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Annex 29

Original: English
April 2019

REPORT OF THE MEETING OF THE OIE AD HOC GROUP ON ANIMAL WELFARE AND LAYING HEN PRODUCTION SYSTEMS¹

Paris (France), 2–4 April 2019

The OIE *ad hoc* Group on Animal welfare and laying hen production systems (the *ad hoc* Group) met at OIE Headquarters from 2–4 April 2019.

The agenda and *ad hoc* Group participants are presented in Annex I and II.

1. Welcome and introduction

Dr Leopoldo Stuardo, Chargé de mission of the Standards Department, on behalf of the Director General, welcomed *ad hoc* Group participants and thanked them for their support to the OIE on this important topic.

Dr Stefan Gunnarsson, chair of the *ad hoc* Group, opened the meeting and thanked the members for their dedicated work.

2. February 2019 meeting of the Terrestrial Animal Health Standard Commission

Dr Stuardo updated the *ad hoc* Group on discussions held during the February 2019 meeting of the Terrestrial Animal Health Code Commission (Code Commission). Dr Stuardo explained that given the significant number of comments received the Code Commission had requested that the *ad hoc* Group be reconvened to review these comments and revise the draft chapter as necessary. The Code Commission had noted the opposing positions expressed and recommended that the *ad hoc* Group continue to focus on animal-based measurables based on scientific evidence when revising the draft chapter and ensure that the text is drafted in a manner that is consistent with other animal welfare production system chapters in the OIE *Terrestrial Animal Health Code (Terrestrial Code)*. The Code Commission also requested that the *ad hoc* Group also take into account social and economic considerations, as well as the possible impact on food security when developing the revised text.

3. Review of comments

Comments were received from Argentina, Canada, Chile, China (People's Republic), Colombia, Costa Rica, Ecuador, Guatemala, Honduras, India, Japan, Malaysia, Mexico, Mongolia, New Caledonia, Norway, Peru, Philippines, Thailand, United States of America (USA), the Member States of European Union (EU) and the African Union Interafrican Bureau for Animal Resources (AU-IBAR) on behalf of African Member Countries of the OIE. Comments were also received from the International Coalition for Animal Welfare (ICFAW) and the International Egg Commission (IEC).

¹ Note: This *ad hoc* Group report reflects the views of its members and may not necessarily reflect the views of the OIE. This report should be read in conjunction with the September 2019 report of the Terrestrial Animal Health Standards Commission because this report provides its considerations and comments. It is available at <http://www.oie.int/en/international-standard-setting/specialists-commissions-groups/code-commission-reports/meetings-reports/>

Annex 29 (contd)

The *ad hoc* Group considered all comments and made amendments to improve clarity and readability, where relevant. Where amendments were of an editorial nature, no explanatory text has been provided. In addition, the *ad hoc* Group did not consider comments where a rationale had not been provided, that were difficult to interpret, or were too specific in nature, for example when only a relevant to one region or housing system.

The *ad hoc* Group developed the revised draft Chapter 7.Z. which is attached as Annex III.

General comments

The *ad hoc* Group acknowledged the significant number of comments received on the draft chapter, circulated in the September 2018 report of the Code Commission, in particular comments requesting that the chapter consider the social, economic and cultural diversity of OIE Member Countries. To address this point, the *ad hoc* Group introduced a preamble to the chapter, highlighting that the chapter allowed for the continuous development of country specific animal welfare recommendations and monitoring for compliance. The *ad hoc* Group acknowledged that the role of ethics in animal welfare cannot be summarised easily and in a manner that encompasses the belief systems of all Member Countries; and therefore focused, as much as possible, on the scientific basis for the recommendations presented in the chapter.

These recommendations have been drafted in a generic manner and have not been tailored to specific production systems. To help achieve the development of country-specific animal welfare recommendations the *ad hoc* Group amended the first sentence of the second paragraph of Article 7.Z.5 to clarify that good welfare outcomes for pullets and hens can be achieved in a range of housing systems.

The *ad hoc* Group did not agree with comments that the draft chapter placed undue emphasis on behavioural aspects of pullet and hen welfare. This perception may arise from the inclusion of 'behavioural outcomes' within animal-based assessments on how pullets and hens are faring within existing production systems, in addition to recommendations to accommodate specific behaviours identified as 'behavioural needs' that pullets and hens are highly motivated to perform. Thirteen behaviour outcomes are listed within Article 7.Z.3 *Criteria (or measurables) for the welfare of pullets and hens* relative to nine outcomes that primarily relate to pullet and hen health and performance. It is noteworthy that the majority of behaviour outcomes listed have relevance across all three conceptual frameworks of animal welfare, namely health and biological functioning, affective states and normal living. Furthermore, among the 24 recommendations listed in the draft chapter, only four specifically suggest the provision of resources that facilitate motivated behaviours (dustbathing [Article 7.Z.10], foraging [Article 7.Z.11], nesting [Article 7.Z.12], and perching [Article 7.Z.13]).

The *ad hoc* Group also replaced the word 'litter' with 'substrate', as it considered this to be a broader term that also includes other material useful to develop some highly motivated behaviour. The *ad hoc* Group made this modification throughout the draft chapter for consistency.

The *ad hoc* Group agreed to add the word 'animal' before 'welfare', for consistency throughout the draft chapter when appropriate.

Article 7.Z.1. Definitions

The *ad hoc* Group did not agree with the comment to include breeding flocks in the definition of laying hens. There are specific production and welfare aspects related to poultry breeding, including broiler and layer breeding, which are distinct from pullet rearing, broiler production and commercial egg production. It remains the view of the *ad hoc* Group that the welfare of poultry used in breeding should be addressed separately. Therefore, the *ad hoc* Group requested the advice of the Code Commission as to whether breeding flocks should be included in the draft chapter. The *ad hoc* Group did not agree with the comment to specify the type of production systems in the definitions since the recommendations in the draft chapter are based on the welfare of layer hens and pullets, and the recommendations are drafted in such a way as to have applicability in all production systems.

Annex 29 (contd)**Article 7.Z.2. Scope**

The *ad hoc* Group did not agree with a comment to delete ‘*with or without mechanical environmental control*’ under the description of Indoor Systems. The *ad hoc* Group recalled the response provided in its March 2018 meeting report indicating that there is a variation in the systems used in different parts of the world without environmental control. For clarity on the type of environmental control being referred to, the *ad hoc* Group proposed to retain the word ‘*mechanical*’ in the description of completely housed systems in the scope.

With reference to the comment to specify the use of cages in indoor systems, the *ad hoc* Group did not agree as there are indoor systems where cages are not used.

The *ad hoc* Group agreed with a comment to add a third category of systems where pullets and hens are confined in an outdoor area and without access to a poultry house, i.e. ‘*Completely outdoor systems*’. For consistency, the headings for the other two production systems were also amended to ‘*Completely housed systems*’ and ‘*Partially housed systems*’.

