions it was agreed that the opening session of all Specialist Commission meetings would be dedicated to a half-day 'Induction session'.

The purpose of these sessions, for new and previously elected members, was to start to get to know each other, to better understand how the work of each of the Commission's fits into the mission of the OIE and to clarify the roles of Commission members and OIE Secretariat and other staff. There was general agreement that this new initiative was very valuable for all concerned and will assist in ensuring the success of the work of each Commission. The OIE will continue to explore other novel ways of supporting the Commissions in their work.

2. Adoption of the agenda

The Agenda was adopted, noting that it would not consider the *ad hoc* Group report on BSE as additional meetings were planned to continue revising the relevant chapter of the *Terrestrial Code*. The Code Commission also noted that Chapter 8.8. on FMD would be reviewed once the issue of the new concept of

zoning (temporary protection zone) is addressed in the horizontal chapter on zoning and compartmentalisation (see Agenda Item 3.a)). The adopted agenda of the meeting is attached as **Annex 2**.

3. Cooperation with other Specialist Commissions

a) Technical working group meeting with the Presidents and Vice Presidents of the Scientific Commission and the Code Commission related to the concept of 'temporary protection zone'

The Presidents and 1st Vice-Presidents of the Scientific Commission and Code Commission held a technical working group meeting in the margins of the two Commission meetings to discuss the concept of a temporary protection zone that was first circulated for Member Countries comments after the Specialist Commissions meeting in September 2017. The meeting was chaired by the OIE Deputy Director General for International Standards and Science, Dr Matthew Stone.

The main objective of the meeting was to consider the Member Countries comments received after circulating the draft concept, to explore its links with currently existing concepts of the *Terrestrial Code* (i.e. protection zone, containment zone) and to agree on the best approach to further develop and communicate the new concept to the Member Countries.

The strategic drivers of the temporary protection/preventive zone, the relevance for its inclusion in the horizontal chapter (i.e. Chapter 4.3. on Zoning and compartmentalisation) and whether it should be applicable to all diseases or to only those diseases for which the OIE recognises an official status, were extensively discussed.

It was agreed that the OIE Headquarters would draft a discussion paper, based mainly on the current concept of "protection zone", exploring the application and impact of the concept related to different diseases. This paper would be reviewed by both Commissions during the February 2019 meetings.

b) 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 to discuss issues of mutual interest in the *Aquatic* and *Terrestrial Codes*, notably:

- proposed amendments to Chapter 1.1. Notification of diseases, infections and infestations, and provision of epidemiological information, in order to better align this Chapter in both Codes;
- progress regarding proposed new and revised chapters in Section 4 of the Codes; and
- the development of a guidance document on the application of the criteria for listing an OIE disease.

c) Consultation with the Biological Commission

The meeting schedule did not allow for a meeting with the President of the Biological Commission. However, there was consultation on some items of work that was coordinated through the Secretariats. In agreement with the advice from the Biological Commission, the Code Commission agreed to the updated taxonomy of the pathogenic agent *Chlamydia abortus*, where it is referred to in Chapter 14.4., including the title.

The revised title and Article 14.4.1. are attached as <u>Annex 3</u> for Member Country comments and is proposed for adoption at the 87th General Session in May 2019.

EU comment

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

In addition, we would suggest amending the taxonomy of this infection accordingly also in the OIE list in Chapter 1.3., for reasons of consistency and in order to avoid possible confusion.

4. Examination of Member Countries' comments at the 86th General Session

4.1. Zoning and compartmentalisation (Chapter 4.3.)

The following Member Countries made comments at the 86th General Session: Argentina and Thailand.

In response to a Member Country comments on the definition of 'compartment' used in this chapter, specifically in reference to the need to reflect more explicitly the status of the compartment, the Code Commission asked the OIE Headquarters to closely look at the implications in the recently adopted Chapter 4.3. and the possibility of revising Chapter 4.4. on Application of compartmentalisation. It also requested the OIE Headquarters to seek advice from the Scientific Commission about the Member Country comments.

In further response to the same Member Country comment, the Code Commission clarified that, in Article 4.4.7., the free status of a compartment could be suspended if there was a significant breach in biosecurity even in the absence of outbreaks. In this case, the disease free status of the compartment could only be reinstated by applying measures necessary to re-establish the original biosecurity level.

In response to a Member Country request to provide more guidance on activities to be undertaken in each type of zone, the Code Commission agreed to develop a new chapter on the application of zoning and added this to its work programme.

The Code Commission disagreed with a Member Country proposal to delete the words 'and vector surveillance' after 'specific surveillance' in Article 4.3.4., as it is not compulsory to conduct 'past or ongoing specific surveillance' or 'vector surveillance'. The words 'may require' indicate this clearly. The Code Commission further noted that the provisions on "vector surveillance" should remain considering the important epidemiological role of vectors for some diseases.

The Code Commission disagreed with a Member Country request to add a new sentence to clarify the possibility of the concurrent establishment of more than one containment zone. The Code Commission noted that if the outbreaks are not related, establishment of more than one containment zone is possible and this is sufficiently explained by "a containment zone, which includes all **epidemiologically linked** outbreaks may be established...".

In response to a Member Country proposal to delete the last new paragraph related to the event of an occurrence of a case of the infection or infestation for which the containment zone was established in Article 4.3.7., the Code Commission disagreed and reaffirmed the importance of this text to clarify the concept of a containment zone and its advantages for the rest of the country.

4.2. Vaccination (Chapter 4.17.)

The following Member Countries made comments at the 86th General Session: the EU.

In reviewing Member Countries comments made during the 86th General Session suggesting that in their view the definition of 'population immunity' is not correct, the Code Commission and the Scientific Commission disagreed. The Code Commission noted that 'population immunity' is the measure of immunity in the target population immunised at a specific time and the current definition in this chapter is appropriate. The Code Commission also noted that the 'population immunity' is not an absolute term and it reflects a given level of immunity, even if it is not sufficient to prevent the spread of the disease.

4.3. The role of Veterinary Services in food safety systems (Chapter 6.2.)

The following Member Countries made comments at the 86th General Session: New Zealand on behalf of the Quads.

EU comment

The EU also made comments at the 86th General Session on this chapter. Indeed, comments were sent in writing to the OIE prior to the General Session, and have been referred to in the oral intervention made on behalf of the 28 EU Member States during the relevant session. We note that these comments have not been addressed and request that the OIE consider them at the February 2019 meeting of the Code Commission. Reference is made to the EU comments in Annex 4.

In response to a Member Country comment that Article 6.2.4. was confusing with respect to the role of the Veterinary Services and the Competent Authority in food safety and veterinary public health, the Code Commission reviewed this article. The Code Commission tried to address any inconsistencies in the text but noted that without the provision of alternative text by the Member Country it was difficult to address their concerns. The Code Commission requested that any further Member Countries comments include the submission of alternative text and a rationale to assist the Code Commission to fully understand their concerns. The Code Commission agreed to make the following amendments in Article 6.2.4.:

In point 1. Roles and responsibilities of Veterinary Services, the Code Commission agreed to replace the words 'Veterinary Services' with 'Veterinary Authorities or other Competent Authorities' in the third paragraph for clarity as it is the Veterinary Authority or Competent Authority, that should retain overall responsibility for the delivery and performance of any activities delegated to third party providers.

In point 2. c) Assurance schemes and certification of food of animal origin for international trade, The Code Commission agreed with a Member Country comment that the use of the term 'Competent Authority' was incorrect and proposed to replace this term with 'responsible agencies' which is consistent with the use of the term in Article 6.2.1.

In response to a Member Country comment, the Code Commission revised the definitions for 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services' to better reflect the roles that these entities play in veterinary public health.

The Code Commission made amendments to the definition of 'Competent Authority' to make a clear differentiation with the definition of 'Veterinary Authority'.

The Code Commission also added the words 'the OIE Delegate' in the definition of 'Veterinary Authority', as it is true that in accordance with the OIE Rules, the Veterinary Authority should be under the OIE Delegate's responsibilities or at least the OIE Delegate should be part of the Veterinary Authority.

The revised Article 6.2.4. is attached as <u>Annex 4</u> for Member Country comments and is proposed for adoption at the 87th General Session in May 2019.

EU comment

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

However we note that previous EU comments on this chapter, provided to the OIE in writing prior to the 86th OIE General Session and referred to orally during that session have not been addressed. Those comments pertain to Articles 6.2.3. and 6.2.4. and are available here

https://ec.europa.eu/food/sites/food/files/safety/docs/ia_standards_oie_eu_position_tahscreport_201805.pdf.

The revised Glossary definitions for 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services' are attached as **Annex 13** for Member Country comments.

4.4. Guiding principles for the use of measures to assess animal welfare (Article 7.1.4.)

The following Member Countries made comments at the 86th General Session: Japan and Paraguay on behalf of the 30 OIE Members of the Americas.

Some Member Countries commented on point 3) noting the importance of not excluding other entities, universities and research institutions from the collection of relevant data to establish the threshold to meet animal-based measures as they considered that deletion of the phrase 'and other relevant bodies' would result in the loss of a valuable source of data. The Code Commission did not agree to reinstate the reference to 'other relevant bodies' and clarified that the Competent Authority is the entity responsible for officially collecting data, and also clarified that the data provided to the Competent Authority can come from different sources such as universities or research institutions, which is expressed in the proposed text as 'all **relevant** data should be collected'. However, the Code

Commission agreed to reinsert the sentence and move it from the end of point 3), in the version proposed for adoption during the 86th General Session, to the end of point 5), as a new sentence, for improved readability.

The revised Article 7.1.4. is attached as <u>Annex 5</u> for Member Country comments and is proposed for adoption at the 87th General Session in May 2019.

EU comment

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

One comment is inserted in the text of Annex 5.

4.5. Animal welfare and pig production systems (Chapter 7.13.)

The following Member Countries made comments at the 86th General Session: Chad, on behalf of the 54 Members of the African Union and the OIE African Region, Germany on behalf of the 28 Member States of the EU and USA on behalf of the 30 OIE Members of the Americas.

Article 7.13.1.

Regarding Member Countries request to replace 'mental' state with 'behaviour' in the definition of 'environmental enrichment', due to the difficulties to define the 'mental state' in an animal, the Code Commission did not agree with the proposal, as both terms are not interchangeable. The term 'behaviour' refers in this chapter to a response to a given situation and a 'mental state' is a condition at a particular time. They also recalled that the term 'mental state' is consistent with the recently revised definition of animal welfare.

Article 7.13.4.

The Code Commission agreed with the comment of Member Countries to include the word 'other' in the second paragraph of the section on behaviour as they agreed this addition would help to differentiate behaviours associated with poor animal welfare from behaviours indicating good animal welfare.

Article 7.13.9.

The Code Commission did not agree with the rationale given by Member Countries to delete the third bullet point on the provision of feed and water saying that this point was more relevant to Article 7.13.10. on the environmental enrichment aspects. The Code Commission recalled that its position was in agreement with the rationale provided by the *ad hoc* Group on animal welfare and pig production systems in its January 2018 report. The *ad hoc* Group indicated that the provision of specific forage and foraging behaviour are related to the improvement of nutritional aspects and not to environmental aspects.

The Code Commission did not agree with the proposal of Member Countries to add a new sentence concerning the early mixing after servicing of sows and gilts as this management procedure is not supported by any scientific literature. The Code Commission reminded Member Countries that the *ad hoc* Group had noted this in its report of January 2018.

Article 7.13.13.

The Code Commission did not agree with the comments of some Member Countries to promote the use of group housing systems in Point 1) as this aspect is already mentioned in the last paragraph of Article 7.13.12. on housing. The Code Commission did not agree with the proposal to add a new sentence about the period in which sows and gilts should be kept in stalls after service as it is too prescriptive.

Article 7.13.15.

The Code Commission did not agree with the proposal of Member Countries to keep the animal-based criteria for excessive soiling and tear staining. However, they agreed to modify the list of criteria to include 'discharges from nose or eyes', being an animal-based measurable, as examples of physical

appearance aspects to be considered when assessing animal welfare in relation to air quality conditions.

The revised Articles 7.13.4. and 7.13.15. of Chapter 7.13. is attached as **Annex 6** for Member Country comments and is proposed for adoption at the 87th General Session in May 2019.

EU comment

The EU thanks the OIE for considering the majority of its comments and supports the proposed changes to this chapter.

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

The following Member Countries made comments at the 86th General Session: Argentina.

The Code Commission disagreed with a proposal from a Member Country to only use the term 'equid' rather than 'equine' throughout this chapter and noted that in accordance with the past discussion at the Code Commission meetings about the terms used for animal species, the respective use of these terms is correct in the chapter, where 'equid' is a noun and 'equine' is an adjective.

5. Texts circulated for Member Countries' comments at the September 2017 and February 2018 meetings

5.1. Glossary

Comments were received from New Zealand and Switzerland.

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

Early warning system

The Code Commission disagreed with comments from a Member Country requesting the inclusion of more detailed information in the definition and agreed with the Scientific Commission to keep the definition short, as should be the case in the Glossary, while the details are found in the relevant chapters. In response to the same Member Country proposal to reinstate the word 'identification', the Code Commission disagreed as 'identification' of the pathogenic agent is a further step after detection that can take some time, while 'Early warning system' is meant for rapid response. The Code Commission disagreed with the same Member Country proposal to delete the word 'communication' as it did not consider this to be a synonym of reporting. Communication has a wider meaning and could be done by authorities or relevant stakeholders to the public. Finally, the Code Commission noted that as the definition of 'Early detection system' would be replaced with 'Early warning system' in the Glossary, the current definition of 'Early detection system' should appear as 'strikethrough' and requested the OIE Headquarters to make a necessary amendment on the Glossary.

Sanitary measure

The Code Commission noted comments received in support of the proposed definition.

The revised Glossary is attached as <u>Annex 7</u> for Member Country comments and is proposed for adoption at the 87th General Session in May 2019.

EU comment

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

5.2. Animal health surveillance (Chapter 1.4.)

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

In response to a Member Country comment regarding some inconsistencies in the use of the term 'disease', the Code Commission noted that the definition of the term 'disease' was deleted from the Glossary at the 86th General Session in May 2018. The Code Commission reiterated that the term 'disease' would not disappear from the *Terrestrial Code* but rather will be used as a general term, not a defined term. As a consequence, the term now appears not in italics. The Code Commission noted

that it would seek consistency in the use of the term 'disease' throughout the *Terrestrial Code*, including the User's Guide with assistance from the OIE Headquarters, in order to make any necessary amendments for clarity.

Article 1.4.1.

In point 1), the Code Commission and the Scientific Commission agreed not to accept a proposal from a Member Country to add the words 'or presence of a zoonotic pathogen' after 'infection or infestation', as the definition of 'infection' already includes the presence of a pathogenic agent in animals or humans.

The Code Commission agreed with Member Countries comments to reinstate the previous wording 'to facilitate the control of infection or infestation'. The Code Commission also agreed to amend the sentence related to the type of surveillance to include the words 'objectives of the surveillance' after 'depends on' agreeing that it also depends on the surveillance objectives. The Code Commission also made editorial amendments to improve the clarity.

In point 2), in response to a Member Country comment to add the words 'be harvested, hunted, traded and' after 'they can', the Code Commission disagreed as surveillance for wildlife is considered in the *Terrestrial Code* because of their potential roles in affecting animals and humans.

In point 3) b), the Code Commission agreed with a Member Country comment to add the words 'population demographic data' before 'animal production data', as it is important for the analysis of surveillance data.

Article 1.4.2.

In 'sampling unit', the Code Commission disagreed with a Member Country comment to add a new sentence about minimum unit of observation, as it is already included in the definition of 'sample' above. In response to another Member Country comments proposing editorial changes, the Code Commission agreed to delete the third sentence because 'sampling frame' is not used in the *Terrestrial Code*.

Article 1.4.3.

In point 1) a), the Code Commission partially agreed with the proposal to delete the last text added in the February 2018 and added the word 'stated' at the end of the last sentence. In response to a proposal of several Member Countries to replace the word 'disease' with 'infection or infestation' as this would be a more appropriate term than 'disease', the Code Commission disagreed and reaffirmed that when the *Terrestrial Code* is referring to the epidemiology it is in a general sense regarding the disease and not related to the control of a specific infection or infestation.

In point 1) b), the Code Commission amended the first sentence to add the words 'and frequency' after 'duration' and deleted the last sentence in Point 1) b) as this is included in the above. In response to a proposal of a Member Country to add the word 'environmental condition' after 'climate', the Code Commission agreed to add the words 'environmental factors, including' in the last indent.

In point 1) *c*), in response to a Member Country comment to add the common name to the taxonomy, the Code Commission disagreed as it does not add value.

In point 1) *e*), the Code Commission agreed with a Member Country proposal to delete the last text of this point.

In point 1) *ebis*), in response to a Member Country request for clarification and the proposal to add the definition of 'test', the Code Commission added the word 'laboratory' before 'tests' in the last sentence to highlight the fact that the *Terrestrial Manual* deals with laboratory tests.

In point 1) f), the Code Commission amended the text in response to a Member Country proposal to replace the words 'should only be carried out when' with 'may be carried out only when'. The Code Commission highlighted that statistical analysis cannot be carried out without good quality data.

In point 1) g), the Code Commission disagreed with Member Countries proposals to include the words 'coverage and' before 'representativeness' in this point as the representativeness in this chapter includes the species of animals and the ways they are distributed.

In point 2) *a*), the Code Commission disagreed with a Member Country proposal to make editorial changes as it did not improve the clarity. In response to another Member Country proposal to make reference to target species, the Code Commission requested OIE Headquarter to seek opinions from the Biological Commission and the Scientific Commission on the proposal.

The Code Commission disagreed with a Member Country proposal to make changes in relation to pooled samples as it does not add further clarity.

In point 2) b), the Code Commission disagreed with a Member Country proposal to add data validation as it confirmed that data management includes data validation and there is no need to specify it explicitly. The Code Commission also disagreed with a Member Country proposal to delete the words 'particularly for data involving wildlife' as the survey of wildlife often requires the involvement of other Competent Authorities and hence needed to be noted.

In point 3), in response to a Member Country proposal to change the subtitle to 'Surveillance evaluation', the Code Commission disagreed because the content of the paragraph is about quality assurance approach.

Article 1.4.4.

The Code Commission disagreed with a Member Country proposal to make editorial changes in the paragraph 1 as it agreed with the *ad hoc* Group on surveillance that this is more understandable.

In point 2) b) i) Objective, in response to a Member Country comment on the application of risk factor, the Code Commission proposed editorial changes to add the words 'probability-based' in the second sentence and considered the proposals from the Scientific Commission to make necessary changes to add 'Those weights should be underpinned by relevant scientific evidence and should'. In response to Member Countries comments to avoid misunderstandings as non-probability-based sampling is by definition not representative of the target population, the Code Commission added 'can be considered as' as non-probability-based sampling may not be representative of the target population and deleted the following sentence to improve the clarity.

In point 2) *b) iii)* Sample selection, in response to a Member Country comment to add the word 'risk' in probability-based sampling methods, the Code Commission agreed and added the words 'risk-based sampling'.

In point 3), the Code Commission made editorial amendments in response to Member Country comments on risk-based methods and deleted the words '(e.g. large economic losses or trade restrictions)' as it is important to keep all aspects of risk assessment in this point, including consequence, but not to give specific examples. In response to a Member Country comment on justification for surveillance techniques, the Code Commission disagreed as the objective of surveillance deals with the consequence of disease not only the presence of disease related to declaration of the disease free status.

In point 4), Member Countries proposed to replace the words 'Competent Authority' with 'Veterinary Authority' for consistency, but the Code Commission disagreed, as an authority other than the Veterinary Authority could be the responsible authority in the slaughterhouse.

In point 5), in response to Member Country comments on the last sentence on 'sentinel units', the Code Commission amended the point for clarity. The Code Commission and the Scientific Commission agreed to accept Member Countries proposals to insert 'or re-emergence'.

In point 7), in response to a proposal of a Member Country to delete the last sentence on software, the Code Commission agreed to delete it as the sentence is about data management, which is not relevant to the syndromic surveillance, but move it in point 2) b) of Article 1.4.3.

In point 8) b), the Code Commission noted the proposal of a Member Country to make reference to laboratory investigation records and added 'in particular for retrospective studies' to improve clarity.

In response to Member Countries proposals to include a new sentence on valid analysis of data, the Code Commission and the Scientific Commission agreed to add the words 'quality control and quality assurance systems, including'. The Code Commission disagreed with a Member Country comment on the list of specimen surveillance, as it did not add clarity to the text and was too prescriptive.

In response to Member Countries proposals to include published data and grey literature in point 8) g) Additional supporting data, the Code Commission noted that all the data listed in this point can come from published data or grey literature but it is not necessary to articulate in the *Terrestrial Code*. However, the Code Commission amended the subtitle of point 8) to read 'Other useful data' to improve the clarity.

Article 1.4.5.

The Code Commission disagreed with a Member Country proposal to move the definition of 'early warning systems' to the Glossary as the parts of early warning systems that have been moved to the surveillance chapter are the recommendations which are not stated in the Glossary and it is more appropriate to have the detailed information in the surveillance chapter.

The Code Commission disagreed with Member Countries proposals to move the second paragraph of draft Article 4.Y.4. on Surveillance and early warning systems to this chapter, as some parts of this article are not relevant to early **warning** systems but early **action**. However, the Code Commission agreed to move the sentence on the case confirmation from draft Article 4.Y.4 to this chapter.

In point 1), the Code Commission did not accept the comment of a Member Country to reference 'representative coverage', as representative coverage is relevant to statistical sampling while the point here is about the presence, tools and actions of *Veterinary Services* to understand the sanitary situation of the animal population.

In point 4), the Code Commission disagreed with the proposal of a Member Country to include the words 'unusual animal health incidents including', as this is already included in point 3) above. The Code Commission accepted the proposal of a Member Country to include the words 'veterinarians and other'.

The Code Commission and the Scientific Commission disagreed with a Member Country comment on deleting point 4), as notifiable diseases and emerging diseases are compulsory to report to the OIE. However, the Code Commission accepted the proposal of several Member Countries to delete all the indents in point 4) and amended the text to add 'including the description of the findings'.

In point 5), the Code Commission accepted the proposal of Member Countries to delete all the indents as the list is not exhaustive and can be considered to be too prescriptive. However, the Code Commission noted that it is an important aspect in early warning systems and added the words 'in order to confirm the case and to acquire accurate knowledge of the situation for further action:'.

In point 7), the Code Commission disagreed with the proposal of a Member Country to amend 'a national chain of command' as the national chain of command is under the supervision of the *Veterinary Authority* which covers the *Veterinary Services* including private sectors.

The Code Commission agreed with the proposal of Member Countries to move the second last sentence to the first paragraph of this article and deleted the last sentence as it is already covered in Chapter 1.1.

Article 1.4.6.

The Code Commission and the Scientific Commission disagreed with the proposal of a Member Country to add a paragraph to provide clarity regarding the two types of freedom (self-declaration and official recognition by the OIE), as this is referred in Chapter 1.6. and this chapter deals with surveillance to demonstrate absence of disease regardless of the procedures.

The Code Commission disagreed with a Member Country proposal to retain the subtitle, as it considered the revised subtitle logically fits with the structure of this article.

In response to the proposal of a Member Country to replace the word 'present' with the words 'detected by scientific methods' to improve clarity, the Code Commission disagreed and noted that if the agent is detected the country is not free and the sentence is to demonstrate statistical freedom that is based upon the presumed level of prevalence.

The Code Commission disagreed with Member Countries proposals to insert the words 'where applicable' after 'as indicated' as it is implicit in the relevant chapters.

In point 2) a) iii), the Code Commission disagreed with a Member Country proposal to retain the proposed deleted text to ensure clarity, as this point concerns all types of susceptible animals.

In point 2) *a)* iv), the Code Commission and the Scientific Commission disagreed with a Member Country proposal to reinstate this point, as unless otherwise specified in the relevant listed disease-specific chapters, vaccination of animals does not affect the status of the country or zone and should not disrupt trade. The Code Commission disagreed with the same Member Country proposal to reinstate some points as disease reporting is already covered in other points.

In point 2) *a) iv)*, the Code Commission disagreed with a Member Country proposal to add a point on the wildlife because this is already covered in the relevant disease-specific chapters.

In point 2) b) Historical freedom, the Code Commission agreed with the Scientific Commission's request to add new points regarding claiming historical freedom.

In point 2) b) iii), the Code Commission and the Scientific Commission disagreed with the proposal of a Member Country to replace '25 years' with '10 years', as the provision in point 2) b) iii) depends only on the detection of occurrence of a disease, while the provision under point 2) b) i) is more stringent and requires much more efforts for a country to gather evidence to claim freedom.

In point 2) *c) ii)*, the Code Commission and the Scientific Commission disagreed with the proposal of a Member Country to add text on a minimum frequency, as it is already included in Article 1.4.3. In response to the editorial proposal from Member Countries to improve the clarity of this point, the Code Commission deleted "if exists" as "relevant chapter" is enough to explain that some chapters include pathogen specific surveillance and others do not.

In point 3) b), the Code Commission disagreed with the proposal of several Member Countries to improve clarity, as it is already included in Article 1.4.3. The Code Commission agreed on other editorial proposals from Member Countries to improve the clarity of this point.

In point 4) c), in response to a Member Country proposal to add the word 'compartment' after 'a country or zone', the Code Commission disagreed as this is about the maintenance of freedom for a country or zone that has achieved freedom, and for a compartment Chapter 4.4. on Application of compartmentalisation could be used. The Code Commission also disagreed with a Member Country proposal to retain the proposed deleted text to ensure clarity, as this point concerns all types of susceptible animals.

The revised Chapter 1.4. is attached as <u>Annex 8</u> for Member Country comments and is proposed for adoption at the 87th General Session in May 2019.

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 8.

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

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

In response to several Member Countries comments on the standard operating procedure (SOP) for self-declaration, the Code Commission noted that it should be discussed with the Scientific Commission because the OIE's SOP for submission of a self-declaration of disease freedom is not a

part of the *Terrestrial Code*, but a **procedure** related to the work of the Scientific Commission and the OIE Headquarters. The Code Commission also noted that Article 1.1.5. is related to the notification of the absence of diseases, and therefore has a relationship to the procedure regarding disease free country or zone (see Agenda Item 7.1.b), and it proposed to consider whether the article should be moved to Chapter 1.6. in its next meeting in February 2019.

Article 1.6.1.

The Code Commission disagreed with a Member Country proposal to include a reference to Article 1.4.6. on Surveillance for freedom from an infection or infestation in the first sentence, as this chapter is about the procedure for self-declaration and not the conditions to be met by Member Countries.

In response to editorial amendments from several Member Countries in paragraph 2, the Code Commission disagreed, as they do not add clarity to the text. The Code Commission clarified that the term 'relevant chapter' means not only the listed-disease chapters but all relevant chapters of the *Terrestrial Code*.

In response to Member Countries comments on footnotes of specific URLs in the *Terrestrial Code*, the Code Commission requested that the OIE Headquarters include a hyperlink only in the OIE web version once it is adopted.

The Code Commission disagreed with a Member Country proposal to replace the word 'disease' with 'infection/infestation' because the use of disease here means any disease and includes diseases that are not listed or do not have a specific chapter in the *Terrestrial Code*.

In response to a Member Country proposal to add text for specific surveillance the Code Commission did not agree because the surveillance referred to is not specific and it could be any general surveillance.

The Code Commission disagreed to delete the words 'of freedom for from' after 'self-declarations' because it does not add value, but accepted comments to replace '1.6.1bis.' with '1.6.2.'.

Article 1.6.2.

In response to several Member Countries comments to add the words 'and endorsement' after 'Official recognition' and other editorial changes, the Code Commission amended the article for clarity.

In response to Member Countries proposals to remove the reference to risk status of BSE, the Code Commission noted that BSE chapter is now being revised by the OIE taking into account all Member Countries comments.

The Code Commission agreed with Member Countries comments regarding possible discrepancies between the wording in points a), c), d), e) and f) and the new chapters 1.7., 1.9., 1.10., 1.11. and 1.12., and noted that the Code Commission along with the OIE Headquarters will look at the possible discrepancies to ensure alignment with the *Terrestrial Code* convention for naming diseases.

The Code Commission accepted a Member Country comment to add the words 'of status' after 'official recognition'.

The Code Commission accepted Member Countries comments to reinstate the parentheses after the chapter numbers for clarity and readability.

The Code Commission also accepted editorial comments on the last paragraph.

The revised Chapter 1.6. is attached as **Annex 14** for Member Country comments.

EU comment

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

With reference to the EU comment in Annex 20, we request that Article 1.1.5. be moved to this chapter before its revision is finalised.

Further comments are inserted in the text of Annex 14.

5.4. Draft new chapter on official control of listed and emerging diseases (Chapter 4.Y.)

Comments were received from Australia, Canada, China, Colombia, Malaysia, New Caledonia, Singapore, Switzerland, Thailand, EU and AU-IBAR.

Title

The Code Commission continued to use official control in the title, but it proposed to address concerns from a Member County by adding new text on the purpose of the chapter in Article 4.Y.1.

In response to a Member Country proposal to make a reference to 'official control programme', the Code Commission disagreed as 'official control programme' is a defined term in the Glossary and "means a programme which is approved, and managed or supervised by the Veterinary Authority of a Member Country for the purposes of controlling a vector, pathogenic agent or disease by specific measures applied throughout that Member Country, or within a zone or compartment of that Member Country."

Article 4.Y.1.

Paragraph 1, in response to a Member Country proposal to replace 'listed' with 'notifiable', the Code Commission disagreed, as the sentence is to specify that this chapter could be used for diseases other than listed diseases. In response to the same Member Country proposal to replace the words 'the likely impact of the disease' with 'cost-effective risk reduction', the Code Commission disagreed as cost effectiveness is already covered in the paragraph 4.

The Code Commission did not accept a proposal from a Member Country to add the words 'and/or eradication' after 'long-term control', as this is not the objective of this chapter and not relevant to this point. However, the Code Commission made amendments for clarity and consistency.

Paragraph 2, the Code Commission accepted a Member Country proposal to make an editorial change.

The Code Commission also added a new sentence on the purpose of the chapter as "Although this chapter focuses primarily on *listed* and *emerging diseases*, the recommendations may also be used by the *Veterinary Authorities* for any *notifiable diseases* or diseases against which they have established *official control programmes*." to make it clear that the chapter could be used for any notifiable diseases.

Paragraph 4, the Code Commission accepted a proposal from a Member Country to replace the word 'They' with 'Official control programmes' for clarity. The Code Commission also agreed to add the word 'preferably' and delete 'when possible', and add 'should' in the last sentence, for clarity.

Paragraph 6, the Code Commission proposed amendments to the paragraph to add the list of the components of an official control programme addressing the comments of a Member Country and the Scientific Commission. The Code Commission added the words 'critical...for diseases that are not present in the Member Country are measures to prevent the introduction' for better understanding and clarity and deleted the last sentence as it is already covered in the added list.

Article 4.Y.2.

In point 2), the Code Commission accepted a Member Country proposal to replace the word 'power' with 'authority'.

The Code Commission considered a Member Country suggestion to add 'hiring additional technical and professional staff if necessary' after 'epidemiological enquiries' and agreed to include a new point on 'sources of financing for dedicated supportive staff'.

In regard to the concerns raised by several Member Countries on the added words 'or for losses incurred due to movement restrictions', the Code Commission clarified in the text that these losses were not incurred due to international trade but as a result of movement restrictions imposed by the control programme. The Code Commission emphasised that not to give a compensation to affected farmers could be used as an excuse for an illegal movement of commodities.

In point 3), the Code Commission agreed with a Member Country proposal to make a reference to 'assess risks and prioritize actions' and replaced the word 'identify' with 'assess'.

The Code Commission disagreed with a Member Country proposal to add the words 'and/or animal products' after 'testing of animal', as samples could be any parts taken from the animals.

The Code Commission proposed amendments to the second last indent to replace the words 'compulsory emergency' with 'implementation of' and add 'programme' after 'vaccination', in order to address the concerns that this chapter is for all kind of situations not only for emergencies.

The Code Commission disagreed with a Member Country proposal to add new point related to a good communication protocol, as this is too specific to an emergency situation.

The Code Commission made amendments on the last indent to take into account comments of Member Countries and the Scientific Commission.

Article 4.Y.3.

The Code Commission made amendments to the subtitle to read 'Emergency preparedness' and paragraph 1, as this article is describing the emergency situation and there is a need to mention the occurrence of a disease that is not present in the country or zone or sudden increase of a disease that is present.

Point 1), the Code Commission disagreed with Member Countries proposals to make a reference to prioritisation, as this is already covered in the paragraph.

Point 3), the Code Commission agreed with the proposal of a Member Country to include the words 'and other relevant agencies' after 'neighbouring countries'.

Article 4.Y.4.

The Code Commission accepted Member Countries proposal to amend the subtitle to read 'Surveillance and early warning systems' for consistency with draft Article 1.4.5. and revised the paragraph to add the words 'are an integral component of emergency preparedness' after 'Early warning systems'.

In response to Member Countries proposal to move some of the information contained in the paragraph to Article 1.4.5., the Code Commission agreed that the first three sentences from the new text to be moved to point 5) of Article 1.4.5.

The Code Commission accepted Member Countries proposal to add the words 'at least' before 'the implementation' and made additional amendment to improve clarity.

Article 4.Y.5.

The Code Commission made amendments to the subtitle to read 'General considerations for outbreak management' for clarity.

The Code Commission agreed with a Member Country proposal to add a new point as point 1) on epidemiological investigation.

The Code Commission made an amendment to include the word 'commodities' after 'animal'.

The Code Commission disagreed with a Member County proposal to add a new point related to surveillance and tracing, as it agreed with the Scientific Commission's opinion that this is not relevant and surveillance and tracing is not meant to stop the spread of infection.

The Code Commission agreed with a proposal of a Member Country to include the words 'control of vectors' as a new point.

Article 4.Y.6.

The Code Commission thanked Member Countries who submitted a proposal for a definition of animal products. In response to a clarification request from a Member Country, considering the below definition of 'commodity' in the Glossary, the Code Commission proposed to replace the words 'animal products' with 'other commodities' in the subtitle for clarity.

COMMODITY

means live animals, products of animal origin, animal genetic material, biological products and pathological material.

The Code Commission agreed with the proposal of a Member Country to make a reference to vectors, as it can cause indirect infection. In response to other Member Country proposal to include people themselves as a fomite, the Code Commission agreed, as this was relevant to this article. The Code Commission proposed to delete the words 'active' and 'effectively' taking another comment from the same Member Country into account.

The Code Commission accepted a Member Country proposal to replace the word 'infection' with 'transmission of pathogenic agents', as this was relevant to cause indirect infection.

In response to Member Countries proposal to replace the words 'contagious disease(s)' with 'infectious disease(s)' consistently throughout the chapter, the Code Commission proposed to use the word 'transmissible' instead of 'contagious' as it could encompass both meanings of 'contagious' and 'infectious'. The Code Commission also requested the OIE Headquarters to seek an opinion from the Scientific Commission as to whether it agreed with the proposed change.

The Code Commission accepted Member Countries proposals to include 'of animals' after 'culling' and replace 'their products' with 'other commodities' for clarity.

In point 1) Stamping-out policy, Code Commission agreed with a Member Country proposal to delete the words 'include all establishment of' before 'a defined *zone*', as to allow the inclusion of wildlife as well as farmed populations. The Code Commission also agreed with another Member Country proposal to include a new sentence "Depopulation and carcass disposal can be applied to *wildlife* within a defined *zone*, based on the assessment of associated *risks*." as the paragraph 4.

In response to a Member Country request for clarification on transportation of animals, the Code Commission confirmed that the words 'slaughtered animals' means that the animals are slaughtered in an approved and dedicated slaughterhouse.

In point 2) Test and cull, the Code Commission disagreed with a Member Country proposal to amend the title to include 'selective killing and disposal' as these words mean partial stamping-out in the OIE World Animal Health Information System (WAHIS) and are not relevant to this point.

The Code Commission agreed with a Member Country proposal to make a reference to the change of design strategy as the disease prevalence changes.

Article 4.Y.7.

The Code Commission disagreed with a Member Country proposal to add the word 'or disinsection' after 'vectors', as the protection of vectors does include possible disinsection.

Article 4.Y.8.

In response to Member Countries proposal to add text on disinsection, the Code Commission agreed and proposed amendments to add a new sentence "Disinfection and disinsection should be applied in accordance with Chapter 4.13". Meanwhile, the Code Commission noted that Chapter 4.13. needed to address disinsection and agreed to include this item into its work programme.

Article 4.Y.9.

The Code Commission proposed amendments to replace the word 'produced' with 'induced' in response to Member Countries comments and to improve clarity. In response to the same Member Countries proposal to replace the word 'strategies' with 'strategy', the Code Commission agreed for correct grammar.

The Code Commission agreed with the proposal of Member Countries to include a reference that the vaccination is to be used to reduce clinical signs or economic losses in this article.

The Code Commission made other amendments for clarity and consistency with Chapter 4.17.

Article 4.Y.10.

The Code Commission made an amendment in the first paragraph, for clarity.

Article 4.Y.11.

The Code Commission made amendments on the subtitle to read 'Communication' and in the second sentence, for clarity.

Article 4.Y.12.

The Code Commission made minor editorial amendments to improve the clarity of this article.

The revised draft Chapter 4.Y. is attached as **Annex 15** 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 15.

5.5. Draft new chapter on introduction to recommendations for disease prevention and control (Chapter 4.Z.)

Comments were received from Argentina, Australia, Canada, China, Japan, South Africa, Switzerland, EU and AU-IBAR.

In response to Member Countries requests for clarification on the reason for not including non-infectious diseases in the first sentence, the Code Commission amended the text to replace the word 'infectious' with 'transmissible' for clarity and consistency with the title.

In paragraph 6, the Code Commission disagreed with a Member Country comment to add reference to 'cost effective risk reduction' as this is already covered in the definition of 'risk analysis' which includes cost and economic factors.

In response to several Member Countries comments on the indents, the Code Commission updated and amended the text for clarity and completeness.

In response to Member Countries comments to add the words 'sufficiently competent' before 'veterinarians and veterinary paraprofessionals', the Code Commission disagreed as the meaning of competency is already included in the definition of veterinarians.

In response to a Member Country comment to propose the inclusion of media in the indents, the Code Commission disagreed as it was already covered in the effective awareness.

The Code Commission disagreed with a Member Country proposal to include 'capacity to set clear objectives and targets' in the indents, as it was too specific and the Code Commission meant it to be broader and more general to the topics.

In response to Member Countries comments to add the words 'neighbouring countries or' before 'regional cooperation', the Code Commission disagreed as neighbouring country is included in regional countries.

The revised draft chapter 4.Z is attached as <u>Annex 9</u> for Member Country comments and is proposed for adoption at the 87th General Session in May 2019.

EU comment

The EU supports this new chapter.

5.6. Draft new chapter on animal welfare and laying hen production systems (Chapter 7.Z.)

Comments were received from Australia, Canada, China, Costa Rica, Guatemala, Japan, New Caledonia, New Zealand, Norway, Singapore, Switzerland, Thailand, USA, EU, AU-IBAR, ICFAW and IEC.

The Code Commission considered the report of the *ad hoc* Group on Animal Welfare and Laying Hen Production Systems which met from 6 to 8 March 2018. The Code Commission focused its attention on reviewing the content of the draft articles, noting that it would undertake a more thorough review of the structure of the chapter once the text is finalised.

The Code Commission highlighted that the *ad hoc* Group had considered all Member Country comments and that the report provides detailed justifications for the proposed amendments to the draft chapter. Therefore, the report of the Code Commission will only note proposals that differed from the *ad hoc* Group. Consequently, the Code Commission emphasised the importance of reading the *ad hoc* Group report in conjunction with this report in order to understand the rationale for amendments made. The Code Commission also made some minor amendments throughout the chapter to improve grammar and clarity. The Code Commission requested that comments regarding issues of translation in the Spanish version be addressed by OIE Headquarters.

Article 7.Z.1.

The Code Commission excluded breeding hens from the definition for 'laying hen' to clarify which bird categories this chapter covers.

Article 7.Z.2.

The Code Commission added a new sentence in the first paragraph to highlight that only commercial laying hen production systems are included in the scope of this chapter; pullets and hens kept in backyards are not addressed in this chapter.

Article 7.Z.3.

Terminology used in this chapter such as 'criteria' and 'measurable', 'laying hen' and 'hen', and 'good welfare' and 'positive state of welfare' were amended, where relevant, to ensure alignment with other animal welfare chapters in the *Terrestrial Code*.

In point 7) Mortality, culling and morbidity rates, the Code Commission deleted the word 'recorded' from this point as they considered that this article addresses criteria (or measurable) and indicators should be included in the recommendations article.

In point 8) Performance, d) and e) were edited by the Code Commission to provide examples as to how egg production quality and downgrades can be measured.

In point 9) Plumage condition, the Code Commission added the word 'injurious' to feather pecking to ensure consistency with other articles as feather pecking behaviour can also be considered as a normal behaviour in some circumstances.

In point 10) Water and feed Consumption, the Code Commission deleted references to signs and symptoms as it considered these to be indicators that are addressed in Article 7.Z.8. as animal-based measurable.

Article 7.Z.7.

The Code Commission reinstated the item 'production system' as it considered that the type of production system is a factor that can influence space allowance.

Article 7.Z.8.

The Code Commission deleted the word 'aggression' as an animal-based measurable, as aggression is considered as a behaviour and as such is not a measurable factor.

The list of criteria was amended to ensure harmonisation with other animal welfare chapters in the *Terrestrial Code*.

Articles 7.Z.12. and 7.Z.13.

The Code Commission made some editorial changes in the first paragraph to ensure consistency with the terminology used in other animal welfare chapters of the *Terrestrial Code*.

Article 7.Z.15.

The Code Commission deleted the recommendation from the first paragraph that 'thermal environment parameters' should be consulted in management guidelines provided by breeder companies as they considered this information was not appropriate for the chapter.

Article 7.Z.17.

The Code Commission reworded the fourth paragraph for consistency with the terminology used in other chapters of the *Terrestrial Code*.

Article 7.Z.20.

The Code Commission agreed that induced moulting can lead to animal welfare problems, and highlighted this by adding a sentence in the first paragraph.

Article 7.Z.21.

This article was reviewed by the Code Commission to harmonise the terminology used in other *Terrestrial Code* chapters.

Article 7.Z.24.

The Code Commission added a new sentence to emphasise the need to humanely kill injured or sick pullets or hens, as soon as possible and in accordance with Chapter 7.6.

Article 7.Z.25.

With respect to using the mortality rate as an animal-based measure during depopulation or arrival at destination, the Code Commission agreed to exclude any mention of the stage at which it should be carried out, as this criterion could also be measured in other situations.

Article 7.Z.26.

The Code Commission edited the first paragraph to improve its readability.

Article 7.Z.29.

The Code Commission highlighted that production systems should be designed and maintained to prevent access by predators and wild birds.

Finally, regarding the proposal of the *ad hoc* Group to reorder the articles of the chapter to have a more fluid structure, the Code Commission decided to postpone this discussion until their next meeting.

The revised new Chapter 7.Z. is attached as **Annex 16** for Member Country comments.

EU comment

The EU thanks the OIE for its work on the revision of this new draft chapter and for taking several of the EU comments into account.

The EU can support the proposed changes and has some additional comments. Furthermore, the EU would like also to reiterate some of its previous comments.

Comments are inserted in the text of Annex 16.

The report of the ad hoc Group is attached as **Annex 22** for Member Countries information.

5.7. Draft new chapter on killing of reptiles for their skins, meat and other products (Chapter 7.Y.)

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

The Code Commission commended the work of the *ad hoc* Group on killing of reptiles for their skins, meat and other products which was conducted electronically during August 2018. Given that the *ad hoc* Group report provides detailed justifications for the proposed amendments to this chapter, this report will only note proposals made by the Code Commission that differed from the proposals of the *ad hoc* Group. Consequently, the Code Commission highlighted the importance of reading the *ad hoc* Group report in conjunction with this report in order to understand the rationale for amendments made.

The Code Commission also made amendments throughout the chapter to improve grammar and clarity and requested that comments regarding issues of translation in the Spanish version be addressed by OIE Headquarters.

Article 7.Y.3.

Point 2) on Competency and training of the personnel, the Code Commission did not agree with the proposal that animal handlers should be responsible for monitoring the effectiveness of the stunning process as they considered this activity should be conducted by more specialised staff. The Commission amended the text accordingly.

The Code Commission did not agree with amendments to the third bullet point related to the behavioural aspects to be taken into account when handling, restraining, stunning and killing reptiles and amended the text to improve readability.

Article 7.Y.7.

The Code Commission did not agree with the *ad hoc* Group proposal to add a new bullet point regarding unacceptable practices during restraint as they considered that this addition did not improve clarity.

Article 7.Y.9.

Regarding recommendations for the effective use of electrical stunning, the Code Commission agreed to modify the fifth bullet point to include some aspects that may vary the length of time of application of the current for a correct stunning procedure.

The revised new Chapter 7.Y. is attached as <u>Annex 10</u> for Member Country comments and is proposed for adoption at the 87th General Session in May 2019.

EU comment

EU comment

The EU thanks the OIE for its work and for taking the majority of the EU comments into account.

We in general support this draft new chapter and have a few additional comments that are inserted in the text of Annex 10.

The report of the *ad hoc* Group is attached as **Annex 23** for Member Country information.

5.8. Infection with rabies virus (Chapter 8.14.)

Comments were received from Australia, Canada, China, Chinese Taipei, Japan, New Caledonia, New Zealand, EU, AU-IBAR and ICFAW.

In response to a Member Country comment on the naming of the rabies virus, the Code Commission disagreed and noted that the term lyssavirus is not a common name. It noted that the explanation had been already given in the report of *ad hoc* Group on rabies.

Extract of the report of November 2017 ad hoc Group on rabies

"The Group noted that the current internationally accepted taxonomic name that refers to the former classical rabies virus, genotype 1, is "Rabies lyssavirus" (ICTV, 2015). The Group also emphasised the role of Rabies lyssavirus as responsible for the vast majority animal and human rabies cases. The Group pointed out that lyssavirus species other than Rabies lyssavirus may also cause the disease, but have more restricted geographical distribution and host range, and that public health consequences are limited.

The Group consulted an expert from the International Committee on Taxonomy of Viruses, and concluded that the common name of the pathogenic agent, formerly named as "classical rabies virus, genotype 1", should be maintained as "rabies virus" throughout the chapter.

The Group discussed the need to include other Lyssavirus species in the case definition. The public and animal health impact of other Lyssavirus species and the notification implications were discussed. The conclusion was that for the purposes of the Terrestrial Code, a rabies case should remain as any animal infected with rabies virus only."

The Code Commission understood in principle but disagreed with a Member Country comment on the possible misunderstanding on the necessity of post-exposure vaccination in humans. It noted that the comment is more related to public health issues and not relevant in the chapter.

Article 8.14.1.

The Code Commission disagreed with Member Countries proposal to add "group of" before "diseases" in the first sentence. The Code Commission agreed with the Scientific Commission not to accept this proposal, as it is well accepted in international rabies community that rabies is indeed not a group of diseases but a unique disease, even if caused by different viruses.

In response to Member Countries comments on replacing the second sentence of the first paragraph with a new sentence taken from the International Committee on Taxonomy of Viruses stating that bats are the principal reservoir hosts for most lyssaviruses, while agreeing in general sense, the Code Commission disagreed noting that in many regions carnivore populations are considered to play the role of reservoir. However, the Code Commission replaced the word 'Members' with 'Populations' in the beginning of the second sentence to improve clarity.

In response to a proposal of Member Country to add the words 'is present in many countries and territories' and delete 'found worldwide', the Code Commission partially agreed to replace the word 'worldwide' with 'in most parts of the world'. In response to a Member Country proposal to add the word 'infected', the Code Commission disagreed noting that it is implicit.

The Code Commission agreed to Member Countries proposal to add the words 'the taxonomic prototype species in the Lyssavirus genus' for more clarity in the beginning of the second paragraph.

In regard to other lyssavirus species in the third paragraph, the Code Commission agreed to make editorial changes. To be clear about other lyssavirus, the Code Commission agreed with the Scientific

Commission and proposed to relocate the seventh paragraph of this article to paragraph 4 and made further editorial changes for clarity and readability.

In response to Member Countries comment related to the incubation period, the Code Commission made it clear that the incubation period depends on viruses, hosts and sites of entry and made editorial changes.

In response to a Member Country request to delete the sentence related to the infective period and to add a new sentence on description of clinical symptoms, the Code Commission disagreed noting that the description of infective period is important to certification and clinical symptoms can be referenced in the *Terrestrial Manual*. The Code Commission agreed with the Scientific Commission to replace 'through' with 'last until' following Member Countries question on the meaning of 'and through death'.

The Code Commission agreed to delete the word 'the' before the 'rabies virus' in the first indent of eighth paragraph. In regard to the second indent about the need to define 'dog population', the Code Commission agreed with the Scientific Commission to add '(Canis familiaris)' and made changes to clarify the definition of 'dog-mediated rabies'.

In response to Member Countries comment on the term of epidemiological studies, the Code Commission agreed with the Scientific Commission and noted that there is no need to provide further details. The objective of an epidemiological study is to provide evidence of the virus circulation in dog population and it is maintained in dog population independent from other species.

Article 8.14.2.

In point 1) b) and c), the Code Commission disagreed with Member Countries proposal to address animals not showing clinical signs in a free country or zone and to merge both points or move point b). The Code Commission noted that point 1) b) is for compulsory reporting of clinical signs and point 1) c) deals with the investigation of suspected cases.

In point 1) c), the Code Commission disagreed with Member Countries proposals to make editorial changes as it did not improve the clarity of the text.

In point 1) *d*), the Code Commission agreed with a Member Country comment to add the words 'infection with' and 'virus'. In response to a request for clarification from another Member Country, the Code Commission clarified that other relevant recommendations for the prevention of rabies can be found in Sections 4, 5 and 7 of the *Terrestrial Code*.

