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Work programme – Australian comments

Glossary

- As noted in our comments on Annex 15 we feel the definitions for 'Competent Authority', 'Veterinary Authority', 'Veterinary Services' currently in the Code are more appropriate than any that have been proposed

Section 4 3)

- We support the development of this new chapter on the application of zoning

Diseases not yet in the Code

- We support the review of some of these diseases against the listing criteria.
- Those that meet the criteria should have a code chapter so we support the progression of this work

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Australian Comments – indicated in blue font

DRAFT CHAPTER 3.1.

QUALITY OF VETERINARY SERVICES

General comment: Reference articles throughout text should be reviewed and corrected where necessary at completion of the comment process. Correct article referencing is obligatory to understanding and application of this chapter.

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Australian Comments – indicated in blue font

DRAFT CHAPTER 3.2.

EVALUATION OF VETERINARY SERVICES

Article 3.2.4.

Evaluation of the Veterinary Services of a Member Country by another Member Country

1) Every Member Country should recognise the right of another Member Country to request, in a non-discriminatory manner, an evaluation of its *Veterinary Services* to facilitate decision-making on trade.

2) The evaluation should be in accordance with Chapter 3.1.

3) The evaluation process may be desktop or field based, and cover whole or part of the *Veterinary Services,* depending on its objective.

4) A Member Country which intends to conduct an evaluation of another Member Country's *Veterinary Services* should give them notice in writing. This should define the purpose and scope of the evaluation and detail the information required.

5) Prior to the evaluation, the parties should agree on the objective, scope and approach of the evaluation, including any financing and confidentiality requirements ~~of confidentiality~~.

6) The evaluation should be conducted in accordance with the Fundamental Operating Principles set-out for *Veterinary Services* in Article 3.~~2~~1.2 in a timely and efficient manner, ensuring the level of evaluation activity is undertaken only to the extent necessary.

Rationale: Correction of relevant article reference from Article 3.2.2 to Article 3.1.2.

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DRAFT CHAPTER 3.X.

INTRODUCTION TO RECOMMENDATIONS ON VETERINARY SERVICES

General comment: Comments on this chapter are impacted by the glossary definitions for Competent Authority, Veterinary Authority and Veterinary Services therefore until the definitions are finalised or a decision made to retain the current definitions this chapter should not be adopted.

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Australian Comments – indicated in blue font

DRAFT CHAPTER 7.Z.

ANIMAL WELFARE AND LAYING HEN PRODUCTION SYSTEMS

General comment:

Changes made throughout continuing the change to 'layer pullets' and 'laying hens' where appropriate

Article 7.Z.2.

Scope

This chapter provides recommendations for the *animal welfare* aspects of commercial laying hen production systems. It covers the production period from the arrival of *day-old* ~~*birds*~~ layer pullets onto the layer pullet-rearing farm through to the removal of end-of-lay hens from the laying production facilities. Layer pullet and ~~L~~laying hens kept in village or backyard flocks and used to produce eggs for personal consumption are not included.

Commercial laying hen production systems involve the confinement of layer pullets and laying hens, the application of *biosecurity* and trade in eggs or layer pullets.

Article 7.Z.3.

Outcome-based criteria (or measurables) for the welfare of layer pullets and laying hens

The welfare of layer pullets and laying hens should be assessed using outcome-based criteria or measurables, preferably animal-based measurables, as described in Article 7.1.4. Outcome-based criteria or measurables are particularly useful for evaluating compliance and improving *animal welfare*. Animal-based outcomes are usually the most sensitive measurables ~~(e.g. mortality rate)~~. However, resource and management-based outcomes can also have important applications ~~(e.g.~~ for example, interpretation of mortality rate data may be informed by decisions made to euthanise~~)~~. There is no one single measurable that addresses all aspects of *animal welfare*. The use of measurables and the appropriate thresholds should be adapted to the different situations in which layer pullets and laying hens are kept, also taking into account the genetics used, resources provided, and the design and management of the system. Animal-based criteria or measurables can be considered as tools to monitor and refine these factors.

Criteria (or measurables) that can be used at farm level include conditions such as skeletal and foot problems, disease and *infection* or *infestation* that can be assessed during routine or targeted *monitoring*, or at depopulation. It is recommended that target values or thresholds for *animal welfare* measurables be determined by taking into account current scientific knowledge and appropriate national, sectorial or regional data and recommendations for layer pullets or laying hens. Determining the age and stage of production at which problems are detected may help to determine the cause.

The following animal-based and outcome-based measurables, in alphabetical order in English, may be useful indicators of layer pullet or laying hen welfare:

…

2. Behaviour

The presence or absence of certain behaviours may indicate either good *animal welfare* or an *animal welfare* problem, such as fear, pain or sickness. Some behaviours may not be uniquely indicative of one type of problem; they may be exhibited for a variety of reasons. *Gallus gallus domesticus* has evolved behaviours that it is motivated to perform, and a good understanding of layer pullet and laying hens normal behaviour [Nicol, 2015], including its social interactions [Estevez *et al.*, 2007; Rodríguez-Aurrekoetxea A. and Estevez I., 2014], is required for appropriate management and decision-making. Opportunities to display these behaviours are influenced by the physical and social environment [Widowski *et al.*, 2016; Lay *et al*, 2011; O'Connor *et al*, 2011].

…

b) Fear behaviour

Fearful layer pullets and laying hens show high reactivity to various stimuli [Jones, 1987; Zeltner and Hirt, 2008] and this may result in traumatic injuries or suffocation if the layer pullets or laying hens pile on top of one another. Fearful layer pullets and laying hens may be less productive [Barnett *et al.*, 1992] and more prone to injurious feather pecking behaviour [de Haas *et al.*, 2014]. Methods have been developed for evaluating fearfulness [Forkman *et al.*, 2007], for example by observing layer pullet and laying hen behaviour in response to novel objects or when people, including *animal handlers,* walk through the layer pullet and laying hen areas of the poultry house [Jones, 1996; Waiblinger *et al.*, 2006].

c) Feeding and drinking behaviour

Changes in feeding or drinking behaviour may indicate management problems, including inadequate spaces for, or inappropriate placement of, feeders or drinkers, dietary imbalances, poor *feed* or water quality, or *feed* contamination [Garner *et al.*, 2012; Thogerson *et al.*, 2009a; Thogerson *et al.*, 2009b]. *Feed* and water intake is often reduced when layer pullets or laying hens are ill. *Feed* or water intake may also change as a result of heat stress [Lara ~~L. J.~~ & Rostagno, 2013; Lin H. *et al.*, 2006] or cold stress [Alves *et al.*, 2012]

h) Perching

Perching is a motivated behaviour. Layer pullets and laying hens may seek elevation during the day; however, the motivation to seek elevation is particularly strong at night when layer pullets and laying hens select a site for resting or sleeping [EFSA, 2015]. Reduced perching behaviour in the *flock* may indicate problems with environmental factors, such as inadequate perch or poor space design, injuries or layer pullet rearing experience [Janczak and Riber, 2015; Gunnarsson *et al.*, 1999].

k) Spatial distribution

Uneven spatial distribution of layer pullets and laying hens may indicate fear reactions, thermal discomfort or, uneven availability or use of resources such as light, *feed* or water, shelter, nesting areas or comfortable resting locations [Rodríguez-Aurrekoetxea and Estevez, 2016; Bright and Johnson, 2011].

…

9. Performance

Daily, weekly and cumulative performance should be within expected ranges. Any unforeseen reduction in these rates may reflect an *animal welfare* problem. Types of measures that can be used include:

a) layer pullet growth rate, which measures average daily mass gain per layer pullet ~~and *flock* uniformity~~;

b) layer pullet *flock* uniformity, which measures the range in weight of the *flock*;

~~c~~b) layer pullet feed conversion, which measures the quantity of *feed* consumed by a *flock* relative to the total live mass produced, expressed as the mass of *feed* consumed per unit of body mass;

~~c~~d) laying hen feed conversion, which measures quantity of *feed* consumed by a *flock* relative to the unit of egg production;

~~d~~e) egg production, which measures the number, size and weight of eggs per laying hen housed;

~~e~~f) egg quality and downgrades, which can be measured by, for example, grade percentage, shell strength, Haugh units, abnormalities and mis-laid or floor eggs.

Article 7.Z.5.

Location, design, construction and equipment of establishments

The location of layer pullet and laying hen *establishments* should be safe from the effects of fires and floods and other natural disasters to the extent practicable. In addition, *establishments* should be located or designed to avoid or minimise disease risks and exposure of layer pullets and laying hens to chemical and physical contaminants, noise and adverse climatic conditions.

Good welfare outcomes for layer pullets and laying hens can be achieved in a range of housing systems. Houses, outdoor areas and accessible equipment should be designed after considering the opportunities for layer pullets and laying hens to perform motivated behaviours, as well as health, environmental factors, and animal management capability. They should also be maintained to avoid injury or discomfort. Layer pullet and laying hen houses should be constructed with materials, electrical and fuel installations that minimise the risk of fire and other hazards and are easy to clean and maintain. Producers should have a maintenance programme in place, including record-keeping for all equipment and contingency plans to address failures that could jeopardise the welfare of layer pullets and laying hens.

Outcome-based measurables ~~include~~ include: body condition, dust bathing, fear behaviour, feeding and drinking behaviour, foot problems, foraging behaviour, incidence of diseases, *infections* and *infestations* and metabolic disorders, injury rates and severity, locomotory and comfort behaviours, mortality, culling and morbidity rates, nesting, perching, performance, plumage condition, resting and sleeping, social behaviour and spatial distribution, thermoregulatory behaviour and vocalisations.

Rationale: Australia does not support the removal of the word 'include' in the Articles 7.Z.5 to 7.Z.29. We note the Code Commission explanation that the terminology in Article 7.Z.3 'may be useful indicators' implies that these lists are not definitive, however as an article can easily be read in isolation retention of 'include' avoids any possible confusion. We have not repeated this comment for every article.

Article 7.Z.6.

Matching the layer pullets and laying hens with the housing and production system

Animal welfare and health considerations should balance any decisions on performance when choosing the genetics to be used for a particular location, housing and production system. The layer pullet rearing system should pre-adapt these ~~birds~~ layer pullets for the intended laying hen production system [Aerni *et al.*, 2005].

Article 7.Z.7.

Space allowance

Layer pullets and laying hens should be housed with a space allowance that allows them to have adequate access to resources and to adopt normal postures. Providing sufficient space for the expression of locomotory

and comfort behaviours that contribute to good musculoskeletal health and plumage condition is desirable. Problems with space allowance may increase stress and the occurrence of injuries.

The following factors, in alphabetical order in English, should be considered when determining space allowance:

– age and weight of layer pullets and laying hens,

– ambient conditions,

– *biosecurity* strategy,

– equipment selection,

– feed and watering systems,

-- flock or group size,

Rationale: Flock or group size is a key determining factor of the space needs per bird.

– flooring substrate,

– genetics,

– housing design,

– management capabilities,

– production system,

– usable space,

– ventilation.

Article 7.Z.8.

Nutrition

Layer pullets and laying hens should be fed a diet appropriate to their age, production stage, housing system and genetics. The form of the *feed* should be acceptable to the layer pullets and laying hens and contain adequate nutrients to meet requirements for good *animal welfare* and health. *Feed* and water should be free from contaminants, debris and pathogenic microorganisms or other potential *hazards*.

Rationale: The metabolic energy needs of hens in cage-free systems is greater than those housed in cages because they are more active. They therefore require 5-15% more feed, or a higher energy density diet, than caged hens. Feather pecking behaviour can also be affected by hen nutrition in cage-free systems.

Mens, A.J.W., van Krimpen, M.M. & Kwakkel, R.P. (2020). Nutritional approaches to reduce or prevent feather pecking in laying hens: any potential to intervene during rearing? World's Poult. Sci. J., 76(3):591-610.

The feeding and watering systems should be inspected regularly and cleaned as needed, to prevent the growth of hazardous microorganisms.

Layer pullets and laying hens should be provided with adequate access to *feed* on a daily basis. Water should be continuously available except under veterinary advice. Special provisions should be made to enable newly hatched layer pullets to access appropriate *feed* and water.

Outcome-based measurables ~~include~~: body condition, foraging behaviour, incidence of diseases, *infections*, i*nfestations* and metabolic disorders, mortality, culling and morbidity rates, performance, plumage condition, vocalisations and water and *feed* consumption.

Article 7.Z.15.

Thermal environment

Thermal conditions for layer pullets and laying hens should be maintained within a range that is appropriate for their stage of life and the genetics used; extreme heat, humidity and cold should be avoided. A heat index can assist in identifying the thermal comfort zones for layer pullets and laying hens at varying temperatures, air velocities and relative humidity levels [Xin and Harmon, 1998], and can be found in management guidelines provided by laying hen genetics companies.

Although layer pullets and laying hens can adapt to a range of thermal environments, particularly if appropriate breeds and housing are used for the anticipated conditions, sudden fluctuations in temperature can cause heat or cold stress.

When environmental conditions move outside of these zones, strategies should be used to mitigate the adverse effects on the layer pullets and laying hens. These may include adjusting air speed, provision of heat or evaporative cooling [Yahav, 2009].

The thermal environment should be monitored regularly so that problems with the system ~~can~~ ~~be~~ are detected and corrected before they cause an *animal welfare* problem.

Rationale: Grammatical correction. ‘Are’ or ‘can be’

Article 7.Z.19.

Prevention and control of injurious feather pecking and cannibalism

Injurious feather pecking and cannibalism are challenges in layer pullet and laying hen production systems.

