EUROPEAN UNION

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Subject: **87th General Session of the OIE - May 2019**

Dear Director General,

Please find attached, for your informal information, annexes indicating the intended positions of the European Union (EU) to be raised on the reports of the Terrestrial and Aquatic Animal Health Standards Commissions (Annexes 1 and 2, respectively) and drafts proposed for adoption at the 87th General Session of the World Assembly of National Delegates of the OIE in May 2019 in Paris.

Furthermore, we take this opportunity to inform you that the EU supports the adoption of the draft revised chapters of the OIE *Terrestrial Manual* to be proposed for adoption in May 2019, with the exception of Chapters 3.1.6. on Echinococcosis and 3.8.1. on African swine fever. The intended EU position on those OIE *Terrestrial Manual* chapters is at Annex 3.

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

Yours sincerely,

Dr Geronimo Brănescu CVO and OIE Delegate Romania	Dr Bernard Van Goethem Director for Crisis Management in Food, Animals and Plants European Commission, DG Health and Food Safety
	

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Annexes: 3

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

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World Organisation for Animal Health
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Annex 1

Original: English

February 2019

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

Paris, 19–28 February 2019

EU comment

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

A number of general comments on this report of the February 2019 meeting of the Code Commission as well as the intended positions of the EU on the draft Terrestrial Code chapters proposed for adoption at the 87th OIE General Session are inserted in the text below, while specific comments are inserted in the text of the respective annexes to the report.

Please note that the EU positions regarding Annexes 3 to 13 (part A) as well as the EU comments on Annex 25 (part B) are appended to this document, while the EU comments on Annexes 14 to 24 (part B) will be provided to the OIE separately by 4 July 2019.

The EU would like to stress once again its continued commitment to participate in the work of the OIE and to offer all technical support needed by the Code Commission and its ad hoc groups for future work on the Terrestrial Code.

The OIE Terrestrial Animal Health Standards Commission (the Code Commission) met at OIE Headquarters in Paris from 19 to 28 February 2019. The list of participants is attached as **Annex 1**.

The Code Commission thanked the following Member Countries for providing comments: Argentina, Australia, Canada, Chile, China (People's Republic), Chinese Taipei, Colombia, Costa Rica, Georgia, Guatemala, Honduras, India, Japan, Malaysia, Mexico, Mongolia, New Caledonia, New Zealand, Norway, Peru, the Philippines, South Africa, Switzerland, Thailand, USA, the Member States of European Union (EU) and the African Union Interafrican Bureau for Animal Resources (AU-IBAR) on behalf of African Member Countries of the OIE. Comments were also received from the Global Alliance of Pet Food Associations (GAPFA) International Egg Commission (IEC), the International Poultry Council (IPC), the International Coalition for Animal Welfare (ICFAW) and other experts.

The Code Commission reviewed Member Country comments, which were submitted on time and supported by a rationale and amended relevant chapters of the OIE *Terrestrial Animal Health Code* (the *Terrestrial Code*) where appropriate. **The Code Commission did not consider comments where a rationale had not been provided or that were difficult to interpret.** Due to 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. Where amendments were of an editorial nature, no explanatory text has been provided.

The amendments are presented in the usual manner by '<u>double underline</u>' and '~~strikethrough~~' and the chapters are annexed to this report. In Annexes 4 to 18, amendments proposed at this meeting are highlighted with a coloured background to distinguish them from those proposed previously.

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

Member Countries should note that texts in **Part A** (**Annexes 3 to 13**) of this report will be proposed for adoption at the 87th General Session in May 2019. **Part B** (**Annexes 14 to 25**) includes some texts that have been circulated for Member Country comments.

All comments on relevant texts in **Part B** must reach OIE Headquarters **by 4 July 2019** for them to be considered at the September 2019 meeting of the Code Commission. Comments received after the due date will not be submitted to the Code Commission for its consideration. In addition, the Code Commission would like to highlight that comments should be submitted through the OIE Delegate of Member Countries or organisations which the OIE has a Cooperative Agreement with.

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 '<u>double underline</u>'. 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 **<u>not</u>** to reproduce the full text of a chapter as this makes it easy to miss comments while preparing the working documents.

1. Welcome and orientation

1.1. Meeting with the Director General

The Code Commission met with Dr Monique Eloit, the OIE Director General, on 21 February 2019. Dr Eloit welcomed the Code Commission members and thanked them for their support and commitment to achieving OIE objectives.

The Director General updated the Code Commission on the schedule for the General Session in May 2019 and recent changes in the organisation structure of OIE Headquarters and discussed with members of the Code Commission its work programme, and other topics related to the work and performance of the Commission.

2. Performance management framework

The Code Commission met with Dr Matthew Stone, the OIE Deputy Director General (DDG) for International Standards and Science, on 19 February 2019. Dr Stone presented the new Performance Management Framework and discussed with Code Commission members the objective of this framework, which is the continuous improvement of the work of all the Specialist Commissions and the OIE Secretariat in order to improve their work for the benefit of the OIE Member Countries. He noted that this process includes regular meetings between Commission members and the DDG, the Presidents and the Director General, and a brief meeting review at the end of each meeting.

3. Adoption of agenda

The proposed agenda was discussed, taking into consideration priorities of the work programme and time availability. The adopted agenda of the meeting is attached as **Annex 2**.

4. Cooperation with other Specialist Commissions

4.1. Scientific Commission for Animal Diseases

- **Joint meeting**

  The Code Commission and the Scientific Commission held a Joint meeting on 21 February 2019 chaired by the Director General, Dr Monique Eloit. The meeting provided an opportunity for members of the two Commissions to meet and discuss items of common interest, notably: relevant chapters to be proposed for adoption at the upcoming General Session; the establishment of a formal written Standard Operating Procedure guiding listing decisions for pathogenic agents; a proposed work programme for the harmonisation of requirements for the official recognition and maintenance of disease-free status and endorsement of official control programmes in disease-specific chapters; and the Specialist Commission Presidents' presentations at the General Session.

  All members agreed that this meeting provided an excellent mechanism to strengthen collaboration between the two Commissions. It was agreed to hold this meeting annually during the February Commission meetings.

- **Technical working group meeting** related to the concept of 'temporary protection zone'

  Following on from the initiative started in September 2018, the Presidents and First Vice Presidents of the Scientific Commission and Code Commission held a technical working group meeting at the margins of the two Commission meetings. 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 discuss and further develop existing zoning provisions in the *Terrestrial Code* and the OIE procedure for official recognition of disease status, in order to allow and encourage Member Countries to implement enhanced preventive measures to protect their sanitary status in response to an increased risk of disease incursion, while minimising the impact on their status and consequently on trade.

The two Commissions agreed on an approach to be followed and requested OIE Headquarters to present the draft amendments to Chapter 4.3. and disease-specific chapters, where relevant, for consideration at their respective meetings.

4.2. Biological Standards Commission

The meeting schedule did not allow for a meeting with the President of the Biological Standards Commission. OIE Headquarters provided a brief update on the activities of the Biological Standards Commission from its September 2018 meeting, including the chapters for revision in the *Terrestrial Manual* and other items of interest for the Code Commission. In addition, there was consultation on some of the comments received that was coordinated through the Secretariats.

5. Texts to be proposed for adoption at the General Session in May 2019

5.1. Glossary

Comments were received from Argentina, Australia, Canada and Malaysia.

Sanitary measure

The Code Commission did not agree with comments to include 'compartment' in the definition of 'sanitary measure' because sanitary measures are taken by a Member Country to protect its territory, i.e. a given geographical area, while a compartment as defined in the Glossary is based on biosecurity management.

The Code Commission did not agree with a comment to align the definition of 'sanitary measure' with the one of the Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organisation as the definition in the Glossary of the *Terrestrial Code* is more relevant for its use in animal health than the WTO definition, and the term 'hazard' is already defined in the Glossary.

The Glossary definitions for 'sanitary measure' and 'early warning system' are attached as **Annex 3** and are proposed for adoption at the 87th General Session in May 2019.

EU position

The EU in general supports the adoption of this modified Glossary. One comment is inserted in the text of Annex 3.

5.2. Animal health surveillance (Chapter 1.4.)

Comments were received from Argentina, Australia, Canada, Georgia, Japan, Malaysia, New Caledonia, New Zealand, Peru, USA, EU and AU-IBAR.

The Code Commission considered all comments and made amendments to improve clarity and readability, where relevant. Where amendments were of an editorial nature, no explanatory text has been provided. In addition, the Code Commission did not consider comments where a rationale had not been provided or that were difficult to interpret.

In response to a comment proposing a revised structure for the chapter, the Code Commission noted that given this chapter is to be proposed for adoption in May 2019, it would consider this suggestion at a future time.

Amendments were made in the chapter in response to a comment on ensuring consistency in the use of the terms 'target population' and 'study population'.

Article 1.4.1.

In line with the approach taken in Chapter 1.1., the Code Commission did not agree with a comment suggesting to retain the word 'disease' in association with 'infection or infestation'. The Code Commission explained that as a general principle, and following extensive discussions that accompanied the deletion of its definition from the Glossary, the term 'disease' is used throughout the *Terrestrial Code* to refer to general aspects pertaining to the expression, epidemiology and transmission of pathogenic agents with the exception of some defined terms that include the word 'disease' (listed disease, notifiable disease, emerging disease). On the other hand, the terms 'infection'

and ‘infestation’, which are also defined terms, are used in more specific contexts such as cases, incursion, outbreaks, control and eradication. All three terms, i.e. ‘disease’, ‘infection’ and ‘infestation’ can be used when referring to a status, such as ‘freedom from’.

The Code Commission noted that given the significant work involved in making these amendments, the application of this new approach for these terms may not have been applied consistently throughout the *Terrestrial Code*. The Code Commission therefore requested OIE Headquarters to conduct a thorough review on the application of these terms and to provide an update at its September 2019 meeting.

Article 1.4.2.

In agreement with the advice of the Scientific Commission, the Code Commission did not agree with a comment proposing to add a definition for ‘surveillance system sensitivity’ and changing the definition for ‘confidence’, as it considered that the current definition of ‘confidence’ captures the concept of surveillance system sensitivity. Moreover, a definition for the term ‘surveillance system sensitivity’ is not necessary given that this term is not used in the chapter.

Article 1.4.3.

For point 1(b), the Code Commission agreed with a comment to add a new indent on ‘disease prevention and control measures’, as it considered that measures such as vaccination or restocking after disinfection could also influence the timing of surveillance.

For point 1(c), in line with the views of the Scientific Commission, the Code Commission did not agree with a comment to include more detail under ‘Case definition’ to discriminate between suspicious, probable, confirmed and rejected cases. While recognising that some national control programmes may benefit from the inclusion of such definitions, the Code Commission stressed that the purpose of this point is to define confirmed cases. The Code Commission also agreed with the Scientific Commission that in some disease-specific chapters, the definition of a suspected case may be included when relevant (e.g. rabies and rinderpest).

For point 1(ebis), the Code Commission did not agree with comments to change the title from ‘Diagnostic tests’ to ‘Diagnostic tools’ noting that the text of the point is not limited only to laboratory testing but may also refer to different diagnostic methods that could allow for the detection of a disease. This approach was supported by the Biological Standards Commission which explained that in the *Terrestrial Manual* the term used for laboratory tests is ‘test method’ which is defined as a ‘specified technical procedure for detection of an analyte (synonymous with assay)’.

In response to a comment received on ‘penside tests’, the Code Commission agreed with the advice of the Biological Standards Commission that the provisions for diagnostic tests covers ‘penside tests’ and amended the text to improve clarity. Both Commissions emphasised that according to Chapter 1.1.6. ‘Principles and methods of validation of diagnostic assays for infectious diseases’ of the *Terrestrial Manual*, all diagnostic assays (laboratory and field assays) should be validated for the species in which they will be used.

In the second paragraph of point 1(ebis), the Code Commission considered the comments received, in particular the parameters that could have an impact on the conclusions drawn from surveillance, and sought advice from the Biological Standards Commission and Scientific Commission. Based on their advice, the Code Commission proposed modifications to the wording to improve clarity. The Code Commission agreed to delete ‘imperfect’ as there is no such thing as a perfect test. However, the Code Commission did not remove ‘predictive values’ as these are essential parameters.

For point 1(f), a comment was received for the OIE to provide practical guidance on applying sophisticated mathematical or statistical analyses in surveillance, including collection of appropriate field data. The Code Commission, in consultation with the Scientific Commission, agreed that the quality of data is critical for the interpretation of the results from models and any other statistical analysis, and considered this to be covered in point 2(b) on ‘Data collection and management’. The Commissions also noted that this issue was addressed in detail in the following OIE publications:

Guide to Terrestrial Animal Health Surveillance and *Handbook on Import Risk Analysis for Animals and Animal Products*.

For point 2(a), advice was sought from the Scientific Commission and Biological Standards Commission on a comment received in September 2018 requesting to refer to target species. The Code Commission agreed to replace 'each species in which they may be used' with 'target species' for clarity. In agreement with the advice from the two other Commissions, the Code Commission did not accept the comment to include reference to expert estimates to support tests where validation data is lacking for non-target species, as it is hard to give an estimation when a test has not been validated in a species. In this case, Member Countries should refer to Chapter 1.1.6. of the *Terrestrial Manual* or other relevant data.

In the first paragraph of point 3, the Code Commission agreed to delete the word 'significant' as it considered that the primary role of the auditing would be to identify **any** deviation of procedures from those specified in the design, so that reviews may be conducted and appropriate corrective actions implemented where necessary.

Article 1.4.4.

For point 1, the Code Commission did not agree with a comment to refer to 'risk' communication as this article refers to general communication activities, and not only to risk communication that is part of the Glossary definition of risk analysis. This decision was also applied to similar comments received on this point in other parts of this chapter.

For point 2, the Code Commission did not agree with a comment to add 'sampling' before 'units', as it considered that sampling is undertaken to select units from the study population, and the resulting units being sampled then become 'sampling units'. This is in line with the definitions provided in Article 1.4.2.

For point 2(b)(i), after consultation with the Scientific Commission, the Code Commission agreed with the comments to clarify the wording on the objective of sampling. The Commissions' rationale for this amendment was that **either** probability-based or non-probability-based sampling method may be recommended, depending on the objective of the study. In some cases, samples are deliberately non-representative (e.g. risk-based sampling), and this type of sampling can be more appropriate if the aim is to maximise disease detection. In that case, representativeness is not necessarily required, but could be ensured if risk factors are weighted and underpinned by scientific evidence. If these requirements are met, the results of a non-probability sampling could also be extrapolated to the target population.

For point 2(b)(ii), the Code Commission did not agree with a comment requesting to add more detail on the size of the population according to the different alternatives described in the definition for epidemiological unit. The Code Commission considered it was not necessary, as it would depend on the methodology selected and the epidemiological unit being considered.

For point 2(b)(iii), the Code Commission sought the advice of the Scientific Commission on a comment to merge cluster and risk-based sampling. The Scientific Commission did not agree with the comment that cluster sampling is always part of risk-based sampling, explaining that cluster sampling can be used as part of risk-based sampling but can also be used in other contexts. Based on this advice, the Code Commission did not agree to modify the current text.

In the same point, the Code Commission did not agree to remove 'expert choice' because it may be relevant in some cases.

Regarding a comment on the term 'risk' being featured in both probability-based and non-probability-based sampling methods, in agreement with advice from the Scientific Commission, the Code Commission recalled that risk-based methods can be used in both sampling methods.

The Code Commission did not agree with comments requesting to either delete or to provide further elaboration on the sampling methods in point 2(b)(iii). The Code Commission concurred with the Scientific Commission that it was not within the scope of the *Terrestrial Code* to provide definitions

for the different sampling methods, and encouraged Member Countries to refer to relevant epidemiological texts.

For point 3, the Code Commission did not agree with a comment to replace 'risk assessment' with 'scientific evaluation of risk of pathogen entry and establishment' as all the components of risk assessment are useful in establishing risk-based methods for surveillance.

For point 4, the Code Commission agreed to include a new paragraph at the end to address important surveillance data that may be generated from locations other than slaughterhouses/abattoirs, such as rendering plants and hunting places.

For point 6, the Code Commission agreed with a comment to include the need for training and awareness of animal keepers on signs of disease that need to be investigated, noting that this is crucial for the early detection of a disease.

In response to a comment regarding the structure and organisation of points under this article, the Code Commission explained that the objective of this article was to highlight topics considered most relevant for the Veterinary Service to develop, while covering under point 8 'Other useful data', other sources of information arising from existing activities that could provide surveillance data.

Article 1.4.5.

For point 1, the Code Commission replaced 'coverage' with 'access to, and authority over' in response to a comment that the term 'coverage' needed to be clarified.

For point 3, the Code Commission did not agree with a comment to modify the text as it considered that training and awareness programmes for various stakeholders involved in the handling of animals from the farm to the slaughterhouse/abattoir are essential for detecting and reporting unusual animal health events.

For point 5, the Code Commission agreed with a comment to amend the text to better reflect that epidemiological investigations of **suspected cases** are conducted to confirm cases, and epidemiological investigations of **cases** are carried out to acquire accurate knowledge of the situation.

Article 1.4.6.

In response to a comment related to the concept of 'disease freedom' provided in the proposed Article 1.4.6., the Code Commission stressed that the proposed text does not imply any change to the current principles for zoning or country freedom already defined in the *Terrestrial Code*.

For point 1, proposed amendments were made by the Code Commission for clarity.

For point 2(a)(iii), following a comment from OIE Headquarters on amendments to ensure harmonisation of relevant provisions across all disease chapters with official recognition, and in agreement with the Scientific Commission, the Code Commission proposed to add new text on the movement of commodities.

For point 2(a)(iv), the Code Commission did not agree with a comment to qualify that for some diseases, the presence of infection or infestation in wildlife does not preclude demonstration of freedom if the wildlife are geographically isolated or separated by adequate biosecurity, as this is already covered in the third paragraph of point 1 of this article.

For point 2(a), the Code Commission did not agree with a comment to include a new indent that no vaccination against the disease had been carried out except for emergency vaccination, as a prerequisite to declare a country or a zone free from an infection or infestation. The Code Commission recalled that a former point on this had been deleted in agreement with the Scientific Commission, as vaccination of animals should be considered a valuable tool to prevent infection or infestation. The impact of vaccination on disease status may be found in Article 4.17.11. and in disease-specific chapters, where relevant. Furthermore, the Code Commission noted that Chapter 4.17. also includes details regarding vaccination and surveillance, and thus no amendments were necessary.