The Code Commission reinstated point 5) to state "if an imported case is confirmed outside a quarantine station, epidemiological investigations have ruled out the possibility of secondary cases" to address the possibility of the issue of imported cases in relation to the maintenance of free status.

In response to Member Countries comments, the Code Commission agreed with the Scientific Commission to make a reference to the meaning of preventive vaccination in Chapter 4.17.

In point 2), the Code Commission agreed with the Scientific Commission to delete 'at risk' as it does not add any value to this provision.

In point 3), the Code Commission amended the text to improve its clarity.

Article 8.14.2ter

In point 1) *a*), the Code Commission added the words 'in the entire country' after 'notifiable disease' to improve clarity and for consistency with other disease-specific chapters.

In point 1) b), in response to Member Countries comments on adding wildlife in the reporting of animals and need to specify the target animals subject to each sub-paragraphs a) and d), the Code Commission disagreed as the animals include all animals and the text is meant to assess the status of the dog population not other populations. The Code Commission agreed to delete 'control' as it is not part of the surveillance programme to prove the freedom from dog-mediated rabies. The Code

Commission also agreed to unitalicise the term 'early warning system' as the definition is not yet adopted in the Glossary.

In point 1) c), the Code Commission agreed with Member Countries proposal to make editorial changes. In response to another Member Country comments to make a reference to Article 8.14.9., the Code Commission agreed to replace it with 'including Articles 8.14.4. to 8.14.7.'.

In point 1) *e*), the Code Commission agreed with the Scientific Commission to add the word 'dog population control programme has been implemented and maintained'.

In point 2), in response to Member Countries comments to add the words 'except stray dogs' after 'wildlife', the Code Commission partially agreed to replace the word 'wildlife' with 'wild animals' in order not to exclude feral dogs from dog-mediated rabies.

Article 8.14.4.

The Code Commission agreed with Member Countries comments to add the words 'or zone' at the end of the first sentence of Point 2) *a*).

Article 8.14.5.

The Code Commission accepted comments of a Member Country to improve the clarity of point 3) *a*). It did not accept a proposal of Member Countries to replace 'one month' with 'six months' in the same point. The Code Commission clarified that animals can be protected by vaccination and if animals show antibody titres of at least 0.5. IU/ml they are safe to trade. The Code Commission added the words 'not more than 12 months prior to shipment' after 'vaccinated or revaccinated' and added the words 'after the last vaccination' after '12 months'.

In response to comments from an organisation to replace 'six months' with 'four months', the Code Commission disagreed as the incubation period is already defined in the chapter.

Article 8.14.6.

In response to many Member Countries comments to amend the article, the Code Commission took the Scientific Commission's opinion into account and proposed to keep only import requirements for other members of the order Carnivora and members of the order Chiroptera and not to recommend vaccination in trade because there is no known protocol for vaccination nor validated serological tests for species other than dogs. The Code Commission also proposed to replace the words 'susceptible animals' with the words 'members of the order Carnivora and of the members of the order Chiroptera' in the subtitle. The Code Commission proposed to delete the points 2) b) and 3) and add the words 'separation from susceptible animals was maintained and where' in point 2).

Article 8.14.7.

In response to a Member Country question on the deletion of the words 'of rabies', the Code Commission noted that a case is defined in the chapter and it is implicit.

In response to Member Countries comments to add the word 'susceptible' before 'laboratory animals' as only certain species of laboratory animals are susceptible to rabies, the Code Commission agreed with them. In response to the same Member Countries comments on the reference to the specific chapters of the *Terrestrial Manual*, the Code Commission agreed and made the respective amendment.

Article 8.14.8.

In response to Member Countries comments on the need to have a new chapter with a relevant questionnaire in Section 1 of the *Terrestrial Code*, the Code Commission agreed with the Scientific Commission and it confirmed that such chapter with the questionnaire would be developed before the adoption of this revised chapter, and a reference of it would be included in this article.

In point 1), in response to a Member Country comments to add new text regarding the requirement of having specific legislation, the Code Commission agreed that it is necessary to add legislation

requirement for the Member Country and added the words '(including relevant legislation)' after 'documented evidence' in point 2) and also added the words 'dog-mediated rabies is a notifiable disease and that' in point 3) c).

In point 2), the Code Commission disagreed with Member Countries comments on the nature of the OIE PVS Pathway as the tool is well known as voluntary and the sentence is already using 'may be'.

In point 3), the Code Commission agreed with Member Countries comments to delete the words 'or zone' to avoid confusion.

In point 4) *c*), in response to Member Countries comments on reference to Chapter 7.7. on Stray dog population control, the Code Commission agreed to amend the text.

In point 6) a), the Code Commission agreed with a Member Country comment that the *Terrestrial Manual* deals with vaccine rather than vaccination and added the words 'the vaccines are produced' after 'compulsory and'.

In point 6) b), in response to Member Countries comments on clarification for vaccination, the Code Commission referred the Member Countries to the new Chapter 4.17. on Vaccination. In response to an organisation comments on the need to add the movement of dogs, the Code Commission disagreed because the control of movements of dogs is covered in other articles.

Article 8.14.9.

The Code Commission modified the subtitle to read 'Surveillance', taking into account the specific nature of the description contained in the article.

In point 1), the Code Commission agreed with the Scientific Commission to add the words 'shows any change in behaviour followed by death within 10 days or that' in the second paragraph to improve clarity.

In point 2) b), in response to Member Countries comments to include reference to animals that may be found dead, the Code Commission agreed with the Scientific Commission to add new sentence at the end of first paragraph 'Animals (especially carnivores and bats) found dead are recognised as an important source of information for rabies *surveillance* and should be part of the clinical *surveillance*'.

In point 2), in response to a Member Country comment to add the words 'governmental legislation', the Code Commission disagreed because legislation is already addressed in the previous article.

In point 2) *e*), in response to Member Countries comments to move the last sentence to the official control programme, the Code Commission agreed and developed the new Article 8.14.10. on Cooperation with other Competent Authorities to include this text.

The revised Chapter 8.14. is attached as <u>Annex 11</u> for Member Country comments and is proposed for adoption at the 87th General Session in May 2019.

EU comment

The EU thanks the OIE for having taken many of our previous comments into acount. However, we cannot support this chapter as currently presented unless our serious concern in relation to point 3 a) of Article 8.14.5. is addressed.

Comments are inserted in the text of Annex 11.

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

The Code Commission reviewed advice provided by OIE reference laboratories for lumpy skin disease (LSD) on whether lactose could be included as a safe commodity in this chapter. The Code Commission considered there was still insufficient scientific evidence to include lactose as a safe commodity and requested the OIE Headquarters to seek further information from the relevant industries on the standardised treatment process in order to verify if the treatment inactivates LSD virus. The point was added to the Code Commission work programme.

5.10. Infection with African swine fever virus (Articles 15.1.1bis., 15.1.2., 15.1.3., 15.1.22.)

Comments were received from Australia, China, Colombia, Japan, Switzerland, USA and EU.

The Code Commission recalled that at the General Session in May 2017 the revised chapter was adopted with two countries opposing adoption. The comments of the Member Countries had been taken into account at the September 2017 and the February 2018 meetings, and in response to the proposed changes several Member Countries submitted additional comments.

In response to a Member Country comments to develop a new definition of 'direct human supervision or control' to make specific reference to presence or freedom in *wild* vs domestic pigs, the Code Commission considered the comments from the Scientific Commission and proposed a revised Glossary definition of 'captive wild [animal]' to add 'i.e. population management, regular contacts or handling, feeding, harvesting and *slaughter*,' after 'under direct human supervision or control'.

Article 15.1.1bis.

In regard to the request to replace the words 'F0 value of 3.00 or more' with 'F0 value of 8 or more' in canned meat, the Code Commission, after reviewing the documents from the Codex Alimentarius canning/sterilization Commission (Codex) relating to the of meat (http://www.fao.org/docrep/010/ai407e/AI407E22.htm), noted that Codex defines F-value 3 as "121□ over 3 min, etc." and it also suggests that it could be detrimental for the quality of certain canned goods if they are treated above F-value 4. The Code Commission reconfirmed that the normal process of F value 3 would among others mitigate the ASFV risk and be used in normal industrial process. Thus the Code Commission amended the safe commodity to reflect the wording of 'F-value of 3 or above' used in Codex.

Article 15.1.2.

In point 3), in response to a request of a Member Country to include the words 'and *feral*' after 'captive wild', the Code Commission disagreed as the Veterinary Services have no authority over feral pigs as defined in the Glossary definition of 'feral [animals]'.

Article 15.1.3.

In point 1), the Code Commission and the Scientific Commission did not accept a Member Country proposal to add the words 'or equivalent measures as determined by risk analysis' after '15.1.20.', as equivalence was covered in Chapter 5.3. on OIE procedures relevant to the Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization of the *Terrestrial Code*. However, the Code Commission amended the text to improve the clarity of the sentence.

In point 2), the Code Commission did not accept a Member Country comment to replace the number of years with the number of months as it was not in line with the convention used in the *Terrestrial Code* and would result in inconsistency across the *Terrestrial Code*.

In point 2) c), the Code Commission disagreed with a proposal to add the words 'Pigs and' as the definition of 'commodity' includes live animals and other products.

In point 3) c), the Code Commission deleted the words 'Pigs and' before 'pig commodities' in accordance with the definition of 'commodity'.

In response to a request of several Member Countries to delete the proposed text in Article 15.1.3., the Code Commission agreed as the sentence refers to the trade conditions and not the disease free status. However, the Code Commission added the words 'including *cases* of *infection* with ASFV in *feral* or *wild* pigs' after '1) or 2) above' and 'especially point 7)' after 'Article 15.1.2.' in the paragraph 1 to clarify that a country or zone may under certain conditions be free in domestic and captive wild pigs while having cases in wild pigs, and as such the specific trade requirements for countries or zones free from ASF in domestic and captive wild pigs should be applied, guaranteeing safe trade.

The revised Articles 15.1.1bis, 15.1.2., 15.1.3. and 15.1.22. are attached as <u>Annex 12</u> for Member Country comments and are proposed for adoption at the 87th General Session in May 2019.

EU comment

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

Comments are inserted in the text of Annex 12.

The revised definition of 'captive wild' is attached as **Annex 13** for Member Country comments.

EU comment

The EU thanks the OIE and in general supports most of the proposed changes to the Glossary. However, we do not support the changes proposed to the definition of captive wild animal.

Comments are inserted in the text of Annex 13.

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

The Code Commission noted the ongoing work by the Scientific Commission and the OIE Headquarters on the harmonisation of the provisions for the official recognition and maintenance of disease free status in the *Terrestrial Code* and that this chapter had been revised by the Code Commission in September 2017 but not circulated for Member Country comments.

For the effective management of time, the Code Commission made some amendments that would not be directly subjected to the scope of the ongoing harmonisation work. In particular, the following point was confirmed in this meeting.

Article 15.2.3.

In response to the questions posed by a Member Country in regards to their general concern that the this chapter gave no consideration to the different health status of different countries based on the presence or absence of infection with classical swine fever virus (CSFV) in their wild/feral pig populations, the Code Commission noted that the Scientific Commission had disapproved to add the provision for three types of free status (historical freedom, freedom in all pigs and freedom in domestic and captive wild pigs) in the CSF chapter. The Code Commission agreed to maintain the current text.

The revised Chapter 15.2. is attached as **Annex 17** for Member Country comments.

EU comment

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

Comments are inserted in the text of Annex 17.

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

6.1. Harmonisation of the *Terrestrial Code* chapters on diseases with official status recognition by the OIE

The OIE Headquarters explained to the Code Commission that there are a number of inconsistencies across the chapters on five diseases with official recognition by the OIE in the *Terrestrial Code* and that significant work had been undertaken on proposals to harmonise the requirements for the initial recognition and maintenance of official status.

The Code Commission thanked the OIE Headquarters for its work and noted that it was aware there are some discrepancies in these chapters, but this was mainly due to the differences of timing in updating each chapter and different interests in some chapters such as FMD.

The Code Commission also noted that the disease-specific chapters should only deal with the criteria for the free status and how to demonstrate it, while procedural matters should be included elsewhere. The Code Commission thus requested the OIE Headquarters include all procedural issues in Chapter 1.6. or chapters on disease-specific questionnaires. It also requested that the ongoing revision of the CSF chapter be used to propose amendments related to the maintenance criteria for free status. This should be presented for consideration at its February 2019 meeting.

6.2. Veterinary legislation (Chapter 3.4.)

The OIE Headquarters advised the Code Commission that the *ad hoc* Group on Veterinary Legislation met from 23 to 25 January 2018. The OIE Headquarters noted that the *ad hoc* Group proposed the revision of Chapter 3.4. on Veterinary legislation to include the OIE Biological threat strategy and address some deficiencies and the lack of clarity found in the chapter.

The Code Commission considered the proposed amendments to Chapter 3.4. that the *ad hoc* Group identified and discussed some suggestions on how to address these issues and broadly endorsed the report of *ad hoc* Group.

The Code Commission reviewed the revised chapter and modified it for consistency with the *Terrestrial Code*, for clarity and to improve grammar and readability.

The revised Chapter 3.4. is attached as **Annex 18** for Member Countries comments.

EU comment

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

Comments are inserted in the text of Annex 18.

The report of ad hoc Group is attached as **Annex 24** for Member Countries information.

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

Comments were received from Canada.

The Code Commission noted that there was a longstanding problem for Member Countries to decide on the application of the appropriate conditions between Chapter 4.6. on Collection and processing of bovine, small ruminant and porcine semen and the disease-specific chapters. With these inconsistencies in mind, the Code Commission considered the comments from a Member Country to seek OIE's advice on which chapter the country should follow for the importation of both fresh and frozen porcine semen between Chapter 4.6. and a disease-specific chapter such as Chapter 15.5. on Transmissible gastroenteritis.

In this respect, the Code Commission agreed that strong inconsistencies exist between Chapter 4.6. and some disease-specific chapters. It also noted the revision of Chapter 4.6. was on the work programme of the Code Commission, and the revision of Chapter 4.5 on General hygiene in semen collection and processing centres was also necessary for updates.

The Code Commission requested the OIE Headquarters to seek advice from experts from the relevant OIE reference centres and industry who have expertise on semen collection to revise both Chapters 4.5. and 4.6. together. The Code Commission also emphasised that the current chapters did not cover horse semen and this should be considered in the revised chapters.

6.4. Infection with avian influenza viruses (Chapter 10.4.) including review of the report of the *ad hoc* Group on avian influenza (June 2018)

Comments were received from Australia, Brazil, Canada, Japan, New Zealand, Singapore, Thailand, USA, EU, AU-IBAR, IPC and AVEC & ELPHA.

The Code Commission thanked the *ad hoc* Group on avian influenza for its work to revise Chapter 10.4. on Infection with avian influenza viruses.

The Code Commission reviewed the revised chapter presented by the *ad hoc* Group and made editorial amendments for consistency and to improve the clarity of the text.

The Code Commission noted there was no scientific evidence to substantiate the current three-month recovery period and considered reducing this period to at least 28 days. The Code Commission requested that the OIE Headquarters seek advice from experts on the surveillance requirements to support reducing the minimum recovery period to less than three months. It also discussed the need to consider whether low pathogenicity avian influenza meets the criteria for listing in Chapter 1.3. and requested that the OIE Headquarters seek expert advice in this regard.

EU comment

The EU strongly supports reducing the recovery period from 3 months to 28 days, as experience shows that 3 months is clearly too long a period that leads to significant and unjustified trade restrictions.

Furthermore, the EU urges the OIE to revise chapter 1.3. concurrently with the discussions on Chaper 10.4.

The Biological Commission did not support the movement of the diagnostic diagrams in Article 10.4.33. to the *Terrestrial Manual*, therefore the Code Commission requested the OIE Headquarters to consider putting the diagrams on the OIE website.

The revised Chapter 10.4. is attached as **Annex 19** for Member Country comments.

EU comment

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

The report of the *ad hoc* Group is attached as **Annex 25** for Member Countries information.

7. Other issues

7.1. Update of the Code Commission's work programme

Comments were received from Australia and EU in 86th General Session.

In response to comments from Member Countries pertaining to the Code Commission's work programme, the Code Commission noted the listing of Porcine epidemic diarrhoea virus (PEDV) was already included in its work programme and the disease would be assessed against the criteria for listing by experts. Acknowledging that this is an ongoing work, the Code Commission expected that the results of the assessment would be available soon for its review.

The following items were presented by the OIE Headquarters, with consequences for the Code Commission's work programme.

a) Veterinary Services (Chapter 3.1) and Evaluation of Veterinary Services (Chapter 3.2)

The OIE Headquarters advised the Code Commission that the *ad hoc* Group on Evaluation of Veterinary Services met from 28 to 31 May 2018 to revise the OIE PVS Tool, and the group had recommended to revise Chapters 3.1. and 3.2 to utilise the return of experiences on the PVS Pathway. The *ad hoc* Group will meet again in November 2018 and the report will be available to the Code Commission for its review in February 2019.

The OIE Headquarters explained that the *ad hoc* Group had developed two new critical competencies for the PVS Tool, to address antimicrobial resistance and veterinary clinical services.

The Code Commission agreed with the report of the *ad hoc* Group and requested the OIE Headquarters to share the Terms of References for the next Group for its review. It also discussed with

the OIE Headquarters the definitions of 'Competent Authority', 'Veterinary Authority', 'Veterinary Services' and proposed amendments for clarity and consistencies.

The Code Commission thanked the OIE Headquarters for the update and expressed appreciation for the *ad hoc* Group's work, which it considers will assist many Member Countries to improve Veterinary Services where the PVS Tool plays an important role.

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

The OIE Headquarters explained that there are many inconsistencies when a Member Country reports a case to the OIE using Chapter 1.1. This is especially evident when a final report is submitted to declare an 'event' closed, the confusion appears to be as a result of inappropriate usage of the word 'outbreak' in point 1) b) of Article 1.1.3. The OIE Headquarters also noted that there was a need to provide a definition of 'strain' in the *Terrestrial Code*, as many different meanings are used by Member Countries depending on the diseases.

The Code Commission agreed and proposed to make amendments in points 1), 2) and 3) of Article 1.1.3. to improve clarity and readability. Regarding the definition of 'new strain', the Code Commission agreed with the Biological Commission and the Aquatic Commission that it did not see a need for a definition as it depends on the interpretation of strain and it would relate to a phenotypic change corresponding to a genotypic change that can be diagnosed consistently.

The Code Commission also accepted the comments from the OIE Headquarters to add a new point *d*) of Article 1.1.3. in order to provide a clear reason to notify the recurrence of an eradicated strain of a *listed disease* when there is an ongoing event of the same disease.

The Code Commission reviewed the revised chapter and modified it for consistency with the *Terrestrial Code*, for clarity and to improve grammar and readability.

The Code Commission noted that Article 1.1.5. is not related to the notification but to the disease free country or zone and it proposed to delete the article as it should be better placed in Chapter 1.6. (see Agenda Item 5.3.)

The revised Chapter 1.1. is attached as **Annex 20** for Member Country comments.

EU comment

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

Comments are inserted in the text of Annex 20.

c) Infection with Rift Valley fever virus (Chapter 8.15)

The OIE Headquarters informed the Code Commission that during recent increases in human cases of Rift Valley fever (RVF) in eastern African countries, countries did not submit immediate notifications because of some inconsistencies or gaps found between the RVF chapter and point 1) b) of Article 1.1.3.

The Code Commission agreed that there are difficulties of notification regarding Chapter 8.15., especially when the situation evolves from an inter-epizootic to an epizootic period. The Code Commission requested the OIE Headquarters better align points 6) b) and c) of Article 8.15.1. with Articles 8.15.4 and 8.15.5., possibly including references to point 1) b) of Article 1.1.3. and including the text in Article 8.15.5. by referencing human cases as a consequence of epizootic. The Code Commission requested the OIE Headquarters present a draft revised text in its February 2019 meeting.

d) Stray dog population control (Chapter 7.7.)

The OIE Headquarters noted that as part of the global rabies eradication strategy, there have been discussions within the OIE on the need to update Chapter 7.7. on Stray dog population control to improve responsible dog ownership, monitoring and evaluation of stray dog control schemes. The Code Commission considered the request and with the understanding that rabies control is a priority

area of work for the OIE, it proposed to add the revision of the chapter to its work programme and requested the OIE Headquarters seek expert advice in order to progress with revision of the chapter. The Code Commission emphasised that the chapter is not only for animal welfare issue but also for the disease control purpose such as rabies and echinococcosis and requested the OIE Headquarters that these aspects be considered while selecting the experts for the revision of the chapter.

e) Infection with rinderpest virus (Chapter 8.16.)

The OIE Headquarters advised the Code Commission that during the two regional rinderpest tabletop exercises to test the Global Rinderpest Action Plan (November 2017 and March 2018) and the stakeholder conference (March 2018), concerns were expressed about the provisions of the chapter that were not inclusive of countries that do not wish to slaughter vaccinated animals as a means to recover freedom, after rinderpest re-emergence. It was also noted that, in the event of a re-emergence of the disease, for trade purposes the chapter reverts to the trade requirements in the 2010 edition of the *Terrestrial Code* and reinstate them to the current version, should the provisions for recovery of freedom not be complied within the stipulated timeframe.

The Code Commission agreed with the comments from some Member Countries on the need to update the chapter, and accepted the proposal from the OIE Headquarters to work on the revision of the chapter, in collaboration with the OIE Headquarters, under the advice of the FAO-OIE Rinderpest Joint Advisory Committee (JAC). The OIE headquarters was advised to discuss this issue at the next JAC meeting and submit the outcome of the discussion for review of the Scientific Commission on its next meeting in February 2019.

The Code Commission also requested that the revision work include clarification on the definitions of 'case' and 'suspected case' and the reporting obligations of countries where a suspected case is detected.

f) Request for international trade standards for animal serum products used in cell culture media

The Code Commission thanked a Member Country for submitting its national practice and agreed with Biological Commission that Member Countries should use the *Terrestrial Manual*, especially Chapter 1.1.9. for international trade of animal serum products used in cell culture media.

g) Action arising from February 2018 meeting (definition of "epidemiological unit")

The Code Commission and the Scientific Commission agreed with Member Countries proposals to amend the Glossary definition for epidemiological unit to include the possibility that an epidemiological unit can consist of only one animal, as it can often be the case for equids, and it proposed to add the words 'or, in some circumstances, to a single animal' after 'animal handling facility'.

The revised Glossary definition for epidemiological unit is attached as **Annex 13** for Member Country comments.

EU comment

The EU thanks the OIE and in general supports most of the proposed changes to the Glossary. However, we do not support the changes proposed to the definition of captive wild animal.

Comments are inserted in the text of Annex 13.

h) Revision of Chapter 7.5. Slaughter of animals and Chapter 7.6. Killing for disease control purposes

The Code Commission considered the report of the *ad hoc* Group on the revision of Chapters 7.5. on Slaughter of animals and 7.6. on Killing for disease control purposes which met from 3 to 4 April 2018.

The Code Commission agreed with the modified Terms of Reference and the proposal to restructure the articles, and to review some text and some definitions. The Code Commission requested that the *ad hoc* Group be reconvened to progress this work which will be considered by the Code Commission at its February 2019 meeting.

i) Report of the meeting of the *ad hoc* Group on African animal trypanosomoses (March 2018)

The Code Commission reviewed the report of the ad hoc Group on animal African trypanosomoses noting the work of the ad hoc Group is ongoing (listing of different species of trypanosomoses and development of the surveillance articles), including to give advice on the pending revision of Chapter 12.3. on Dourine and on the draft new chapter on infection with Trypanozoon (surra). The Code Commission agreed to keep the item in the work programme, but to postpone further discussion until the report of the next *ad hoc* Group on animal African typanosomoses and the opinion of the Scientific Commission were available.

j) OIE list of notifiable diseases

The Code Commission discussed once more the need for clarification following comments made by some Member Countries on some listed diseases in revision and on some diseases not listed. It reiterated its request to the Headquarters to seek relevant expertise. The item remains in the Code Commission's work programme.

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

- Revision of definitions of 'Competent Authority', 'Veterinary Authority', 'Veterinary Services', 'Captive wild' and 'epidemiological unit' (see Agenda Item 4.3., 5.10. and 7.1.g))
- Harmonisation of articles of official status recognition by the OIE (see Agenda Item 6.1.)
- Revision of Chapter 1.1. (see Agenda Item 7.1.b))
- Revision of Chapters 3.1. and 3.2. (see Agenda Item 7.1.a))
- Revision of Chapter 3.4. (see Agenda Item 6.2.)
- Revision of Chapter 4.5. (together with Chapter 4.6.) (see Agenda Item 6.3.)
- Revision of Chapter 8.15. (see Agenda Item 7.1.c))
- Revision of Chapter 8.16. (see Agenda Item 7.1.e))
- Revision of safe commodities list to include lactose (see Agenda Item 5.9.).

The updated work programme is attached as **Annex 21** for Member Countries information and comments.

EU comment

The EU thanks the OIE and in general supports the future work programme of the Code Commission. Comments are inserted in the text of Annex 21.

7.2. Date of next meetings

The Code Commission agreed that the date for its next meeting would be 18 to 28 February 2019 in order to facilitate a joint meeting with the Biological Commission and the Scientific Commission in preparation for the 87th General Session of the World Assembly of OIE Delegates.

The Code Commission also discussed the dates for future meetings and asked the Secretariat to schedule them as far as possible on the second and third weeks of September and of February.
/Annexes

Annex 3

CHAPTER 14.4.

INFECTION WITH CHLAMYDOPHILA CHLAMYDIA ABORTUS (ENZOOTIC ABORTION OF EWES, OVINE CHLAMYDIOSIS)

EU comment

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

In addition, we would suggest amending the taxonomy of this infection accordingly also in the OIE list in Chapter 1.3., for reasons of consistency and in order to avoid possible confusion.

Article 14.4.1.

General provisions

For the purposes of the *Terrestrial Code*, enzootic abortion of ewes (EAE), also known as ovine chlamydiosis or ovine enzootic abortion, is an *infection* of domestic sheep and goats by the bacterium *Chlamydophila Chlamydia abortus*.

Susceptible animals become infected through ingestion of infectious materials. In lambs and non-pregnant ewes, the *infection* remains latent until conception. Ewes exposed to *infection* late in pregnancy may not exhibit signs of *infection* until the subsequent pregnancy. Countries should take account of these risk factors.

Standards for diagnostic tests are described in the Terrestrial Manual.



CHAPTER 6.2.

THE ROLE OF THE VETERINARY SERVICES IN FOOD SAFETY SYSTEMS

EU comment

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

However we note that previous EU comments on this chapter, provided to the OIE in writing prior to the 86th OIE General Session and referred to orally during that session have not been addressed. Those comments pertain to Articles 6.2.3. and 6.2.4. and are available here

https://ec.europa.eu/food/sites/food/files/safety/docs/ia standards oie eu position tahsc -report 201805.pdf.

[...]

Article 6.2.4.

Roles and responsibilities of Veterinary Services in a food safety system

Roles and responsibilities of Veterinary Services

Veterinary Authorities or other Competent Authorities should provide an appropriate institutional environment to allow Veterinary Services to implement the necessary policies and standards, and ensure adequate resources for them to carry out their tasks in a sustainable manner. Veterinary Services should have a clear chain of command and respective roles and responsibilities should be clearly defined and well documented.

Veterinary Services should be fully involved, in accordance with their mandate and organisational structure at the national level, in the design and implementation of a risk-based food safety system. In the implementation of food safety systems for food of animal origin, Veterinary Services should retain responsibility for verification and audit and facilitate a flexible approach to operational activities.

Veterinary Services <u>Authorities</u> or other <u>Competent Authorities</u> should retain overall responsibility for the delivery and performance of any activities delegated to third party providers.

Where relevant, *Veterinary Services* should have an active role in other food safety-related activities, such as investigations of foodborne disease *outbreaks*, food defense, disaster management, and identifying emerging *risks*. In addition, *Veterinary Services* should have an active role in the development and management of coordinated *surveillance* and control programmes for foodborne pathogens of <u>animal origin important for public health-importance</u>.

EU comment

We suggest inserting the words "and advising on mitigation measures" after "identifying emerging risks" in the paragraph above. Indeed, in addition to the examples on investigations of outbreaks and identification of risks, the veterinary advice would complete better the range of activities of the Veterinary Services. In addition, advising on mitigation measures fits well with the responsibilities and competences of the Veterinary Authority and Veterinary Service to supervise and implement standards and recommendations in the OIE Codes, as outlined in the relevant Glossary definitions.

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

Depending on the responsibilities of the *Competent Authority*, the responsibilities of the *Veterinary Services* may be limited to the first part of the food chain, while in other cases the *Veterinary Services* may be responsible for the whole food chain.

EU comment

The EU suggests replacing "Competent Authority" with "<u>Veterinary Authority</u>" in the paragraph above. Indeed, according to the Glossary, the Veterinary Services are under the overall control and direction of the Veterinary Authority, therefore their responsibilities are function of the responsibilities of the Veterinary Authority.

Furthermore, we query what is meant by "the first part of the food chain". Indeed, this is not clear and should be specified. We thus refer to the previous EU comment, asking that the parenthesis be reinstated (i.e. please add the following after "first part of the food chain": "(from farm to slaughterhouse/abattoir and associated premises for further processing)").

a) Primary production

Through their presence on farms and collaboration with farmers, *Veterinary Services* play a key role in ensuring that *animals* are healthy and kept under good sanitary and hygienic conditions, as well as in *biosecurity* and early detection, *surveillance* and treatment of animal diseases, including conditions of public health significance.

EU comment

The EU suggests replacing the word "presence" with "<u>professional visits</u>" in the paragraph above. Indeed, it may be more appropriate to indicate professional visits on farms rather than presence which may raise expectations for a permanent presence.

Veterinary Services provide direction to farmers on practices that prevent or minimise physical and chemical hazards (for example, mycotoxins, environmental contaminants and pesticide residues) in primary production, including *feed*.

EU comment

At the end of the paragraph above, we would suggest replacing "including feed" with "and feed". Indeed, feed should be added to primary production rather than be included in primary production, as the section on primary production focuses on farm animals.

Veterinary Services play a central role in ensuring the responsible and prudent use of *veterinary medicinal products*, including *antimicrobial agents* in accordance with Chapter 6.10. in animal husbandry. This helps to minimise the likelihood of noncompliant levels of veterinary drug residues in food 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) 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 6.3. *Veterinary Services* have an essential role in ensuring that these activities, including *meat* inspection, minimise 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-and post-mortem inspection. *Slaughterhouse/abattoir* inspection of live animals and their carcasses plays a key role both in 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 *Veterinary Services*.

Veterinary Services may be responsible for overseeing the control measures during processing and distribution of food of animal origin. They also play an important role in raising the awareness of food producers, processors and distributors regarding measures required to assure food safety.

c) Assurance schemes and certification of food of animal origin for international trade

Veterinary Services have an 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 responsible agencies 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

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, including the implementation of control measures. This work should be carried out in close collaboration with public health professionals, analysts, epidemiologists, food producers, processors and traders and any others involved.

Because of the global nature of the food trade, *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.

CHAPTER 7.1.

INTRODUCTION TO THE RECOMMENDATIONS FOR ANIMAL WELFARE

EU comment

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

One comment is inserted in the text below.

[...]

Article 7.1.4

Guiding principles for the use of measures to assess animal welfare

[...]

5) Users of the standard should select the most appropriate animal-based measures for their farming system or environment, 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. To guide users, Competent Authorities should collect all relevant data that can be used to set target values.

EU comment

The EU would like to suggest modifying the last sentence of the paragraph above as follow:

"To guide users, Competent Authorities should collect all relevant data that can be used to set target <u>and threshold</u> values."

Justification

The EU believes that a target value defines a potential optimal value to achieve while a threshold value relates to a predefined level that must be reached. Hence, the relevance of including the term of threshold value for defining minimum levels for corrective interventions.

[]	

CHAPTER 7.13.

ANIMAL WELFARE AND PIG PRODUCTION SYSTEMS

EU comment

The EU thanks the OIE for considering the majority of its comments and supports the proposed changes to this chapter.

[...]
Article 7.13.4.

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 such as regional differences, *herd* health, pig breed or crossbreed, and climate. Consideration should also be given to the resources provided and the design of the systems. These criteria can be considered as tools to monitor the efficiency of design and management, given that they can affect *animal welfare*.

Behaviour

Certain behaviours appear to be indicators of good animal welfare and health in pigs such as play and specific vocalisations.

Certain <u>other</u> behaviours could indicate an *animal welfare* and health problem. These include sudden immobility, escape attempts, changes in *feed* and water intake, altered locomotory behaviour or posture, altered lying time, postures and patterns, altered respiratory rate and panting, coughing, shivering and huddling, high-pitched vocalisations and increased call rate, increased agonistic (including aggression), stereotypic, apathetic or other abnormal behaviours.

Environments that induce stereotypies typically also reduce animal welfare. Although stereotypies are generally held to indicate poor welfare, there are some instances where there is a poor association between stereotypies and stress. For example, frustration-induced stress may be somewhat rectified if the behaviour itself reduces the underlying motivation. Within a group, individuals that perform stereotypies may thus be coping more successfully than those that do not. Nevertheless, stereotypies indicate either a present problem for the animal or a past problem that has resolved. As with other indicators, caution should be used when using stereotypies as a welfare measure in isolation from other indicators.

[...]
Article 7.13.15.

Air quality

Good air quality and ventilation are important for the welfare and health of pigs and reduce the risk of respiratory discomfort, diseases and abnormal behaviour. Dust, toxins, microorganisms and noxious gases, including ammonia, hydrogen sulphide, and methane caused by decomposing animal waste, can be problematic in indoor systems.

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.

Proper ventilation, without draughts, particularly for young pigs, 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 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 most likely a problem for pigs.

Animal-based criteria (or measurables): morbidity, mortality and culling rates, physical appearance (discharges from nose or eyes), behaviour (especially respiratory rate, coughing and tail biting), change in body weight and body condition.

[...]

GLOSSARY

EU comment

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

EARLY DETECTION SYSTEM

means a system for the timely detection and identification of an incursion or emergence of diseases or infections in a country, zone or compartment. An early detection system should be under the control of the Veterinary Services and should include the following characteristics:

- a) representative coverage of target animal populations by field services;
- b) ability to undertake effective disease investigation and reporting;
- c) access to laboratories capable of diagnosing and differentiating relevant diseases;
- a training programme for veterinarians, veterinary paraprofessionals, livestock owners/keepers and others involved in handling animals for detecting and reporting unusual animal health incidents;
- e) the legal obligation of private veterinarians to report to the Veterinary Authority;
- f) a national chain command.

EARLY WARNING SYSTEM

means a system for the timely detection, identification and reporting and communication of an incursion or emergence of diseases, infections or infestations in a country, zone or compartment.

SANITARY MEASURE

means a measure, such as those described in various chapters of the *Terrestrial Code*, destined designed to protect animal or human health or life within the whole territory or a zone of the a Member Country from risks arising from the entry, establishment and/or spread of a hazard.

CHAPTER 1.4.

ANIMAL HEALTH SURVEILLANCE

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 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 disease 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 objectives of the surveillance, 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 adapted to national or local settings. 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 Chapters 3.1. to 3.4. on Veterinary Services;
 - b) that, where possible, surveillance data be complemented by other sources of information, such as scientific publications, research data, population demographic 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.

Specificity: means the proportion of uninfected sampling units that are correctly identified as negative.

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. Design of surveillance system

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 <u>disease</u> *infection* or *infestation* and the degree to which the *subpopulation* is representative of the target *population* stated.

Definitions of appropriate *populations* should be based on the specific recommendations of the relevant chapters of the *Terrestrial Code*.

b) Timing and temporal validity of surveillance data

The timing and duration and frequency of surveillance should be determined taking into consideration factors such as:

- objectives of the surveillance;
- biology and epidemiology (e.g. <u>pathogenesis</u>, vectors, transmission pathways, seasonality);

- risk of introduction and spread;
- husbandry practices and production systems;
- accessibility of target population;
- geographical factors;
- <u>environmental factors, including</u> climate conditions.

Surveillance should be carried out at a frequency that reflects the epidemiology of the infection of 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.

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.

ebis) Diagnostic tests

<u>Surveillance</u> involves the detection of <u>infection</u> or <u>infestation</u> according to appropriate <u>case</u> definitions. <u>Tests used in surveillance</u> may range from detailed laboratory examinations to clinical observations and the analysis of production records.

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 drawn from *surveillance*. Therefore, these parameters should be taken into account in the design of *surveillance* systems and analysis of *surveillance* data.

Laboratory Ttests should be chosen in accordance with the relevant chapters of the Terrestrial Manual.

EU comment

As the section above deals not only with laboratory tests but also with clinical observations, production records etc., the title "Diagnostics tests" seems confusing. Indeed, that title would seem to restrict surveillance to just tests described in the Terrestrial Manual. We would therefore suggest the following title:

"Diagnostic tests tools".

Furthermore, there is no such thing as a perfect test, and the performance of a test is decribed by sensitivity and specificity, not by predictive values. The EU therefore suggests rewording the second paragraph of section ebis) as follows:

"The performance of a test at the *population* level (including field observations) may be described in terms of its sensitivity, and specificity and predictive values. These

<u>parameters, together with</u> <u>Imperfect sensitivity or specificity, as well as</u> prevalence, will have an impact on the conclusions drawn from *surveillance*. Therefore, these parameters <u>and</u> should be taken into account in the design of *surveillance* systems and analysis of *surveillance* data.".

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 may be carried out only 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 purposes 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.

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.

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. Software may offer the possilibity of extraction of multiple source data for aggregation and analysis. 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 collected by probability-based or non-probability-based methods, 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. <u>Disease reporting systems</u>

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 between the <u>Veterinary Authority</u> and other relevant authorities.

Participatory *surveillance* methods may be useful to collect epidemiological data that can support disease reporting systems.

EU comment

We suggest including a definition of "Disease reporting systems" in Article 1.4.2., which could then be further expanded here.

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.

2. Surveys

In addition to the principles in Article 1.4.3., the following should be considered when planning, implementing and analysing surveys.

Surveys may be conducted on the entire target population (i.e. a census) or on a sample.

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.

a) 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.

EU comment

The EU suggests addressing the question of timeliness in the point above. Indeed, this would be important in the context of survey versus monitoring, or cohort analytical studies.

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.

b) Sampling

i) Objective

The objective of prebability 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 so that data from the study population can be extrapolated to the target population in a statistically-valid manner. When selecting epidemiological units within a population, probability-based sampling, such as a simple random selection, should be used.

EU comment

The EU suggests reinserting the word "probability" in the paragraph above, for consistency with the wording of the paragraph below.

Where probability-based sampling is not feasible, non-probability-based methods may be applied and should provide the best practical chance of generating a sample that is can be considered as representative of the target population. The objective of non-probability based sampling should be to maximise the likelihood of detection of the infection or infestation. However, this type of sampling may not only be representative of the study and target population, unless if risk factors are weighted, and those weights should be underpinned by relevant scientific evidence and should capture the relative differences in risk and proportion between the subpopulation and the population.

EU comment

Sometimes the biases are such that it is not possible to correct the value because of lack of information on the part of the population that is missed, or on the quantification of the risk factors. The wording proposed therefore seems somehow too accommodating and does not suggest that this is not always feasible.

The sampling method used at all stages should be fully documented.

ii) 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* and possible clustering, the level of confidence desired of the survey results and the performance of the tests used.

EU comment

In the point above, referring only to the size of the population does not provide sufficient link with the concept of epidemiological unit previously defined. Indeed, especially in veterinary epidemiology, the sample size should address the number of units (herds, flocks) and the number of animals per unit.

<u>In addition, for surveys designed to estimate a parameter (e.g. prevalence) consideration should be given to the desired precision of the estimate.</u>

iii) Sample selection

- probability-based sampling methods, such as:
 - simple random selection;
 - cluster sampling;
 - <u>stratified sampling;</u>
 - systematic sampling; or
 - risk-based sampling.

EU comment

Cluster sampling is part of risk-based sampling, both indents could thus be merged ("risk-based sampling, e.g. cluster sampling;"). However, simply listing these examples without further explanation does not seem to have any added value; we would thus suggest adding short summaries or definitions of the different sampling methods listed.

- <u>non-probability-based sampling methods, depending on:</u>
 - convenience;
 - expert choice;
 - quota;
 - <u>risk.</u>

3. Risk-based methods

Surveillance activities targeting selected subpopulations in which an infection or infestation is more likely to be introduced or found, or more likely to spread, or cause other consequences (e.g., large economic losses or trade restrictions) are useful to increase the efficiency of detection and can contribute to early detection, freedom claims, disease control activities, and estimation of prevalence. Risk-based methods can be used for both probability-based and non-probability-based selection of sampling units methods and data collection. The effect of the selection (i.e. its impact on probability of detection) should be estimated.

Risk-based methods should be based on *risk assessment* and are useful to optimise the use of *surveillance* resources.

EU comment

The point above should also apply to risk-bases sampling.

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:

EU comment

The EU suggests inserting the words ", rendering plants or other locations" after "slaughterhouses/abattoirs", as inspection of carcasses of fallen stock at rendering plants, pathology institutes, farms or any other place where post mortem examinations are being done depending on national / local regulations / practice would also be very useful.

a) clinical and pathological signs;

EU comment

The EU suggests adding the words "and further diagnostic procedures" at the end of the point above, as this should not be limited to clinical/pathological signs alone.

- b) the training, experience and number of the inspection staff;
- c) the extent to which the Competent Authority is involved involvement of the Competent Authority in the supervision of ante-mortem and post-mortem inspection, including reporting systems;
- 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.

5. <u>Laboratory investigation records</u>

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.

57. Surveillance of Sentinel units

Surveillance of 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

<u>infestation</u>. Sentinel <u>units</u> provide the opportunity to target <u>surveillance</u> depending on the risk of introduction <u>or re-emergence</u>, likelihood of <u>infection</u> or <u>infestation</u>, cost and other practical constraints. Sentinel <u>units</u> may provide evidence of freedom from <u>or distribution of</u>, <u>infection</u> or <u>infestation</u>, <u>or of their distribution</u>.

68. Clinical observations surveillance

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.

EU comment

The second sentence of the paragraph above misses an important part which is the need for awareness of the animal keeper on signs of disease that need investigation, which is crucial to allow for the next steps to take place.

Thus, the EU suggests inserting the words "<u>Awareness of animal keepers on signs of disease that need investigation,</u>" at the beginning of the second sentence before "training of potential".

79. Syndromic data surveillance

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*. Seftware may offer the prospect of extraction of syndromic data for aggregation and analysis.

810. Other useful data sources

EU comment

It is not clear why the points below are separated from the ones above; instead of under a separate heading "other useful data" they could come right after "syndromic surveillance" above.

a) 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.

b) Laboratory investigation records

Laboratory investigation records may provide useful data for surveillance, in particular for retrospective studies. 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 quality control and quality assurance systems, including 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.

<u>Biological specimen banks</u>

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.

da) 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.

eb) 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.

fe) 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.

gd) Additional supporting data such as:

- 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.

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.

<u>Surveillance</u> information gathered from the same country, <u>zone</u> or <u>compartment</u> at different times may provide cumulative evidence of <u>animal health status</u>. 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.

EU comment

Combination of surveillance results always needs to consider differences in protocols, in particular which samples were taken, how they were analysed, etc., in order to have meaningful conclusions.

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 overestimate or an under-estimate of the parameters of interest.

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.

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 1.4.5.

Early warning systems

An early warning system is essential for the timely detection, reporting and communication of occurrence, incursion or emergence of diseases, *infections* or *infestations*, and is an integral component of emergency preparedness. It should be under the control of the *Veterinary Authority* and should include the following:

- 1) appropriate coverage of target animal populations by the Veterinary Services;
- 2) laboratories capable of diagnosing and differentiating relevant infections or infestations;
- 3) 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;
- <u>a legal obligation by veterinarians and other relevant stakeholders to report suspected cases or cases of notifiable diseases or emerging diseases to the Veterinary Authority, with following information including the description of the findings:</u>
 - 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;
- <u>epidemiological investigations of suspected cases and cases conducted by the Veterinary Services, taking into account the following: in order to confirm the case and to acquire accurate knowledge of the situation for further action.</u>

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.

- 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;
- <u>all suspected case investigations should provide a result, either positive or negative. Criteria should be</u> established in advance for a case definition:

- 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.

When a case of a listed disease is detected, notification shall be made to the OIE in accordance with Chapter 1.1.

Article 1.4.6.

Surveillance to demonstrate for 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. <u>Demonstration of freedom</u>

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 <u>infection</u> or <u>infestation</u> in an animal <u>population</u> in the country, <u>zone</u> or <u>compartment</u>. Scientific methods cannot provide absolute certainty of this absence. Therefore, demonstrating freedom, <u>except for historical freedom</u> involves providing sufficient evidence to demonstrate to a desired level of confidence (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 <u>population</u>.

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 <u>when</u> *infection* or *infestation* <u>is</u> 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*.

Evidence from probability-based and nonprobability risk-based data sources collection, as stated before, may increase the sensitivity of the surveillance 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;
 - iv) 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) for at least the past 10 years:

- no vaccination against the disease has been carried out;
- the prerequisites listed in point a) are complied with for at least the past 10 years;
- 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 demonstrated:
 - i) the prerequisites listed in a) are have been complied with for at least as long as the surveillance has been in place:
 - 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.

3. Requirements to declare a compartment free from infection or infestation

- The prerequisites listed in points 2 a)i) to <u>iiii++</u>) are complied with <u>for at least as long as the surveillance</u> has been in place;
- b) ongoing pathogen-specific surveillance has been applied as described in this chapter and in the relevant chapter of the Terrestrial Code, if they it exists, and has not detected any occurrence of the infection or infestation.

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 the pathogenic agent is likely to produce identifiable clinical or pathological signs in susceptible animals;
- e) vaccination against the disease is not applied;
- 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:

Annex 8 (contd)

- 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 840) 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:

- 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;
- 6) effective systems of communication between the Voterinary 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.

SECTION 4.

GENERAL RECOMMENDATIONS: DISEASE PREVENTION AND CONTROL

CHAPTER 4.Z.

INTRODUCTION TO RECOMMENDATIONS FOR DISEASE PREVENTION AND CONTROL

EU comment

The EU supports this new chapter.

Article 4.Z.1.

Effective prevention and control of contagious infectious transmissible animal diseases, including zoonoses, is a central mandate of the *Veterinary Services* of each Member Country.

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 even eradicate them infectious transmissible animal diseases.

The following chapters of this section describe these tools and the different aspects of recommendations for disease prevention and control to that should be implemented by the Veterinary Services.

To <u>effectively</u> prevent <u>effectively</u> introduction and transmission of <u>eentagious</u> <u>infectious</u> animal diseases while minimising potential negative impacts of <u>sanitary measures</u>, <u>Veterinary Services</u> should consider <u>devising a set of developing</u> measures <u>selected from based on</u> the recommendations <u>described</u> in this section, taking into account various factors including their impact on trade, <u>animal welfare</u>, public health and environment. In parallel with disease-specific <u>sanitary measures</u>, <u>Veterinary Services</u> should <u>take into account consider</u> relevant commodity-based <u>sanitary measures</u>.

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 differ between diseases and between countries 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*.

Prerequisites for devising developing such programmes may include:

- quality Veterinary Services including legislative framework, and laboratory capacity and adequate and committed funding;
- appropriate education <u>and training</u> to secure veterinarians and veterinary paraprofessionals;
- close link with research institutions;
- effective awareness of, and active cooperation with, private stakeholders;
- public-private partnerships;
- <u>cooperation between Veterinary Authorities and other Competent Authorities;</u>
- regional cooperation among Veterinary Authorities on transboundary animal diseases.



CHAPTER 7.Y.

KILLING OF REPTILES FOR THEIR SKINS, MEAT AND OTHER PRODUCTS

EU comment

The EU thanks the OIE for its work and for taking the majority of the EU comments into account.

We in general support this draft new chapter and have a few additional comments that are inserted in the text below.

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

Some of the definitions in this chapter differ from those in the Glossary and Chapter 7.5., as they are adapted to reptiles, given the specific characteristics of these animals.

For the purposes of this chapter:

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 <u>loss of un</u>consciousness until the <u>animal reptile</u> 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.

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

Because of the anatomy and physiology of reptiles, specific various factors should be considered when choosing the appropriate restraining, stunning and killing method. Such factors include the size of the reptile animal tolerance and intolerance of certain species to particular methods, reptile animal handling and restraint, ease of access to veins and safety of the animal handlers.

1. Animal welfare plan

Facilities in which reptiles are killed should have an *animal welfare* plan and associated procedures. The purposes of such a plan should be to maintain good *animal welfare* at all stages of handling of <u>animals reptiles</u> until their *death*.

The *animal welfare* plan should contain standard operating procedures for each step of reptile animal handling to ensure that it is properly implemented, based on relevant recommendations in this chapter, including criteria indicators shown in Article 7.Y.56. It should also include corrective actions to address specific risks, for example, power failures or other circumstances that could negatively affect the welfare of reptiles animals.

2. Competency and training of the personnel

Animal handlers should be competent in handling and moving, stunning and verifying menitering effective stun, and killing of reptiles, as well as in recognising species and understanding relevant behaviours of these animals and the underlying animal welfare and technical principles necessary to carry out their tasks.

EU comment

The EU proposes to reinstate "monitoring" instead of "verifying" in the paragraph above:

"Animal handlers should be competent in handling and moving, stunning and verifying monitoring effective stun, and killing of reptiles, as well as in recognising species and understanding relevant behaviours of these animals and the underlying animal welfare and technical principles necessary to carry out their tasks."

Justification

Whilst we appreciate the point noted by the *ad hoc* group, verification and monitoring are two different activities. Monitoring involves checks to test effectiveness, whilst verification ensures that monitoring has taken place effectively. Generally the animal handler will monitor, and someone else could verify thereafter. Requiring animal handlers to have only competency in verification poses risk of excluding the monitoring of the process.

References

EU Official Controls Regulation (EU) 2017/625 describes monitoring and verification roles.

There should be sufficient number of personnel, who should be <u>trained</u>, 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.

The manager of the facility should ensure that personnel are physically and mentally able to carry out their tasks through the period of their work shift.