Layer pullet and laying hen m~~M~~anagement methods that may reduce the risk of occurrence include:

– adapting the diet and form of *feed* during rearing and lay [Lambton *et al.*, 2010],

– choosing genetics associated with a low propensity for injurious feather pecking [Craig and Muir, 1996; Kjaer and Hocking, 2004],

– increasing age at onset of lay [Pötzsch, 2001],

– increasing space allowance during rearing [Jung and Knierim, 2018],

– managing light during rearing and lay [Nicol *et al.*, 2013; van Niekerk *et al.,* 2013],

– minimising fear-related stimuli [Uitdehaag K. A. *et al.*, 2009],

– providing elevated perches during rearing and lay [Green *et al.*, 2000],

~~providing nesting areas during lay [Shi *et al.*,2019a; Shi *et al.*, 2019b].~~

Rationale We note that the Code Commission has now introduced a bullet point in 7.Z.19 that states ‘providing nesting areas during lay [Shi et al.,2019a; Shi et al., 2019b], as one of the management methods that can be used to reduce the occurrence of feather pecking and cannibalism. This addition is not correct. The references used to support the insertion are studies of layer breeder hens in the presence of males. This chapter does not deal with layer breeding at all: it is specifically excluded. Additionally, we are not aware of any references that support the provision and use of nesting areas for commercial laying hens as a means to reduce the occurrence of

feather pecking and cannibalism. This insertion has no scientific basis for the draft Chapter and should be removed.

– providing foraging or other manipulable materials during rearing and lay [Huber-Eicher and Wechsler, 1998; de Jong *et al.*, 2010; Daigle *et al.*, 2014; Dixon *et al.*, 2010; Nicol, 2018],

– reducing group size during rearing and lay [Bilcik and Keeling, 1999].

Management methods should be implemented, where applicable, and in the event of injury affected layer pullets and laying hens should be promptly removed and treated or euthanised.

If these management methods are unsuccessful, partial beak removal [Gentle *et al.*, 1997] may be considered as a final course of action.

Outcome-based measurables ~~include~~: foraging behaviour, injurious feather pecking and cannibalism, injury rate and severity, mortality, culling and morbidity rates, plumage condition, and vocalisation.

Article 7.Z.22.

Animal health management, preventive medicine and veterinary treatment

Animal handlers responsible for the care of layer pullets and laying hens should have knowledge of normal layer pullet and laying hen behaviour, and be able to detect signs of ill-health or distress, such as a change in *feed* or water intake, reduced production, changes in behaviour and abnormalities in plumage condition, faeces or other physical features.

If *animal handlers* are unable to identify the cause of disease, ill-health or distress, or are unable to correct these, or if they suspect the presence of a *notifiable disease*, they should seek advice from a *veterinarian* or other qualified advisers. Veterinary treatments should be prescribed by a *veterinarian*.

There should be an effective programme for the prevention of diseases and infestations that is consistent with the programmes established by *Veterinary Services* as appropriate, and which includes record-keeping.

Rationale: Laying hens can suffer from internal and external parasites as well as diseases. As these are handled separately throughout the chapter, it is important to include them both here in the preventive medicine programme. This should be standard in any hen health program.

Mula, M. F., van Vugt, S. M. A., Goselink Y.S.M., & van den Brand, H. (2020). Effects of heating laying hen houses between consecutive laying cycles on the survival of the poultry red mite *Dermanyssus gallinae*. Veterinary Parasitology *In press* doi.org/10.1016/j.vetpar.2020.109307

Vaccinations and treatments should be administered by personnel skilled in the procedures and with consideration for the welfare of the layer pullets and laying hens.

Sick or injured layer pullets and laying hens should be placed in a hospital area for observation and treatment, or euthanised in accordance with Chapter 7.6. as soon as possible.

Outcome-based measurables ~~include~~: body condition, incidence of diseases, *infections*, *infestations* and metabolic disorders, injury rate and severity, mortality, culling and morbidity rates and performance.

Article 7.Z.26.

Contingency plans

The contingency plans should be consistent with national programmes established or recommended by *Veterinary Services*. Emergency killing, procedures should be a part of the plan and be in accordance with the methods recommended in Chapter 7.6.

Article 7.Z.29.

Protection from predators and wild birds

Layer pullets and laying hens should be protected from predators in indoor and outdoor areas. All production systems should be designed and maintained to prevent access by predators and *wild* birds.

Rationale: Align title of article with contents

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CHAPTER 8.Y.

INFECTION WITH SPECIFIC ANIMAL SALIVARIAN TRYPANOSOMES ~~OF AFRICAN ORIGIN~~

Rationale: Australia suggests the term 'animal trypanosomes of African origin' be changed to 'specific animal salivarian trypanosomes' across the whole chapter, including the title, for the following reasons:

- In 'General provisions' Article 8.Y.1.4 clearly defines the range of trypanosomes targeted by the code, i.e. For the purposes of the *Terrestrial Code*, *infection* with animal trypanosomes of African origin is defined as an *infection* of susceptible animals with one or more Salivarian trypanosomes of the subgenus *Duttonella* (only *T. vivax*), *Nannomonas* (only *T. congolense* and *T. simiae*) and *Trypanozoon* (*T. brucei sspp* excluding *T. evansi* and *T. equiperdum*), hereafter referred to as 'pathogenic agent'.

- Although the trypanosomes targeted by this code are known to be first found in Africa, some of these parasites have long spread to other continents since. For example, surra (caused by Trypanosoma evansi) is now present in Africa, the Middle East and Asia.

- As a global body, OIE should avoid creating disease names that have geographical indicators of little or no scientific/technical value. The current approach would unnecessarily create a new disease term ('animal trypanosomes of African origin') which is not specific nor useful for the purpose of this code.

Article 8.Y.1

General provisions

1) Infection with specific animal salivarian trypanosomes ~~of African origin~~ is a disease complex caused by several protozoan parasites of the genus *Trypanosoma*, transmitted mainly cyclically by the genus *Glossina* (tsetse flies), but also mechanically by several biting flies (*e.g.* tabanids, *Stomoxys* spp). The disease can be caused by many different trypanosomes and can affect various mammals such as horses, donkeys, camels, goats, sheep, pigs, dogs, cats and non-human primates. ~~From the socio-economic point of view~~ The disease ~~is~~ has a ~~particularly~~ significant socio-economic impact ~~deleterious~~ ~~in~~ on ~~cattle~~ livestock production. ~~Some trypanosomes of African origin (*i.e.* *T. brucei gambiense*, and *T. brucei rhodesiense*)~~ can also affect humans and are responsible for a disease known as sleeping sickness or human African trypanosomosis, which is almost always fatal if untreated ~~(sleeping sickness also known as human African trypanosomosis)~~.

Rationale: Given it's a general statement about the widespread nature of this disease outside Africa, 'significant' socio-economic impact on animals applies not only to cattle but also to other species (especially suidae and equidae) depending on countries affected. Australia suggests 'cattle production' be changed to 'livestock production' in this statement to reflect the scope of such impact.

2) *Infection* with several trypanosome species in the same animal could exist although ~~they~~ this may not always be detected ~~be evidenced~~ using routine testing methods.

3) For the purposes of this chapter, 'susceptible animals' means domestic and *wild animals* from the following families: bovidae, suidae, equidae, camelidae, canidae, felidae and non-human primates.

4) For the purposes of the *Terrestrial Code*, *infection* with animal trypanosomes of African origin is defined as an *infection* of susceptible animals with one or more ~~S~~salivarian trypanosomes of the subgenus *Duttonella* (only *T. vivax*), *Nannomonas* (only *T. congolense* and *T. simiae*) and *Trypanozoon* (*T. brucei sspp* excluding *T. evansi* and *T. equiperdum*), hereafter referred to as 'pathogenic agent'.

Rationale: no need to use capital letter 'S' in the word 'Salivarian'

Article 8.Y.3.

Country or zone free from infection with animal trypanosomes of African origin

A *country* or *zone* may be considered free from *infection* with animal trypanosomes of African origin when:

1) the *infection* is notifiable in the entire country;

2) measures to prevent the introduction of the *infection* have been in place: in particular, the importations or movements of susceptible animals and other *commodities* into the country or *zone* have been carried out in accordance with this chapter and other relevant chapters of the *Terrestrial Code*;

3) and either:

   a) the relevant provisions in point 2 of Article 1.4.6. have been complied with; or

   b) for at least the past two years:

      i) *surveillance* in accordance with Articles 8.Y.13. to 8.Y.16. has been in place in the entire country;

      ii) there has been no *case* of *infection* with animal trypanosomes of African origin in the country~~,~~ or *zone* ~~or *compartment*~~.; or

   c) ~~the absence of competent *vectors* has been demonstrated by a *surveillance* programme in accordance with Chapter 1.5. and Article 8.Y.9.~~

A country or *zone* free from *infection* with animal trypanosomes of African origin ~~neighbouring~~ adjacent to an infected country or *zone* should include a *zone* in which *surveillance* is conducted in accordance with Articles 8.Y.13. to 8.Y.16.

Rationale: The absence of competent vectors should **not** be the only basis on which a country can declare freedom from a disease. Our epidemiological knowledge of vectors that are capable of transmitting disease in a country that is considered 'free' from a disease is very limited. A vector that is found in a disease-free country may prove to be competent but is not internationally recognised as a 'competent vector' because it has not been seen in an outbreak or the research has never been done.

Declaring disease freedom should be on the basis of susceptible species testing, not on the basis of 'known' vectors because our knowledge of potential vectors in disease-free countries is generally very limited.

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CHAPTER 12.6.

INFECTION WITH EQUINE INFLUENZA VIRUS

[...]

Article 12.6.6.

Recommendations for the importation of domestic equids for unrestricted movement

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

1) came from an EI free country, *zone* or *compartment* in which they had been resident for at least 21 days; in the case of a vaccinated domestic equid, information on its *vaccination* status should be included in the veterinary certificate;

OR

2) ~~came from a country, *zone* or *compartment* not known to be free from EI,~~ were subjected to pre-export isolation for 21 days and showed no clinical sign of EI during isolation nor on the day of shipment; and

3) were ~~immunised~~ vaccinated in accordance with the recommendations of the manufacturer with a vaccine complying with the standards described in the *Terrestrial Manual* and considered effective against the epidemiologically relevant virus strains, ~~between 21 and 90 days before shipment either with a primary course or a booster; information on their *vaccination* status should be included in the veterinary certificate or the passport in accordance with Chapter 5.12.~~ in accordance with one of the following procedures:

   a) between 14 and 90 days before shipment either with a primary course or a booster; or

   ~~b) between 14 and 180 days before shipment, if they are older than four years of age, previously having received up to the date of this pre-shipment *vaccination*, at least four doses of the same vaccine at intervals not greater than 180 days.~~

Rationale: Australia notes the paper, which supports pre-export vaccination being to up to 180 days prior to export in horses with some prior vaccinations, was published in late Feb 2020 and was not available at the last round of consultations on this chapter. However, it is unclear how the study has addressed issues with the selection of horses as prior vaccination histories were not consistent or were unknown for some populations of horses it used.

While this study assessed the longevity of vaccine responses by single radial haemolysis (SRH) measurement, it did not assess the outcome of viral challenge during that period, including measurement of viral shedding.

There is ample evidence that viral shedding with minimal clinical signs by poor vaccine responding horses is a major concern for introduction of equine influenza into a naïve population. As the proposed changes do not include measurement of vaccine response to confirm the individual horse's response, Australia continues to support pre-export vaccination taking place no less than 90 days prior to export.

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GLOSSARY

COMPETENT AUTHORITY

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

VETERINARY AUTHORITY

means the Governmental Authority of a Member Country~~, comprising the OIE Delegate, *veterinarians*, other professionals and paraprofessionals,~~ comprising *veterinarians*, other professionals and paraprofessionals, having the ~~primary~~ responsibility and competence for ensuring ~~in the whole territory and competence for coordinating ensuring or supervising~~ that the animal health and *welfare* measures and international veterinary certification in the whole territory are consistent with~~implementation of animal health, and *animal welfare* and veterinary public health measures, international veterinary certification and other~~ the standards ~~and recommendations of in~~ and recommendations in the *Terrestrial Code* and the OIE *Aquatic Animal Health Code*~~in the whole territory~~.

VETERINARY SERVICES

means ~~the combination of the~~ governmental and non-governmental individuals and organisations that ~~perform activities to~~ implement animal health and *welfare* measures and ~~animal health, and *animal welfare* and veterinary public health measures and~~ other ~~the~~ standards and ~~and~~ recommendations ~~of~~ in the *Terrestrial Code* and the OIE *Aquatic Animal Health Code* in the territory. The Veterinary Services are under the overall control and direction of the *Veterinary Authority*. Private sector organisations, *veterinarians*, veterinary paraprofessionals or aquatic animal health professionals are normally accredited or approved by the *Veterinary Authority* or other Authority operating under the *Competent Authority* to deliver the delegated functions.~~and the OIE *Aquatic Animal Health Code* in the territory. The Veterinary Services are under the overall control and direction of the *Veterinary Authority*. Private sector organisations, *veterinarians*, *veterinary paraprofessionals* or aquatic animal health professionals are normally accredited or approved by the *Veterinary Authority* to deliver the delegated functions~~.

Edited definitions in clean text:

COMPETENT AUTHORITY

~~means a Governmental Authority of a Member Country having responsibility in the whole or part of the territory for the implementation of certain standards of the *Terrestrial Code*.~~

means the *Veterinary Authority* or other Governmental Authority of a Member Country having the responsibility and competence for ensuring or supervising the implementation of animal health and *welfare* measures, international veterinary

certification and other standards and recommendations in the *Terrestrial Code* and in the OIE *Aquatic Animal Health Code* in the whole territory

VETERINARY AUTHORITY

~~means the Governmental Authority of a Member Country having the primary responsibility in the whole territory for coordinating the implementation of the standards of the *Terrestrial Code*.~~

means the Governmental Authority of a Member Country, comprising *veterinarians*, other professionals and paraprofessionals, having the responsibility and competence for ensuring that the animal health and *welfare* measures and international veterinary certification in the whole territory are consistent with standards and recommendations in the *Terrestrial Code* and the OIE *Aquatic Animal Health Code*.