Article 7.Z.3. Criteria (or measurables) for the welfare of pullets and laying hens

The *ad hoc* Group, in response to comments, reviewed the list of criteria and modified the list to only include those that focus on animal welfare outcomes rather than causes of animal welfare problems, while retaining the existing text as much as possible. Given that some comments suggested the inclusion of resource-based and management-based outcome measurables, the *ad hoc* Group proposed modifications to the first paragraph to emphasise that the chapter refers preferentially to animal-based outcome measurables for the assessment of the welfare of the pullets and hens. Whereas resource-based and management-based criteria are often inputs (e.g. engineering standards), this modification clarified that resource and management-based outcome measurables are also valid for the assessment of welfare and may have important applications.

To improve readability, the *ad hoc* Group merged the first and second paragraphs of this introductory section. For brevity, only measurables which have direct application in commercial pullet and hen production have been listed in this chapter.

The *ad hoc* Group did not agree with comments requesting to specify that the criteria are only valid for a specific production system. The *ad hoc* Group reiterated that the manner in which the chapter has been drafted seeks to allow continuous local level development of country-appropriate welfare standards, irrespective of production system, and considered that this aspect was clarified with the new preamble.

The *ad hoc* Group did not agree with the proposal to use the words ‘*strain or genotype of birds*’ instead of ‘*genetics*’, as the latter is a broadly used technical term, which also covers the different ‘*strains*’ used.

In response to a comment and also to support the implementation of the recommendations regarding painful procedures, the *ad hoc* Group proposed to add a new criteria for ‘*beak condition*’.

In the third paragraph of the introductory section, the *ad hoc* Group agreed with a comment to replace the word ‘*bone*’ with ‘*skeletal*’, as the latter is a broader term and replaced the word ‘*sampling*’ with ‘*monitoring*’ as it is better aligned with the definition and context of the paragraph.

The *ad hoc* Group did not agree with comments proposing the addition of more criteria and noted that the list is meant to give key examples and not be exhaustive.

1. Beak condition

The *ad hoc* Group agreed to add a new criteria for beak condition as this provides useful information about the extent to which pullets and hens are able to engage in normal behaviour.

Annex 29 (contd)2. Behaviour

The *ad hoc* Group did not agree with a comment to replace ‘*physical and social environment*’ with ‘*housing system, space and light level*’ as it considered that the existing term encompassed the suggested change and is less restrictive.

In response to comments, the *ad hoc* Group replaced ‘*domestic fowl*’ with ‘*Gallus gallus domesticus*’ to avoid confusion.

With regard to a comment to add more examples to the list of animal welfare problems, the *ad hoc* Group did not agree and noted that the list is not meant to be exhaustive.

a) Dust bathing

The *ad hoc* Group agreed with comments to delete ‘*good welfare*’ because it did not accurately reflect the wording used in the scientific references. The *ad hoc* Group agreed to replace term this with ‘*associated with positive affect*’.

In response to a comment, the *ad hoc* Group modified the wording of the first part of this point, as it agreed that while dust bathing is an intricate behaviour, it would be more appropriate to consider it a ‘*complex behaviour*’ as it involves a number of different patterns and is influenced by external factors.

The *ad hoc* Group agreed with a comment that questioned the validity of dust bathing to remove parasites and replaced this with more appropriate text.

The *ad hoc* Group did not agree with a comment to include additional references as to the importance of managing the substrate in relation to pullet and hen health, as this is addressed in Article 7.Z.10. Dustbathing areas.

b) Fear behaviour

The *ad hoc* Group did not agree with a comment to include more details on the importance of reducing fear during the rearing period as it considered this to be sufficiently covered in the current text.

The *ad hoc* Group agreed with a comment to include text regarding the effect of the presence of humans on the assessment of fearfulness, and modified the text accordingly and included a scientific reference.

c) Feeding and drinking behaviour

No comments were received for this section.

d) Foraging activity

The *ad hoc* Group did not agree with a comment that foraging is not an indicator of good animal welfare. The *ad hoc* Group emphasised that the paragraph stresses that it is the ‘relative change’ in foraging activity, rather than the presence or absence of the activity *per se*, that is an indicator of animal welfare.

The *ad hoc* Group did not agree with a comment to further elaborate the role of foraging, as it considered this was already addressed in the second sentence of the paragraph.

The *ad hoc* Group agreed with a comment to clarify the type of movement which could be indicative of a problem with the substrate, and also modified the scientific references supporting the statement regarding the reduction of the incidence of injurious feather pecking when there is an increase of the foraging activity.

The *ad hoc* Group added new a sentence at the beginning of the description to indicate that foraging activity is considered a highly motivated behaviour, and it is relevant to develop recommendations to help pullet and hens to perform this behaviour.

Annex 29 (contd)

The *ad hoc* Group did not agree with a comment to add a sentence on respecting ‘*the recommended linear length of feeders for any specific genetic line*’, given that this is a resource-based input criterion and did not belong to this part of the chapter which describes important animal-based outcome measurables. Also, the focus is on outputs (e.g. feeding without undue competition, body weight) rather than on quantitative inputs.

e) Injurious feather pecking and cannibalism

The *ad hoc* Group did not agree with the suggestion to add the word ‘*abnormal*’ at the beginning of this point, explaining that because there is no specific reason as to why this behaviour is triggered, it would be difficult to ascertain ‘*abnormal*’ versus ‘*normal*’. In any case, by definition, this is an unacceptable behaviour regardless of the production system used.

The *ad hoc* Group considered further comments and added an indication of the difficulty in controlling this behaviour due to the multicausality of its origins and included a scientific reference from Nicol, 2018 to support this addition.

f) Locomotory and comfort behaviours

The *ad hoc* Group did not agree with the proposal to add ‘*flying*’ because it is not significant in the context of locomotory and comfort behaviour. The *ad hoc* Group also did not agree to add stress and frustration as a consequence of not being able to perform these behaviours, but rather added the word ‘*welfare*’ to cover the broader consequences.

The *ad hoc* Group reworded the text, and new scientific references were added, i.e. Bracke and Hopster, 2006 and Hartcher and Jones, 2017, to highlight the importance of recognising the negative consequences of not being able to perform locomotory and comfort behaviours.

g) Nesting

The *ad hoc* Group did not agree with a comment to add the word ‘*excessive*’ to uneven nest box use, as the key aspect to consider is the irregular use of nest areas and not the intensity of this behaviour.

Regarding the proposal to include the consequences of not being able to perform nesting behaviours, the *ad hoc* Group agreed to add two new examples to illustrate why this behaviour is important for the welfare of the pullets and hens. The relevant scientific references to support this modification were also included.

h) Perching

The *ad hoc* Group did not include a proposal to include a sentence on the importance of providing perches to pullets at an early age but agreed to include this Article 7.Z.13 on perches.

The *ad hoc* Group did not agree to include additional examples of why it is important to provide perches as it was already stated that perching is a highly motivated behaviour.

i) Resting and sleeping

The *ad hoc* Group did not agree with a comment to include a text regarding adequate light and dark periods to allow rest, as this recommendation is already included in Article 7.Z.17 on lighting.

j) Social behaviour

The *ad hoc* Group agreed with a comment to improve the readability of this point by deleting the term ‘*species*’ and to also emphasise that pullets and hens are highly social.