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 Reptiles should be acquired legally in accordance with <u>all national jurisdictions legislation, including those of the importation and exportation countries</u> 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.

When moving reptiles If animals captured in the wild are to be used, capture and transport techniques should not compromise be humane and give due regard to human and animal health, welfare and safety.

43. Behaviour-Behavioural considerations for handling and killing

Handling restraining stunning and killing methods should take into account specific reptile behaviours indicating fear, pain or distress, such as well as:

- reptiles are sensitive to and will respond sensitivity and responsiveness to visual, and tactile, auditory, and vibrational stimuli as well as noise and vibrations;
- ability to escape handling and restraint the restraint and handling of reptiles can be difficult because of their agility and strength;
- <u>ability to reptiles can</u> inflict significant bite wounds to handlers, and <u>frequently with</u> wound infection or envenomation are not uncommon;
- low body temperatures may result in slow movements, torpor and reduced responsiveness due to low body temperatures or slow metabolic rates, which may result in slow movements, and that should not be regarded as indicators of quiescence or unconsciousness;
- absence of vocalisation, is common or normal which is typical in reptiles, even in highly traumatic situations.

Article 7.Y.4.

Source and transportation of reptiles

Reptiles should be acquired legally, in accordance with all national legislation, including those of the importation and exportation countries, and with 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.

When moving reptiles, capture and transport techniques should not compromise human and animal health, welfare and safety.

Article 7.Y.45.

Selection of a killing process

In the case of reptiles, the *killing* process should involve either stunning followed by a killing method or direct killing method. Where stunning is used, death should be ensured 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. When prior stunning is used and the stunning is not irreversible, reptiles should be killed before consciousness is recovered.

Criteria which may influence the choice of methods used in the killing process include:

- species and size of the reptile;
- level of knowledge and skill required to perform the procedure effectively;
- safety of the operator;
- compatibility with processing requirements and reptile animal product purposes;
- 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 reptile animal or humans;

EU comment

The EU proposes to replace "reptile" with "other animals" in the indent above as follows:

" - 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 reptile other animals or humans;"

Justification

The EU believes that this indent relates to prevent other animals or humans eating the reptile that has been killed.

- ability to maintain equipment in proper working order;
- cost of the method.

The killing process used should:

- avoid excitement agitation, fear, and stress, and pain to the reptile animal;
- be appropriate for the species, size, age and health of the animal reptile;
- be reliable and reproducible;
- ensure that any stunning used is in accordance with Article 7.Y.2.;and
- include the use of <u>a stunning method (in accordance with Article 7.Y.2.) followed by a killing step, or alternatively a one-step direct killing method.
 a killing method if the stunning method does not result in death of the animal reptile during unconsciousness; and
 </u>
- whenre it includes a stunning step, ensure that death occurs during unconsciousness kill the reptile while it is unconscious.

While economic or cost factors may influence the choice of the method used for stunning or killing, these factors should not compromise the welfare of the reptiles and the outcomes described in this chapter.

Article 7.Y. $\frac{56}{}$.

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 <u>verification_establishment</u> of unconsciousness or *death*, the presence of any of the following criteria should be regarded as sufficient to establish suspicion of consciousness:

EU comment

The EU proposes to replace "verification" for "monitoring" in the sentence above as follows:

"Whilst multiple criteria are preferable for the <u>verification monitoring</u> of unconsciousness or *death*, the presence of any of the following criteria should be regarded as sufficient to establish suspicion of consciousness:"

Justification

The same as for our comment above.

- pupillary response to light or movementing objects;
- 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-;
- jaw tone (except crocodilians).

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;
- cardiac activity (while presence of a heartbeat does not necessarily mean that an the reptile animal is alive, permanent cessation of a heartbeat indicates death). Cardiac activity should not be used as the sole indicator of death It is important to note that a reptile's heartbeat may change from beats per minute to beats per hour.

Article 7.Y.<mark>67</mark>.

Physical restraint

Physical restraint is often required in the process of *stunning* and *killing* of reptiles to control movement and improve the precision of application. Special considerations for the restraint of reptiles are needed due to the physical and behavioural characteristics of this taxonomic group.

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-reptile;
- 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.

Procedures or practices unacceptable on animal welfare grounds are:

- not breaking legs, cuting limb tendons or blind animals damaging the eyes of the reptiles in order to immobilise them:
- not severing the spinal cord to immobilise animals the reptiles. causing any unnecessary injuries, for example, severing the spinal cord, breaking limbs, cutting limb tendons or damaging eyes, whether for immobilisation or any other reason;
- pulling or probing sensitive body parts, other than for the purposes of verifying some reflex such as the cloacal reflex.

Animal-based criteria (or measurables): excessive struggling, excessive movements, excessive vocalisation, trauma and injuries.

Article 7.Y.
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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 <u>reptile</u> <u>animal</u> 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 reptile;
- be reliable and reproducible;
- avoid <u>agitation</u>, <u>excitement</u>, <u>and</u> stress<u>and pain</u> to the <u>animal reptile</u>;
- avoid or minimise restraint in accordance with Article 7.Y.67/2.;
- result in the immediate onset of unconsciousness or the absence of pain, distress and suffering until the onset of unconsciousness that lasts until the reptile animal is dead;
- be followed by a killing method if stunning does not result in death of the reptile animal during unconsciousness.

The equipment used should be maintained and operated properly <u>and</u> 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.<u>56</u>.and in accordance with this article, a back-up stunning or *killing* method should be used immediately (Articles 7.Y.<u>89</u>. to 7.Y.15.).

Animal-based criteria (or measurables): immediate onset of unconsciousness or *death* as described in Article 7.Y.<u>56</u>.

Article 7.Y.<mark>89</mark>.

Electrical stunning (for crocodilians only)

Electrical stunning is the application, through the brain of an electric current of sufficient strength and duration, and suitable frequency to through electrodes for the purpose of causeing immediate unconsciousness that lasts until death.

Recommendations for effective use in relation to animal welfare:

- the equipment and the procedure for its application should be approved by the Competent Authority or an accredited designated authority;
- the 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: Parameters may vary with size, age, weight etc., within a species:
- minimum <u>length of time of application of the current stun duration</u> should be achieved. <u>Duration may vary with size, age, weight etc., within a species</u>;
- animals reptiles should be killed in accordance to Articles 7.Y.910 to 7.Y.15. without delay following confirmation of effective stunning to avoid recovery of consciousness:
- reptiles should be effectively restrained when accurate application of the electrodes is dependent upon it;
- equipment should be selected to suit the type and size of the reptile;

equipment should be cleaned, maintained and stored following manufacturer's recommendations.

Animal-based criteria (or measurables): immediate onset of unconsciousness as described in Article 7.Y.56.

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.<u>910</u>. to 7.Y.15. should be used immediately to ensure *death*.

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 <u>species</u>, type and size of animal the reptile;
- equipment should be cleaned, maintained and stored, following manufacturer's recommendations.

Animal-based criteria (or measurables): immediate onset of unconsciousness and or death as described in Article 7.Y.5.

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.910. to 7.Y.15. should be used immediately to assure *death*.

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 appropriate to the anatomy of the cranium and brain;
- the equipment should be appropriately selected and maintained and adjusted for the species, size and type of reptile;
- cartridge or compressed air specifications should be determined to deliver the correct bolt velocity;
- equipment and charge should be selected to suit the <u>species</u>, type and size of animal the reptile;
- equipment should be cleaned, maintained and stored, preferably following manufacturer's recommendations.

Outcome-based criteria (or measurable): immediate onset of unconsciousness or *death* as described in Article 7.Y.<u>56</u>.

Article 7.Y. 1112.

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.910. to 7.Y.15. should be used immediately to ensure *death*. It is important to note that due to anatomical differences between species (e.g. thickness of braincase in crocodilians), this method may be difficult to apply and in such cases, other stunning and killing methods should preferentially be used.

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 <u>species</u> type and size of animal the reptile.

Animal-based criteria (or measurables): immediate onset of unconsciousness or *death* as described in Article 7.Y.<mark>56</mark>.

Article 7.Y. 1213.

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 reptile 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 reptile 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 <u>species</u>, type and size of <u>animal the reptile</u>;
- 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.<u>56</u>.

Article 7.Y. 1314.

Pithing

Pithing is an adjunct method used to ensure death by destruction of brain tissue. It is 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 terms therough brain destruction. After insertion of the rod or probe it should be promptly turned a minimum of four to six times in a centrifugal motion to ensure destruction of the brain tissue.

Recommendations for effective use in relation to animal welfare:

- should only be used in unconscious animal reptiles;
- 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.56.

Article 7.Y. 1415.

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 decapitation 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 decapitation or severance of the spinal cord acceptable only in stunned and unconscious reptiles animals and when followed by immediate destruction of the brain by pithing or percussive blow.

Recommendations for effective use in relation to animal welfare:

- should only be used on unconscious animal-reptiles;
- 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.56.

Article 7.Y. 1516.

Chemical agents

There are a number of acceptable chemical agents that, subject to relevant regulatory approvals, 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.910. to 7.Y.15. should be used immediately to ensure *death*.

The effectiveness of the chemical agent will vary according to the metabolic rate of reptiles.

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 species and size of animal reptiles;
- ensure the route of administration is appropriate for the animal reptiles.

Animal-based criteria (or measurables): confirmation of death as described in Article 7.Y.56.

Article 7.Y. 1617.

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.<u>910</u>. to Article 7.Y.15., are considered inappropriate and unacceptable. Some examples of unacceptable methods are:

- exsanguination,
- 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-inhalation of asphyxiating gases carbon dioxide (CO₂), carbon monoxide (CO) or nitrogen (N),
- use of paralysing paralytic agent drugs;

cervical dislocation.

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CHAPTER 8.14.

INFECTION WITH RABIES VIRUS

EU comment

The EU thanks the OIE for having taken many of our previous comments into acount. However, we cannot support this chapter as currently presented unless our serious concern in relation to point 3 a) of Article 8.14.5. is addressed.

Furthermore, we reiterate our previous suggestion to add guidance in this Code chapter on the control of rabies in wildlife, including as regards oral vaccination (see EU comments on the Work Programme of the Code Commission of December 2016, https://ec.europa.eu/food/sites/food/files/safety/docs/ia_standards_oie_eu_position_tahsc_report_201609.pdf, p. 228). Indeed, the current Code chapter does not include an article with recommendations on the control of rabies in wildlife. Even some very general guidance in this Code chapter would however be crucial in order to progress further towards a rabies free region of Europe, as evidenced during the discussions on the Technical Item on rabies at the 27th Conference of the OIE Regional Commission for Europe (Lisbon, September 2016). The EU would therefore highly welcome the addition of an article in the Code, and is happy to offer all its technical support.

Further comments are inserted in the text below.

Article 8.14.1.

General provisions

Rabies is a disease caused by neurotropic viruses of the genus *Lyssavirus* in the family *Rhabdoviridae* of the order *Mononegavirales* and is transmissible to all mammals. Members of the orders *Carnivora* and *Chiroptera* are considered to be the main reservoir hosts.

EU comment

The EU notes that while Item 5.8. of the report states that the Code Commission replaced the word "Members" with "Populations" in the second sentence of the paragraph above, this is in fact not the case in the text of Annex 11.

Rabies virus, the taxonomic prototype species in the *Lyssavirus* genus formerly referred to as 'classical rabies virus, genotype-1', is found worldwide in most parts of the world, and is responsible for the vast majority of reported animal and human rabies cases. The most common source of exposure of humans to rabies virus is the dog.

Other <u>IL</u>yssavirus species have more restricted geographical and host range, with the majority having been isolated from bats, with limited public and animal health implications.

EU comment

The EU suggests italicising the word "Lyssavirus" in the paragraph above as it is the scientific name of the virus genus which is usually indicated in italics (as opposed to common names). This would also be consistent with the first two paragraphs of the article.

The aim of this chapter is to mitigate the risk of infection with rabies virus to the public and animal health and to prevent the international spread of rabies virus.

Official control programmes to reduce the economic and public health burden of rabies are recommended, even in those countries where only haematophagous bat-mediated rabies or wild carnivore-mediated rabies are present.

The incubation period for rabies is highly variable depending on viruses, hosts and sites of entry, and the majority of cases infected animals will develop disease within six months of exposure.

The infective period for rabies virus is variable and can start before the onset of clinical signs. In dogs, cats and ferrets virus shedding can start up to 10 days before the onset of the first clinical signs and through last until death.

Official control programmes to reduce the economic and public health burden of the disease are recommended even in those countries where only haematephagous but mediated rabies or wild carnivore mediated rabies are present.

The aim of this chapter is to mitigate the risk of rabies to human and animal health and to prevent the international spread of rabies virus.

For the purposes of the Terrestrial Code:

- 4) rabies is a disease caused by one member of the Lyssavirus genus: the Rabies virus (formerly referred to as classical rabies virus, gentype-1); all mammals are susceptible to infection;
- a case is any animal infected with the rabies virus species;
- <u>dog-mediated rabies is defined as any infection with case caused by rabies virus maintained in the dog population (Canis familiaris) independently of other animal reservoir species, as determined by epidemiological studies;</u>

EU comment

While it has improved, the case definition of dog-mediated rabies in our opinion is still not entirely clear. Indeed, from the text it is not clear whether onward transmission of dog rabies (e.g. from a cat infected by a dog to another animal) would qualify as "dog-mediated". From the SCAD report, the intention seems to be to include this. Perhaps a solution would be to refer to "any rabies virus variant maintained in the dog population" in the definition above.

Furthermore, the EU suggests referring to the dog as "Canis lupus familiaris", as it is a subspecies of the grey wolf (Canis lupus) and not a separate species.

the incubation period of infection with rabies virus shall be six months.

Globally, the most common source of exposure of humans to rabies virus is the dog. Other mammals, particularly members of the Orders Carnivora and Chiroptera, also present a risk.

The aim of this chapter is to mitigate the risk of rabies to human and animal health and to prevent the international spread of the disease.

For the purposes of the *Terrestrial Code*, a country that does not fulfil the requirements in Article 8.14.3. is considered to be infected with Rabies virus.

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

Article 8.14.2.

Control of rabies in dogs

In order to minimise public health risks due to rabies, and eventually eradicate rabies in dogs, *Veterinary* Authorities should implement the following:

- 1) rabies should be notifiable in the whole country and any change in the epidemiological situation or relevant events should be reported in accordance with Chapter 1.1.;
- 2) an effective system of disease surveillance in accordance with Chapter 1.4. should be in operation, with a minimum requirement being an ongoing early detection programme to ensure investigation and reporting of suspected cases of rabies in animals;
- 3) specific regulatory measures for the prevention and control of rabies should be implemented consistent with the recommendations in the *Terrestrial Code*, including *vaccination*, identification and effective procedures for the importation of dogs, cats and ferrets;
- 4) a programme for the management of stray dog populations consistent with Chapter 7.7. should be implemented and maintained.

Article 8.14.<u>2</u>3.

Rabies free Country or zone free from infection with rabies virus

- 1) A country <u>or zone</u> may be considered free <u>from infection with rabies virus</u> when:
 - <u>a1</u>) <u>the disease</u> <u>infection with rabies virus</u> is <u>a</u> <u>notifiable</u> <u>disease in the entire country</u> and any change in the epidemiological situation or relevant events are reported in accordance with Chapter 1.1.;

EU comment

The EU suggests inserting a new point 1 regarding the history of disease reporting, same as in Article 8.14.8., as follows:

- "1) have a record of regular and prompt animal *disease* reporting in accordance with Chapter 1.1.;"
 - <u>b)</u> <u>all susceptible animals showing clinical signs suggestive of rabies are subjected to appropriate field and laboratory investigations;</u>
 - <u>c</u>2) an ongoing system of <u>disease</u> surveillance in accordance with Chapter 1.4. <u>and Article 8.14.9.</u> has been in <u>operation place</u> for the past <u>two years 24 months</u>, with a minimum requirement being an <u>ongoing</u> early <u>warning system</u> <u>detection programme</u> to ensure investigation and reporting of <u>animals suspected of being infected rabies suspect animals</u>;
 - regulatory measures for the prevention of <u>infection with</u> rabies <u>virus</u> are implemented consistent in accordance with the <u>relevant</u> recommendations in the <u>Terrestrial Code</u> including Articles 8.14.4. to 8.14.7., including for the importation of animal;

EU comment

The EU notes that point d) above also pertains to regulatory measures from Article 8.14.3. "Recommendations on import of domestic and captive wild animals". We would therefore suggest replacing "Articles 8.14.4. to 8.14.7." with "Articles 8.14.3. to 8.14.7."

- <u>e</u>4) no case of indigenously acquired <u>infection with</u> rabies virus <u>infection</u> has been confirmed during the past two years 24 months;
- 5) no imported case in the Orders Carnivora or Chiroptera has been confirmed outside a *quarantine* station for the past six months.
- f) if an imported case is confirmed outside a quarantine station, epidemological investigations have ruled out the possibility of secondary cases.

- Preventive vaccination of at-risk animals does not affect the rabies free status.
- 3) An imported human case of rabies does not affect the rabies free status.

Article 8.14.2bis.

Country or zone infected with rabies virus

A country or zone that does not fulfil the requirements of Article 8.14.2. is considered to be infected with rabies virus.

Article 8.14.2ter.

Country or zone free from dog-mediated rabies

- 1) A country or zone may be considered free from dog-mediated rabies when:
 - <u>a)</u> <u>dog-mediated rabies is a notifiable disease in the entire country</u> and any change in the epidemiological situation or relevant events are reported in accordance with Chapter 1.1.;

EU comment

The EU suggests inserting a new point a) regarding the history of disease reporting, same as suggested for Article 8.14.2. above.

<u>b)</u> an ongoing system of <u>surveillance</u> in accordance with Chapter 1.4. and Article 8.14.9. has been in place for the past 24 months, with a minimum requirement being an <u>early warning system</u> to ensure <u>control</u>, investigation and reporting of animals suspected of <u>infection</u> with rabies virus;

EU comment

The words "early warning system" should not be italicised, as that term's definition is not yet included in the Glossary.

<u>c)</u> regulatory measures for the prevention of <u>infection</u> with rabies virus are implemented in accordance with the relevant recommendations in the <u>Terrestrial Code</u> and including Articles 8.14.94. to 8.14.7.;

EU comment

The EU notes that point c) above also pertains to regulatory measures from Article 8.14.3. "Recommendations on import of domestic and captive wild animals". We would therefore suggest replacing "Articles 8.14.4. to 8.14.7." with "Articles 8.14.3. to 8.14.7."

- d) no case of indigenously acquired dog-mediated rabies has occurred during the past 24 months;
- e) a dog population control programme for the management of stray dog populations is has been implemented and maintained in accordance with Chapter 7.7.
- 2) The following do not affect the status of a country or zone free from dog-mediated rabies:
 - preventive vaccination;
 - presence of rabies virus in wildlife animals;
 - imported human cases of rabies.

EU comment

The EU suggests adding a provision in the article above regarding the possibility of keeping the rabies free status if there has been an imported case in a quarantine station or, if outside, epidemiological investigations have ruled out the possibility of secondary case. Indeed, such a provision is included in Article 8.14.2 (country or zone free from

infection with rabies virus), however is not proposed for Article 8.14.2 ter (country or zone free from dog mediated rabies), however it would be useful to have the same kind of derogation also for the status of dog mediated rabies freedom.

Article 8.14.<u>3</u>4.

Recommendations for importation <u>of domestic and captive wild mammals</u> from <u>countries</u> or zones free from infection with rabies virus <u>free countries</u>

For domestic mammals, and captive wild mammals

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

- showed no clinical sign of rabies the day prior to or on the day of shipment;
- 2) and either:
 - a) were kept since birth or at least six months prior to shipment in a free country or zone; or
 - b) were imported in accordance with the regulations stipulated in Articles 8.14.<u>5</u>6., 8.14.<u>6</u>7., <u>or.</u>8.14.<u>78.-or.8.14.9.</u>

Article 8.14.<u>4</u>5.

Recommendations for importation of wild $\underline{\text{and feral}}$ mammals from $\underline{\text{rabies free}}$ countries $\underline{\text{or zones free from infection with}}$ rabies virus

For wild mammals

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

- 1) showed no clinical sign of rabies the day prior to or on the day of shipment;
- 2) and either:
 - a) have been captured at a distance that precludes any contact with animals in an infected country or zone. The distance should be defined in accordance with the biology of the species exported, including home range and long distance movements; or
 - b) have been kept in captivity for the six months prior to shipment in a country or zone free from infection with rabies virus free country.

Article 8.14.56.

Recommendations for importation of dogs, cats and ferrets from countries $\underline{\text{or zones}}$ $\underline{\text{considered}}$ infected with rabies $\underline{\text{virus}}$

Veterinary Authorities should require the presentation of an international veterinary certificate complying with the model of Chapter 5.11. attesting that the animals:

- 1) showed no clinical sign of rabies the day prior to or on the day of shipment;
- 2) were permanently identified and their identification number stated in the certificate;
- 3) and either:

a) were vaccinated or revaccinated not more than 12 months prior to shipment in accordance with the recommendations of the manufacturer. The with a vaccine should have been that was produced and used in accordance with the Terrestrial Manual and They were subjected not less than 4 3 one months and not more than 12 months prior to shipment after the last vaccination to an antibody titration test as prescribed in the Terrestrial Manual with a positive result of at least 0.5IU/ml;

EU comment

The EU thanks the OIE for having taken into account some of our previous comments on the point above. While the text has somewhat improved, there is still one crucial element missing, i.e. the waiting period between the blood sampling for the antibody titration test and the shipment. In fact in that respect, the text has even deteriorated.

First of all, we disagree to a certain extent with the statement in the Code Commission report that "animals can be protected by vaccination and if animals show antibody titres of at least 0.5 IU/ml they are safe to trade" as that is not always the case. That statement seems to have been taken from the SCAD September 2018 meeting report (see p. 34: "The Commission disagreed with a Member proposal that primary vaccination should be received no less than 6 months prior to shipment. It was well documented by the ad hoc Group that if a dog, cat or ferret reaches a rabies antibody threshold of 0.5 IU/ml, it should be considered protected and safe for importation, regardless of the timing of vaccination. Thus, the Commission considered a minimum of 30 days appropriate to ensure that a vaccinated animal reaches the expected antibody threshold after vaccination."), however has been taken out of context: reference to the antibody titre seems to have been made to clarify that it is not necessary to wait for 6 months after vaccination before shipment of the animal, as suggested by another member country, but rather that 1 month would suffice for the vaccination to elicit the antibody titre deemed protective.

Indeed, as explained in the previous EU comments, an animal that is incubating rabies could be vaccinated and antibody tested with a favorable result of at least 0.5 IU/ml and still not be safe to trade. Reference is made to our previous comments (available here https://ec.europa.eu/food/sites/food/files/safety/docs/ia standards oie eu comments tah sc-report 201807.pdf) and to the scientific opinion of EFSA (https://www.efsa.europa.eu/en/efsajournal/pub/436) that inter alia states the following:

"(...) The risk of transmission of rabies by pet movement is related to moving an animal incubating disease. Pre-exposure vaccination of pets confers quick and almost complete protection to subsequent exposure by contact, e.g. bites. On the other hand, infection prior to vaccination cannot be controlled by immunisation but will require a quarantine and observation period covering the incubation period to be revealed. Previously, quarantine was implemented by physical isolation but with the advent of efficient vaccines, an "immunological quarantine" can be implemented with much less consequence for animal welfare.

The unrestricted risk that a pet is incubating rabies at the time of primo-vaccination is equal to the prevalence of rabies-incubating pets in the population of origin. The prevalence can be estimated from the observed incidence of rabies in the population combined with an estimate of population size and the distribution of incubation times after natural infection. Following induction of protective immunity by vaccinating animal already incubating rabies will still develop clinical disease as a function of time after vaccination. Observing a vaccinated animal over a certain period will thus gradually reduce the risk (termed type A in this opinion) that this animal incubates rabies, given that it has not developed clinical signs. (...)

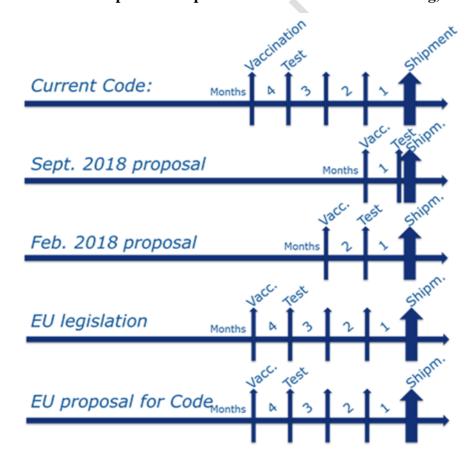
In quantitative terms, the type A risk constitutes by far the major risk. Therefore, a waiting time (defined as the time spent between vaccination and pet movement to the destined country), is the major effective measure to mitigate the risk of rabies introduction due to an animal being infected before primo-vaccination."

While according to the current version of the Code, the animals can be shipped at the earliest 3 months after the antibody test (effectively meaning shipment at the earliest 4 months after the last vaccination, as usually the test is done at the earliest 1 month after vaccination), the text as currently proposed would allow animals to be shipped as little

as 1 month after the last vaccination (if shipped right after the positive test result). This in fact gives even less assurance than the version presented for comments with the February 2018 Code Commission report, where it was antibody test not less than 1 month prior to shipment (i.e. effectively not less than 2 months after last vaccination). By contrast, and as explained in our previous comments, according to the relevant EU rules on the imports of dogs, cats and ferrets (Annex IV [Validity requirements for the rabies antibody titration test] to Regulation (EU) No 576/2013, see https://ec.europa.eu/food/animals/pet-movement/eu-legislation/non-eu-imports en), the antibody test must be carried out on a sample collected at least 30 days after the date of vaccination and not less than three months before the date of movement. This effectively means there is a period of at least 4 months between vaccination and shipment (similar to the recommendation of the current OIE Code version), giving sufficient assurance that the animal is not incubating rabies and the antibody titer really stems from the vaccination and not possible rabies infection. We note that the SCAD fully supports our view (see SCAD September 2018 meeting report, p. 34: The Commission considered several comments from some Members and agreed to modify the text to clarify that the antibody test is not only linked to the day of shipment but also to the day of vaccination. The Commission noted that antibody level testing should happen at least one month after vaccination, and that a minimum of three months should elapse between testing and shipment, in order to ensure that the detected antibodies were elicited by the vaccination and not by a possible natural infection. Therefore, a minimum of four months should elapse between vaccination and shipment.).

The graphic illustration below clarifies the timeline of these different options.

<u>Graphic illustration of the timeline of the different options discussed above</u> (taking into account earliest possible shipment after vaccination and testing):



The text of point 3 a) as proposed now is thus clearly not acceptable for the EU. In order to alleviate our concerns as explained above, we would suggest the following wording (that would effectively be in line with the current version of the Code as regards the timeline, and in line with the views expressed by the SCAD):

"a) were vaccinated or revaccinated not more than 12 months prior to shipment in accordance with the recommendations of the manufacturer, with a vaccine that was produced in accordance with the Terrestrial Manual. They were subjected not less than one month and not more than 12 months after the last vaccination and not less than three months before shipment to an antibody titration test as prescribed in the Terrestrial Manual with a positive result of at least 0.5IU/ml;".

OR

b) were kept in a *quarantine station* for six months prior to export.

Article 8.14.<u>6</u>7.

Recommendations for importation of <u>other <u>susceptible animals</u> domestic ruminants, equids, camelids and suids <u>members of the order Carnivora and of members of the order Chiroptera</u> from countries <u>or zones</u> considered infected with rabies <u>virus</u></u>

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

- 1) showed no clinical sign of rabies on the day prior to or on the day of shipment;
- 2) were permanently identified and the identification number stated in the certificate;
- 23) either EITHER
 - were kept for the 6 months prior to shipment in an establishment where separation from susceptible animals was maintained and where there has been no case of rabies for at least 12 months prior to shipment.

OR

- b) were vaccinated or revaccinated in accordance with the recommendations of the manufacturer. The vaccine was produced and used in accordance with the Terrestrial Manual.:
- 3) if domestic animals, were permanently identified and the identification number stated in the certificate.

Article 8.14.<u>7</u>8.

Recommendations for importation of susceptible laboratory animals from countries or zones considered infected with rabies virus

For rodents and lagomorphs born and reared in a biosecure facility

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

- 1) showed no clinical sign of rabies the day <u>prior to or on the day</u> of shipment;
- 2) were <u>born and</u> kept since birth in a biosecure facility <u>as described in the Terrestrial Manual Chapter 1.1.1</u> on <u>Management of veterinary diagnostic laboratories</u>, and where there has been no <u>case of rabies</u> for at least 12 months prior to shipment.

Article 8.14.8.

OIE endorsed official control programme for dog-mediated rabies

The overall objective of an OIE endorsed official control programme for dog-mediated rabies is for Member Countries to progressively improve their dog-mediated rabies situation and eventually be able to make a self-declaration in accordance with Chapter 1.6. as a country free from dog-mediated rabies. The official control programme should be applicable to the entire country even if certain measures are directed towards defined subpopulations only.

Member Countries may, on a voluntary basis, apply for endorsement of their official control programme for dogmediated rabies when they have implemented measures in accordance with this article.

For its official control programme for dog-mediated rabies to be endorsed by the OIE, the Member Country should:

- 1) have a record of regular and prompt animal disease reporting in accordance with Chapter 1.1.;
- 2) <u>submit documented evidence (including relevant legislation)</u> of the capacity of the <u>Veterinary Services to control dog-mediated rabies. This evidence may be provided using data generated by the OIE PVS Pathway;</u>
- 3) <u>submit a detailed plan of the programme to control and eventually eradicate dog-mediated rabies in the country er-zone</u> including:
 - a) the timeline;
 - <u>b)</u> the performance indicators for assessing the effectiveness of the control measures to be implemented;
 - <u>documentation indicating that dog-mediated rabies is a notifiable disease and that the official control programme for dog-mediated rabies is applicable to the entire country:</u>
- 4) submit a dossier on dog-mediated rabies in the country describing the following:
 - <u>a)</u> the general epidemiology in the country highlighting the current knowledge and gaps in knowledge <u>and</u> the progress that has been made in controlling dog-mediated rabies;
 - b) the measures implemented to prevent introduction of infection;
 - <u>bbis)</u> the rapid detection of, and response to, dog-mediated rabies cases, to reduce the *incidence* and to eliminate transmission in at least one zone in the country;
 - <u>c)</u> <u>dog population management including stray dog control programme in accordance with Chapter 7.7.</u>;
 - <u>d</u>) collaboration agreements or programmes with other *Competent Authorities* such as those <u>responsible</u> for public health and management of *wild* and *feral animals*;
- 5) submit evidence that surveillance of dog-mediated rabies is in place:
 - a) by taking into account provisions in Chapter 1.4. and Article 8.14.9.;
 - b) by having diagnostic capability and procedures, including regular submission of samples to a laboratory that carries out diagnosis to support epidemiological investigation;
- 6) where vaccination is practised as part of the official control programme for dog-mediated rabies, provide:
 - <u>a)</u> evidence (such as copies of legislation) that *vaccination* of selected populations is compulsory and the vaccines are produced in accordance with the *Terrestrial Manual*;
 - <u>b)</u> detailed information on *vaccination* campaigns, in particular on:
 - i) target populations;
 - ii) monitoring of vaccination coverage;
 - <u>iii)</u> technical specifications of the vaccines used and description of the regulatory procedures in place;
- 7) provide preparedness and contingency plans.

The Member Country's official control programme for dog-mediated rabies will be included in the list of programmes endorsed by the OIE only after the submitted evidence, based on the provisions of Article 1.6-Xbis., has been accepted by the OIE. Retention on the list requires an annual update on the progress of the official control programme and information on significant changes concerning the points above. Changes in the

epidemiological situation and other significant events should be reported to the OIE in accordance with Chapter 1.1.

The OIE may withdraw the endorsement of the official control programme if there is evidence of:

- non-compliance with the timelines or performance indicators of the programme; or
- significant problems with the performance of the Veterinary Services; or
- an increase in the incidence of dog-mediated rabies that cannot be explained or addressed by the programme.

Article 8.14.9.

Recommendations for importation of wildlife from countries considered infected with rabies

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

- 1) showed no clinical sign of rabies the day prior to or on the day of shipment;
- 2) were kept for the six months prior to shipment in an establishment where separation from susceptible animals was maintained and where there has been no case of rabies for at least 12 months prior to shipment.

<u>Article 8.14.9.</u>

General principles of sSurveillance

A Member Country should justify the surveillance strategy chosen in accordance with Chapter 1.4., as being adequate to detect the presence of infection with rabies virus, given the prevailing epidemiological situation. Surveillance should be under the responsibility of the Veterinary Authority.

For the purposes of rabies *surveillance* a suspected case is a susceptible animal that shows any change in behaviour followed by death within 10 days or that displays any of the following clinical signs: hypersalivation, paralysis, lethargy, abnormal aggression, abnormal vocalisation.

In particular, Member Countries should have in place:

- a) a formal and ongoing system for detecting and investigating suspected cases;
- <u>b)</u> <u>a procedure for the rapid collection and transport of samples from suspected cases to a laboratory for diagnosis:</u>
- <u>c)</u> <u>a system for recording, managing and analysing diagnostic and surveillance data.</u>

Rabies surveillance provides data that are indicators of the effectiveness of a rabies control programme and of the maintenance of freedom of *infection* with rabies virus in a country or *zone*.

- 2) In addition to principles in Chapter 1.4. the following are critical for rabies surveillance:
 - a) Public awareness

The Veterinary Services should implement programmes to raise awareness among the public, as well as veterinary paraprofessionals, veterinarians and diagnosticians, who should report promptly any cases or suspected cases.

b) Clinical surveillance

Clinical surveillance is a critical component of rabies surveillance and essential for detecting suspected cases. Therefore, a process should be in place and documented for the identification and investigation of suspected cases as well as for sample collection for laboratory diagnosis when rabies cannot be

ruled out. Animals (especially carnivores and bats) found dead are recognised as an important source of information for rabies surveillance and should be part of the clinical surveillance.

<u>Laboratory testing should use the recommended sampling techniques, types of samples and tests</u> described in the *Terrestrial Manual*.

c) Sampling

<u>Surveillance</u> should target suspected <u>cases</u>. <u>Probability sampling strategies are not always useful, as sampling of healthy animals (e.g. not involved in human exposure) rarely returns useful <u>surveillance</u> data.</u>

d) Epidemiological investigation

In all situations, especially in countries or zones considering self-declaration of freedom, routine epidemiological investigation of cases and molecular characterisation of virus isolates from human and animal cases is encouraged. Such an investigation allows identification of sources of infection, their geographic origin and their epidemiological significance.



Article 8.14.10.

Cooperation with other Competent Authorities

The Veterinary Authority should coordinate in a timely manner with public health and other Competent Authorities and share information to support the decision-making process for the management of human and animal exposure.

<u>In all regions, Veterinary Authorities of neighbouring countries should cooperate in the control of dog-mediated rabies.</u>

CHAPTER 15.1.

INFECTION WITH AFRICAN SWINE FEVER VIRUS

EU comment

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

Comments are inserted in the text below.

[...]

Article 15.1.1.-bis

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*:

- canned meat in a hermetically sealed container with a FQ-value of 3.00 or more above;
- 2) gelatine.

Other pig commodities of pigs should can be traded safely if in accordance with the relevant articles of this chapter.

Article 15.1.2.

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

- 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;
- 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 foral pigs or African wild suids.

Article 15.1.3.

Country or zone free from ASF

Historical freedom

A country or *zone* may be considered <u>historically</u> free from ASF without pathogen-specific *surveillance* if the provisions of point 1 *a*) of Article 1.4.6. are complied with-<u>and pig commodities are imported in accordance</u> with Articles 15.1.7. to 15.1.20.

2. Freedom in all suids

A country or *zone* which does not meet the conditions of point 1) above may be considered free from ASF <u>in</u> <u>all suids</u> when it complies with all the criteria of Article 15.1.2. and when:

- a) surveillance in accordance with Articles 15.1.27. to 15.1.32. has been in place for the past three years;
- there has been no case of infection with ASFV during the past three years; this period can be reduced to 12 months when the surveillance has demonstrated no evidence of presence or involvement of Ornithodoros ticks;
- c) pig commodities are imported in accordance with Articles 15.1.7. to 15.1.20.
- 3. Freedom in domestic and captive wild pigs

A country or *zone* which does not meet the conditions of point 1) or 2) above, including cases of infection with ASFV in feral or wild pigs, may be considered free from ASF in domestic and captive wild pigs when it complies with all the criteria of Article 15.1.2, especially point 7), and when:

EU comment

For reasons of clarity, the EU suggests replacing the word "including" with the words "even when there are" before "cases of infection", for the sentence above to read as follows:

"A country or zone which does not meet the conditions of point 1) or 2) above, including even when there are cases of infection with ASFV in feral or wild pigs, [...]".

- a) surveillance in accordance with Articles 15.1.27. to 15.1.32. has been in place for the past three years;
- there has been no case of infection with ASFV in domestic or captive wild pigs during the past three
 years; this period can be reduced to 12 months when the surveillance has demonstrated no evidence
 of presence or involvement of Ornithodoros ticks;
- pigs and pig commodities are imported in accordance with Articles 15.1.7. to 15.1.20.

Commodities of domestic or captive wild pigs can be traded safely in accordance with the relevant articles of this chapter from countries free from ASF in domestic and captive wild pigs, even if they notify infection with ASFV in wild or foral pigs or African wild suids.

[...]
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:

Heat treatment

Meat should be subjected to one of the following:

- a) heat treatment in a hermetically sealed container with a F0 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*.

EU comment

As former point 1 a) of this article has been moved to the new article on safe

commodities, keeping the wording of former point 1 b) above unchanged may cause confusion. Indeed, having heat treatment for at least 30 minutes at a minimum temperature of 70 degrees Celsius as the only heat treatment option in this article would seem in contradiction with the relevant entry in the safe commodities article, as the F value of 3 is usually reached within well below 30 minutes. The EU therefore suggests including a reference to other possible time-temperature combinations in point 1 above, similar to what is done in other chapters (e.g. Chapter 10.4. that mentions "any equivalent treatment which has been demonstrated to inactivate avian influenza virus").

2. Dry cured pig meat

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



GLOSSARY

EU comment

The EU thanks the OIE and in general supports most of the proposed changes to the Glossary. However, we do not support the changes proposed to the definition of captive wild animal.

Comments are inserted in the text below.

In general, the EU trusts that efforts will continue within the OIE to align as far as possible the definitions on Competent Authority, Veterinary Authority and Veterinary Services in both the Terrestrial and Aquatic Codes. It is also in this spirit that the EU favors mentioning both OIE Codes in these three definitions (see comments below).

COMPETENT AUTHORITY

means the Veterinary Authority or other <u>a</u> Governmental Authority of a Member Country having the responsibility and that has competence for ensuring or supervising the implementation of animal health and welfare measures, international veterinary certification and other standards and recommendations in the Terrestrial Code and in the OIE Aquatic Animal Health Code in the whole territory, which are not under the competence of the Veterinary Authority.

EU comment

The EU does not support the deletion of the words "and in the OIE Aquatic Animal Health Code" after the words "Terrestrial Code". Indeed, as depending on the country both OIE Codes (in whole or in part) can be under the remit of a Competent Authority other than the Veterinary Authority, it is important to mention both. This would also be in line with the definition of Veterinary Services below, where both Codes are mentioned.

VETERINARY AUTHORITY

means the Governmental Authority of a Member Country, comprising the OIE Delegate, veterinarians, other professionals and paraprofessionals, having the responsibility and competence for ensuring or supervising the implementation of animal health, and animal welfare and veterinary public health measures, international veterinary certification and other standards and recommendations in the Terrestrial Code in the whole territory.

EU comment

The EU suggests inserting the words "and the OIE Aquatic Animal Health Code" after the words "Terrestrial Code". Indeed, as both OIE Codes are under the remit of the Veterinary Authority in many countries, it is important to mention both. This would also be in line with the definition of Veterinary Services below.

VETERINARY SERVICES

means the governmental and non-governmental organisations that implement animal health, and animal welfare and veterinary public health measures and other standards and recommendations in the Terrestrial Code and the OIE Aquatic Animal Health Code in the territory. The Veterinary Services are under the overall control and direction of the Veterinary Authority. Private sector organisations, veterinarians, veterinary

paraprofessionals or aquatic animal health professionals are normally accredited or approved by the *Veterinary Authority* to deliver the delegated functions.

EU comment

The EU suggests adding "and may also contribute to some activities of the Competent Authority" after "and direction of the Veterinary Authority". This is to include the option for contribution by the Veterinary Services in areas covered by the Competent Authority where veterinary input may be necessary or beneficial, and would be in line with the Glossary definition of Competent Authority and with Article 6.2.4. Roles and responsibilities of Veterinary Services in food safety systems. Indeed, the Glossary definition of Competent Authority includes options for supervising the implementation of standards and recommendations of the Code which are not under the competence of the Veterinary Authority. However, some of those may need veterinary competence. Furthermore, in Article 6.2.4. it is indicated that the responsibilities of the Veterinary Services may be limited to the first part of the food chain or may indeed cover the whole food chain. Thus, Veterinar Services contribute to a number of activities beyond primary production.

CAPTIVE WILD [ANIMAL]

means an *animal* that has a phenotype not significantly affected by human selection but that is captive or otherwise lives under direct human supervision or control, <u>i.e. population management, regular contacts or handling, feeding, harvesting and *slaughter*, including zoo *animals* and pets.</u>

EU comment

The EU does not support the change to the definition of "captive wild [animal]" above as proposed. Indeed, rather than improve clarity this could create more confusion and would open room for possible misinterpretation. For example, wild boars in Europe that are neither kept in captivity nor under direct human supervision or control, but are merely occasionally fed for luring and harvested by hunters could be misunderstood as falling within that definition. However that is clearly not the case, as they are neither "handled" nor "slaughtered". Indeed, the situation of these wild boars would rather be equivalent to fishing wild fish in a lake with bait on a fishing rod.

In addition, the words "population management" should be deleted. Indeed, "population management" in relation to wildlife usually refers to a strategy that seeks to maintain a target population at a level that can be supported by the ecosystem. This can involve protecting a threatened population from declining further in numbers, or even re-stocking a population. Conversely, when the numbers of a target population have become too great to be sustained by the food or territory available, then predators can be introduced, or a human-mediated cull can be done. Many wildlife populations are being regulated in order to maintain the populations at levels that can be supported by the ecosystems (i.e. their habitats), and thus subjects to population management by hunters or Forestry Authorities. To include "population management" as an example would make the definition of captive wild animals much too broad: it would essentially mean that most wild populations in the EU would need to be regarded as "captive", which would certainly be contrary to the intended.

To avoid this possible confusion, the EU suggests inserting the word "<u>regular</u>" before "feeding" (as occasional feeding would not qualify as "direct human supervision or

control"), and deleting the word "<u>harvesting</u>" (as it does not fit with the rest of the proposed criteria). Indeed, if the criteria "handling, <u>regular</u> feeding and slaughter" all together are met, this could be assumed to be "direct human supervision or control".

Furthermore, it is unclear what is meant by "regular contacts", or in what way such "regular contacts" would constitute "human supervision or control". Again, to avoid possible confusion, the EU would suggest deleting the words ", regular contacts".

Thus, the definition should be reworded as follows:

"means an *animal* that has a phenotype not significantly affected by human selection but that is captive or otherwise lives under direct human supervision or control, i.e. population management, regular contacts or handling, regular feeding, harvesting and or slaughter, including zoo animals and pets."

EPIDEMIOLOGICAL UNIT

means a group of *animals* with a defined epidemiological relationship that share approximately the same likelihood of exposure to a pathogenic agent. This may be because they share a common environment (e.g. *animals* in a pen), or because of common management practices. Usually, this is a *herd* or a *flock*. However, an *epidemiological unit* may also refer to groups such as *animals* belonging to residents of a village, or *animals* sharing a communal animal handling facility or, in some circumstances, to a single *animal*. The epidemiological relationship may differ from disease to disease, or even strain to strain of the pathogenic agent.

EU comment

The phrase "animals belonging to residents of a village, or *animals* sharing a communal animal handling facility" is already covered under the preceding phrase "common management practices" in the second sentence of the definition above. Furthermore, it may cause confusion to combine these examples in a sentence with the statement that epidemiological units can consist of a single animal. Therefore, these examples should not be included in a separate sentence but rather be linked to "common management practices", as follows:

"(...) This may be because they share a common environment (e.g. animals in a pen), or because of common management practices (including animals belonging to residents of a village, or animals sharing a communal animal handling facility). Usually, this is a herd or a flock. H, however, in some cases an epidemiological unit may also refer to groups such as animals belonging to residents of a village, or animals sharing a communal animal handling facility or, in some circumstances, to a single animal. (...)".

CHAPTER 1.6.

PROCEDURES FOR PUBLICATION OF A SELF-DECLARATION DISEASE FREEDOM, RECOGNITION OF AN OFFICIAL DISEASE FOR ENDORSEMENT AND <u>STATUS</u> ΟF OFFICIAL PROGRAMME RECOGNITION CONTROL BYTHE OIE

EU comment

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

With reference to the EU comment in Annex 20, we request that Article 1.1.5. be moved to this chapter before its revision is finalised.

Further comments are inserted in the text below.

Article 1.6.1.

General principles Publication by the OIE of a self-declaration of disease freedom by a Member Country

A Member Countryries may wish to make a self-declaration as to of the freedom of a country, zone or compartment from an OIE listed disease or another animal disease. The Member Country may inform the OIE of the its claimed status and the OIE may publish the claim. Publication does not imply endorsement of the claim. and request that the OIE publish the self-declaration for information of OIE Member Countries.

A Member Country requesting the publication of a self-declaration should follow the Standard Operating Procedure (available on the OIE website)¹ for submission of a self-declaration of disease freedom and provide documented information on its compliance with the relevant chapters of the *Terrestrial Code*, including:

evidence that the disease is a notifiable disease in the entire country;

EU comment

We note that the wording of the point above differs from that in the Standard Operating Procedures published on the OIE website, whereas the wording of the three points below are an exact match. To avoid an confusion, the EU suggests aligning the wording in this Code chapter and the SOPs.

- history of absence or eradication of the disease in the country, zone or compartment;
- <u>surveillance</u> and early warning system for all relevant species in the country, zone or compartment;
- measures implemented to maintain freedom in the country, zone or compartment.

The self-declaration may be published only after all the information provided has been received and an administrative and technical screening has been performed by the OIE. Publication does not imply endorsement of the claim of freedom by the OIE and does not reflect the official opinion of the OIE. Responsibility for the

OIE Terrestrial Animal Health Standards Commission/September 2018

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¹-http://www.oie.int/en/animal-health-in-the-world/self-declared-disease-status/

accuracy of the information contained in a self-declaration lies entirely with the OIE Delegate of the Member Country concerned.

The OIE does not publish self-declarations for effected for from bovine spongiform encephalopathy (BSE), foot and mouth disease (FMD), contagious bovine pleuropneumonia (CBPP), African horse sickness (AHS), peste despetits ruminants (PPR) and classical swine fever (CSF) diseases listed under point 1) of Article 1.6.21bis.

Article 1.6.21bis.

Official recognition and endorsement by the OIE

EU comment

For accuracy and consistency with Article 1.6.1., we suggest amending the title of this article as follows, even if it will make it rather long:

"Official recognition of disease status and endorsement of official control programmes by the OIE".

- A Member Countryies may request:
- official recognition of status by the OIE of as to:
 - a) freedom of a country or zone from African horse sickness (AHS);
 - b) risk status of a country or zone with regard to bovine spongiform encephalopathy (BSE);
 - freedom of a country or zone from classical swine fever (CSF);
 - d) freedom of a country or zone from contagious bovine pleuropneumonia (CBPP);
 - freedom of a country or zone from foot and mouth disease (FMD), with or without vaccination;
 - f) freedom of a country or zone from peste despetits ruminants (PPR);
- 2) endorsement by the OIE of:
 - a) an official control programme for contagious bovine pleuropneumonia;
 - b) an official control programme for foot and mouth disease;
 - c) an official control programme for peste des petits ruminants.
- 1) the risk status of a country or zone with regard to BSE;
- 2) the freedom of a country or zone from FMD, with or without vaccination;
- 3) the freedom of a country or zone from CBPP;
- 4) the freedom of a country or zone from AHS;
- 5) the freedom of a country or zone from PPR;
- the freedom of a country or zone from CSF.

The OIE does not grant official recognition of status or endorsement of an official control programme for other diseases other than those listed under points 1) and 2) above.

In these cases, Member Countries should present documentation setting out the compliance of their *Veterinary Services* with the applicant country or *zone* with the provisions of Chapters 1.1., 3.1. and 3.2. of the *Terrestrial Code* and with the provisions of the relevant disease-specific chapters in the *Terrestrial Code* and the *Terrestrial Manual*.

When requesting official recognition of disease status or endorsement by the OIE of an official control programme, the Member Country should submit to the OIE Status Department a dossier providing the information requested in the following Chapters (as appropriate): 1.7. (for AHS), 1.8. (for BSE), 1.9. (for CSF), 1.10. (for CBPP), 1.11. (for FMD) or 1.12 (for PPR).

The OIE framework for the official recognition and maintenance of disease status is described in Resolution No. XV (administrative procedures) and Resolution No. XVI (financial obligations) adopted during the 83rd General Session in May 2015, as well as in the Standard Operating Procedures available on the OIE website (available on the OIE website)².

EU comment

There seems to be an unnecessary repetition at the end of the sentence above. Indeed, the words "available on the OIE website" before the parenthesis could be deleted.

The country or the zone, or the country having its official control programme endorsed will be included in the relevant list only after the evidence submitted, based on the provisions of Chapters 1.7. to 1.12., has been adopted by the World Assembly of OIE Delegates.

EU comment

The EU suggests amending the sentence above so as to avoid unnecessary repetition of the words "or the country" and to include mention of disease status recognition as an action, as follows:

"The country or the zone, or the country having its <u>official disease status recognised or</u> official control programme endorsed will be included in the relevant list only after the evidence submitted, based on the provisions of Chapters 1.7. to 1.12., has been adopted by the World Assembly of OIE Delegates.".