For point 2(b)(i) and 2(b)(iii), advice was sought from the Scientific Commission in response to a comment requesting a rationale for the times prescribed. Both the Scientific Commission and the Code Commission noted that these time references were included when the chapter was first adopted in 2005 and that no new scientific evidence has been provided to date to support modification of the currently accepted timeframes. However, the Code Commission explained that the concept of historical freedom is related to the absence of infection for a sufficient time so that the susceptible population that might have been exposed to the disease would be completely renewed. When the chapter was first adopted, it was agreed that the 25-year period was linked to the lifespan of most domestic susceptible population, and the 10-year waiting period was based on the detection of identifiable clinical or pathological signs which may be masked in the presence of immunity due to vaccination.

For point 2(c), in response to comments pertaining to the length of time for surveillance to be conducted, the Code Commission did not include new text but changed the order of the points listed for clarity. This was also applied to point 3 for consistency.

For former point 4(e) on 'vaccination against the disease is not applied' which was previously deleted, the Code Commission agreed with a comment regarding its relevance and proposed to cover this in point 1 of this article by adding a sentence in the first paragraph that reads 'It should take into account any prevention measures in place such as vaccination in accordance with this chapter and Chapter 4.17.'.

The revised Chapter 1.4. Animal health surveillance is attached as **Annex 4** and is proposed for adoption at the 87th General Session in May 2019.

EU position

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

Comments are inserted in the text of Annex 4.

5.3. Draft new chapter on Introduction to recommendations for the prevention and control of transmissible animal diseases (Chapter 4.Z.)

Comments were received from Australia and AU-IBAR.

Title

The Code Commission agreed with a comment to include 'transmissible animal diseases' in the title of this chapter to improve consistency.

Article 4.Z.1.

The Code Commission agreed with proposed changes that improved clarity of the chapter.

In the third paragraph, the Code Commission did not agree with a comment to replace 'should' with 'could'. The Code Commission reminded Member Countries that the use of 'should' is standard language of the *Terrestrial Code* when referring to recommendations to be implemented, and this does not infer an absolute obligation. 'Shall' on the other hand, refers to something compulsory in the *Terrestrial Code* as used in Chapter 1.1.

In the seventh paragraph, the Code Commission did not agree with a comment to indicate that prerequisites 'may' include those listed, noting that all of the outlined prerequisites are required to ensure that prevention and control programmes are effective, including public-private partnerships.

For the first indent, the Code Commission did not agree with a comment to include 'sufficient oversight from the Veterinary Authority' as it considered that this was already addressed in the definition of Veterinary Services.

For the sixth indent, the Code Commission did not agree with a comment to include 'relevant' before Competent Authorities as this was implied.

The revised Chapter 4.Z. Introduction to recommendations for the prevention and control of transmissible animal diseases is attached as **Annex 5** and is proposed for adoption at the 87th General Session in May 2019.

EU position

The EU supports the adoption of this new chapter.

5.4. The role of the Veterinary Services in food safety systems (Articles 6.2.3. and 6.2.4.)

Comments were received from Australia, Canada, New Zealand and EU.

The Code Commission considered all comments and made amendments to improve clarity and readability, where relevant. Where amendments were of an editorial nature, no explanatory text has been provided. In addition, the Code Commission did not consider comments where a rationale had not been provided or that were difficult to interpret.

The Code Commission reiterated that the scope of Chapter 6.2. is on the role of Veterinary Services in food safety and is not intended to prescribe the structure of regulatory controls of food safety systems. The Code Commission acknowledged that the role of Veterinary Services can be very limited or very extensive but in either case, the work of the Veterinary Services should be under the supervision of the Veterinary Authority or other Competent Authority, as noted in point 1 of Article 6.2.4. The Code Commission emphasised that this chain of command is clear and that it is up to each Member Country to organise its Veterinary Services and overall regulatory control over food safety in order to comply with ensuring production of safe food of animal origin. The Code Commission also clarified that the scope is limited to pathogenic agents of animal origin of veterinary public health importance.

The Code Commission reminded Member Countries that revisions to this chapter had been adopted in 2018 and that the Code Commission had only proposed changes to Article 6.2.4. to address a Member Country's concern raised during the General Session discussion prior to adoption. Therefore, comments submitted should have addressed only the proposed amendments and not other text which had been recently adopted. Only one comment on Article 6.2.3. was addressed (see below).

A number of comments emphasised major concerns regarding the proposed amendments to the Glossary definitions of Competent Authority, Veterinary Services and Veterinary Authority as they considered these proposed new definitions to be restrictive, that the changes may impact the accuracy and interpretation of this and other chapters, and that they did not reflect the regulatory controls for food safety in all OIE Member Countries. The Code Commission acknowledged the comments received and agreed to take them into account in the ongoing work to revise these definitions (see Item 6.1.). The Code Commission emphasised that the current Glossary definitions of Competent Authority, Veterinary Services and Veterinary Authority should be referred to for the interpretation of this and other chapters, until changes to the definitions have been agreed and adopted by the World Assembly of Delegates.
The Code Commission referred Member Countries to Item 6.1. Glossary regarding the process for reviewing these definitions.

Article 6.2.3.

In response to a comment to move 'regularly' before 'assess' in the last sentence of this article, the Code Commission acknowledged that it had missed this comment at its last meeting and modified the text accordingly.

Article 6.2.4.

The Code Commission did not agree to replace Veterinary Services or Veterinary Authorities with Competent Authority throughout this article noting that the scope of this article is the roles and responsibilities of Veterinary Services in a food safety system and that the purpose of this article is to

clarify where Veterinary Services have a precise role, as well as their relation with the Veterinary Authority or Competent Authorities, where relevant. The Code Commission highlighted that the important aspect is that a country should have in place relevant activities to ensure the production of safe food. In addition, the Code Commission agreed that until any amendments to the definitions of Competent Authority, Veterinary Services and Veterinary Authority are adopted, no change to the use or interpretation of these terms should be made.

In the fourth paragraph of point 1, the Code Commission considered comments to add 'risk analysis' and 'advising on mitigation measures'. Whilst the Code Commission agreed that these are part of other food-safety related activities, it did not agree to add these texts as it considered them to be too specific compared to the other examples provided. It also noted that the term 'such as' introduces examples and does not imply an exhaustive list.

In the fifth paragraph of point 1, the Code Commission did not agree with a comment to include 'for veterinary public health as specified in the *Terrestrial Code* with the given rationale that food safety systems are much wider than those covered in the *Terrestrial Code*. The Code Commission explained that when using the term Veterinary Services, it is within the context of the *Terrestrial Code* and thus it was not necessary to specify this reference.

In the first paragraph of point 2, the Code Commission agreed with comments to clarify what was meant by 'the first part of the food chain'. Taking into consideration the different ways of structuring regulatory controls over food safety systems among Member Countries, the Code Commission agreed that it was not possible to clearly define this aspect and replaced '**the** first (part)' by '**a** (part)' to allow more flexibility for Member Countries.

In the first paragraph of point 2(a), the Code Commission agreed that the sentence was overly long and split the sentence to improve clarity.

In the second paragraph of point 2(a), the Code Commission explained that the words 'including feed' was to emphasise the importance of feed as part of primary production activities. The Code Commission agreed to keep the text as written.

In the first paragraph of point 2(b), the Code Commission agreed to add the adjective 'animal' to the term 'by-products' for clarity. The Code Commission requested OIE Headquarters to consider whether a Glossary definition for this term was necessary.

The revised Articles 6.2.3. and 6.2.4. are attached as **Annex 6** and are proposed for adoption at the 87th General Session in May 2019.

EU position

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

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

Comments were received from Canada, Japan, Mongolia, Norway, Switzerland and the EU.

The Code Commission considered all comments and made amendments to improve clarity and readability, where relevant. Where amendments were of an editorial nature, no explanatory text has been provided. In addition, the Code Commission did not consider comments where a rationale had not been provided or that were difficult to interpret.

The Code Commission agreed with a comment to include the term 'threshold' to complement the use of 'target values', reflecting minimum acceptable levels and potential optimal values respectively, before corrective interventions are taken.

The revised Article 7.1.4. Guiding principles for the use of measures to assess animal welfare is attached as **Annex 7** and is proposed for adoption at the 87th General Session in May 2019.

EU position

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

5.6. Animal welfare and pig production systems (Articles 7.13.4. and 7.13.15.)

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

Article 7.13.15.

The Code Commission did not agree with a comment to delete 'discharges from nose or eyes', which was provided as an example of an animal-based measurable for air quality, as it considered that this example is in line with other examples provided in Article 7.13.4. Criteria (or measurables) for the welfare of pigs.

In response to a request for clarification regarding the use of the term 'culling rate' as an animal-based measurable, the Code Commission explained that culling rates are used to define the proportion of animals removed from production because of age, health or animal welfare concerns.

Articles 7.13.4. and 7.13.15 are attached as **Annex 8** and are proposed for adoption at the 87th General Session in May 2019.

EU position

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

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

Comments were received from Argentina, Australia, Canada, Costa Rica, Guatemala, Honduras, New Caledonia, Norway, South Africa, Switzerland, Thailand, USA, EU and AU-IBAR.

OIE Headquarters informed the Code Commission that the *ad hoc* Group on Killing of reptiles for their skins, meat and other products could not meet electronically to review comments received on the draft Chapter 7.Y. circulated in the Code Commission's September 2018 meeting report. Nevertheless, some members of the *ad hoc* Group provided their individual responses on the comments received and these responses were considered by the Code Commission.

The Code Commission considered all comments and made amendments to improve clarity and readability, where relevant. Where amendments were of an editorial nature, no explanatory text has been provided. In addition, the Code Commission did not consider comments where a rationale had not been provided or that were difficult to interpret.

The Code Commission noted that comments received were supportive of the draft chapter.

Although the term 'animal' was replaced by 'reptile' at its September 2018 meeting, additional amendments were made by the Code Commission after a further review of these terms to ensure consistency.

The Code Commission did not agree with a comment to include a table summarising different stunning and killing methods and associated animal welfare issues, noting that tables are no longer used in the animal welfare chapters. The Code Commission requested OIE Headquarters to explore the possibility of including such information in the animal welfare pages on the OIE Website.

In response to some comments requesting improvements in the Spanish and French versions of this draft chapter, the Code Commission proposed amendments to the Spanish and French versions and requested OIE Headquarters to consider these suggestions when preparing the revised draft chapters.

Article 7.Y.3.

The Code Commission did not agree with comments to replace 'verifying' with 'monitoring' and reminded Member Countries that as explained in its September 2018 report, 'verification' refers to

checking an individual reptile, while monitoring suggests on-going confirmation of the process conducted by more specialised staff.

In point 3 on 'Behavioural consideration for handling, restraining and stunning and killing', the Code Commission partially agreed with a comment to reword the first sentence to emphasise that reptiles have specific characteristics that should be considered during handling. The Code Commission also amended the article heading accordingly.

In the third indent of point 3, the Code Commission agreed with a comment to complement the information regarding the ability of reptiles to harm handlers, agreeing that reptiles are also capable of causing significant injuries via constriction or blunt trauma.

The Code Commission agreed with a comment to add a new indent 'propensity to regurgitate and choke when restrained inappropriately' to highlight that taping the jaw of the reptile risks suffocating the animal.

Article 7.Y.5.

The Code Commission did not agree with a comment to modify the first paragraph as it did not consider that the proposal improved readability. However, the Code Commission agreed with a comment to add a new indent regarding 'the extent to which movement of the reptile can be restricted', which might influence the choice of the killing method.

In the first indent of the third paragraph regarding the expected outcomes of the killing process, the Code Commission agreed to replace the term 'avoid' with 'minimise' as it was a more appropriate term. 'Avoid' could be interpreted as the total absence of welfare problems whereas 'minimise' reflects what is achievable in practice.

The Code Commission did not agree with a comment to add a new indent in this section to address the stress to neighbouring reptiles but agreed that this could be addressed by making 'reptile' plural in the first indent so that this point now addresses all the reptiles in the same enclosure that could be affected by killing.

Article 7.Y.6.

In the second paragraph, the Code Commission did not agree with a comment to replace the term 'verification' with 'monitoring' noting that this was consistent with its response to a similar comment considered in Article 7.Y.3.

The Code Commission did not agree with comments to add 'righting reflex' and 'response to pinch test' to the list of criteria regarded as sufficient to establish suspicion of consciousness when stunning reptiles. This decision was based on expert advice that there is insufficient scientific information to consider this a reliable criterion.

For the third and fourth indents, the Code Commission agreed with a comment to specify that the blink or nictitating membrane response to determine death in reptiles can only be used in species where eyelids are present and amended the text accordingly. The Code Commission agreed that this amendment also addressed another comment to specify that snakes are not included in this criteria.

The Code Commission did not agree with comments to modify the last point of this article, firstly because the comment on brain destruction is related to the method to kill the reptile, which is addressed in Article 7.Y.14. on pithing; and secondly, as it is well understood that cardiac activity could be influenced by other physiological and environmental conditions in reptiles, it should not be used as the sole indicator of death.

Article 7.Y.8.

The Code Commission agreed with a comment to replace the term 'avoid' with 'minimise', for consistency with changes made in Article 7.Y.5.

Article 7.Y.9.

In the eighth indent of the second paragraph, the Code Commission agreed with a comment to add 'species' for consistency with similar text used in this chapter.

The Code Commission did not agree with the proposal to limit the use of the electrical stunning method to crocodiles less than two metres, noting that scientific literature does not support this proposal. In addition, the Code Commission noted that this method in reptiles could be associated with handling difficulties rather than the effectiveness of the stunning method.

Article 7.Y.13.

The Code Commission did not agree with the comment to include a new point indicating that reptiles should be effectively restrained when using the gunshot method, noting that this could be misinterpreted as manual restraint, which is explicitly not recommended when using gunshot as a killing method because of the safety concerns for the personnel involved.

Regarding a comment on including illustrations to depict the accurate shot position when using the gunshot method, the Code Commission stated that illustrations and diagrams have been removed from animal welfare chapters in the *Terrestrial Code*, but could be provided as a guidance document on the OIE website once this chapter is adopted.

Article 7.Y.15.

The Code Commission did not agree with a comment to include a time limit between stunning and severance of the spinal cord. The Code Commission considered this addition to be unnecessary given that the text indicates that severance of the spinal cord should take place immediately after stunning and only when the reptile is unconscious.

Article 7.Y.16.

For the second indent, the Code Commission agreed with a comment to replace 'dosage' with 'dose', but not the addition of 'dose rate'.

The Code Commission did not agree with a comment to include age as a factor to consider when using chemical agents and noted that the age of a reptile is correlated with its size and therefore size should be considered when determining the dose of a chemical agent, especially if the desired outcome is the death of the reptile.

The Code Commission did not agree with a comment to include a new indent to emphasise that chemical agents should not be used when the meat is for human consumption. The Code Commission considered that this aspect is already addressed in the first paragraph of this article, where it states that the use of these agents should be 'in accordance with the requirements of the *Competent Authority*'.

Article 7.Y.17.

For the ninth indent, the Code Commission agreed with comments to replace the term 'paralysing' with 'neuro-muscular blocking drugs' noting that the latter is a more accurate term.

The revised new Chapter 7.Y. Killing of reptiles for their skins, meat and other products is attached as **Annex 9** and is proposed for adoption at the 87th General Session in May 2019.

EU position

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

5.8. Infection with rabies virus (Chapter 8.14.)

Comments were received from Argentina, Australia, Canada, China (People's Republic), Chinese Taipei, Japan, New Caledonia, New Zealand, Switzerland, USA and EU.

The Code Commission considered all comments and made amendments to improve clarity and readability, where relevant. Where amendments were of an editorial nature, no explanatory text has been provided. In addition, the Code Commission did not consider comments where a rationale had not been provided or that were difficult to interpret.

Regarding a general comment to include recommendations for the control of rabies in wildlife in this chapter, the Code Commission agreed with the opinion of the Scientific Commission that the provisions, as written, already captured provisions for disease freedom that are applicable to both domestic and wildlife. In addition, the Code Commission pointed out that the *Terrestrial Manual* includes tools for monitoring vaccination campaigns in wildlife. The Code Commission highlighted that the current global priority is dog-mediated rabies, and therefore additional provisions for wildlife would be looked at in the next revision of the chapter.

Article 8.14.1.

The Code Commission accepted comments that improved the clarity of this Article.

In the fifth paragraph, the Code Commission agreed with a comment to delete 'haematophagous' agreeing that it is not only haematophagous bats that carry the rabies virus.

In the definition of dog-mediated rabies under the second indent, the Code Commission and Scientific Commission did not agree with a comment to specify variants as they did not consider it would improve the definition and may on the contrary, restrict the scope of the definition. If the rabies virus strain evolves and becomes adapted to the dog population, even if the variant was originally associated with other species (e.g. bat-associated variants), the new evolved strain should also be considered dog-mediated.

The Code Commission and the Scientific Commission agreed that the correct scientific name for dog is '*Canis lupus familiaris'* and therefore replaced the term '*Canis familiaris'*.

Article 8.14.2.

In point 1, the Code Commission agreed with a comment to insert a new point on 'record of regular and prompt animal disease reporting' for relevance and consistency with the ongoing harmonisation work of the OIE for diseases with official recognition.

Article 8.14.2ter.

As above, the Code Commission agreed with a comment to insert a new point regarding the history of disease reporting under point 1(a).

Although it is already specified in point 1(e) that a country or zone may be considered free from dog-mediated rabies when no case of 'indigenously acquired dog-mediated rabies' has occurred during the past 24 months, for clarity, the Code Commission accepted a comment to insert an indent to point 2 that an imported case confirmed outside a quarantine station does not affect the disease status.

The Code Commission did not agree with a proposal to include 'the presence of rabies virus in cattle transmitted by haematophagous bats and antigenic variants that do not correspond to rabies transmitted by dogs' in point 2, as it considered this unnecessary given the scope of the article (dog-mediated rabies), the definition of dog-mediated rabies, and provisions in point 1.

Article 8.14.5.

Considering the divergent views between the Code Commission, the Scientific Commission, the OIE *ad hoc* Group for rabies and some of the comments received, the Code Commission proposed to revert to the text in the current version of the *Terrestrial Code* for this article (i.e. provisions in Article 8.14.6. of the current *Terrestrial Code*). In order to inform further discussions on the timeframe for vaccination, testing and shipment of animals, the Code Commission requested OIE Headquarters to seek further expert opinion on this issue, in particular the likelihood that animals with positive antibody titres may be incubating the virus and thus pose a risk for importing countries.