Annex 29 (contd)

The *ad hoc* Group did not agree with a comment to add a new sentence regarding the effect on the individuals that are victimised by aggressive behaviour, as it considered this to be an unnecessary level of detail. The *ad hoc* Group also noted that there are no scientific references that confirm that this happens frequently, and that aggression was already included in the last sentence of this point.

The *ad hoc* Group did not agree to include the social behaviour of males, as males are not included in the scope of this chapter.

k) Spatial distribution

The *ad hoc* Group agreed to modify some of the terms used for consistency with terminology used in the rest of the chapter.

The *ad hoc* Group partially agreed with a comment to add an indication that '*fear behaviour*' could influence the spatial distribution, but did not agree to include '*disturbances*', as this is not an indicator of uneven spatial distribution.

l) Thermoregulatory behaviour

The *ad hoc* Group did not agree with a comment to include a new sentence regarding the effect of thermal stress in newly hatched poultry, as this is already included in Article 7.Z.15 *Thermal environment*, where the recommendation is to maintain the thermal conditions within a range that is appropriate for their stage of life.

The *ad hoc* Group did not agree with a comment to include text regarding changes in feed and water consumption as this is already included in point 11: *Water and feed consumption* of this article.

m) Vocalisation

The *ad hoc* Group did not agree with a comment to add a sentence to indicate results of a change in the vocalisation patterns, as the objective of this part of the text is to focus on the causes and not the results. However, the *ad hoc* Group agreed to include '*and their causes*' to better clarify this aspect.

3. Body condition

No comments were received for this section.

4. Eye conditions

No comments were received for this section.

5. Foot problems

In response to a comment to include '*cages in bad conditions*' a cause of foot problems, the *ad hoc* Group did not agree, as it was not the intention of the chapter to be linking specific production systems to specific outcomes. Nevertheless, it included a new sentence at the end of the first paragraph referring to inadequate system maintenance.

The *ad hoc* Group agreed to include '*contact dermatitis*', as a foot problem associated with inappropriate flooring, poorly designed perches, poorly maintained substrate and inadequate system maintenance. The *ad hoc* Group also included a new scientific reference to support their amendments.

Following comments, and to improve the clarity and avoid repetition, the *ad hoc* Group deleted the second paragraph and the first sentence of the third paragraph of this point.

Annex 29 (contd)6. Incidence of diseases, infections, metabolic disorders and infestations

The *ad hoc* Group did not agree with the proposal to add a new paragraph on the animal health impacts caused by an inadequate management of the substrate and nest boxes, as it did not consider this to be a criterion or measurables.

7. Injury rate and severity

In response to a query on the inclusion of 'nutrition', the *ad hoc* Group clarified that nutritional deficiencies, such as those caused by a deficiency in calcium intake, could provoke skeletal problems. Corresponding amendments were made to this sentence to clarify this point.

The *ad hoc* Group did not agree with a comment to include 'pecking' as a consequence of the actions of other birds, as it consider that pecking is the process, and not the outcome *per se*. Regarding another comment, the *ad hoc* Group agreed to include the genetic aspects related to management to reduce the incidence of injuries, but used the term 'genetics used' for consistency with previous modifications.

8. Mortality, culling and morbidity rates

The *ad hoc* Group agreed with the suggestion to add a new sentence at the end of this point to further emphasise the need to understand the reasons behind changes in morbidity and mortality rates.

9. Performance

The *ad hoc* Group agreed with comments on the use of the term 'pullets and hens' for consistency, and also accepted other editorial proposals to bring clarity to the text.

The *ad hoc* Group did not agree with a comment to add the 'mass of feed consumed per egg mass produced' to complement the indicator listed in sub-Article (c), as it considered that this is already implied in the current text.

The *ad hoc* Group did not agree with the comment to delete the use of Haugh units because it is not an indicator of animal welfare. The *ad hoc* Group noted that while Haugh units may also be affected by egg handling and storage conditions, it does not negate its validity as an indicator of egg quality from other causes such as welfare problems. Furthermore, the text states that an unforeseen reduction in these rates 'may' be reflective of welfare problems and not exclusively so.

10. Plumage condition

The *ad hoc* Group did not agree with a comment to delete the reference to the use of scoring systems, as this is consistent with other animal welfare chapters already adopted such as Chapter 7.13 *Animal welfare and pig production systems*.

The *ad hoc* Group did not agree with the comment to add 'overcrowding' as a cause of feather loss and damage, but rather proposed a modification to improve the clarity of the text and to highlight the importance of assessing the coverage and cleanliness of the plumage as a tool to detect animal welfare problems.

11. Water and feed condition

The *ad hoc* Group agreed with the comment that both water and feed quality and supply are separately of potential concern and amended the text accordingly.

Annex 29 (contd)**Article 7.Z.4. Recommendations**

In response to editorial comments and for consistency with terminology used in other animal welfare chapters in the *Terrestrial Code*, the *ad hoc* Group modified the first and third paragraphs. It also agreed with a comment to include ‘*genetics used*’ as a management factor to be considered.

The *ad hoc* Group did not agree to add ‘*the care of various agro-climatic conditions*’ as a provision to consider for the good welfare of pullet and hens, as the chapter read as a whole addresses all climatic conditions in which pullets and hens are kept. However, the *ad hoc* Group agreed to include a sentence to indicate that all pullet and hens production systems, independent of climatic conditions, are addressed by this chapter.

The *ad hoc* Group did not agree with comments to specify the design and management aspects for each commercial production system, as this consideration was included in the preamble of Article 7.Z.3 *Criteria (or measurables) for the welfare of pullets and hens*. Furthermore, the last sentence of the third paragraph states that the suitability of the criteria or measurables will be determined by the system in which the pullets and hens are housed.

The *ad hoc* Group agreed to add text referring to outcomes in terms of animal welfare and health in a range of housing systems, but placed this at the beginning of the second paragraph of Article 7.Z.5 *Location, design, construction and equipment of establishments*.

The *ad hoc* Group proposed to add a sentence indicating that the outcome-based measurables after each recommendation are listed in alphabetical order and do not indicate any specific ranking or relative importance.

Article 7.Z.5. Location, design, construction and equipment of establishments

The *ad hoc* Group did not agree with a comment to modify the title of this article to include ‘*maintenance*’ it considered that these aspects are considered in Article 7.Z.26. *Contingency plans*, where it recommends considering the maintenance provisions for the equipment, including backup systems.

The *ad hoc* Group agreed with a proposal to add a sentence in the second paragraph to indicate that other considerations such as health, environment, and animal management capability are also important in designing suitable housing systems.

The *ad hoc* Group did not agree with a comment proposing to delete the point on the consideration for pullets and hens to perform highly motivated behaviours when designing housing systems, nothing that the importance of performing these behavioural patterns are well described and supported in Article 7.Z.3 *Criteria (or measurables) for the welfare of pullets and hens*.