VETERINARY SERVICES

~~means the combination of governmental and non-governmental individuals and organisations that perform activities to implement the standards of the *Terrestrial Code*.~~

means the governmental and non-governmental individuals and organisations that implement animal health and *welfare* measures and other standards and recommendations in the *Terrestrial Code* and the OIE *Aquatic Animal Health Code* in the territory. The Veterinary Services are under the overall control and direction of the *Veterinary Authority*. Private sector organisations, *veterinarians, veterinary paraprofessionals* or aquatic animal health professionals are normally accredited or approved by the *Veterinary Authority* or other Authority operating under the *Competent Authority* to deliver the delegated functions.

Rationale:

Australia is concerned that the changes proposed in these three definitions by the TAHSC merely require that the national *Veterinary Authorities*, their *Veterinary Services*, and national *Competent Authorities* implement some or all standards of the *Terrestrial Code*. That is not consistent with the broad missions of the OIE.

In addition, not all Chapters (and Articles of) are regarded as 'standards'; some are recommendations or guidelines. However, the text of the Terrestrial Code does not always clarify which Articles or Chapters are 'standards' and which are to be regarded as 'guidance'. This is confusing if taken as necessary to define the scope of national *Veterinary Authorities*, their *Veterinary Services*, and national *Competent Authorities*.

Australia notes that there are 140 uses of these three terms in Section 1 of the Terrestrial Code, including chapters on official recognition and self-declaration procedures and responsibilities for OIE Members. The definitional change, if further pursued, would therefore need to be supported by a full editorial review of these terms in the Terrestrial Code to ensure consistency.

Furthermore, the proposed draft Chapter 3.X uses the following to describe the role of *Veterinary Services*. *Veterinary Services have responsibility for implementing the activities necessary for the Member country to comply with OIE standards.* That is inconsistent with the proposed change to the definition.

There is significant potential for the OIE proposed changes to create needless confusion in Members as to what activities are in and out of scope in official veterinary services. In addition, the changes, when compared to prior editions of the *Terrestrial Code,* may be interpreted to provide justification for a diminution of powers of national *Veterinary Authorities* and *Competent Authorities* to deal broadly with public health, animal health and food safety, and international animal health certification and notification.

For those reasons Australia does not support the changes proposed by the TAHSC. However, if there is to be any change to the existing definitions, Australia has provided alternative text that is consistent with the principles of the OIE and its missions; and that delineates the broad role of a *Competent Authority*, the structure and focus of the *Veterinary Authority*, and the flexible arrangements that at present underpin the *Veterinary Services* of the 182 Members of the OIE General Assembly; and is suitable for both the *Terrestrial* and *Aquatic Codes*.

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Australian Comments – indicated in blue font

CHAPTER 8.14.

INFECTION WITH RABIES VIRUS

~~Article 8.14.6bis.~~

~~Recommendations for importation of dogs from countries or zones 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 dogs:~~

~~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 in accordance with the recommendations of the manufacturer, with a vaccine that was produced in accordance with the Terrestrial Manual and were subjected, not less than 30 days and not more than 12 months prior to shipment, to an antibody titration test as prescribed in the Terrestrial Manual with a positive result of at least 0.5 IU/ml;~~

~~or~~

~~b) were kept in a quarantine station for six months prior to shipment.~~

Article 8.14.7.

Recommendations for importation of ~~dogs,~~ dogs cats and ferrets from countries or zones 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 in accordance with the recommendations of the manufacturer, with a vaccine that was produced in accordance with the *Terrestrial Manual* and were subjected not less than 3 months and not more than 12 months prior to shipment to an antibody titration test as prescribed in the *Terrestrial Manual* with a positive result of at least 0.5 IU/ml;

   or

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

Rationale: Consistent with previous comments to the Code Commission, Australia will not support the proposed change to Article 8.14.6bis, where the recommendations of the importation of dogs from infected countries have

been separated from those for cats and ferrets. These new conditions for dogs specify that dogs can have a RNATT performed not less than 30 days and not more than 12 months prior to shipment. The previous requirement for this test was between 3 and 12 months prior to export.

Australia notes that several members raised concerns in February 2018 about a range of proposed changes to the chapter at that time.

Australia and other members raised significant concerns that the proposed reduction in the minimum time between verifying effective protection by vaccination (demonstrated by the RNATT) and export would increase the likelihood that rabies-infected animals may be imported prior to clinical signs becoming apparent. That change in likelihood means countries would be exposed to significantly increased risk when compared to the level of protection afforded by conditions in the Code previously applicable to dogs, cats and ferrets.

The report of the ad hoc Group on Rabies provided a "concept paper" to support those changes, which was released in the February 2020 Scientific Commission report. As the references provided as evidence for these changes only refer to dogs, the Code Commission has now proposed these changes only for dogs. This results in different levels of requirements in the Code for different species of companion animals. That is not practicable for most countries' import systems, which jointly handle dogs and cats.

Australia considers that there are a number of significant problems with using this concept paper to support the proposed change.

- There are a number of caveats about the information presented in the report. That information is a collation of data from many different sources generated under different conditions and with varied dependencies. These are not acknowledged and the datasets utilised are all assumed to have the same level of reliability, allowing for summation. For example, the paper presents survival curves which are noted not to be representative of the survival rates of dogs in the general population, but which are relied upon as informing risk levels concerning the timing of vaccinations, RNATT and export.

- The concept paper is inconsistent with the OIE Code, which lists the incubation period of rabies as 180 days. The concept paper has used 19 days, stating that fewer than 5% of infected, unvaccinated dogs were alive after 30 days after exposure. Because of the impact of rabies, a fatal zoonoses that many countries have expended significant resources to manage or eradicate, that 'less than 5%' number of dogs, which may still be incubating the disease at the time of export under these proposed requirements and despite demonstration of an acceptable RNATT, presents a very real threat to the human and animal population of importing countries. The much lower percentage of infected dogs that remain alive after three months clearly illustrates there is an increased likelihood that a dog incubating rabies may enter the territory of an OIE member under these proposed conditions by comparison with the existing requirements.

- The concept paper presents a quantitative risk assessment which has equated the likelihood of importation with the risk. This is inconsistent with the OIE's own standard on risk assessment for determining import conditions (Chapter 2.1 of the Code). There is no assessment of the consequence of entry of this rabid dog in a rabies free country that informs this conclusion. The biosecurity risk for a country currently free of rabies is also very different for a country where rabies is present even if controlled due to the extreme consequences of a detection of rabies outside of quarantine.

- Cho and Lawson (1989) was used to support a maximum time of 20 days from vaccination until death for a rabid dog that has been vaccinated. However, in that study, dogs were vaccinated 6 hrs, then 3,7,14, 28 and 90 days after challenge. In the control vaccinated group, all 8 dogs died between 12 to 15 days after challenge, not vaccination. This means they would have received 3-4 vaccine doses within approximately a two-week period following exposure. That vaccine regime is not consistent with commercial vaccination schedules for dogs, which usually involve a single vaccination with boosters every 1-3 years. It is not possible to assume that the multiple vaccination schedule in this study would have had no effect on the infective capacity of lower levels of the virus in peripheral tissue that, in normal circumstances, may have resulted in classical rabies after an incubation time consistent with the incubation time stated in the current Code.

- In addition, the work of Goddard et al (2012) is misrepresented in this paper to support the argument for moving to a 1-month period between the RNATT and import. Goddard et al doesn't investigate the type A and B scenarios outlined in the concept paper but instead examines the difference between a 6 (previous UK policy) and 3 months (EU policy non MS) waiting period. The authors conclude that there is negligible risk in moving from a 6 to 3 month waiting period, however, their work specifically states that waiting periods below 90 days substantially increase the risk. The authors of the concept paper have incorrectly presented Goddard et al as consistent with the existence of negligible risk where a 1 month waiting period from RNATT to import is implemented by rabies free countries.

- The concept paper presents an argument that reducing the waiting period will increase compliance and hence decrease risk. The authors have not however assessed whether that increase in compliance would balance the increased likelihood of importing a dog that is incubating rabies under the proposed conditions. This is poor justification for a rabies free country to accept increased biosecurity risk as a trade-off for improved compliance. Any decrease in compliance should be addressed by the verification systems of the importing country to ensure the level of protection is met, not by lowering the level of protection provided by the import requirements so that there is a reduced level of non-compliance. This is especially so for a country free from specific diseases, such as rabies. All the examples of importation of rabid animals with falsified documentation presented in the concept paper involved importation into the US and EU, where rabies is already present but under various official controls.

References

Cho HC, Lawson KF. Protection of dogs against death from experimental rabies by postexposure administration of rabies vaccine and hyperimmune globulin (human). Can J Vet Res 1989; 53(4): 434-7.
Goddard et al.; 2012; A quantitative release assessment for the noncommercial movement of companion animals: risk of rabies reintroduction to the United kingdom; Risk Analysis; 32(10); 1769- 1783

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Australian Comments – indicated in blue font

CHAPTER 7.7.

DOG POPULATION MANAGEMENT

Article 7.7.2.

Scope

The scope of this chapter is to provide recommendations for the management of dog *(Canis lupus familiaris)* populations to improve human health and safety, animal health and *animal welfare* and to minimise their potential negative socio-economic and environmental impacts. The recommendations will also assist Members in the implementation of zoonotic disease control programmes ~~such as~~ with a focus on *infection* with rabies virus in accordance with Chapter 8.14.

Rationale: The focus of the chapter is the control of rabies.

Article 7.7.3.

Guiding principles

Building upon the guiding principles described in Chapter 7.1., the following apply:

– DPM has direct benefits to public health and safety, and animal health and welfare.

– Dogs are domesticated species and therefore dependent on human communities, thus there is an ethical responsibility to ensure their health and welfare even in the absence of ownership.

– Recognising diversity of stakeholders in the management of dog populations, it is crucial to clarify roles and responsibilities.

– Dog ecology is linked with human activities. Therefore, effective management of dog populations should be accompanied by changes in human behaviour, including promotion of *responsible dog ownership.*

– Acknowledging that the *owned dog* population is a common source of free-roaming dogs, DPM programmes should consider all dogs.

– Understanding local dog population dynamics and community attitudes is a key element to determine whether and how DPM programmes might contribute to rabies control and which tools would be most successful.

– Considering that sources and drivers of free-roaming dogs and management goals differ across communities, DPM should be individually tailored at local and national level.

– DPM programmes should be designed to be sustainable, compliant with legislative requirements and evaluated. ~~and refined.~~

Rationale: Removed the word ‘refined’ because it is not clear what is meant by a ‘refined’ DPM program. Replaced with an acknowledgement that the DPM programs must be compliant with local laws and jurisdictional legislation.

Article 7.7.4.

Definitions for the purpose of this chapter

DPM programme means a combination of DPM measures that enhance the care of dogs and influence dog population dynamics to sustainably improve dog health and welfare, public health and safety, and the environment, ~~and~~ while taking into consideration related economic benefit and costs.

Rationale: Grammatical correction for clarity.

Article 7.7.10.

Assessment, monitoring and evaluation

DPM programmes should be regularly evaluated and adapted to improve effectiveness and to respond to changes in a wider context that influence dog population dynamics. This requires an evidence base from data collected through initial assessment and continued *monitoring* using objective methods.

Rationale: Grammatical.

Article 7.7.12.

Monitoring and evaluation

Monitoring aims to check the progress of DPM programme measures against targets and support performance management. It should allow for regular adjustments of implementation of measures and collection of data on indicators of objectives. It should also include *monitoring* of costs associated with measures and costs or savings relating to objectives to support cost-benefit analysis.

Rationale: Grammatical.

Evaluation is a periodic assessment of progress using data collected through *monitoring*, usually carried out at milestones to assess whether the DPM programme is achieving the desired objectives and to adapt the DPM programme to improve effectiveness and efficiency. Where methods of *monitoring* are equivalent – clearly defined, repeatable and consistent – evaluation can compare effectiveness and efficiency across DPM programmes.

Rationale: The word 'equivalent' requires further explanation to clarify the meaning. Monitoring methods need to be well described so that they can be applied in the same way at different locations and points in time and with changing personnel. This enables direct comparisons to be made for evaluation.

Article 7.7.13.

Registration and identification of dogs

Outcomes of *registration* and identification of dogs include the following:

– supports enforcement of legislation through proof of ownership;

– improves success rate in reuniting lost dogs to their owners;

– enables traceability in commercial breeding and sale;

– supports neutering of dogs;

– encourages responsible ownership behaviours;

– support for an animal health programme, e.g., mandatory rabies *vaccination* and traceability.

These outcomes require widespread adoption of *registration* and *identification*.

Rationale: A key aspect of registration and identification is to keep records of the number of dogs in a population that are neutered, and also potentially encourage neutering (eg through financial incentives).

Article 7.7.15.

Commercial dog breeding and sale

Outcomes of regulating commercial breeding and sale include:

– protection of dog health and welfare,

– avoidance of abandonment,

– transparency in dog breeding and sales.

Competent Authorities should require mandatory *registration* of all breeders and sellers. For commercial breeders and sellers, where the number of litters produced per year exceeds a threshold set by regulations, a further requirement for licensing can be imposed, including the requirement for inspection before trade can begin.

Advertisements for dog sales should be required to carry the *registration* or licence number of the breeder and seller.

To ensure dogs traceability, the breeder should be established through identification and *registration* as the first owner.

The seller should ensure *registration* details of the dog are updated with those of the first buyer following transfer of ownership.