Retention on the list requires that the information in relevant chapters be re-submitted annually and that changes in the epidemiological situation or other significant events should be reported to the OIE in accordance with the requirements in Chapter 1.1.

⁻http://www.oie.int/en/animal-health-in-the-world/official-disease-status/official-recognition-policy-and-procedures/

CHAPTER 4.Y.

OFFICIAL CONTROL MANAGEMENT OF OUTBREAKS OF LISTED AND 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.

Article 4.Y.1.

Introduction

When a *listed disease* or <u>emerging disease</u>, including a zoonosis, occurs in a <u>Member C</u>ountry, *Veterinary Services* should implement a <u>response control measures</u> proportionate to the likely impact of the disease and as a <u>result of a risk analysis</u>, in order to minimise its spread and consequences and, if possible, eradicate it. <u>These measures can vary from rapid response (e.g. to a new <u>hazard-disease</u>) and <u>management of outbreaks</u>, to longterm control (e.g. of an endemic disease) <u>infection or infestation</u>.</u>

The purposes of this chapter is to provide recommendations to prepare, develop and implement <u>official</u> control <u>programmes</u> for plans in response to <u>outbreaks</u> occurrence <u>outbreaks</u> of <u>listed and emerging or listed diseases</u>, 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 <u>programmes plans</u>. Although this chapter focuses primarily on <u>listed</u> and <u>emerging diseases</u>, the recommendations may also be used by the <u>Veterinary Authorities</u> for any <u>notifiable diseases</u> or diseases against which they have established <u>official control programmes</u>.

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.

Centrel plans They Official control programmes 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 preferably be supported by relevant cost-benefit analysis when possible and should include the necessary regulatory, technical and financial tools.

<u>Official control programmes</u> Centrol 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 <u>infection</u> or <u>infestation</u>.

EU comment

For reasons of clarity, the EU suggests adding "from a given population" at the end of the paragraph above.

The general components of an official control programme include:

- 1) a plan of the programme to control or eradicate the relevant disease in the country or zone;
- regular and prompt animal disease reporting;
- 3) surveillance of the relevant disease in accordance with Chapter 1.4.;

<u>rapid detection of, and response to, the relevant disease, to reduce the incidence and to eliminate transmission:</u>

EU comment

The EU suggests inserting "the impact or" before "the incidence" in point 4 above, as that may also be relevant depending on the disease and the goal of the official control programme.

<u>measures implemented to prevent introduction or spread of the relevant disease, including biosecurity and movement control:</u>

EU comment

We suggest inserting the words "and where appropriate control measures to protect <u>public health</u>" at the end of point 5) above, as the text in this list at present focusses on non-zoonotic diseases.

6) vaccination programme as relevant;

EU comment

Please replace "as relevant" with "if appropriate". Indeed, there may be vaccination programmes relevant to disease outbreaks but with other factors (such as trade and public health) considered, their use may not be appropriate.

7) preparedness and contingency plans;

EU comment

The EU suggests inserting the words "<u>if relevant</u>" after "preparedness and contingency plans" above, as implementation of appropriate control measures after risk analysis will not necessarily need a contingency plan as described in Article 4.Y.3.

8) communication and collaboration with other relevant Competent Authorities.

In any case, Ithe critical components of control plans for management of outbreaks for diseases that are not present in the Member Country are measures to prevent the introduction, and early detection warning system (including a warning procedure), and and rapid response and quick and effective action, possibly followed by long-term measures. Plans should always include an exit strategy.

EU comment

The EU suggests adding the words "<u>where relevant</u>" after "exit strategy". Indeed, an exit strategy may not always be needed, e.g. when the goal is merely reducing the impact of the disease and not eradication.

Learning from past *outbreaks*₂ and reviewing the response sequence <u>and revising the methods</u> are critical for <u>adaptation to evolving epidemiological situations</u> circumstances and for better performance in future <u>situations</u>. <u>Experiences of the Veterinary Services of other Member Countries may also provide useful lessons</u>. Plans should be tested regularly to ensure that they are fit-for-purpose, practical, feasible and well-understood and that <u>field</u> staff are trained and other stakeholders <u>are</u> fully aware of their <u>respective</u> roles and <u>responsibilities</u> in implementing the response. <u>This is especially important for diseases that are not present in the Member Country.</u>

Article 4.Y.2.

Legal framework and regulatory environment

- In order to be able to effectively control <u>listed diseases and emerging diseases and listed diseases</u>, 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 infectious transmissible animal diseases, including zoonoses;

- 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 authority; 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;

EU comment

Outdoor activities such as hunting and corresponding biosecurity measures should also be addressed in the point above.

- sources of financing for dedicated supporting staff;
- sources of financing for epidemiological enquiries, laboratory diagnostic, disinfectants, insecticides, vaccines and other critical supplies;

EU comment

Capacity of communication and awareness campaigns could also be added to the point above.

 sources of financing and compensation policy for livestock <u>commodities</u> and property that may be destroyed as part of disease control programmes, <u>or for direct losses incurred due to movement</u> <u>restrictions imposed by the control programme</u>;

EU comment

The EU suggests inserting the words "<u>(including from the livestock sector via insurance schemes)</u>" after "as part of disease control programmes" to clarify that compensation can also come from the sector itself and is not limited to public funding and government policy.

Furthermore, as indicated previously, the EU does not support the second part of the sentence regarding losses due to movement restrictions, as these cannot be covered by public funding. It is also not clear how to separate "direct" from "indirect" losses in this context. Thus, the second part of the sentence starting with "or for direct losses" should be deleted, or it should be clarified that these losses could at most be covered by private schemes.

- 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 assess 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 listed disease or 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;
 - <u>procedures for epidemiological investigations of outbreaks including tracing of animals and animal products;</u>
 - 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 <u>animal identification</u> and the management of <u>animal identification systems</u> the identification of <u>animals</u>:

- procedures for the restrictions of movements, including possible standstill or compulsory veterinary certification, of relevant animals, and animal products and fomites within, to, or from given zones or establishments or other related enterprises;
- procedures for the destruction or slaughter and safe disposal or processing of infected or potentially infected animals, including relevant wildlife; and
- <u>procedures for the destruction and safe disposal or processing of</u> contaminated or potentially contaminated <u>animal</u> products and <u>other</u> materials <u>such as fodder, bedding and litter</u>;
- <u>procedures for cleaning, disinfection and disinsection of establishments and related premises, vehicles/vessels or equipment;</u>
- procedures for compensation for the owners of animals or animal products, including defined standards and means of implementing such a compensation;
- procedures for cleaning, disinfection and disinsection of establishments and related premises, vehicles or equipment;
- procedures for the compulsory emergency implementation of vaccination programmes or treatment of animals, as relevant, and for any other necessary disease control actions-;
- procedures for post-control surveillance and possible gaining or recovery of status, as relevant.

Article 4.Y.3.

Emergency Ppreparedness

In case of occurrence of a disease that was not present in the country or zone, or of sudden increase of incidence of a disease that is present, Rrapid and effective response to a new occurrence or emergence of contagious infectious diseases is dependent on the level of preparedness. The Veterinary Authority should integrate preparedness planning and practice within the official control programmes against these diseases 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.

EU comment

The EU suggests inserting the word "<u>transmissible</u>" before "disease" in the first line of the paragraph above, for reasons of clarity and consistency with other parts of the text.

Preparedness should be <u>justified</u> <u>supported</u> by *risk analysis*, should be planned <u>in advance</u>, and should include <u>training</u>, capacity building and simulation exercises.

Risk analysis

Risk analysis, including import risk analysis, in accordance with Chapter 2.1., should be used to determine which a list of notifiable diseases that 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 <u>reviewed</u> <u>updated</u> 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) <u>and be updated accordingly, taking into account the latest scientific findings.</u>

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 a notifiable disease or

an emerging disease or a notifiable disease occurs;

- a response or contingency plan, which details what should be done in the event of an occurrence of a notifiable disease or 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, including food supply, possibly including procedures and practices modified in light of the experience gained during the management of the eutbreak notifiable disease or the emerging disease.

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. <u>Simulation exercises may be organised between the *Veterinary Services* of neighbouring countries and other relevant agencies.</u>

Article 4.Y.4.

Surveillance and early warning detection systems

4) Depending on the priorities identified by the *Veterinary Authority*, *Veterinary Services* should implement adequate *surveillance* for *listed diseases* in accordance with Chapter 1.4. er and <u>listed disease-specific</u> 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 are an integral component of emergency preparedness. They should be in place for diseases *infections* or *infestations* for which a rapid response is desired, and should comply with the relevant articles of Chapter 1.4. When used, *Vyector surveillance* should be conducted in accordance with Chapter 1.5.

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 at least the implementation of local control measures as a precaution. When Once a case is confirmed, full sanitary measures should be implemented as planned.

EU comment

With the previous sentences deleted, for reasons of clarity, the EU suggests inserting the words "of a listed or emerging disease" after "Strong suspicion" at the beginning of the sentence above.

In addition, it is not clear what is meant by "local" in the context of the paragraph above. Perhaps "local <u>preventive</u> control measures as a <u>precaution</u>." would be more appropriate.

Furthermore, the words "as planned" should be deleted as it gives the impression that preventive control measures were no planned, even though they should be.

- 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 for outbreak management

EU comment

It does not seem logical to have the article with the general considerations after Article 4.Y.2 in which all the concepts have been introduced through necessary procedures. We would therefore suggest moving Article 4.Y.5. up.

<u>Upon confirmation of Once</u> an *outbreak* <u>of a notifiable disease or an emerging disease or a notifiable disease that is subject to an <u>official control programme</u> is <u>confirmed</u> effective <u>risk management</u> depends on the application of a combination of measures that are operating at the same time or consecutively, aimed at:</u>

 epidemiological investigation to trace back and forward animals in contact and potentially infected or contaminated products:

- 42) eliminating the source of pathogenic agent, through:
 - the killing or slaughter of animals infected or suspected of being infected, as appropriate, and safe disposal of dead animals and potentially contaminated products;
 - the cleaning, disinfection and, if relevant, disinsection of premises and equipment;
- 23) stopping the spread of infection, through:
 - movement restrictions on animals <u>commodities</u>, vehicles, and equipment and people, as appropriate;
 - biosecurity;
 - vaccination, treatment or culling of animals at risk;
 - control of vectors;
 - communication and public awareness.

Different strategies may be chosen depending on the expected outcome of the programme (i.e. eradication, containment or partial control) and 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. The strategies chosen will, in turn, influence the final objective of the control programme.

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, as described in regulations, policies or guidance.

In case of highly contagious transmissible or high impact disease events, the management plan should be closely coordinated through an inter-sectoral mechanism such as an incident command system.

EU comment

The term "management plan" appears in the two paragraphs above, while it is not used in any other article of the chapter. It is therefore unclear what exactly it refers to, what is meant by it or how it fits into this Chapter (e.g. is it linked to one or more of the four plans in "Emergency preparedness" of Article 4.Y.3. or is it linked to the "official control programme" in Article 4.Y.1.?).

Furthermore, the paragraph above could be expanded to include the link to public health in the case of zoonoses.

Article 4.Y.6.

Culling <u>of animals</u> and disposal <u>of dead animals and animal products other commodities</u>

Living infected animals can be are the greatest source of pathogenic agents. These animals may directly transmit the pathogenic agent to other animals₂. They may and also cause lead to indirect infection transmission of pathogenic agents through live organisms (vectors, people) or 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 transmissible diseases.

Veterinary Services should adapt any <u>strategy for culling</u> of <u>animals</u>, <u>killing</u> or <u>disposal of dead animals</u> and <u>their products</u> other <u>commodities</u> strategy to the transmission pathways of the <u>pathogenic</u> agent. <u>A stamping-out policy</u> is <u>should be</u> the preferred strategy for highly <u>contagious transmissible</u> diseases and for situations where the

country or *zone* was formerly <u>previously</u> free or freedom was impending, while other strategies, such as test and cull, are better suited to less contagious transmissible diseases and situations where the disease is endemic.

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.

The slaughter or killing of animals should be performed in accordance with Chapter 7.5. or Chapter 7.6., respectively.

The disposal of dead *animals* and their potentially contaminated products should be performed in accordance with Chapter 4.12.

Stamping-out policy

<u>A stamping-out policy</u> consists primarily in <u>of</u> the <u>killing</u> of all the <u>animals affected</u> infected or suspected of being affected, including those which that have been directly or indirectly exposed to the causal pathogenic agent. This strategy is used for the most centagious transmissible diseases.

<u>A stamping-out policy</u> 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.

Depopulation and carcass disposal can be applied to wildlife within a defined zone, based on the assessment of associated risks.

Killing should preferably be performed on site, and the carcasses <u>either</u> 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.

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.

<u>Stamping-out policy</u> procedures systematically include the cleaning and *disinfection* of *establishments* and *vehicles*/<u>vessels</u> 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.

2. Test and cull

This strategy consists <u>primarily</u> of finding the <u>preven</u> infected <u>animals</u> in order to remove them from the population and either <u>slaughter</u> or kill and dispose of them. <u>This strategy is the should be</u> used for less <u>contagious</u> transmissible or slow-spreading diseases. <u>Veterinary Services may apply different test and cull strategies based on the epidemiology of the <u>infection or infestation or on the characteristics of available diagnostic tests</u>. In particular, the design of test and cull strategy will depend on the sensitivity and specificity of the tests. <u>Veterinary Services may adjust test and cull strategies to the changes of the <u>prevalence</u>.</u></u>

EU comment

The test and cull strategy may also not be appropriate for "slow spreading diseases" as the detection capacity of infection is a key parameter. We would thus prefer simply indicating that it is not appropriate for highly transmissible diseases, as follows:

"This strategy is <u>not appropriate</u> used for <u>less highly</u> transmissible or slow-spreading diseases."

Apart from the selection of *animals* to be culled, the same principles apply as for *stamping-out <u>policy</u>* 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 <u>and their associated products</u>, and to people, <u>vehicles/vessels</u> and equipment. They may vary from pre-movement certification to total standstill, and be limited to one or more <u>establishments</u>, or cover specific <u>zones</u>, or the entire country. The restrictions can include the complete isolation of individual <u>animals</u> or group of <u>animals</u>, and specific rules applied to movements, such as protection from <u>vectors</u>.

EU comment

A reference to Article 4.Y.10. and Chapter 4.3. on zoning and compartmentalisation could be included in the paragraph above.

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, and law enforcement agencies, and with communication media, as well as with the Veterinary Services of neighbouring countries in the case of transboundary animal diseases.

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, <u>of equipment</u>, of *vehicles*/<u>vessels</u>, and of the environment <u>or anything capable of acting as a fomite</u>.

<u>Disinfection</u> and <u>disinsection should be applied in accordance with Chapter 4.13.</u> When <u>disinfection</u> is <u>applied, specific</u> disinfectant solutions should be used for footbaths or disinfectant baths for vehicles' wheels. <u>Single</u> use material and clothes <u>or material and clothes that can be effectively cleaned and disinfected</u> should be used for the handling of <u>animals</u> and animal products; <u>Protection</u> of premises from <u>wildlife</u> <u>and other unwanted animals</u> should be ensured; <u>Wastes</u>, waste-water and other effluents should be collected and treated appropriately.

Article 4.Y.9.

Vaccination and treatment

Vaccination as part of an official control programme in response to a contagious disease outbreak should be conducted in accordance with Chapter 4.17.

Vaccination programmes, especially 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 barrier, blanket, vaccination or ring or targeted vaccination.

EU comment

The EU suggests inserting the words "<u>or antigen</u>" before "banks", as for some diseases antigen banks are more common than vaccine banks.

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 induced by *infection* with the pathogenic agent.

EU comment

For some diseases it is also possible to differentiate the live vaccine strain from field strains in animals that are tested positive in PCR assays (e.g. Lumpy Skin Disease); this could also be mentioned in the paragraph above.

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 <u>circulation</u> <u>prevalence</u> of the *infection* until <u>its</u> levels are <u>is</u> low enough for <u>the implementation of another strategyies</u> such as a test and cull strategy.

Vaccination can also be used to minimise the impact of an infection by reducing clinical signs or economic losses.

EU comment

In the sentence above, when discussing vaccination to reduce economic losses, this should be balanced with the losses due to the impact of vaccination on trade. Indeed, while this is addresses in Chapter 4.17., it would be worth stating it also here. The EU therefore suggests amending the sentence as follows:

"Vaccination can also be used to minimise the impact of an infection by reducing clinical signs or economic losses, however a cost benefit analysis with regards to trade and public health should be considered.".

Whenever *vaccination* is to be used as a tool to control *outbreaks* or spread of disease, the control plan should include consider an exit strategy, i.e. when and how to stop the *vaccination* or whether *vaccination* should become systematic routine.

Article 4.Y.10.

Zoning

The *Veterinary Authority* should use the tool of zoning in *official control programmes*, in accordance with Chapter 4.3.

The use of zoning for disease control <u>and eradication</u> is inherently linked with measures of *killing_or_slaughter*, 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.

Zones <u>established</u> <u>defined</u> <u>in response to outbreaks of notifiable diseases or emerging diseases er listed</u> <u>diseases</u> <u>may be are usually infected zones, <u>containment zones and</u> <u>protection zones, and containment zones, and containment zones, thousely of zones, e.g. such as zones of intensified surveillance, or zones of intensified vaccination can also be used.</u></u>

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 <u>part of the official</u> <u>control programme and be</u> carried out, among others, through awareness campaigns targeted at breeders, <u>veterinary paraprofessionals</u>, local authorities, <u>the media</u>, consumers and general public.

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 <u>official</u> control <u>programme</u> plan, and assess the status of the <u>remaining</u> animal populations in the different <u>zones</u> 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 <u>listed</u> 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.

CHAPTER 7.Z.

ANIMAL WELFARE AND LAYING HEN PRODUCTION SYSTEMS

EU comment

The EU thanks the OIE for its work on the revision of this new draft chapter and for taking several of the EU comments into account.

The EU can support the proposed changes and has some additional comments. Furthermore, the EU would like also to reiterate some of its previous comments.

Comments are inserted in the text below.

Article 7.Z.1.

Definitions

For the purposes 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. <u>Breeding hens are excluded.</u>

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 addresses the welfare aspects of commercial laying hen production systems. This chapter It covers the production period from the arrival of day-old birds on the pullet-rearing farm to the removal of end-of-lay hens from the laying production facilities. Laying hens kept in village or backyard flocks and used for personal consumption are excluded.

Commercial production systems involve the confinement of <u>pullets and hensbirds</u>, the application of *biosecurity* and trade in the eggs or pullets. These recommendations cover pullets or <u>laying</u> hens kept in cage or non-cage systems, whether indoors or outdoors.

Commercial pullet or hen production systems include:

Indoor systems

Pullets or hens are completely confined in a poultry house, with or without <u>mechanical</u> environmental control <u>and with no designated outdoor area</u>.

Outdoor systems

Pullets or hens are kept in premises with or without <u>mechanical</u> environmental control <u>but have access to that include</u> a designated outdoor area.

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 and or hens

The welfare of pullets <u>and</u> or hens should be assessed using outcome-based measurables, <u>specifically animal-based measurables</u>. 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 <u>animal welfare</u>. The use of these <u>measurables</u> indicators and the appropriate thresholds should be adapted to the different situations where hens are managed, also taking into account the <u>genetics</u> <u>used strain of bird concerned</u>.

Consideration should also be given to the resources provided as well as the design and management of the system. Animal-based criteria can be considered as tools to monitor and refine these factors.

Criteria that can be measured in the farm setting include <u>behaviour</u>, body and plumage condition, egg shell condition, mortality and morbidity rates, <u>bone and foot problems</u>, etc. together with other factors such as genetics <u>and environment</u>. The age at which abnormalities of these criteria are observed can help to determine the origin <u>causation of potential problems</u>. 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 would like to propose the following editorial revision:

"Criteria that can be measured in the farm setting include behaviour, body and plumage condition, egg shell condition, mortality and morbidity rates, bone and foot problems, etc. <u>Ttogether with other factors such as genetics and environment.</u> tThe age at which abnormalities of these criteria are observed, other factors such as genetics and environment can help to determine the origin causation of potential problems."

Justification

The proposed revision puts more emphasis on the role of 'genetics and environment'.

Conditions such as bone and foot problems, disease, infection or infestation can be assessed during routine or targeted sampling and at depopulation. It is recommended that target values or thresholds for welfare measurables be determined with reference to current scientific knowledge and appropriate national, sectorial or regional standards for pullets or hens.

The following outcome-based criteria and measurables are can be useful indicators of pullet or hen welfare:

Behaviour

The presence or absence of certain chicken behaviours could indicate either good animal welfare or an animal welfare problem, such as 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-Aurrekeetxea, 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. The domestic fowl have evolved behaviours that they are highly motivated to perform and a good understanding of their normal behaviour [Nicol, 2015], including their social interactions [Estevez et al., 2007; Rodríguez-Aurrekoetxea A. and Estevez I., 2014], is required for appropriate management decision making. Opportunities to display these behaviours are influenced by the physical and social environment [Widowski et al., 2016; Lay et al., 2011; O'Connor et al., 2011].

EU comment

The EU agrees with the OIE to move the sentence below from the locomotory and comfort behaviours section to the behaviour section but suggests keeping its initial version and adding the element of 'the light level' as follows:

"Opportunities to display these behaviours are influenced by the physical housing system and social environment, space and light level [Widowski et al., 2016; Lay et al, 2011; O'Connor et al, 2011]."

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.

Opportunities to display these behaviours are influenced by housing system and space

a) Dust bathing

Dust bathing is an intricate body maintenance behaviour. During dust bathing, <u>pullets and hensbirds</u> work loose material, such as litter, through their feathers. This behaviour helps remove <u>stale lipids dirt</u> [Van Liere and Bokma, 1987] and parasites [Martin and Mullen, 2012], which contributes to maintaining plumage condition, which in turn helps to maintain body temperature and <u>to</u> 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]. <u>The presence of complete sequences of dust bathing may indicate good welfare [Widowski and Duncan, 2000].</u>

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 <u>traumatic</u> injur<u>iesy</u>, <u>and suffocation</u> when the <u>pullets and hensbirds</u> pile on top of, <u>and sometimes suffocate</u>, one another. Fearful <u>pullets and hensbirds</u> may be less productive [Barnett J. et al., 1992] <u>and more prone to injurious feather pecking behaviour [Hass et al., 2014]</u>. Methods have been developed for evaluating fearfulness, <u>for example when</u> <u>while animal handlers</u> walk through the poultry house or <u>pullets and hensbird</u> area [Jones, 1996; Forkman et al., 2007].

c) Feeding and drinking behaviour

Reduced Changes in feeding or drinking behaviour eanmay indicate management problems, including inadequate spaces for, or inappropriate placement of, feeders or drinkers, dietary imbalances, poor feed or water quality, or feed contamination [Garner et al., 2012; Thogerson et al., 2009a; Thogerson et al., 2009b]. Feeding and drinking are often depressed when birds are ill, and intake may also be reduced change during periods of heat [Lara L. J. & Rostagno M. H., 2013; Lin H. et al., 2006] stress and increased or during cold stress [Alves et al., 2012] [Garner et al, 2012; Thogerson et al, 2009b].

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 substrate quality or the presence of conditions that decrease pullets and hensbird movement [Appleby et al., 2004; Lay et al., 2011; Weeks and Nicol, 2006]. When in the presence of an adequate substrate, laying hens spend a large amount of time foraging even when food is readily accessible [Weeks and Nicol, 2006.]. Frequent foraging bouts may indicate good welfare [Dawkins, 1989; Duncan and Hughes, 1972] and reduce the incidence of injurious feather pecking [Blokhuis, 1989].

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 or death. These behaviours can have multifactorial causes [Hartcher, 2016; Estevez, 2015; Nicol et al., 2013; Rodenburg, 2013; Lambton, 2013; Newberry, 2004].

f) Locomotorytion and comfort behaviours

Locomotorytion and comfort behaviours are important for the health of the pullets and hens, allowing for skeletal, body and plumage development and their maintenance, These behaviours and may include walking, running, leaping, turning, stretching legs and wings, wing flapping, feather ruffling and tail wagging and preening [Dawkins and Hardie, 2007; Shipov et al., 2010; Norgaard, 1990].

EU comment

The EU suggests adding also "flying":

"These behaviours may include walking, running, leaping, <u>flying</u>, turning, stretching legs and wings, wing flapping, feather ruffling, tail wagging and preening."

Justification

The EU considers that "flying" is also part of these behaviours.

References

Appleby, M. C., J. A. Mench, and B. O. Hughes. 2004. Poultry behaviour and welfare Poultry behaviour and welfare. Wallingford, U.K.: CABI Publishing

Opportunities to display these behaviours are influenced by housing system and space [Widowski et al., 2016; Lay et al., 2011].

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].

h) Perching

Perching is a natural and highly motivated behaviour. Birds Pullets and hens 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].

EU comment

The EU proposes to add a new sentence after the above reference:

"Perches need to be presented to the pullets at an early age."

Justification

Same scientific reference: Janczak and Riber, 2015; Gunnarsson et al., 1999

In line also with Article 7.z.6.

i) Resting and sleeping

Sleeping is a natural behaviour in pullets and hens, including slow-wave and fast-wave sleep states [Blokhuis, 1983]. Sleep is an adaptive state that allows animals to recover from daily stress, conserve energy and consolidate memory [Siegel, 2009]. Pullets and hens display highly synchronized resting and sleeping behaviours, which can be disrupted by light intensity, photoperiod, environmental or social factors [Malleau et al., 2007; Alvino et al., 2009].

ii) Social behaviour

<u>Pullets and hensChickens</u> 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], <u>aiding help in thermoregulation</u> and plumage maintenance. <u>Social behaviour may differ according to the characteristics of the social environment (Estevez *et al.*, 2002; 2007). Problems in social behaviour can be assessed using scoring systems for measuring the degree of aggression damage and competition for resources [Estevez *et al.*, 2002].</u>

EU comment

The EU suggest instead of "species" in the first paragraph to consider adding

"animals":

"Pullets and hens are a highly social species animals, engaging in synchronised behaviour"

Justification

Species refers to chickens. In the context of pullets and hens animals is the appropriate term.

ik) Spatial distribution

Uneven spatial distribution of the birds may indicate thermal discomfort or uneven availability <u>or use</u> of resources, such as light, food or water, shelter, nesting area <u>and</u> comfortable resting locations. [Rodríguez-Aurrekoetxea and Estevez, 2016; <u>Cornetto and Estevez, 2001</u>; <u>Bright and Johnson, 2011</u>].

EU comment

The EU suggests replacing the word "food" by "feed":

"Uneven spatial distribution of the birds may indicate thermal discomfort or uneven availability or use of resources, such as light, food feed or water, shelter, nesting area and comfortable resting locations. [Rodríguez-Aurrekoetxea and Estevez, 2016; Cornetto and Estevez, 2001; Bright and Johnson, 2011]."

Justification

For consistency of terminology with the rest of the chapter.

kl) 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.

1m) 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 <u>animal</u> welfare <u>outcomes</u> problems for individual birds. At *flock* level, uneven body condition may be an indicator of <u>potential poor animal</u> welfare <u>problems</u>. 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]. <u>The choice of sampling methods should take into account feather cover that can mask actual body condition.</u>

3. Eye conditions

Conjunctivitis can indicate <u>disease or</u> the presence of irritants such as dust and ammonia. High ammonia levels can also cause corneal burns and eventual blindness. Abnormal eye development <u>can may</u> be associated with low light intensity [Jenkins *et al.*, 1979; Lewis and Gous, 2009; Prescott *et al.*, 2003].

4. Foot problems

Hyperkeratosis, and bumblefoot, excessive claw growth, broken claws and toe injuries are painful conditions associated with inappropriate flooring, poorly designed perches or poorly maintained litter [EFSA, 2005; Lay et al., 2001; Abrahamsson and Tauson, 1995; Abrahamsson and Tauson, 1997].

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, <u>manure</u> 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.

Injury rate and severity

<u>Injuries are associated with pain and risk of infection</u>. The rate and severity of injuries <u>ean-indicate health and welfare problems</u> in the *flock* during production. They can be a consequence of the actions of <u>Injuries include those caused by</u> other birds (e.g. scratches, feather loss or wounding), <u>management (e.g. nutrition)</u> environmental conditions, (e.g. fractures and keel bone deformation), and <u>or</u> by human intervention (e.g. during handling and catching).

EU comment

The EU would like to have clarified the reason for the inclusion of nutrition as an example, and as the only example, of a management practices that could lead to injury.

Justification

The OIE *ad hoc* Group report (point 6 page 8) refers to the inclusion of husbandry management; however we question "nutrition" as an example of a husbandry management that could lead to injury and not including other examples such as genetics.

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.

Performance

Daily, weekly and cumulative performance should be within expected ranges. Any unforeseen <u>reduction</u> decreases in these rates could <u>may</u> 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.
- 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 e.g. the number of eggs per hen housed.
- e) Egg quality <u>and downgrades</u>, such as when measured by <u>e.g.</u> <u>grade percentage</u>, shell strength-and. <u>Haugh units</u>, abnormalities and <u>mis-laid or floor eggs</u>.

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 injurious feather pecking behaviour, nutritional problems, external parasites and abrasions resulting from faults in the equipment housing system [Rodriguez-Aurrekoetxea and Estevez, 2016; Drake et al., 2010]. Plumage dirtiness may be associated with illness, the environmental conditions and or production system. Plumage scoring systems have been developed for these purposes [Blokhuis, 2007].

10. Water and feed consumption

Monitoring daily water and feed consumption is a useful tool to which may indicate thermal stress, 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 Changes in intake, crowding at feeders and drinkers and wet litter and diarrhoea, dermatitis, dehydration, changes in

egg quality or quantity, production and body condition may be associated with problems with the water or feed quality and supply.

Article 7.Z.4.

Recommendations

Ensuring good welfare of pullets and hens is contingent on several management factors, including system design, environmental 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.Z.5. to 7.Z.29. provide recommendations for measures applied to pullets and hens.

Each recommendation in Article 7.Z.5. to 7.Z.29. includes a list of relevant animal-based criteria and measurables derived from Article 7.Z.3. This does not exclude other criteria and measurables being used where or when appropriate. The suitability of some of these criteria and measurables will be determined by the system in which the pullets and hens are housed.

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, design, construction and equipment of establishments

The location of pullets 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 accessible equipment should be designed, after consideration of bird the opportunities for pullets and hens to perform highly motivated behaviours (e.g. perching and nesting), to promote good animal welfare and be maintained to avoid injury or discomfort pain to the birds.

EU comment

The EU proposes to add "foraging" to the examples of highly motivated behaviours under the second paragraph of this Article:

"Pullet and layer houses, outdoor areas and accessible equipment should be designed, after consideration of bird the opportunities for pullets and hens to perform highly motivated behaviours (e.g. perching $\frac{\text{and}_{\frac{1}{2}}}{\text{nesting}}$ nesting and foraging), to promote good animal welfare and be maintained to avoid injury or discomfort."

Justification

The LayWel report, Deliverable 7.1 (page 27) and the 2004 EFSA report states that foraging is a "very important part of the normal behavioural repertoire" of laying hens.

The 2004 EFSA Opinion describes foraging as a high priority behaviour and states that if hens cannot perform foraging "this may result in significant frustration, or deprivation ... which is detrimental to their welfare".

This also makes the list consistent with paragraphs 7.z.11, 7.z.12 and 7.z.13

References

LayWel Deliverable 7.1. Overall strengths and weaknesses of each defined housing system for laying hens, and detailing the overall welfare impact of each housing system http://www.laywel.eu/web/pdf/deliverable%2071%20welfare%20assessment.pdf

Opinion of the Scientific Panel on Animal Health and Welfare on a request from the Commission related to the welfare aspects of various systems of keeping laying hens.

The EFSA Journal (2005) 197, 1-23, The welfare aspects of various systems of keeping laying hens

Furthermore, the EU proposes adding a new paragraph after the second one as follows:

"The equipment should be designed in a way that allows keepers to inspect all the birds in line with the provisions of article 7.Z.28"

Justification

To emphasise in this section the importance in taking into account the inspection aspect in the design and provision of equipment.

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 and contingency plans in place to deal with, the failures of which could jeopardise bird pullet and hen welfare.

Outcome Animal-based measurables include: culling and morbidity <u>rates</u>, fear behaviour, feeding, <u>and</u> drinking <u>behaviour</u>, and foraging <u>activity</u>, foot problems, incidence of diseases, *infections* and *infestations*, injury rates and severity, locomotion and comfort behaviours, mortality <u>rates</u>, performance, plumage condition, <u>resting and sleeping</u>, social behaviour and spatial distribution, thermoregulatory behaviour, vocalisations.

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 <u>pre-adapt</u> prepare the bird for the <u>intended</u> layer production system [Aerni et al., 2005].

<u>AnimalOutcome</u>-based measurables include: dust bathing, feeding, and drinking <u>behaviours</u>, foraging <u>activity</u>, incidence of diseases, injurious feather pecking and cannibalism, injury rate and severity, locomotoryion and comfort behaviours, mortality <u>rate</u>, nesting, <u>infestations</u>, perching, performance, plumage condition, <u>resting and sleeping</u>, social behaviour, spatial distribution.

Article 7.Z.7.

Stocking density Space allowance

Pullets and hens should be housed <u>with</u> at a <u>space allowance</u> <u>stocking density</u> that allows them to have adequate access to resources and to express locomotoryien and comfort behaviours. The following factors should be taken into account:

EU comment

The EU would like to reiterate the importance of including a minimum space allowance and asks OIE to take into account the following revision:

"Pullets and hens should be housed with at a space allowance that allows them to have adequate access to resources and to express locomotory and comfort behaviours; this space allowance should be at the very minimum 750 cm² per hen in cage systems."

Justification

The EU believes that specifying a minimum threshold value on space allowance in cage systems should be included in this section. There is substantive scientific evidence supporting that insufficient space allowance impairs hens to express priority behaviours. Furthermore, providing a minimum of 750 cm² per bird is found to have resulted in significant improvements in hen welfare.

References

Opinion of the scientific panel on animal health and welfare on a request from the Commission related to the welfare aspects of various systems of keeping laying hens' (Question N EFSA-Q-2003-092) EFSA Journal (2005) 197, 1-23,

Report of the Scientific Veterinary Committee, Animal Welfare Section on the Welfare of Laying Hens, Brussels, 30 October 1996.

- management capabilities,
- ambient conditions,
- housing <u>design</u> system
- usable space,
- production system,
- litter quality,
- ventilation,
- biosecurity strategy,
- genetics strain,
- age and bird mass.

<u>AnimalOutcome</u>-based measurables include: <u>dust bathing, feeding and drinking and foraging behaviour, foraging activity, feeding, incidence of diseases, *infections* and *infestations*, injury rate and severity, locomotoryion and comfort behaviours, mortality rate, nesting, perching, performance, plumage condition, <u>resting and sleeping</u>, social behaviour, spatial distribution.</u>

Article 7.Z.8.

Nutrition

Pullets and hens should always be fed a diet appropriate to their age<u>, production stage</u> and genetic<u>s</u> 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, <u>debris</u> and microorganisms hazardous to bird health.

The feeding and watering systems should be <u>inspected regularly and</u> cleaned <u>as needed</u> regularly to prevent the growth of hazardous microorganisms.

Birds <u>Pullets and hens</u> 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 <u>newly hatched</u> <u>pullets chicks</u> to access appropriate feed and water.

<u>AnimalOuteome</u>-based measurables include: <u>aggression, body condition, performance (egg quality)</u>, water and feed consumption, foraging <u>activity</u> <u>behaviour</u>, incidence of disease, *infections* and *infestations*, injurious feather pecking, injury rate and severity, metabolic disorders, mortality rate, performance, <u>plumage condition</u>, vocalisations.

Article 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 and construction of the floor should allow birds pullets and hens to express normal locomotoryien and comfort behaviours. The floors should provide adequate support the birds adequately, prevent injuries, entrapments and ensure good health and that manure does not contaminate other birds pullets and hens. Changes of flooring types from pullet to layer housing should be avoided. The flooring should be easy to clean and disinfect and should not cause harm.

The prevision 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 managed to remain dry and friable, replaced or adequately treated or replaced when required to prevent diseases and minimise any detrimental effects on welfare, infections and infestations.

<u>AnimalOutcome</u>-based measurables include: comfort behaviour, dust bathing, foot problems, foraging, incidence of diseases, *infections* and *infestations*, injury rates and severity, locomotoryion, performance, plumage condition, resting and sleeping.

Article 7.Z.10.

Dust bathing areas

The provision of friable, dry litter material is desirable to encourage dust bathing by pullets and hens.

EU comment

The EU proposes to modify the above sentence as follows:

"The provision of $\underline{\underline{F}}$ friable, dry litter material is desirable to encourage dust bathing by pullets and hens should be provided."

Justification

Dust-bathing is also a high priority behaviour.

References

EFSA Journal (2005) 197, 1-23. The welfare aspects of various systems of keeping laying hens

De Jong, I.C. and Blokhuis, H.J. The welfare of laying hens, Proceedings of the XII European Poultry Conference, Verona, Italy, 12-14 sept 2006

Hens are highly motivated to access litter for dust bathing, and showed very strong preference of hens for dust bathing in peat moss (there was no preference to stay on a certain substrate in general, but the efforts and the total expenditure to take a dust bath in peat moss were high).

De Jong et al. (2007), Applied Animal Behaviour Science 104 (2007) 24-36.

Matthews, L.R., Temple, W., Foster, T.M., Walker, A.W., McAdie, T.M., 1995. Comparison of the demand for dustbathing substrates by layer hens. In: Rutter, S.M., Rushen, J., Randle, H.D., Eddison, J.C. (Eds.), Proceedings of the 29th International Congress of the ISAE, Conference Universities' Federation of Animal Welfare, Exeter, pp. 11–12.

'Hens have been found to work for access to a range of additional resources including pecking, scratching and dust bathing substrates, perches (particularly prior to nightfall), additional space and nestboxes.' And: 'Modified or enriched cages allow for these activities, as well as perching, and, potentially dust bathing, but do not allow full expression of exploratory or comfort behaviours. Free-range systems, percheries and other types of colony housing provide opportunities for all of the above, although at high stocking densities social competition and limited space may restrict performance of these behaviours for certain birds.'

Cooper, J.J., Albentosa, M.J., 2003. Behavioural priorities of laying hens. Avian Poultry Biol. Rev. 14, 127–149.

"...irregular dustbathing pattern exhibited by birds that dustbathe without litter could be a sign of frustration; an indication that dustbathing without litter - unlike dustbathing in litter - does not provide the required feedback".

Wichmann and Keeling, 2009. The influence of losing or gaining access to peat on the dustbathing behaviour of laying hens. Animal Welfare 18: 149-157.

"...sham dustbathing is not satisfying or perceived as normal dustbathing, even for birds that developed dustbathing behaviour in the absence of litter because birds that had no previous experience of peat were as motivated to work to gain access to this substrate as birds used to dustbathing in peat."

Wichman, A., and L. J. Keeling. 2008. Hens are motivated to dustbathe in peat irrespective of being reared with or without a suitable dustbathing substrate. Animal Behaviour 75:1525-1533. doi 10.1016/j.anbehav.2007.10.009

"...observed that non of the dustbaths performed in furnished cages were complete, whereas about 55% of the dustbaths performed in the single tier battery systems were complete..."

De Jong, I.C. and Blokhuis, H.J. The welfare of laying hens. In: Proceedings of the XII European Poultry Conference, Verona, Italy, 12-14 sept 2006.

Preference of litter of at least 10 cm for dustbathing and foraging:

Van Emous, R. A., Ogink, N. W. M. and Gunnink, H. (2017) Effect of litter depths on general and dustbathing behaviour in laying hens. in Xth European Symposium on Poultry Welfare Book of Abstracts: World's Poultry Science Association (WPSA). pp. 163-163.

When dDust bathing areas are offered, they should be 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 maintain clean [Lentfer et al., 2011] [Weeks and Nicol, 2006].

<u>Animal</u>Outcome-based measurables include: dust bathing, injury rate and severity, plumage condition, spatial distribution.

Article 7.Z.11.

Foraging areas

The provision of friable, dry litter material is desirable to encourage foraging activity by pullets and hens.

EU comment

The EU proposes to amend the above sentence as follows:

"The provision of $\underline{\underline{F}}$ friable, dry litter material is desirable to encourage foraging by pullets and hens should be provided."

Justification

Foraging is also high priority behaviour. Furthermore, it is well known that hens spend a large part of the day foraging, and substrates preferably have to be manipulable. Hens cannot forage on wire floors. They need litter for pecking and scratching.

References

EFSA Journal (2005) 197, 1-23. The welfare aspects of various systems of keeping laying hens

De Jong, I.C. and Blokhuis, H.J. The welfare of laying hens, Proceedings of the XII European Poultry Conference, Verona, Italy, 12-14 sept 2006

Foraging is a high priority behaviour; there is a high motivation for foraging. There is significantly more foraging behaviour in systems with litter. If hens can chose, they choose for litter and domesticated hens still want to work to get their feed, regardless of feed being freely available or not.

The research of De Jong et al. (2007) Applied Animal Behaviour Science 104 (2007) 24-36.

Matthews, L.R., Temple, W., Foster, T.M., Walker, A.W., McAdie, T.M., 1995. Comparison of the demand for dustbathing substrates by layer hens. In: Rutter, S.M., Rushen, J., Randle, H.D., Eddison, J.C. (Eds.), Proceedings of the 29th International Congress of the ISAE, Conference Universities' Federation of Animal Welfare, Exeter, pp. 11–12

Campbell, D. L. M., D. M. Karcher, and J. M. Siegford. 2016. Location tracking of individual laying hens housed in aviaries with different litter substrates. Applied Animal Behaviour Science 184:74-79. doi 10.1016/j.applanim.2016.09.001

' Foraging is a behavioural need, with peat, sand and wood shavings preferred substrates in choice experiments. There is no reduction in time spent foraging when a cost is imposed, nor when feed is freely available.'

Weeks, C. A., and C. J. Nicol. 2006. Behavioural needs, priorities and preferences of laying hens. Worlds Poult. Sci. J. 62:296-307. doi 10.1079/wps200598

'Hens have been found to work for access to a range of additional resources including pecking, scratching and dust bathing substrates, perches (particularly prior to nightfall), additional space and nestboxes.' And: 'Modified or enriched cages allow for these activities, as well as perching, and, potentially dust bathing, but do not allow full expression of exploratory or comfort behaviours. Free-range systems, percheries and other types of colony housing provide opportunities for all of the above, although at high stocking densities social competition and limited space may restrict performance of these behaviours for certain birds.'

Cooper, J.J., Albentosa, M.J., 2003. Behavioural priorities of laying hens. Avian Poultry Biol. Rev. 14, 127–149.

When fForaging areas are offered, they should provide suitable materials, <u>and be</u> designed and positioned to encourage foraging <u>activity</u>, allow synchronised behaviour, prevent undue competition and not cause damage or injuries. Foraging areas should be easy to inspect and <u>maintain</u> elean.

<u>AnimalOutcome</u>-based measurables include: foraging <u>activity</u>, injurious feather pecking and cannibalism, injury rate and severity, spatial distribution.

Article 7.Z.12.

When nNesting areas should be provided are offered, they and 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 maintaindisinfect.

EU comment

The EU asks the OIE to consider modifying the text at the beginning of the above paragraph as following:

"<u>Adequate numbers of nesting</u> areas should be provided and be built of suitable materials, designed and positioned to encourage nesting, prevent undue competition and not cause damage or injuries."

Justification

Hens deprived of nests show higher levels of corticosterone and signs of stress than hens with access. Therefore, providing adequate numbers of nesting areas is deemed relevant in that context.

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.

<u>AnimalOutcome</u>-based measurables include: injurious feather pecking and cannibalism, injury rate and severity, nesting, performance, (mis-laid or floor eggs), spatial distribution.

Article 7.Z.13.

Perches

When pPerches should be provided are effered, they and should be built of suitable materials, designed, elevated and positioned to encourage perching for all pullets and hens, to prevent keel bone deformation er, foot problems or other harms, and to maintain stability of the birds during perching. In the absence of designated perches, platforms, grids and slats that are perceived by the pullets and hens 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 maintain, disinfect and positioned to minimise faecal fouling [Hester, 2014; EFSA, 2015].

Perch elevation should be carefully considered to minimise injurious feather pecking, cannibalism, keel deformities and fractures.

<u>Animal</u>Outcome-based measurables include: foot problems, injurious feather pecking and cannibalism, injury rate and severity, perching, <u>plumage condition</u>, <u>resting and sleeping</u>, spatial distribution.

EU comment

The EU asks OIE to re-consider amending the text of the above paragraph as following:

"Outcome-based measurables include: foot problems, injurious feather pecking and cannibalism, injury rate (<u>i.e. keel bone problems</u>) and severity, perching, plumage condition, resting and sleeping, spatial distribution."

Justification

Reference to keel bone problems brings a specific measurable that ought to be individually mentioned.

References

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 <u>and hens</u> can be given access to outdoor areas <u>as seen as when</u> they have sufficient feather cover and <u>are old enough to can</u> range safely. There should be sufficient appropriately designed <u>exit areas openings</u> to allow them to leave and re-enter the poultry house freely.

EU comment

The EU asks OIE to consider including the following text at the beginning of the above paragraph:

"Pullets and hens can be given access to outdoor areas when they have sufficient feather cover and can range safely. There should be sufficient <u>space allowance and</u> appropriately designed openings to allow them to leave and re-enter the poultry house freely."

Justification

Space allowance should be adequate and allow pullets and hens to perform their speciespecific behaviors.

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 standing water and mud. The outdoor area should be able to contain the Pullets and hens 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; Hegelund et al., 2005; Nagle and Glatz, 2012]. 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 harmful plants and contaminants.

<u>AnimalOutcome</u>-based measurables include: fear behaviour, foot problems, foraging <u>activity</u>, incidence of diseases, injury rate and severity, locomot<u>oryion</u> and comfort behaviours, morbidity rate, mortality rate, *infestations*, performance, plumage condition, social behaviour, spatial distribution, thermoregulatory behaviour, vocalisation.

EU comment

The EU would like the OIE to reconsider the decision not to include percentage of pullets and hens that use the outdoor area as a new animal-based measurable as below:

"Animal-based measurables include: fear behaviour, foot problems, foraging activity,

incidence of diseases, injury rate and severity, locomotory and comfort behaviours, morbidity rate, mortality rate, *infestations*, performance, plumage condition, social behaviour, spatial distribution, thermoregulatory behaviour, vocalisation- percentage of pullets and hens that use the outdoor area."

Justification

The cited papers support the benefit to animal welfare of the wider use of the outdoor area.

Methods such as visual monitoring/observing/counting & recording and video recordings can be used to measure or at least estimate the percentage of pullets and hens that use the outdoor area.

References

Nicol C.J., Pötzsch, C., Lewis, K., & Green, L.E. (2003) Matched concurrent case-control study of risk factors for feather pecking in hens on free-range commercial farms in the UK, British Poultry Science, 44:4, 515-523

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.

Hegelund L., Sørensen J.T., Kjær J.B. & Kristensen I.S. (2005) Use of the range area in organic egg production systems: effect of climatic factors, flock size, age and artificial cover. British Poultry Science 46(1):1-8

Article 7.Z.15.

Thermal environment

Thermal conditions for pullets and hens should be <u>maintained within a range that is</u> appropriate for their stage of life, and extremes of heat, humidity and cold should be avoided. A heat index can assist in identifying the <u>thermal</u> comfort zones for the pullets and hens at varying temperature, <u>air velocity</u> and relative humidity levels, <u>and can be</u> found in <u>management guidelines provided by primary laying hen genetics companies</u> [Xin and Harmon, 1998].

When environmental conditions move outside of these zones, strategies should be used to mitigate the adverse effects on the <u>pullets and hens</u> <u>birds</u>. 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 detected and corrected before it causes a welfare problem.

<u>Animal</u>Outcome-based measurables include: morbidity rate, mortality rate, performance, spatial distribution, thermoregulatory behaviours, water and feed consumption.

Article 7.Z.16.

Air quality

Ventilation, housing, and manure management can affect air quality. Actions are required to maintain air quality at all times, including the removal or mitigation of noxious of waste gases such as carbon dioxide and ammonia, dust and excess moisture content from in the environment.

The aAmmonia 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.

EU comment

The EU would prefer to retain the removed sentence:

"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."

Justification

Even though Art. 7.Z.26 mentions backup generators 'where relevant', a stronger emphasis should be put on the need of back-up power and alarm system.

<u>AnimalOutcome</u>-based measurables include: eye conditions, incidence of respiratory diseases, <u>plumage</u> <u>condition</u>, 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 to promote for normal development of the birds, for finding feed and water, to stimulate activity, to stimulate onset of lay, 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 <u>pullets and hens</u> 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 should be considered are desired.

<u>AnimalOutcome</u>-based measurables include: eye conditions, injurious feather pecking <u>and cannibalism</u>, injury rate and severity, locomot<u>oryion</u>-behaviours, nesting, performance, <u>plumage condition</u>, <u>resting and sleeping</u>, spatial distribution.

Article 7.Z.18.

Noise

Pullets and hens are adaptable to different levels and types of noise at However, Eexposure of birds pullets and hens 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].

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].

<u>AnimalOutcome</u>-based measurables include: fear behaviours, injury rate and severity, <u>mortality rate</u>, performance, <u>resting and sleeping</u>, <u>vocalisation</u>.

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; van Niekerk et al., 2013],
- choosing genetics strain with a low propensity to injurious feather pecking [Craig and Muir, 1996; Kjaer and Hocking, 2004],
- influencing age of onset of lay [Green et al., 2010],
- providing foraging <u>or other manipulable</u> materials in rearing and lay [Huber-Eicher and Wechsler, 1998; <u>de</u> <u>Jong et al.</u>, 2010; <u>Daigle et al.</u>, 2014],
- adapting diet and form of feed in rearing and lay [Lambton et al., 2010],

reducing stocking density [Zimmerman et al., 2006];

EU comment

The EU would like keeping:

- reducing stocking density [Zimmerman et al., 2006];

Justification

The EU believes there is sufficient scientific evidence showing that reducing stocking density allows hens to express their priority behaviours.