The *ad hoc* Group did not agree with a comment to add text regarding the need for more than one source of water supply, as it was considered to be too detailed. Additionally, there are provisions on alternative access and supply of water in Article 7.Z.26. *Contingency plans*.

The *ad hoc* Group proposed to delete the examples of highly motivated behaviours in this article in order not to be restricted to only using some of these behaviours.

The *ad hoc* Group agreed to the suggestion to add a new sentence on encouraging the use of durable materials in facilities and equipment to facilitate cleaning and disinfection, and to include text on the importance of implementing a record keeping system for the equipment and contingency plans.

The *ad hoc* Group did not agree to include a sentence to address provisions when the pullet and hens depend on mechanical systems, for example ventilation, as such considerations are included in Article 7.Z.26. *Contingency plans*.

Article 7.Z.6. Matching the birds and the housing and production system

The *ad hoc* Group did not agree with a comment to delete the first sentence and for the second sentence to be amended as the *ad hoc* Group did not consider that the proposed amendment improved readability of the paragraph as was suggested.

The *ad hoc* Group did not agree with a comment to add a sentence regarding the possibility to match the pullet and hens as much as possible with the layer housing systems, as it was considered too restrictive and the text already addresses the relevance of pre-adaptation.

The *ad hoc* Group proposed to add the words '*infections and infestations*' in the list of outcome-based measurables to be consistent with the terms used in Article 7.Z.3 *Criteria (or measurables) for the welfare of pullets and hens*.

Article 7.Z.7. Space allowance

The *ad hoc* Group proposed to modify the first paragraph to improve clarity and consistency, and to address consideration of important aspects such the access to resources and normal postures when determining the space allowance in a housing system. These modifications also addressed other comments, those proposing considerations that pullets and hens are able to adopt normal posture in a housing system.

In response to comments, the *ad hoc* Group did not agree to include consideration of the different commercial systems when determining space allowance, as it already agreed to not differentiate between production systems as defined in Article 7.Z.1. *Definitions*.

The *ad hoc* Group did not agree to include a specific metric to determine space allowance as it considered this to be too restrictive.

In response to a comment to add '*technology*' to the list of factors, the *ad hoc* Group did not agree, but included a new factor in the list ('*equipment selection*') to cover this aspect.

The *ad hoc* Group agreed with the proposal to add a text regarding water and feed availability as it considered these to be important elements in managing the space allowance.

The *ad hoc* Group reordered the factors to be considered when determining the space allowance into alphabetical order.

Article 7.Z.8. Nutrition

The *ad hoc* Group, in response to comments, modified the structure of the first paragraph and merged it with the second paragraph along with some editorial changes to improve readability.

The *ad hoc* Group did not agree with a comment to include the provision of minerals during the rearing period as it considered this to be too detailed.

In response to a comment on the effect of diet formulation and form on behavioural patterns, the *ad hoc* Group considered that this was already addressed in the second sentence of the first paragraph, which refers to the form and quality of feed.

Article 7.Z.9. Flooring

The *ad hoc* Group agreed with comments to use the language used in other relevant animal welfare chapters in the *Terrestrial Code* in order to ensure consistency. In response to comments, the *ad hoc* Group made modifications to the first paragraph to address all of the production systems included in the scope of the chapter. The modifications also took into account a comment related to the behaviours that could be affected by the flooring design.

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Regarding a comment concerning considerations to manure contamination of other pullet and hens, the *ad hoc* Group agreed to include the proposed text at the end of the first paragraph.

The *ad hoc* Group agreed with a comment that the provision of substrate will not be possible in all housing systems and modified the text of the first sentence of the second paragraph to state '*When substrate is provided*'.

The *ad hoc* Group made amendments to the list of outcome-based measurables to ensure consistency with the language used in Article 7.Z.3 *Criteria (or measurables) for the welfare of pullets and hens*.

Article 7.Z.10. Dust bathing areas

Regarding a comment on the possibility of implementing a transition period for the implementation of this chapter, the *ad hoc* Group discussed that they did not have the scope to determine this and referred this comment to the OIE and Code Commission.

The *ad hoc* Group did not agree with a comment to distinguish the specific production system in which dust bathing areas could be used, as *ad hoc* Group agreed that the recommendation should be applicable to all production systems considered in the scope of the chapter. In response to the suggestion to modify the text to be more inclusive, the *ad hoc* Group agreed to emphasise that access to dust bathing areas is desirable and replaced the words '*should be*' with '*When provided*'.

The *ad hoc* Group agreed with a comment to add '*incidence of diseases, infections and infestations*' to the list of outcome-based measurables to be considered under this recommendation, as the provided substrate may cause respiratory diseases and infestations (e.g. coccidiosis and red mites).

Article 7.Z.11. Foraging areas

The *ad hoc* Group agreed with comments to amend the text to ensure consistency and to include all production systems covered in the scope of this chapter. Consequently, the *ad hoc* Group amended the text to include the importance of having access to foraging areas and to consider all production systems by adding the caveat '*When provided*'. The *ad hoc* Group emphasised that the substrate areas in systems with outdoor areas should also be inspected.

The *ad hoc* Group agreed with comments, to include '*incidence of diseases, infections and infestations*' in the list of outcome-based measurables and noted that this also ensured consistency with the previous article.

Article 7.Z.12. Nesting areas

Regarding a comment to specify the type of production system, the *ad hoc* Group did not agree to specify the system and noted that the chapter should be applicable to all the systems described in the scope.

In response to the suggestion to modify the text to be more inclusive, the *ad hoc* Group agreed to emphasise that access to nesting areas is highly desirable and replaced the words '*should be*' with '*When provided*'. Also, the *ad hoc* Group did not agree with the proposal to include text regarding the possibility of parasite and microorganisms build-up in nesting areas it considered this to be sufficiently addressed in the list of outcomes.

The *ad hoc* Group agreed with comments to include '*incidence of diseases, infections and infestations*' in the list of outcome-based measurables.

Article 7.Z.13. Perches

Regarding a comment to specify the type of production system, the *ad hoc* Group did not agree to specify any systems and the chapter should be applicable to all the systems described in the scope.

Annex 29 (contd)

For consistency with the amendments made in previous articles and to address comments on making the text more inclusive to all production systems, the *ad hoc* Group included a text regarding the importance and the need for having access to perches and replaced the words ‘*should be*’ with ‘*when provided*’.

The *ad hoc* Group agreed with the suggestion to include text regarding the age when perches should be available, when provided.

In response to a comment to add examples of specific injuries in the outcome-based measurables, the *ad hoc* Group considered that this was unnecessary.

The *ad hoc* Group did not agree with a comment to replace ‘*perching*’ with ‘*perching space*’ in the list of outcome-based measurables, as this would correspond to an input parameter rather than to an outcome. However, the *ad hoc* Group added text ‘*prevent undue competition*’ in relation to the space availability of perches.