In response to a comment regarding the conditions in the model veterinary certificate, the Code Commission confirmed that if this article is significantly revised, Chapter 5.11. on the model international veterinary certificate would need to be updated accordingly.

Article 8.14.6.

The Code Commission clarified that the rationale for limiting the provisions to members of the Order *Carnivora* and *Chiroptera* was based on the consideration that non-carnivorous mammals are dead-end hosts and play no significant role in the epidemiology of rabies. It considered that the risk for the spread of rabies via these mammals through international trade was low, and a standalone article to address each species or type of susceptible mammals was not warranted. The Code Commission also noted that this did not limit a country from undertaking its own risk analysis and applying relevant measures on the risk posed by these animals.

Nonetheless, in view of the divergent views of the Code Commission, the Scientific Commission, the OIE *ad hoc* Group on rabies and some comments received on this article, the Code Commission proposed to revert to the provisions in Article 8.14.7. of the current *Terrestrial Code* pertaining to the importation of mammals, in order to proceed with the proposal for adoption of the two revised Articles 8.14.8. and 8.14.9. on OIE endorsed official control programme and surveillance respectively.

The Code Commission requested OIE Headquarters to seek expert advice on the epidemiological significance and the necessity for risk mitigation measures for susceptible animals not included in the Orders of *Carnivora* and *Chiroptera* for the next revision of this chapter.

Article 8.14.7.

Concerning a comment on provisions for wild caught animals for use in laboratories, the Code Commission stated that this would be addressed with the revised Article 8.14.6., as noted above.

Article 8.14.8.

For point 2, the Code Commission agreed in principle with a comment to include 'the capacity of the Competent Authority or Veterinary Authority' to control dog-mediated rabies, but made an amendment that also recognises the role of other authorities, by replacing 'capacity of the Veterinary Services' with '**its** capacity', which means the capacity of the Member Country as a whole.

In the fourth paragraph, given that the questionnaire for rabies is still under development, the Code Commission removed specific reference to Article 1.6.Xbis. The Code Commission agreed with the Scientific Commission that the application procedure for the endorsement of the national control programme for rabies by the OIE should be developed and adopted as a resolution by the World Assembly of Delegates. It also requested that the details of the questionnaire be reviewed by experts, together with the issues described above regarding the new revised Articles 8.14.5. and 8.14.6.

For the second indent of the last paragraph, in response to a comment on the 'significant problems' with the performance of the Veterinary Services, the Code Commission modified the text to include a reference to Section 3 of the *Terrestrial Code* for clarity.

The revised Chapter 8.14. Infection with rabies virus is attached as **Annex 10** and is proposed for adoption at the 87th General Session in May 2019.

EU position

The EU thanks the OIE for having taken many of its previous comments into account. The EU can support most of the changes proposed to the chapter, except for those proposed in Article 8.14.6. An important comment is inserted in the text of Annex 10, that should be taken into account before adoption.

5.9. Infection with *Chlamydophila abortus* (Enzootic abortion of ewes, ovine chlamydiosis) (Article 14.4.1.)

Comments were received from the EU.

In agreement with the advice from the Biological Standards Commission, the Code Commission changed the name of the pathogenic agent from *Chlamydophila abortus* to *Chlamydia abortus* in Article 14.4.1.

The Code Commission also amended Article 1.3.3. in accordance with this change.

EU comment

In this context, the EU notes the change in taxonomy of the pathogenic agent of bovine pleuropleunomia, as advised in the February 2019 report of the Biological Standards Commission (see Item 3.7. on p. 6). If confirmed, it would be desirable to make the relevant changes in the Terrestrial Code and Manual concurrently.

The revised Article 14.4.1. is attached as **Annex 11** and is proposed for adoption at the 87th General Session in May 2019.

EU position

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

The revised Article 1.3.3. is attached as **Annex 12** and is proposed for adoption at the 87th General Session in May 2019.

EU position

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

5.10. Infection with African swine fever virus (Articles 15.1.1bis., 15.1.2., 15.1.3., 15.1.16., 15.1.22., 15.1.31.)

Comments were received from Australia, Canada, Chile, Chinese Taipei, Costa Rica, Guatemala, Honduras, Japan, New Zealand and EU.

The Code Commission considered all comments and made amendments to improve clarity and readability, where relevant. Where amendments were of an editorial nature, no explanatory text has been provided. In addition, the Code Commission did not consider comments where a rationale had not been provided or that were difficult to interpret.

Article 15.1.1bis.

The Code Commission agreed with comments to use 'commodities of suids' instead of 'pig commodities' acknowledging that the term 'pig' applies only to *Sus scrofa* while the chapter also refers to commodities from other suids. This amendment was made throughout the chapter, where relevant, to ensure consistency.

Article 15.1.2.

In points 1 and 2, the Code Commission agreed with a comment to include 'pathological lesions' in addition to clinical signs, noting that pathological lesions are an important consideration if pigs are found dead or examined at slaughter, and play a determinant role for the detection of this disease. This amendment was made throughout the chapter, where relevant.

For point 5, a comment was received on the importance of testing dead animals in surveillance programmes. The Code Commission noted that surveillance in domestic populations is adequately covered in Articles 15.1.27. to 15.1.30. and 15.1.32., but made changes to Article 15.1.31. to strengthen the recommendations for the testing of wild or feral animals found dead, road kills, animals showing abnormal behaviour and hunted animals in surveillance programmes.

In response to a comment requesting the OIE to provide additional technical guidance on implementing appropriate biosecurity to comply with the criteria of Article 15.1.2., notably the effective separation of domestic pig population from wild pig populations, the Code Commission considered that sufficient guidance is provided in Chapter 4.4. on Application on compartmentalisation, in particular Article 4.4.3., and in other horizontal chapters. The Code Commission drew Member Countries' attention to the OIE/FAO GF-TADs *Handbook on African Swine Fever in wild boar and biosecurity during hunting*[1], as well as to the GF-TADs *Good practices for biosecurity in the pig sector*[2] and the FAO *Manual on ASF Detection and Diagnosis*[3]. The Code Commission emphasised the importance of Member Countries implementing provisions in the *Terrestrial Code* and other existing documents in order to prevent and control the transmission of this disease.

Article 15.1.3.

For point 3, the Code Commission agreed with comments to revise the wording of the first paragraph to improve consistency with point 7 of Article 15.1.2. The Code Commission did not agree with a comment to delete the specific reference to point 7 of Article 15.1.2. as it considered that it was important to highlight this point because biosecurity is essential to prevent the spread of African Swine Fever (ASF).

In response to a comment requesting clarification on the proposed deletion of the last paragraph of Article 15.1.3., the Code Commission recalled that the provisions of this paragraph are covered in Article 15.1.1bis. The rationale had also been provided in its September 2018 meeting report, where modifications were made to the first paragraph of point 3 to highlight that cases of infection with ASF virus in feral or wild pigs do not preclude freedom in domestic and captive wild pigs and possible safe trade of pig commodities in accordance with the relevant certification and risk mitigation articles of the chapter.

Article 15.1.16.

A few editorial changes were made to article 15.1.16. for clarity and accuracy.

Article 15.1.22.

For point 1, the Code Commission agreed with a comment to include a reference to other possible validated time-temperature combinations, and modified the text accordingly noting that this was also consistent with other disease-specific chapters (e.g. Chapter 10.4. on Infection with avian influenza viruses).

In response to some comments to request reviewing the minimum curing period for dry cured pig meat, the Code Commission reminded Member Countries that the current text had been adopted after years of discussion in the Code Commission and Scientific Commission and consultations with experts and Member Countries. Since then, the Code Commission has not acknowledged any major trade issues that arose due to the existing provision nor recognised any global epidemiological changes pertaining to this product. More importantly, there is no new scientific evidence that justifies the review of the current provision.

Article 15.1.31.

In Article 15.1.31., amendments were made as per the explanation given above under Article 15.1.2. to strengthen the recommendations for the testing of wild or feral animals found dead, road kills, animals showing abnormal behaviour and hunted animals in surveillance programmes.

The revised Articles 15.1.1bis., 15.1.2., 15.1.3., 15.1.16., 15.1.22. and 15.1.31. are attached as **Annex 13** and are proposed for adoption at the 87th General Session in May 2019.

[1] http://web.oie.int/RR-Europe/eng/eng/Regprog/docs/docs/GF-TADs%20Handbook_ASF_WILDBOAR%20version%202018-12-19.pdf
[2] http://www.fao.org/3/i1435e/i1435e00.pdf
[3] http://www.fao.org/3/i7228en/I7228EN.pdf

EU position

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

6. Texts circulated for Member Country comments

6.1. Glossary

Comments were received from Australia, Canada, Chile, India, New Zealand, Switzerland, USA and the EU.

Competent Authority, Veterinary Authority, Veterinary Services

The Code Commission considered comments received on the proposed amendments to the Glossary definitions for 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services'. Taking into consideration the different views expressed by Member Countries, and the importance of these definitions not only in the *Terrestrial Code* but also in the *Aquatic Code* and other OIE activities such as the PVS Pathway, the Code Commission requested OIE Headquarters to refer the comments to the *ad hoc* Group on Evaluation of Veterinary Services currently working on revisions of Chapters 3.1. and 3.2. The Code Commission agreed that it would review the recommendations of the *ad hoc* Group at its September 2019 meeting.

OIE Headquarters also proposed that the *ad hoc* Group recommendations be considered by the other Specialist Commissions to ensure alignment across all OIE standards.

Captive wild [animal]

Taking into consideration the different views expressed by Member Countries and the complexity posed by the diversity of species and scenarios covered under this definition, the Code Commission requested OIE Headquarters to forward the comments received to the OIE Working Group on Wildlife for its review. The Code Commission was informed that this Working Group will meet in December 2019.

Epidemiological unit

In response to comments the Code Commission amended the text of 'epidemiological unit' to improve clarity.

The revised definition for 'epidemiological unit' is attached in **Annex 14** for Member Country comments.

EU comment

[*Will be provided separately by 4 July 2019*]

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

Comments were received from the EU.

Regarding the use of the terms 'disease' and 'infection and infestation', the Code Commission would like to refer to the explanatory text given under Item 5.2., Article 1.4.1.

Article 1.1.2.

For point 3, the Code Commission replaced 'immediate' with 'within 24 hours' for consistency with Article 1.1.3.

For point 6, the Code Commission did not agree with a comment to remove 'biosecurity', noting that sanitary measures are not the same as biosecurity. Biosecurity applies at the level of epidemiological

units whereas sanitary measures are decided by the Competent Authority and applied to its territory, and as such it is relevant for both biosecurity and sanitary measures to be mentioned.

Article 1.1.3.

In response to a comment as to whether 'strain' of the pathogenic agent is the appropriate term to be used for notification versus other terms such as 'serotype' and 'subtype', and whether establishing a definition for strain would be useful, the Code Commission considered the information provided by the Biological Standards Commission, the Scientific Commission and OIE Headquarters. Given that the specific term (e.g. strain, serotype and subtype) for notification is specified under each disease-specific chapter, the Code Commission concluded that there is no need to refer to all of these terms in Chapter 1.1., the term 'strain' being understood here as encompassing all possibilities. Correspondingly, the Code Commission agreed that there was no need to develop a Glossary definition for 'strain'.

Article 1.1.5.

At its September 2018 meeting, the Code Commission noted that given Article 1.1.5. is related to the notification of the absence of diseases, it therefore has a relationship with the procedures for self-declaration of disease freedom, as well as for the recognition of an official disease status by the OIE. The Code Commission thus proposed to evaluate whether this article was better placed in Chapter 1.6. The Code Commission considered a comment, as well as the advice from the Scientific Commission and OIE Headquarters regarding this proposal and agreed to maintain the proposed deletion of Article 1.1.5. from Chapter 1.1., considering that:

- Points 1 and 2 of Article 1.1.5. refer to country or zone freedom, which is outside the scope of Chapter 1.1.

- Notification of the end of a disease occurrence or spread (i.e. no further cases), is covered by Article 1.1.3. (2) and (3) and Article 1.1.4.

For details regarding the inclusion of the content of Article 1.1.5. in Chapter 1.6., refer to Item 6.3.

The revised Chapter 1.1. Notification of diseases, infections and infestations, and provision of epidemiological information is attached as **Annex 15** for Member Countries comments.

EU comment

[*Will be provided separately by 4 July 2019*]

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

Comments were received from Australia, India, Malaysia and EU.

The Code Commission considered all comments and made amendments to improve clarity and readability, where relevant. Where amendments were of an editorial nature, no explanatory text has been provided. In addition, the Code Commission did not consider comments where a rationale had not been provided or that were difficult to interpret.

At its September 2018 meeting, the Code Commission had agreed with a proposal presented by OIE Headquarters to harmonise the provisions for official recognition and maintenance of disease-free status, and endorsement and maintenance of official control programmes (refer to Item 8.9.). The Code Commission had recommended that provisions common to the five diseases with official recognition of disease-free status be addressed in Chapter 1.6., instead of repeating these provisions in each disease-specific chapter.

The Code Commission considered the proposal from OIE Headquarters that had been endorsed by the Scientific Commission, and agreed to introduce amendments to relevant articles of Chapter 1.6. related to harmonisation.

Additionally, following from the discussion at the September 2018 meeting to move Article 1.1.5. to Chapter 1.6., instead of retaining the current wording in Article 1.1.5., the Code Commission proposed to cover the points via the amendments in Chapter 1.6., noting that most of the content was already addressed in Chapter 1.6., i.e.

- If a self-declaration of disease freedom was made by a Member Country, an outbreak of the disease would suspend the self-declared free status;

- For diseases with official recognition of animal health status, a disease outbreak in the relevant animal population would imply the automatic suspension of the official status;

- If the free status is lost, the Standard Operating Procedures (SOP) would require the Member Country to submit a new self-declaration/recovery of free status or application for recovery of official status, before re-publication of its self-declared status or reinstatement of an official status.

- Point 3 of Article 1.1.5. refers to the establishment of free zone(s) and the criteria on which the free status is based etc. The criteria and procedure are already covered in this draft chapter.

Article 1.6.1.

The Code Commission agreed with a comment noting that the wording of the second paragraph differed from that in the SOP published on the OIE website and requested OIE Headquarters to amend the SOP to align it with the text used in this article.

The Code Commission did not agree with a comment requesting to use the word 'shall' instead of 'may' when referring to the publication of a self-declaration, as they considered it was not an appropriate word because it implies a legal obligation.

As part of the harmonisation work, a new paragraph was added referring to the loss of a self-declared free status in the event of an outbreak in the country, zone or compartment with a self-declared free status.

Article 1.6.2.

The Code Commission agreed with a comment to amend the title of this article for accuracy and consistency with Article 1.6.1. The Code Commission proposed to use the term 'animal health status' as it is defined in the Glossary. The Code Commission also applied the amendment throughout the chapter for consistency.

Taking into consideration the modifications being proposed to Chapter 8.14. Infection with rabies virus (refer to Item 5.8.), the Code Commission agreed to include a new point 2 (d) referring to the possibility for Member Countries to request endorsement of 'an official control programme for dog-mediated rabies' from the OIE.

The Code Commission agreed with a proposal from OIE Headquarters to simplify the wording of the paragraph referring to the OIE framework for official recognition to provide a general reference to the resolutions of the World Assembly of Delegates so as to avoid discrepancies when the resolution numbers are updated.

The Code Commission agreed with a comment and amended the wording of the last paragraph to improve clarity.

As part of the harmonisation work, references to Chapters 1.4. and 4.3. were added when relevant, and a new paragraph was added referring to the recognition of zones.

Article 1.6.3.

As part of the harmonisation work, a new Article 1.6.3. Maintenance of official recognition and endorsement by the OIE was added using the last paragraph of the previous draft Article 1.6.2. and further details on the requirements and processes.

The Code Commission did not agree with a comment suggesting editorial changes to the wording of the first paragraph, agreeing that it did not improve the text.

The revised Chapter 1.6. Procedures for self-declaration and for official recognition by the OIE is attached as **Annex 16** for Member Countries comments.

EU comment

[*Will be provided separately by 4 July 2019*]

6.4. Veterinary legislation (Chapter 3.4.)

Comments were received from Australia, Canada, China (People's Republic), India, Malaysia, Mexico, USA, EU and AU-IBAR.

The Code Commission considered all comments and made amendments to improve clarity and readability, where relevant. Where amendments were of an editorial nature, no explanatory text has been provided. In addition, the Code Commission did not consider comments where a rationale had not been provided or that were difficult to interpret.

Comments pertaining to the definitions for Competent Authority, Veterinary Authority and Veterinary Services were not addressed, pending further work (see Item 6.1.).

Article 3.4.1.

In the third paragraph, the Code Commission did not agree to include 'specific' before legal instruments as it considered this to be unnecessary, noting that fines and sanctions could be considered part of veterinary legislation.

In the fourth paragraph, the Code Commission accepted a comment to include 'international' before 'standards and instruments' for clarity. The Code Commission did not agree with a comment to include 'guidelines and provisions for animal health' noting that guidelines do not have the same legal status as standards and legal instruments.

Article 3.4.2.

For the definition of 'legal instrument', the Code Commission did not agree with a comment to include 'enforceable', as it is already stated in the definition that a legal instrument is a legally binding rule.

For the definition of 'veterinary domain', the Code Commission did not agree with a comment to include 'environmental health' as it considered that veterinary public health already included environmental health. Furthermore, the 'One Health approach' is specified in the definition.

The Code Commission did not agree to delete 'veterinary' from 'veterinary public health' as this is a specific term used throughout the *Terrestrial Code*. The Code Commission reminded Member Countries that Chapter 6.1. notes that veterinary public health is a component of public health.

Article 3.4.3.

For point 1, the Code Commission agreed with the comment to delete 'scrupulously' but modified the sentence to explain the importance of respecting the hierarchy of legislation for effective implementation of veterinary legislation.

For point 2, the Code Commission did not agree to include 'supranational' as it considered that in this context, 'regional' is taken to mean more than one country and thus encompasses supranational and may include legislation pertaining to more than one country.

For point 4, the Code Commission accepted a comment to include 'as appropriate', as it agreed that an impact analysis depending on the situation is not always necessary.

The Code Commission did not agree with a comment to list the stakeholders involved in the consultative process for the drafting of the legislation as the drafting process typically did not include these other stakeholders. The Code Commission emphasised that the involvement of these stakeholders is important in the development of legislation, and noted that this is already addressed in the second paragraph.