References

Widowski *et al.* 2016. Laying hen welfare I. Social environment and space. World's Poultry Science. J. 72: 333-342.

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.

- reducing group size in rearing and lay [Bilcik and Keeling, 1999],
- providing elevated perches in rearing and lay [Green et al., 2010],
- treating beaks in chicks [Gentle and Hughes, 1997], especially by using new non-invasive beak treatments that are being developed,
- minimising fear-related stimuli [<u>Uitdehaag K. A. et al.</u>, 2009].
- introducing males [Bestman and Wagenaar, 2003].

EU comment

The EU proposes to reinstate a bullet point as follows:

"- Preventing and minimizing parasite infestations (poultry red mite)"

Justification

The EU maintains its previous comment by providing further details since the scientific reference was omitted from the previous EU comment.

References

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. Better plumage condition was found in wire mesh aviaries (P < 0.001), in aviaries with no red mite infestation (P = 0.004), and in free-range systems (P = 0.011) compared to plastic slatted aviaries, in houses with red mite infestations, and those without a free-range area.

Management methods to control the occurrence include the above list, where applicable, and prompt removal of affected <u>pullets and hens</u>birds to a hospital area or euthanasia.

If these management strategies fail, therapeutic beak <u>treatment trimming</u> is the last resort. <u>may be considered as</u> a final course of action.

<u>Animal</u>Outcome-based measurables include: injurious feather pecking and cannibalism, injury rate and severity, mortality <u>and culling</u> rate, plumage condition, vocalisation.

Article 7.Z.20.

Moulting

Induced moulting can lead to animal welfare problems if not well managed. When induced moulting is practised, techniques that do not involve withdrawal of feed should be used and are consistent with Article 7.Z.8. should be used. Hens should have light and 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 and culling rate during the moult period should not exceed normal variations in flock mortality and culling rate.

<u>AnimalOutcome</u>-based measurables include: body condition, feeding and drinking, foraging <u>activity</u> [Biggs *et al.*, 2004; Saiozkan *et al.*, 2016; Petek and Alpay, 2008], injurious feather pecking and cannibalism, injury rate and severity, morbidity rate, mortality <u>and culling</u> rate, performance, plumage condition, social behaviour.

Article 7.Z.21.

Painful interventions

Painful interventions, such as beak <u>treatmenttrimming</u>, should not be practised unless <u>absolutely</u> necessary and pain mitigation interventions should be used. <u>Beak trimming at a mature age can cause chronic pain.</u> Other mutilations (e.g. dubbing and toe trimming) should not be performed in pullets and hens. Pain-free alternatives <u>should be favoured</u> are preferred. If preventive beak <u>treatmenttrimming</u> is required, it should be carried out by <u>trained and skilled personnel</u> 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. <u>Current methods include infrared treatment or hot blade cutting.</u> <u>Beak trimming at a mature age can cause chronic pain If management strategies to control injurious feather pecking and cannibalism fail, therapeutic beak treatment may be considered as a final course of action [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]. <u>Other mutilations (e.g. dubbing and toe trimming) should not be performed in pullets and hens.</u></u>

EU comment

The EU proposes to keep trimming instead of treatment:

"Painful interventions, such as beak treatment trimming, should not be practised unless absolutely necessary and pain mitigation interventions should be used."

Justification

This EU comment should apply to other references in this chapter where trimming has been replaced by treatment.

For EU the beak trimming and beak treatment are too different issues. Beak trimming is found to induce chronic pain while the beak treatment is much broader and generally associated with an improvement of the quality of live and in particular of the welfare of animals.

Furthermore, the EU suggests adding an example for providing more clarity as regards "pain-free alternatives":

"Pain free alternatives should be favoured <u>including utilising the range of management</u> methods that may reduce the risk of occurrence at 7.Z.19."

Justification

Guidance would be helpful as to the pain-free approaches that are available.

References

FeatherWel, 2013. Improving feather cover: A guide to reducing the risk of injurious pecking occurring in non-cage laying hens. University of Bristol

In addition the EU would like to maintain the following sentence:

"Hot blade cutting should be used only if infrared method is not available."

Justification

Infrared technique is considered a better method in terms of animal welfare. Therefore, it is only where infrared method is not available, that the hot blade method should be used.

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

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.

AnimalOutcome-based measurables include: <u>feeding and drinking behaviour</u> and foraging <u>activity</u>, <u>feeding</u>, injurious feather pecking and cannibalism, <u>locomotory</u> and comfort behaviours, mortality rate, morbidity rate, performance, plumage condition, vocalisations.

EU comment

The EU proposed to consider including "intact beak" as animal-based measurable at end of the above paragraph:

"Animal-based measurables include: feeding and drinking behaviour and foraging activity, injurious feather pecking and cannibalism, locomotory and comfort behaviours, mortality rate, morbidity rate, performance, plumage condition, vocalisations- intact beak."

Justification

The EU believes that there is a need for specific reference to a concrete animal-based measurable in relation to the beak.

References

Welfare Quality® assessment protocol for poultry (2009), Welfare Quality® consortium, The Netherlands (http://edepot.wur.nl/233471), Chapter 6.1.3.3 Absence of pain induced by management procedures – Beak trimming.

Article 7.Z.22.

Animal health management, preventive medicine and veterinary treatment

Animal handlers responsible for the care of pullets and hens should have be knowledge aware of normal pullet and hen behaviour, the and be able to detect signs of ill-health or distress, such as a change in feed and water intake, reduced production, changes in behaviour, abnormal plumage condition appearance of feathers, faeces, or other physical features.

If they are net unable to identify the causes of disease, ill-health or distress, or unable 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.

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.

<u>AnimalOutcome</u>-based measurables include: <u>body condition</u>, 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 <u>pullets and hensbirds</u> 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.

<u>AnimalOutcome</u>-based measurables include: incidence of diseases, *infestations*, merbidity rate_mortality_rate, culling and morbidity rates, mertality rate, performance.

Article 7.Z.24.

Humane killing of individual birds or flocks

Individual sick or injured pullets or hens requiring euthanasia should be humanely killed as soon as possible. When an individual or groups of <u>pullets or hens</u> birds are killed for <u>euthanasia</u>, diagnostic purposes, depopulation of end-of-lay *flocks* or for purposes of disease control, <u>the</u> techniques used should be performed in a humane manner in accordance with Chapter 7.6.

Article 7.Z.25.

Depopulation of pullet and layer hen facilities

This article refers to removal of pullets and laying hens from facilities for whatever reason and should be read in conjunction with Article 7.Z.24.

<u>Pullets and hens</u> 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-Pullets and hens 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* in accordance with the condition of Article 7.Z.28. and every attempt should be made to minimise stress, fear reactions and injur<u>iesy</u>. If a <u>pullet or henbird</u> is injured during catching, it should be humanely killed.

Birds Pullets and hens should be handled and placed into the transport container according to Chapter 7.3. Article 7.Z.14.

Catching should preferably be carried out under dim or blue light to calm the birds pullets and hens.

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.

<u>Animal</u>Outcome-based measurables include: fear behaviour, injury rate and severity, mortality at depopulation and on arrival at the destination, spatial distribution, vocalisation.

Article 7.Z.26.

Emergency Contingency plans

Pullet and hen producers should have emergency contingency plans to minimise and mitigate the consequences of natural disasters, disease *outbreaks* and the failure of mechanical equipment. Planning should include a fire safety plan and where relevant, may include the provision, maintenance and testing 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, a fire safety plan and a plan for managing ventilation emergencies.

The emergency contingency plans should be consistent with national programmes established or recommended by *Veterinary Services*. Humane emergency *killing* procedures should be a part of the plan according to the methods recommended in Chapter 7.6.

Animal Outcome-based measurables include: culling, morbidity and mortality rates.

Article 7.Z.27.

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 <u>pullet and henbird</u> behaviour, handling techniques, emergency killing procedures, *biosecurity*, general signs of diseases, and indicators of poor *animal welfare* and procedures for their alleviation.

<u>AnimalOutcome</u>-based measurables include: fear behaviour, incidence of diseases, locomotoryion and comfort behaviours, performance, morbidity rate, mortality, culling and morbidity rate, spatial distribution, vocalisation.

Article 7.Z.28.

Inspection and handling

EU comment

The EU would like to invite the OIE to consider its previous comment for moving this article at the beginning of the chapter as to become Article 7.z.6.

Justification

This comment appears not to have been addressed by the Ad hoc group.

Pullets and hens <u>and facilities</u> <u>and equipment within their premises</u> should be inspected at least daily. Inspection should have <u>the following</u> 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.

to identify sick or injured pullets and hens and to treat or cull them;

- to pick up dead pullets and hens;
- to detect and correct any welfare or health problem in the flock; and
- to detect and correct malfunctioning equipment and other facility problems.

EU comment

The EU maintains its previous comment and suggests OIE to include 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 <u>birds pullets and hens</u> are not unnecessarily disturbed, for example *animal handlers* should move quietly and slowly through the *flock*.

When pullets and hens are handled, particularly when birds are placed into or removed from the house, they should not be injured, and should be held in postures that minimise fear and stress unnecessarily frightened or stressed (e.g. should be restrained in an upright posture) [Gregory & Wilkins, 1989; Gross & Siegel, 2007; Kannan & Mench, 1996]. The distances pullets and hens are carried should be minimised. Laying hens are prone to bone fractures when not handled properly. AnimalOutcome-based measurables include: fear behaviour, injury rate and severity, morbidity rate, mortality, culling and morbidity rates, performance, spatial distribution, vocalisation.

Article 7.Z.29.

Protection from predators

Pullets and hens should be protected from predators in indoor and outdoor areas. <u>All production systems should be designed and maintained to prevent access by predators and wild birds.</u>

<u>Animal</u>Outcome-based measurables include: fear behaviour, mortality, injury rate and severity, locomotory and comfort behaviours, mortality, culling and morbidity rates, performance, spatial distribution, vocalisation.

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CHAPTER 15.2.

INFECTION WITH CLASSICAL SWINE FEVER VIRUS

EU comment

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

Comments are inserted in the text below.

Article 15.2.1.

General provisions

The pig (Sus scrofa, both domestic and wild) is the only natural host for classical swine fever virus (CSFV). For the purposes of this chapter, a distinction is made between:

- <u>domestic and captive wild pigs, whether permanently housed or free ranging, used for the production of meat, or other commercial products or purposes use, or for breeding; and</u>
- wild and feral pigs.

For the purposes of the *Terrestrial Code*, classical swine fever (CSF) is defined as an *infection* of pigs with classical swine fever virus (CSFV).

The following defines the occurrence of infection with CSFV:

1) a strain of CSFV (excluding vaccine strains) has been isolated from samples from a pig;

OR

2) viral antigen or nucleic acid specific to CSFV (excluding vaccine strains) has been identified detected, or viral ribonucleic acid (RNA) specific to a strain of CSFV has been demonstrated to be present, in samples from one or more a pigs showing clinical signs or pathological lesions suggestive of CSF, or epidemiologically linked to a suspected or confirmed or suspected outbreak case of CSF, or giving cause for suspicion of previous association or contact with CSFV, with or without clinical signs consistent with CSF;

OR

3) virus specific antibodies specific to CSFV that are not a consequence of vaccination or infection with other pestiviruses, have been identified detected in samples from one or more a pigs in a hord showing clinical signs or pathological lesions consistent with CSF, or epidemiologically linked to a suspected or confirmed or suspected outbroak case of CSF, or giving cause for suspicion of previous association or contact with CSFV.

The pig is the only natural host for CSFV. The definition of pig includes all varieties of *Sus scrofa*, both domestic and wild. For the purposes of this chapter, a distinction is made between:

- domestic and captive wild pigs, permanently captive or farmed free range, used for the production of meat, or other commercial products or use, or for breeding these categories of pigs;
- wild and feral pigs.

For the purposes of the <u>Terrestrial Code</u>, the <u>incubation period shall be 14 days</u>. Pigs exposed to CSFV prenatally may <u>not show clinical signs at birth and</u> be persistently infected throughout life and may have an <u>incubation period</u> of several months before showing signs of disease. Pigs exposed postnatally have an <u>incubation period</u> of 2-14 days, and are usually infective between post-infection days 5 and 14, but up to 3 months in cases of chronic <u>infections</u>. Pigs exposed to CSFV postnatally have an <u>infective period</u> of up to three months.

EU comment

For clarity reasons, the EU suggests moving the last sentence of the paragraphe above to after the the first sentence, as it seems more logical to group the information on pigs infected postnatally together. The paragraph would thus read as follows:

"For the purposes of the Terrestrial Code, the incubation period shall be 14 days. <u>Pigs exposed to CSFV have an infective period of up to three months.</u> Pigs exposed to CSFV prenatally may not show clinical signs at birth and be persistently infected throughout life. <u>Pigs exposed to CSFV postnatally have an infective period of up to three months.</u>".

A Member Country should not impose bans on the trade in commodities of domestic and captive wild pigs in response to a notification of infection with CSFV in wild and feral pigs provided that Article 15.2.2. is implemented.

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 Article 15.2.2, even if they notify infection with CSFV in wild or foral pigs.

Standards for diagnostic tests and vaccines are described in the Terrestrial Manual.

Article 15.2.1bis.

Safe commodities

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

- 1) meat in a hermetically sealed container with a F-value of 3 or above:
- 2) gelatine.

Other pig commodities can be traded safely if in accordance with the relevant articles of this chapter.

Article 15.2.2.

General criteria for the determination of the $\frac{classical}{classical}$ swine fever $\frac{CSF}{classical}$ status of a country, zone or compartment

- CSF should be <u>is</u> notifiable in the whole territory, and all pigs showing clinical signs <u>or pathological lesions</u> suggestive of CSF should be <u>are</u> subjected to appropriate field or *laboratory* investigations;
- an on-going awareness programme should be is in place to encourage reporting of all cases pigs showing signs suggestive of CSF;
- 3) the Veterinary Authority should have <u>has</u> current knowledge of, and authority over, all domestic and captive wild pig herds in the country, zone or compartment;
- 4) the Veterinary Authority should have <u>has</u> current knowledge about <u>of</u> the <u>population</u> <u>distribution</u> and habitat of *wild* and *feral* pigs in the country or *zone*;
- 5) for domestic and *captive wild* pigs, appropriate *surveillance* in accordance with Articles 15.2.26. to 15.2.32. is in place;
- 6) for *wild* and *feral* pigs, if present in the country or *zone*, a *surveillance* programme is in place according to Article 15.2.31., taking into account the presence of natural and artificial boundaries, the ecology of the *wild* and *feral* pig population, and an assessment of the *risks* of *disease* spread;
- 7) based on the assessed *risk* of spread within the *wild* and *feral* pig population, and according to Article 15.2.29., the domestic and *captive wild* pig population should be <u>is</u> separated from the *wild* and *feral* pig population by appropriate measures.

Article 15.2.3.

Country or zone free from CSF Classical swine fever free country or zone

A country or zone may be considered free from CSF when Article 15.2.2. is complied with, and when:

- 1) surveillance in accordance with Articles 15.2.26. to 15.2.32. has been in place for at least 12 months;
- 2) there has been no *outbreak* of CSF in domestic and *captive wild* pigs during the past 12 months;
- no evidence of infection with CSFV has been found in domestic and captive wild pigs during the past 12 months;
- 4) no *vaccination* against CSF has been carried out in domestic and *captive wild* pigs during the past 12 months unless there are means, validated according to Chapter 2.8.3. of the *Terrestrial Manual*, of distinguishing between vaccinated and infected pigs;
- 5) imported pigs and pig commodities comply with the requirements in Articles 15.2.7. to 15.2.21bis.

The <u>proposed free</u> country or the <u>proposed free</u> zone will be included in the list of CSF free countries or zones only after the submitted evidence, based on the provisions of Article 1.6.910., has been accepted by the OIE.

EU comment

The correct reference seems to be Chapter 1.9., not Article 1.6.10. (which does not seem to exist).

Retention on the list requires that the information in points 1). 2) to or 53) above be re-submitted annually and changes in the epidemiological situation or other significant events should be reported to the OIE according to the requirements in Chapter 1.1.

EU comment

The EU queries the background got the changes proposed in the paragraph above. Indeed, reference to points 1, 2 and 3 seems correct, as all these elements would be needed for the annual reconfirmation. Therefore, "or" should be changed to "and".

Article 15.2.4.

Compartment free from CSF Classical swine fever free compartment

The bilateral recognition of a <u>compartment</u> free <u>from</u> CSF free compartment should follow the relevant requirements of this chapter and the principles laid down in Chapters 4.3. and 4.4. <u>Pigs in a the compartment free from CSF should be separated from any other pigs by the application of effective biosecurity.</u>

Article 15.2.5.

Establishment of a containment zone within a $\frac{\text{classical swine fever free}}{\text{country or zone free from CSF}}$

In the event of limited *outbreaks* or *cases* of CSF within a CSF free country or *zone* previously free from CSF, including within a *protection zone*, a *containment zone*, which includes all *outbreaks*, can be established for the purpose of minimising the impact on the entire country or *zone*.

For this to be achieved and for the Member Country to take full advantage of this process, the *Veterinary Authority* should submit documented evidence as soon as possible to the OIE.

In addition to the requirements for the establishment of a *containment zone* outlined in point 3 of Article 4.3.3., the *surveillance* programme should take into consideration the involvement of *wild* and *feral* pigs and measures to avoid their dispersion.

EU comment

The reference in the paragraph above should be Article 4.3.7., not 4.3.3..

Furthemore, instead of referring only to point 3 of Article 4.3.7. in the paragraph above, the whole article should be referred to, as all of its points are relevant.

The free status of the areas outside the *containment zone* is suspended while the *containment zone* is being established. The free status of these areas may be reinstated irrespective of the provisions of Article 15.2.6., once the *containment zone* is clearly established. It should be demonstrated that *commodities* for *international trade* have originated outside the *containment zone*.

In the event of the recurrence of CSF in the *containment zone*, the approval of the *containment zone* is withdrawnand the free status of the country or *zone* is suspended until the relevant requirements of Article 15.2.36. have been fulfilled.

The recovery of the CSF free status of the *containment zone* should follow the provisions of Article 15.2.6 and be achieved within 12 months of its approval.

Article 15.2.6.

Recovery of free status

Should <u>an outbreak of CSF occur in a previously</u> a <u>CSF outbreak occur in a free country or zone, the free its</u> status may be restored <u>when where</u> <u>surveillance</u> in accordance with Articles 15.2.2630, to 15.2.32, has been carried out with negative results either:

1) three months after the disposal of the last case where a stamping-out policy without vaccination is practised;

OR

- 2) when where a stamping-out policy with emergency vaccination is practised:
 - a) three months after the disposal of the last case and or the slaughter of all vaccinated animals, whichever occurred last; or
 - b) three months after the disposal of the last case without the slaughter of vaccinated animals when there are means, validated according to Chapter 2.8.3. of the Terrestrial Manual, of distinguishing between vaccinated and infected pigs;

OR

3) when where a stamping-out policy is not practised, the provisions of Article 15.2.3. should be followed.

The country or *zone* will regain CSF free status only after the submitted evidence, based on the provisions of Article 1.6.9., has been accepted by the OIE.

The country or *zone* will regain CSF free status only after the submitted evidence, based on the provisions of Article 1.6.10., has been accepted by the OIE.

Article 15.2.6bis.

<u>Direct transfer of pigs within a country from an infected zone to a free zone for slaughter</u>

In order not to jeopardise the status of a free zone, pigs should only leave the *infected zone* if transported by mechanised *vehicle* directly for *slaughter* in the nearest designated *slaughterhouse/abattoir* under the following conditions:

- no pig has been introduced into the establishment of origin and no pig in the establishment of origin has shown clinical signs of CSF for at least 30 days prior to slaughter.
- 2) the pigs were kept in the establishment of origin for at least three months prior to movement for slaughter,
- CSF has not occurred within a 10-kilometre radius of the establishment of origin for at least three months
 prior to movement;

- 4) the pigs should be transported under the supervision of the Veterinary Services in a vehicle, which was cleaned and disinfected before loading, directly from the establishment of origin to the slaughterhouse/abattoir without coming into contact with other pigs;
- 5) such a slaughterhouse/abattoir is not approved for the export of fresh meat during-from the time the pigs arrived from the infected zone until it is handling the meat of those pigs have left the premises from the infected zone:
- 6) vehicles and the slaughterhouse/abattoir should be subjected to disinfection immediately after use.

The pigs should be subjected to ante- and post-mortem inspections in accordance with Chapter 6.2. with favourable results and the *meat* should be treated according to in accordance with Article 15.2.23. The *fresh meat* from those pigs should be identified and kept separate from other pig products until treated.

Any other products obtained from the pigs, and any products coming into contact with them, should be considered contaminated and treated in accordance with Article 15.2.22. or Articles 15.2.24. to 15.2.25.ter to destroy any residual virus CSFV potentially present.

Article 15.2.6ter.

<u>Direct transfer of pigs within a country from a containment zone to a free zone for slaughter</u>

In order not to jeopardise the status of a free zone, pigs should only leave the containment zone if transported by mechanised vehicle directly to for slaughter in the nearest designated slaughterhouse/abattoir under the following conditions:

- 1) the containment zone has been officially established according to the requirements in Article 15.2.5.;
- 2) the pigs should be transported under the supervision of the Veterinary Services in a vehicle, which was cleaned and disinfected before loading, directly from the establishment of origin to the slaughterhouse/abattoir without coming into contact with other pigs;
- 3) such a slaughterhouse/abattoir is not approved for the export of fresh meat during-from the time the pigs arrived from the containment zone until the meat of those pigs have left the premises the time it is handling the meat of pigs from the containment zone;
- 4) vehicles and the slaughterhouse/abattoir should be subjected to disinfection immediately after use.

The pigs should be subjected to ante- and post-mortem inspections in accordance with Chapter 6.2. with favourable results and the *meat* should be treated according to in accordance with Article 15.2.23. The *fresh* meat from those pigs should be identified and kept separate from other pig products until treated.

Any other products obtained from the pigs, and any products coming into contact with them, should be considered contaminated and treated in accordance with Article 15.2.22. or Articles 15.2.24. to 15.2.25ter. to destroy any residual virus CSFV potentially present.

EU comment

The EU suggests deleting both Articles 15.2.6bis. and 15.2.6ter. above. Indeed, in both articles, the recommendation is that the meat should be treated in accordance with Article 15.2.23. However, Article 15.2.23. is the article on procedures for the inactivation of CSFV in meat. This means that all the requirement in Articles 15.2.6bis. and 15.2.6ter. are superfluous, as in any case one could just use Article 15.2.23. on its own, without any need for these new articles. The requirements in Article 15.2.23. are indeed sufficient for imports even from an infected country or zone.

Article 15.2.7.

Recommendations for importation from countries, zones or compartments free from $\frac{1}{2}$

For domestic and captive wild pigs

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

- 1) showed no clinical sign of CSF on the day of shipment;
- were kept in a country, zone or compartment free from CSF since birth or for at least the past three months in a country, zone or compartment free from CSF;
- 3) have were not been vaccinated against CSF, nor are they the progeny of vaccinated sows, unless there are means, validated according to in accordance with Chapter 2.8.3. of the *Terrestrial Manual*, of distinguishing between vaccinated and infected pigs.

Article 15.2.8.

Recommendations for importation from countries or zones considered infected with classical swine fever virus not free from CSF

For domestic and captive wild pigs

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

- 1) showed no clinical sign of CSF on the day of shipment;
- 2) and either:
 - a) were kept since birth or for the past three months in a CSF free compartment, or
 - <u>b)</u> were isolated for 28 days prior to shipment in a *quarantine station*, and were subjected to a virological test and a serological test performed on a sample collected at least 21 days after entry into the *quarantine station*, with negative results;
- 3) have were not been vaccinated against CSF, nor are they the progeny of vaccinated sows, unless there are means, validated according to in accordance with Chapter 2.8.3. of the *Terrestrial Manual*, of distinguishing between vaccinated and infected pigs.

Article 15.2.9.

Recommendations for the importation of wild and feral pigs

Regardless of the CSF status of the country of origin, Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the animals pigs:

- 1) showed no clinical sign of CSF on the day of shipment;
- 2) were kept <u>isolated</u>in a <u>quarantine station</u> for 40 <u>28</u> days prior to shipment, and were subjected to a virological test and a serological test performed <u>on a sample collected</u> at least 21 days after entry into the quarantine station, with negative results;
- 3) have were not been vaccinated against CSF, unless there are means, validated according to Chapter 2.8.3. of the Terrestrial Manual, of distinguishing between vaccinated and infected pigs.

Article 15.2.10.

Recommendations for importation from countries, zones or compartments free from $\frac{1}{2}$

For semen of domestic and captive wild pigs

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

- 1) the donor animals males:
 - were kept in a country, zone or compartment free from CSF-since birth or for at least three months
 prior to collection in a country, zone or compartment free from CSF;
 - b) showed no clinical sign of CSF on the day of collection of the semen;
- 2) the semen was collected, processed and stored in conformity accordance with the provisions of Chapters 4.5. and 4.6.

Article 15.2.11.

Recommendations for importation from countries or zones considered infected with classical swine fever virus not free from CSF

For semen of domestic and captive wild pigs

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

- 1) the donor animals males:
 - a) were kept in a compartment free from CSF since birth or for at least three months prior to collection in an establishment in which surveillance, in accordance with Articles 15.2.26. to 15.2.32., demonstrated that no case of CSF occurred in the past 12 months;
 - showed no clinical sign of CSF on the day of collection of the semen and for the following 40 days;
 - c) met one of the following conditions:
 - were subjected to a virological test performed on a blood sample taken on the day of collection, with negative results; or
 - <u>iii)</u> <u>were</u> not been vaccinated against CSF and were subjected to a serological test performed <u>on a sample taken</u> at least 21 days after collection, with negative results; or
 - have been vaccinated against CSF and were subjected to a serological test performed on a sample taken at least 21 days after collection, which and it has been conclusively demonstrated that any antibody is due to was caused by the vaccine; or
 - iii) have been vaccinated against CSF and were subjected to a virological test performed on a sample taken on the day of collection and it has been conclusively demonstrated that the boar is negative for virus genome;
- 2) the semen was collected, processed and stored in conformity <u>accordance</u> with the provisions of Chapters 4.5. and 4.6.

Article 15.2.12.

Recommendations for importation from countries, zones or compartments free from classical swine fever CSF

For in vivo derived embryos of domestic pigs

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

- 1) the donor females; showed no clinical sign of CSF on the day of collection of the embryos;
 - <u>a)</u> were kept since birth or for at least three months prior to collection in a country, zone or compartment free from CSF;
 - b) showed no clinical sign of CSF on the day of collection of the embryos;
- 2) the semen used to fertilise the oocytes complied with the conditions in Articles 15.2.10. or Article 15.2.11., as relevant;

3) the embryos were collected, processed and stored in accordance with Chapters 4.7. and 4.9., as relevant.

Article 15.2.13.

Recommendations for importation from countries or zones considered infected with classical swine fever virus not free from CSF

For in vivo derived embryos of domestic pigs

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

- the donor females:
 - a) were kept in a compartment free from CSF since birth or for at least three months prior to collection in an establishment in which surveillance, in accordance with Articles 15.2.26. to 15.2.32., demonstrated that no case of CSF occurred in the past three months;
 - showed no clinical sign of CSF on the day of collection of the embryos-and for the following 40 days;
 - c) and either met one of the following conditions:
 - i) were subjected to a virological test performed on a blood sample taken on the day of collection, with negative results; or
 - <u>iii)</u> have <u>were_not been_vaccinated against CSF and were subjected, with negative results, to a serological test performed at least 21 days after collection; or</u>
 - have been were vaccinated against CSF and were subjected to a serological test performed on a sample taken at least 21 days after collection, which and it has been conclusively demonstrated by means, validated according to Chapter 2.8.3. of the Terrestrial Manual, that any antibody is due to was caused elicited by the vaccine;
- 2) the embryos were collected, processed and stored in accordance with Chapters 4.7. and 4.9., as relevant.

Article 15.2.14.

Recommendations for importation from countries, zones or compartments free from $\frac{1}{100}$ classical swine fever $\frac{1}{100}$

For fresh meat of domestic and captive wild pigs

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the entire consignment of fresh meat comes from animals pigs which:

- 1) have been kept in a country, zone or compartment free from CSF, or which have been imported in accordance with Article 15.2.7. or Article 15.2.8.;
- 2) have been slaughtered in an approved *slaughterhouse/abattoir*, <u>where they</u> have been subjected to anteand post-mortem inspections in accordance with Chapter 6.2. <u>with favourable results</u>-and have been found free from any sign suggestive of CSF.

Article 15. 2.14 bis.

Recommendations for importation from countries or zones not free from CSF, where an official control programme exists

EU comment

The EU notes that there currently is no article in this chapter with recommendations or requirements for countries or zones not free from CSF where an official control

programme exists. The EU therefore suggests developing an article similar to Article 8.8.39. for this chapter.

For fresh meat of domestic pigs and captive wild pigs

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

1) the meat comes from pigs from which the meat comes complying complied complying with Article 15.2.8.;

EU comment

For reasons of clarity, the EU suggests replacing the word "comes" with "<u>derives</u>" in point 1) above.

- <u>2)</u> the pigs were transported under the supervision of the *Veterinary Services*, in a *vehicle* which was cleaned and disinfected before the pigs were loaded;
- 3) the pigs were transported directly to the approved slaughterhouse/abattoir without coming into contact either during transport or at the slaughterhouse/abattoir with other pigs which do not fulfil the conditions of Article 15.2.8.required for expert;
- <u>4)</u> the pigs were slaughtered in an approved slaughterhouse/abattoir.
 - a) which is officially approved designated for export by the Veterinary Authority;
 - <u>b)</u> in which no case of CSF was detected during the period between the last disinfection carried out before slaughter and the shipment for export has been dispatched from the slaughterhouse/abattoir,
- 5) the pigs were subjected to ante- and post-mortem inspections in accordance with Chapter 6.2. with favourable results;
- 6) appropriate precautions have been taken after slaughter to avoid contact cross-contamination of the fresh meat with any source of CSFV.

Article 15.2.15.

Recommendations for the importation of fresh meat of wild and feral pigs

Regardless of the CSF status of the country of origin, Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the entire consignment of fresh meat comes from animals pigs:

- 1) that were killed in a country or zone free from CSF in accordance with point 1) or point 2) of Article 15.2.3.;
- 42) that which have been were subjected with favourable results to a post-mortem inspection in accordance with Chapter 6.2. in an approved examination centre facility approved by the Veterinary Authority for export purposes., with favourable results and have been found free from any sign suggestive of CSF;
- 2) from each of which a sample has been was collected and has been subjected to a virological test and a serological test for CSF, with negative results.

EU comment

The EU suggests deleting the whole article above, as already requested in our previous comments. Indeed, as the free status does not relate to wild and feral pigs (i.e. there can be cases in wild boar in a free country or zone), referring to a country or zone free from CSF does not provide any guarantee in relation to this high risk commodity, for which there should not be recommendations in the Code.

Article 15.2.16.

Recommendations for the importation of meat and meat products of pigs intended for use in animal feeding, for agricultural or industrial use, or for pharmaceutical or surgical use

Veterinary Authorities of importing countries should require the presentation of an international veterinary certificate attesting that the <u>meat products</u>:

- 1) have been were prepared:
 - a) exclusively from fresh meat meeting the conditions laid down in Articles 15.2.14., 15.2.14bis. or 15.2.15.;
 - b) in a processing establishment facility that, at the time of processing:
 - i) is approved for export by the Veterinary Authority for export purposes;
 - ii) processing processes only meat of pigs meeting satisfying the conditions laid down in Articles 15.2.14., 15.2.14bis, or 15.2.15.;

OR

2) have been were processed in accordance with one of the processes in Article 15.2.23. in an establishment a facility approved by the Veterinary Authority for export purposes so as to ensure the destruction of the CSFV in conformity with one of the procedures referred to in Article 15.2.23., and that the necessary appropriate precautions were taken after processing to avoid centact cross-contamination of the product with any source of CSFV.

Article 15.2.17.

Recommendations for the importation of pig products not derived from fresh meat intended for use in animal feeding

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

- 1) originated from domestic and captive wild pigs in a CSF free country, zone or compartment and have been prepared in a processing establishment approved by the Veterinary Authority for export purposes; or
- 2) have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the CSFV in accordance with Article 15.2.22., and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSFV.

Article 15.2.18.

Recommendations for the importation of pig products not derived from fresh meat intended for agricultural or industrial use

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

- 1) originated from domestic and captive wild pigs in a CSF free country, zone or compartment and have been prepared in a processing establishment approved by the Veterinary Authority for export purposes; or
- 2) have been processed in an establishment approved by the Veterinary Authority for export purposes so as to ensure the destruction of the CSFV, and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSFV.

Article 15.2.19.

Recommendations for the importation of bristles

Veterinary Authorities of importing countries should require the presentation of an international veterinary certificate attesting that the <u>bristles products</u>:

- originated from domestic and or captive wild pigs in a CSF free country, zone or compartment free from CSF and have been were prepared processed in a processing establishment facility approved by the Veterinary Authority for export purposes; or
- 2) have been were processed in accordance with one of the processes in Article 15.2.25bis. in an establishment a facility approved by the Veterinary Authority for export purposes so as to ensure the destruction of the CSFV, and that the necessary appropriate precautions were taken after processing to avoid centact cross-contamination of the product with any source of CSFV.

Article 15.2.20.

Recommendations for the importation of litter and manure from pigs

Veterinary Authorities of importing countries should require the presentation of an international veterinary certificate attesting that the litter or manure products:

- originated from domestic and or captive wild pigs in a CSF free country, zone or compartment free from CSF and have been prepared were processed in a processing establishment facility approved by the Veterinary Authority for export purposes; or
- 2) have been were processed in accordance with one of the procedures in Article 15.2.25ter. in an establishment a facility approved by the Veterinary Authority for export purposes so as to ensure the destruction of the CSFV, and that the necessary appropriate precautions were taken after processing to avoid centact cross-contamination of the product with any source of CSFV.

Article 15.2.21.

Recommendations for the importation of skins and trophies from pigs

Veterinary Authorities of importing countries should require the presentation of an international veterinary certificate attesting that the skins or trophies products:

- originated from domestic and or captive wild pigs in a CSF free country, zone or compartment free from CSF and have been prepared were processed in a processing establishment facility approved by the Veterinary Authority for export purposes; or
- 2) have been were processed in accordance with one of the procedures in Article 15.2.25. in an establishment a facility approved by the Veterinary Authority for export purposes so as to ensure the destruction of the CSFV in conformity with one of the procedures referred to in Article 15.2.25., and that the necessary appropriate precautions were taken after processing to avoid contact cross-contamination of the product with any source of CSFV.

Article 15.2.21bis.

Recommendations for the importation of other pig products

<u>Veterinary Authorities of importing countries should require the presentation of an international veterinary certificate attesting that the products:</u>

- 1) originated from domestic or captive wild pigs in a country, zone or compartment free from CSF and were processed in a facility approved by the Veterinary Authority for export purposes; or
- <u>authority</u> for export purposes, and that appropriate precautions were taken after processing to avoid contact cross-contamination of the product with any source of CSFV.

EU comment

For consistency with the wording used in other articles in the Code, we suggest amending point 2) above as follows:

"were processed in a manner to ensure the destruction of that has been demonstrated to inactivate CSFV in a facility".

Article 15.2.22.

Procedures for the inactivation of the classical swine fever virus CSFV in swill

For the inactivation of CSFV in swill, one of the following procedures should be used:

- 1) the swill should be <u>is</u> maintained at a temperature of at least 90°C for at least 60 minutes, with continuous stirring; or
- 2) the swill should be is maintained at a temperature of at least 121°C for at least 10 minutes at an absolute pressure of 3 bar-, or
- 3) the swill is subjected to an equivalent treatment that has been demonstrated to inactivate CSFV.

Article 15.2.23.

Procedures for the inactivation of the classical swine fever virus CSFV in meat

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

1. Heat treatment

Meat should be subjected to one of the following treatments:

- a) heat treatment in a hermetically sealed container with a F0 value of 3.00 or more;
- heat treatment for at least 30 minutes at a minimum temperature of 70°C, which should be reached throughout the *meat*.

2. Natural fermentation and maturation

The *meat* should be subjected to a treatment consisting of natural fermentation and maturation having resulting in the following characteristics:

- a) an Aw aw value of not more than 0.93, or
- b) a pH value of not more than 6.0.

Hams should be subjected to a natural fermentation and maturation process for at least 190 days and loins for 140 days.

Dry cured pork pig meat

- a) Italian style hams with bone-in should be cured with salt and dried for a minimum of 313 days.
- b) Spanish style pork meat with bone-in should be cured with salt and dried for a minimum of 252 days for Iberian hams, 140 days for Iberian shoulders, 126 days for Iberian loin, and 140 days for Serrano hams.

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

Article 15.2.24.

Procedures for the inactivation of $\frac{\text{the classical swine fever virus }}{\text{csfV}}$ in casings of pigs

For the inactivation of CSFV in casings of pigs, the following procedures should be used: salting treating for at least 30 days either with phosphate supplemented dry salt or saturated brine (Aw $\underline{a_w}$ < 0.80) containing 86.5% NaCl, 10.7% Na2₂HPO4₄ and 2.8% Na3₃PO4₄ (weight/weight/weight), and kept and at a temperature of greater than 20°C or above during this entire period.

Article 15.2.24bis.

Procedures for the inactivation of CSFV in bristles

For the inactivation of CSFV in bristles for industrial use, they should be boiled for at least 30 minutes.

<u> Article 15.2.24ter.</u>

Procedures for the inactivation of CSFV in litter and manure from pigs

For the inactivation of CSFV in litter and manure from pigs, one of the following procedures should be used:

- 1) moist heat treatment for at least one hour at a minimum temperature of 55°C; or
- 2) moist heat treatment for at least 30 minutes at a minimum temperature of 70°C.

Article 15.2.25.

Procedures for the inactivation of $\frac{1}{2}$ the classical swine fever virus \underline{CSFV} in skins and trophies

For the inactivation of CSFV in skins and trophies, one of the following procedures should be used:

- 1) boiling in water for an appropriate time so as to ensure that any matter other than bone, tusks or teeth is removed;
- 2) gamma irradiation at a dose of at least 20 kiloGray at room temperature (20°C or higher);
- soaking, with agitation, in a 4 percent %(w/v) solution of washing soda (sodium carbonate [Na²₂CO³₃]) maintained at pH 11.5 or above for at least 48 hours;
- 4) soaking, with agitation, in a formic acid solution (100 kg salt [NaCl] and 12 kg formic acid per 1,000 litres water) maintained at below pH 3.0 for at least 48 hours; wetting and dressing agents may be added;
- 5) in the case of raw hides, salting for at least 28 days with sea salt containing 2 percent % washing soda (sodium carbonate [Na22CO33]).

<u>Article 15.2.25bis.</u>

Procedures for the inactivation of CSFV in bristles

For the inactivation of CSFV in bristles for industrial use, they should be boiled for at least 30 minutes.

Article 15.2.25ter.

Procedures for the inactivation of CSFV in litter and manure from pigs

For the inactivation of CSFV in litter and manure from pigs, one of the following procedures should be used:

- moist heat treatment for at least one hour at a minimum temperature of 55°C; or
- 2) moist heat treatment for at least 30 minutes at a minimum temperature of 70°C.

Article 15.2.26.

Introduction to surveillance: introduction

Articles 15.2.26. to 15.2.32. define the principles and provide a guide on the *surveillance* for CSF, complementary to Chapter 1.4., applicable to Member Countries seeking the OIE recognition of CSF status. This may be for the entire country or a *zone*. Guidance is also provided for Member Countries seeking recovery of CSF status for the entire country or for a *zone* following an *outbreak* and for the maintenance of CSF status.

The impact and epidemiology of CSF may vary in different regions of the world. The *surveillance* strategies employed for demonstrating freedom from CSF at an acceptable level of confidence should be adapted to the local situation. For example, the approach should be tailored in order to prove freedom from CSF for a country or *zone* where *wild* and *feral* pigs provide a potential reservoir of *infection*, or where CSF is present in adjacent neighbouring countries. The method should examine the epidemiology of CSF in the region concerned and adapt to the specific risk factors encountered. This should include provision of scientifically based supporting data. There is, therefore, latitude available to Member Countries to provide a well-reasoned argument to prove that absence of *infection* with CSFV is assured at an acceptable level of confidence.

Surveillance for CSF should be in the form of a continuing programme designed to establish that susceptible populations in a country, zone or compartment are free from infection with CSFV or to detect the introduction of CSFV into a population already defined as free. Consideration should be given to the specific characteristics of CSF epidemiology which include:

- the role of swill feeding, the impact of different production systems and the role of wild and feral pigs on disease spread;
- the role of semen in transmission of the virus;
- the lack of pathognomonic gross lesions and clinical signs;
- the frequency of clinically inapparent infections;
- the occurrence of persistent and chronic infections;
- the genotypic, antigenic, and virulence variability exhibited by different strains of CSFV.

Article 15.2.27.

General conditions and methods for surveillance: general conditions and methods

- A surveillance system in accordance with Chapter 1.4. and under the responsibility of the Veterinary Authority should address the following aspects:
 - a) formal and ongoing system for detecting and investigating outbreaks of disease or CSFV infection should be in place;
 - b) a procedure should be in place for the rapid collection and transport of samples from suspected cases to a laboratory for CSF diagnosis;
 - c) appropriate laboratory testing capability for CSF diagnosis;
 - <u>de</u>) a system for recording, managing and analysing diagnostic and surveillance data should be in place.
- 2) The CSF surveillance programme should:
 - include an early warning <u>detection</u> system throughout the production, marketing and processing chain for reporting suspected cases. Diagnosticians and those with regular contact with pigs should report promptly any suspicion of CSF to the <u>Veterinary Authority</u>. The <u>notification reporting</u> system under the <u>Veterinary Authority</u> should be supported directly or indirectly (e.g. through private <u>veterinarians</u> or <u>veterinary paraprofessionals</u>) by government-information programmes. Since many strains of CSFV do not induce pathognomonic gross lesions or clinical signs, cases in which CSF cannot be ruled out should be immediately investigated. Other important <u>diseases</u> such as African swine fever should also be considered in any differential diagnosis. <u>As part of the contingency plan, p</u>ersonnel responsible for

surveillance should be able to call for assistance from a team with expertise in CSF diagnosis, epidemiological evaluation, and control;

b) implement, when relevant, regular and frequent clinical inspections and laboratory testing of high-risk groups (for example, where swill feeding is practised), or those adjacent_neighbouring to a CSF infected country or zone (for example, bordering areas where infected wild and feral pigs are present).

An effective surveillance system will periodically identify suspected cases that require follow-up and investigation to confirm or exclude *infection* with CSFV. The rate at which such suspected cases are likely to occur will differ between epidemiological situations and cannot, therefore, be reliably predicted. Applications for recognition of CSF status should, as a consequence, provide details in accordance with Article 1.6.10. of the occurrence of suspected cases and how they were investigated and dealt with.

Member Countries should review their *surveillance* strategies whenever an increase in the likelihood of incursion of CSFV is perceived identified. Such changes include but are not limited to:

- <u>a</u>) <u>an emergence or an increase in the prevalence of CSF in countries or *zones* from which live pigs or products are imported;</u>
- an increase in the prevalence of CSF in wild or feral pigs in the country or zone;
- an increase in the prevalence of CSF in adjacent-neighbouring countries or zones;
- <u>an increased entry from, or exposure to, infected wild or feral pig populations of adjacent-neighbouring</u> countries or zones.

Article 15.2.28.

Surveillance strategies

Introduction

The population covered by *surveillance* aimed at detecting *disease* and *infection* should include domestic and *wild* pig populations within the country or *zone* to be recognised as free from *infection* with CSFV.

The strategy employed to <u>establish</u> <u>estimate</u> the prevalence or <u>demonstrate</u> the absence of <u>infection</u> with CSFV <u>infection</u> may be based on <u>clinical investigation</u> or on randomised or targeted clinical investigation or sampling at an acceptable level of statistical confidence. If an increased likelihood of <u>infection</u> in particular localities or subpopulations can be identified, targeted sampling may be an appropriate strategy. This may include:

- a) swill fed farms;
- b) pigs reared outdoors;
- c) specific high-risk wild and feral pig subpopulations and their proximity.

Risk factors may include, among others, temporal and spatial distribution of past *outbreaks*, pig movements and demographics, ete-and types of production systems.

<u>Serology in unvaccinated populations is often the most effective and efficient surveillance methodology,</u> for reasons of cost, <u>persistence extended duration</u> of antibody levels and the existence of clinically inapparent infections, <u>serology in unvaccinated populations is often the most effective and efficient surveillance methodology.</u> In some circumstances, such as differential diagnosis of other *diseases*, clinical and virological *surveillance* may also have value.

The *surveillance* strategy chosen should be justified as adequate to detect the presence of *infection* with CSFV in accordance with Chapter 1.4. and the epidemiological situation. Cumulative survey results in combination with the results of routine *surveillance*, over time, will increase the level of confidence in the *surveillance* strategy.

When applying randomised sampling, either at the level of the entire population or withing targeted sub-populations, the design of the sampling strategy should incorporate epidemiologically appropriate design

prevalences for the selected populations. The sample size selected for testing should be large enough to detect *infection* if it were to occur at a predefined minimum rate. The choice of design prevalence and confidence level should be justified based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Selection of the design prevalence in particular, needs to be based on the prevailing or historical epidemiological situation.

Irrespective of the approach selected, the sensitivity and specificity of the diagnostic tests should be considered in the survey design, the sample size determination and the interpretation of the results obtained.

The *surveillance* system design should anticipate the occurrence of false positive reactions. This is especially true of the serological diagnosis of CSF because of the recognised cross-reactivity with ruminant pestiviruses, among other factors mentioned in point 4. There needs to be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether or not they are indicative of *infection* with CSFV. This should involve confirmatory and differential tests for pestiviruses, as well as further investigations concerning the original sampling unit as well as *animals* which may be epidemiologically linked.

2. Clinical surveillance

Clinical *surveillance* continues to be the cornerstone of CSF detection. However, due to the low virulence of some CSFV strains and the spread of *diseases* such as African swine fever, and those associated with porcine circovirus 2 *infection*, clinical *surveillance* should be supplemented, as appropriate, by serological and virological *surveillance*.

Clinical signs and pathological findings are useful for early detection; in particular, any cases where clinical signs or lesions suggestive of CSF are accompanied by high morbidity or mortality, these should be investigated without delay. In CSFV *infections* involving low virulence strains, high mortality may only be seen in young *animals* and adults may not present clinical signs.

Wild and feral pigs rarely present the opportunity for clinical observation, but should form part of any surveillance scheme and should, ideally, be monitored for virus as well as antibody antibodies.

3. Virological surveillance

Virological surveillance should be conducted:

- a) to monitor at risk populations;
- b) to investigate clinically suspected cases:
- to follow up positive serological results;
- d) to investigate increased mortality.

Molecular detection methods can be applied to large-scale screening for the presence of virus. If targeted at high-risk groups, they provide an opportunity for early detection that can considerably reduce the subsequent spread of *disease*. Epidemiological understanding of the pathways of spread of CSFV can be greatly enhanced by molecular analyses of viruses in endemic areas and those involved in *outbreaks* in *disease* free areas <u>previously free from CSF</u>. Therefore, CSFV isolates should be sent to an OIE Reference Laboratory for further characterisation.

4. <u>Serological surveillance</u>

Serological *surveillance* aims at detecting antibodies against CSFV. Positive CSFV antibody test results can have five possible causes:

- a) natural infection with CSFV;
- b) vaccination against CSF;
- c) maternal antibodies;
- d) cross-reactions with other pestiviruses;

e) non-specific reactors.

The *infection* of pigs with other pestiviruses may complicate a *surveillance* strategy based on serology. Antibodies to bovine viral diarrhoea viruses (BVDV) and Border disease virus (BDV) can give positive results in serological tests for CSF, due to common antigens. Such samples will require differential tests to confirm their identity. One route by which ruminant pestiviruses can infect pigs is the use of vaccines contaminated with BVDV.

CSFV may lead to persistently infected, seronegative young animals, which continuously shed virus. CSFV *infection* may also lead to chronically infected pigs which may have undetectable or fluctuating antibody levels. Even though serological methods will not detect these animals, such animals are likely to be in a minority in a *herd* and would not confound a diagnosis based on serology as part of a *herd* investigation.

It may be possible to use <u>for CSF surveillance</u> sera collected for other survey purposes <u>for CSF surveillance</u>. However, the principles of survey design and the requirement for statistical validity should not be compromised.

In countries or *zones* where *vaccination* has been recently discontinued, targeted serosurveillance of young unvaccinated animals can indicate the presence of *infection*. Maternal antibodies are usually found up to 8-10 weeks of age but may be occasionally last up to four and a half months and can interfere with the interpretation of serological results.

Marker vaccines and accompanying DIVA tests which fulfil the requirements of the *Terrestrial Manual* may allow discrimination between vaccinal antibody and that induced by natural *infection*. The serosurveillance results using DIVA techniques may be interpreted either at animal or *herd* level.

Member Countries should review their surveillance strategies whenever an increase in the risk of incursion of CSFV is perceived. Such changes include but are not limited to:

- a) an emergence or an increase in the prevalence of CSF in countries or zones from which live pigs or products are imported;
- b) an increase in the prevalence of CSF in wild or feral pigs in the country or zone;
- c) an increase in the prevalence of CSF in adjacent countries or zones;
- an increased entry from, or exposure to, infected wild or feral pig populations of adjacent countries or zones.

Article 15.2.29.

Additional surveillance $\frac{\text{procedures}}{\text{procedures}}$ for Member Countries applying for OIE recognition of $\frac{\text{classical swine fever}}{\text{cSF}}$ free status

The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances in and around the country or *zone* and should be planned and implemented according to the conditions for status recognition described in Article 15.2.2. and 15.2.3. and methods described elsewhere in this chapter. The objective is to demonstrate the absence of *infection* with CSFV in domestic and *captive wild* pigs during the last 12 months and to assess the *infection* status in *wild* and *feral* pig populations as described in Article 15.2.31.