The *ad hoc* Group did not agree to include examples for injury rate, as these are already mentioned in point 7 of Article 7.Z.3.

Article 7.Z.14. Outdoor areas

The *ad hoc* Group did not agree with the suggestion to add text referring to ‘*space allowance*’ in the first paragraph as this is considered in Article 7.Z.7. *Space allowance*.

The *ad hoc* Group did not agree with comments to specify that there should be enough appropriate design openings for ‘*outdoor*’ systems, as it was considered unnecessary given that this article refers to outdoor systems of any kind. The *ad hoc* Group agreed with the proposed text to improve readability of the third paragraph. In the same paragraph, the *ad hoc* Group did not accept the proposal to add a new sentence regarding the potential risk for water and feed due the interaction with wild animals, as it is already included in Article 7.Z.8. *Nutrition*.

The *ad hoc* Group agreed to add text regarding the need to protect pullets and hens from adverse climatic conditions.

The *ad hoc* Group did not agree with proposal to add the ‘*percentage of pullets and hens that use outdoor areas*’, as it considered this was addressed in Article 7.Z.3. in the spatial distribution criteria. Also, the *ad hoc* Group did not agree to include ‘*predation rate*’ to the list, as it is considered this to be covered by the measurables of mortality rates, and of injury rates and severity.

Article 7.Z.15. Thermal environment

The *ad hoc* Group agreed with a comment to reinstate the sentence regarding the use of the guidelines provided by laying hens genetic companies to identify the thermal comfort zones in the first paragraph, as it considered that this inclusion is current and relevant for the commercial genetics used, and comparable information was lacking in the peer reviewed scientific literature. In the same paragraph, the *ad hoc* Group added ‘*genetics used*’ as a consideration for the thermal conditions in which pullets and hens should be maintained.

The *ad hoc* Group did not agree to include examples for thermoregulatory behaviour, as these are already mentioned in point 1 of Article 7.Z.3. The *ad hoc* Group agreed to add “*temperature and humidity*” to the list of outcome-based measurables even though these are not directly outcome-based measurables but rather resource-based measurables as deviations from acceptable parameters are likely to lead to animal welfare problems.

Article 7.Z.16. Air quality

The *ad hoc* Group agreed with a comment to include ‘*space allowance*’ as one of the factors that may affect air quality, as it agreed that air quality may be affected by the density of the pullets and hens.

Annex 29 (contd)

The *ad hoc* Group did not agree with a comment to add text regarding the monitoring of specified gas concentrations, as it considered that monitoring aspects are included in the actions required to maintain good air quality. Nevertheless, the *ad hoc* Group added a sentence linking air quality and good animal welfare to emphasise the importance of this recommendation.

The *ad hoc* Group did not agree with the comment to add a sentence indicating that air quality should be in relation to unpleasant sensations in humans, as this was considered to be imprecise.

The *ad hoc* Group did not agree with the proposal to add a sentence in relation to the need for artificial ventilation systems and backup power as it considered this to be particular to specific housing systems, and pointed out that backup systems are covered in Article 7.Z.26.

The *ad hoc* Group agreed with the suggestion to include some examples of resource-based measurables, such as ammonia level, carbon dioxide level, temperature, humidity and dust levels. The *ad hoc* Group also added to the list other important outcome-based measurables for this recommendation such as infections, metabolic disorders and infestations, morbidity and mortality rate, and thermoregulatory behaviours.

Article 7.Z.17. Lighting

The *ad hoc* Group did not agree with comments suggesting the inclusion of the duration of light during the light period, as it was already noted that the period should be ‘adequate’, specific to the housing system, and the absence of scientific literature investigating light duration relative to animal welfare rather than to production.

The *ad hoc* Group agreed to add ‘sleep’ to the activities that pullets and hens should perform in order to reduce stress and to promote circadian rhythms in the second paragraph.

The *ad hoc* Group did not agree with a comment to add ‘indoor systems’ when referring to changes in lighting, at the beginning of the third paragraph, as it was considered too specific and difficult to manage, and is addressed by the term ‘step-wise’. To improve readability of this paragraph the *ad hoc* Group made amendments to include the gradualness concept in the lighting changes. The *ad hoc* Group also added two new scientific references to support these amendments.

The *ad hoc* Group did not agree to include ‘production percentage’ in the list of outcome-based measurables as this aspect is included in ‘performance’.

Article 7.Z.18. Noise

In response to comments, the *ad hoc* Group made amendments to the first paragraph for readability.

Article 7.Z.19. Prevention and control of injurious feather pecking and cannibalism

The *ad hoc* Group agreed with a comment to replace the word ‘influencing’ by ‘increasing’ in the third indent to be more specific. The *ad hoc* Group also replaced the scientific reference to support this statement.

In response to a comment regarding the stocking density as a management factor to reduce the occurrence of injurious feather pecking and cannibalism, the *ad hoc* Group modified the fourth indent, indicating that the management action corresponds to increasing the space allowance during the rearing phase. The *ad hoc* Group also included a new scientific reference to support this amendment.

The *ad hoc* Group did not agree with a comment to include a new indent regarding the impact of changes in the diet, as this was covered by the first indent regarding the adaptation to the diet and the form of feed in rearing and lay.

Annex 29 (contd)

The *ad hoc* Group did not agree with a proposal to add a new indent on the provision of outdoor access from a young age, noting that the list is not exhaustive and that not all systems allow for outside access.

The *ad hoc* Group deleted the seventh indent in response to comments and to be consistent with the modification that were done in Article 7.Z.21.

The *ad hoc* Group did not agree with a comment to include preventing and minimising parasitic infestation as a management method as the literature cited did not support this statement.

The *ad hoc* Group did not agree with the proposal to include a sentence regarding the available method for therapeutic partial beak removal as this topic is addressed in Article 7.Z.21.

Article 7.Z.20. Moulting

The *ad hoc* Group did not agree with a comment to delete the last sentence of the first paragraph as it was of the view that this is an important recommendation which is well documented in the literature; new scientific references were added.

The *ad hoc* Group agreed to add a scientific reference from Anderson, 2015, which will be useful to assist the reader regarding lighting regimes required for an effective moulting.

The *ad hoc* Group did not agree with a comment to add a sentence regarding management practices that should not be routinely conducted, as it considered that the recommendations should focus on positive actions.

Article 7.Z.21. Painful interventions

The *ad hoc* Group proposed to modify the title of this article to '*Painful procedures*' to be consistent with changes made throughout this article.

In response to several comments on the first paragraph the *ad hoc* Group agreed that terms widely used in the industry, such as '*beak trimming*' and '*beak treatment*' could have different meanings depending on locality and therefore proposed amendments that described the action, i.e. '*partial beak removal*' so that there was no ambiguity as to what the term means.

The *ad hoc* Group did not agree with comments proposing to add text regarding the training and skills of the personnel in carrying out these procedures, as this was considered in Article 7.Z.27.

In response to comments to ensure consistency with other OIE animal welfare chapters agreed to include a new paragraph on alternatives in relation to painful procedures.