Regulations of breeding practices should include limits on number of litters, minimum breeding age to protect the health and welfare of dam, good health of both parents and avoidance of selective breeding that leads to inherited diseases and extreme conformations. Regulations of both breeders and sellers should also outline specific requirements for accommodation, veterinary care, husbandry, puppy socialisation and habituation to their environment, minimum puppy age before leaving the dam and training of staff. Sales of puppies or adult dogs should be limited to adults (not children), and sales from exhibitions or from the street should be banned.

Rationale: Added 'not children' to ensure that it is clear to the reader that we are referring to adult humans.

Article 7.7.25.

Dog capture and handling

The least aversive method of capture and handling should be used to minimise harm and discomfort to the dog, while also considering safety of the handler. Further, handlers should strive to make the handling experience as positive as possible from the perspective of the dog; this includes looking for ways to reward the dog during handling.

Handlers should use minimum *restraint* to provide the dog with opportunities to exert choice and control, so that they cope better with the handling.

Rationale: Any decisions on capture and handling must consider both the welfare of the dog and safety of the handler.

Article 7.7.26.

Dog housing

Competent Authorities should develop minimum standards for the housing (physical facilities) and care of dogs to ensure the physical, mental and social needs of dogs are met. Enforcement of standards are supported by licensing and inspection of facilities (Barnard *et al.*, 2014). The following minimum standards should be considered:

a) Facilities

– sustainable finances to cover ongoing running costs;

– site selection: access to drainage, waste disposal, water and electricity are essential and environmental factors such as noise and pollution should be considered;

– kennel size, design and occupancy, taking exercise and expected length of stay into account and providing sufficient area for dogs to separate the functions of eating or drinking, resting, urinating and defecating, as well as maintaining acceptable environmental temperatures;

– disease control measures including isolation and *quarantine station*;

– maximum capacity of the facility.

Rationale: Grammatical addition (yellow highlighted comma). Protection from extreme heat or cold is fundamental to facility design, and not just part of an assessment of dog housing.

Article 7.7.27.

Euthanasia

Euthanasia of dogs, used alone, is not effective for DPM. If used, it should be done humanely and implemented in combination with other measures as part of a DPM programme to achieve effective long-term management. Reducing dog population size is not an effective means of reducing the number of rabies cases [WHO, 2018].

As a process, *euthanasia* involves pre-*euthanasia* and handling procedures, *euthanasia* methods and agents, confirmation of *death*, and carcass disposal. When *euthanasia* is practised, the general principles in the *Terrestrial Code* should be applied, with the emphasis on using practical methods which achieve the most rapid, painless, and distress free-*death* possible while ensuring operator safety. *Euthanasia* should be conducted under the supervision of a *veterinarian*. To ensure *animal welfare* and operator safety, the personnel conducting *euthanasia* should have a complete understanding of, and proficiency in, the *euthanasia* method to be used.

a) Restraint

When a dog needs to be restrained for any procedure, including *euthanasia*, this should always be done with full regard for operator ~~security~~ safety and *animal welfare*. Animal handling should also minimise distress experienced by the dog prior to loss of consciousness. Some *euthanasia* methods should be used ~~in~~ with prior sedation or anaesthesia to be considered humane. Regardless of the *euthanasia* method used, pre-*euthanasia* sedation or anaesthesia should be used ~~to~~ where it will minimise anxiety or facilitate safe *restraint*.

Rationale: Replaced the term ‘security’ with ‘safety’. The intent of adequate restraint in respect to the operator is to ensure operator ‘safety’ not operator ‘security’.
Grammatical changes.
Anaesthesia or sedation may be unnecessary when euthanising a calm dog with intravenous barbiturates.

b) Euthanasia methods

The following are recommended methods of canine *euthanasia*:

– intravenous barbiturates,

– intraperitoneal barbiturates in small dogs or puppies, (not preferred, and should only be used where the intravenous route is not feasible or dangerous),

– intravenous anaesthetic overdose,

– inhaled anaesthetic overdose in small dogs (not neonates).

- free-bullet with proper anatomic placement at close range by highly trained personnel,

If anesthetised:

– administration of barbiturates by alternate routes (intracardiac, intrarenal, intrahepatic, intraosseous).

If sedated:

– intravenous *euthanasia* specific formulation of embutramide, chloroquine and lidocaine;

- intravenous *euthanasia* specific formulation of embutramide, mebezonium and tetracaine.

Methods, procedures and practices that are unacceptable as primary methods of *euthanasia* on *animal welfare* grounds include air embolism, asphyxiation, burning, chloral hydrate, chloroform, cyanide, decompression, drowning, exsanguination, formalin, household products and solvents, hypothermia, insulin, neuromuscular blocking agents (magnesium sulphate, potassium chloride, nicotine, and all curariform agents), manually applied blunt force trauma to the head, rapid freezing, thoracic compression, strychnine, nitrous oxide, ether, kill-trapping, CO from engine fumes, CO_2 if the required concentration and flow rates are not regulated and monitored, free-bullet without proper anatomic placement at close range by highly trained personnel, penetrating captive bolt, electrocution if not already under general anaesthesia, *stunning* without secondary kill method.

Rationale:

Intraperitoneal administration of barbiturates is associated with peritoneal irritation and pain, and is slower acting than intravenous administration and, therefore, is not a preferable method if other options are available.

There are several accepted euthanasia methods that are not listed here. Firearms has been added to acknowledge that the use of firearms is an accepted form of euthanasia and may be the preferred approach (from a practical and welfare perspective) to destroy stray dogs that cannot be safely restrained. Reference: *Methods for the euthanasia of dogs and cats: comparison and recommendations.* World Society for the Protection of Animals (WSPA) page 9 https://caninerabiesblueprint.org/IMG/pdf/Link72_Euthanasia_WSPA.pdf

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CHAPTER 8.8

INFECTION WITH FOOT AND MOUTH DISEASE VIRUS

General comment:

Australia strongly supports the proposed changes to allow countries to return to FMD freedom if vaccinated animals are retained in the population. This will reduce disincentives for the use of emergency vaccination, which in turn will reduce the number of animals destroyed for disease control purposes. This is in line with public expectations.

Article 8.8.1bis.

Safe commodities

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

~~1) UHT milk and derivatives thereof;~~

2) *meat* in hermetically sealed container with a F_0 value of 3 or above;

~~3) *meat* and bone meal and blood meal;~~

4) gelatine;

5) *in vivo* derived bovine embryos collected, processed and stored in accordance with Chapter 4.8.

Other *commodities* of susceptible species can be traded safely if in accordance with the relevant articles in this chapter.

Rationale: Australia does not agree with the removal of specific advice for international trade in UHT milk and meat and bone meal and blood meal from Articles 8.8. and 8.8.26 respectively, and their inclusion in the 'safe commodities list.

The movement of these commodities into the safe commodities has been accompanied by a loss of specific processing requirements, which provides guidance on the key aspects of processing that are required to ensure adequate inactivation of FMDV and management of the disease transmission risk. Without guidance on the basic processing expected, there is the risk of product inadequately treated being mistakenly assumed to be safe by importing countries.

This is particularly likely to impact countries where veterinary services may not be as well developed or resourced and so lack the ability to perform the necessary risk analysis to allow them to implement import requirements containing additional detail (such as thermal inactivation parameters) needed to address this issue.

In addition, the movement of UHT milk to the safe commodities list no longer differentiates between the different end uses for this product. The TAHSC report identifies that the

movement of UHT milk to the safe commodity list was based on existing provisions in Article 8.8.25. Article 8.8.25 notes that processing in accordance with articles 8.8.35 and 8.8.36 is required to manage the risk of disease transmission. Article 8.8.36 required that UHT milk must have undergone an additional physical treatment to ensure the inactivation of FMDV, however this requirement is absent from Article 8.8.1bis. The TAHSC does not provide any explanation as to why this additional processing requirement has been removed. In the interest of transparency, Australia requests that the scientific evidence providing the basis for this decrease in risk management be provided for the review of OIE member countries.

Article 8.8.2.

~~FMD free~~ Country or zone free from FMD where vaccination is not practised

In defining a *zone* where *vaccination* is not practised the principles of Chapter 4.~~3~~4. should be followed.

Susceptible animals in the ~~FMD free~~ country or *zone* free from FMD, where *vaccination* is not practised should be protected by the application of *biosecurity* ~~measures~~ that prevents the entry of FMDV into the free country or *zone*.

Taking into consideration physical or geographical barriers with any neighbouring infected country or *zone*, these measures may include a *protection zone*. If a protection zone is established, it should comply with Article 4.4.6. If vaccination is implemented in the protection zone, the animal health status of the rest of the country or zone is not affected.

Rationale: The second last paragraph of Article 8.8.3 should be made into paragraph 3 of Articles 8.8.2 and 8.8.3 as this advice is more logical in this position. Slight rewording for clarity consistent with this change is suggested.

To qualify for inclusion in the list of ~~FMD free~~ countries or *zones* free from FMD, where *vaccination* is not practised, a Member Country should:

1) have a record of regular and prompt animal *disease* reporting;

2) send a declaration to the OIE stating that during the past 12 months, within the proposed ~~FMD~~ free country or *zone*:

   a) there has been no *case* of FMD;

   b) no *vaccination* against FMD has been carried out;

3) supply documented evidence that for the past 12 months:

   a) *surveillance* in accordance with Articles 8.8.40. to 8.8.42. has been implemented to detect clinical signs of FMD and demonstrate no evidence of:

      i) *infection* with FMDV in unvaccinated animals;

      ii) ~~FMDV~~ transmission of FMDV in previously vaccinated animals when the ~~FMD~~ free country or *zone* where *vaccination* is practised is seeking to become one where *vaccination* is not practised;

   b) regulatory measures for the prevention and early detection of FMD have been implemented;

4) describe in detail and provide ~~supply~~ documented evidence that for the past 12 months ~~the following have been properly implemented and supervised~~:

   a) ~~in the case of a FMD free *zone*,~~ the boundaries of ~~the~~ any proposed ~~FMD~~ free *zone* have been established and effectively supervised;

   b) the boundaries and *biosecurity* ~~measures~~ of ~~a~~ any *protection zone*~~, if applicable~~ have been established and effectively supervised;

c) the system for preventing the entry of FMDV into the proposed ~~FMD~~ free country or *zone* has been established and effectively supervised;

d) the control of the movement of susceptible animals, their *meat* ~~and~~ other products, and fomites into the proposed ~~FMD~~ free country or *zone*, in particular the measures described in Articles 8.8.8.~~, 8.8.9. and~~ to 8.8.12. has been effectively implemented and supervised;

e) measures to prevent the introduction of ~~no~~ vaccinated animals ~~has been introduced,~~ except in accordance with Articles 8.8.8. ~~and~~ 8.8.9., 8.8.9bis., 8.8.11. and 8.8.11bis. have been effectively implemented and supervised. Any vaccinated animals introduced for direct *slaughter* were subjected to ante- and post-mortem inspections in accordance with Chapter 6.2. with favourable results. For ruminants the head, including the pharynx, tongue and associated lymph nodes, was either destroyed or treated in accordance with Article 8.8.31.

The Member Country or the proposed free *zone* will be included in the list of ~~FMD free~~ countries or *zones* free from FMD, where *vaccination* is not practised only after the submitted evidence, based on the provisions of Article 1.6.6., has been accepted by the OIE.

Retention on the list requires that the information in points 2, 3 and 4 above be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3b) and 4 should be reported to the OIE in accordance with the requirements in Chapter 1.1.

~~A country or *zone* free from FMD may maintain its free status despite an incursion of potentially infected African buffaloes provided that the *surveillance* programme substantiates the absence of transmission of FMDV.~~

Provided the conditions of point~~s 1 to 4~~ 3 ~~are~~ is fulfilled, the status of a country or *zone* will not be affected by applying official emergency *vaccination* to FMD susceptible animals in zoological collections in the face of a FMD threat identified by the *Veterinary Authorities*, provided that the following conditions are met:

– the zoological collection has the primary purpose of exhibiting animals or preserving rare species, has been identified, including the boundaries of the facility, and is included in the country's contingency plan for FMD;

– appropriate *biosecurity* measures are in place, including effective separation from other susceptible domestic *population*s or *wildlife*;

– the animals are identified as belonging to the collection and any movements can be traced;

– the vaccine used complies with the standards described in the *Terrestrial Manual*;

– *vaccination* is conducted under the supervision of the *Veterinary Authority*;

– the zoological collection is placed under *surveillance* (including virological and serological surveillance as appropriate for African buffalo within the collection) for at least 12 months after *vaccination*.

Rationale: Australia believes the current wording about surveillance does not adequately ensure that carrier buffalo, a major wild reservoir species for this disease, would be detected. Clinical surveillance alone would not necessarily detect buffalo that are carriers of FMD virus, and buffalo could carry the virus for longer than the proposed surveillance period. For this reason, we suggest that the surveillance requirements are clarified to note additional surveillance (serological and virological) would be required for African buffalo populations present within the zoological collection.

In the event of the application for ~~the status of~~ a new ~~FMD~~ free *zone* ~~where *vaccination* is not practised to be assigned to a new *zone*~~ being adjacent to another ~~FMD~~ ~~free~~ *zone* of the same status ~~where *vaccination* is not practised~~, it should be stated if the new *zone* is being merged with the adjacent *zone* to become one enlarged *zone*. If the two *zones* remain separate, details should be provided on the control measures to be applied for the maintenance of the status of the separate *zones* and particularly on the identification and the control of the movement of animals between the *zones* of the same status in accordance with Chapter 4.3.

In the case of an incursion of stray African buffalo from a neighbouring infected country or zone or country or country or zone previously infected in the last 5 years, a *protection zone* according to Article 4.4.6. should be established to manage the threat and maintain the free status of the rest of the country.