For point 5, the Code Commission did not agree with a comment to reinstate 'transparent'. It considered this redundant as transparency is covered in point 3 and also implied under point 4.

The Code Commission agreed to include 'provide legal certainty' in the text as it improves clarity and is consistent with the title of this point. It did not agree to delete 'stable' but instead moved 'stable' to the next sentence to retain emphasis that this element is also important.

The Code Commission partially agreed with a comment that legislation should be 'regularly evaluated and amended as appropriate' but used the word 'updated' instead of 'amended' as legislation should be kept up to date, while assuring legal security.

The Code Commission did not agree with a comment to delete 'regularly updated' with the given rationale that it is not possible to control how regularly legislation is reviewed. The Code Commission noted that this comment may apply if legislation was limited to primary law; however, the definition of legislation in this chapter includes both primary law and regulations, and regulations could be regularly updated by the Veterinary Authority.

Article 3.4.4.

For point 2, the Code Commission did not agree with a comment to delete 'unambiguous'. On the contrary, it considered it essential that the law is unambiguous.

The Code Commission did not agree to include 'avoid arbitrariness' at the end of point 2, as the preceding provisions on the drafting of veterinary legislation would have addressed this, including legal certainty.

For point 3, the Code Commission agreed to delete 'sufficient' noting that this term is vague and subjective.

For point 4, the Code Commission did not agree to delete 'duplication'. It recognised that at times duplication is inevitable especially when there is overlapping mandates between different sections of the government, and thus modified the text by adding 'unnecessary' in front of 'duplication'.

For point 5, the Code Commission did not agree to include 'validity'. Instead it created a new point 8 to take into account the impact of new legislation on pre-existing legislation and regulations when the new legislation comes into effect.

Article 3.4.5.

In the first paragraph, the Code Commission agreed to replace 'capacitated' with 'have the necessary technical, administrative and infrastructure capacity' for clarity.

In the second paragraph, the Code Commission partially accepted a comment to replace 'short' with 'as short as possible' and modified the sentence to reflect this.

For point 1(b), the Code Commission agreed to include 'and in accordance with professional standards' as it considered this to be an important consideration.

For point 1(c), the Code Commission agreed to include 'transparency' as it considered this to be relevant.

For point 1(d)(iii), the Code Commission agreed with a comment to include 'fomites' under the third and seventh indents. The Code Commission clarified that as 'commodity' is a defined term in the Glossary of the *Terrestrial Code*, it agreed to use 'commodity' to refer to animals, animal products, by-products and products of animal origin including food. With regard to the terms 'animal products', 'animal by-products' and 'products of animal origin', the Code Commission noted that there are no Glossary definitions for these although they are widely used in the *Terrestrial Code*, with possible different interpretations, and requested OIE Headquarters to work on some draft new definitions (see Item 6.5.).

Regarding a comment to italicise 'establishment' in the third and fourth indents, the Code Commission clarified that in this context, establishment does not refer to the term as defined in the Glossary and therefore should not be italicised. To avoid confusion, the Code Commission replaced 'establishment' with 'facility'.

The Code Commission agreed with a comment to include additional powers under primary legislation, and thus included 'establishment of compensation mechanisms', 'listing disease for mandatory reporting' and 'ordering of disinfection'.

In the last line of point 1, the Code Commission replaced 'must' with 'should' in accordance with the standard terminology used in the *Terrestrial Code*. It agreed with a comment to include 'clearly' before 'identified' but not 'outlined in a limited manner' as it considered this to be implied the way the text is written.

Article 3.4.6.

For point 1(d), the Code Commission agreed to replace 'make secondary legislation or otherwise deal with' with 'provide basic principles for or regulate' so that it is less prescriptive.

For point 1(d)(i), in response to a comment that it is not clear what is meant by various categories of veterinarians, the Code Commission modified the statement to read 'various specialisations of veterinarians and categories of veterinary paraprofessionals'. This amendment was also applied to other relevant points to ensure consistency. It also agreed to include 'animal welfare'.

For point 1(d)(iv), the Code Commission did not agree with a comment that the veterinary statutory body does not have the authority to recognise qualifications of veterinarians and paraprofessionals. The Code Commission clarified that it could be the case that the Competent Authority defines the rules for authorisation, but it is the veterinary statutory body that prescribes the conditions for recognising such qualifications in accordance with these rules.

For point 1(d)(vii), the Code Commission acknowledged a comment that the veterinary statutory body is not the authority that identifies exceptional situations such as epizootics under which persons other than veterinarians can undertake activities normally carried out by veterinarians. This would normally reside with the Competent Authority. As such, the Code Commission agreed to modify the sentence to reflect that the veterinary statutory body may 'define the conditions' under which this may be carried out, but it is the responsibility of the Competent Authority to decide the situations where this could be allowed.

Article 3.4.7.

For point 1(c), the Code Commission agreed with a comment that laboratory testing could be external as well as in-house, and deleted the word 'in-house'.

For point 2(c), the Code Commission agreed that 'oversight' improves the clarity of this sentence and modified the text accordingly.

For point 3, the Code Commission agreed to add 'including their disposal when applicable' for completeness and modified the text accordingly.

Article 3.4.9.

For the first paragraph, in response to a comment on notifying OIE-listed diseases to the Competent Authority, the Code Commission made amendments to include 'mandatory reporting' and clarify that diseases of importance do not only refer to diseases that are present in the country.

In point 2(b)(i), the Code Commission accepted a comment to include 'activate, implement and coordinate activities' for clarity.

Article 3.4.10.

For point 2, the Code Commission did not accept a comment to include 'responsibility of the Competent Authority' noting that there are other actors besides the Competent Authority.

Article 3.4.11.

For the first paragraph, the Code Commission did not agree to include 'within the framework of One Health' noting that it was already addressed in the definition of veterinary domain.

For point 1(b), the Code Commission agreed to delete 'laboratory biosafety and biosecurity' as these terms do not fit under this section.

For point 2, the Code Commission agreed to replace 'veterinary medicines and biologicals' with 'veterinary medicinal products' for consistency.

For point 3(b)(i), the Code Commission agreed to add 'veterinary medicinal products incorporated into' before 'medicated feeds' for clarity.

For point 3(b)(iv), the Code Commission did not agree with the comment to add 'for use in food producing animals', noting that the withdrawal period by definition relates to the use in food producing animals and thus is already implied.

The Code Commission did not agree to reinstate the deleted point 4 on 'Quality of veterinary medicine and biologicals', but agreed to include the element of safety and efficacy in veterinary medical products in the general measures in point 1(b).

For point 5(g), the Code Commission did not agree that 'reporting on adverse effects to the Competent Authority' is a repetition of point 4(d), as point 4 concerns the supply chain at the production, storage and wholesale level, while point 5 concerns the supply chain at the retail level.

Article 3.4.12.

For point 1(a), the Code Commission agreed to delete 'veterinary' in accordance with the wording in Chapter 6.3.

For point 2(b), the Code Commission agreed to replace 'health identification marks' with 'visible marks that indicate the product has been inspected' to improve clarity.

The revised Chapter 3.4. Veterinary Legislation is attached as **Annex 17** for Member Country comments.

EU comment

[*Will be provided separately by 4 July 2019*]

6.5. Draft new chapter on official control programmes for listed and emerging diseases (Chapter 4.Y.)

Comments were received from Argentina, Australia, Canada, China (People's Republic), Chinese Taipei, New Caledonia, Switzerland, USA, EU and AU-IBAR.

The Code Commission considered all comments and made amendments to improve clarity and readability, where relevant. Where amendments were of an editorial nature, no explanatory text has been provided. In addition, the Code Commission did not consider comments where a rationale had not been provided or that were difficult to interpret.

The Code Commission and the Scientific Commission agreed to replace the term 'contagious' diseases with 'transmissible' diseases throughout the chapter. The Code Commission also agreed with the Scientific Commission to include 'programmes' in the title for consistency with the text.

The Code Commission considered a comment requesting clarification of the use of the terms 'listed and emerging diseases' and 'notifiable disease' throughout the chapter, and whether 'notifiable disease' would be more appropriate for the title of the chapter. The Code Commission highlighted that the Glossary definitions for 'notification' and 'notifiable diseases' referred to notification at different levels. 'Notification' means the procedure by which the **Veterinary Authority informs the OIE** or the OIE informs the Veterinary Authority, of the occurrence of disease, infection or infestation in accordance with Chapter 1.1., whereas 'notifiable disease' refers to an **internal reporting of a disease to the Veterinary Authority** (within an OIE Member Country) in accordance with national regulations. As this chapter focuses on diseases that are notifiable to the OIE, the Code Commission agreed that the title of the chapter should remain unchanged as 'listed and emerging disease'. However, the Code Commission clarified that when text refers to diseases reportable within a Member Country, the defined term 'notifiable disease' is used.

The Code Commission acknowledged that use of the terms such as 'notify', 'notifiable disease', 'report' and 'reportable disease' in the *Terrestrial Code* may lead to possible misunderstanding and added a review of these terms to its work programme.

In response to comments received on the use of the terms 'animals', 'animal products', 'animal by-products' and 'commodities', the Code Commission amended the text accordingly with the term 'commodity', where relevant, as this is a defined term that includes 'live animals, products of animal origin, animal genetic material, biological products and pathological material'. Notwithstanding this amendment, the Code Commission noted that there is no Glossary definition for products of animal origin, animal products and animal by-products, and requested OIE Headquarters to propose some definitions for these terms that could be considered for inclusion in the Glossary of the *Terrestrial Code* (see Item 6.4.).

Article 4.Y.1.

In the first paragraph, the Code Commission accepted a comment to remove 'including a zoonosis' as it was implicit in the meaning of animal diseases, which may or may not be zoonotic.

The Code Commission accepted a comment to replace 'a new disease' in the parenthesis with 'the first occurrence of a disease' as rapid response would also be relevant in the first occurrence of a disease, whether new or previously recognised.

In the fourth paragraph, the Code Commission did not agree with a comment to replace 'developed through' with 'informed by' but did agree to use the term 'based on' for clarity.

In the fifth paragraph, the Code Commission did not accept a comment to add 'from a given population' at the end of the last sentence as it is implicit in that a reduction of the impact of a given disease or eradication of an infection or infestation is from a given population.

In the section regarding the 'general components of an official control programme', the Code Commission agreed with the Scientific Commission to re-order the points according to the sequence of the articles from 4.Y.2. to 4.Y.12. The Code Commission also agreed with a comment from the Scientific Commission on including a provision on the legal framework and regulatory environment. This has been included as a new point 2 'appropriate veterinary legislation'.

For point 3, the Code Commission replaced 'preparedness and contingency plans' with 'emergency preparedness plans and emergency response plans' for clarity and consistency.

For point 6, the Code Commission did not agree with a comment to insert 'the impact of' before 'incidence' as it considered it unnecessary. However, the Code Commission rephrased the sentence for clarity.

For point 7, the Code Commission included 'sanitary measures' for completeness.

For point 8, the Code Commission agreed with a comment to replace 'as relevant' with 'as appropriate'. The Code Commission also applied this amendment to the other points, where appropriate.

The Code Commission agreed with a comment to include 'measures to protect public health' and inserted a new point 9 on this.

The Code Commission did not agree with a comment to include a new point on 'exit strategy' and to delete the entire paragraph on critical components of control programmes for diseases that are not present in the Member Country. The Code Commission agreed that 'exit strategy' would not apply in all situations and should therefore not be included in the general list provided. In addition, the Code Commission noted that the intention of this paragraph was to emphasise specific components of control plans important for diseases that are not present in the country and thus this paragraph should be retained. However, the Code Commission recognised that there could be more than one exit strategy and thus inserted 'options' after 'exit strategy'. The Code Commission did not agree with a comment to include 'where relevant' after exit strategy as it considered it was already implied in the text as written.

Article 4.Y.2.

For the second indent under point 2, the Code Commission agreed with a comment to include 'additional supporting staff', but not to remove dedicated staff, which should also be addressed.

The Code Commission agreed with a comment to include 'source of financing for communication and awareness campaigns' and included this in a new indent.

A number of comments were received regarding the new fifth indent of point 2 on sources of financing and compensation policy. The Code Commission agreed that the provisions should not be too prescriptive and agreed to simplify the text accordingly, allowing more latitude for Member Countries to develop relevant compensation policies.

For the second indent under point 3, in response to a comment to replace 'reporting' with 'notification', the Code Commission clarified that reporting is used when referring to internal reporting within the country, whereas notification, as per the Glossary definition means notifying the OIE.

For the fourth indent, the Code Commission proposed to include 'forward and backward' tracing for clarity.

The Code Commission agreed with a comment to include procedures for contaminated waste water, manure and other effluents and created a new point on procedures for 'contaminated or potentially contaminated fodder and effluents such as bedding, litter, manure and waste water'.

Article 4.Y.3.

In the first paragraph, the Code Commission did not agree with a comment to insert 'transmissible' before 'disease', but instead agreed to amend the text to 'emerging disease or a listed disease' as this is consistent with the title of the chapter and the terminology used in Chapter 1.1. The Code Commission also agreed to include a new point that 'the Veterinary Authority should define emergencies' in its official control programmes.

For point 1, the Code Commission did not agree with a comment to replace 'risk analysis' with 'risk ranking' or 'risk management tools', noting that risk analysis as defined in the Glossary includes both risk assessment and risk management.

For point 2, the Code Commission acknowledged a comment but decided to revise the entire paragraph to explain in further detail what emergency preparedness plans should consist of.

Article 4.Y.4.

The Code Commission agreed with a comment to insert 'of a listed or emerging disease' after 'strong suspicion' for consistency with the title.

The Code Commission did not agree with a comment to replace 'local control measures' with 'preventative control measures' because control measures are not always preventative. Instead it proposed to use '**pre-emptive** control measures' for clarity.

Article 4.Y.5.

The Code Commission did not agree with a comment to move Article 4.Y.5. earlier in the chapter explaining that the sequence of Articles 4.Y.2. to 4.Y.10. follows the sequence of the general components of an official control programme as described in Article 4.Y.1.

For point 1, the Code Commission agreed to include 'fomites' under backward and forward tracing. The Code Commission explained that fomites could include vehicles, people, clothing, feed and equipment. The same applies for point 3.

In response to a comment requesting clarity on the term 'management plan' in the third and fourth paragraphs, the Code Commission amended the text to clarify the meaning.

Article 4.Y.6.

In the second paragraph, the Code Commission did not agree with a comment to include 'relevant' before 'to the transmission pathways of the pathogenic agents' noting that the sentence already states that the Veterinary Services should adapt any strategy to the transmission pathway.

In the fifth paragraph, the Code Commission agreed with a comment to amend the text to ensure consistency and clarity in the terminology used when referring to dead animals and other potentially contaminated commodities and amended the sentence accordingly. This change was applied throughout the chapter.

In point 2, the Code Commission did not agree with a comment to include the term 'not appropriate' in reference to test and cull for highly transmissible diseases. However, the Code Commission proposed an amendment to clarify that this strategy is 'more suitable' for less transmissible or slow-spreading diseases.

Article 4.Y.7.

As per the rationale given above in the general comments for this chapter, the Code Commission replaced 'animal products and contaminated materials' with 'contaminated commodities and fomites' for consistency. Thus, it did not accept a comment on including 'by-products'. However, it accepted a comment to include 'fomites' and to include the examples in parenthesis.

Article 4.Y.8.

The Code Commission agreed to move the article on 'Zoning' (Article 4.Y.10. in the previous draft) to after Article 4.Y.7. on 'Movement Control' to follow the logical sequence of the components described in Article 4.Y.1.

For the last sentence of the third paragraph, the Code Commission did not agree with a comment to include 'clearly defined' after 'zones' noting that this is already in the Glossary definition for zone. However, the Code Commission acknowledged that it is not clear what zones of intensified surveillance or intensified vaccination may mean, and therefore amended the text to explain that these are zones where specific surveillance, vaccination or other activities are conducted.

Article 4.Y.10.

In the second paragraph, the Code Commission agreed to insert ‘or antigen’ before ‘banks’ noting that for some diseases antigen banks are more common than vaccine banks.

In the third paragraph, the Code Commission agreed to include differentiation between 'live vaccine strains from field strains’ as this is possible for some diseases.

In the sixth paragraph, the Code Commission agreed to include that a ‘cost benefit analysis with regard to trade and public health’ should be considered when vaccination is used.

The Code Commission agreed that treatment may be part of an official control programme and thus proposed a new paragraph at the end of this article to address treatment. ‘Treatment’ was also reinstated in the title of this article.

The revised Chapter 4.Y. Official control programmes for listed and emerging diseases is attached as **Annex 18** for Member Country comments.

EU comment

[*Will be provided separately by 4 July 2019*]

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

Comments were received from Argentina, Canada, Chile, China (People’s Republic), Colombia, Costa Rica, Ecuador, Guatemala, Honduras, India, Japan, Malaysia, Mexico, Mongolia, New Caledonia, Norway, Peru, Philippines, Thailand, USA, EU, AU-IBAR, IEC, ICFAW and experts.

The Code Commission noted the significant number of comments received and that many comments expressed opposing positions with respect to some of the recommendations proposed in the draft chapter. The Code Commission requested that the *ad hoc* Group on animal welfare and laying hen production systems be reconvened to review all comments received and to amend the draft chapter accordingly. The Code Commission was informed that the *ad hoc* Group would be reconvened in April 2019 so that it can consider the *ad hoc* Group’s report at its September 2019 meeting.

The Code Commission recommended that the *ad hoc* Group continue to focus on animal-based measurables based on scientific evidence when revising the draft chapter and ensure that the text is drafted in a manner that is consistent with other animal welfare production system chapters in the *Terrestrial Code*. The Code Commission also requested that the *ad hoc* Group take into account social and economic considerations, as well as impacts on food security when developing the revised text. However, all text should be evidence-based.

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

Comments were received from Argentina, Australia, Canada, China (People’s Republic), Costa Rica, Guatemala, Honduras, India, Japan, Malaysia, South Africa, Thailand, USA, EU, AU-IBAR, GAPFA, IPC and experts.

The Code Commission noted the large number of comments that had been submitted. The Code Commission considered all comments and identified those comments that needed further expert advice, and requested that these be referred to the *ad hoc* Group on avian influenza. The Code Commission addressed the other comments and proposed that the amended text be provided to the *ad hoc* Group for information. The Code Commission would review the report of the *ad hoc* Group at its September 2019 meeting.