Article 15.2.30.

Additional surveillance procedures for recovery of free status

In addition to the general conditions described in this chapter, a Member Country seeking recovery of country or zone CSF free status, including a *containment zone*, should show evidence of an active *surveillance* programme to demonstrate absence of *infection* with CSFV.

Populations under this *surveillance* programme should include:

- 1) establishments in the proximity of the outbreaks;
- establishments epidemiologically linked to the outbreaks;
- 3) animals moved from or used to repopulate affected establishments;

- 4) any establishments where contiguous culling has been carried out;
- 5) wild and feral pig populations in the area of the outbreaks.

The domestic and *captive wild* pig populations should undergo regular clinical, pathological, virological and serological examinations, planned and implemented according to the general conditions and methods described in these recommendations. Epidemiological evidence of the *infection* status in *wild* and *feral* pigs should be compiled. To regain CSF free status, the *surveillance* approach should provide at least the same level of confidence as within the original application for recognition of freedom.

Article 15.2.31.

Surveillance for classical swine fever virus <u>CSFV</u> in wild and feral pigs

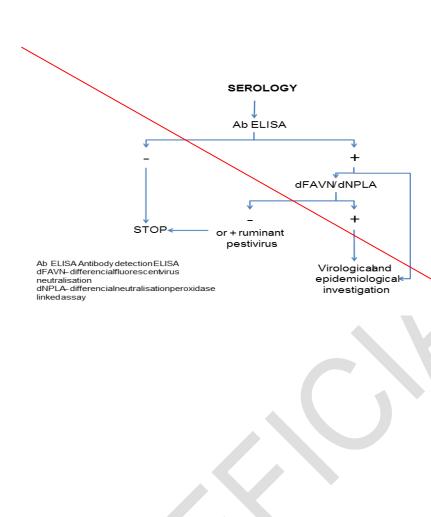
- 1) The objective of a *surveillance* programme is either to demonstrate that CSFV *infection* is not present in *wild* and *feral* pigs or, if known to be present, to estimate the distribution and prevalence of the *infection*. While the same principles apply, *surveillance* in *wild* and *feral* pigs presents additional challenges including:
 - a) determination of the distribution, size and movement patterns associated with the *wild* and *feral* pig population;
 - b) relevance and practicality of assessing the possible presence of CSFV infection within the population;
 - c) determination of the practicability of establishing a *zone* taking into account the degree of interaction with domestic and *captive wild* pigs within the proposed *zone*.

The geographic distribution and estimated size of *wild* and *feral* pig populations need to be assessed as a prerequisite for designing a monitoring system. Sources of information to aid in the design of a monitoring system may include governmental and non-governmental *wildlife* organisations such as hunter associations.

- 2) For implementation of the monitoring <u>surveillance</u> programme, it will be necessary to define the limits of the area over which wild and feral pigs range should be defined, in order to delineate the epidemiological units within the monitoring programme. It is often difficult to define epidemiological units for <u>Subpopulations of wild and feral pigs may be separated from each other by natural or</u>. The most practical approach is based on natural and artificial barriers.
- 3) The menitoring <u>surveillance</u> programme should involve serological and virological testing, including <u>animals</u> <u>pigs</u> <u>hunted or</u> found dead, road kills, <u>animals</u> <u>pigs</u> showing abnormal behaviour or exhibiting gross lesions during dressing.
- 4) There may be situations where a more targeted *surveillance* programme can provide additional assurance. The criteria to define high risk areas for targeted *surveillance* include:
 - a) areas with past history of CSF;
 - b) subregions with large populations of wild and feral pigs;
 - c) border regions with CSF affected countries or zones;
 - d) interface between wild and feral pig populations, and domestic and captive wild pig populations;
 - e) areas with farms with free-ranging and outdoor pigs;
 - areas with a high level of hunting activity, where animal dispersion and feeding as well as inappropriate disposal of waste can occur;
 - other risk areas determined by the Veterinary Authority such as ports, airports, garbage dumps and picnic and camping areas.

Article 15.2.32

The use and interpretation of diagnostic tests in surveillance



CHAPTER 3.4.

VETERINARY LEGISLATION

EU comment

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

Comments are inserted in the text below.

Article 3.4.1.

Introduction and objective

Good governance is a recognised global public good and is of critical importance to Member Countries. Legislation is a key element in achieving good governance.

Veterinary legislation should, at a minimum, provide a basis for Competent Authorities to meet their obligations as defined in the Terrestrial Code and the relevant recommendations of the Codex Alimentarius Commission. It should also comply with the relevant requirements of international instruments dedicated to the mitigation of biological threats. In addition, there is an obligation for World Trade Organization (WTO) Members under the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) to notify the WTO of changes in sanitary measures, including changes in legislation that affect trade, and provide relevant information.

For the purposes of the *Terrestrial Code*, *veterinary legislation* comprises all legal instruments necessary for the governance of the veterinary domain.

EU comment

The EU suggests inserting the word "specific" before "legal instruments" in the paragraph above, as otherwise also general administrative laws e.g. on fines and sanctions would be covered, which usually are not part of veterinary legislation per se.

The objective of this chapter is to provide advice and assistance to Member Countries when formulating or modernising *veterinary legislation* so as to comply with OIE standards <u>and other relevant standards and instruments</u>, thus ensuring good governance of the entire veterinary domain.

EU comment

The EU suggests inserting the word "<u>international</u>" before "standards and instruments" in the paragraph above, as the scope would otherwise be very wide and unclear, and to be in line with the wording proposed to be added in the second paragraph of this article.

Article 3.4.2.

Definitions

For the purposes of this chapter the following definitions apply:

Hierarchy of legislation: means the ranking of the legal instruments as prescribed under the fundamental law (e.g. the constitution) of a country. Respect for the hierarchy means that each legal instrument must comply with higher order legal instruments.

Legal instrument: means the legally binding rule that is issued by a body with the required legal authority to issue the instrument.

Primary legislation: means the legal instruments issued by the legislative body of a Member Country.

Secondary legislation: means the legal instruments issued by the executive body of a Member Country under the authority of primary legislation.

Stakeholder: means a person, group, or organisation that can affect or be affected by the impacts of *veterinary legislation*.

Veterinary domain: means all the activities that are directly or indirectly related to *animals*, their products and by-products, which help to protect, maintain and improve the animal health, and animal welfare and veterinary public health of humans, including by means of the protection of animal health and animal welfare, and food safety consistent with a One Health approach.

Article 3.4.3.

General principles

Respect for the hierarchy of legislation

Veterinary legislation should scrupulously respect the hierarchy between primary legislation and secondary legislation.

EU comment

We suggest deleting the word "scrupulously" in the paragraph above, as it may otherwise be understood as extending to political statements etc. which may be part e.g. of a constitution.

2. Legal basis

Competent Authorities should have available the primary legislation and secondary legislation necessary to carry out their activities at all administrative and geographic levels within the whole territory.

When primary legislation requires that secondary legislation be made to implement the legislative scheme, or to provide details to the legislative scheme, the relevant secondary legislation should be developed and enacted as soon as possible.

Veterinary legislation should be consistent with national, regional and international law, as appropriate, including civil, penal and administrative laws.

EU comment

It is not clear what "regional law" refers to, as it does not seem to relate to supranational regional organisations (like the EU in Europe or the Regional Economic Communities in Africa). We would therefore suggest inserting the term ".supranational" after "regional".

3. Transparency

Veterinary legislation should be inventoried and be readily accessible and intelligible for use, updating and modification, as appropriate.

Competent Authorities should ensure communication of veterinary legislation and related documentation to stakeholders.

4. Consultation

The drafting of new and revised legislation relevant to the veterinary domain should be a consultative process involving *Competent Authorities* and legal experts to ensure that the resulting legislation <u>has been evaluated through an impact analysis and</u> is scientifically, technically and legally sound.

EU comment

The EU is of the opinion that the proposed addition above is too prescriptive. Indeed, while in general impact assessments do improve the quality of legislation and should be performed where possible, an impact analysis is not always necessary when drafting new or revising existing legislation. This is indeed depending on many factors, and there are clear criteria in place in the EU as to in which cases and to what extent an impact analysis is necessary. The EU therefore suggests adding the words "where relevant" or "as appropriate" after "impact analysis".

To facilitate implementation of the *veterinary legislation*, *Competent Authorities* should establish relationships with stakeholders, including taking steps to ensure that they participate in the development of significant legislation and required follow-up.

Quality of legislation and legal certainty

Veterinary legislation should be clear, coherent, and stable and transparent and protect citizens against unintended adverse side effects of legal instruments. It The legislation should be regularly updated to be technically relevant, acceptable to society, able to be effectively implemented and sustainable in technical, financial and administrative terms. A high quality of legislation is essential for achieving legal certainty.

EU comment

There seems to be a contradiction between the first two sentences above: the first one requires legislation to be stable, whereas the second one implies that it needs to be updated regularly. This clearly shows that legislation cannot and should not be "stable". What is probably intended is to convey that changes in legislation should not be erratic or arbitrary, but follow good practices and clear criteria (such as to adapt to new science and technology, or new or amended international standards). The EU therefore suggests replacing the word "stable" with "provide legal certainty" and the words "regularly updated" with "regularly evaluated and amended as appropriate".

Article 3.4.4.

The drafting of veterinary legislation

Veterinary legislation should:

- 1) be drafted in a manner that establishes clear <u>authorities,</u> rights, responsibilities and obligations (i.e. 'normative');
- be unambiguous, with clear and consistent syntax and vocabulary;
- 32) be precise, accurate and consistent in the repeated use of the terminology; be accurate, clear, precise and unambiguous, and use consistent terminology;
- 3) include only definitions that are sufficient, necessary and relevant to the country;

EU comment

It is not clear what is meant by "sufficient" in point 3) above. Furthermore, it may be necessary to have veterinary legislation pertaining to "exotic" animal diseases not present and thus not currently relevant for the country, for reasons of disease prevention and to be ready in case of incursion. The point above should thus simply be deleted.

- 4) contain no definitions or provisions that create any duplication or contradiction or ambiguity;
- 5) include a clear statement of scope and objectives;

- 6) provide for the application of penalties and sanctions, either criminal or administrative, as appropriate to the situation; and
- 7) make provision for the financing needed for the execution of all activities of *Competent Authorities*; or these activities the financing should be ensured should be supported by appropriate financing in accordance with the national funding system.

Article 3.4.5.

Competent Authorities

Competent Authorities should be legally mandated, capacitated and organised to ensure that all necessary actions are taken quickly timely and coherently to effectively address animal health, animal welfare and veterinary public health and animal welfare matters of concern emergencies effectively.

Veterinary legislation should provide for a chain of command that is as effective as possible (i.e. short, with all responsibilities clearly defined). For this purpose, the responsibilities and powers of Competent Authorities, from the central level to those responsible for the implementation of legislation in the field, should be clearly defined. Where more than one Competent Authority is involved such as in relation to environmental, food safety or other public health matters, including biological threats and natural disasters, a reliable system of coordination and cooperation should be in place.

EU comment

We suggest replacing the word "short" in the paragraph above with "<u>as</u> short <u>as</u> <u>possible</u>", for clarity reasons.

Competent Authorities should appoint technically qualified officials to take any actions needed for implementation or verification of compliance with the *veterinary legislation*, respecting the principles of independence and impartiality prescribed in Article 3.1.2.

Necessary powers of the Competent Authority

The *veterinary legislation* should also ensure that:

- a) officials have the legal authority to intervene in accordance with the legislation and the penal procedures in force; the Competent Authority has all the necessary legal authorities to achieve the purposes of the legislation, including the powers to enforce the legislation;
- b) while executing their legal mandate, officials are protected against legal action and physical harm for actions carried out in good faith;

EU comment

We suggest adding the words "and in accordance with professional standards" at the end of the sentence above, as this seems relevant as well.

- the powers and functions of officials are explicitly and thoroughly listed to protect the rights of stakeholders and the general public against any abuse of authority. This includes respecting confidentiality, as appropriate; and
- at least the following powers are available through the primary legislation:
 - i) access to premises and vehicles for carrying out inspections:
 - ii) access to documents;
 - iii) taking samples; application of specific sanitary measures such as:
 - taking samples;
 - W) ___retention (setting aside) of animals and goods, pending a decision on final disposition;

- vi) = suspension of one or more activities of an inspected establishment;
- vii) ___temporary, partial or complete closure of inspected establishments; and
- viii) suspension or withdrawal of authorisations or approvals-; and
- <u>restrictions on movement of commodities, vehicles/vessels and, if required, people.</u>

These essential powers must be identified as they can result in actions that may conflict with individual rights ascribed in fundamental laws.

EU comment

The EU suggests amending the second sentence above for clarity as follows:

"These essential powers must be <u>clearly</u> identified <u>and outlined in a limited manner</u> as they can result in actions that may conflict with individual rights ascribed in fundamental laws."

Indeed, these powers need to be used only to the extent necessary to achieve animal health goals.

2. <u>Delegation of powers by the Competent Authority</u>

The *veterinary legislation* should provide the possibility for *Competent Authorities* to delegate specific tasks related to official activities. The specific tasks delegated, the competencies required, the bodies to which the tasks are delegated, and the conditions of supervision by the *Competent Authority* and the conditions of withdrawals of delegations should be defined.

For this purpose, the veterinary legislation should:

- a) define the field of activities and the specific tasks covered by the delegation;
- b) provide for the control, supervision and, when appropriate, financing of the delegation;
- c) define the procedures for making delegation;
- d) define the competencies to be held by persons receiving delegation; and
- e) define the conditions of withdrawals of delegations.

Article 3.4.6.

Veterinarians and veterinary paraprofessionals

1. Veterinary medicine/science

In order to ensure quality in the conduct of veterinary medicine/science, the veterinary legislation should:

- a) define the prerogatives of veterinarians and of the various categories of veterinary paraprofessionals that are recognised by the Member Country;
- b) define the minimum initial and continuous educational requirements and competencies for veterinarians and veterinary paraprofessionals:
- prescribe the conditions for recognition of the qualifications for veterinarians and veterinary paraprofessionals;
- d) define the conditions to perform the activities of veterinary medicine/science; and
- e) identify the exceptional situations, such as epizootics, under which persons other than veterinarians

can undertake activities that are normally carried out by veterinarians.

2. The control of veterinarians and veterinary paraprofessionals

Veterinary legislation should provide a basis for regulation of veterinarians and veterinary paraprofessionals in the public interest. To that end, the legislation should:

- a) describe the general system of control in terms of the political, administrative and geographic configuration of the country;
- describe the various categories of veterinary paraprofessionals recognised by the Member Country in accordance with its needs, notably in animal health and food safety, and for each category, prescribe its training, qualifications, tasks and extent of supervision;
- e) prescribe the powers to deal with conduct and competence issues, including licensing requirements, that apply to veterinarians and veterinary paraprofessionals;
- d) provide for the possibility of delegation of powers to a professional organisation such as a veterinary statutory body; and
- e) where powers have been so delegated, describe the prerogatives, the functioning and responsibilities of the mandated professional organisation.
- 1. The regulation of veterinarians and veterinary paraprofessionals

<u>Veterinary legislation</u> should provide a basis for the regulation of <u>veterinarians</u> and <u>veterinary</u> paraprofessionals in the interests of the public. To this end, the legislation should:

- a) provide for the creation of a veterinary statutory body;
- b) describe the prerogatives, the functioning and responsibilities of the veterinary statutory body;
- <u>c)</u> <u>describe the general structure and system of regulation of veterinarians and veterinary paraprofessionals by the veterinary statutory body, and</u>
- <u>d)</u> give authority to the <u>veterinary statutory body</u> to make secondary legislation or otherwise deal with the following matters:

EU comment

As this will very much depend on the legal system of each country, the EU does not support the prescriptive wording regarding secondary legislation in point d) above. We would suggest the following alternative wording:

- d) give authority to the veterinary statutory body to make secondary legislation or otherwise deal with provide basic principles or regulate the following matters:
 - i) describe the various categories of veterinarians and veterinary paraprofessionals recognised in the country in accordance with its needs, notably in animal health and food safety;

EU comment

It is not clear what is meant by "various categories of veterinarians". There should only be one category of veterinarian. Besides that, there can be various specialisations (e.g. internal medicine, equine medicine, microbiology etc.) that should be regulated by the VSB. Perhaps this needs to be clarified to avoid confusion.

- <u>iii)</u> <u>define the prerogatives of the various categories of veterinarians and veterinary paraprofessionals</u> that are recognised in the country:
- <u>iii)</u> <u>define the minimum initial and continuous educational requirements and competencies for the various categories of veterinarians and veterinary paraprofessionals;</u>

<u>iv) prescribe the conditions for recognition of the qualifications for veterinarians and veterinary paraprofessionals;</u>

EU comment

The point above is problematic. Indeed, in the EU, it is not the VSB that has authority to recognise qualifications of veterinarians and paraprofessionals from abroad (i.e. whether their veterinary education diploma for example is to be recognized as equivalent in order for them to exercise the profession); this lies with the Competent Authority. The point above should therefore be limited to the recognition of specialisations of veterinarians and paraprofessionals.

- <u>v)</u> <u>define the conditions to perform the activities of veterinary medicine/science, including the extent</u> of supervision for each category of *veterinary paraprofessionals;*
- <u>vi) prescribe the powers to deal with conduct and competence issues, including licensing requirements, that apply to veterinarians and veterinary paraprofessionals;</u>
- <u>vii)</u> identify the exceptional situations, such as epizootics, under which persons other than <u>veterinarians</u> can undertake activities that are normally carried out by <u>veterinarians</u>.

EU comment

Again, the point above is problematic, as in the EU it is not up to the VSB to regulate this type of issue which is within the competence of the Competent Authority.

If the veterinary legislation does not create a veterinary statutory body for the regulation of veterinarians and veterinary paraprofessionals, the legislation should at least address all the elements listed in paragraphs 1.
 d) (i) to (vii) to ensure quality in the conduct of veterinary medicine/science.

Article 3.4.7.

Laboratories in the veterinary domain

Facilities

Veterinary legislation should define the role, responsibilities, obligations and quality requirements for:

- a) reference laboratories, which are responsible for controlling the veterinary diagnostic and analytical network, including the maintenance of reference methods;
- b) laboratories designated by the Competent Authority for carrying out the analysis of official samples; and
- c) laboratories recognised by the Competent Authority to conduct analyses in-house testing required under the legislation e.g. for the purposes of safety and quality control. e.g. bacteriological testing for pathogenic agents in milk at a dairy processing plant.

Veterinary legislation should define the conditions for the classification, approval, operations and supervision of each of these types of *laboratories*, including conditions for *laboratory biosafety* and *biosecurity*.

2. Reagents, diagnostic kits and biological agents and products

Veterinary legislation should provide a basis for actions to address the elements listed below:

- a) procedures for authorising the use and transfer of reagents, diagnostic kits and biological agents and products that are used to perform official analyses and other purposes approved by the Competent Authority;
- b) quality assurance by manufacturers <u>and providers</u> of reagents used in official analyses <u>and other</u> <u>purposes approved by the *Competent Authority*</u>; and
- c) surveillance of marketing of reagents, <u>diagnostic kits and biological agents and products</u> where these can affect the quality of analyses required by the *veterinary legislation*.

3. Laboratory containment and control of biological agents and products

<u>Veterinary legislation</u> should make provisions for the effective containment and control of biological agents and products into, within and out of the laboratory as described in Chapter 5.8 of the <u>Terrestrial Code</u> and Chapter 1.1.4. of the <u>Terrestrial Manual</u>.

Article 3.4.8.

Health provisions relating to animal production

1. Identification and traceability

Veterinary legislation should provide a basis for actions to address all the elements in point 6) of Article 4.2.3.

2. Animal markets and other gatherings

Veterinary legislation should address, for animal markets and other commercially or epidemiologically significant animal gatherings, the following elements:

- a) registration of animal markets and other animal gatherings;
- health measures to prevent disease transmission, including procedures for eleaning and disinfection, and animal welfare measures; and
- c) provision for veterinary checks inspections.

3. Animal reproduction

Veterinary legislation should provide a basis for actions to address the health regulation of animal reproduction as appropriate in relation to the *risk* of disease transmission. Health regulations may be implemented at the level of *animals*, genetic material, establishments or operators.

4. Animal feed

Veterinary legislation should provide a basis for actions to address the elements listed below:

- a) standards for the production, composition and quality control of animal feed <u>in relation to the risk of</u> <u>disease transmission</u>;
- b) registration and, if necessary, approval of establishments and the provision of health requirements for relevant operations; and
- c) recall from the market of any product likely to present a hazard to human health or animal health.

5. Animal by-products

Veterinary legislation should provide a basis for actions to address the elements listed below:

- a) definition of the animal by-products subject to the legislation;
- b) rules for collection, transport, processing, use and disposal of animal by-products;
- registration and, if necessary, approval of establishments and the provision of health requirements for relevant operations; and
- d) rules to be followed by animal owners.

6. Disinfection

Veterinary legislation should provide a basis for actions to address the regulation and use of products and methods of disinfection relating to the prevention and control of animal diseases.

Article 3.4.9.

Animal diseases

Veterinary legislation should provide a basis for the Competent Authority to manage diseases of importance to the country-and to list those diseases, guided by the recommendations in Chapters 1.1 and 1.2, as well as emerging diseases, using a risk-based approach. The legislation should also provide for the listing of diseases of importance to the country.

1. Surveillance

Veterinary legislation should provide a basis for the collection, transmission and utilisation of epidemiological data relevant to diseases listed by the Competent Authority.

2. Disease prevention and control

- a) Veterinary legislation should include general animal health measures applicable to all diseases and, if necessary, additional or specific measures such as surveillance, establishment of a regulatory programme or emergency response for particular diseases listed in the country.
- b) The legislation should also provide a basis for contingency plans to include the following for use in disease responses:
 - i) administrative and logistic organisation;
 - ii) exceptional powers of the Competent Authority; and
 - iii) special and temporary measures to address all identified *risks* to human or animal health including accidental or deliberate introduction of biological agents or products.
- c) Veterinary legislation should provide for the financing of animal disease control measures, such as operational expenses and, as appropriate, owners' compensation in the event of killing or slaughtering of animals and seizure or destruction of carcasses, meat, animal feed or other things or the financing of these measures should be ensured in accordance with the national funding system.

Emerging diseases

Veterinary legislation should provide for measures to investigate and respond to emerging diseases including those due to natural, accidental or deliberate introduction of biological agents, using a risk-based approach.

Article 3.4.10.

Animal welfare

1. General provisions

Veterinary legislation should provide a basis for actions to address the animal welfare related requirements in Section 7.

To this end, the legislation should contain, as a minimum, a legal definition of cruelty as an offence, and provisions for direct intervention of the *Competent Authority* in the case of neglect by animal keepers.

2. Stray dogs and other free-roaming animals

Veterinary legislation should provide a basis for actions to address the requirements in Chapter 7.7. and, as appropriate, prohibition of the abandonment of *animals*, and management of abandoned *animals*, including transfer of ownership, veterinary interventions and *euthanasia*.

Article 3.4.11.

Veterinary medicines and biologicals medicinal products

Veterinary legislation should provide a basis for assuring the quality of veterinary medicines and biologicals

<u>medicinal products</u> and minimising the *risk* to human, animal and environmental health associated with their use including the development of antimicrobial resistance.

1. General measures

Veterinary legislation should provide a basis for actions to address the elements listed below:

- a) definition of veterinary medicines and biologicals medicinal products, including any specific exclusions;
 and
- b) regulation of the importation, manufacture, distribution and usage of, and commerce in, *veterinary* medicines and biologicals medicinal products, including laboratory biosafety and biosecurity measures.
- 2. Raw materials for use in veterinary medicines and biologicals

Veterinary legislation should provide a basis for actions to address the elements listed below:

- a) quality standards for raw materials used in the manufacture or composition of veterinary medicines and biologicals medicinal products and arrangements for checking quality;
- b) establishment of the withdrawal periods and maximum residue limits for veterinary medicines and biologicals, as appropriate; and
- <u>eb</u>) requirements for restrictions on substances in veterinary medicines and biologicals <u>medicinal products</u> that may, through their effects, interfere with the <u>interpretation of veterinary diagnostic test results or the</u> conduct of <u>other</u> veterinary checks.
- 3. Authorisation of veterinary medicinal products medicines and biologicals
 - Veterinary legislation should ensure that only authorised veterinary medicines and biologicals medicinal products may be placed on the market.
 - b) Special provisions should be made for:
 - i) medicated feed;

EU comment

For clarity reasons, the EU suggests inserting the words "<u>veterinary medicinal products</u> <u>incorporated into</u>" before "medicated feed" in point i) above.

- ii) products prepared by authorised veterinarians or authorised pharmacists; and
- iii) emergencies and temporary situations; and
- <u>iv)</u> establishment of withdrawal periods for relevant <u>veterinary medicinal products</u> and maximum residue limits for the active substance contained in each such product.
- c) Veterinary legislation should address the technical, administrative and financial conditions associated with the granting, renewal, refusal and withdrawal of authorisations.
- d) In defining the procedures for seeking and granting authorisations, the legislation should:
 - i) describe the role responsibilities of the relevant Competent Authorities; and
 - ii) establish rules providing for the transparency in decision making.
- Veterinary legislation may provide for the possibility of recognition of the equivalence of authorisations made by other countries.

4. Quality of veterinary medicines and biologicals

Veterinary legislation should address the following elements:

- a) the conduct of clinical and non-clinical trials to verify all claims made by the manufacturer;
- b) conditions for the conduct of trials;
- c) qualifications of experts involved in trials; and
- d) surveillance for adverse effects arising from the use of veterinary medicines and biologicals.
- 54. Establishments producing, storing and wholesaling veterinary medicines and biologicals medicinal products

Veterinary legislation should provide a basis for actions to address the following elements:

- a) registration or authorisation of all operators manufacturing importing, storing, processing, wholesaling
 or otherwise distributing veterinary medicines and biologicals medicinal products or raw materials for
 use in making veterinary medicines and biologicals medicinal products;
- b) definition of the responsibilities of operators;
- c) good manufacturing practices appropriate;
- d) reporting on adverse effects to the Competent Authority; and
- e) mechanisms for traceability and recall.
- 65. Retailing, use and traceability of veterinary medicines and biologicals medicinal products

Veterinary legislation should provide a basis for actions to address the following elements:

- a) control over the distribution of veterinary medicines and biologicals medicinal products and arrangements for traceability, recall and conditions of use;
- establishment of rules for the prescription and provision of veterinary medicines and biologicals medicinal products to end users;
- restriction to <u>veterinarians</u> or other authorised professionals and, as appropriate, authorised <u>veterinary</u> paraprofessionals, of commerce in <u>veterinary</u> medicines and <u>biologicals</u> medicinal <u>products</u> that are subject to prescription;
- d) obligation of veterinarians, other authorised professionals or authorised veterinary paraprofessionals to inform end users of the withdrawal periods of relevant veterinary medicinal products and the obligation of end users to observe those withdrawal periods when using those products;
- <u>de</u>) the supervision by an authorised professional of organisations approved for holding and use of <u>veterinary medicines and biologicals medicinal products</u>;
- ef) the regulation of advertising claims and other marketing and promotional activities; and
- fg) reporting on adverse effects to the Competent Authority.

Article 3.4.12.

Human food production chain

Veterinary legislation should provide a basis for actions to safeguard the human food production chain through controls at all critical steps, consistent with national food safety standards <u>and taking into account the *risk* of accidental and deliberate contamination</u>. The role of the Veterinary Services in food safety is described in Chapter 6.1.

1. General provisions

Veterinary legislation should provide a basis for actions to address the following elements:

a) the conduct of veterinary ante- and post-mortem inspections at slaughterhouses/abattoirs;

- ab) controls over all stages of the production, processing and distribution of food of animal origin;
- <u>bo</u>) recording all significant animal and public health events that occur during primary production <u>including</u> <u>slaughter</u>;
- ed) giving operators of food production premises the primary responsibility for compliance with food safety requirements, including traceability established by the *Competent Authority*;
- de) inspection for compliance with food standards, where this is relevant to health or safety;
- ef) inspection and audit of premises;
- fg) prohibition of the marketing of products not fit for human consumption; and
- <u>gh</u>) provisions for recall from the marketplace of all products likely to be hazardous for human or animal health.

2. Products of animal origin intended for human consumption

Veterinary legislation should provide a basis for actions to address the following elements:

- a) arrangements for inspection and audit;
- the conduct of inspection and audit;
- health standards <u>including measures to control diseases</u>, and <u>monitoring and enforcement of maximum</u> residue levels (MRL); and
- **eb**) the application of health identification marks that are visible to the intermediary or and final user.

The Competent Authority should have the necessary powers and means to rapidly withdraw any products deemed to be hazardous from the food chain or to prescribe uses or treatments that ensure the safety of such products for human or animal health.

3. Operators responsible for premises and establishments pertaining to the food chain

Veterinary legislation should provide a basis for actions to address the following elements as appropriate:

- a) registration of premises and establishments by the Competent Authority;
- b) the use of risk-based management procedures; and
- c) prior authorisation of operations that are likely to constitute a significant *risk* to human or animal health.

Article 3.4.13.

Import and export procedures and veterinary certification

Veterinary legislation should provide a basis for actions to address the elements relating to import and export procedures and veterinary certification referred to in Sections 2 Risk Analysis and 5 Trade measures, import/export procedures and veterinary certification.

OIE Terrestrial Animal Health Standards Commission/September 2018

CHAPTER 10.4.

INFECTION WITH <u>HIGH PATHOGENICITY</u> AVIAN INFLUENZA VIRUSES

EU comment

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

In particular, with reference to the recent assessment by the European Food Safety Authority of low pathogenic avian influenza virus transmission via raw poultry meat and raw table eggs published on 15 October 2018 (available here https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2018.5431), we strongly support the recommendations of this draft revised chapter regarding LPAI.

In general, the EU suggests also revising the relevant entries in the list of diseases in Chapter 1.3. at the same time as this chapter is revised, as both are interrelated and it is necessary to be clear on what the future notification obligations of OIE member countries will be.

Furthermore, there is a need for an article to define what the requirements are for a "free flock", as that concept is used in the chapter without a clear definition of what requirements would need to be met by establishments to qualify.

Comments are inserted in the text below.

Article 10.4.1.

General provisions

1) The objective of this chapter is to mitigate animal and public health risks posed by avian influenza viruses, and prevent their international spread. The chapter focuses on high pathogenicity avian influenza viruses, which cause the *listed disease* of concern. However, since they have the ability to mutate into high pathogenicity viruses, low pathogenicity avian influenza viruses of H5 and H7 subtypes should be included in any *surveillance* and control programmes for high pathogenicity viruses. This chapter deals not only with the occurrence of clinical signs caused by avian influenza, but also with the presence of *infection* with avian influenza viruses in the absence of clinical signs.

EU comment

The second sentence of the paragraph above ("The chapter focuses on high pathogenicity avian influenza viruses, which cause the listed disease of concern.") is problematic. Indeed, currently there are two relevant entries in Chapter 1.3., i.e. Infection with avian influenza viruses and Infection with influenza A viruses of high pathogenicity in birds other than poultry including wild birds. While the EU agrees that the revised chapter should focus on HPAI, Chapter 1.3. needs to be adjusted accordingly at the same time, both for reasons of consistency and clarity of notification obligations.

In addition, we note that the terms "avian influenza" or "infection with avian influenza viruses" as well as LPAI are no longer defined in the draft revised version of the chapter, which may cause confusion, especially as regards notification obligations (in case Chapter 1.3. were to remain unchanged). Indeed, in the current version of Chapter 10.4., the latter term includes LPAI H5 and H7 viruses.

For the purposes of the *Terrestrial Code*, avian influenza is defined as an *infection* of *poultry* caused by any influenza A virus of the H5 or H7 subtypes or by any influenza A virus with an intravenous pathogenicity index (IVPI) greater than 1.2 (or as an alternative at least 75% mortality) as described below. These viruses are divided into high pathogenicity avian influenza viruses and low pathogenicity avian influenza viruses:

- a) high pathogenicity avian influenza viruses have an IVPI in six-week-old chickens greater than 1.2 or, as an alternative, cause at least 75% mortality in four-to eight-week-old chickens infected intravenously. H5 and H7 viruses which do not have an IVPI of greater than 1.2 or cause less than 75% mortality in an intravenous lethality test should be sequenced to determine whether multiple basic amino acids are present at the cleavage site of the haemagglutinin molecule (HAO); if the amino acid motif is similar to that observed for other high pathogenicity avian influenza isolates, the isolate being tested should be considered as high pathogenicity avian influenza virus;
- b) low pathogenicity avian influenza viruses are all influenza A viruses of H5 and H7 subtypes that are not high pathogenicity avian influenza viruses.

2) For the purposes of the Terrestrial Code:

- <u>a)</u> <u>High pathogenicity avian influenza means an *infection* of *poultry* by any influenza A virus with an intravenous pathogenicity index (IVPI):</u>
 - in six-week-old chickens greater than 1.2 or, as an alternative, causes at least 75% mortality in four-to eight-week-old chickens infected intravenously. Viruses of H5 and H7 subtypes that do not have an IVPI of greater than 1.2 or cause less than 75% mortality in an intravenous lethality test should be sequenced to determine whether multiple basic amino acids are present at the cleavage site of the haemagglutinin molecule (HA0); if the amino acid motif is similar to that observed for other high pathogenicity avian influenza isolates, the isolate being tested should be considered as a high pathogenicity avian influenza virus.

EU comment

As pointed out in the EU comment above, the definition of "low pathogenicity avian influenza" has been deleted from this revised draft chapter. For H5 and H7 subtype viruses with an IVPI < 1.2 and a polybasic cleavage site sequence not previously described, this leaves a worrying gap in the notification requirements. The OFFLU network has established a document (cited in the OIE *Terrestrial Manual*) for the pathotype interpretation of H5/H7 cleavage site sequences: in that document, any detection of an unrecorded sequence showing any insertions or more than one basic amino acid compared to known low pathogenicity avian influenza virus cleavage sites should be interpreted with caution regarding the pathotype of the virus and expert advice should be sought from an OIE/FAO reference laboratory (see http://www.offlu.net/fileadmin/home/en/resource-centre/pdf/Influenza A Cleavage Sites.pdf).

In order to ensure timely notification of such cases, either the definition in paragraph 2) a) above should be amended to include the above-mentionned cases (i.e. unrecorded H5/H7 sequences showing any insertions or more than one basic amino acid compared to known low pathogenicity avian influenza virus cleavage sites), or these should be added to the "sudden and unexpected change in the distribution, host range, or increase in incidence or virulence of, or morbidity or mortality caused by avian influenza viruses" mentioned below in point 3) of Article 10.4.1., as being notifiable to the OIE.

<u>b)</u> <u>The</u> following defines the occurrence of *infection* with a <u>high pathogenicity</u> avian influenza virus: the virus has been isolated and identified as such or specific viral ribonucleic acid has been detected in one or more samples from *poultry* or a product derived from *poultry*.

EU comment

As indicated, the relevant entry in Chapter 1.3. should be amended accordingly (i.e. "Infection with a <u>high pathogenicity</u> avian influenza viruses").

3) Poultry is defined as 'all domesticated birds, including backyard poultry, used for the production of meat or eggs for consumption, for the production of other commercial products, for restocking supplies of game, or for breeding these categories of birds, as well as fighting cocks used for any purpose'.

Birds that are kept in captivity for any reason other than those reasons referred to in the preceding paragraph, including those that are kept for shows, races, exhibitions, competitions or for breeding or selling these categories of birds as well as pet birds, are not considered to be *poultry*.

<u>Poultry means all domesticated birds used for the production of meat or eggs for consumption, for the production of other commercial products, or for breeding these categories of birds, as well as fighting cocks used for any purpose. All birds used for restocking supplies of game are considered poultry. If birds are kept in a single household and their products are only used in the same household, these birds are not considered poultry.</u>

Birds that are kept in captivity for any reason other than those referred to in the preceding paragraph, including those that are kept for shows, races, exhibitions, competitions or for breeding or selling these categories of birds as well as pet birds, are not considered *poultry*;

EU comment

The EU in general supports the newly proposed definition of poultry above. However, we note that there is a different definition for "poultry" currently in the Glossary, and the definition proposed in this draft revised chapter is marked as "For the purposes of the Terrestrial Code" (and not "For the purposes of this chapter"). This discrepancy needs to be addressed (e.g. by amending the Glossary definition accordingly, at the same time as this chapter is adopted).

In addition, the breeding flocks producing offspring raised for restocking supplies of game logically are also to be explicitly included, in the same way they are mentioned for birds used for the production of meat / eggs / other commercial products. Therefore, the EU suggests amending the second sentence of point c) above as follows:

"All birds used for restocking supplies of game, including the corresponding breeding flocks, are considered poultry.".

Finally, the EU suggests also excluding birds kept in zoos from the definition of poultry, by inserting the word "<u>zoos</u>" after "competitions" in the second paragraph of point c) above. Indeed, while birds kept in zoos can get infected (e.g. by contact with wild birds), zoos are epidemiological units well separated from poultry, where quarantine and testing regimes apply upon movement, and where a stamping-out policy will normally not be applied or be limited to certain animals only.

- d) the incubation period at the flock level for high pathogenicity avian influenza shall be 14 days.
- 3) In accordance with Chapter 1.1., a sudden and unexpected change in the distribution, host range, or increase in incidence or virulence of, or morbidity or mortality caused by avian influenza viruses is notifiable to the OIE, as well as zoonotic avian influenza viruses. Occurrences of influenza A viruses of high pathogenicity in birds other than poultry, including wild birds, are notifiable. Six-monthly reports on the presence of avian influenza viruses in a country or zone should include low pathogenicity viruses of H5 and H7 subtypes.

EU comment

The first two sentences of the paragraph above are problematic. Indeed, they seem to recall (and thus repeat) some of the notification obligations according to Chapter 1.1., as well as that of the "non-poultry" entry for HPAI in Chapter 1.3. This is confusing, especially since only the disease specific chapter is being revised, while the relevant entries in Chapter 1.3. are not. As both are linked and need to be read in parallel, Chapter 1.3. should preferably be revised (and eventually adopted) at the same time. What's more, it is unclear what is covered by "avian influenza viruses", as that term is no longer defined in the draft revised chapter (i.e. are H5 and H7 LPAI in poultry covered, or any influenza A viruses in any animal including humans?).

Furthermore, we note that the third sentence of the paragraph above does not represent a notification obligation, but a recommendation ("should"). Again, while we support this in principle, care must be taken to ensure consistency with Chapter 1.3. A further option to clarify the status of this six-monthly notification could be to refer to surveillance (as indicated in the second indent of Article 10.4.3.) by inserting the words "include information on surveillance for" before "low pathogenicity".

Finally, we suggest adding the words "<u>in poultry</u>" at the end of the third sentence of the paragraph above, to clarify that this notification recommendation does not pertain to birds other than poultry including wild birds (where LPAI can be ubiquitous, e.g. waterfowl).

A notification of infection with influenza A viruses of high pathogenicity in birds other than poultry, including wild birds, or of low pathogenicity avian influenza viruses in poultry does not affect the status of the country or zone. A Member Country should not impose bans on the trade in poultry and poultry commodities in response to such notification, or to other information on the presence of any influenza A virus in birds other than poultry, including wild birds.

EU comment

Given that the Glossary definition of "commodity" covers live animals and it is desirable to explicitly make reference to them in the paragraph above, the EU suggests slightly rewording the second sentence of the paragraph above as follows:

"A Member Country should not impose bans on the trade in <u>live</u> poultry and <u>other</u> poultry commodities in response to such notification, [...]".

For the purposes of the Terrestrial Code, the incubation period for avian influenza shall be 21 days.

- 5) This chapter deals not only with the occurrence of clinical signs caused by avian influenza, but also with the presence of infection with avian influenza viruses in the absence of clinical signs.
- 6) Antibodies against H5 or H7 subtype, which have been detected in poultry and are not a consequence of vaccination, should be immediately investigated. In the case of isolated serological positive results, infection with avian influenza viruses may be ruled out on the basis of a thorough epidemiological and laboratory investigation that does not demonstrate further evidence of such an infection.
- 7) For the purposes of the Terrestrial Code, 'avian influenza free establishment' means an establishment in which the poultry have shown no evidence of infection with avian influenza viruses, based on surveillance in accordance with Articles 10.4.27. to 10.4.33.
- 8) Infection with influenza A viruses of high pathogenicity in birds other than poultry, including wild birds, should be notified according to Article 1.1.3. However, a Member Country should not impose bans on the trade in poultry and poultry commodities in response to such a notification, or other information on the presence of any influenza A virus in birds other than poultry, including wild birds.

4) The use of vaccination against high pathogenicity avian influenza in poultry may be recommended under specified conditions, while not affecting the status of a free country or zone if the vaccine complies with the standards in the Terrestrial Manual. Vaccination is an effective complementary control tool that can be used when a stamping-out policy alone is not sufficient. The decision whether to vaccinate or not is to be made by the Veterinary Authorities based on the avian influenza situation as well as the ability of the Veterinary Services to execute the proper vaccination strategy, as described in Chapter 4.17. Any vaccine used should comply with the standards described in the Terrestrial Manual.

EU comment

As "high pathogenicity avian influenza" is defined for the purposes of this chapter as an infection of poultry, the words "in poultry" would not seem to be necessary in the first line of the paragraph above.

However, we suggest replacing the words "vaccination against high pathogenicity avian influenza" with "vaccination against <u>avian influenza viruses of H5 and H7 subtypes</u>". Indeed, vaccination "directed" against low pathogenicity avian influenza viruses of these two subtypes could have the same effect as vaccinating against HPAI and impact surveillance results.

Furthermore, it is not clear what is meant by "when a stamping-out policy alone is not sufficient". We would suggest adding something like "to control the disease".

Finally, the term "Veterinary Authorities" should be replaced with "Veterinary Authority", and the word "execute" should be replaced with the word "implement", for clarity.

<u>59</u>) Standards for diagnostic tests<u>and vaccines</u>, including pathogenicity testing, are described in the *Terrestrial Manual*. Any vaccine used should comply with the standards described in the Terrestrial Manual.

Article 10.4.1bis.

Safe commodities

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

1) heat-treated poultry meat in a hermetically sealed container with a F-value of 3.00 or above;

EU comment

With reference to Item 5.10. of the Code Commission report (Chapter on ASF), the EU suggests amending point 1) above for consistency, as follows:

- 1) [...] with a F-value of 3.00 or above;".
- 2) extruded dry pet food and poultry-based coated ingredients after extrusion;
- 3) rendered meat and bone meal, blood meal, feather meal, and poultry oil;
- feathers and down from poultry and other birds processed by washing and steam-drying.

Other commodities of poultry and other birds can be traded safely if in accordance with the relevant articles of this chapter.

Article 10.4.2.

Determination of the avian influenza status of a country, zone or compartment

The avian influenza status of a country, a zone or a compartment can be determined on the basis of the following criteria:

- 4) avian influenza is notifiable in the whole country, an ongoing avian influenza awareness programme is in place, and all notified suspect occurrences of avian influenza are subjected to field and, where applicable, laboratory investigations;
- 2) appropriate surveillance is in place to demonstrate the presence of infection in the absence of clinical signs in poultry, and the risk posed by birds other than poultry; this may be achieved through an avian influenza surveillance programme in accordance with Articles 10.4.27. to 10.4.33.;
- 3) consideration of all epidemiological factors for avian influenza occurrence and their historical perspective.

Country, zone or compartment free from avian influenza

A country, zone or compartment may be considered free from avian influenza when it has been shown that infection with avian influenza viruses in *poultry* has not been present in the country, zone or compartment for the past 12 months, based on surveillance in accordance with Articles 10.4.27. to 10.4.33.

If infection has occurred in poultry in a previously free country, zone or compartment, avian influenza free status can be regained:

- 1) In the case of infections with high pathogenicity avian influenza viruses, three months after a stamping-out policy (including disinfection of all affected establishments) is applied, providing that surveillance in accordance with Articles 10.4.27. to 10.4.33. has been carried out during that three month period.
- 2) In the case of infections with low pathogenicity avian influenza viruses, poultry may be kept for slaughter for human consumption subject to conditions specified in Article 10.4.19, or a stamping-out policy may be applied; in either case, three months after the disinfection of all affected establishments, providing that surveillance in accordance with Articles 10.4.27, to 10.4.33, has been carried out during that three-month period.

A country, or zone or compartment may be considered free from infection with high pathogenicity avian influenza viruses in poultry when:

<u>infection with high pathogenicity avian influenza viruses in poultry is a notifiable disease in the entire country:</u>

EU comment

For consistency with point 2 b) of Article 10.4.1., we suggest amending the indent above as follows:

"- infection with high pathogenicity avian influenza viruses [...]".

(This comment is valid also for the third indent below.)

Furthermore, as "high pathogenicity avian influenza" is defined for the purposes of this chapter as an infection of poultry, the words "in poultry" do not seem to be necessary in the first line of the paragraph above.

<u>an ongoing avian influenza surveillance is implemented to monitor the general situation of H5 and H7 low pathogenicity avian influenza viruses in poultry and an awareness programme is in place related to biosecurity and management of H5 and H7 low pathogenicity avian influenza viruses;</u>

EU comment

For clarity and consistency with point 1 of Article 10.4.1., we suggest referring to "H5 and H7 low pathogenicity avian influenza viruses of H5 and H7 subtypes" in the indent above (and throughout the chapter).

Furthermore, we note that "low pathogenicity avian influenza viruses" is not defined in the chapter, which may cause confusion.

- <u>based on surveillance in accordance with Chapter 1.4. and Articles 10.4.27. to 10.4.33.</u> it has been shown demonstrated that infection with high pathogenicity avian influenza viruses in poultry as defined in Article 10.4.1. has not been present occurred in the country, or zone or compartment for the past 12 months; Although its status with respect to low pathogenicity avian influenza viruses may be unknown; or
- bird commodities are imported in accordance with Articles 10.4.5. to 10.4.23.

The surveillance should may need to be adapted to parts of the country or existing zones or compartment depending on historical or geographical factors, industry structure, population data, or proximity to recent outbreaks or the use of vaccination.

If infection has occurred in poultry in a previously free country, zone or compartment, the free status can be regained three menths after a stamping-out policy (including disinfection of all affected establishments) is applied, providing that surveillance in accordance with Articles 10.4.27. to 10.4.33. has been carried out during that three-menth period.

Article 10.4.3bis.

Compartment free from high pathogenicity avian influenza

The establishment of a compartment free from high pathogenicity avian influenza should follow the relevant requirements of this chapter and the principles in Chapters 4.3. and 4.4.

EU comment

The word "establishment" in the paragraph above should not be in italics, as it does not refer to the Glossary definition.

Article 10.4.3ter.

Establishment of a containment zone within a country or zone free from high pathogenicity avian influenza

In the event of *outbreaks* of high pathogenicity avian influenza within a previously free country or *zone*, a *containment* zone, which includes all epidemiologically linked *outbreaks*, may be established for the purposes of minimising the impact on the rest of the country or *zone*.

EU comment

The EU suggests clarifying that it is possible to establish more than one containment zone in a country, when there is more than one incursion of infection into a country which is not epidemiologically linked, separated in space and time (or even occurring at the same time).

In addition to the requirements for the establishment of a containment zone outlined in Article 4.3.7., the <u>surveillance</u> programme should take into account the density of <u>poultry</u> production, types of <u>poultry</u>, local management practices (including inter-premise movement pattern of <u>poultry</u>, people and equipment), relevant <u>biosecurity</u> and presence and potential role of birds other than <u>poultry</u>, including <u>wild</u> birds and the proximity of <u>poultry</u> establishments to perennial and seasonal water bodies.

EU comment

The word "establishment" in the paragraph above should not be in italics, as it does not refer to the Glossary definition.

The free status of the areas outside the *containment zone* is suspended while the *containment zone* is being established. It may be reinstated irrespective of the provisions of Article 10.4.3quater., once the *containment zone* is clearly established. It should be demonstrated that *commodities* for *international trade* either have originated outside the *containment zone* or comply with the relevant articles of this chapter.

EU comment

We note that the wording used in the paragraph above regarding the establishment of the containment zone slightly deviates from that of Article 4.3.7. If the intention of this inconsistency is to allow deviating from the general provision of Article 4.3.7., we believe this should be worded more explicitly to avoid any confusion and to ensure uniform interpretation by trading partners, for example by inserting wording such as "<u>By way of derogation from Article 4.3.7.</u>" and by clarifying the timing in relation to the two incubation periods (i.e. that trade can restart after less than that time under certain conditions).

Article 10.4.3quater.

Recovery of free status

If infection has occurred in poultry in a previously free country or zone, the free status can be regained after a minimum period of 28 days after a stamping-out policy has been completed, provided that surveillance in accordance with Articles 10.4.27. to 10.4.33., in particular point 3) of Article 10.4.30., has been carried out during that period and has demonstrated the absence of infection.

EU comment

For reasons of clarity, we suggest inserting the words "with high pathogenicity avian influenza virus" after "infection" in the first line of the paragraph above.

Furthermore, we suggest inserting a parenthesis "(starting after the disinfection of all affected establishments)" after "has been completed", to avoid any uncertainty as to when exactly the 28 day period would start.

Indeed, even if the Glossary definition of stamping-out policy is precise (consisting of three elements, i.e. killing of animals, disposal of carcasses, cleaning and disinfection), there has been a lot of confusion around this in the past, as disease specific chapters in the Code are not aligned in this respect.

If a stamping-out policy is not implemented, Article 10.4.3. applies.

Article 10.4.5.

Recommendations for importation from a country, zone or compartment free from $\underline{\text{high}}$ $\underline{\text{pathogenicity}}$ avian influenza

For live poultry (other than day-old poultry)

EU comment

The word "poultry" should be italicised in the heading above, and in all headings throughout the chapter.

Furthermore, the EU suggests deleting the word "live" before "poultry" in the heading above (and throughout the chapter whenever referring to international trade, i.e. not in relation to "live bird markets" in point 2 b) of Article 10.4.28.). Indeed, that word seems

superfluous, as poultry (and day-old poultry or day-old birds) being traded internationally are usually alive.