~~If An *protection zone* used is established, to preserve the *status* of a free country or *zone* from a newly identified likelihood of introduction of FMDV it should comply with Article 4.43.6. If *vaccination* is implemented in the~~

~~*protection zone*, this will not affect the freedom of the rest of the country or *zone* the *animal health status* of the rest of the country or *zone* is not affected.~~

Rationale: This paragraph about establishment of a protection zone for an incursion of stray African buffalo requires more information for clarity. A specific recommendation to establish a protection zone for stray African buffalo from a country or zone previously infected within the last 5 years should be included in this paragraph, as African buffalo may be persistently infected with FMDV for up to 5 years (Condy et al. 1985)

Recommend moving the last paragraph of Article 8.8.2 to paragraph 3 of Article 8.8.2 where establishment of a protection zone for a country free from FMD where vaccination is practised is discussed, with minor rewording .

Article 8.8.3.

~~FMD free~~ Country or zone free from FMD where vaccination is practised

In defining a *zone* where *vaccination* is practised the principles of Chapter 4.3. should be followed.

Susceptible animals in the ~~FMD free~~ country or *zone* free from FMD where *vaccination* is practised should be protected by the application of *biosecurity* ~~measures~~ that prevents the entry of FMDV into the free country or *zone*.

Rationale: The OIE Glossary definition of biosecurity is "a set of management and physical measures' therefore the word measures is not required. Consistent with Article 8.8.2.

Taking into consideration physical or geographical barriers with any neighbouring infected country or *zone*, these measures may include a *protection zone*. If a *protection zone* is established, it should comply with Article 4.4.6. In accordance with Article 4.4.6. once a *protection zone* has been approved by the OIE, the freedom of the rest of the country or *zone* remains unchanged.

Rationale: The second last paragraph of Article 8.8.3 should be made into paragraph 3 of Articles 8.8.2 and 8.8.3 as this advice is more logical in this position. Slight rewording for clarity consistent with this change is suggested.

Based on the epidemiology of FMD in the country, it may be decided to vaccinate only a defined *subpopulation* comprised of certain species or other subsets of the total susceptible *population*.

To qualify for inclusion in the list of ~~FMD free~~ countries or *zones* free from FMD where *vaccination* is practised, a Member Country should:

1) have a record of regular and prompt animal *disease* reporting;

2) send a declaration to the OIE stating that, based on the *surveillance* described in point 3, within the proposed ~~FMD~~ free country or *zone*:

   ~~a) there has been no *case* of FMD during the past two years;~~

   ~~b~~a) there has been no ~~evidence~~ of ~~FMDV~~ transmission of FMDV during the past 12 months;

   b) there has been no *case* with clinical sign of FMD during the past 12 months;

3) supply documented evidence that:

   a) *surveillance* to detect clinical signs of FMD has been implemented in accordance with Articles 8.8.40. to 8.8.42. ~~has been implemented to detect clinical signs of FMD~~ for the past two years and demonstrates ~~no evidence of~~ that there has been no:

      i) *infection* with FMDV in unvaccinated animals for the past ~~two years~~ 12 months;

      ii) ~~FMDV~~ transmission of FMDV in vaccinated animals for the past 12 months;

b) regulatory measures for the prevention and early detection of FMD have been implemented for the past ~~12 months~~ two years;

c) compulsory systematic *vaccination* in the target *population* has been carried out to achieve adequate *vaccination* coverage and population immunity for the past 12 months ~~two years;~~

d) *vaccination* has been carried out following appropriate vaccine strain selection for the past 12 months ~~two years;~~

4) describe in detail and ~~supply~~ provide documented evidence that for the past 12 months ~~the following have been properly implemented and supervised~~:

a) ~~in case of FMD free *zone*,~~ the boundaries of the proposed ~~FMD~~ free *zone* have been established and effectively supervised;

b) the boundaries and *biosecurity* ~~measures~~ of any *protection zone*~~,~~ ~~if applicable~~ have been established and effectively supervised;

c) the system for preventing the entry of FMDV into the proposed ~~FMD~~ free country or *zone*, in particular the measures described in Articles 8.8.8., 8.8.9. and 8.8.12. has been established and effectively supervised;

d) the control of the movement of susceptible animals and their products into the proposed ~~FMD~~ free country or *zone* has been effectively implemented and supervised.

The Member Country or the proposed free *zone* will be included in the list of ~~FMD free~~ countries or *zones* free from FMD where *vaccination* is practised only after the submitted evidence, based on the provisions of Article 1.6.6., has been accepted by the OIE.

Retention on the list requires that the information in points 2, 3 and 4 above be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3b) and 4 should be reported to the OIE in accordance with the requirements in Chapter 1.1.

If a Member Country that meets the requirements of a ~~FMD free~~ country or *zone* free from FMD where *vaccination* is practised wishes to change its status to ~~FMD free~~ country or *zone* free from FMD where *vaccination* is not practised, it should notify the OIE in advance of the intended date of cessation of *vaccination* and apply for the new status within 24 months of the cessation. The status of this country or *zone* remains unchanged until compliance with Article 8.8.2. is approved by the OIE. If the dossier for the new status is not provided within 24 months then the status of the country or *zone* as being free with *vaccination* will be suspended. If the country does not comply with requirements of Article 8.8.2., evidence should be provided within three months that it complies with Article 8.8.3. Otherwise the status will be withdrawn.

If a Member Country that meets the requirements of a country or *zone* free from FMD where *vaccination* is not practised and is recognised by the OIE as such, wishes to change its status to country or *zone* free from FMD where *vaccination* is practised, it should provide the OIE with an application and a plan following the structure of the Questionnaire of Article 1.6.6~~., indicating the intended date of beginning of *vaccination*~~. The status as country or *zone* free from FMD where *vaccination* is not practised ~~of this country or *zone*~~ remains unchanged until the application and plan are approved by the OIE. As soon as recognised free with *vaccination* the country or *zone* will begin the *vaccination*. The Member Country should provide evidence within six months that it complies with Article 8.8.3. for this time period. Otherwise the status will be withdrawn.

~~If a country needs to define a *protection zone* i~~n accordance with Article 4.34.6. in response to an increased risk, including by the application of *vaccination*, once a the *protection zone* has been approved by the OIE, the freedom of the rest of the country or *zone* remains unchanged.

Rationale: As for above rationale, recommend moving with slight rewording of this second last paragraph of Article 8.8.3 to paragraph 2 of Article 8.8.2 and 8.8.3 where establishment of a protection zone is discussed.

In the event of the application for ~~the status of~~ a new ~~FMD free~~ free *zone* ~~where *vaccination* is practised to be assigned to a new *zone*~~ being adjacent to another ~~FMD~~ ~~free~~ *zone* of the same status ~~where *vaccination* is practised~~, it should be stated if the new *zone* is being merged with the adjacent *zone* to become one enlarged *zone*. If the two *zones* remain separate, details should be provided on the control measures to be applied for the maintenance of the status of the separate *zones* and particularly on the identification and the control of the movement of animals between the *zones* of the same status in accordance with Chapter 4.3.

Article 8.8.4.

~~FMD free~~ Compartment free from FMD where vaccination is not practised

A ~~FMD free~~ *compartment* free from FMD where *vaccination* is not practised can be established in ~~either a FMD free~~ any country or *zone* ~~or in an infected country or zone~~. In defining such a *compartment* the principles of Chapters 4.~~3~~4. and 4.~~4~~5. should be followed. Susceptible animals in the ~~FMD~~ free *compartment* should be separated from any other susceptible animals by the effective application of an ~~effective~~ *biosecurity plan* ~~management system~~.

A Member Country wishing to establish a ~~FMD free~~ *compartment* free from FMD where *vaccination* is not practised should:

1) have a record of regular and prompt animal *disease* reporting and, if not ~~FMD~~ free, have an *official control programme* and a *surveillance* system for FMD in place in accordance with Articles 8.8.40. to 8.8.42. that allows knowledge of the prevalence, distribution and characteristics of FMD in the country or *zone*;

2) declare for the ~~FMD~~ free *compartment* that:

   a) there has been no *case* of FMD during the past 12 months;

   b) no ~~evidence of~~ *infection* with FMDV has been ~~found~~ detected during the past 12 months;

   c) *vaccination* against FMD is prohibited;

   d) no animal vaccinated against FMD within the past 12 months is in the *compartment*;

   e) animals, semen, embryos and animal products may only enter the *compartment* in accordance with relevant articles in this chapter;

   f) documented evidence shows that *surveillance* in accordance with Articles 8.8.40. to 8.8.42. is in operation;

   g) an *animal identification* and *traceability* system in accordance with Chapters 4.1. and 4.2. is in place;

3) describe in detail:

   a) the animal *subpopulation* in the *compartment*;

   b) the *biosecurity plan* to mitigate the risks identified by the *surveillance* carried out in accordance with point 1.

The *compartment* should be approved by the *Veterinary Authority*. The ~~first~~ approval should only be granted when no *case* ~~or transmission~~ of FMD or transmission of FMDV has occurred within a 10 ~~ten~~ kilometre radius of the *compartment* during the ~~past~~ three months prior to the effective establishment of the *biosecurity plan*.

Rationale: Correction. Transmission is of the virus.

Article 8.8.10.

Recommendations for importation from ~~FMD free~~ countries, ~~or~~ zones or compartments free from FMD where vaccination is not practised ~~or FMD free compartments free from FMD~~

For FMD susceptible animals

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

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

2) were kept since birth or for at least the past three months in a ~~FMD free~~ country, ~~or~~ *zone* or *compartment* free from FMD where *vaccination* is not practised ~~or a FMD free *compartment*~~ ~~free from FMD~~;

3) if transiting an infected *zone*, were not exposed to any source of FMDV during transportation to the *place of shipment*~~.~~;

4) if previously vaccinated, comply with point 4 of Article 8.8.11.

Rationale: Editorial

Article 8.8.15.

Recommendations for importation from ~~FMD free~~ countries ~~or,~~ zones or compartments free from FMD where vaccination is practised

For frozen semen of domestic ruminants and pigs

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

1) the donor males:

   a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;

   b) were kept for at least three months prior to collection in a ~~FMD free~~ country or *zone* free from FMD where *vaccination* is practised;

   c) either

      i) have been vaccinated at least twice~~,~~ with the last *vaccination* not ~~less~~ more than ~~one~~ six months ~~and not more than six months prior to collection~~, unless protective immunity has been demonstrated for more than six months, and not less than one month prior to collection;

      or

      ii) were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMDV using a DIVA assay, with negative results;

2) the semen:

   a) was collected, processed and stored in accordance with Chapters 4.5. and 4.6.;

   b) was stored in the country of origin for a period of at least one month following collection, and during this period no animal on the *establishment* where the donor ~~animals~~ males were kept showed any sign of FMD.

Rationale: Vaccinated population; DIVA assay will be required.

Article 8.8.26.

Recommendations for importation from FMD infected countries or zones infected with FMDV

For blood-meal and meat-meals from FMD susceptible animals

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

1) the manufacturing method for these products included heating to a minimum core temperature of 70°C for at least 30 minutes.;

2) the necessary precautions were taken after processing to avoid contact of the products with any potential source of FMDV.

Rationale: Australia does not agree that it is appropriate to remove this. As discussed above, the movement of these commodities into the safe commodities has been accompanied by a loss of specific processing requirements, which provides some guidance on the key aspects of processing that are required to ensure adequate inactivation of FMDV and management of the disease transmission risk. Without guidance on the basic processing expected, there is the risk of product inadequately treated being mistakenly assumed to be safe by importing countries.

Terrestrial Animal Health Standards Commission Report
September 2020

Australian Comments – indicated in blue font

CHAPTER 8.16.

INFECTION WITH RINDERPEST VIRUS

Article 8.16.6

Country free from rinderpest

In the event of re-emergence of rinderpest, all OIE Member Countries without a case will remain free from rinderpest. However, all OIE Member Countries without a case will be asked to provide a *risk assessment* to the OIE, within 1 month of the first reported case, and free status will be suspended if their *risk assessment* is not received within that time or is not accepted by the OIE.

Some countries will be at heightened *risk*. In particular, countries meeting the conditions below would be regarded as being at heightened risk and should carry out appropriate *surveillance*, capable of detecting the presence of *infection* even in the absence of clinical signs; this may be achieved through a *surveillance* programme in accordance with Article 8.16.11. in addition to ongoing *surveillance* in accordance with Article 8.16.3.:

1) countries that are adjacent to a country infected with RPV; or

2) countries that have relevant epidemiological or ecological links through trade or animal movements to a country infected with RPV.

Rationale: Currently there is no time frame given for OIE member countries to submit their risk assessment, and for the OIE to accept this risk assessment in the event of re-emergence of rinderpest. This may lead to confusion regarding the re-introduction of sanitary measures for rinderpest for continuation of international trade of animals and animal products. Australia recommends that a reasonable time limit be included to give clear guidance in the event of re-emergence of rinderpest.

Annex 20

CHAPTER 11.4.

BOVINE SPONGIFORM ENCEPHALOPATHY

Australian comments

General Comments

Australia recommends the addition of the word 'status' in several titles and articles throughout the chapter where BSE risk is specified. This assists by providing a subject for the titles and by emphasising the relevance of a country's Official Status.

Australia questions the basis for removal of detailed information on processing of gelatine and collagen to be regarded as safe in international trade. It is noted that Article 11.4.15 of the current Code describes industrial practices that are not specifically directed against BSE, however these parameters form sound, evidence-based international minimum standards. Unless it is certain that gelatine and collagen can only be produced by meeting these parameters it would be preferable to retain them in some form.

Article 11.4.1.