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

Comments were received from Argentina, Australia, Canada, Chile, Chinese Taipei, Japan, Mexico, New Zealand, USA and EU.

As explained in Item 8.9. this chapter will be amended to ensure harmonisation of the procedures and requirements for official recognition and maintenance of disease-free status.

Therefore, the Code Commission agreed not to circulate this chapter for Member Country comments until the harmonisation work has been included, in order to avoid Member Countries having to comment on several different versions.

The Code Commission requested OIE Headquarters to incorporate the necessary amendments as part of the harmonisation work and to present the amended draft, along with previous amendments for its consideration at its September 2019 meeting.

7. New amendments or draft new chapters proposed for Member Country comments

7.1. User's Guide

For point 3 of Section B, for consistency with terminology used across the *Terrestrial Code,* the Code Commission replaced 'diagnosis, surveillance and notification of pathogenic agents' with 'diagnosis, surveillance and notification of diseases, infections and infestations'.

Given that Chapter 2.2. on safety of commodities was revised and adopted in 2018, the Code Commission updated the User's Guide to reflect this. Based on a similar reference in the *Aquatic Code*, the Code Commission included a sentence referring to the 'criteria used to assess the safety of commodities' under point 5 of Section C.

The revised User's Guide is attached as **Annex 19** for Member Country comments.

EU comment

[*Will be provided separately by 4 July 2019*]

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

The Code Commission reviewed the opinion provided by a panel of experts, and endorsed by the Scientific Commission as to whether *Mycobacterium caprae* and *Mycobacterium tuberculosis* fulfilled the listing criteria in accordance with Chapter 1.2. of the *Terrestrial Code*. The detailed report of the panel of experts and considerations of the Scientific Commission may be found in the report of the September 2018 meeting of the Scientific Commission.

The Code Commission agreed with the conclusion of the Scientific Commission that *M. tuberculosis* did not meet the criteria for inclusion in Article 1.3.1. as an OIE listed disease and proposed to amend Article 1.3.1. and Chapter 8.11. accordingly. Therefore, for the purposes of the *Terrestrial Code,* only *M. bovis* and *M. caprae* should be considered in the case definition.

The Code Commission amended Article 1.3.1. in accordance with this change.

The revised Chapter 8.11. Infection with Mycobacterium tuberculosis complex is attached as **Annex 20** for Member Country comments.

EU comment

[*Will be provided separately by 4 July 2019*]

The revised Article 1.3.1. is attached as **Annex 21** for Member Country comments.

EU comment

[*Will be provided separately by 4 July 2019*]

7.3. Infection with Rift Valley fever virus (Chapter 8.15.)

OIE Headquarters updated the Code Commission with the proposed changes to Chapter 8.15. following the September 2018 meeting, where the Code Commission had requested for alignment between point 6 of Article 8.15.1. with Articles 8.15.4. and 8.15.5., possibly including references to point 1 of Article 1.1.3. on notification and referencing human cases as a consequence of epizootic in Article 8.15.5.

The objective of these amendments is to clarify the obligations of Member Countries to notify when there is an epizootic of Rift Valley fever in an endemic country or zone.

The Code Commission proposed amendments to Articles 8.15.1. and 8.15.5.

Article 8.15.1.

For point 5, to facilitate reporting, the Code Commission proposed to include new text 'the transition from inter-epizootic period to epizootic complies with point 1(d) of Article 1.1.3'.

For point 6(b) on the definition of 'epizootic of RVF', given that it is highly improbable for human cases to occur in the absence of a number of clinical animal cases[1,2], the Code Commission proposed to include 'or the occurrence of indigenous human cases'. The Code Commission also agreed to delete 'substantially' as this term is subjective.

References

[1] de La Rocque S, Formenty P. (2014) Applying the One Health principles: a trans-sectoral coordination framework for preventing and responding to Rift Valley fever outbreaks. Rev Sci Tech. 2014;33(2):555–567

[2] de LaRocque S, Formenty P (2010) Rift Valley fever: Disease ecology and early warning. Sustainable Management of Animal Production and Health, eds Odongo N, Garcia M, Viljoen G (Food and Agriculture Organization of the United Nations, Rome), pp 327–333

Article 8.15.5.

The Code Commission agreed to include 'indigenous human cases of RFV are occurring, even in the absence of detection of animal cases' to ensure alignment with the proposed amendments in point 6(b) of Article 8.15.1.

The revised Chapter 8.15. Infection with Rift Valley fever virus is attached as **Annex 22** for Member Country comments.

EU comment

[*Will be provided separately by 4 July 2019*]

7.4. Infection with equine influenza (Article 12.6.6.)

The Code Commission considered the recommendations provided by the Scientific Commission to amend Article 12.6.6. 'Recommendations for the importation of domestic equids for unrestricted movement', in view of the results of a clinical trial on the 'Evaluation of current equine influenza vaccination protocols prior to shipment' coordinated by an OIE Reference Laboratory for equine influenza (refer to the Scientific Commission reports of September 2018 and February 2019).

The Code Commission agreed with the Scientific Commission to modify point 3 regarding vaccination requirements, i.e. to define 14 days as the minimum period between vaccination and shipment, and to include a second option of vaccination 'between 14 and 180 days before shipment, if they are older than four years of age, previously having received at least four doses of the same vaccine at intervals not greater than 180 days'.

The revised Article 12.6.6. is attached as **Annex 23** for Member Country comments.

EU comment

[*Will be provided separately by 4 July 2019*]

7.5. Infection with peste des petits ruminants virus (Articles 14.7.3. and 14.7.34.)

Following the work of OIE Headquarters on the harmonisation of requirements for official recognition and maintenance of disease-free status, and for endorsement and maintenance of official control programmes, Chapter 14.7. was identified as the 'model chapter' to present the harmonisation work. Articles 14.7.3. and 14.7.34. have been amended accordingly to incorporate the new proposed wording.

For further information, refer to Item 8.9.

The revised Articles 14.7.3. and 14.7.34. are attached as **Annex 24** for Member Country comments.

EU comment

[*Will be provided separately by 4 July 2019*]

8. Other ongoing topics

8.1. Veterinary Services (Chapter 3.1.) and Evaluation of Veterinary Services (Chapter 3.2.)

OIE Headquarters provided the Code Commission with an update on the work of the *ad hoc* Group on Evaluation of Veterinary Services, who met in November 2018. The *ad hoc* Group sought guidance from the Code Commission on the proposed restructure of Chapters 3.1. and 3.2. The Code Commission provided guidance and feedback on the *ad hoc* Group's work to date and requested that OIE Headquarters ensure that the revisions of these chapters are focused on providing recommendations for the establishment, maintenance and evaluation of quality Veterinary Services, with the aim of assisting Veterinary Services of Member Countries to meet their objectives of improving terrestrial animal health and welfare and veterinary public health, as well as to establish and maintain confidence in their international veterinary certification.

As these chapters are closely linked to the definitions of Veterinary Services, Veterinary Authority, and Competent Authority, the Code Commission requested that the *ad hoc* Group also review comments received on these definitions (see Item 6.1.).

The Code Commission was informed that the *ad hoc* Group on Evaluation of Veterinary Services will meet in the coming months. The Commission will consider the *ad hoc* Group report at its September 2019 meeting.

8.2. Update on the work on semen and embryos (Chapters 4.5. to 4.9.)

OIE Headquarters informed the Code Commission that it had commenced a review of the work needed to improve Chapters 4.5 to 4.9. on semen and embryos and to develop a plan regarding future work. The Code Commission appreciated that progress has been made on this work noting that this is a complicated task and will take time to complete. The Code Commission provided advice as to how to proceed and proposed to commence with work to revise existing chapters on semen.

In addition, the Code Commission noted with pleasure that the International Embryo Transfer Society had requested the development of provisions on bovine *in vitro* produced embryos in relation to bovine viral diarrhea. The Code Commission considered that it was important that the *Terrestrial Code* reflects the latest IETS recommendations and requested that OIE Headquarters prepare some proposed text for inclusion in Chapter 4.8. Collection and processing of oocytes and in vitro produced embryos from livestock and horses, for the Code Commission's consideration at its September 2019 meeting.

8.3. Update on the outcomes of the second *ad hoc* Group meeting on the 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. Slaughter of animals and 7.6. Killing for disease control purposes who met from 27-29 November 2018.

The Code Commission agreed with the proposed revised structure and format for the two chapters and the *ad hoc* Group's proposal to develop a draft definition for 'outcome/animal-based measurables'.

The Code Commission also reviewed the *ad hoc* Group's proposed modifications of definitions for slaughter, euthanasia, stunning and death and requested the *ad hoc* Group to review these further to ensure that there will be no impact associated with the use of these terms in other parts of the *Terrestrial Code*.

The Code Commission requested that the *ad hoc* Group be reconvened to progress this work which the Code Commission will consider at its September 2019 meeting.

8.4. Draft Terms of Reference for an ad hoc Group on the revision of Chapter 7.7. Stray dog population control

The Code Commission agreed with the draft Terms of References for the *ad hoc* Group for the revision of Chapter 7.7. Stray dog population control.

OIE Headquarters informed the Code Commission the *ad hoc* Group is proposed to be convened at the end of 2019. Therefore, the report of the *ad hoc* Group will be considered by the Code Commission at its February 2020 meeting.

8.5. Infection with rinderpest virus (Chapter 8.16.)

OIE Headquarters informed the Code Commission that as agreed at its September 2018 meeting, this chapter needed to be updated to clarify the definitions of 'case' and 'suspected case', the reporting obligations of countries where a suspected case is detected and the measures to be taken in case of re-emergence. The Code Commission had accepted the proposal from OIE Headquarters to work on the revision of the chapter, in collaboration with advice from the FAO-OIE Rinderpest Joint Advisory Committee (JAC).

OIE Headquarters provided the Code Commission with a revised draft chapter that included proposals provided by the JAC. The Code Commission reviewed the revised draft chapter and provided comments on some of the proposed revisions and requested OIE Headquarters to ensure that ongoing work on this chapter takes into account these comments.

OIE Headquarters proposed that an *ad hoc* Group be convened to progress this work that will be reviewed by both the Code Commission and Scientific Commission.

8.6. Outcomes of three *ad hoc* Group meetings on the revision of BSE chapter (Chapter 11.4.)

OIE Headquarters updated the Code Commission on the work of the *ad hoc* Groups on BSE risk assessment and BSE surveillance. The Code Commission was informed that the *ad hoc* Group on BSE risk assessment and surveillance would be meeting in March 2019 to finalise the work on revising Chapter 11.4.

The Code Commission noted that the revision of Chapter 11.4. is considered a high priority by the OIE, and would look forward to reviewing the draft chapter at its September 2019 meeting.

8.7. New/revised articles for the temporary movement of horses

OIE Headquarters updated the Code Commission on work being conducted in consultation with OIE Reference Laboratory experts to review or develop provisions for the temporary movement of horses for Chapter 12.2. Contagious equine metritis and Chapter 12.7. Equine piroplasmosis.

The Code Commission provided feedback and guidance, and agreed that these chapters are outdated and not aligned with more recent disease-specific chapters in the *Terrestrial Code* (Chapter 12.2. has not been revised since its first adoption in 1982 and Chapter 12.7. had only a minor amendment made since its adoption in 1982). The Code Commission requested OIE Headquarters to evaluate the need for a comprehensive review and revision of these chapters, not just limited to the development of articles for the temporary movement of horses, and added the update of these chapters to its work programme.

8.8. Outcomes of *ad hoc* Group on animal trypanosomoses

OIE Headquarters updated the Code Commission on the work of the *ad hoc* Group on Animal African Trypanosomoses, including the recommendation and discussion of the *ad hoc* Group to develop a *Terrestrial Code* chapter on Infection with animal trypanosomoses of African origin, in addition to the existing draft chapters 8.X. Infection with *Trypanosoma evansi* (non-equine surra) and Chapter 12.3. Infection with Trypanozoon in equids (dourine, equine surra).

The Code Commission noted the work of the *ad hoc* Group in developing the chapter on Infection with animal trypanososes of African origin, which is expected to be presented to the Code Commission at its September 2019 meeting.

8.9. Harmonisation of Terrestrial Code chapters for diseases with OIE official status recognition

At its September 2018 meeting, the Code Commission agreed on a proposal presented by OIE Headquarters and endorsed by the Scientific Commission, to harmonise the requirements for official recognition and maintenance of disease-free status, and for endorsement and maintenance of official control programmes. The Code Commission also recommended that common provisions applicable to the five diseases with official recognition of disease-free status, especially regarding procedural aspects, be addressed in the horizontal chapters instead of repeating them in each disease specific chapter.

The Code Commission agreed that this work requires amendments of Chapters 1.4. and 1.6. which are addressed under other specific items of this report (see Items 5.2. and 6.3.), as well as the revision of the following chapters: 8.8. Infection with foot and mouth disease virus, 11.5. Infection with *Mycoplasma mycoides* subsp. mycoides SC (Contagious bovine pleuropneumonia), 12.1. Infection with African horse sickness virus, 14.7. Infection with peste des petits ruminants virus, and 15.2. Infection with classical swine fever virus.

The Code Commission agreed that this harmonisation work should be presented to Member Countries using a 'model chapter' so that they could see what is involved in this work. The Code Commission agreed that Chapter 14.7. Infection with peste des petits ruminants virus should be used as the 'model chapter' given that it has been recently adopted and there were no ongoing or pending issues since its adoption. The Code Commission, together with the Scientific Commission, will consider Member Country comments on this 'model' example before continuing the harmonisation amendments for the other relevant chapters (see Item 7.5.) .

The Code Commission considered, and agreed with, the amendments proposed by OIE Headquarters to Articles 14.7.3. and 14.7.34. to include the new proposed wording. The Code Commission highlighted that the modifications introduced in both Articles were mainly to align the text to the approach described above.

8.10. Establishment of a Standard Operating Procedure guiding listing decisions for pathogenic agents

The Code Commission was informed that OIE Headquarters will develop an SOP for the listing and delisting of pathogenic agents in Chapter 1.3. of the *Terrestrial Code.*

The Code Commission considered a guidance document drafted by OIE Headquarters which was endorsed by the Scientific Commission. The document is intended to be used by OIE Headquarters to guide relevant experts in the application of the criteria defined in Article 1.2.2. of the *Terrestrial Code* when undertaking an assessment of a pathogenic agent.

The Code Commission agreed with the proposed approach, but highlighted the need to take into account Article 1.2.1. when deciding whether a disease should be considered for inclusion in Chapter 1.3., not only the assessment against the criteria in Article 1.2.2. Specifically, the second paragraph of Article 1.2.1. which refers to the objective of listing a disease should be considered first, before discussing the specific criteria in Article 1.2.2.

8.11. Consideration of specified dairy products as safe commodities

In response to a Member Country's request, the Code Commission had previously agreed to consider whether lactose could be considered as a safe commodity, in accordance with Chapter 2.2. Criteria applied by the OIE for assessing the safety of commodities, for inclusion in the relevant disease-specific chapters. The OIE sought technical advice from the International Dairy Federation on the

manufacturing processes involved in the production of lactose, in particular whether there was a standard manufacturing process for this product and details of heat treatments used.

The Code Commission considered the information provided and acknowledged that a standardised manufacturing protocol exists that includes various heating and drying steps including pasteurisation.

The Code Commission requested OIE Headquarters to collect some additional information in order to determine the best way to define this commodity in the *Terrestrial Code.*

Once the Code Commission has this information, assessments will be undertaken to identify which pathogenic agents would be inactivated by the standardised manufacturing process for lactose and therefore could be considered as a safe commodity in the corresponding disease-specific chapters.

8.12. Control of Shiga toxin-producing E. coli (STEC) in food-producing animals

OIE Headquarters updated the Code Commission on past discussions regarding the control of Shiga toxin-producing *Escherichia coli* (STEC) in food-producing animals and informed the Code Commission that it had previously agreed to include this item on its work programme in light of new work on STEC that had been proposed by the Codex Alimentarius Commission. The Code Commission agreed to keep this item on its work progamme and to consider it again at its September 2019 meeting in view of new work on the development of Codex Guidelines for the control of Shiga toxin-producing *E. coli* (STEC) in beef.

8.13. Update on standards for pet food

OIE Headquarters updated the Code Commission on previous discussions regarding the possible inclusion of provisions for pet food as safe products in the *Terrestrial Code*, noting that this has been a long-standing issue. At its February 2018 meeting, the Code Commission had considered a request from the Global Alliance of Pet Food Associations (GAPFA) to recommence work on the development of provisions for pet food. GAPFA had expressed willingness to provide relevant information on the treatment of ingredients used in the production of pet food that might facilitate this work.

OIE Headquarters informed the Code Commission that the GAPFA has commenced work to gather scientific information that could inform the assessment of pet food products against the criteria for assessing the safety of commodities in accordance with Chapter 2.2., and will provide this information to the OIE once completed.

The Code Commission agreed that it will discuss this further after receiving this scientific information.

9. New topics

9.1. Responsible and prudent use of antimicrobial agents in veterinary medicine (Chapter 6.10.)

Comments were received for Chapter 6.10. from the EU.

The Code Commission acknowledged comments requesting a review of Chapter 6.10. Responsible and prudent use of antimicrobial agents in veterinary medicine and to also consider some proposed amendments given that this chapter has not been significantly reviewed for some time.

The Code Commission noted that Chapter 6.10. had not been circulated for comments but acknowledged that the adoption in 2018 of some revised definitions in Chapter 6.9. Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals could have an impact on Chapter 6.10. The Code Commission requested OIE Headquarters to send these comments to an expert group for further guidance. This item has also been added to the Code Commission's work programme.

9.2. Update on OIE Curricula Guidelines for Veterinary Paraprofessionals

OIE Headquarters updated the Code Commission on the work of the *ad hoc* Group on Veterinary Paraprofessionals, which was to finalise the OIE Curricula Guidelines for Veterinary Paraprofessionals for publication and dissemination at the May 2019 General Session.

10. Applications for OIE Collaborating Centres

Application for OIE Collaborating Centre on Animal Welfare

The Code Commission considered and discussed the information presented by the Biological Standards Commission and a summary prepared by OIE Headquarters on the collaboration of this centre with the OIE.

The Code Commission agreed that it had no objection to this centre being recognised as an OIE Collaborating Centre.