The *ad hoc* Group agreed with a proposal to include '*body condition*' and '*beak condition*' (new criterion defined in Article 7.Z.3.) in the list of outcome-based measurables.

Article 7.Z.22. Animal health management, preventive medicine and veterinary treatment

The *ad hoc* Group did not agree with a comment to include text on how animal handlers should be '*trained*', as the key point is having the knowledge. In addition, Article 7.Z.27. covers training.

The *ad hoc* Group proposed to include record keeping as a tool for an effective programme for disease prevention and treatment.

The *ad hoc* Group did not agree with a comment to include the '*multi age condition of the farms*' in the list of outcome-based measurables, as this is not an outcome but a specific practice applied in some circumstances.

Annex 29 (contd)**Article 7.Z.23. Biosecurity**

The *ad hoc* Group partially agreed with a comment to include a sentence to indicate that biosecurity plans should be ‘*reviewed regularly*’ as management changes could impact the risk of pathogen and pest transmission.

The *ad hoc* Group partially agreed with a comment to add partial restocking of ‘*flock area*’ to the fifth indent, in addition to ‘*the house*’, and deleted the words ‘*the house*’ so that the point would not be limited to housed flocks only but would consider all production systems addressed.

The *ad hoc* Group reordered the list of infection and infestation routes in alphabetical order.

Article 7.Z.24. Humane killing of individual birds or flocks

The *ad hoc* Group noted that Chapter 7.6. *Killing for disease control purposes* is currently under revision and requested the OIE Secretariat to ensure that the proposed text be considered during this revision to ensure alignment

The *ad hoc* Group agreed with a comment to modify this article and made amendments to the first paragraph for clarity. It also agreed to include a new sentence regarding the competences of the person taking the decision to kill an animal, the necessary equipment, and documented procedures to correctly perform the humane killing.

The *ad hoc* Group also agreed to add a list of reasons for conducting a humane killing or euthanasia. The proposed list is in alphabetical order and is not a ranking of the reasons.

The text “*Outcome-based measurables include: injury rate and severity.*” was added for consistency.

Article 7.Z.25. Depopulation of pullet and laying hen facilities

The *ad hoc* Group agreed to include the word ‘*flock*’ in the first sentence, to clarify that the article covers the flock and not just small groups or individual pullet and hens.

The *ad hoc* Group agreed with a comment proposing the inclusion of a sentence in the second paragraph to highlight the importance of minimising the feed withdrawal period and modified the text accordingly.

The *ad hoc* Group did not agree to add text regarding the reason for not transporting diseased or injured pullets and hens, as transport issues are addressed in Chapter 7.3 *Land transport*. Furthermore, there are references to these aspects in the scope, and the suggested additions were considered to be too detailed.

The *ad hoc* Group partially agreed with a comment to take into consideration some specific issues during transport and amended text referring to plumage condition, which could affect thermal stress and injury during transport. The *ad hoc* Group added scientific references to support this modification.

The *ad hoc* Group did not agree with comments to include a sentence on how pullets and hens should be handled, as this was already included in Article 7.Z.28.

Article 7.Z.26. Contingency plans

The *ad hoc* Group agreed with comments to delete the text regarding fire safety plans at the end of the first paragraph as this was a duplication of the second sentence.

Article 7.Z.27. Personnel competency

The *ad hoc* Group proposed to modify the first paragraph adding a sentence to specify the characteristics that animal handlers should have in order to maintain the welfare of the pullets and hens.

Annex 29 (contd)

The *ad hoc* Group did not agree with a comment proposing to include a new sentence concerning the need to review the training needs as it considered that this aspect is well addressed by the reference to ‘appropriate’ training.

In response to a proposal to add ‘*euthanasia methods*’ to the knowledge that animal handlers should have, the *ad hoc* Group modified the second paragraph to address this comment and to align this article with the modifications made to Article 7.Z.24 *Humane killing of individual birds or flocks*.

The *ad hoc* Group agree with a comment to include ‘*body condition*’ in the list of outcome-based measurables.

Article 7.Z.28. Inspection and handling

The *ad hoc* Group did not agree to include text regarding the method of killing pullets and hens but instead included a reference to Article 7.Z.24.

In response to a comment to add a text regarding the importance of the correct disposal of dead pullet and hens to reduce the contact with potential pathogenic agents, the *ad hoc* Group added text referring to Chapter 4.12 *Disposal of dead animals*.

The *ad hoc* Group did not agree with the proposal to add a new sentence regarding record keeping and maintenance of the equipment as these are already addressed in Articles 7.Z.22. and 7.Z.26.

The *ad hoc* Group reordered the objectives of the inspections.

The *ad hoc* Group did not agree with a comment to add text regarding the handling of pullets and hens in a manner to avoid stress and injuries, as it considered that it was clear as written in the current text. However, the *ad hoc* Group replaced the word ‘*posture*’ by ‘*manner*’ to improve readability.

Article 7.Z.29. Protection from predators

The *ad hoc* Group did not agree to add ‘*predation*’ to the list of outcome-based measurables, as it was considered to be included in the mortality criteria.

3. Proposal to reorder articles

In response to previous comments received regarding the order of articles, the *ad hoc* Group proposed a new order for the articles that provides a more logical flow in the draft chapter for the Code Commission’s consideration.

The proposed new order of articles is presented as Appendix IV.

4. Next steps

The *ad hoc* Group was informed that its report, including the amended draft chapter, will be considered by the Code Commission at its next meeting in September 2019.

.../Annexes

Annex 29 (contd)Annex I

**OIE AD HOC GROUP ON ANIMAL WELFARE AND
LAYING HEN PRODUCTION SYSTEMS**

Paris 2–4 April 2019

List of participants

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Annex 29 (contd)

Annex II

**OIE AD HOC GROUP ON ANIMAL WELFARE AND
LAYING HEN PRODUCTION SYSTEMS**

Paris 2–4 April 2019

Adopted agenda

- 1) Welcome and introduction
 - 2) February 2019 Terrestrial Animal Health Standard Commission meeting report
 - 3) Consideration of Member Country's comments
 - 4) Proposal to reorder articles
 - 5) Next steps
-

Annex 29 (contd)

Annex III

[Note: this Annex has been replaced by Annexes 11 and 12 to the report of the meeting of the OIE Terrestrial Animal Health Standards Commission which was held on 10–19 September 2019.]