General provisions

1) The recommendations in this chapter are intended to mitigate the human and animal health risks associated with the presence of the bovine spongiform encephalopathy (BSE) agents in cattle only. BSE manifests in two main forms: classical BSE and atypical BSE. Atypical BSE is a condition that occurs at a very low rate and is assumed to occur spontaneously in any cattle population. Oral exposure to contaminated *feed* is the main route of transmission of classical BSE. Given that cattle have been experimentally infected by the oral route with a low molecular weight type of atypical BSE (L-type BSE~~,~~), atypical BSE is also ~~potentially~~ considered capable of being recycled in a cattle population if cattle are orally exposed to contaminated *feed*.

2) BSE primarily affects cattle. Other animal species may be naturally and experimentally susceptible to BSE, but they are not regarded as being epidemiologically significant, particularly when feeding ruminants with ruminant-derived protein meal is not practiced.

3) For the purposes of the *Terrestrial Code*:

~~1~~a) BSE is an invariably fatal neurological prion disease of cattle caused by PrP^{BSE}, including both classical (C-type BSE) and atypical strains (H- and L-type BSE~~). for respectively having a protease-resistant PrP^{BSE} fragment of higher and lower molecular mass than classical BSE~~). The term 'BSE' includes both classical and atypical forms, unless otherwise specified.

~~2~~b) The occurrence of a BSE *case* is defined by the immunohistochemical (IHC) or immunochemical detection of PrP^{BSE} in brain tissue of a bovid of the species *Bos taurus* or *Bos indicus*, with discrimination between atypical and classical BSE strains based on the Western immunoblot banding pattern, as described in the *Terrestrial Manual*.

4) For the purposes of this chapter:

~~3~~a) 'Cattle' means ~~a~~ bovids of the species *Bos taurus* or *Bos indicus.*

4b) 'Protein meal' means any final or intermediate solid protein-containing product, obtained when animal tissues are rendered, excluding blood and blood products, peptides of a molecular weight less than 10,000 daltons and amino-acids.

5) When *commodities* are imported in accordance with this chapter, the BSE risk of the *importing country* or *zone* of destination is not affected by the BSE risk of the *exporting country*, *zone* or *compartment* of origin.

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

Rationale: Additional technical detail does not improve the definition but does make comprehension more difficult. If this level of detail is necessary if more be more appropriately included in the OIE Manual.

Article 11.4.1bis.

Safe commodities

When authorising the importation or transit of the following *commodities* derived from cattle, *Veterinary Authorities* should not require any conditions related to BSE, regardless of the BSE risk posed by the cattle population of the *exporting country*, *zone* or *compartment*:

Annex 20 (contd)

1) *milk* and *milk products*;

2) semen and *in vivo* derived cattle embryos collected and handled in accordance with the relevant chapters of the *Terrestrial Code*;

3) hides and skins;

4) gelatine and collagen;

5) tallow with maximum level of insoluble impurities of 0.15% in weight and derivatives made from this tallow;

~~6) tallow derivatives;~~

~~7~~6) dicalcium phosphate (with no trace of protein or fat~~).~~);

7) foetal blood.

Other *commodities* of cattle can be traded safely if in accordance with the relevant articles of this chapter.

Article 11.4.2.

~~The~~ General criteria for the determination of the BSE risk of the cattle population of a country, zone or compartment

~~The~~ Due to its etiological and epidemiological features, the BSE risk of ~~the cattle population of~~ a country, *zone* or *compartment* is determined on the basis of the following criteria:

1) a BSE *risk assessment*, in accordance with the provisions of ~~Chapter 1.8.~~the "Application for official recognition by the OIE of risk status for bovine spongiform encephalopathy" that evaluates the ~~likelihood~~risk of BSE being recycled within the cattle population by identifying all potential factors associated with the occurrence of BSE and their historic perspective. Member Countries should review the *risk assessment* annually to determine whether the situation has changed.

   ~~A~~The *risk assessment* for the purpose of BSE, based on the framework provided by Article 2.1.4, consists of:

   a) Entry assessment

      ~~An~~The entry assessment evaluates the likelihood that the classical BSE agent has been introduced into the country, *zone* or *compartment* ~~via imported~~through the importation of the following *commodities*~~.~~ in the preceding eight years:

      i) Cattle;

      ii) Ruminant-derived protein meal;

      iii) *Feed* (not intended for pets) that contains ruminant-derived protein meal;

      iv) Fertilizers that contain ruminant-derived protein meal;

      v) Any other *commodity* that either is or could be contaminated by *commodities* listed in Article 11.4.14.

   b) Exposure assessment

      ~~An~~The exposure assessment evaluates the likelihood of cattle being exposed to BSE during the preceding eight years, either through imported *commodities* or as a result of the presence of BSE agents in the indigenous cattle population of the country, *zone* or *compartment*.

The first step in the exposure assessment involves an evaluation of livestock industry practices through a consideration of the impact of:

i) Livestock industry practices on preventing cattle from being fed ruminant-derived protein meal, taking account of:

- demographics of the cattle population and production systems;
- feeding practices;
- slaughtering and waste management practices;
- rendering practices;
- *feed* production, labelling, distribution and storage.

Rationale: Labelling is a key component of effective feed control.

Depending on the outcome from this step, an evaluation of mitigation measures specifically targeting BSE may also need to be included through a consideration of the impact of:

ii) Specific risk mitigation measures on preventing cattle from being fed ruminant-derived protein meal, taking account of:

- the nature and scope of a *feed* ban on feeding ruminants with protein meal derived from ruminants;
- the fate of *commodities* with the greatest BSE infectivity (those *commodities* listed in point 1 of Article 11.4.14.);
- parameters of the rendering process;
- prevention of cross-contamination during rendering, *feed* production, transport, storage and feeding;
- awareness programme under the scope of the *feed* ban;
- monitoring and enforcement of the *feed* ban.

Depending on the outcome of the exposure assessment, a consequence assessment (in point c) below) may not be required.

c) Consequence assessment

~~A~~The consequence assessment evaluates the likelihood of cattle becoming infected ~~with~~ following exposure to the BSE agents together with the likely extent and duration of any subsequent recycling and amplification within the cattle population during the preceding eight years. The factors to be considered in the consequence assessment are:

i) age at exposure;

ii) production type;

iii) the impact of cattle industry practices or the implementation of BSE specific mitigation measures under a *feed* ban.

Annex 20 (contd)

d) Risk estimation

The risk estimation combines the results and conclusions arising from the entry, exposure and consequence assessments to provide an overall measure of the risk that BSE agents have been recycled in the cattle population through the feeding of ruminant-derived protein meal, with indigenous *cases* arising ~~as a consequence~~;

2) the ongoing implementation of a *surveillance* programme for classical BSE in the cattle population in accordance with Article 11.4.18.;

3) the history of occurrence and management of BSE *cases*.

Article 11.4.3.

Negligible BSE risk status

The BSE risk of ~~the cattle population of~~ a country, *zone* or *compartment* can be considered to be negligible if the following conditions for the cattle population are met for at least the preceding eight years:

1) A *risk assessment* as described in Article 11.4.2. that has identified all potential risk factors associated with the occurrence of BSE has been conducted, and the Member Country has demonstrated through documented evidence that the ~~likelihood~~risk of BSE agents being recycled in the cattle population has been negligible ~~as the result of:~~.

~~EITHER:~~

~~a) livestock industry practices ensuring that protein meal derived from ruminants has not been fed to ruminants;~~

~~OR~~

~~b) effective and continuous mitigation of each identified risk ensuring that protein meal derived from ruminants has not been fed to ruminants.~~

2) The *surveillance* provisions as described in Article 11.4.~~20~~18. have been implemented.

3) EITHER:

a) there has been no *case* of BSE or, if there has been a *case*, every *case* of BSE has been demonstrated to have been imported or has been diagnosed as atypical BSE as defined in this chapter;

OR

b) if there has been an indigenous *case* of classical BSE;

EITHER:

i) all *cases* were born at least eight years ago;

OR

ii) where a *case* was born within the preceding eight years, subsequent investigations have confirmed that the ~~likelihood~~risk of BSE being recycled within the cattle population has continued to be negligible.

4) Any *cases* of BSE that have been detected have been completely destroyed or disposed of to ensure that they do not enter the animal *feed* chain.

The country or the *zone* will be included in the list of countries or *zones* posing a negligible risk for BSE in accordance with Chapter 1.6. Retention on the list requires annual confirmation of the conditions in points 1 to 4 above. Documented evidence should be resubmitted annually for points 1 to 4 above.

Any changes in the epidemiological situation or other significant events should be notified to the OIE in accordance with Chapter 1.1.

Article 11.4.3bis.

Recovery of negligible BSE risk status

~~When~~Should an indigenous *case* of classical BSE ~~is reported~~ in an animal born within the preceding eight years occur in a country or *zone* recognised as ~~having~~posing a negligible ~~BSE~~ risk for BSE, the status~~,~~ of the ~~negligible BSE risk status~~country or *zone* is suspended ~~and the recommendations for controlled BSE risk status apply, pending~~. The status may be recovered when the outcome of subsequent investigations ~~confirming~~confirms that the ~~likelihood~~risk of BSE being recycled within the cattle population continues to be negligible. ~~The~~In the interim, the provisions for a country or *zone* ~~will regain~~with a controlled BSE risk status apply.

The negligible BSE risk status of the country or *zone* will be reinstated only after the submitted evidence has been accepted by the OIE.

Rationale: This article discusses the BSE risk of a country, zone or compartment, yet only notes the ability for the status of a country or zone to be recognised. Consistency in addressing compartmentalisation may be beneficial. A grammatical correction also noted.

Article 11.4.4.

Controlled BSE risk status

The BSE risk of the cattle population of a country, *zone* or *compartment* can be considered to be controlled provided the conditions of Article 11.4.3. are met, but at least one of the conditions has not been met during ~~for at least~~ the preceding eight years.

The country or the *zone* will be included in the list of countries or *zones* posing a controlled risk for BSE in accordance with Chapter 1.6. Retention on the list requires annual confirmation of the conditions in points 1 to 4 of Article 11.4.3. Documented evidence should be resubmitted annually for points 1 to 4 of Article 11.4.3.

Any changes in the epidemiological situation or other significant events should be notified to the OIE in accordance with Chapter 1.1.

Rationale: It is not clear how to interpret or apply the controlled BSE risk status specification that ‘at least one of the conditions has not been met’. This appears to allow open-ended non-compliance. A grammatical correction also noted.

Article 11.4.5.

Undetermined BSE risk status

The BSE risk of the cattle population of a country, *zone* or *compartment* is considered to be undetermined if it cannot be demonstrated that it meets the requirements for negligible or controlled BSE risk.

~~Article 11.4.6.~~

~~**Recommendations for importation of cattle from a country, zone or compartment posing a negligible BSE risk**~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that cattle selected for export came from a country, *zone* or *compartment* posing a negligible BSE risk.~~

Article 11.4.7.

Recommendations for importation of cattle from a country, zone or compartment ~~posing~~ with a negligible or controlled BSE risk status

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

Annex 20 (contd)

1) the cattle selected for export~~:~~

~~1)~~ came from a country, *zone* or *compartment* ~~posing~~ with a negligible or controlled BSE risk status and are identified through an *animal identification system* enabling each *animal* to be traced throughout its lifetime;

AND EITHER:

2) the cattle selected for export were born in the country, *zone* or *compartment* during the period when the ~~likelihood~~risk of the BSE agents being recycled in the cattle population has been demonstrated to be negligible;

OR

~~3)~~

~~a) are identified by a permanent individual identification system from birth enabling each animal to be traced throughout its lifetime; and~~

~~b)~~ ~~are~~ it is demonstrated ~~as having~~that the cattle selected for export have not been fed protein meal derived from ruminants.

Article 11.4.8.

Recommendations for importation of cattle from a country, zone or compartment ~~posing~~ with an undetermined BSE risk status

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that ~~cattle selected for export~~:

1) the cattle selected for export are identified ~~by a permanent individual~~ through an *animal identification system* ~~from birth~~ enabling each animal to be traced throughout its lifetime;

2) ~~are~~it is demonstrated ~~as having~~ that the cattle selected for export have not been fed protein meal derived from ruminants.

~~Article 11.4.9.~~

~~**Recommendations for importation of fresh meat and meat products from a country, zone or compartment posing a negligible BSE risk**~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the cattle from which the *fresh meat* and *meat products* were derived:~~

~~1)~~ ~~came from a country, *zone* or *compartment* posing a negligible BSE risk;~~

~~2)~~ ~~have been subjected to an ante-mortem inspection with favourable results.~~

Article 11.4.10.

Recommendations for importation of fresh meat and meat products from a country, zone or compartment ~~posing~~ with a negligible or controlled BSE risk status

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

1) the cattle from which the *fresh meat* and *meat products* were derived came from a country, *zone* or *compartment* ~~posing~~ with a ~~controlled BSE risk~~negligible or controlled BSE risk status and are identified through an *animal identification system*;

Annex 20 (contd)

2) they have been subjected to an ante-mortem inspection with favourable results;

AND EITHER:

3) they were born in the country, *zone* or *compartment* during the period when the ~~likelihood~~ risk of the BSE agents being recycled in the cattle population has been demonstrated to be negligible;

OR

4) the *fresh meat* and *meat products*:

   a) derived from cattle not subjected to a *stunning* process with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, or to any other procedure that can contaminate blood with nervous tissue, prior to *slaughter*; and

   b) were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:

      i) the *commodities* listed in points ~~1) a) and 1) b)~~ of Article 11.4.14.;

      ii) mechanically separated meat from the skull ~~and~~or from the vertebral column from cattle over 30 months of age.

Rationale: Grammatical correction.

Article 11.4.11.