The Code Commission also highlighted that it would be important for the OIE to enlarge its network of expertise in this matter. Additionally, they considered that the expertise of this candidate appears to be complementary to another OIE Collaborating Centre in the same region that is already recognised, and so a collaborative and coordinated approach should be sought.

Application for OIE Collaborating Centre for Continuing Education and Veterinary Capacity Building

The Code Commission considered and discussed the information presented by the Biological Standards Commission. One member of the Code Commission abstained from participating in the assessment.

The Code Commission agreed that it had no objection to this centre being recognised as an OIE Collaborating Centre.

The Code Commission highlighted the important role that this centre has been playing by providing training on epidemiology, surveillance and disease control to the Veterinary Services in its region.

11. Update of the Code Commission's work programme

Comments were received from the EU.

The Code Commission acknowledged the comment on updating Chapter 1.3. in tandem with the amendments to Chapter 10.4. on avian influenza, and will consider this at its September 2019 meeting following the meeting of the *ad hoc* Group on avian influenza (see Item 6.7.). In general, the Code Commission will always consider potential changes to Chapter 1.3. when updating listed disease-specific chapters.

With regard to the comment on rabies, Mycobacterium tuberculosis complex, bovine spongiform encephalopathy and Chapter 6.10. on Responsible and prudent use of antimicrobial agents in veterinary medicine, the updates are referred to in Items 5.9., 7.2., 8.6. and 9.1. respectively.

The following items were added to the work programme:

- Section 5 on trade measures, import/export procedures and veterinary certification, to undertake a holistic review of the existing chapters (especially 5.4. to 5.7.) and for better harmonisation with the *Aquatic Code*
- Definitions for animal products, products of animal origin, animal by-products (see Item 6.5.)
- Chapter 6.10. on Responsible and prudent use of antimicrobial agents in veterinary medicine (see Item 9.1.)
- Chapter 12.2. Contagious equine metritis and Chapter 12.7. Equine piroplasmosis (see Item 8.7.)
- Pet food (for certification or safe commodities), replacing a former item on model certificate for pet food (see Item 8.13.).

The order of items under 'Sections 8 to 15' has been revised after re-prioritisation by the Code Commission. Amendments were also made to individual items in the work programme for clarity.

The updated work programme is attached as **Annex 25** for Member Countries information and comments.

EU comment

The EU thanks the OIE for having taken into account or addressed many of its previous comments and in general supports the future work programme of the Code Commission.

Specific comments are inserted in the text of Annex 25.

12. Date of next meeting

The next meeting will be from 10 to 19 September 2019.

_____

…/Annexes

Annex 3

GLOSSARY

EU position

The EU in general supports the adoption of this modified Glossary. One comment is inserted in the text below.

~~***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;~~

~~*d)* 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*.

EU comment

The EU notes that the wording of the definition is not consistent with the text inserted in the draft Article 1.4.5. Indeed, the first paragraph of that article also mentions "occurrence" of disease, which is not the same as "incursion". To avoid confusion and for reasons of consistence with the wording in Article 1.4.5., we would therefore suggest inserting the word "occurrence, " before "incursion" also in the Glossary definition above.

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*.

Annex 4

CHAPTER 1.4.

ANIMAL HEALTH SURVEILLANCE

EU position

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

Comments are inserted in the text below.

Article 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 disease ~~*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. pathogenesis, *vectors*, transmission pathways, seasonality);

– *risk* of introduction and spread;

– husbandry practices and production systems;

– disease prevention and control measures (e.g. *vaccination*, restocking after *disinfection*);

EU comment

The EU suggests deleting the words "restocking after disinfection" as – contrary to vaccination – it is not a good example of a disease prevention and control measure.

– accessibility of target *population*;

– geographical factors;

– environmental factors, including climate conditions.

~~*Surveillance* should be carried out at a frequency that reflects the epidemiology of the *infection* or *infestation* and the *risk* of its introduction and spread.~~

c) Case definition

Where one exists, the *case* definition in the relevant chapter of the *Terrestrial Code* should be used. If the *Terrestrial Code* does not give a *case* definition, a *case* should be defined using clear criteria for each *infection* or *infestation* under *surveillance*. For *wildlife infection* or *infestation surveillance*, it is essential to correctly identify and report host animal taxonomy, including genus and species.

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

Surveillance involves the use of tests for 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 to rapid field and detailed laboratory assays.

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.~~ These values together with ~~as well as~~ prevalence~~,~~ will have an impact on the conclusions drawn from *surveillance*~~. Therefore, these parameters~~ and should be taken into account in the design of *surveillance* systems and analysis of *surveillance* data.

Laboratory ~~T~~tests should be chosen in accordance with the relevant chapters of the *Terrestrial Manual.*

EU comment

The EU acknowledges that further to its previous comment (avialable here: https://ec.europa.eu/food/sites/food/files/safety/docs/ia_standards_oie_eu_position_tahsc-report_201809.pdf, p. 42-57), the text of point ebis) above has been amended. However,

we still think that the title "diagnostic tests" does not well reflect the content of this section, which includes field diagnostics such as clinical observations which we do not understand to be "tests". Perhaps a title such as "Diagnostic investigations" would be more inclusive; the word "test" could then be replaced with "investigations" in the first paragraph. Furthermore, the words "Laboratory tests" in the last paragraph should be replaced with "Laboratory test methods" or "Laboratory assays", in line with the definitions included in the Terrestrial Manual.

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.

2. Implementation of the surveillance system

a) Diagnostic tests

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

~~Tests should be chosen in accordance with the relevant chapters of the *Terrestrial Manual.*~~

~~*i)* Sensitivity and specificity: The performance of a test at the *population* level (including field observations) may be described in terms of its sensitivity, specificity and predictive values. Imperfect sensitivity or specificity, as well as prevalence, will have an impact on the conclusions from *surveillance*. Therefore, these parameters should be taken into account in the design of *surveillance* systems and analysis of *surveillance* data.~~

The sensitivity and specificity values of the tests used should be specified for ~~each species in which they may be used~~ target species 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 possibility 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. Disease reporting systems

Disease reporting systems are based on reporting of animal health-related events to the *Veterinary Authority*. Data derived from disease reporting systems can be used in combination with other data sources to substantiate claims of *animal health status*, to generate data for *risk analysis* or for early warning and response. Effective laboratory support is an important component of any reporting system. Reporting systems relying on laboratory confirmation of suspected clinical *cases* should use tests that have high specificity as described in the *Terrestrial Manual*.

Whenever the responsibility for disease reporting falls outside the scope of the *Veterinary Authority*, for example human *cases* of zoonotic diseases or *infections* or *infestations* in *wildlife*, effective communication and data sharing should be established ~~with~~ between the *Veterinary Authority* and other relevant authorities.

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

~~2. Data generated by control programmes and health schemes~~

~~While focusing on the control or eradication of specific *infections* or *infestations*, control programmes or health schemes can be used to generate data that can contribute to other *surveillance* objectives.~~

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.

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 ~~probability~~ sampling from a *population* is to select a subset of *units* ~~that is representative of~~ from 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~~ from a target *population* to have a representative sample, probability-based sampling, such as a simple random selection, should be used.

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*.

When the objective of non-probability-based sampling is to maximise the likelihood of detection of the *infection* or *infestation*, this type of sampling may not be 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 tThose weights should be underpinned by relevant scientific evidence and should capture the relative differences in risk and proportion between the *subpopulation* and the *population*.~~

When using non-probability-based sampling, representativeness can only be achieved if *risk* factors are weighted and the weights are supported by relevant scientific evidence capturing the relative differences in *risk* and proportion between the study *population* and the target *population*.

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.

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

iii) Sample selection

- Probability-based sampling methods, such as:
  - simple random selection;
  - cluster sampling;
  - stratified sampling;
  - systematic sampling; ~~or~~
  - risk-based sampling.
- Non-probability-based sampling methods, depending on:
  - convenience;
  - expert choice;
  - quota;
  - *risk.*

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 a *risk assessment* and are useful to optimise the use of *surveillance* resources.

EU comment

The EU notes that the use of the term "prevalence" in the context of the paragraph above does not match the glossary defnition of that term. Indeed, the definition of prevalence in the glossary ("means the total number of cases or outbreaks of a disease that are present in a population at risk, in a particular geographical area, at one specified time or during a given period.") is different from common understanding, which usually is "the proportion of the population which at a given point in time has the disease". That is how we understand the term "prevalence" in the context of the paragraph above, which should therefore not be italisised here. However, as this problem appears also in several other parts of the text, an alternative would be to review the Glossary definition instead.

4. Ante-mortem and post-mortem inspections

Inspection of *animals* at *slaughterhouses/abattoirs* may provide valuable *surveillance* data. The sensitivity and specificity of *slaughterhouse/abattoir* inspections for detecting the presence of specified diseases will be influenced by:

a) clinical and pathological signs;

b) the training, experience and number of the inspection staff;

c) the extent to which the *Competent Authority* is involved ~~involvement of the *Competent Authority*~~ in the supervision of ante-mortem and post-mortem inspections, 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.

Post-mortem inspection conducted in locations other than *slaughterhouses/abattoirs* (e.g. rendering plants, hunting places) may also provide valuable *surveillance* data.

~~5. Laboratory investigation records~~

~~Laboratory investigation records may provide useful data for *surveillance*. Multiple sources of data such as national, accredited, university and private sector *laboratories* should be integrated in order to increase the coverage of the *surveillance* system.~~

~~Valid analysis of data from different *laboratories* depends on the existence of standardised diagnostic procedures and standardised methods for data recording and interpretation as well as a mechanism to ensure the traceability of specimens to *herd or flock* or locality of origin.~~

~~6.~~ ~~Biological specimen banks~~

~~Specimen banks consist of stored specimens, gathered through representative sampling or opportunistic collection. Specimen banks may contribute to retrospective studies, including providing support for claims of historical freedom from *infection* or *infestation*, and may allow certain studies to be conducted more quickly and at lower cost than other approaches.~~

5~~7~~. Surveillance of ~~S~~sentinel units

Surveillance of ~~S~~sentinel *units* involve the identification and regular testing of one or more *animals* of known health or immune status in a specified geographical location to detect the occurrence of *infection* or *infestation.* Sentinel *units* provide the opportunity to target *surveillance* depending on the risk of introduction or re-emergence, likelihood of *infection* or *infestation,* cost and other practical constraints. Sentinel *units* may provide evidence of freedom from, or distribution of, disease, *infection* or *infestation*~~, or of their distribution~~.

6~~8~~. 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. Awareness and ~~T~~training of potential field observers, including *animal* keepers, in the application of the *case* definition and reporting ~~is~~ are important. Ideally, both the number of positive observations and the total number of observations should be recorded.

7~~9~~. 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*. ~~Software may offer the prospect of extraction of syndromic data for aggregation and analysis.~~

8~~10~~. Other useful data ~~sources~~

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.

c) 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 disease, *infection* or *infestation*, and may allow certain studies to be conducted more quickly and at lower cost than other approaches.

d~~a~~) Wildlife data

Specimens for *surveillance* from *wildlife* may be available from sources such as hunters and trappers, road-kills, *wild animal meat* markets, sanitary inspection of hunted *animals*, morbidity and mortality observations by the general public, *wildlife* rehabilitation centres, *wildlife* biologists and *wildlife* agency field personnel, farmers and other landholders, naturalists and conservationists. *Wildlife* data such as census data, trends over time, and reproductive success can be used in a manner similar to farm production records for epidemiological purposes.

e~~b~~) Public health data

For zoonotic diseases public health data may be an indicator of a potential change in the *animal health status*. The *Veterinary Authority* should coordinate with human health authorities and share data for integration into *specific surveillance* systems.

f~~c~~) Environmental data

Relevant environmental data such as rainfall, temperature, extreme climatic events, presence and abundance of potential *vectors* as described in Chapter 1.5., should also be integrated into the *surveillance* system.

g~~d~~) Additional supporting data such as:

i) data on the epidemiology of the *infection* or *infestation*, including host *population* distribution;

ii) data on animal movements, including transhumance and natural *wildlife* migrations;

iii) trading patterns for *animals* and animal products;

iv) national animal health regulations, including information on compliance and effectiveness;

v) history of imports of potentially infected material;

vi) *biosecurity* in place; and

vii) the *risk* of introduction of *infection* or *infestation*.

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.

~~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:

EU comment

Reference is made to the EU comment in Annex 3 on the Glossary definition of early warning system and the inconsistency of the wording used in that definition and the paragrfaph above.

1) appropriate ~~coverage~~ access to, and authority over, ~~of~~ the 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*, *animal* owners or keepers and others involved in handling *animals* at the farm or other places where they are kept during their tarnsport or at the *slaughterhouse/abattoir*, for detecting and reporting unusual animal health incidents;

4) 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~~:~~;

EU comment

The EU suggests deleting the words “including the description of the findings” in point 4) above, as it does not make sense to keep them now that the detailed information below on the types of finding to be reported has been deleted. Indeed, keeping that text might lead to the misunderstanding that only a description of the clinical observations/findings should be reported to the veterinary authority, which is incorrect as several other information should be reported as well (such as relevant dates, location, etc.).

- ~~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;~~

5) epidemiological investigations of suspected *cases* and *cases* conducted by the *Veterinary Services*~~, taking into account the following:~~ in order to confirm ~~the~~ *case*~~s~~ and to acquire accurate knowledge of the situation for further action.

   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;~~

   - ~~all suspected *case* investigations should provide a result, either positive or negative. Criteria should be 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 a~~n~~ disease, infection or infestation

~~This article provides general principles for declaring freedom from an *infection* or *infestation*, including for the recognition of historical freedom.~~

1. Demonstration of freedom

   A *surveillance* system to demonstrate freedom from a~~n~~ disease, *infection* and *infestation* should meet the following, in addition to the general principles outlined in Article 1.4.3. It should also take into account any prevention measures in place such as *vaccination* in accordance with this chapter and Chapter 4.17.

   Freedom implies the absence of ~~the pathogenic agent~~ *infection* or *infestation* in an animal *population* in the

country, *zone* or *compartment*. Scientific methods cannot provide absolute certainty of this absence. Therefore, demonstrating freedom, except for historical freedom, 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 *population*.

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 chapters of the *Terrestrial Code*.

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. The ~~implications~~ consequences ~~for the status of domestic *animals* of when~~ of the presence of *infection* or *infestation* ~~is present~~ in *wildlife* in the same country or *zone* on the status of domestic *animals* should be assessed in each situation, as ~~indicated~~ described in the relevant chapters of the *Terrestrial Code*.

EU comment

In the paragraph above, the EU requests replacing the word "prove" with "demonstrate". Indeed, it is probably impossible to prove the absence of infection or infestation in a population, as there will never be 100% certainty about this. The term "demonstrate" on the other hand is commonly used in the Code in that context.

Evidence from probability ~~based~~ and non-probability 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 chapters 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: in particular, the importations or movements of *commodities* into the country or *zone* have been carried out in accordance with the relevant chapters of the *Terrestrial Code*;

~~*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~~;

ii) the pathogenic agent is likely to produce identifiable clinical or pathological signs in susceptible animals;

iii) for at least 25 years there has been no occurrence of *infection* or *infestation* ~~or eradication has been achieved for the same length of time~~.

c) Where historical freedom cannot be ~~achieved~~ demonstrated:

~~*i)* the prerequisites listed in a) are have been complied with for at least as long as the *surveillance* has been in place;~~

~~i~~) a pathogen-specific *surveillance* programme 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*~~.~~;

ii) the prerequisites listed in point *a)* have been complied with for at least as long as the pathogen-specific *surveillance* has been in place.

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

~~*a)* The prerequisites listed in points 2 *a)i)* to *iiiv)* are complied with for at least as long as the *surveillance* has been in place;~~

~~b~~a) ~~ongoing~~ a pathogen-specific *surveillance* programme has been applied as described in this chapter and in the relevant chapter of the *Terrestrial Code*~~, if they it exists~~s, and has not detected any occurrence of the *infection* or *infestation*~~.~~;

b) the prerequisites listed in points 2 *a)i)* to *iii)* have been complied with for at least as long as the pathogen-specific *surveillance* has been in place.

4. Recommendations for the maintenance of freedom from a disease, 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;~~

e~~f~~) the *infection* or *infestation* is not known to be established in *wildlife*. ~~It can be difficult to collect sufficient epidemiological data to prove absence of *infection* or *infestation* in *wild animal populations*. In such circumstances, a range of supporting evidence should be used to make this assessment.~~

Article 1.4.7.

Surveillance ~~considerations~~ in support of disease control programmes

Surveillance is an important component in disease control programmes and can be used to determine the distribution and occurrence of *infection* or *infestation* or of other relevant health-related events. It can be used to assess progress and aid in decision-making in the control or eradication of selected *infections* or *infestations*.

Surveillance used to assess progress in control or eradication of selected *infections* or *infestations* should be designed to collect data about a number of variables such as:

1) prevalence or incidence of *infection* or *infestation*;
2) morbidity and mortality;
3) frequency of *risk* factors and their quantification;
4) frequency distribution of results of the laboratory tests;
5) post-vaccination monitoring results;
6) frequency distribution of *infection* or *infestation* in *wildlife*.

The spatial and temporal distribution of these variables and other data such as *wildlife*, public health and environmental data as described in point 8~~10~~) of Article 1.4.4. can be useful in the assessment of disease control programmes.

~~Article 1.4.8.~~

~~**Early warning systems**~~

~~An *early warning system* is essential for the timely detection, identification and reporting of occurrence, incursion or emergence of *infections* or *infestations*, and should include the following:~~

~~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 *Veterinary Authority* and relevant stakeholders;~~

~~7) a national chain of command.~~

~~*Early warning systems* are an essential component of emergency preparedness.~~

~~Article 1.4.9.~~

~~**Combination and interpretation of surveillance results**~~

~~Depending on the objective of *surveillance*, the combination of multiple sources of data may provide an indication of the overall sensitivity of the system and may increase the confidence in the results. The methodology used to combine the evidence from multiple data sources should be scientifically valid, and fully documented, including references to published material.~~

~~*Surveillance* information gathered from the same country, *zone* or *compartment* at different times may provide cumulative evidence of *animal health status*. Repeated surveys may be analysed to provide a cumulative level of confidence. However, the combination of data collected over time from multiple sources may be able to achieve an equivalent level of confidence.~~

~~Analysis of *surveillance* information gathered intermittently or continuously over time should, where possible, incorporate the time of collection of the information to take the decreased value of older information into account. The sensitivity and specificity of tests used and completeness of data from each source should also be taken into account for the final overall confidence level estimation.~~

~~In assessing the efficiency of the *surveillance* system based on multiple sources, the *Veterinary Authority* should consider the relative contribution of each component to the overall sensitivity, while considering the primary objective of each *surveillance* component.~~

~~Results from *animal* health *surveillance* systems are subject to one or more potential biases. When assessing the results, care should be taken to identify potential biases that can inadvertently lead to an over-estimate or an under-estimate of the parameters of interest.~~

Annex 5

SECTION 4.