Annex 29 (contd)Annex IV**Proposed reordering of articles**

- 7.Z.1. Definitions
 - 7.Z.2. Scope
 - 7.Z.3. Criteria and measurables for the welfare of pullets and hens
 - 7.Z.4. Recommendations
 - 7.Z.5. Location, design, construction and equipment of establishments
 - 7.Z.6. Contingency plans (previously 7.Z.26.)
 - 7.Z.7. Protection from predators (previously 7.Z.29.)
 - 7.Z.8. Space allowance (previously 7.Z.7.)
 - 7.Z.9. Nesting areas (previously 7.Z.12.)
 - 7.Z.10. Perches (previously 7.Z.13.)
 - 7.Z.11. Flooring (previously 7.Z.9.)
 - 7.Z.12. Dust bathing areas (previously 7.Z.10)
 - 7.Z.13. Foraging areas (previously 7.Z.11.)
 - 7.Z.14. Outdoor areas
 - 7.Z.15. Matching the birds and the housing and production system (previously 7.Z.6.)
 - 7.Z.16. Personnel competency (previously 7.Z.27.)
 - 7.Z.17. Inspection and handling (previously 7.Z.28.)
 - 7.Z.18. Nutrition (previously 7.Z.8.)
 - 7.Z.19. Air quality (previously 7.Z.16.)
 - 7.Z.20. Thermal environment (previously 7.Z.15.)
 - 7.Z.21. Lighting (previously 7.Z.17)
 - 7.Z.22. Prevention and control of injurious feather pecking and cannibalism (7.Z.19.)
 - 7.Z.23. Moulting (previously 7.Z.20.)
 - 7.Z.24. Noise (previously 7.Z.18.)
 - 7.Z.25. Biosecurity (previously 7.Z.23.)
 - 7.Z.26. Animal health management, preventive medicine and veterinary treatment (previously 7.Z.22.)
 - 7.Z.27. Painful interventions (previously 7.Z.21.)
 - 7.Z.28. Humane killing of individual birds or flocks (previously 7.Z.24.)
 - 7.Z.29. Depopulation of pullet and laying hens facilities (previously 7.Z.25.)
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Annex 30

Original: English
June 2019

REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP ON AVIAN INFLUENZA² Paris (France), 11–13 June 2019

The OIE *ad hoc* Group on avian influenza (the *ad hoc* Group) met at OIE Headquarters in Paris from 11–13 June 2019.

The agenda and the list of participants are presented in Annex I and in Annex II, respectively.

1. Introduction

A representative from the Standards Department delivered a short presentation to provide the context of *ad hoc* Group work within the OIE's mandate and the OIE standard-setting process, with particular emphasis on the roles and responsibilities of *ad hoc* Groups, Specialist Commissions and the OIE Secretariat.

The Secretariat also provided a summary of the history of this work and the outcomes of the last two *ad hoc* Group meetings, relevant discussions of meetings of the Terrestrial Animal Health Standards Commission (Code Commission) and the Scientific Commission for Animal Diseases (Scientific Commission) since the last *ad hoc* Group meeting. The Secretariat noted that due to the unavailability of some previous *ad hoc* Group members a new member was invited to participate.

2. Welcome

Dr Matthew Stone, OIE Deputy Director General for International Standards and Science, on behalf of Dr Monique Eloit, Director General of the OIE, welcomed members of the *ad hoc* Group and the representatives from the Code Commission and the Scientific Commission and thanked them for their continued support for this important OIE work.

Dr Stone noted that in addition to the *ad hoc* Group's task to review Members' comments received on the revised draft chapter circulated in the Code Commission's September 2018 report, the *ad hoc* Group had also been requested to undertake an assessment of H5 and H7 low pathogenicity avian influenza (LPAI) against the criteria in Chapter 1.2. of the *Terrestrial Animal Health Code (Terrestrial Code)*. He further noted that the experiences of this *ad hoc* Group in conducting the assessment would provide valuable feedback for OIE Headquarters to develop the internal standard operating procedure and guidance documents for these assessments, and encouraged the *ad hoc* Group to share their opinions with the Secretariat.

Dr Stone also emphasised the importance of the participation of representatives of the Code and Scientific Commissions in this *ad hoc* Group noting that coordination between these Specialist Commissions will be important in order to ensure this work progresses in a coordinated manner at their September 2019 meetings.

² Note: This *ad hoc* Group report reflects the views of its members and may not necessarily reflect the views of the OIE. This report should be read in conjunction with the September 2019 report of the Terrestrial Animal Health Standards Commission because this report provides its considerations and comments. It is available at <http://www.oie.int/en/international-standard-setting/specialists-commissions-groups/code-commission-reports/meetings-reports/>

Annex 30 (contd)

Dr David Swayne, Chair of the *ad hoc* Group, welcomed the experts, noting a change of membership, and appreciated their commitment to the work, in particular their engagement in pre-meeting activities. He also commended the Secretariat's preparatory work for this meeting.

3. Assessment of 'H5 and H7 low pathogenicity avian influenza' against the criteria for the inclusion of diseases, infections and infestations in the OIE list in Chapter 1.2. of the *Terrestrial Code*

At the request of the Code Commission, at its September 2018 meeting, the *ad hoc* Group undertook the assessment of 'H5 and H7 low pathogenicity avian influenza (LPAI)' against the criteria in Article 1.2.2. of Chapter 1.2. 'Criteria for the inclusion of diseases, infections and infestations in the OIE list'.

It was agreed that the assessment undertaken would be for the 'low pathogenicity avian influenza viruses' as defined in point 1(b) of Article 10.4.1., i.e. 'low pathogenicity avian influenza viruses are all influenza A viruses of H5 and H7 subtypes that are not avian influenza viruses' of the 2018 edition of Chapter 10.4. 'Infection with avian influenza viruses' of the *Terrestrial Code*. In advance of the meeting, members of the *ad hoc* Group were provided with detailed information on the assessment process and were requested to undertake assessments against each criterion. During the *ad hoc* Group meeting each criterion was discussed, based on the scientific evidence available, and a consensus was reached by the *ad hoc* Group.

In summary, the *ad hoc* Group agreed that H5 and H7 low pathogenicity avian influenza does not meet the criteria for the inclusion of diseases, infections and infestations in the OIE list disease described in Chapter 1.2. of the *Terrestrial Code*. The complete assessment is presented in Annex III.

4. Consideration of comments received on the revised draft Chapter 10.4. 'Infection with avian influenza viruses'

At its February 2019 meeting, the Code Commission considered comments received on the revised draft Chapter 10.4. 'Infection with avian influenza viruses' that had been circulated in its September 2018 report. The Commission addressed some comments and referred those that needed further expert advice to this *ad hoc* Group for its consideration.

The *ad hoc* Group considered comments received from Argentina, Australia, Canada, China (People's Republic), Costa Rica, Guatemala, Honduras, India, Japan, Malaysia, South Africa, Thailand, United States of America (USA), the Member States of European Union (EU) and the African Union Interafrican Bureau for Animal Resources (AU-IBAR) on behalf of African Member Countries of the OIE. Comments received from the International Poultry Council and other experts were also considered, as well as comments made by some Members at the 87th General Session on the proposed draft chapter.

The *ad hoc* Group reviewed all comments and proposed amendments to the text of the chapter, where appropriate. The *ad hoc* Group did not address comments where a rationale had not been provided or that were difficult to interpret.

In response to general comments regarding notification or surveillance of LPAI and the scope of the chapter, the *ad hoc* Group agreed that the conclusion and rationale of the assessment presented in Annex III should provide an adequate response, and therefore individual responses were not provided in this report. However, the *ad hoc* Group did provide some specific comments relating to the issues around LPAI in relevant sections of this report. In addition to amendments in response to comments, the *ad hoc* Group also proposed other amendments for clarity, consistency and improved readability.