Recommendations for importation of fresh meat and meat products from a country, zone or compartment posing an undetermined BSE risk

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

1) the cattle from which the fresh meat and meat products were derived~~:~~

~~a)~~ are identified through an *animal identification system*;

2) it is demonstrated ~~as having~~that the cattle from which the *fresh meat* and *meat products* were derived have not been fed protein meal derived from ruminants;

~~b~~3) the cattle from which the *fresh meat* and *meat products* were derived:

   a) were subjected to an ante-mortem inspection with favourable results;

   ~~c~~b) were not subjected to a *stunning* process with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, or to any other procedure that can contaminate blood with nervous tissue, prior to *slaughter*;

~~2~~4) the *fresh meat* and *meat products* were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:

a) the *commodities* listed in point~~s~~ 1~~)~~ ~~*a) and 1) b)*~~ of Article 11.4.14.;

b) mechanically separated meat from the skull ~~and~~nor from the vertebral column from cattle over 30 months of age.

Rationale: Grammatical correction.

Annex 20 (contd)

Article 11.4.12.

Recommendations for importation of cattle-derived protein meal from a country, zone or compartment ~~posing~~ with a negligible BSE risk status

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the cattle from which the protein meal was derived ~~came from a country, *zone* or *compartment* posing a negligible BSE risk.~~ :

1) came from a country, *zone* or *compartment* ~~posing~~ **with** a negligible BSE risk **status**;

2) are identified through an *animal identification system* and were born in the country, *zone* or *compartment* during the period when the risk of the BSE agents being recycled in the cattle population has been demonstrated to be negligible.

Article 11.4.13.

Recommendations for importation of blood and blood products derived from cattle (except foetal blood)

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

EITHER:

1) the blood and blood products came from a country, *zone* or *compartment* posing a negligible or controlled BSE risk; and

~~OR~~

2) the ~~blood and blood products came from a country, *zone* or *compartment* posing a controlled BSE risk and the~~ cattle from which the blood and blood products were derived are identified through an *animal identification system* and were born in the country, *zone* or *compartment* during the period when the ~~likelihood~~ risk of the BSE agents being recycled in the cattle population has been demonstrated to be negligible;

OR

3) the blood and blood products were:

   a) collected from cattle not subjected to a *stunning* process~~, or to any other procedure that can contaminate the blood with nervous tissue.~~ with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, or to any other procedure that can contaminate blood with nervous tissue, prior to *slaughter*; and

   b) collected and processed in a manner that ensures they are not contaminated with nervous tissue.

Rationale: Point a amended for consistency with Article 11.4.10 and 11.4.11.

Article 11.4.14.

Recommendations in relation to the trade of the commodities with the greatest BSE infectivity

~~1)~~ Unless covered by other articles in this chapter, the following *commodities* ~~originating from a country, *zone* or *compartment* posing a controlled or undetermined BSE risk, and any *commodity* contaminated by them,~~ should not be traded ~~for the preparation of food, *feed*, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices~~:

~~a~~1) ~~distal~~ Distal ileum from cattle of any age; ~~*b)*~~ skull, brain, eyes, vertebral column and spinal cord from cattle that were at the time of *slaughter* over 30 months of age~~.~~; or any *commodity* contaminated by them, for the preparation of protein products, food, *feed*, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices, which originate from a country, *zone* or *compartment* posing:

Annex 20 (contd)

a) an undetermined BSE risk;

b) a controlled BSE risk or a negligible BSE risk if the *commodities* are derived from cattle born before the period when the risk of the BSE agents being recycled in the cattle population has been demonstrated to be negligible.

2) Protein products, food, *feed*, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices prepared using *commodities* listed in point~~s~~ 1~~) *a)* or 1) *b)*~~ above ~~of this article, which originate from a country, *zone* or *compartment* posing a controlled or undetermined BSE risk, should not be traded~~.

3) Cattle-derived protein meal, or any *commodities* containing such product~~s~~, which originate from a country, *zone* or *compartment* with ~~posing~~ a controlled or undetermined BSE risk status~~, should not be traded~~.

~~These points do not apply to cattle in a country or *zone* with a controlled BSE risk when they are born during the period when the likelihood of the BSE agents being recycled in the cattle population has been demonstrated to be negligible.~~

Article 11.4.15.

Recommendations for importation of tallow (other than as defined in Article 11.4bis.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

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

1) ~~the tallow~~ came from a country, *zone* or *compartment* with ~~posing~~ a negligible BSE risk status; or

2) ~~the tallow~~ is derived from cattle which have been subjected to an ante-mortem inspection with favourable results, and has not been prepared using the *commodities* listed in ~~points~~point 1~~) a) and 1) b)~~ of Article 11.4.14.

Article 11.4.16.

Recommendations for importation of dicalcium phosphate (other than as defined in Article 11.4.1bis.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

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

1) ~~the dicalcium phosphate~~ came from a country, *zone* or *compartment* ~~posing~~ with a negligible BSE risk status; or

2) ~~the dicalcium phosphate~~ is a co-product of bone gelatine.

Article 11.4.16bis.

Recommendations for importation of tallow derivatives (other than as defined in Article 11.4.1bis.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

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

Annex 20 (contd)

1) originate from a country, *zone* or *compartment* with ~~that poses~~ a negligible BSE risk status; or

2) are derived from tallow that meets the conditions referred to in Article 11.4.15.; or

~~3) have been produced by hydrolysis, saponification or transesterification that uses high temperature and pressure.~~

Rationale: Point 1 as per previous rationale. If not accepted, wording should be adjusted from 'that poses' to 'posing' for consistency. Point 3 should only be included if minimum temperature and pressure are specified.

Article 11.4.17.

Procedures for reduction of BSE infectivity in protein meal

The following procedure should be used to reduce the infectivity of any ~~transmissible spongiform encephalopathy~~BSE agents ~~which~~that may be present during the production of protein meal containing ruminant proteins.

1) The raw material should be reduced to a maximum particle size of 50 mm before heating~~.~~;

2) The raw material should be heated under saturated steam conditions to a temperature of not less than 133°C for a minimum of 20 minutes at an absolute pressure of 3 bar.

Article 11.4.18.

Surveillance

~~1) *Surveillance* for BSE consists of the regular reporting of animals with clinical signs suggestive of BSE to the *Veterinary Authority* for subsequent investigation and diagnosis. The credibility of the *surveillance* programme is supported by:~~

~~a) compulsory notification of BSE throughout the whole territory by all those stakeholders involved in the rearing and production of livestock including farmers, herdsmen, *veterinarians*, transporters and *slaughterhouse/abattoir* workers;~~

~~b) an ongoing awareness programme to ensure that all stakeholders are familiar with the clinical signs suggestive of BSE as well as the reporting requirements;~~

~~c) appropriate *laboratory* investigations in accordance with the *Terrestrial Manual* and follow up field investigation as necessary of all clinical suspects.~~

~~2~~1) BSE is a progressive, fatal disease of the nervous system of cattle that usually has an insidious onset that is refractory to treatment. A range of clinical signs that vary in severity and between animals have been described for classical BSE:

a) progressive behavioural changes that are refractory to treatment such as increased excitability, depression, nervousness, excessive and asymmetrical ear and eye movements, apparent increased salivation, increased licking of the muzzle, teeth grinding, hypersensitivity to touch and/or sound (hyperaesthesia), tremors, excessive ~~vocalization~~vocalisation, panic-stricken response and excessive alertness;

b) postural and locomotory changes such as abnormal posture (dog sitting), abnormal gait (particularly pelvic limb ataxia), low carriage of the head (head shyness), difficulty avoiding obstacles, inability to stand and recumbency;

c) ~~generalized~~generalised non-specific signs such as reduced *milk* yield, loss of body condition, weight loss, bradycardia and other disturbances of cardiac rhythm.

Annex 20 (contd)

Some of these signs are also likely to be relevant for atypical BSE, particularly those associated with difficulty in rising and recumbency. A nervous form of atypical BSE resembling classical BSE may be observed with over-reactivity to external stimuli, unexpected startle responses and ataxia. In contrast, a dull form of atypical BSE may be observed with dullness combined with a low head carriage and compulsive behaviour (licking, chewing, pacing in circles).

The clinical signs of BSE usually progress on a spectrum over a few weeks to several months, but ~~in~~on rare occasions cases can develop acutely and progress rapidly. ~~In the continuum of the disease spectrum, t~~The ~~The~~ final stages of this disease spectrum are characterised by recumbency, coma and death.

~~Cattle displaying some of the above-mentioned progressive neurological signs without signs of infectious illness, and that are refractory to treatment, are candidates for examination.~~

Since these signs are not pathognomonic for either classical or atypical BSE, all Member Countries with cattle populations ~~may~~ are likely to observe individual animals displaying clinical signs suggestive of BSE. ~~The rate at which they are likely to occur~~General statements about the likely frequency of occurrence of such animals cannot be ~~reliably predicted~~made as they will vary depending on the epidemiological situation in a particular country. ~~In addition, in~~

2) Surveillance for BSE consists of the reporting of all animals that lie on the ~~continuum of the~~ clinical BSE spectrum to the *Veterinary Authority* for subsequent investigation and follow-up.

In those countries where cattle are intensively reared and subjected to regular observation, it is likely that ~~such~~ animals that display clinical signs suggestive of BSE will be more readily seen. Behavioural changes, that may be very subtle in the early clinical phase, are best identified by those who handle animals on a daily basis and who can monitor them closely for a progression of the signs. In more extensive systems however, where cattle are not monitored as closely, situations may ~~inevitably~~ arise where an animal might be considered as a clinical suspect, yet if it was not observed for a period of time, it may only be initially seen as a downer (non-ambulatory) or found dead (fallen stock). ~~Under such circumstances, if there is an appropriate supporting clinical history, these animals that lie on the continuum of a progressive disease from clinical suspect to downer to fallen stock may still be suitable candidates for *surveillance*.~~

The investigation of potential surveillance candidates should take into account that the vast majority of BSE cases arise as single, isolated events. The concurrent occurrence of multiple animals with behavioural or neurological signs, non-ambulatory or fallen stock is most likely associated with other causes.

The following animals that lie on the ~~continuum of the~~ disease spectrum should be targeted for BSE *surveillance*:

a) those displaying some of the progressive clinical signs mentioned in point 1 of Article 11.4.18. suggestive of BSE that are refractory to treatment, and where other common causes of behavioural or neurological signs (e.g., infectious, metabolic, traumatic, neoplastic or toxic causes) have been ruled out;

b) *those showing behavioural or neurological signs during ~~that have been subjected to an~~ ante-mortem inspection ~~with unfavourable results~~ at slaughterhouses/abattoirs*;

c) those presented as downers (non-ambulatory), with an appropriate supporting clinical history;

d) those found dead (fallen stock), with an appropriate supporting clinical history.

Rationale: Introducing the word continuum adds unneeded complexity when it has already been described that clinical signs of the disease are progressive and lie on a spectrum. For point b, the inspection determination is not relevant if suspicious clinical signs have been observed.

All these animals should be followed up with appropriate laboratory testing in accordance with the *Terrestrial Manual* to accurately confirm or rule out the presence of BSE agents.

Annex 20 (contd)

3) The credibility of the *surveillance* programme is supported by:

a) ongoing awareness and training programmes to ensure that all those stakeholders involved in the rearing and production of livestock including farmers, herdsmen, *veterinarians*, transporters and *slaughterhouse/abattoir* workers are familiar with the clinical signs suggestive of BSE as well as the statutory reporting requirements;

b) the fact that BSE is a compulsorily *notifiable disease* throughout the whole territory;

c) appropriate *laboratory* testing in accordance with the *Terrestrial Manual*;

d) robust, documented, evaluation procedures and protocols for the identification and reporting of potential candidates for BSE *surveillance*, for determination of animals to be subjected to laboratory testing, for the collection and submission of samples for laboratory testing, and for follow-up epidemiological investigation for BSE positive findings.

Terrestrial Animal Health Standards Commission Report
September 2020

Australian Comments – indicated in blue font

CHAPTER 1.8.

APPLICATION FOR OFFICIAL RECOGNITION BY THE OIE OF RISK STATUS FOR BOVINE SPONGIFORM ENCEPHALOPATHY

Article 1.8.5.

BSE risk assessment

2. Exposure assessment

a) Livestock industry practices.

iii) Slaughtering and waste management practices.

Describe the practices for fallen stock and cattle euthanised as part of a BSE surveillance programme under Article 1.8.6 that occur on farm, during transport, at livestock *markets* or auctions or prior to *slaughter*, with particular reference to their transportation, disposal or destruction, including composting, burial, rendering or incineration. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic.

Rationale: The phrase is added for completeness. Cattle euthanised as part of a BSE surveillance programme are at high risk of having BSE, yet are not specifically mentioned or given a category and could conceivably enter a food chain before test results become available.

Terrestrial Animal Health Standards Commission Report
September 2020

Australian Comments – indicated in blue font

CHAPTER 11.11.

TRICHOMONOSIS

Article 11.11.1.

General provisions

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

Article 11.11.2.

Recommendations for the importation of cattle for breeding

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

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

2) the animals were kept in a *herd* in which no *case* of trichomonosis has been reported; and/or

3) ~~for~~ females which have been mated~~, direct microscopic examination and culture of vaginal mucus were negative~~ were subjected to an agent identification test on vaginal mucous with negative results.

Article 11.11.3.

Recommendations for the importation of bulls for breeding (natural service or artificial insemination)

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

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

2) the animals were kept in a *herd* in which no *case* of trichomonosis has been reported; and/or

3) the animals have never been used for natural service; or

4) the animals have only mated virgin heifers; or

5) the animals were subjected to ~~a direct microscopic and cultural examination of preputial specimens~~ an agent identification test on preputial specimens with negative results.

Article 11.11.4.