~~GENERAL RECOMMENDATIONS:~~ DISEASE PREVENTION AND CONTROL

CHAPTER 4.Z.

INTRODUCTION TO RECOMMENDATIONS FOR THE ~~DISEASE~~ PREVENTION AND CONTROL OF TRANSMISSIBLE ANIMAL DISEASES

EU position

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

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 and training to secure *veterinarians* and *veterinary paraprofessionals*;
– close links with research institutions;
– effective awareness of, and active cooperation with, private stakeholders;
– public-private partnerships;
– cooperation between *Veterinary Authorities* and other *Competent Authorities*;
– regional cooperation among *Veterinary Authorities* on transboundary animal diseases.

Annex 6

CHAPTER 6.2.

THE ROLE OF THE VETERINARY SERVICES IN FOOD SAFETY SYSTEMS

EU position

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

[...]

Article 6.2.3.

Characteristics of a food safety system

1. Food chain approach

Food safety is best assured by an integrated, multidisciplinary approach that considers the entire food chain. A food safety system should take into account the complexity of food production and the globalisation of the food supply, and should be risk-based. It should consider *hazards* and potential associated *risks* at each stage of the food chain, i.e. primary production, transport, processing, storage and distribution, and integrate *risk management* responses to such *risks* at the most appropriate points along the food chain.

The prevention, detection, and control of foodborne *hazards* throughout the food chain is generally more effective in reducing or eliminating the *risk* of unwanted health effects than relying on controls of the final product. The application of traceability systems and sharing food chain information enhance the effectiveness of a food safety system. Everyone involved in the food chain, including food business operators, *Veterinary Services* and consumers, has a responsibility to ensure that food is safe.

2. Risk-based food safety systems

Risk-based food safety systems include measures based on good practices (such as good agricultural practice, good hygienic practice), hazard analysis and critical control points (HACCP) principles and *risk analysis*. The design and application of a risk-based food safety system depends on the availability of adequate scientific information and effective utilisation of the technical resources of food business operators and *Competent Authorities*.

Monitoring food safety outcomes and reviewing control measures are essential to ensure the effective performance of a risk-based food safety system. For example, providing information on the occurrence of *infections* on the farm prior to dispatch of animals for *slaughter* may allow more targeted, risk-based inspection at the *slaughterhouse/abattoir*.

3. Responsibilities of food business operators for food safety

Food business operators, including *feed* producers, farmers, processors, wholesalers, distributors, importers, exporters and retailers, have primary responsibility for ensuring the safety of their products and should be able to demonstrate that they comply with relevant food safety regulatory requirements. Food business operators have a responsibility to inform the *Competent Authority* in their country of any non-compliance associated with their product and take action to manage the *risk* e.g. the withdrawal of the product.

4. Responsibilities of the relevant Competent Authorities

Competent Authorities are responsible for developing policies, legislation and regulations relevant to food safety. They should also take steps to communicate these within their country and with trading partners.

Competent Authorities should ensure that roles and responsibilities for food safety systems, including responses to foodborne disease *outbreaks*, are addressed in a coordinated manner.

Annex 6 (contd)

The relevant *Competent Authorities* should verify that the control systems used by food business operators are appropriate, validated and effective, and operated in such a way that the regulatory requirements are met. This can be achieved through activities such as inspection and audit. In the event of noncompliance, appropriate corrective actions and sanctions should be applied.

If the *Competent Authority* delegates some control responsibilities to a third party, it should regularly assess ~~regularly~~ that third party's competency.

Article 6.2.4.

Roles and responsibilities of Veterinary Services in a food safety system

1. 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~~ Authorities or other *Competent Authorities* 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 animal origin important for public health ~~importance~~.

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~~ a part of the food chain, while in other cases the *Veterinary Services* may be responsible for the whole food chain.

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~~ *Veterinary Services* also play a key role in *biosecurity* and early detection, *surveillance* and treatment of animal diseases, including conditions of public health significance.

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*.

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 animal 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.

Annex 7

CHAPTER 7.1.

INTRODUCTION TO THE RECOMMENDATIONS FOR ANIMAL WELFARE

EU position

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

[...]

Article 7.1.4

Guiding principles for the use of measures to assess animal welfare

1) For the OIE animal welfare standards to be applicable globally, they should emphasise favourable outcomes for the animals, although, in some circumstances, it may be necessary to recommend specific conditions of the animals' environment and management. Outcomes are generally measured by assessing the extent to which animals experience the "five freedoms" described in Article 7.1.2.

2) For each principle listed in Article 7.1.5., the most relevant criteria (or measurables), ideally comprising animal-based measures, should be included in the standard. Any given animal-based measure may be linked to more than one principle.

3) Recommendations should, whenever possible, define explicit targets or thresholds that should be met for animal-based measures. Such target values should be based on relevant science and experience of experts.

4) In addition to animal-based measures, resource-based measures and management-based measures may be used and should be defined on the basis of science and expert experience showing that a welfare outcome is clearly linked to a resource or to a management procedure.

5) Users of the standard should select the most appropriate animal-based measures for their farming system or 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 data relevant ~~data that can be use~~ for the users to set target and threshold values.

6) Whatever the basis of the measure, if outcomes are unsatisfactory, users should consider what changes to resources or management are necessary to improve outcomes.

[...]

Annex 8

CHAPTER 7.13.

ANIMAL WELFARE AND PIG PRODUCTION SYSTEMS

EU position

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

1. Behaviour

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

Certain other 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.

[...]

Annex 9

CHAPTER 7.Y.

KILLING OF REPTILES FOR THEIR SKINS, MEAT AND OTHER PRODUCTS

EU position

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

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 loss of ~~un~~consciousness until the ~~animal~~ reptile 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 ~~animals~~ reptiles 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.~~5~~6. 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 ~~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.

There should be sufficient number of personnel, who should be trained, 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 all national jurisdictions legislation, including those of the importation and exportation countries 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.~~

~~4~~3. ~~Behaviour Behavioural c~~Considerations for handling, restraining, stunning and killing

Handling, restraining, stunning and *killing* methods should take into account the following ~~specific reptile behaviours~~ characteristics of reptiles ~~indicating fear, pain or distress, such as well as~~:

– ~~reptiles are sensitive to and will respond~~ sensitivity and responsiveness to visual, ~~and~~ tactile, auditory, olfactory 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;

– ability to ~~reptiles can~~ inflict significant injuries ~~bite wounds~~ to handlers, ~~and~~ via bite wounds, ~~frequently with~~ wound infection, constriction, blunt trauma or envenomation ~~are not uncommon~~;

– ~~low body temperatures may result in slow movements, torpor and~~ 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;

– propensity to regurgitate and choke when restrained inappropriately.

Annex 9 (contd)

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).

Reptiles should be accompanied by r~~R~~elevant documentation related to ~~the~~ their 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.4~~5~~.

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;

– the extent to which movement of the reptile can be restricted during the *killing* process;

– 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 a reptile, ~~animal~~ animals or humans;

– ability to maintain equipment in proper working order~~;~~.

~~– cost of the method.~~

The *killing* process used should:

– minimise ~~avoid excitement~~ agitation, fear, ~~and~~ stress~~,~~ and pain to the reptile~~s~~ ~~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 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

– when~~re~~ it includes a stunning step, ensure that *death* occurs during unconsciousness ~~kill the reptile while it is unconscious.~~

Annex 9 (contd)

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.~~5~~6.

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*.

As far as criteria to measure the effectiveness of stunning and *killing* methods are concerned and whilst multiple criteria are preferable for the verification ~~establishment~~ of unconsciousness or *death*, the presence of any of the following criteria should be regarded as sufficient to establish suspicion of consciousness:

– pupillary response to light or mov~~ement~~ting 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 in species where eyelids are present;

– spontaneous eyelid opening or closing in species where eyelids are present;

– 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.~~6~~7.

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.

Annex 9 (contd)

As far as recommendations for effective physical restraint in relation to *animal welfare* are concerned, 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~~ reptiles 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.~~7~~8.

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 reptile ~~animal~~ following unconsciousness, or may require an additional *killing* step.

If stunning is used, the method should:

– be appropriate for the species, size, age and health of the ~~animal~~ reptile;

– be reliable and reproducible;

– minimise ~~avoid~~ agitation, ~~excitement~~, ~~and~~ stress and pain to the ~~animal~~ reptile;

– avoid or minimise restraint in accordance with Article 7.Y.~~6~~7.;

– 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 and in accordance with the manufacturer's recommendations, in particular with regard to the species and size of the animal. The maintenance of the

equipment is the responsibility of the management of the facility, and should be under the supervision of the *Competent Authority* or accredited delegated body. If the primary method of stunning fails to produce unconsciousness as described in Article 7.Y.~~5~~6. and, in accordance with this article, a back-up stunning or *killing* method should be used immediately (Articles 7.Y.~~8~~9. to 7.Y.~~15.~~16.).

Animal-based criteria (or measurables): immediate onset of unconsciousness or *death* as described in Article 7.Y.~~5~~6.

Article 7.Y.~~8~~9.

Electrical stunning (for crocodilians only)

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

Recommendations for effective use of electrical stunning in relation to *animal welfare* are:

– 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 length of time of application of the current ~~stun duration~~ should be achieved. Duration may vary with size, age, weight, etc., within a species;

– ~~animals~~ reptiles should be killed in accordance to Articles 7.Y.~~9~~10. to 7.Y.~~15.~~16. 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 species, type ~~species~~ 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.~~5~~6.

Article 7.Y.~~9~~10.

Penetrative captive bolt

The aim of this method is to produce a state of unconsciousness and cause severe damage to the brain by the impact and penetration of a captive bolt using a mechanical device. The force of impact and the physical damage caused by the passage of the bolt should result in immediate unconsciousness and *death*. If *death* does not occur following the passage of the penetrative bolt, then an additional *killing* method in accordance with Articles 7.Y.~~9~~10. to 7.Y.16. should be used immediately to ensure *death*.

Recommendations for the effective use of a penetrative captive bolt in relation to *animal welfare* are:

– ~~animals~~ reptiles 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 species, size and type 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.~~6.

Article 7.Y.~~10~~11.

Non-penetrative captive bolt

The non-penetrative captive bolt method is sometimes called 'concussive stunning', although concussion is the underlying principle for both penetrative and non-penetrative methods. The concussion may result in both unconsciousness and *death*. If *death* does not occur following the application of the percussive blow, then an additional *killing* method in accordance with Articles 7.Y.~~9~~10. to 7.Y.16. should be used immediately to assure *death*.

Recommendations for an effective use of non-penetrative captive bolt in relation to *animal welfare* are:

– ~~animals~~ reptiles 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 the reptile;

– cartridge or compressed air specifications should be determined to deliver the correct bolt velocity;

– equipment and charge should be selected to suit the species, size and type of ~~animal~~ the reptile;

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

~~Outcome~~Animal-based criteria (or measurable): immediate onset of unconsciousness or *death* as described in Article 7.Y.~~5~~6.

Article 7.Y.~~11~~12.

Percussive blow to the head

A percussive blow to the head to induce cerebral concussion can be achieved manually. A concussive state is normally associated with a sudden loss of consciousness with associated loss of reflexes. Inducing unconsciousness requires the transfer of sufficient energy into the brain to disrupt normal neural function. If the severity of the blow is sufficient then it will result in the *death* of the animal. If *death* does not occur following the application of the percussive blow, then an additional *killing* method in accordance with Articles 7.Y.~~9~~10. to 7.Y.16. 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.

Annex 9 (contd)

Recommendations for effective use of percussive blow to the head in relation to *animal welfare* are:

– ~~animals~~ reptiles 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 species, size and type of ~~animal~~ the reptile.

Animal-based criteria (or measurables): immediate onset of unconsciousness or *death* as described in Article 7.Y.~~5~~6.

Article 7.Y.~~12~~13.

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 a~~n~~ 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~~10. to 7.Y.16. 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 of gunshot in relation to *animal welfare* are:

– accurate targeting of the brain should be ensured;

– select~~ed~~ firearm and projectile should be suitable for the species, size and type of ~~animal~~ the reptile;

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

Animal-based criteria (or measurables): immediate onset of unconsciousness or *death* as described in Article 7.Y.~~5~~6.

Article 7.Y.~~13~~14.

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 ~~to ensure thorough 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 of pithing in relation to *animal welfare* are:

– pithing 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.~~5~~6.

Article 7.Y.~~14~~15.

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 of decapitation or spinal cord severance in relation to *animal welfare* are:

– decapitation or spinal cord severance should only be used on unconscious ~~animal~~ reptiles;

– decapitation or spinal cord severance should always be followed immediately by physical intervention to destroy the brain, i.e. immediate crushing of the brain or pithing.

Animal-based criteria (or measurables): confirmation of *death* as described in Article 7.Y.~~5~~6.

Article 7.Y.~~15~~16.

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.~~9~~10. to 7.Y.16. 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 of chemical agents in relation to *animal welfare* are:

– ensure proper physical restraint is used for administration;

– ensure chemicals and dos~~ag~~es used are appropriate for the species and size of ~~animal~~ the reptile~~s~~;

– 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.~~5~~6.

Article 7.Y.~~16~~17.

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 Article~~s~~ 7.Y.~~9~~10. to Article 7.Y.16., ~~are~~ is 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 (CO_2), carbon monoxide (CO) or nitrogen (N_2),

– use of ~~paralysing~~ neuro-muscular blocking ~~paralytic agent~~ drugs,

– cervical dislocation.

Annex 9 (contd)

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Annex 10

CHAPTER 8.14.

INFECTION WITH RABIES VIRUS

EU position

The EU thanks the OIE for having taken many of its previous comments into account. The EU can support most of the changes proposed to the chapter, except for those proposed in Article 8.14.6. An important comment is inserted in the text of that article, that should be taken into account before adoption.

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. Populations of the orders Carnivora and Chiroptera are considered to be the main reservoir hosts.

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 ~~*L*~~*Lyssavirus* species can cause clinical signs similar to those caused by rabies virus, but have more restricted geographical and host range, with the majority having been isolated only from bats, ~~with~~ thus having limited public and animal health implications.

The aim of this chapter is to mitigate the *risk* ~~of *infection* with rabies virus~~ to the public and animal health posed by *infection* with rabies virus 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 ten 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 haematophagous bat-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*:

~~1)~~ ~~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~~;

– dog-mediated rabies is defined as any ~~*infection* with~~ *case* caused by rabies virus maintained in the dog population *(Canis lupus familiaris)* independently of other animal reservoir species, as determined by epidemiological studies;

– 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 8.14.2~~3~~.

~~**Rabies free** **C**~~**Country or zone free from infection with rabies virus**

1) A country or *zone* may be considered free from *infection* with rabies virus when:

a~~1~~) it has a record of regular and prompt animal disease reporting in accordance with Chapter 1.1.;

b) ~~the disease~~ *infection* with rabies virus is a *notifiable disease* in the entire country and any change in the epidemiological situation or relevant events are reported in accordance with Chapter 1.1.;

~~*b*~~*c*) all susceptible animals showing clinical signs suggestive of rabies are subjected to appropriate field and laboratory investigations;

~~*c*~~2*d*) an ongoing system of ~~*disease*~~ *surveillance* in accordance with Chapter 1.4. and Article 8.14.9. has been in ~~operation~~ place for the past ~~two years~~ 24 months, with a minimum requirement being an ~~ongoing~~ early warning system ~~detection programme~~ to ensure investigation and reporting of animals suspected of being infected~~rabies suspect animals~~;

~~*d*~~3*e*) regulatory measures for the prevention of *infection* with rabies virus are implemented ~~consistent~~ in accordance with the relevant recommendations in the *Terrestrial Code* including Articles 8.14.4. to 8.14.7.~~, including for the importation of animal~~;

~~e~~4*f)* no *case* of indigenously acquired *infection* with rabies virus ~~*infection*~~ 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~~g*)* if an imported *case* is confirmed outside a *quarantine station*, epidemological investigations have ruled out the possibility of secondary *cases*.

2) 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 8.14.2.-bis

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 8.14.2.-ter

Country or zone free from dog-mediated rabies

1) A country or *zone* may be considered free from dog-mediated rabies when:

a) it has a record of regular and prompt animal disease reporting in accordance with Chapter 1.1.;

b) dog-mediated rabies is a *notifiable disease* in the entire country and any change in the epidemiological situation or relevant events are reported in accordance with Chapter 1.1.;

~~b~~c*)* an ongoing system of *surveillance* 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 early warning system to ensure ~~control,~~ investigation and reporting of animals suspected of *infection* with rabies virus;

~~c~~d*)* regulatory measures for the prevention of *infection* with rabies virus are implemented in accordance with the relevant recommendations in the *Terrestrial Code* ~~and~~ including Articles 8.14.~~9~~4. to 8.14.7.;

~~d~~e*)* no *case* of indigenously acquired dog-mediated rabies has occurred during the past 24 months;

~~e~~f*)* 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 *wild~~life~~ animals*;

– imported human cases of rabies~~.~~;

~~–~~ imported *case* outside a *quarantine station* whenever epidemological investigations have ruled out the possibility of secondary *cases*.

Article 8.14.3~~4~~.

Recommendations for importation of domestic and captive wild mammals from countries or zones free from infection with rabies virus ~~free countries~~

Annex 10 (contd)

~~For domestic mammals, and captive 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) 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 8.14.5~~6~~., 8.14.6~~7~~., or 8.14.7~~8~~.~~ or 8.14.9.~~

Article 8.14.4~~5~~.

Recommendations for importation of wild and feral mammals from ~~rabies free~~ countries 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 8.14.5~~6~~.

Recommendations for importation of dogs, cats and ferrets from countries or zones ~~considered~~ infected with rabies 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~~ and were subjected not less than ~~1~~ ~~3~~ ~~one~~ 3 month~~s~~s and not more than 12 months ~~prior to shipment~~ ~~after the last *vaccination*~~ prior to 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~~ shipment.

Annex 10 (contd)

Article 8.14.6~~7~~.