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

- 1) the *poultry* showed no clinical signs of avian influenza on the day of shipment;
- 2) <u>a)</u> the poultry were kept in <u>originated from</u> an avian influenza free <u>a</u> country, zone or compartment <u>free</u> from high pathogenicity avian influenza since they were hatched or for at least the past 21 days;
 - b) the poultry originated from a flock free from infection with any H5 or H7 influenza A viruses;

EU comment

As mentioned in the general EU comment above, it is not clear what the requirements are for a "free flock". Indeed, that concept is used in the chapter without a clear definition of what requirements would need to be met by establishments to qualify; this should be included in the next version of the draft chapter (e.g. as regards sample size, type of test to be performed, periodicity of testing required to ensure free status at the flock level).

Furthermore, for clarity and consistency, we suggest replacing the words "infection with any H5 or H7 influenza A viruses" with "infection with any H5 or H7 influenza A viruses of H5 or H7 subtypes".

3) the *poultry* are transported in new or appropriately sanitized *containers*.

If the *poultry* have been vaccinated against avian influenza, the nature of the vaccine used and the date of *vaccination* should be attached to mentioned in the *international veterinary certificate*.

EU comment

It is not clear whether the provision in the paragraph above regarding vaccination of poultry refers to vaccination against avian influenza of H5/H7 subtypes only or covers all HA subtypes. This should preferably be clarified.

Article 10.4.6.

Recommendations for the importation of live birds other than poultry

Regardless of the avian influenza status of the country of origin, Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:

1) on the day of shipment, the birds showed no clinical signs of *infection* with a virus which would be considered avian influenza in *poultry*;

EU comment

Since "avian influenza" is no longer defined in this draft revised chapter and is thus not reserved for poultry, the wording of point 1 above can be simplified as follows:

"1) on the day of shipment, the birds showed no clinical signs of infection with a virus which would be considered avian influenza in poultry;".

This comment is valid also for point 2) below, and throughout the chapter.

2) the birds were kept in isolation approved by the Veterinary Services since they were hatched or for at least 24 28 days prior to shipment and showed no clinical signs of infection with a virus which would be considered avian influenza in poultry during the isolation period; a statistically valid sample of the birds, selected in accordance with the provisions of Article 10.4.29., was subjected to a diagnostic test <u>for influenza A viruses</u> within 14 days prior to shipment, <u>with negative results</u> <u>for H5 and H7</u>-to demonstrate freedom from <u>infection</u> with a virus which would be considered avaina influenza in poultry;

EU comment

The EU notes that Article 10.4.29. is deleted; the reference in point 3) above should therefore be revised.

Furthermore, we query whether the wording "was subjected to a diagnostic test for influenza A viruses" is intentional, i.e. requires virological testing only. (This comment is valid also for other articles where this wording is used.)

4) the birds are transported in new or appropriately sanitized containers.

If the birds have been vaccinated against avian influenza, the nature of the vaccine used and the date of vaccination should be attached to mentioned in the international veterinary certificate.

Article 10.4.7.

Recommendations for importation from a country, zone or compartment free from avian influenza

For day-old live poultry

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

- 1) the poultry were kept in an avian influenza free country, zone or compartment since they were hatched;
- 2) the poultry were derived from parent flocks which had been kept in an avian influenza free country, zone or compartment for at least 21 days prior to and at the time of the collection of the eggs;
- 3) the poultry are transported in new or appropriately sanitized containers.

If the poultry or the parent flocks have been vaccinated against avian influenza, the nature of the vaccine used and the date of vaccination should be attached to the certificate.

Article 10.4.8.

Recommendations for importation from a country, zone or compartment free from $\frac{1}{1}$ influence $\frac{1}{1$

For day-old live poultry

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

the poultry were kept in a country, zone or compartment free from influenza since they were hatched;

EU comment

To avoid confusion, we suggest inserting the words "<u>day-old</u>" before "poultry", both in point 1) above and throughout the rest of the article.

- 2) a) the poultry were derived from parent flocks free from infection with any H5 or H7 influenza A viruses which had been kept in an avian influenza free establishment for at least 21 days prior to and at the time of the collection of the eggs from which the day-old poultry hatched; or
 - <u>b)</u> the day-old live poultry that hatched from eggs that have had their surfaces sanitized in accordance with point 4 d) of Article 6.5.5.;
- 23) the *poultry* are transported in new or appropriately sanitized *containers*.

If the *poultry* or the parent *flocks* have been vaccinated against avian influenza, the nature of the vaccine used and the date of *vaccination* should be attached to mentioned in the *international veterinary certificate*.

Article 10.4.9.

Recommendations for the importation of day-old live birds other than poultry

Regardless of the avian influenza status of the country of origin, Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:

1) on the day of shipment, the birds showed no clinical signs of *infection* with a virus which would be considered avian influenza in *poultry*;

EU comment

The wording of point 1) above is odd. For reasons of clarity, reference should be made to a disease, not to an infection with a virus, that would be responsible for clinical signs. (This comment is valid also for other articles where this wording is used.)

- 2) the birds were hatched and kept in isolation approved by the Veterinary Services;
- 3) the parent flock birds were subjected to a diagnostic test for influenza A viruses at the time of the collection of the eggs, with negative results for H5 and H7 to demonstrate freedom from infection with a virus which would be considered avian influenza in poultry;

EU comment

To be consistent with Article 10.4.6., point 3) above should begin as follows:

- "3) <u>a statistically valid sample of birds from</u> the parent flock birds were <u>was</u> subjected to (...)"
- 4) the birds are transported in new or appropriately sanitized containers.

If the birds or parent *flocks* have been vaccinated against avian influenza, the nature of the vaccine used and the date of *vaccination* should be <u>attached to mentioned in</u> the <u>international veterinary</u> certificate.

Article 10.4.10.

Recommendations for importation from a country, zone or compartment free from avian influenza

For hatching eggs of poultry

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

- 1) the eggs came from an avian influenza free country, zone or compartment,
- 2) the eggs were derived from parent flocks which had been kept in an avian influenza free country, zone or compartment for at least 21 days prior to and at the time of the collection of the eggs;
- 3) the eggs are transported in new or appropriately sanitized packaging materials.

If the parent flocks have been vaccinated against avian influenza, the nature of the vaccine used and the date of vaccination should be attached to the certificate.

Article 10.4.11.

Recommendations for importation from a country, zone or compartment free from infection with high pathogenicity avian influenza viruses in poultry

For hatching eggs of poultry

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

- the eggs came from a country, zone or compartment free from influenza viruses in poultry;
- 2) <u>a)</u> the eggs were derived from parent *flocks* <u>free from infection</u> with any H5 or H7 influenza A viruses which had been kept in an avian influenza free establishment for at least 21 days prior to and at the time of the collection of the eggs; or
 - b3) the eggs have had their surfaces sanitized (in accordance with Chapter 6.5. point 4 d) of Article 6.5.5.);
- <u>34</u>) the eggs are transported in new or appropriately sanitized packaging materials.

If the parent *flocks* have been vaccinated against avian influenza, the nature of the vaccine used and the date of vaccination should be attached to mentioned in the <u>international veterinary</u> certificate.

Article 10.4.12.

Recommendations for the importation of hatching eggs from birds other than poultry

Regardless of the avian influenza status of the country of origin, Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:

- a statistically valid sample of birds from the parent flock birds were was subjected to a diagnostic test for influenza A viruses seven 14 days prior to and at the time of the collection of the eggs, with negative results for H5 and H7 to demonstrate freedom from infection with a virus which would be considered avian influenza in poultry;
- 2) the eggs have had their surfaces sanitized (in accordance with point 4 d) of Article 6.5.5. Chapter 6.5.;
- 3) the eggs are transported in new or appropriately sanitized packaging materials.

If the parent *flocks* have been vaccinated against avian influenza, the nature of the vaccine used and the date of *vaccination* should be <u>attached to mentioned in</u> the <u>international veterinary</u> certificate.

Article 10.4.13.

Recommendations for importation from a country, zone or compartment free from avian influenza

For eggs for human consumption

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

- the eggs were produced and packed in an avian influenza free country, zone or compartment;
- 2) the eggs are transported in new or appropriately sanitized packaging materials.

Article 10.4.14.

Recommendations for importation from a country, zone or compartment free from infection with high pathogenicity avian influenza viruses in poultry

For eggs for human consumption

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

1) the eggs were produced and packed in a country, *zone* or *compartment* free from *infection* with high pathogenicity avian influenza viruses in *poultry*;

- 2) the eggs have had their surfaces sanitized (in accordance with Chapter 6.5.);
- 23) the eggs are transported in new or appropriately sanitized packaging materials.

EU comment

The EU suggests moving the articles on eggs / egg products for human consumption to after the articles on semen, as usually food products come after animal genetic material.

Article 10.4.15.

Recommendations for importation of egg products of poultry

Regardless of the avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) the commodity is derived from eggs which meet the requirements of Articles 10.4.13. or 10.4.14. or
- 2) the *commodity* has been processed to ensure the <u>destruction</u> inactivation of <u>high pathogenicity</u> avian influenza virus in accordance with Article 10.4.25.:

AND

3) the necessary precautions were taken to avoid contact of the *commodity* with any source of <u>high</u> <u>pathogenicity avian influenza virus</u>.

Article 10.4.16.

Recommend8ations for importation from a country, zone or compartment free from avian influenza

For poultry semen

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

- 1) showed no clinical sign of avian influenza on the day of semen collection;
- 2) were kept in an avian influenza free country, zone or compartment for at least 21 days prior to and at the time of semen collection.

Article 10.4.17.

Recommendations for the importation from a country, zone or compartment free from infection with high pathogenicity avian influenza viruses in poultry

For poultry semen

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

 showed no clinical signs of infection with high pathogenicity avian influenza viruses in poultry on the day of semen collection;

EU comment

For reasons of clarity, point 1) above should read as follows:

- "1) showed no clinical signs of <u>disease caused by</u> avian influenza <u>infection</u> on the day of semen collection;".
- 2) were kept in a country, *zone* or *compartment* free from *infection* with high pathogenicity avian influenza viruses in *poultry* for at least 21 days prior to and at the time of semen collection.

Article 10.4.18.

Recommendations for the importation of semen of birds other than poultry

Regardless of the avian influenza status of the country of origin, Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the donor birds:

- 1) were kept in isolation approved by the Veterinary Services for at least 24 28 days prior to semen collection;
- 2) showed no clinical signs of *infection* with a virus which would be considered avian influenza in *poultry* during the isolation period;
- 3) were tested within 14 days prior to semen collection and shown to be free from *infection* with a virus which would be considered avian influenza in *poultry*.

EU comment

For reasons of consistency (see EU comment above), point 3) above should begin as follows:

"3) a statistically valid sample of donor birds were tested (...)".

Furthermore, the wording of the last part of point 3) ("infection with a virus which would be considered avian influenza in poultry") sounds a bit awkward and is confusing. The wording would be clearer if reference to "highly pathogenic avian influenza" or "avian influenza infection" would be made instead. However this raises again the point made in an EU comment above, i.e. the definition of "avian influenza" has been deleted from this revised draft chapter, whereas such a definition would be very useful in this context.

Article 10.4.19.

Recommendations for importation from a country, zone or compartment free from avian influenza or free from infection with high pathogenicity avian influenza viruses in poultry

For fresh meat of poultry

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the entire consignment of fresh meat comes from poultry:

- which have been kept in <u>originated from</u> a country, zone or compartment free from <u>infection</u> with high pathogenicity avian influenza <u>viruses</u> in <u>poultry</u> since they were hatched or for at least the past 21 days;
- 2) which have been slaughtered in an approved *abattoir* in a country, *zone* or *compartment* free from *infection* with high pathogenicity avian influenza viruses in *poultry* and have been subjected to ante- and post-mortem inspections in accordance with Chapter 6.3. and have been found free of any signs suggestive of avian influenza with favorable results.

Article 10.4.20.

Recommendations for the importation of meat products of poultry

Regardless of the avian influenza status of the country of origin, Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:

- 1) the commodity is derived from fresh meat which meets the requirements of Article 10.4.19.; or
- 2) the *commodity* has been processed to ensure the <u>destruction</u> inactivation of <u>high pathogenicity</u> avian influenza virus in accordance with Article 10.4.26.;

AND

3) the necessary precautions were taken to avoid contact of the *commodity* with any source of <u>high</u> <u>pathogenicity</u> avian influenza virus.

Article 10.4.21.

Recommendations for the importation of poultry products not listed in Article 10.4.1bis and intended for use in animal feeding, or for agricultural or industrial use

Regardless of the status of the country of origin, Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:

- these commodities were processed in a country, zone or compartment free from high pathogenicity avian influenza and from poultry which originated in a country, zone or compartment free from high pathogenicity avian influenza; or
- 2) these commodities have been processed to ensure the inactivation of high pathogenicity avian influenza virus using:
 - a) moist heat treatment for 30 minutes at 56 °C; or
 - b) heat treatment where the internal temperature throughout the product reaches at least 74 °C; or
 - c) any equivalent treatment that has been demonstrated to inactivate avian influenza virus;

AND

3) the necessary precautions were taken to avoid contact of the commodity with any source of high pathogenicity avian influenza virus.

Article 10.4.21.

Recommendations for the importation of products of poultry origin, other than feather meal and poultry meal, intended for use in animal feeding, or for agricultural or industrial use

Regardless of the avian influenza status of the country of origin, Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:

- these commodities were processed in an avian influenza free country, zone or compartment from poultry which were kept in an avian influenza free country, zone or compartment from the time they were hatched until the time of slaughter or for at least the 21 days preceding slaughter; or
- 2) these commodities have been processed to ensure the destruction of avian influenza virus using:
 - a) moist heat treatment for 30 minutes at 56°C; or
 - b) any equivalent treatment which has been demonstrated to inactivate avian influenza virus;

AND

3) the necessary precautions were taken to avoid contact of the commodity with any source of avian influenza virus.

Article 10.4.22.

Recommendations for the importation of feathers and down of poultry $\underline{\text{not listed in}}$ $\underline{\text{Article 10.4.1bis.}}$

Regardless of the avian influenza status of the country of origin, Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:

- these commodities originated from poultry as described in Article 10.4.19. and were processed in an avian influenza free a country, zone or compartment free from high pathogenicity avian influenza; or
- 2) these *commodities* have been processed to ensure the inactivation of <u>high pathogenicity</u> avian influenza virus using one of the following:
 - a) washed and steam dried at 100°C for 30 minutes;
 - b) fumigation with formalin (10% formaldehyde) for 8 hours;
 - be) irradiation with a dose of 20 kGy;
 - ce) any equivalent treatment which has been demonstrated to inactivate avian influenza virus;

AND

 the necessary precautions were taken to avoid contact of the commodity with any source of <u>high</u> <u>pathogenicity</u> avian influenza virus.

Article 10.4.23.

Recommendations for the importation of feathers and down of birds other than poultry

EU comment

For consistency with Article 10.4.22., the title above should read:

"Recommendations for the importation of feathers and down of birds other than poultry not listed in article 10.4.1bis".

Indeed, birds other than poultry are actually mentioned in point 4) of Article 10.4.1bis.

Regardless of the avian influenza status of the country of origin, Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:

- these commodities have been processed to ensure the destruction inactivation of any virus which would be considered high pathogenicity avian influenza in poultry using one of the following:
 - a) washed and steam dried at 100°C for 30 minutes;
 - b) fumigation with formalin (10% formaldehyde) for 8 hours;
 - be) irradiation with a dose of 20 kGy;
 - ed) any equivalent treatment which has been demonstrated to inactivate avian influenza virus;

EU comment

For clarity and consistency with Article 10.4.22., we suggest inserting the word "AND" between point 1) above and point 2) below.

2) the necessary precautions were taken to avoid contact of the *commodity* with any source of viruses which would be considered <u>high pathogenicity</u> avian influenza in *poultry*.

Article 10.4.24.

Recommendations for the importation of feather meal and poultry meal

Regardless of the avian influenza status of the country of origin, Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:

- these commodities were processed in an avian influenza free country, zone or compartment from poultry which were kept in an avian influenza free country, zone or compartment from the time they were hatched until the time of slaughter or for at least the 21 days preceding slaughter, or
- 2) these commodities have been processed either:
 - a) with moist heat at a minimum temperature of 118°C for minimum of 40 minutes; or
 - b) with a continuous hydrolysing process under at least 3.79 bar of pressure with steam at a minimum temperature of 122°C for a minimum of 15 minutes; or
 - with an alternative rendering process that ensures that the internal temperature throughout the product reaches at least 74°C;

AND

3) the necessary precautions were taken to avoid contact of the commodity with any source of avian influenza viruses.

Article 10.4.25.

Procedures for the inactivation of $\underline{\text{high pathogenicity}}$ avian influenza viruses in eggs and egg products

The following times for industry standard temperatures are suitable for the inactivation of <u>high pathogenicity</u> avian influenza viruses present in eggs and egg products:

	Core temperature (°C)	Time
Whole egg	60	188 seconds
Whole egg blends	60	188 seconds
Whole egg blends	61.1	94 seconds
Liquid egg white	55.6	870 seconds
Liquid egg white	56.7	232 seconds
Plain or pure egg yolk	60	288 seconds
10% salted yolk	62.2	138 seconds
Dried egg white	67	20 hours
Dried egg white	54.4	50.4 hours
Dried egg white	51.7	73.2 hours

The listed temperatures are indicative of a range that achieves a 7-log kill of avian influenza virus. These are listed as examples in a variety of egg products, but when scientifically documented, variances from these times and temperatures and for additional egg products may also be suitable when they achieve equivalent inactivation of the virus.

EU comment

For clarity reasons, the EU suggests replacing the words "kill of avian influenza virus" with "reduction of avian influenza virus infectivity" in the paragraph above (and also in Article 10.4.26. below), as that is the adequate technical wording.

Article 10.4.26.

Procedures for the inactivation of $\underline{\text{high pathogenicity}}$ avian influenza viruses in meat

The following times for industry standard temperatures are suitable for the inactivation of <u>high pathogenicity</u> avian influenza viruses.

	Core temperature (°C)	Time
Poultry meat	60.0	507 seconds
	65.0	42 seconds
	70.0	3.5 seconds
	73.9	0.51 second

The listed temperatures are indicative of a range that achieves a 7-log kill. Where scientifically documented, variances from these times and temperatures may also be suitable when they achieve the inactivation of the virus.

Article 10.4.26bis.

<u>Procedures for the inactivation of high pathogenicity avian influenza viruses in scientific specimens and skins and trophies</u>

For the inactivation of high pathogenicity avian influenza virus in scientific specimens and skins and trophies, one of the following procedures should be used:

- boiling in water for an appropriate time so as to ensure that any matter other than bone, claws or beaks is removed; or
- 2) soaking, with agitation, in a 4% (w/v) solution of washing soda (sodium carbonate-Na₂CO₃) maintained at pH 11.5 or above for at least 48 hours; or
- 3) soaking, with agitation, in a formic acid solution (100 kg salt [NaCl] and 12 kg formic acid per 1,000 litres water) maintained below pH 3.0 for at least 48 hours; wetting and dressing agents may be added; or
- <u>4)</u> in the case of raw hides, treating for at least 28 days with salt (NaCl) containing 2% washing soda (sodium carbonate-Na₂CO₃); or
- 5) treatment with 1% formalin for a minimum of six days;
- <u>any equivalent treatment which has been demonstrated to inactivate the virus.</u>

Article 10.4.27.

Introduction to surveillance of high pathogenicity avian influenza

Articles 10.4.27. to 10.4.33. define the principles and provide a guide on the *surveillance* for avian influenza complementary to Chapter 1.4., applicable to Member Countries seeking to determine their <u>high pathogenicity</u> avian influenza status. <u>Surveillance is also necessary to support vaccination programmes, to monitor general situation of H5 and H7 low pathogenicity avian influenza viruses in <u>poultry</u> and for monitoring avian influenza in <u>wild birds.</u> This may be for the entire country, <u>zone</u> or <u>compartment</u>. Guidance for Member Countries seeking free status following an <u>outbreak</u> and for the maintenance of avian influenza status is also provided.</u>

The presence of influenza A viruses in *wild* birds creates a particular problem. In essence, no Member Country can declare itself free from influenza A in *wild* birds. However, the definition of avian influenza in this chapter refers to the *infection* in *poultry* only, and Articles 10.4.27. to 10.4.33. were developed under this definition.

The impact and epidemiology of avian influenza differ widely in different regions of the world and therefore it is impossible to provide specific detailed recommendations for all situations. Surveillance strategies employed for demonstrating freedom from avian influenza at an acceptable level of confidence should be adapted to the local situation. Variables such as the frequency of contacts of poultry with wild birds, different biosecurity levels and production systems and the commingling of different susceptible species including domestic waterfowl require specific surveillance strategies to address each specific situation. It is incumbent upon the Member Country to provide scientific data that explains the epidemiology of avian influenza in the region concerned and also demonstrates how all the risk factors are managed. There is therefore considerable latitude available to Member Countries to provide a well-reasoned argument to prove that absence of infection with avian influenza viruses is assured at an acceptable level of confidence. Surveillance of H5 and H7 low pathogenicity avian influenza viruses in poultry is relevant as they might mutate into high pathogenicity viruses. There is currently no scientific evidence to predict if and when mutation might occur. Outbreaks of low pathogenicity viruses can be managed at establishment level, however spread to other poultry establishments increases the risk of virus mutation, in

particular if it is not detected and managed. Therefore, a surveillance system should be in place to detect clusters of infected poutry establishments where H5 and H7 low pathogenicity viruses spread between poultry establishments.

Surveillance for avian influenza should be in the form of a continuing programme designed to establish that the country, zone or compartment, for which application is made, is free from infection with avian influenza viruses.

In cases where potential public health implications are suspected, reporting to the appropriate public health authorities is essential.

Article 10.4.28.

General conditions and methods for surveillance Surveillance for early warning of high pathogenicity avian influenza

Surveillance for avian influenza should be in the form of a continuing programme designed to detect the presence of infection with high pathogenicity avian influenza viruses in the country or zone in a timely manner. A surveillance system in accordance with Chapter 1.4. should be under the responsibility of the Veterinary Authority. In particular:

EU comment

For consistency throughout the chapter, the word "viruses" should be replaced with "virus" in the paragraph above.

- a) a formal and ongoing system for detecting and investigating outbreaks of disease or infection with avian influenza viruses should be in place;
- b) a procedure should be in place for the rapid collection and transport of samples from suspect cases of avian influenza to a laboratory for avian influenza diagnosis:
- e) a system for recording, managing and analysing diagnostic and surveillance data should be in place.
- 2) The high pathogenicity avian influenza surveillance programme should:
 - include an early warning system in accordance with Article 1.4.5. throughout the production, marketing and processing chain for reporting suspicious suspected cases. Farmers and workers, who have day-to-day contact with poultry, as well as diagnosticians, should report promptly any suspicion of high pathogenicity avian influenza to the Veterinary Authority. They should be supported directly or indirectly (e.g. through private veterinarians or veterinary para-professionals) by government information programmes and the Veterinary Authority. All suspected cases of high pathogenicity avian influenza should be investigated immediately. As suspicion cannot always be resolved by epidemiological and clinical investigation alone, samples should be taken and submitted to a laboratory for appropriate tests. This requires that sampling kits and other equipment are available for those responsible for surveillance. Personnel responsible for surveillance should be able to call for assistance from a team with expertise in avian influenza diagnosis and control. In cases where potential public health implications are suspected, notification to the appropriate public health authorities is essential;
 - b) implement, when <u>as</u> relevant, regular and frequent clinical inspection, and <u>or</u> serological and virological testing of high-risk groups of *animals*, such as those adjacent to an <u>high pathogenicity</u> avian influenza infected country or *zone*, places where birds and *poultry* of different origins are mixed, such as live bird markets, *poultry* in close proximity to waterfowl or other potential sources of influenza A viruses. <u>This activity is particularly applicable to domestic waterfowl where detection of high pathogenicity avian influenza via clinical suspicion can be of low sensitivity;</u>
 - <u>ensure that antibodies against influenza A viruses, which have been detected in poultry and are not a consequence of vaccination, be immediately investigated.</u> In the case of isolated serological positive results, infection with high pathogenicity avian influenza viruses may be ruled out on the basis of a thorough epidemiological and laboratory investigation that does not demonstrate further evidence of such an infection.

An effective surveillance system will periodically identify suspicious cases that require follow-up and investigation to confirm or exclude that the cause of the condition is influenza A viruses. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Decumentation for freedom from *infection* with avian influenza viruses should, in consequence, provide details of

the occurrence of suspicious cases and how they were investigated and dealt with. This should include the results of *laboratory* testing and the control measures to which the *animals* concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

Article 10.4.29.

Surveillance strategies

Introduction

The target population for *surveillance* aimed at identification of *disease* and *infection* should cover all the susceptible *poultry* species within the country, *zone* or *compartment*. Active and passive *surveillance* for avian influenza should be ongoing with the frequency of active *surveillance* being appropriate to the epidemiological situation in the country. *Surveillance* should be composed of random and targeted approaches using molecular, virological, serological and clinical methods.

The strategy employed may be based on randomised sampling requiring surveillance consistent with demonstrating the absence of *infection* with avian influenza viruses at an acceptable level of confidence. Random surveillance is conducted using serological tests. Positive serological results should be followed up with molecular or virological methods.

Targeted surveillance (e.g. based on the increased likelihood of infection in particular localities or species) may be an appropriate strategy. Virological and serological methods should be used concurrently to define the avian influenza status of high risk populations.

A Member Country should justify the *surveillance* strategy chosen as adequate to detect the presence of *infection* with avian influenza viruses in accordance with Chapter 1.4. and the prevailing epidemiological situation, including cases of high pathogenicity influenza A detected in any birds. It may, for example, be appropriate to target clinical *surveillance* at particular species likely to exhibit clear clinical signs (e.g. chickens). Similarly, virological and serological testing could be targeted to species that may not show clinical signs (e.g. ducks).

If a Member Country wishes to declare freedom from *infection* with avian influenza viruses in a specific zone or *compartment*, the design of the survey and the basis for the sampling process would need to be aimed at the population within the zone or *compartment*.

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 *infection* if it were to occur at a predetermined minimum rate. The sample size and expected *disease* 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 clearly 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 positives 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 flocks which may be epidemiologically linked to it.

The principles involved in surveillance for disease and infection are technically well defined. The design of surveillance programmes to prove the absence of infection with, or circulation of, avian influenza viruses should be carefully followed to avoid producing results that are either insufficiently reliable, or excessively costly and logistically complicated. The design of any surveillance programme, therefore, requires inputs from professionals competent and experienced in this field.

2. Clinical surveillance

Clinical surveillance aims at the detection of clinical signs of avian influenza at the flock level. Whereas significant emphasis is placed on the diagnostic value of mass serological screening, surveillance based on clinical inspection should not be underrated. Monitoring of production parameters, such as increased mortality, reduced feed and water consumption, presence of clinical signs of a respiratory disease or a drop in egg production, is important for the early detection of infection with avian influenza viruses. In some cases, the only indication of infection with low pathogenicity avian influenza virus may be a drop in feed consumption or egg production.

Clinical surveillance and laboratory testing should always be applied in series to clarify the status of avian influenza suspects detected by either of these complementary diagnostic approaches. Laboratory testing may confirm clinical suspicion, while clinical surveillance may contribute to confirmation of positive serology. Any sampling unit within which suspicious animals are detected should have restrictions imposed upon it until avian influenza infection is ruled out.

Identification of suspect flocks is vital to the identification of sources of avian influenza viruses and to enable the molecular, antigenic and other biological characteristics of the virus to be determined. It is essential that avian influenza virus isolates are sent regularly to the regional Reference Laboratory for genetic and antigenic characterisation.

3. Virological surveillance

Virological surveillance should be conducted:

- a) to monitor at risk populations;
- b) to confirm clinically suspect cases;
- c) to follow up positive serological results;
- d) to test 'normal' daily mortality, to ensure early detection of infection in the face of vaccination or in establishments epidemiologically linked to an outbreak.

4. Serological surveillance

Serological surveillance aims at the detection of antibodies against avian influenza virus. Positive avian influenza viruses antibody test results can have four possible causes:

- a) natural infection with avian influenza viruses;
- b) vaccination against avian influenza;
- e) maternal antibodies derived from a vaccinated or infected parent *flock* are usually found in the yolk and can persist in progeny for up to four weeks;
- d) lack of specificity of the test.

It may be possible to use serum collected for other survey purposes for avian influenza surveillance. However, the principles of survey design described in these recommendations and the requirement for a statistically valid survey for the presence of avian influenza viruses should not be compromised.

The discovery of clusters of seropositive *flocks* may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or *infection*. As clustering may signal *infection*, the investigation of all instances should be incorporated in the survey design. Clustering of positive *flocks* is always epidemiologically significant and therefore should be investigated.

If vaccination cannot be excluded as the cause of positive serological reactions, diagnostic methods to differentiate antibodies due to infection or vaccination should be employed.

The results of random or targeted serological surveys are important in providing reliable evidence that no infection with avian influenza viruses is present in a country, zone or compartment. It is therefore essential that the survey be thoroughly documented.

5. <u>Virological and serological surveillance in vaccinated populations</u>

The surveillance strategy is dependent on the type of vaccine used. The protection against influenza A virus is haemagglutinin subtype specific. Therefore, two broad vaccination strategies exist: 1) inactivated whole viruses, and 2) haemagglutinin expression-based vaccines.

In the case of vaccinated populations, the *surveillance* strategy should be based on virological or serological methods and clinical *surveillance*. It may be appropriate to use sentinel birds for this purpose. These birds should be unvaccinated, virus antibody free birds and clearly and permanently identified. Sentinel birds should be used only if no appropriate *laboratory* procedures are available. The interpretation of serological results in the presence of *vaccination* is described in Article 10.4.33.

Article 10.4.30.

<u>Surveillance for demonstrating</u> Documentation of freedom from avian influenza or freedom from infection with high pathogenicity avian influenza viruses in poultry

 Additional surveillance requirements for Member Countries declaring freedom of the country, zone or compartment from avian influenza or from infection with high pathogenicity avian influenza viruses in poultry

In addition to the general conditions described in above mentioned articles, a $\underline{\underline{A}}$ Member Country declaring freedom of the entire country, or a zone or a compartment from avian influenza or from infection with high pathogenicity avian influenza viruses in poultry should provide evidence for the existence of an effective surveillance programme.

The strategy and design of the *surveillance* programme depend on the prevailing epidemiological circumstances and should be planned and implemented according to general conditions and methods described in this chapter and in Article 1.4.6, to demonstrate absence of *infection* with avian influenza viruses or with high pathogenicity avian influenza viruses, during the preceding 12 months in susceptible *poultry* populations (vaccinated and non-vaccinated). This requires the availability of demographic data on the *poultry* population and the support of a *laboratory* able to undertake identification of *infection* with avian influenza viruses through virus detection and antibody tests. This *surveillance* may be targeted to *poultry* population at specific risks linked to the types of production, possible direct or indirect contact with *wild* birds, multi-age *flocks*, local trade patterns including live bird markets, use of possibly contaminated surface water, and the presence of more than one species on the holding *establishment* and poor *biosecurity* measures in place. It should include the monitoring of high pathogenicity avian influenza virus in *wild* birds and of H5 and H7 low pathogenicity avian influenza virus in poultry, in order to adapt the biosecurity and possible control measures.

EU comment

In the paragraph above, please replace "This surveillance may be targeted to poultry population" with "This surveillance may be targeted to poultry population<u>s</u>" (grammar).

Documentation for freedom from *infection* with high pathogenicity avian influenza should provide details of the *poultry* population, the occurrence of suspected cases and how they were investigated and dealt with. This should include the results of *laboratory* testing and the *biosecurity* and control measures to which the animals concerned were subjected during the investigation.

2. Additional requirements for countries, zones or compartments that practice vaccination

Vaccination to prevent the transmission of high pathogenicity avian influenza virus may be part of a disease control programme. The level of flock immunity required to prevent transmission depends on the flock size, composition (e.g. species) and density of the susceptible poultry population. It is therefore impossible to be prescriptive. Based on the epidemiology of avian influenza in the country, zone or compartment, it may be that a decision is reached to vaccinate only certain species or other poultry subpopulations.

In all vaccinated *flocks* there is a need to perform virological and serological tests to ensure the absence of virus circulation. The use of sentinel *poultry* may provide further confidence of the absence of virus circulation. The tests have to be repeated at least every six months or at shorter intervals according to the *risk* in the country, *zone* or *compartment*.

Evidence to show the effectiveness of the *vaccination* programme should also be provided.

Member Countries seeking the demonstration of freedom from high pathogenicity avian influenza in vaccinated population should refer to Chapter 2.3.4. paragraph C 4 of the *Terrestrial Manual*.

In the paragraph above, again please replace "population" with "populations", or insert "a" before "vaccinated" (grammar).

Furthermore, as the structure and numbering of the Terrestrial Manual changes regularly (as does that of the Code), it would be preferable to mention the title of the Manual chapter to avoid any uncertainty.

3. Additional requirements for recovery of free status

In addition to the conditions described in the point above, a Member Country declaring that it has regained country, zone or compartment freedom after an outbreak of high pathogenicity avian influenza in poultry should show evidence of an active surveillance programme depending on the epidemiological circumstances of the outbreak to demonstrate the absence of the infection. This will require surveillance incorporating virus detection and antibody tests. The use of sentinel birds may facilitate the interpretation of surveillance results. The Member Country should report the results of an active surveillance programme in which the susceptible poultry population undergoes regular clinical examination and active surveillance planned and implemented according to the general conditions and methods described in these recommendations. The surveillance samples should be representative of poultry populations at risk.

Populations under this surveillance programme should include:

- 1) establishments in the proximity of the outbreaks;
- 2) establishments epidemiologically linked to the outbreaks;
- 3) animals moved from or used to re-populate affected establishments;

EU comment

In point 3) above, we suggest replacing the word "animals" with "<u>poultry</u>" or "<u>birds</u>", as these are the animals targeted by this chapter.

Furthermore, it is unclear under what conditions or for what purpose birds could be moved alive from affected or infected establishments. This should preferably be clarified here.

4) any establishments where contiguous culling has been carried out;

Article 10.4.30bis.

Surveillance of wild bird populations

The presence of high pathogenicity avian influenza viruses in wild birds creates a particular problem. In essence, no Member Country can declare itself free from influenza A viruses in wild birds. However, the definition of high pathogenicity avian influenza in this chapter refers to the *infection* in *poultry* only, and Articles 10.4.27. to 10.4.33. were developed under this definition.

Passive surveillance (i.e. sampling of birds found dead) is an appropriate method of surveillance in wild birds as infection with high pathogenicity avian influenza is usually associated with mortality. Mortality events, or clusters of birds found dead should be reported to the local Veterinary Authorities and investigated.

Active surveillance in wild birds usually has lower sensitivity for detection of high pathogenicity avian influenza, but may be necessary for detection of some strains of high pathogenicity avian influenza virus that produce infection without mortality in wild birds.

EU comment

The EU suggests completing the paragraph above as follows:

"Active surveillance in wild birds, i.e. sampling of live and apparently healthy wild birds, usually has lower sensitivity for detection of high pathogenicity avian influenza, but may be necessary for detection of some strains of high pathogenicity avian influenza

virus that produce infection without mortality in wild birds. <u>Active surveillance could</u> <u>also be carried out indirectly by use and regular testing of sentinel ducks in contact with wild water birds in regions and places of high risk for AI introduction.".</u>

Indeed, we would suggest adding a definition of "active surveillance" in order to emphasise the difference to the indirect method using sentinel flocks. Sentinel flocks in contact with wild water birds in selected regions could indicate HPAI-introduction in wild water birds. In addition it monitors infection with LPAI (H5/H/) viruses circulating in wild water birds.

<u>Surveillance in wild birds should be targeted towards species, locations and times of year in which infection is more likely.</u>

<u>Surveillance in wild birds should be enhanced by awareness raising and active searching and monitoring for dead or moribund wild birds when high pathogenicity avian influenza has been detected in the region. The movements of migratory water birds, in particular ducks, geese and swans, should be taken into account as a potential pathway for introduction of virus to uninfected areas.</u>

Article 10.4.30ter.

Monitoring of H5 and H7 low pathogenicity avian influenza in poultry populations

Monitoring the presence of H5 and H7 low pathogenicity avian influenza viruses can be achieved through the combination of clinical investigations where *infection* is suspected through changes in production indicators such as reductions in egg production or *feed* and water intake and active serological and virological *surveillance*.

<u>Serological monitoring should aim at detecting clusters of infected flocks to identify spread between establishments.</u> Epidemiological follow-up (tracing forward and back) of serologically positive flocks should be carried out to determine if there is clustering of infected flocks regardless of whether the seropositive birds are still present on the establishment or whether active virus infection has been detected.

Article 10.4.31.

Additional surveillance requirements for countries, zones or compartments declaring that they have regained freedom from avian influenza or from infection with high pathogenicity avian influenza viruses in poultry following an outbreak

In addition to the general conditions described in the above-mentioned articles, a Member Country declaring that it has regained country, zone or compartment freedom from avian influenza or from infection with high pathogenicity avian influenza viruses in poultry should show evidence of an active surveillance programme depending on the epidemiological circumstances of the outbreak to demonstrate the absence of the infection. This will require surveillance incorporating virus detection and antibody tests. The use of sentinel birds may facilitate the interpretation of surveillance results.

A Member Country declaring freedom of country, zone or compartment after an outbreak of avian influenza should report the results of an active surveillance programme in which the susceptible poultry population undergoes regular clinical examination and active surveillance planned and implemented according to the general conditions and methods described in these recommendations. The surveillance should at least give the confidence that can be given by a randomised representative sample of the populations at risk.

Article 10.4.32.

$\underline{\textbf{Additional s}}\underline{\underline{\textbf{S}}} urveillance \ \underline{\textbf{requirements}} \ \ \underline{\textbf{for}} \ \ \underline{\textbf{the}} \ \ avian \ \ influenza \ \ \textbf{free} \ \ \textbf{establishments}$

The declaration of avian influenza free *establishments* requires the demonstration of absence of *infection* with avian influenza viruses. Birds in these *establishments* should be randomly tested using virus detection or isolation tests, and serological methods, following the general conditions of these recommendations. The frequency of testing should be based on the *risk* of *infection* and at a maximum interval of 24 28 days.

This article is problematic, since the terms "avian influenza" and "infection with avian influenza viruses" are no longer defined in the draft revised version of this chapter. It should therefore be specified that this would include H5 and H7 LPAI in poultry, if that is the intention – which is not clear from the text. There would also need to be some context on when and how to use this recommendation, as in the recent past it has been misused by importing countries to set up clearly unjustified trade barriers (i.e. asking for assurances of establishment freedom for every establishment in a country or zone that was to export).

However, the EU questions whether this article is necessary at all, or would be useful for international trade. Indeed, as the term "avian influenza free establishment" has been deleted from Articles 10.4.1.7., 10.4.8. and 10.4.11. (the latter two relating to requirements for hatching eggs and day-old poultry), the EU suggests simply deleting Article 10.4.32.

Article 10.4.33.

The use and interpretation of serological and virus detection tests

Poultry infected with avian influenza virus produce antibodies against haemagglutinin (HA), neuraminidase (NA), nenstructural proteins (NSPs), nucleoprotein/matrix (NP/M) and the polymerase complex proteins. Detection of antibodies against the polymerase complex proteins is not covered in this chapter. Tests for NP/M antibodies include direct and blocking ELISA, and agar gel immunodiffusion (AGID) tests. Tests for antibodies against NA include the neuraminidase inhibition (NI), indirect fluorescent antibody and direct and blocking ELISA tests. For the HA, antibodies are detected in haemagglutination inhibition (HI), ELISA and neutralisation (SN) tests. The HI test is reliable in avian species but not in mammals. The SN test can be used to detect subtype specific antibodies against the haemagglutinin and is the preferred test for mammals and some avian species. The AGID test is reliable for detection of NP/M antibodies in chickens and turkeys, but not in other avian species. As an alternative, blocking ELISA tests have been developed to detect NP/M antibodies in all avian species.

The HI and NI tests can be used to subtype influenza A viruses into 16 haemagglutinin and 9 neuraminidase subtypes. Such information is helpful for epidemiological investigations and in categorization of influenza A viruses.

Poultry can be vaccinated with a variety of influenza A vaccines including inactivated whole virus vaccines, and haemagglutinin expression-based vaccines. Antibodies against the haemagglutinin confer subtype specific protection. Various strategies can be used to differentiate vaccinated from infected birds including serosurveillance in unvaccinated sentinel birds or specific serological tests in the vaccinated birds.

Influenza A virus infection of unvaccinated birds including sentinels is detected by antibodies against the NP/M, subtype specific HA or NA proteins, or NSP. Poultry vaccinated with inactivated whole virus vaccines containing a virus of the same H sub-type but with a different neuraminidase may be tested for field exposure by applying serological tests directed to the detection of antibodies against the NA of the field virus. For example, birds vaccinated with H7N3 in the face of a H7N1 epidemic may be differentiated from infected birds (DIVA) by detection of subtype specific NA antibodies of the N1 protein of the field virus. Alternatively, in the absence of DIVA, inactivated vaccines may induce low titres of antibodies against NSP and the titre in infected birds would be markedly higher. Encouraging results have been obtained experimentally with this system, but it has not yet been validated in the field. In poultry vaccinated with haemagglutinin expression-based vaccines, antibodies are detected against the specific HA, but not any of the other viral proteins. Infection is evident by antibodies against the NP/M or NSP, or the specific NA protein of the field virus.

All flocks with seropositive results should be investigated. Epidemiological and supplementary laboratory investigation results should document the status of avian influenza infection for each positive flock.

A confirmatory test should have a higher specificity than the screening test and sensitivity at least equivalent than that of the screening test.

Information should be provided on the performance characteristics and validation of tests used.

1. Procedure in case of positive test results if vaccination is used

In case of vaccinated populations, one has to exclude the likelihood that positive test results are indicative of virus circulation. To this end, the following procedure should be followed in the investigation of positive serological test results derived from *surveillance* conducted on vaccinated *poultry*. The investigation should examine all evidence that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were not due to virus circulation. All the epidemiological information should be substantiated, and the results should be collated in the final report.

Knowledge of the type of vaccine used is crucial in developing a serological based strategy to differentiate infected from vaccinated animals.

- a) Inactivated whole virus vaccines can use either homologous or heterologous neuraminidase subtypes between the vaccine and field strains. If poultry in the population have antibodies against NP/M and were vaccinated with inactivated whole virus vaccine, the following strategies should be applied:
 - i) sentinel birds should remain NP/M antibody negative. If positive for NP/M antibodies, indicating influenza A virus infection, specific HI tests should be performed to identify H5 or H7 virus infection;
 - ii) if vaccinated with inactivated whole virus vaccine containing homologous NA to field virus, the presence of antibodies against NSP could be indicative of infection. Sampling should be initiated to exclude the presence of avian influenza virus by either virus isolation or detection of virus specific genomic material or proteins;
 - if vaccinated with inactivated whole virus vaccine containing heterologous NA to field virus, presence of antibodies against the field virus NA or NSP would be indicative of infection. Sampling should be initiated to exclude the presence of avian influenza virus by either virus isolation or detection of virus specific genomic material or proteins.
- b) Haemagglutinin expression-based vaccines contain the HA protein or gene homologous to the HA of the field virus. Sentinel birds as described above can be used to detect avian influenza infection. In vaccinated or sentinel birds, the presence of antibodies against NP/M, NSP or field virus NA is indicative of infection. Sampling should be initiated to exclude the presence of avian influenza virus by either virus isolation or detection of virus specific genomic material or proteins.
- 2. Procedure in case of test results indicative of infection with avian influenza viruses

The detection of antibodies indicative of an *infection* with avian influenza virus in unvaccinated *poultry* should result in the initiation of epidemiological and virological investigations to determine if the *infections* are due to low and high pathogenicity viruses.

Virological testing should be initiated in all antibody positive and at risk populations. The samples should be evaluated for the presence of avian influenza virus, by virus isolation and identification, or detection of influenza A specific proteins or nucleic acids (Figure 2). Virus isolation is the gold standard for detecting infection by avian influenza virus. All influenza A virus isolates should be tested to determine HA and NA subtypes, and in vivo tested in chickens or sequencing of HA proteolytic cleavage site of H5 and H7 subtypes for determination of classification as high or low pathogenicity avian influenza viruses or other influenza A viruses. As an alternative, nucleic acid detection tests have been developed and validated; these tests have the sensitivity of virus isolation, but with the advantage of providing results within a few hours. Samples with detection of H5 and H7 HA subtypes by nucleic acid detection methods should either be submitted for virus isolation, identification, and in vivo testing in chickens, or sequencing of nucleic acids for determination of proteolytic cleavage site as high or low pathogenicity avian influenza viruses. The use of antigen detection systems, because of low sensitivity, should be limited to screening clinical field cases for infection by influenza A virus looking for NP/M proteins. NP/M positive samples should be submitted for virus isolation, identification and pathogenicity determination.

Laboratory results should be examined in the context of the epidemiological situation. Corollary information needed to complement the serological survey and assess the possibility of viral circulation includes but is not limited to:

- a) characterisation of the existing production systems;
- b) results of clinical surveillance of the suspects and their cohorts;
- c) quantification of vaccinations performed on the affected sites;

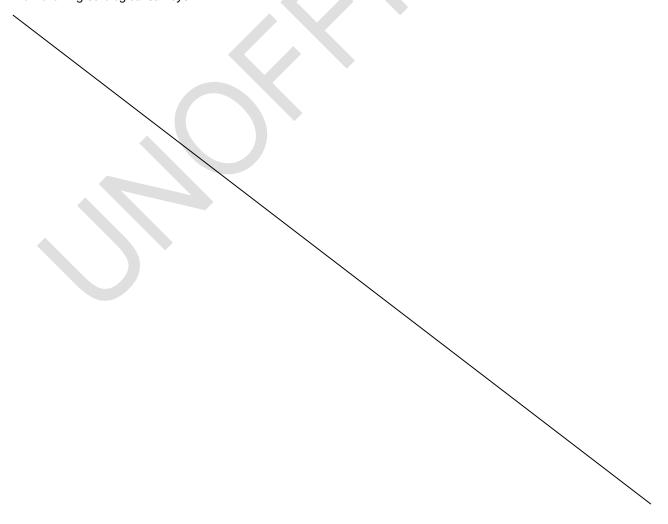
- d) sanitary protocol and history of the affected establishments;
- e) control of animal identification and movements;
- f) other parameters of regional significance in historic avian influenza virus transmission.

The entire investigative process should be documented as standard operating procedure within the epidemiological surveillance programme.

Figures 1 and 2 indicate the tests which are recommended for use in the investigation of poultry flocks.

Key abbreviations and acronyms:		
AGID	Agar gel immunodiffusion	
DIVA	Differentiating infected from vaccinated animals	
ELISA	Enzyme-linked immunosorbent assay	
HA	Haemagglutinin	
H	Haemagglutination inhibition	
NA	Neuraminidase	
NP/M	Nucleoprotein and matrix protein	
NSP	Nonstructural protein	
S	Ne evidence of avian influenza virus	

Fig. 1. Schematic representation of laboratory tests for determining evidence of avian influenza infection through or following serological surveys



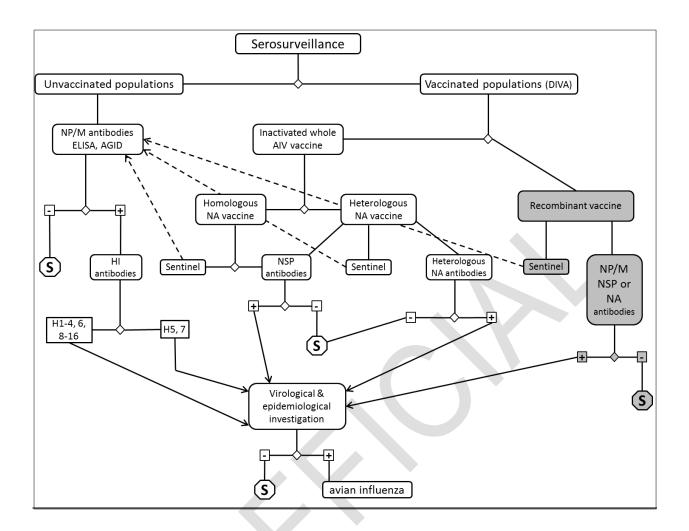
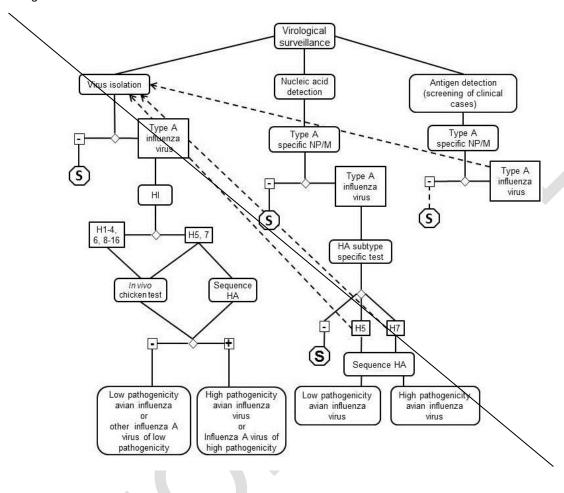


Fig. 2. Schematic representation of laboratory tests for determining evidence of avian influenza infection using virological methods



CHAPTER 1.1.

NOTIFICATION OF DISEASES, INFECTIONS AND INFESTATIONS, AND PROVISION OF EPIDEMIOLOGICAL INFORMATION

EU comment

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

Comments are inserted in the text below.

Article 1.1.1.

For the purposes of the *Terrestrial Code* and in terms of Articles 5, 9 and 10 of the OIE Organic Statutes, Member Countries shall recognise the right of the *Headquarters* to communicate directly with the *Veterinary Authority* of its territory or territories.

All *notifications* and all information sent by the OIE to the *Veterinary Authority* shall be regarded as having been sent to the country concerned and all *notifications* and all information sent to the OIE by the *Veterinary Authority* shall be regarded as having been sent by the country concerned.

Article 1.1.2.