Recommendations for the importation of bovine semen

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

1) the donor animals have never been used for natural service; or

2) the donor animals have only mated virgin heifers; or

3) the donor animals were kept in an *establishment* or *artificial insemination centre* where no *case* of trichomonosis has been reported;

4) the donor animals were subjected to ~~a direct microscopic and cultural examination of preputial specimens~~ an agent identification test on preputial specimens with negative results;

5) the semen was collected, processed and stored in accordance with Chapter 4.6. and 4.7.

Rationale: The current wording does not explicitly specify what site is sampled for the agent identification test to be conducted on. Australia recommends re-inclusion of the specific sites and samples required for testing under stated circumstances to avoid any confusion.

Terrestrial Animal Health Standards Commission Report
September 2020

CHAPTER 12.7.

INFECTION WITH *THEILERIA EQUI* AND *BABESIA CABALLI* (EQUINE PIROPLASMOSIS)

Article 12.7.1.

The use of the term equine piroplasmosis indicates clinical diseases caused by the transmission of *Theileria equi (T. equi)* or *Babesia caballi (B. caballi)* through competent ticks or iatrogenic practices. Vertical transmission has also been reported. This chapter deals not only with the occurrence of clinical signs caused by *infection* with *T. equi* or *B. caballi*, but also with the presence of *infection* with *T. equi* or *B. caballi* in the absence of clinical signs.

Rationale: Australia proposes a change above to include the vertical transmission pathway. Vertical transmission of *T. equi* and *B. caballi* in horses has been reported (Georges, 2011; Sant, 2016).

References

Georges et al.; 2001; A case of transplacental transmission of *Theileria equi* in a foal in Trinidad; Veterinary Parasitology; 175; 363-366.
Sant et al; 2016; Prospective study investigating transplacental transmission of equine piroplasmosis in thoroughbred foals in Trinidad; Veterinary Parasitology; 226; 132-137

Susceptible animals for *infection* with *T. equi* or *B. caballi* are primarily domestic and *wild* equids. Although old-world camelids are susceptible to *infection* and potential reservoirs, they are not found to play a significant role in the epidemiology of the disease.

Equids infected with *T. equi* or *B. caballi* may remain carriers of these blood parasites for long periods, sometimes lifelong and act as sources of *infection* for competent tick *vectors* of the genera *Dermacentor, Rhipicephalus, Hyalomma* ~~and~~, *Amblyomma*, *Ixodes* and *Haemaphysalis*.

Rationale: Ticks from the genera *Ixodes* and *Haemaphysalis* have also been shown to be both natural and experimental vectors for equine piroplasms (Scoles, 2015; Spickler; 2018). Australia proposes adding these genera of ticks to the list above.

References

Scoles and Ueti; 2015; Vector ecology of equine piroplasmosis. Annual Reviews of Entomology; 7;60:561-80. doi: 10.1146/annurev-ento-010814-021110. PMID: 25564746.
Spickler, 2018; Equine piroplasms; at http://www.cfsph.iastate.edu/DiseaseInfo/factsheets.php

For the purposes of the *Terrestrial Code*, the following defines *infection* with *T. equi* or *B. caballi*:

1) identification of the parasite by microscopic examination of a sample from an equid which may be showing clinical or pathological signs consistent with *infection* with *T. equi* or *B. caballi* or epidemiologically linked to a confirmed or suspected *case* of *infection* with *T. equi* or *B. caballi*; or

2) antigen or genetic material specific for *T. equi* or *B. caballi* has been identified in a sample from an equid which may be showing clinical or pathological signs consistent with *infection* with *T. equi* or *B. caballi* or epidemiologically linked to a confirmed or suspected *case* of *infection* with *T. equi* or *B. caballi*; or

3) antibodies specific to *T. equi* or *B. caballi* have been identified in a sample from an equid which may be showing clinical or pathological signs consistent with *infection* with *T. equi* or *B. caballi* or epidemiologically linked to a confirmed or suspected *case* of *infection* with *T. equi* or *B. caballi*.

Rationale: Australia proposes changes to this clause to account for asymptomatic carriers. Not all equids infected with equine piroplasms will develop acute or chronic illness. Asymptomatic carriers are important in the ongoing transmission, especially via importation into a naïve equid population with suitable vectors. This change will make

this article consistent with the stated scope of the chapter from article 12.7.1, which states the chapter also covers infection with equine piroplasms. Australia also notes that the report of the OIE expert group on equine piroplasmosis in the February 2020 SCAD report proposes that the definition of infection with *T. equi* or *B. caballi* be applied in equids without or without clinical signs.

For the purposes of the *Terrestrial Code*, the *incubation period* of *infection* with *T. equi* shall be 19 days, or with *B. caballi* in equids shall be 30 days and the *infective period* shall be lifelong.

Rationale: Australia agrees with the OIE export group on equine piroplasmosis that the incubation period is 12-19 days for *T. equi* and 10-30 days for *B. caballi*. However, Australia proposes that these different incubation periods should be stated as merging them could be trade restrictive in some circumstances.

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

Rationale: As there is no commercial vaccine available for equine piroplasmosis, and so no relevant section in the Terrestrial Manual, Australia proposes this be deleted. Should vaccines become available they would need to be assessed for inclusion in the Terrestrial Manual prior to inclusion in the Terrestrial Code.

Article 12.7.3.

Country or zone free from infection with *T. equi* and *B. caballi*

1) Historical freedom as described in Chapter 1.4. does not apply to *infection* with *T. equi* and *B. caballi.*

2) A country or a *zone* may be considered free from *infection* with *T. equi* and *B. caballi* when:

a) *infection* with *T. equi* and infection with *B. caballi* have been notifiable diseases in the entire country for at least the past 10 years and, in the country or *zone*:

EITHER:

i) there has been no *case* of *infection* with *T. equi* and no *case* of *infection* with *B. caballi* during the past six years; and

ii) a *surveillance* programme performed in accordance with Article 12.7.9. has demonstrated no evidence of *infection* with *T. equi* and no evidence of *infection* with *B. caballi* in the past six years;

OR

iii) an ongoing *surveillance* programme performed in accordance with Article 12.7.9. has found no competent tick *vectors* for at least six years;

b) imports of equids into the country or *zone* are carried out in accordance with this chapter. A country or *zone* free from *infection* with *T. equi* and *B. caballi* in which ongoing *vector surveillance*, performed in accordance with Article 12.7.9., has found no competent tick *vector* will not lose its free status through the introduction of seropositive or infective equids imported temporarily in accordance with Article 12.7.6;

Rationale: Clause 2b does not consider the possible role that iatrogenic or vertical transmission may play in establishing an outbreak. Iatrogenic transmission was considered pivotal in outbreaks in Florida in 2008, in Missouri in 2009 and Ireland in 2009 following the importation of undetected carriers (Short, 2012; Traub-Dargatz; 2010, OIE, 2009). As horses are considered lifelong carriers, they still represent a biosecurity risk for introduction of equine piroplasms to other countries, even when resident in countries where known competent vectors are not present. The only scenario in which this should not change a country's equine health status is when seropositive horses are temporarily imported for specific events in line with article 12.7.6. Australia has proposed the above change in line with this.

References

Short et al.; 2012; Outbreak of equine piroplasmosis in Florida; Journal of the American Veterinary Medical Association; 240 (5); 588-595

Traub-Dargatz et al.; 2010; Equine piroplasmosis. In Proceedings of the 56th annual convention of the American Association of Equine Practitioners (AAEP), Baltimore, Maryland, American Association of Equine Practitioners, Lexington.

OIE, 2009; Summary of immediate notifications and follow-ups – 2009; Equine piroplasmosis; Ireland; Follow up report 3 (final report); available at https://www.oie.int/wahis_2/public/wahid.php/Reviewreport/Review/viewsummary?fupser=&dothis=&reportid=8418

Article 12.7.~~2~~5.

Recommendations for the importation of ~~equines~~ equids

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

1) the animals showed no clinical signs ~~equine piroplasmosis~~ of *infection* with *T. equi* or *B. caballi* on the day of shipment, and

2) EITHER:

a) the animals were kept in a country or *zone* free from *infection* with *T. equi* and *B. caballi* since birth;

OR

~~2) were subjected to diagnostic tests for equine piroplasmosis (Theileriaequi and Babesia caballi) with negative results during the 30 days prior to shipment;~~

b) i) were subjected to a serological ~~or agent identification~~ test ~~with molecular techniques~~ for the detection of *T. equi* and *B. caballi* with negative results carried out on a blood sample taken within the 14 days prior to shipment; and

Rationale: Australia agrees with the report of the OIE expert group on equine piroplasmosis that use of microscopy is not sensitive enough for the purposes of trade. However, the proposed clause 2.b.i. includes molecular techniques for agent identification. The Terrestrial Manual does not describe a specific technique for a molecular test but recommends them based on their widespread use "without dubious results". Given the lack of a standardised and validated molecular test, Australia proposes that only serological tests are included in this Chapter of the Terrestrial Code as being suitable for trade.

~~3) were maintained free from ticks, by preventive treatment when necessary, during the 30 days prior to shipment.~~

ii) were maintained free from competent ticks in accordance with Article 12.7.7. during the 30 days prior to sampling and after sampling until shipment ~~and throughout the transport~~ to the destination country or *zone*.

Rationale: It is not always possible for the exporting country to certify in advance about the outcome of conditions during transport to a destination country. This would only be possible if transport occurred by road through only the exporting country. However, trade in horses is frequently conducted by aircraft, with horses being shipped through multiple countries. Australia proposes that certification referring to transport be removed from this clause and notes conditions for transporting horses are covered in Article 12.7.8.

Article 12.7.~~3~~6.

Recommendations for the temporary importation of equids ~~of competition horses on a temporary basis~~

~~Veterinary Authorities of importing countries should consider the possibility of importing competition horses on a temporary basis and which are positive to the testing procedure referred to in point 2) of Article 12.7.2. under the following safeguards:~~

If the importation of equids on a temporary basis does not comply with the recommendations in Article 12.7.5., *Veterinary Authorities* of *importing countries* should:

~~1.~~

1) require that:

a) ~~the horses are~~ the animals be accompanied by a passport in accordance with the model contained in Chapter 5.12. or be individually identified as belonging to a high health status *subpopulation* as defined in Chapter 4.17.;

~~2.~~b) ~~the Veterinary Authorities of importing countries require~~ the presentation of *an international veterinary certificate* attesting that the animals:

~~a.~~i) showed no clinical sign of ~~equine piroplasmosis~~ *infection* with *T. equi* or *B. caballi* on the day of shipment;

~~b) were treated against ticks within the seven days prior to shipment;~~

ii) were maintained free from ticks in accordance with Article 12.7.7. during the 30 days prior to shipment and during transport;

c) the duration of the temporary importation period and the destination after this period, as well as the conditions required to leave the country or *zone,* be defined;

~~3) the horses are kept in an area where necessary precautions are taken to control ticks and that is under the direct supervision of the Veterinary Authority;~~

~~4) the horses are regularly examined for the presence of ticks under the direct supervision of the Veterinary Authority.~~

2) ensure that during their stay in the country or *zone*:

a) the animals are protected from ticks in accordance with Article 12.7.7;

b) equids are examined daily for the presence of ticks ~~of the genera Dermacentor, Rhipicephalus, Hyalomma and Amblyomma~~ with particular attention to the ears, false nostrils, inter-mandibular space, mane, lower body areas, including the axillae, and inguinal region, and the perineum and tail, with negative results;

If ticks are found during this daily examination, identification of the tick should be undertaken to determine if known vectors are present.

c) the animals are not subjected to any practice that may represent a risk of iatrogenic transmission of *infection* with *T. equi* or *B. caballi*.

d) the animals are isolated from other horses and there are management practices in place to prevent transfer of ticks.

Rationale: Reliable identification of ticks is a specialist procedure that is unlikely to be within the skill set of veterinarians/personnel examining horses for ticks. Consequently, it is not practicable to limit the application of measures following visual and physical examination of horses to detect ticks to certain genera. If ticks are found, then identification should be undertaken by an appropriate laboratory. Scoles and Ueti listed 33 known vectors in 2015. However, during previous outbreaks, new competent vectors were identified during the epidemiological investigation (Scoles, 2011). Consequently, Australia supports tick identification as important in the epidemiological investigation but not practicable for day to day inspections. Australia's proposed changes above are consistent with this.

Australia also proposes that temporarily imported horses should also be isolated from other horses during their stay in the country or zone to prevent the possibility of transfer of ticks. This should include not sharing equipment and preventing nose to nose contact when stabled, during transport or when using facilities.

References

Scoles and Ueti; 2015; Vector ecology of equine piroplasmosis. Annual Reviews of Entomology; 7;60:561-80. doi: 10.1146/annurev-ento-010814-021110. PMID: 25564746

Scoles et al.; 2011 Equine piroplasmosis associated with *Amblyomma cajennense* Ticks, Texas, USA. Emerg Infect Dis.; 7(10):1903-1905. doi:10.3201/eid1710.101182

Article 12.7.9.

Surveillance strategies

5. Vector surveillance

Infection with *T. equi* or *B. caballi* is transmitted between equine hosts by species of Ixodid ticks in the genera *Dermacentor*, *Rhipicephalus*, *Hyalomma*, ~~and~~ *Amblyomma*, Ixodes and Haemaphysalis.

Rationale: Ticks from the genera *Ixodes* and *Haemaphysalis* have also been shown to be both natural and experimental vectors for equine piroplasms (Scoles, 2015; Spickler; 2018). Australia proposes adding these genera of ticks to the list above.

References

Scoles and Ueti; 2015; Vector ecology of equine piroplasmosis. Annual Reviews of Entomology; 7;60:561-80. doi: 10.1146/annurev-ento-010814-021110. PMID: 25564746.
Spickler, 2018; Equine piroplasms; at http://www.cfsph.iastate.edu/DiseaseInfo/factsheets.php