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

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*;~~

2~~3~~) ~~either~~ ~~EITHER~~ either

~~a)~~*a)* 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~~ OR for mammals for which vaccines and protocols are applicable:

~~*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*.~~;

b) were vaccinated or revaccinated in accordance with the recommendations of the manufacturer, with a vaccine that was produced in accordance with the *Terrestrial Manual*.

~~3) if domestic animals, were permanently identified and the identification number stated in the *certificate*.~~

EU comment

The EU cannot support the changes in the article above as proposed. As already indicated in our comments submitted on a previous version of this article (in July 2018, https://ec.europa.eu/food/sites/food/files/safety/docs/ia_standards_oie_eu_comments_tahsc-report_201807.pdf, p. 44), in case of vaccination of certain mammals (e.g. carnivores), further guarantees would seem to be necessary (at the very least, permanent identification of vaccinated domestic animals and a waiting period of 3 months after vaccination prior to shipment, for the same reasons and similar to the provisions for dogs, cats and ferrets).

Furthermore, we note that contrary to the intention of reverting to the current text of Article 8.14.7. as indicated in the report of the Code Commission, the text diverts from the current provisions in that e.g. it does not require permanent identification for domestic animals.

As we believe that the difficulties with this article mainly stem from the fact that existing recommendations for domestic and wild animals have been merged into a single article now comprising all mammals, and in order to avoid delaying the adoption of this revised chapter unnecessarily, the EU requests that both the current Article 8.14.7. (domestic ruminants, equids, camelids and suids) and Article 8.14.9. (wildlife) be reinstated for the time being.

A critical revision of these recommendations, including on whether such recommendations are necessary at all in the Code and for which categories of animals, could thus be postponed to a later stage after the adoption of the revised chapter.

Article 8.14.7~~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 prior to or on the day of shipment;

2) were born and kept since birth in a biosecure facility as described in the *Terrestrial Manual* ~~C~~chapter ~~1.1.1~~ on Management of veterinary diagnostic laboratories, and where there has been no *case* ~~of rabies~~ 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 dog-mediated 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) submit documented evidence (including relevant legislation) of ~~the~~ its capacity ~~of the *Veterinary Services*~~ to control dog-mediated rabies. This evidence may be provided using data generated by the OIE PVS Pathway;

3) submit a detailed plan of the programme to control and eventually eradicate dog-mediated rabies in the country ~~or *zone*~~ including:

   a) the timeline;

   b) the performance indicators for assessing the effectiveness of the control measures to be implemented;

   c) 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;

4) submit a dossier on dog-mediated rabies in the country describing the following:

   a) the general epidemiology in the country highlighting the current knowledge and gaps in knowledge and the progress that has been made in controlling dog-mediated rabies;

   b) the measures implemented to prevent introduction of *infection*;

   bbis) 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;

   c) dog population ~~management including *stray dog*~~ control programme in accordance with Chapter 7.7.;

   d) collaboration agreements or programmes with other *Competent Authorities* such as those responsible 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:

a) evidence (such as copies of legislation) that *vaccination* of selected populations is compulsory and the vaccines are produced in accordance with the *Terrestrial Manual*;

b) detailed information on *vaccination* campaigns, in particular on:

i) target *populations*;

ii) monitoring of *vaccination* coverage;

iii) 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~~ quality of the *Veterinary Services* as per Section 3 of the *Terrestrial Code*; 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.~~

Article 8.14.9.

~~**General principles of s**~~**Surveillance**

1) 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 ten 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*;

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

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

Rabies *surveillance* provides data that are indicators of the effectiveness of a rabies control programme and of the maintenance of freedom ~~of~~ from *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*.

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

c) Sampling

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

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.

~~*e)*~~ 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.

In all regions, *Veterinary Authorities* of neighbouring countries should cooperate in the control of dog-mediated rabies.

Annex 11

CHAPTER 14.4.

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

EU position

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

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*.

[...]

Annex 12

CHAPTER 1.3.

DISEASES, INFECTIONS AND INFESTATIONS LISTED BY THE OIE

EU position

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

[...]

Article 1.3.3.

The following are included within the category of sheep and goat diseases and *infections*:

– Caprine arthritis/encephalitis
– Contagious agalactia
– Contagious caprine pleuropneumonia
– Infection with ~~*Chlamydophila*~~ *Chlamydia abortus* (Enzootic abortion of ewes, ovine chlamydiosis)
– Infection with peste des petits ruminants virus
– Maedi–visna
– Nairobi sheep disease
– Ovine epididymitis *(Brucella ovis)*
– Salmonellosis (*S.* abortusovis)
– Scrapie
– Sheep pox and goat pox.

[...]

Annex 13

CHAPTER 15.1.

INFECTION WITH AFRICAN SWINE FEVER VIRUS

EU position

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

[...]

Article 15.1.1.-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*:

1) ~~canned~~ *meat* in a hermetically sealed container with a F~~0~~-value of 3~~.00~~ or ~~more~~ above;

2) gelatine.

Other ~~pig~~ *commodities* ~~of pigs should~~ of suids 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

1) ASF is a *notifiable disease* in the entire country, and all suids showing clinical signs or pathological lesions suggestive of ASF are subjected to appropriate field and *laboratory* investigations;

2) an ongoing awareness programme is in place to encourage reporting of all suids showing clinical signs or pathological lesions suggestive of ASF;

3) the *Veterinary Authority* has current knowledge of, and authority over, all domestic and *captive wild* pig *herds* in the country, *zone* or *compartment*;

4) the *Veterinary Authority* has current knowledge of the species of *wild* and *feral* pigs and African *wild* suids present, their distribution and habitat in the country or *zone*;

5) for domestic and *captive wild* pigs, an appropriate *surveillance* programme in accordance with Articles15.1.27. to 15.1.30. and 15.1.32. is in place;

6) for *wild* and *feral* pigs, and for African *wild* suids, if present in the country or *zone*, a *surveillance* programme is in place in accordance with Article 15.1.31., considering the presence of natural and artificial boundaries, the ecology of the *wild* and *feral* pig and African *wild* suid populations and an assessment of the likelihood of ASF spread including taking into account the presence of *Ornithodoros* ticks where relevant;

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

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

Annex 13 (contd)

Article 15.1.3.

Country or zone free from ASF

1. Historical freedom

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

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 in all suids 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;

b) there has been no *case* of *infection* with ASFV during the past three years; this period can be reduced to 12 months when the *surveillance* has demonstrated no evidence of presence or involvement of *Ornithodoros* ticks;

c) pig *commodities* of suids are imported in accordance with the relevant Aarticles 15.1.7. to 15.1.20 of this chapter.

3. Freedom in domestic and captive wild pigs

A country or *zone* which does not meet the conditions of point 1) or of point 2) b) above, including i.e. when there are *cases* of *infection* with ASFV in *feral* or *wild* pigs suids, 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:

a) *surveillance* in accordance with Articles 15.1.27. to 15.1.32. has been in place for the past three years;

b) 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;

c) pigs and pig *commodities* of suids are imported in accordance with the relevant Aarticles 15.1.7. to 15.1.20 of this chapter.

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 *feral* pigs or African *wild* suids.

[...]

Article 15.1.16.

Recommendations for the importation of meat products of pigs

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

1) have been prepared:

a) exclusively from *fresh meat* meeting the relevant conditions in Articles 15.1.13., 15.1.14. and 15.1.15.;

b) in a processing facility:

i) approved by the *Veterinary Authority* for export purposes;

ii) processing only *meat* meeting the relevant conditions in Articles 15.1.13., ~~or Article~~ 15.1.14. and 15.1.15.;

OR

2) have been processed in a facility approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of ASFV in accordance with Article 15.1.22., and that the necessary precautions were taken after processing to avoid contact of the product with any source of ASFV.

[...]

Article 15.1.22.

Procedures for the inactivation of ASFV in meat

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

1. Heat treatment

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

~~*a)* heat treatment in a hermetically sealed container with a F0 value of 3.00 or more; or~~

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

b) any equivalent heat treatment which has been demonstrated to inactivate ASFV in *meat*.

2. Dry cured pig meat

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

[...]

Article 15.1.31.

Surveillance for ASFV in wild and feral pigs and African wild suids

1) The objective of a *surveillance* programme is either to demonstrate that *infection* with ASFV is not present in *wild* and *feral* suids or, if known to be present, to estimate the geographical distribution of the *infection*.

Surveillance in *wild* and *feral* suids presents additional challenges including:

a) determination of the distribution, size and movement patterns of the *wild* and *feral* suid population;

b) relevance and practicality of assessing the possible presence of *infection* with ASFV in the population;

c) determination of the practicability of establishing a *zone* taking into account the degree of interaction with domestic and *captive wild* pigs within the proposed *zone*.

The geographic distribution and estimated size of *wild* and *feral* suid populations should be assessed as a prerequisite for designing a population monitoring system following Chapter 1.4.

Annex 13 (contd)

2) For implementation of the *surveillance* programme, the limits of the area over which *wild* and *feral* pigs range should be defined. *Subpopulations* of *wild* and *feral* suids may be separated from each other by natural or artificial barriers.

3) The *surveillance* programme ~~may~~ should include animals found dead, road kills, animals showing abnormal behaviour and hunted animals, and ~~may~~ should also include awareness campaigns targeted at hunters and farmers.

4) There may be situations where a more targeted *surveillance* programme can provide additional assurance. The criteria to define high risk areas for targeted *surveillance* include:

a) areas with past history of ASF;

b) subregions with large populations of *wild* or *feral* pigs or African *wild* suids;

c) border regions with ASF affected countries or *zones*;

d) interface between *wild* and *feral* pig populations, and domestic and *captive wild* pig populations;

e) areas with farms with free-ranging and outdoor pigs;

f) areas with a high level of hunting activity, where animal dispersion and feeding as well as inappropriate disposal of waste can occur;

g) other risk areas determined by the *Veterinary Authority* such as ports, airports, garbage dumps and picnic and camping areas.

[...]

Annex 25 (contd)

WORK PROGRAMME FOR
THE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

EU comment

The EU thanks the OIE for having taken into account or addressed many of its previous comments and in general supports the future work programme of the Code Commission.

In particular, we would like to reiterate our appreciation for the work undertaken and the high priority assigned by the OIE to the revision of the Code chapters on BSE and Avian Influenza. We very much look forward to receiving draft revised chapters after the September 2019 meeting of the code Commission and hope that these important texts will be ready for adoption as soon as possible, and more particularly we hope that the revised chapter on avian influenza will be ready for adoption in May 2020.

The EU also looks forward to work on new glossary definitions for the terms animal products, products of animal origin and animal by-products, as these are long-standing issues that merit attention.

Finally, the EU thanks the OIE for having added a revision of the Code chapter on Responsible and prudent use of antimicrobial agents in veterinary medicine to its work program. Given the high importance of this topic and the current momentum at international level, we encourage the OIE to expedite the work on that chapter. We thus very much look forward to receiving a first draft revised chapter for member comments. We are ready to provide expertise and technical support if required for the relevant OIE expert group.

Subject	Issue by priority order	Status and Action (Onset of process / # of rounds for comments now)
Horizontal chapters		
Restructuring of the *Code*	1) Work with AAHSC towards harmonisation, as appropriate, of the horizontal parts of the *Codes,* notably Glossary, User's Guide, Section 4 on Disease prevention and control and Section 5 on Trade measures, import/export procedures and veterinary certification	Ongoing
	2) Work with BSC for accurate disease description and diagnostic in the *Manual* and case definitions in the *Code* and names of diseases and country and zone disease status	Ongoing
	3) Revision and formatting of chapters (articles numbering, tables and figures)	Ongoing
	4) Revision of the Users' guide	Ongoing
Glossary	1) 'early warning system' and 'sanitary measures'	Revised definitions proposed for adoption (Sep 2017/4th and Feb 2018/3rd, respectively)

Subject	Issue by priority order	Status and Action (Onset of process / # of rounds for comments now)
	2) 'epidemiological unit'	Revised definitions sent for comments (Sep 2018/2nd)
	3) 'Competent Authority', 'Veterinary Authority'. 'Veterinary Services' and 'captive wild [animal]'	'CA', 'VA' and 'VA': the comments sent to AHG (Sep 2018/1st) 'captive wild [animal]':the comments sent to wildlife WG (Sep 2018/1st)
	4) New definitions for 'animal product', 'product of animal origin' and 'animal by-product'	Preliminary discussion
	5) Review the terms 'notify', 'notifiable disease', 'report' and 'reportable disease'	Preliminary discussion
Horizontal issues not yet in the *Code*		
Section 4. Disease control	1) New CH on official control programmes for listed and emerging diseases	Revised new CH proposed for adoption (Feb 2017/5th)
	2) New introductory CH in Section 4	Revised new CH proposed for adoption (Sep 2017/4th)
	3) New CH on biosecurity (Discussion with AAHSC)	Preliminary discussion
	4) New CH on application of zoning	Preliminary discussion
Section 6. Veterinary public health	1) Control of Shiga toxin-producing *E. coli* (STEC) in food-producing animals	Preliminary discussion pending FAO/WHO expert consultation
Section 7. Animal welfare	1) New CH on slaughter and killing methods of farmed reptiles	Revised new CH proposed for adoption (Sep 2017/4th)
	2) New CH on AW and laying hen production systems	The comments sent to AHG (Sep 2017/2nd)
Horizontal chapters in need of revision		
Section 1. Animal disease diagnosis, surveillance and notification	1) CH 1.4. on animal health surveillance (MCs comments and implications for status recognition)	Revised CH proposed for adoption (Feb 2016/5th)
	2) CH 1.6. on procedures for publication of a self-declaration of disease freedom, recognition of an official animal health status and endorsement of an official control programme by the OIE	Revised CH sent for comments (Feb 2018/3rd)
	3) CH 1.1. on notification of diseases	Revised CH sent for comments (Sep 2018/2nd)
	4) CH 1.3. on listed diseases: assess CWD, WNF, PED, *Theileria* spp., *M. paratuberculosis*, Trypanosoma spp., MERS-Cov, against the listing criteria	Pending expert 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 2018/2nd)

Subject	Issue by priority order	Status and Action (Onset of process / # of rounds for comments now)
	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	Preliminary discussion
	2) CH 4.6. on collection and processing of semen	Pending expert advice
	3) CH 4.5. on general hygiene in semen collection and processing centres	Pending expert advice
	4) CH 4.8. on collection and processing of oocytes and *in vitro* produced embryos from livestock and horses	Preliminary discussion
	5) CH 4.7. on collection and processing of *in vivo* derived embryos	Pending expert advice
Section 5. Trade measures	1) CHs 5.4. to 5.7. on measures applicable at departure and on arrival	Preliminary discussion and pending decision on AHG
	2) CH 5.12. on model certificates for competition horses	Preliminary discussion and pending revision of CHs on horse diseases
Section 6. Veterinary public health	1) CH 6.3. on meat inspection	Preliminary discussion pending AHG
	2) CH 6.10. on responsible and prudent use of antimicrobial agents in veterinary medicine	Pending expert advice
Section 7. Animal welfare	1) CH 7.5. on slaughter and CH 7.6. on killing of animals	Pending further work of AHG
	2) CH 7.7. on stray dog population control	Preliminary work of AHG
Diseases not yet in the *Code*		
Disease-specific chapters	1) New CH on surra and revision of CH on Dourine	Pending expert advice
	2) New CH on animal trypanosomoses of African origin	Pending further work of AHG
	3) New CH on Crimean Congo hemorrhagic fever (MCs comments, listed disease without chapter)	Preliminary discussion
Listed disease chapters/articles in need of revision		
Sections 8 to 15	1) CH 10.4. on avian influenza	Some of the comments sent to AHG (Sep 2018/1st)
	2) CH 8.14. on rabies	Revised CH proposed for adoption (Feb 2018/3rd)
	3) CH 11.4. on BSE	Pending work of AHGs (Feb 2015/1st)
	4) CH 15.2. on CSF	The comments to be addressed (Feb 2017/2nd)

Subject	Issue by priority order	Status and Action (Onset of process / # of rounds for comments now)
	5) Revision of Articles 8.15.1., 8.15.4. and 8.15.5. (Infection with Rift Valley fever virus)	Revised CH sent for comments (Feb 2019/1st)
	6) CH 8.16. on rinderpest	Pending work of HQs and JAC
	7) Harmonisation of articles regarding official status recognition by the OIE	Pending work of HQs
	8) Revision of safe commodities list to add lactose	Pending expert advice
	9) CH 12.2. on Contagious equine metritis and CH12.7. on Equine piroplasmosis	Pending work of HQs
	10) CH 11.12. on Theileriosis and new CH 14.X. on infection with *Theileria* in small ruminants	Revised/new CHs sent for expert advice on listing pathogenic agents (Sep 2017/1st)
	11) CH 8.8. on FMD	Pending outcome of discussion on zoning (Sep 2015/2nd)
	12) Revision of Article 15.3.9. on import of semen from countries not free from PRRS	Pending expert advice
	13) CH 14.8. on scrapie	Pending expert opinion
	14) CH 10.5. on avian mycoplasmosis	Pending expert opinion
	15) Pet food (for certification or safe commodities)	Pending expert advice

Subject	Issue by priority order	Status and Action (Onset of process / # of rounds for comments now)
Follow-up revision of chapters recently adopted		
Recently adopted chapters	1) Articles 15.1.1bis., 15.1.2., 15.1.3., 15.1.16., 15.1.22. and 15.1.31 on ASF	Revised CH proposed for adoption (Sep 2017/4th)
	2) CH 4.3. on zoning and compartmentalisation	Pending discussion on temporary protection zone
	3) CH 6.2. on the role of Veterinary Services in food safety systems	Revised CH proposed for adoption (Sep 2018/2nd)
	4) Article 7.1.4. on the guiding principles for the use of measures to assess animal welfare	Revised article proposed for adoption (Sep 2018/2nd)
	5) CH 7.13. on animal welfare and pig production systems	Revised article proposed for adoption (Sep 2018/2nd)

List of abbreviations	
AAHSC	Aquatic Animal Health Standards Commission
AHG	*ad hoc* Group

AMR	Antimicrobial resistance
ASF	African swine fever
AW	Animal Welfare
BSC	Biological Standards Commission
BSE	Bovine Spongiform Encephalopathy
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
MERS-CoV	Middle East Respiratory Syndrome Coronavirus
NGO	Non-Governmental Organisation
PVS	Performance of Veterinary Service
TAHSC	Terrestrial Animal Health Standards Commission
WNF	West Nile fever