- Member Countries shall make available to other Member Countries, through the OIE, whatever information
 is necessary to minimise the spread of important animal diseases, and their pathogenic agents, and to
 assist in achieving better worldwide control of these diseases.
- 2) To achieve this, Member Countries shall comply with the *notification* requirements specified in Articles 1.1.3. and 1.1.4.
- 3) For the purposes of this chapter, an 'event' means a single *outbreak* or a group of epidemiologically related *outbreak*s of a given disease, *infection* or *infestation* that is the subject of a *notification*. An event is specific to a pathogenic agent and strain, when appropriate, and includes all related *outbreaks* reported from the time of the immediate *notification* through to the final report. Reports of an event include susceptible species, number and geographical distribution of affected animals and *epidemiological units*.
- 4) To assist in the clear and concise exchange of information, reports shall conform as closely as possible to the OIE disease reporting format.
- 5) The detection of the pathogenic agent of a *listed disease* in an *animal* should be reported, even in the absence of clinical signs. Recognising that scientific knowledge concerning the relationship between diseases and their pathogenic agents is constantly developing and that the presence of a pathogenic agent does not necessarily imply the presence of a disease, Member Countries shall ensure, through their reports, that they comply with the spirit and intention of point 1) above.
- 6) In addition to notifying new findings in accordance with Articles 1.1.3. and 1.1.4., Member Countries shall also provide information on the measures taken to prevent the spread of diseases, *infections* and *infestations*. Information shall include *biosecurity* and quarantine *sanitary* measures and including restrictions applied to the movement of *animals*, animal products, biological products and other miscellaneous objects which could by their nature be responsible for the transmission of diseases, *infections* or *infestations*. In the case of diseases transmitted by *vectors*, the measures taken against such *vectors* shall also be specified.

The EU questions whether it is necessary to refer explicitly to "biosecurity" in this context. Indeed, it would seem sufficient to replace "quarantine measures" with "sanitary measures", as according to the Glossary definitions of both terms, the latter one is more inclusive, and would already cover biosecurity. Furthermore, "sanitary measures" better reflects the information member countries already provide with their notifications, whereas "biosecurity measures" in addition to that would not be required for all diseases.

Article 1.1.3.

Veterinary Authorities shall, under the responsibility of the Delegate, send to the Headquarters:

- in accordance with relevant provisions in the disease-specific chapters, notification, through the World Animal Health Information System (WAHIS) or by fax or email within 24 hours, of any of the following events:
 - a) first occurrence of a listed disease, infection or infestation in a country, a zone or a compartment;
 - b) recurrence of an <u>eradicated</u> listed disease, infection or infestation in a country, a zone or a compartment following the final report that declared the <u>outbreak</u> <u>event</u> ended;
 - first occurrence of a new strain of a pathogenic agent of a listed disease, infection or infestation in a country, a zone or a compartment;
 - <u>d)</u> recurrence of an eradicated strain of a pathogenic agent of a listed disease in a country, a zone or a compartment following the final report that declared the event ended;

EU comment

The EU questions whether "strain" is the right term to be used in this context. Indeed, this could easily be misunderstood, since the term is currently not defined. Perhaps a Glossary definition would be necessary to avoid any possible confusion (along the lines suggested by the OIE Biological Standards Commission in its September 2018 report).

However depending on the disease, "<u>serotype</u>" would also seem appropriate for what is intended, e.g. in the context of FMD or bluetongue, whereas for avian influenza, perhaps "<u>subtype</u>" would be the relevant term. This would not only be applicable to point d) above but equally so to point c).

The EU therefore invites the OIE to carefully assess what type of information is really necessary for the OIE to receive, and propose changes accordingly. Indeed, it would be very important to be precise and clear about this before moving ahead.

- de a sudden and unexpected change in the distribution or increase in incidence or virulence of, or morbidity or mortality caused by, the pathogenic agent of a listed disease, infection or infestation present within a country, a zone or a compartment;
- ef) occurrence of a listed disease, infection or infestation in an unusual host species;
- 2) weekly reports subsequent to a notification under point 1) above, to provide further information on the evolution of the event which justified the notification. These reports should continue until the <u>listed</u> disease, infection or infestation has been eradicated or the situation has become sufficiently stable so that sixmonthly reporting under point 3) will satisfy the obligation of the Member Country; for each event notified, a final report should be submitted;
- six-monthly reports on the absence or presence and evolution of listed diseases, infections or infestations
 and information of epidemiological significance to other Member Countries;
- 4) annual reports concerning any other information of significance to other Member Countries.

Article 1.1.4.

Veterinary Authorities shall, under the responsibility of the Delegate, send to the Headquarters:

- a notification through WAHIS or by fax or email, when an emerging disease has been detected in a country, a zone or a compartment;
- 2) periodic reports subsequent to a notification of an emerging disease:
 - a) for the time necessary to have reasonable certainty that:
 - the disease, infection or infestation has been eradicated; or
 - the situation has become stable;

OR

- b) until sufficient scientific information is available to determine whether it meets the criteria for inclusion in the OIE list as described in Chapter 1.2.;
- 3) a final report once point 2 a) or b) above is complied with.

Article 1.1.5.

- 1) The Veterinary Authority of a country in which an infected zone is located shall inform the Headquarters when this zone or the entire country becomes free from the disease, infection or infestation.
- 2) A country or zone may be considered to have regained freedom from a specific disease, infection or infestation when all relevant conditions given in the Terrestrial Code have been fulfilled.
- 3) The Veterinary Authority of a Member Country which establishes one or several free zones shall inform the Headquarters giving necessary details, including the criteria on which the free status is based, the requirements for maintaining the status and indicating clearly the location of the zones on a map of the territory of the Member Country.

EU comment

The EU agrees that Article 1.1.5. is not well placed in this chapter and should best be moved to Chapter 1.6. However, we note that while the text is proposed for deletion from this chapter, there is no concurrent proposal to include it in Annex 14. In order to avoid loosing this important information from the Code, we invite the OIE to include a proposal for transferring this article to Chapter 1.6. at the February 2019 meeting of the Code Commission.

Article 1.1.65.

- 1) Although Member Countries are only required to notify *listed diseases, infections* and *infestations* and *emerging diseases*, they are encouraged to provide the OIE with other important animal health information.
- 2) The *Headquarters* shall communicate by email or through the interface of WAHIS to *Veterinary Authorities* all *notifications* received as provided in Articles 1.1.2. to 1.1.54. and other relevant information.

WORK PROGRAMME FOR THE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

EU comment

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

In particular, we would like to thank the OIE for having restarted the work on the revision of the Code chapter on BSE, with first meetings of the ad hoc group in July and October and another one scheduled for November 2018. We trust that BSE will be kept high on the Code Commission's priority list and we look very much forward to receiving the draft revised text for member country comment.

The EU also commends the OIE for its work on Chapter 10.4. on avian influenza. While we fully support the thorough review of that chapter, we would urge the OIE to revise Chapter 1.3. at the same time as regards the relevant entries for avian influenza in the OIE list, as both are interrelated. Reference is made to the EU comments included in Annex 19.

Furthermore, we would like to reiterate our previous suggestion of December 2016 regarding the Code chapter on rabies. Indeed, guidance in the Code on the control of rabies in wildlife including as regards oral vaccination would be crucial in order to progress further towards a rabies free region of Europe. Reference is made to the EU comment in Annex 11.

In addition, with reference to the September 2018 meeting report of the SCAD and the discussions around which members of the *Mycobacterium tuberculosis* complex meet the listing criteria of Chapter 1.2., we would invite the OIE to propose relevant changes to Chapters 1.3. and 8.11. at its February 2019 meeting.

Finally, with reference to the EU comments on the work programme of the Code Commission of May 2018 and the ones provided previously (see https://ec.europa.eu/food/sites/food/files/safety/docs/ia_standards_oie_eu_position_tahsc-report_201805.pdf, p. 306), we are pleased to provide in a separate annex concrete text proposals for a review of Chapter 6.10. on *Responsible and prudent use of antimicrobial agents in veterinary medicine*. Indeed, it would be important to include concrete principles and further recommendations as to the conditions of use in that Code chapter. We trust that our suggestions will be useful for the Code Commission to start work in this area and offer all our technical support.

Subject	Issue by priority order (Reason for new work)	Status and Action (Start date, # of rounds for comments)	
	Horizontal chapters		
Restructuring of the Code	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	

Subject	Issue by priority order (Reason for new work)	Status and Action (Start date, # of rounds for comments)		
	Work with BSC for accurate disease description and diagnostic in the <i>Manual</i> and case definitions in the <i>Code</i> and names of diseases and country and zone disease status (MCs comments)	Ongoing		
	Revision and formatting of chapters (articles numbering, tables and figures) (MCs comments and to improve consistency)	Ongoing		
	Revision of the Users' guide (MCs comments and changes in the <i>Code</i>)	Ongoing		
Glossary	'early warning system' and 'sanitary measures' (experts comments)	Revised definitions sent for adoption (Sep 2016/3rd and Feb 2018/2nd)		
	2) 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services' (AHG comments), 'epidemiological unit' and 'captive wild [animal]' (MCs comments)	Revised definitions sent for comments (Sep 2018/1st)		
	Horizontal issues not yet in the Code			
Section 4. Disease control	New CH on official control of listed and emerging diseases (MCs comments and part of restructuring of Section 4)	Revised new CH sent for adoption(Feb 2017/4th)		
	New introductory CH in Section 4 (Part of restructuring of Section 4)	Revised new CH sent for comments and adoption (Sep 2017/3rd)		
	3) New CH on biosecurity (Discussion with ACC)	Preliminary discussion		
	New CH on application of zoning (MCs comments)	Preliminary discussion		
Section 6. Veterinary public health	Control of Shiga toxin-producing <i>E. coli</i> (STEC) in food-producing animals (MCs comments)	Preliminary discussion pending FAO/WHO expert consultation		
Section 7. Animal Welfare	New CH on slaughter and killing methods of farmed reptiles (MCs comments)	Revised new CH sent for comments and adoption (Sep 2017/3rd)		
Section 7. Animal Welfare	New CH on AW and laying hen production systems (MCs comments)	Revised new CH sent for comments (Sep 2017/2nd)		

Subject		Issue by priority order (Reason for new work)	Status and Action (Start date, # of rounds for comments)
		Horizontal chapters in need of revision	1
Section 1. Animal disease diagnosis, surveillance and	1)	CH 1.4. on animal health surveillance (MCs comments and implications for status recognition)	Revised CH sent for comments and adoption (Feb 2016/4th)
notification	2)	CH 1.6. on status: revision and reorganisation (MCs comments and implications for status	Revised CH sent for comments (Feb 2018/2nd)

		recognition)	
	3)	CH1.1. on notification of diseases (for clarity, HQs and MCs comments)	Revised CH sent for comments (Sep 2018/1st)
	4)	CH 1.3. on listed diseases: assess CWD, WNF, PED, <i>Theileria</i> (<i>orientalis</i> , for small ruminants), <i>M. tuberculosis</i> , <i>M. paratuberculosis</i> against the listing criteria (MCs comments)	Pending expert's advice
Section 3. Veterinary Services	1)	CHs 3.4. on veterinary legislation (the return of experience of the PVS Pathway)	Revised CH sent for comments (Sep 2018/1st)
	2)	CHs 3.1. and 3.2. on Veterinary Services (the return of experience of the PVS Pathway)	Pending proposal from AHG
Section 4. Disease control	1)	CH 4.13. on disinfection (MCs comments)	Preliminary discussion
	2)	CH 4.6. on collection and processing of semen (MCs comments and trade implications)	Pending expert's advice
	3)	CH 4.5. on general hygiene in semen collection and processing centres	Pending expert's advice
	4)	CH 4.7. on collection and processing of <i>in vivo</i> derived embryos (MCs comments)	Pending expert's advice
Section 5. Trade measures	1)	CHs 5.4. to 5.7. on measures applicable at departure and on arrival (MCs comments)	Preliminary discussion and pending decision on AHG
	2)	CH 5.12. on model certificates for competition horses (MCs comments)	Preliminary discussion and pending revision of CHs on horse diseases
	3)	CH 5.10. to include a model certificate for petfood (NGO comments)	Preliminary discussion and pending supporting data from industry
Section 6. Veterinary public health	1)	CH 6.3. on meat inspection (Planned work by TAHSC)	Preliminary discussion pending AHG
Section 7. Animal Welfare	1)	CH 7.5. on slaughter and CH 7.6. on killing of animals (MCs comments)	Pending work of AHG
	2)	CH 7.7. on stray dog population control (global control programme)	Preliminary discussion

Subject	Issue by priority order (Reason for new work)	Status and Action (Start date, # of rounds for comments)	
Diseases not yet in the Code			
Disease-specific chapters) New CH on non-equine surra and rev CH on Dourine (Non-tsetse transmitte Trypanosomosis) (MCs comments)		
) New CH on Tsetse transmitted trypar (MCs comments)	nosomosis Pending work of AHG	
) New CH on Crimean Congo hemorrh (MCs comments, listed disease witho chapter)		
	Listed disease chapters/articles in	need of revision	
Sections 8 to 15) CH 10.4. on AI (MCs comments and timplications)	trade AHG report and draft revised CH sent for comments (Sep 2018/1st)	
) CH 8.13. on rabies (MCs comments a control pragramme)	Revised CH sent for comments and adoption (Feb 2018/2nd)	
) CH 11.4. on BSE (MCs comments an implications)	d trade Pending work of AHGs (Feb 2015/1st)	
) CH 15.2. on CSF (MCs comments an implications for status recognition)	d Revised CH sent for comments (Feb 2017/2nd)	
) Revision of Articles 8.15.1.,4. and 5. (MC commens)	(HQs and Pending work from HQs	
) CH 11.12. on Theileriosis and new Cl infection with <i>Theileria</i> in small rumina (outdated CH)		
) Harmonisation of articles regarding of status recognition by the OIE (SCAD		
) CH 8.8. on FMD (MCs comments and implications for status recognition)	Pending outcome of discussion on zoning (Sep 2015/2nd)	
) Chapter 8.16. on rinderpest (HQs, pro JAC, global rinderpest action plan)	oposal by Pending work of HQs and JAC	
	Revision of Article. 15.3.9. on import of from countries not free from PRRS (N comments)		
	1) CH 14.8. on scrapie (MCs comments	Pending experts opinion on MCs comments	
	CH 10.5. on avian mycoplasmosis (M comments and trade implications)	Cs Pending experts opinion	
	 CH 11.7. on CBPP (implications for si recognition) 	tatus Pending HQs advice	
	Revision of safe commodities list to a (MC comments)	dd lactose Pending experts' advice	

Annex 21 (contd)

Subject	Issue by priority order (Reason for new work)	Status and Action (Start date, # of rounds for comments)	
	Follow-up revision of chapters recently adopted		
Recently adopted chapters	1) Articles 15.1.1bis., 15.1.2., and 15.1.22. on ASF (MCs comments at 85GS)	Revised CH sent for comments and adoption (Sep 2017/3rd)	
	CH 4.3. on zoning and compartmentalisation (MCs comments at 86GS)	Pending discussion on temporary protection zone	
	CH 6.2. on the role of Veterinary Services in food safety systems (MCs comments at 86GS)	Revised CH sent for comments and adoption	
	Article 7.1.4. on the guiding principles for the use of measures to assess animal welfare (MCs comments at 86GS)	Revised article sent for comments and adoption	
	5) CH 7.13. on animal welfare and pig production systems (MCs comments at 86GS)	Revised article sent for comments and adoption	

List of abbreviations		
AAHSC	Aquatic Animal Health Standards Commission	
AHG	ad hoc Group	
AMR	Antimicrobial resistance	
Al	Avian influenza	
ASF	African swine fever	
AW	Animal Welfare	
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	
TAHSC	Terrestrial Animal Health Standards Commission	
WNF	West Nile fever	

CHAPTER 6.10.

RESPONSIBLE AND PRUDENT USE OF ANTIMICROBIAL AGENTS IN VETERINARY MEDICINE

EU comment

With reference to the EU comment on the Code Commission Work Programme (see Annex 21), and as announced in May 2018 (see

https://ec.europa.eu/food/sites/food/files/safety/docs/ia standards oie eu position tahsc-report 201805.pdf, p. 306), please find below concrete text proposals for a review of Chapter 6.10. on Responsible and prudent use of antimicrobial agents in veterinary medicine.

In general, we would suggest extending the scope of this chapter to cover also non-food producing animals. Indeed, these are also important in terms of prudent use of antimicrobial agents, AMR prevention in general and from a public health perspective, and the OIE should play a relevant role also in that area.

Furthermore, we would suggest replacing the terms "marketing authorisation" and "registration" with "relevant regulatory approval" throughout the chapter. Indeed, that would be a generic term that would work in every country, and it was introduced in the Terrestrial Manual in the chapters adopted in May 2018 (reference is made to the report of the September 2017 meeting of the Biological Standards Commission (section 8.3.6., p. 15).

Article 6.10.1.

Purpose

This document provides guidance for the responsible and prudent use of *antimicrobial agents* in veterinary medicine, with the aim of protecting both animal and human health as well as the environment. It defines the respective responsibilities of the *Competent Authority* and stakeholders such as the veterinary pharmaceutical industry, *veterinarians*, animal *feed* manufacturers, distributors and food animal producers who are involved in the authorisation, production, control, importation, exportation, distribution and use of *veterinary medicinal products* (VMP) containing *antimicrobial agents*.

EU comment

The term "food animal producers" is odd. We would suggest replacing it with "farmers of food producing animals" (this change should be made throughout the chapter).

In addition, non-food producing animals should be added to the scope of this chapter.

Responsible and prudent use is determined taking into account the specifications detailed in the marketing authorisation and their implementation when *antimicrobial agents* are administered to *animals* and is part of good veterinary and good agricultural practice.

EU comment

We suggest incorporating the definition of prudent use of antimicrobials agents in the paragraph above, which should preclude their use for growth promotion, as follows:

"Prudent use of antimicrobial agents aims to minimise the prevalence of and contain antimicrobial-resistant micro-organisms. Responsible and prudent use is determined taking into account the specifications detailed in the marketing authorisation relevant regulatory approval and their implementation when antimicrobial agents are administered to animals

and is part of good veterinary and good agricultural practice. <u>Responsible and prudent use of antimicrobial agents in animals does not include their use for growth promotion.</u>"

Furthermore, the EU suggests adding a new paragraph to emphasize the importance of good animal husbandry in order to reduce the need for antimicrobial treatment and the risk for antimicrobial resistance, as follows:

"Good animal husbandry practices, including biosecurity measures to prevent infectious animal diseases, is fundamental as this contributes to a decreased need of using antimicrobial agents in animals and thus reduces the risk for development of antimicrobial resistance."

Activities associated with the responsible and prudent use of *antimicrobial agents* should involve all relevant stakeholders.

Coordination of these activities at the national or regional level is recommended and may support the implementation of targeted actions by the stakeholders involved and enable clear and transparent communications.

Article 6.10.2.

Objectives of responsible and prudent use

Responsible and prudent use includes implementing practical measures and recommendations intended to improve animal health and *animal welfare* while preventing or reducing the selection, emergence and spread of antimicrobial-resistant bacteria in *animals* and humans. Such measures include:

- 1) ensuring the rational use of *antimicrobial agents* in *animals* with the purpose of optimising both their efficacy and safety;
- 2) complying with the ethical obligation and economic need to keep animals in good health;
- preventing or reducing the transfer of resistant micro-organisms or resistance determinants within animal populations, the environment and between animals and humans;
- 4) contributing to the maintenance of the efficacy and usefulness of *antimicrobial agents* used in *animal* and human medicine:
- 5) protecting consumer health by ensuring the safety of food of animal origin with respect to residues of *antimicrobial* agents.

EU comment

The EU suggests amending the article above by incorporating the term prudent use and by including the environment in a one health perspective, as follows:

- "Responsible and prudent use includes implementing practical measures and recommendations intended to improve animal health and animal welfare <u>thus reducing the need for using antimicrobial agents</u> while preventing or reducing the selection, emergence and spread of antimicrobial-resistant bacteria in animals, <u>and humans and the environment</u>. Such measures include:
- 1) ensuring the <u>rational</u> <u>responsible and prudent</u> use of antimicrobial agents in animals with the purpose of <u>optimising ensuring</u> both their efficacy and safety;

 $[\ldots];$

- 3) preventing or reducing <u>minimise</u> and <u>contain</u> the transfer of resistant micro-organisms or resistance determinants within animal populations, the environment and between animals and humans;
- 4) contributing to the maintenance of the efficacy and usefulness of antimicrobial agents used

in veterinary animal and human medicine;

[…]".

Article 6.10.3.

Responsibilities of the Competent Authority

1. Marketing authorisation

All Member Countries should combat the unauthorised manufacture, compounding, importation, advertisement, trade, distribution, storage and use of unlicensed, adulterated and counterfeit products, including bulk active ingredients, through appropriate regulatory controls and other measures.

EU comment

The EU suggests replacing the words "and" with "<u>or</u>" in the paragraph above, to clarify that the points are not cumulative but each one per se needs to be combated.

The *Competent Authority* is responsible for granting marketing authorisation which should be done in accordance with the provisions of the *Terrestrial Code*. It has a significant role in specifying the terms of this authorisation and in providing the appropriate information to *veterinarians* and all other relevant stakeholders.

The Competent Authority should establish and implement efficient statutory registration procedures that evaluate the quality, safety and efficacy of VMP containing antimicrobial agents. According to Article 3.1.2., the Competent Authority should be free from any commercial, financial, hierarchical, political or other pressures which might affect its judgement or decisions.

EU comment

As indicated in the general EU comment above, we would suggest using generic terms to replace "registration" or "licensing" that would work in ever country. Therefore, we suggest replacing the words "statutory registration" with "relevant regulatory" in the paragraph above, and "registration" with "regulatory" in the paragraph below.

These changes should be made throughout the text, as appropriate.

Member Countries lacking the necessary resources to implement an efficient registration procedure for VMP containing *antimicrobial agents*, and which are importing them, should undertake the following measures:

- a) evaluate the efficacy of administrative controls on the import of these VMP;
- b) evaluate the validity of the registration procedures of the exporting and manufacturing country as appropriate;
- c) develop the necessary technical co-operation with experienced relevant authorities to check the quality of imported VMP as well as the validity of the recommended conditions of use.

The Competent Authorities of importing countries should request the pharmaceutical industry to provide quality certificates prepared by the Competent Authority of the exporting and manufacturing country as appropriate.

EU comment

The EU suggests replacing the word "and" with "or" in the paragraph above.

Marketing authorisation is granted on the basis of the data submitted by the pharmaceutical industry or applicant and only if the criteria of safety, quality and efficacy are met.

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).

An evaluation of the potential risks and benefits to both *animals* and humans resulting from the use of *antimicrobial agents*, with particular focus on use in food-producing animals, should be carried out. The evaluation should focus on each individual *antimicrobial agent* and the findings should not be generalised to the antimicrobial class to which the particular active ingredient belongs. Guidance on usage should be provided for all target, route of administration, dosage regimens, withdrawal period and different durations of treatment that are proposed.

For clarity reasons we suggest amending the second sentence of the paragraph above as follows:

"The evaluation <u>may</u> should focus on each individual antimicrobial agent and the findings <u>from one agent</u> should not be generalised to the antimicrobial class to which the particular active ingredient belongs".

Furthermore, the EU suggests inserting the word "<u>species</u>" after "target", and the words "<u>as relevant</u>" after withdrawal period. Indeed, the species should be indicated; and for some substances a withdrawal period is not necessary.

The Competent Authority should expedite the process for new antimicrobial agents in order to address a specific need for the treatment of animal disease.

EU comment

The EU suggests clarifying the sentence above by replacing the words "the process" with "the regulatory approval", and by inserting the word "an" before "animal disease".

(Alternative: "[...] to address a specific needs for the treatment of animal diseases".)

Finally, as there is a growing international consensus that such use should be phased out, the EU suggests adding the following sentences at the end of article above, in line with OIE policies on AMR as confirmed at the recent 2nd OIE Global Conference on AMR in Marrakech, Morocco (<a href="http://www.oie.int/en/for-the-media/press-releases/detail/article/agriculture-ministers-join-forces-to-tackle-antimicrobial-resistance-infarming/?utm_source=Press+Releases&utm_campaign=ac78d1d05a-EMAIL_CAMPAIGN_2018_10_29_04_14_COPY_01&utm_medium=email&utm_term=0_718fbd8136-ac78d1d05a-63139731) and as included in the Recommendations of that Conference ("The participants of the global conference (...) Recommend to the OIE Member Countries

- To follow the recommendations in the OIE List of Antimicrobial Agents of Veterinary Importance in particular regarding restrictions on the use of fluoroquniolones, third and fourth generation cephalosporins and colistin, and to phase out the use of antibiotics as growth promotors, giving priority to the classes in the WHO category of Highest Priority Critically Important Antimicrobials; (...)"):
- "Antimicrobial agents should not be granted regulatory approval for growth promotion, and their use for growth promotion should be phased out. In particular, use for growth promotion purposes of those antibiotics that are listed by the WHO as Highest Priority Critically Important Antibiotics for human medicine should be restricted immediately.".
- 2. Quality control of antimicrobial agents and VMP containing antimicrobial agents

Quality controls should be performed:

- a) in compliance with the provisions of good manufacturing practices;
- to ensure that analysis specifications of antimicrobial agents used as active ingredients comply with the provisions of registration documentations (such as monographs) approved by the relevant Competent Authority;
- to ensure that the quality of antimicrobial agents in the marketed dosage forms is maintained until the expiry date, established under the recommended storage conditions;
- to ensure the stability of antimicrobial agents when mixed with feed or drinking water;

EU comment

The EU suggests deleting the word "drinking" before "water", in order to avoid confusion with the term "drinking water" which is specifically defined in EU legislation relating to the quality and safety of water for human use. For consistency with other relevant articles in the Code, the term "drinkable water" could be used instead (as e.g. in Article 7.13.9.).

to ensure that all antimicrobial agents and the VMP containing them are manufactured to the appropriate
quality and purity in order to guarantee their safety and efficacy.

3. Assessment of therapeutic efficacy

- a) Preclinical trials
 - i) Preclinical trials should:
 - establish the spectrum of activity of antimicrobial agents against relevant pathogenic agents and non-pathogenic agents (commensals);
 - assess the capacity of the antimicrobial agents to select for resistance in vitro and in vivo, taking
 into consideration intrinsically resistant and pre-existing resistant strains;
 - establish an appropriate dosage regimen (dose, dosing interval and duration of the treatment) and
 route of administration necessary to ensure the therapeutic efficacy of the *antimicrobial agents* and
 limit the selection of antimicrobial resistance. Pharmacokinetic and pharmacodynamic data and
 models can assist in this appraisal.

EU comment

The EU suggests adding the following at the end of the third indent of point 3) a) i) above:

"Such data together with clinical data could be used to establish clinical break-points by independent experts.".

Indeed, it is very important for the reliability of susceptibility tests to have clinical breakpoints established by independent experts using appropriate data.

- ii) The activity of *antimicrobial agents* towards the targeted microorganism should be established by pharmacodynamics. The following criteria should be taken into account:
 - spectrum of activity and mode of action;
 - minimum inhibitory and bactericidal concentrations against recent isolates;
 - time- or concentration-dependent activity or co-dependency;
 - activity at the site of infection.
- iii) The dosage regimens allowing maintenance of effective antimicrobial levels should be established by pharmacokinetics. The following criteria should be taken into account:
 - bio-availability in accordance with the route of administration;
 - distribution of the antimicrobial agents in the treated animal and concentration at the site of infection;
 - metabolism;
 - excretion routes.

Use of combinations of antimicrobial agents should be scientifically supported.

b) Clinical trials

Clinical trials in the target animal species should be performed to confirm the validity of the claimed therapeutic indications and dosage regimens established during the preclinical phase. The following criteria should be taken into account:

- i) diversity of the clinical cases encountered when performing multi-centre trials;
- ii) compliance of protocols with good clinical practice;
- iii) eligibility of studied clinical cases, based on appropriate criteria of clinical and bacteriological diagnoses;
- iv) parameters for qualitatively and quantitatively assessing the efficacy of the treatment.

4. Assessment of the potential of antimicrobial agents to select for resistance

Other studies may be requested in support of the assessment of the potential of *antimicrobial agents* to select for resistance. The party applying for market authorisation should, where possible, supply data derived in target animal species under the intended conditions of use.

For this the following may be considered:

- a) the concentration of either active antimicrobial agents or metabolites in the gut of the animal (where the majority of potential food-borne pathogenic agents reside) at the defined dosage level;
- pathway for the human exposure to antimicrobial resistant microorganisms;

EU comment

The EU suggests adding the words "<u>and commensal flora</u>" after "pathogenic agents" in paragraph a) above. Indeed, antimicrobial resistance can also be hosted in the commensal flora which is not always pathogenic for humans, and is an important reservoir.

Furthermore, the EU suggests adding the words "and antimicrobial residues in the environment" after "microorganisms" in point b) above, to turn the attention to this rather neglected pathway.

- c) the degree of cross-resistance;
- the intrinsic and pre-existing, baseline level of resistance in the pathogenic agents of human health concern in both animals and humans.

EU comment

We suggest inserting a new point 4.bis., as follows:

"4.bis. Establishment of clinical breakpoints

In order to interpret the result of a susceptibility test, there is a need for clinical breakpoints for each trinominal bacteria/ antimicrobial/ animal species. Those clinical breakpoints should be established by independent experts.".

Indeed, while the importance of susceptibility testing is mentioned in the text, there won't be reliable susceptibility tests without suitable clinical breakpoints.

- 5. <u>Establishment of acceptable daily intake (ADI), maximum residue limit (MRL) and withdrawal periods in food-producing animals</u>
 - a) When setting the ADI and MRL for an *antimicrobial agent*, the safety evaluation should also include the potential biological effects on the intestinal flora of humans.
 - b) The establishment of an ADI for each *antimicrobial agent*, and an MRL for each animal-derived food, should be undertaken before a VMP containing it is granted marketing authorisation.
 - c) For all VMP containing *antimicrobial agents*, withdrawal periods should be established for each animal species in order to ensure compliance with the MRLs, taking into account:
 - i) the MRLs established for the antimicrobial agent in the target animal edible tissues;
 - ii) the composition of the product and the pharmaceutical form;
 - iii) the dosage regimen;
 - iv) the route of administration.
 - d) The applicant should describe methods for regulatory testing of residues in food based on the established marker residues.

6. Protection of the environment

An assessment of the impact of the proposed antimicrobial use on the environment should be conducted.

7. Establishment of a summary of product characteristics for each VMP containing antimicrobial agents

The summary of product characteristics contains the information necessary for the appropriate use of VMP containing *antimicrobial agents* and constitutes the official reference for their labelling and package insert. This summary should contain the following items:

- a) active ingredient and class;
- b) pharmacological properties;
- c) any potential adverse effects;
- d) target animal species and, as appropriate, age or production category;
- e) therapeutic indications;
- f) target micro-organisms;
- g) dosage regimen and route of administration;
- h) withdrawal periods;

- i) incompatibilities and interactions;
- *j*) storage conditions and shelf-life;
- k) operator safety;
- particular precautions before use;
- m) particular precautions for the proper disposal of un-used or expired products;
- n) information on conditions of use relevant to the potential for selection of resistance;
- o) contraindication.

8. Post-marketing antimicrobial surveillance

The information collected through existing pharmacovigilance programmes, including lack of efficacy, and any other relevant scientific data, should form part of the comprehensive strategy to minimise antimicrobial resistance. In addition to this, the following should be considered:

a) General epidemiological surveillance

The surveillance of animal microorganisms resistant to *antimicrobial agents* is essential. The relevant authorities should implement a programme in accordance with Chapter 1.4.

b) Specific surveillance

Specific surveillance to assess the impact of the use of a specific *antimicrobial agent* may be implemented after the granting of marketing authorisation. The surveillance programme should evaluate not only resistance in target animal pathogenic agents, but also in food-borne pathogenic agents, and commensals if relevant and possible. This will also contribute to general epidemiological surveillance of antimicrobial resistance.

9. Supply and administration of the VMP containing antimicrobial agents

EU comment

The EU suggests inserting the words "antimicrobial agents or the" before "VMP containing" in the title of paragraph 9, as well as in the text of paragraphs 9 and 10 below. Indeed, in certain situations antimicrobial agents can be traded and used in bulk.

This comment is valid also for points 4 and 5 of Article 6.10.6.

The relevant authorities should ensure that all the VMP containing antimicrobial agents used in animals are:

EU comment

The EU suggests adding the words "including through feed and water" at the end of the sentence above, to clarify that these types of administration route are also covered.

a) prescribed by a *veterinarian* or other suitably trained person authorised to prescribe VMP containing *antimicrobial agents* in accordance with the national legislation and under the supervision of a *veterinarian*;

EU comment

The EU notes that while requirements and responsibilities are explicitly set out in this chapter for veterinarians (in article 6.10.6.), corresponding details are not provided for "other suitably trained person authorised to prescribe VMP containing antimicrobial agents", nor do the requirements for veterinarians apply to such persons (nor would they be appropriate). In order to ensure that appropriate oversight of antimicrobial agents is maintained, the EU requests that the requirements and responsibilities for such persons also be set out in detail in this chapter. (This comment is relevant for points 9a) and 10b) of Article 6.10.3.; point 1) of Article 6.10.5.; point 2b) of Article 6.10.7.; and point 1) of Article 6.10.8.)

- b) supplied only through licensed or authorised distribution systems;
- c) administered to *animals* by a *veterinarian* or under the supervision of a *veterinarian* or by other authorised persons.

The relevant authorities should develop effective procedures for the safe collection and disposal or destruction of unused or expired VMPs containing *antimicrobial agents*. Their labels should have appropriate instructions for disposal and destruction.

10. Control of advertising

All advertising of *antimicrobial agents* should be compatible with the principles of responsible and prudent use and should be controlled by codes of advertising standards. The relevant authorities must ensure that the advertising

of these products:

- a) complies with the marketing authorisation granted, in particular regarding the content of the summary of product characteristics;
- b) is restricted to a *veterinarian* or other suitably trained person authorised to prescribe VMP containing *antimicrobial agents* in accordance with the national legislation and under the supervision of a *veterinarian*.

11. Training on the usage of antimicrobial agents

The training on the usage of *antimicrobial agents* should include all the relevant organisations, such as the *Competent Authority*, pharmaceutical industry, veterinary schools, research institutes, veterinary professional organisations and other approved users such as food animal owners and manufacturers of medicated animal *feed*. This training should focus on preserving the effectiveness of *antimicrobial agents* and include:

- a) information on disease prevention, management and mitigation strategies;
- b) the ability of antimicrobial agents to select for resistant microorganisms in animals and the relative importance of that resistance to public and animal health;
- c) the need to observe responsible use recommendations for the use of *antimicrobial agents* in animal husbandry in agreement with the provisions of the marketing authorisations;

EU comment

We suggest amending point c) above to incorporate the term prudent use.

- "c) the need to observe responsible <u>and prudent</u> use recommendations for the use of antimicrobial agents in animal husbandry in agreement with the provisions of the marketing authorisations;".
 - d) appropriate storage conditions, proper disposal of unused or expired VMP;
 - e) record keeping.

12. Research

The relevant authorities should encourage public- and industry-funded research, for example on methods to identify and mitigate the public health risks associated with specific *antimicrobial agent* uses, or on the ecology of antimicrobial resistance.

Article 6.10.4.

Responsibilities of the veterinary pharmaceutical industry with regards to VMP containing antimicrobial agents

1. Marketing authorisation

The veterinary pharmaceutical industry has responsibilities to:

- a) supply all the information requested by the national Competent Authority;
- guarantee the quality of this information in compliance with the provisions of good manufacturing, laboratory and clinical practices;
- implement a pharmacovigilance programme and on request, specific surveillance for bacterial susceptibility and resistance data.

EU comment

The EU suggests adding a new point, as follows:

"d) provide isolates and corresponding data to national, regional or international competent bodies. Those data will enable independent experts to establish clinical breakpoints to assess the results of susceptibility testing."

Indeed, the importance of susceptibility testing is pointed out in Article 6.10.6., however the lacking availability of clinical breakpoints hampers the practical implementation of this action by veterinarians. Furthermore, it should be emphasised that clinical breakpoints have to be established by independent bodies.

2. Marketing and export

For the marketing and export of VMP containing antimicrobial agents:

- a) only licensed and officially approved VMP containing antimicrobial agents should be sold and supplied, and then only through licensed/authorised distribution systems;
- b) the pharmaceutical industry should provide quality certificates prepared by the *Competent Authority* of the exporting and manufacturing countries to the *importing country*;

EU comment

We suggest replacing "and" with "<u>or</u>" in point b) above, as indeed the exporting and manufacturing country are not necessarily the same.

 the national regulatory authority should be provided with the information necessary to evaluate the amount of antimicrobial agents marketed.

3. Advertising

The veterinary pharmaceutical industry should respect principles of responsible and prudent use and should comply with established codes of advertising standards, including to:

- a) distribute information in compliance with the provisions of the granted authorisation;
- b) not advertise VMP containing antimicrobial agents directly to the food animal producer.

4. Training

The veterinary pharmaceutical industry should participate in training programmes as defined in point 11) of Article 6.10.3.

5. Research

The veterinary pharmaceutical industry should contribute to research as defined in point 12) of Article 6.10.3.

Article 6.10.5.

Responsibilities of wholesale and retail distributors

1) Distributors of VMP containing *antimicrobial agents* should only do so on the prescription of a *veterinarian* or other suitably trained person authorised to prescribe VMP containing *antimicrobial agents* in accordance with the national legislation and under the supervision of a *veterinarian*. All products should be appropriately labelled.

EU comment

We suggest amending the sentence above as follows, for better readability:

"Distributors <u>should only distribute</u> of VMP containing antimicrobial agents should only do so on the prescription of [...]".

- 2) The recommendations on the responsible and prudent use of VMP containing *antimicrobial agents* should be reinforced by retail distributors who should keep detailed records of:
 - a) date of supply;
 - b) name of prescriber;
 - c) name of user:
 - d) name of product;
 - e) batch number;
 - f) expiration date;
 - g) quantity supplied;
 - h) copy of prescription.
- 3) Distributors should also be involved in training programmes on the responsible and prudent use of VMP containing antimicrobial agents, as defined in point 11) of Article 6.10.3.

Article 6.10.6.

Responsibilities of veterinarians

The *veterinarian*'s responsibility is to promote public health, animal health and *animal welfare*, including identification, prevention and treatment of animal diseases. The promotion of sound animal husbandry methods, hygiene procedures,

biosecurity and vaccination strategies can help to minimise the need for antimicrobial use in food-producing animals.

EU comment

We suggest amending the paragraph above for clarity, spelling and to incorporate the term "responsible and prudent use", as follows:

"The veterinarian's responsibility is to promote public health, animal health and animal welfare, including identification, prevention and treatment of animal diseases. <u>Veterinarians should always aim for responsible and prudent use of antimicrobial agents.</u> The promotion of sound animal husbandry methods, hygiene procedures, biosecurity and vaccination strategies can help to <u>minimise</u> <u>minimize</u> the need for antimicrobial <u>agent</u> use in food-producing animals."

Veterinarians should only prescribe antimicrobial agents for animals under their care.

1. Use of antimicrobial agents

The responsibilities of veterinarians are to carry out a proper clinical examination of the animal(s) and then:

- a) administer or prescribe antimicrobial agents only when necessary and taking into consideration the OIE list
 of antimicrobial agents of veterinary importance;
- b) make an appropriate choice of *antimicrobial agents* based on clinical experience and diagnostic laboratory information (pathogenic agent isolation, identification and antibiogram) where possible;
- provide a detailed treatment protocol, including precautions and withdrawal times, especially when
 prescribing extra-label or off-label use.

EU comment

The EU suggests amending point a) above as follows, to incorporate the term responsible and prudent use and include principles for preventive and control use of antimicrobial agents:

"a) administer or prescribe antimicrobial agents only when necessary to treat or control infectious diseases. Control and preventive use of antimicrobial agents should not compensate for inadequate animal husbandry practices and should not be done routinely. Preventive use of antimicrobial agents should be limited to exceptional cases, using an appropriate dose for a limited and defined duration. The veterinarian should take taking into consideration the OIE list of antimicrobial agents of veterinary importance into consideration and should follow national or local guidelines for responsible and prudent use. The veterinarian should not administer nor prescribe antimicrobial agents for the purpose of promoting growth or increasing yield;".

Furthermore, we suggest amending point b) above as follows, for clarity and consistency of the term used in the last paragraph of point 2 a) below (and in the Terrestrial Manual Chapter 3.1.):

"b) make an appropriate choice of antimicrobial agents based on clinical experience and where possible diagnostic laboratory information (pathogenic agent isolation, identification and antibiogram antimicrobial susceptibility testing) where possible;".

2. Choosing antimicrobial agents

- a) The expected efficacy of the treatment is based on:
 - i) the clinical experience of the veterinarians, their diagnostic insight and therapeutic judgement;
 - ii) diagnostic laboratory information (pathogenic agent isolation, identification and antibiogram);

EU comment

The EU suggests replacing the term "antibiogram" with "antimicrobial susceptibility testing" also in point ii) above.

- iii) pharmacodynamics including the activity towards the pathogenic agents involved;
- iv) the appropriate dosage regimen and route of administration;

- pharmacokinetics and tissue distribution to ensure that the selected therapeutic agent is effective at the site of infection;
- vi) the epidemiological history of the rearing unit, particularly in relation to the antimicrobial resistance profiles of the pathogenic agents involved.

Should a first-line antimicrobial treatment fail or should the disease recur, a second line treatment should be based on the results of diagnostic tests. In the absence of such results, an appropriate *antimicrobial agent* belonging to a different class or sub-class should be used.

EU comment

The paragraph above should be amended to incorporate the term responsible and prudent use, for consistency with point ii) above and for spelling, as follows:

"Should a first-line antimicrobial treatment, defined by the national or local guidelines for responsible and prudent use, fail or should the disease recur reoccur, a second line treatment should be based on the results of diagnostic laboratory information tests. In the absence of such test results, an appropriate antimicrobial agent belonging to a different class or sub-class should be used.".

In emergencies, a *veterinarian* may treat *animals* without recourse to an accurate diagnosis and antimicrobial susceptibility testing, to prevent the development of clinical disease and for reasons of *animal welfare*.

b) Use of combinations of antimicrobial agents should be scientifically supported. Combinations of antimicrobial agents may be used for their synergistic effect to increase therapeutic efficacy or to broaden the spectrum of activity.

EU comment

The EU suggests amending point b) above as follows:

"b) Use of Combinations of antimicrobial agents should <u>only</u> be <u>used when</u> scientifically supported. Combinations of antimicrobial agents may be used for their synergistic effect to increase therapeutic efficacy <u>when needed</u> or to broaden the spectrum of activity.".

3. Appropriate use of the VMP containing antimicrobial agents chosen

A prescription for VMP containing *antimicrobial agents* should indicate precisely the dosage regimen, the withdrawal period where applicable and the amount of VMP containing *antimicrobial agents* to be provided, depending on the dosage and the number of *animals* to be treated.

The extra-label or off-label use of VMP containing *antimicrobial agents* may be permitted in appropriate circumstances and should be in agreement with the national legislation in force including the withdrawal periods to be used, as applicable. It is the *veterinarian*'s responsibility to define the conditions of responsible use in such a case including the dosage regimen, the route of administration and the withdrawal period.

EU comment

The EU suggests inserting the words "and prudent" after "responsible" in the paragraph above.

The use of compounded VMP containing *antimicrobial agents* and extra-label or off-label use of registered VMP containing *antimicrobial agents* should be limited to circumstances where an appropriate registered product is not available.

EU comment

It is not clear what exactly is meant by "compounded VMP". That term should therefore be clarified or defined. We note that in other parts of the text, the term "combinations" is used instead, and could perhaps also be used here.

As an alternative, the paragraph could be limited to extra-label and off-label use.

Recording of data

Records on VMP containing *antimicrobial agents* should be kept in conformity with the national legislation. Information records should include the following:

a) quantities of VMP used per animal species;

In point a) above, the EU suggests inserting the words "<u>or supplied</u>" after "used" and "<u>on each food-producing animal holding</u>" after "species". Indeed, OIE itself asks annually for detailed data on antimicrobial use and indicates that veterinarians play the central role in the distribution chain.

- b) a list of all VMP supplied to each food-producing animal holding;
- c) treatment schedules including animal identification and withdrawal period;
- d) antimicrobial susceptibility data;
- e) comments concerning the response of animals to treatment;
- f) the investigation of adverse reactions to antimicrobial treatment, including lack of response due to possible antimicrobial resistance. Suspected adverse reactions should be reported to the appropriate regulatory authorities.

EU comment

The EU suggests replacing the word "response" with "<u>efficacy</u>" in the paragraph above, for reasons of clarity.

Veterinarians should also periodically review farm records on the use of VMP containing antimicrobial agents to ensure compliance with their directions or prescriptions and use these records to evaluate the efficacy of treatments.

5. Labelling

All VMP supplied by a veterinarian should be labelled in accordance with the national legislation.

6. Training and continued professional development

Veterinary professional organisations should participate in the training programmes as defined in point 11) of Article 6.10.3. It is recommended that veterinary professional organisations develop for their members species-specific clinical practice recommendations on the responsible and prudent use of VMP containing *antimicrobial agents*.

Article 6.10.7.

Responsibilities of food animal producers

 Food animal producers, with the assistance and guidance of a *veterinarian*, are responsible for implementing animal health and *animal welfare* programmes on their farms in order to promote animal health and food safety.

EU comment

The EU suggests emphasising the responsibility of the food animal producers by amending the point above as follows:

- "1) Food animal producers, with the assistance and guidance of a veterinarian, are responsible for implementing animal health and animal welfare programmes <u>including</u> <u>biosecurity and good husbandry practices</u> on their farms in order to <u>reduce the need for the use of antimicrobial agents in animals</u>, and to promote animal health and food safety.".
- Food animal producers should:
 - a) draw up a health plan with the attending veterinarian that outlines preventive measures (e.g. feedlot health plans, mastitis control plans, endo- and ectoparasite control, vaccination programmes and biosecurity measures);
 - use VMP containing antimicrobial agents only on the prescription of a veterinarian or other suitably trained person authorised to prescribe VMP containing antimicrobial agents in accordance with the national legislation and under the supervision of a veterinarian;
 - use VMP containing antimicrobial agents in accordance with product label instructions, including storage conditions, or the instructions of the attending veterinarian;

EU comment

In line with the EU comment on growth promotion above, the EU suggests adding a new point

after point c) above, as follows:

"d) not use antimicrobial agents in animals for the purpose of promoting growth or increasing yield;"

- isolate sick animals, when appropriate, to avoid the transfer of pathogenic agents; dispose of dead or dying animals promptly under conditions approved by the relevant authorities;
- e) address on-farm biosecurity measures and take basic hygiene precautions as appropriate;
- comply with and record the recommended withdrawal periods to ensure that residue levels in animal-derived food do not present a risk for the consumer;
- use VMP containing antimicrobial agents within the expiry date and dispose of unused and expired surplus
 VMP containing antimicrobial agents under conditions safe for the environment;
- maintain all the laboratory records of bacteriological and susceptibility tests; these data should be made available to the *veterinarian* responsible for treating the *animals*;
- keep adequate records of all VMP containing antimicrobial agents used, including the following:
 - i) name of the product and active substance, batch number and expiry date;
 - ii) name of prescriber and the supplier;
 - iii) date of administration;
 - identification of the animal or group of animals to which the antimicrobial agent was administered;

EU comment

As within the prudent use concept also animals kept in groups (e.g. fattening pigs) should preferably be treated individually to keep the number of treated animals as low as possible and as these animals are not individually identified, the number of treated animals should be recorded as well. We therefore suggest amending point iv) above as follows:

"iv) identification of the animal or group of animals <u>and the number of animals</u> to which the antimicrobial agent was administered;"

- v) clinical conditions treated;
- vi) dosage;
- vii) withdrawal periods including the end-date of the withdrawal periods;
- viii) result of laboratory tests;
- ix) effectiveness of therapy;
- *j*) inform the responsible *veterinarian* of recurrent disease problems.

3) Training

Food animal producers should participate in the training programmes as defined in point 11) of Article 6.9.3. It is recommended that food animal producer organisations work in cooperation with the veterinary professional organisations to implement existing guidelines for the responsible and prudent use of VMP containing *antimicrobial agents*.

Article 6.10.8.

Responsibilities of animal feed manufacturers

- 1) The supply of medicated *feed* containing *antimicrobial agents* to farmers keeping food-producing animals by animal *feed* manufacturers should be allowed only on the prescription of a *veterinarian*. Alternatively, such medicated *feed* may be prescribed by other suitably trained persons authorised to prescribe VMP containing *antimicrobial agents* in accordance with the national legislation and under the supervision of a *veterinarian*. Animal *feed* manufacturers preparing medicated *feed* should do so following rules put in place by the *Competent Authority* in accordance with the national legislation. All medicated *feed* and medicated premixes should be appropriately labelled.
- 2) The regulations and recommendations on the responsible and prudent use of VMP containing *antimicrobial agents* should be reinforced by animal *feed* manufacturers who should keep detailed records.
- 3) Use only approved sources of medications: Animal *feed* manufacturers preparing medicated *feed* should ensure that only approved sources of medications are added to *feed* at a level, and for a species and purpose as permitted by the drug premix label or a veterinary prescription.

In point 3) above, the EU suggests replacing both the word "medications" and the words "drug premix" with the words "pharmaceutical.products", as this is a generic term that would work in all countries.

- 4) Ensure appropriate labelling with product identification, direction for use and withdrawal time: Animal *feed* manufacturers preparing medicated *feed* should ensure that medicated animal *feed* are labelled with the appropriate information (e.g. level of medication, approved claim, intended species, directions for use, warning, cautions) so as to ensure effective and safe use by the producer.
- 5) Implement appropriate production practices to prevent contamination of other *feed*: Animal *feed* manufacturers preparing medicated *feed* should implement appropriate production practices to avoid unnecessary carry over and unsafe cross contamination of unmedicated *feed*.

NB: FIRST ADOPTED IN 2003; MOST RECENT UPDATE ADOPTED IN 2014.