General comments

The *ad hoc* Group noted the overall support for amendments made by the *ad hoc* Group at its previous meeting and that had been circulated for comment.

In response to a comment questioning the appropriateness of associating monitoring of H5 and H7 LPAI strains with free status of HPAI, the *ad hoc* Group clarified that continued monitoring of any hemagglutinin subtype of LPAI is recommended for the following reasons: 1) monitoring of LPAI can provide useful information to verify biosecurity plans in place on farms; and 2) changes in virus virulence and its zoonotic potential needs to be captured; and 3) a surveillance programme for HPAI normally can provide a certain degree of monitoring function of LPAI viruses considering its similarities in designs, sampling and diagnostic flow, and the commonly deployed virus detection and antibody screening test for diagnosis and surveillance detect all influenza A viruses and their infections making monitoring of non-HPAI cost effective and structurally simple.

Based on the conclusions of the assessment of H5 and H7 LPAI (presented in Annex III), the *ad hoc* Group agreed with a comment requesting to revise the relevant listed diseases in Chapter 1.3., and noted that this would be considered by the Code Commission at its September 2019 meeting based on its assessment.

Although the *ad hoc* Group recognised the possibility of referring to the same pathogenic agent in different ways, it did not agree with a comment suggesting to replace ‘high pathogenicity avian influenza virus’ with ‘highly pathogenic avian influenza virus’ throughout the chapter. The *ad hoc* Group agreed that the use of ‘high pathogenicity’ allowed for a better alignment with the English use of ‘low pathogenicity’, which could not be named ‘lowly’ pathogenic.

The *ad hoc* Group did not agree with a comment requesting to change the chapter title to ‘Infection with avian influenza viruses with potential to become highly pathogenic and pandemic’ as ‘pandemic’ by definition refers to the worldwide spread of a new disease in humans, which is outside of the remit of the *Terrestrial Code*.

Article 10.4.1. General provisions

In response to a comment questioning to the use of the terms ‘avian influenza’, ‘infection with avian influenza viruses’, or ‘low pathogenicity avian influenza’ without clear definitions for each, the *ad hoc* Group noted that the objective of this chapter was to mitigate animal and public health risks posed by infection with high pathogenicity avian influenza viruses and amended the text accordingly for clarity.

The *ad hoc* Group discussed a comment requesting to amend the text for the definition of ‘high pathogenicity avian influenza’ and agreed to delete the definition and refer to the definition in the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual)* to avoid any inconsistencies. The *ad hoc* Group recognised that the chapter in the *Terrestrial Code* needs to be well aligned with the corresponding chapter in the *Terrestrial Manual*, and noted that the description of the methods used for the determination of strain virulence in the *Terrestrial Manual* could be further improved; consequently, the *ad hoc* Group requested that OIE Headquarters raise this issue with the Biological Standards Commission and consider revising the *Terrestrial Manual* Chapter 3.3.4. ‘Avian influenza (infection with avian influenza viruses)’.

In response to a comment questioning with respect to disease notifications how to deal with “H5 or H7 viruses with an intravenous pathogenicity index (IVPI) of less than 1.2 and a polybasic cleavage site sequence not previously described”, which is not covered in the current definition of HPAI but is considered to be important in OFFLU, a joint worldwide network of expertise on avian influenza, the *ad hoc* Group requested OIE Headquarters refer this comment to the Biological Standards Commission for its consideration for the relevant definitions in the *Terrestrial Manual*. On a related note, the *ad hoc* Group also noted that ‘specific viral ribonucleic acid’ in point 2(b) to define an occurrence of infection with high pathogenicity avian influenza virus was not specified in the *Terrestrial Manual* chapter and therefore this issue should also be considered by the Biological Standards Commission.

Annex 30 (contd)

The *ad hoc* Group acknowledged a comment requesting the alignment of the definitions for ‘poultry’ used in this chapter and the Glossary and considered that the Code Commission was best placed to consider this comment. The *ad hoc* Group also considered the Code Commission could better address another comment asking that “breeding flocks producing offspring raised for restocking supplies of game”, be explicitly included in the ‘all birds used for restocking supplies of game’.

The *ad hoc* Group agreed with a comment requesting to exclude birds kept in zoos from the definition of poultry and added ‘zoological collections’ to the birds that are not considered poultry.

The *ad hoc* Group did not agree with a comment on the revised definition of ‘poultry’, requesting to include a specific reference stating that “birds in a single household for self-consumption” should “have no epidemiological link with poultry” for them not to be considered poultry. Although the *ad hoc* Group partially agreed with the rationale, it considered that if an epidemiological link existed, it would only be due to a lack of biosecurity.

In response to comments requesting to maintain the current wording for the definition of poultry in order to maintain “including backyard poultry” and to a comment seeking clarification on why birds in a household were not considered poultry, the *ad hoc* Group stressed that the intention was not to exclude all so-called ‘backyard poultry’ from the definition but to rather improve its clarity. The *ad hoc* Group reiterated that the revised definition does not consider birds that are kept in a single household and their products are only used in that same household as poultry, because those birds do not represent an epidemiological risk of spreading the disease. The *ad hoc* Group referred Members to its June 2018 meeting report (Annex 25 of the September 2018 Code Commission report) that noted ‘in many countries, the poultry sector was integrated in such a way that no clear separation could be made between different sectors. Due to the wide range of combinations of different types of production systems, the term ‘backyard flocks’ could not be defined.’

The *ad hoc* Group did not agree with a suggestion to create an independent article for surveillance in domestic birds other than poultry, and reiterated that, despite the removal of backyard poultry’ from the text, the part of such population that is epidemiologically significant with respect to avian influenza (i.e. traded beyond the household where kept) would continue to be considered ‘poultry’ after the change in the definition. The *ad hoc* Group further noted that proposed new wording to replace ‘backyard poultry’ was clearer and the definition of poultry is now well aligned with the risk of disease spread.

The *ad hoc* Group did not agree with a comment requesting to modify a sentence in the revised definition for poultry to read “If birds are kept in a household and their products are used for local consumption, these birds are not considered poultry” as it considered that ‘local’ was too broad and non-specific (e.g. town, municipality, province, state) and that this word may introduce further confusion.

The *ad hoc* Group further discussed the incubation period at the flock level referred to in point 1(d) and noted that for some avian species in the order Anseriformes the incubation period may be longer than 14 days or may not exist due to a lack of clinical signs with such virus infections. Notwithstanding, the *ad hoc* Group agreed that it was important to define this period in the regulatory arena, which can reasonably be applied to all bird species so that Members can make relevant decisions.

Taking into account the outcome of the assessment of H5 and H7 low pathogenicity avian influenza viruses against the criteria in Chapter 1.2. (refer to Item 3), the *ad hoc* Group amended text referring to notification obligations. This amendment addressed several comments received. The *ad hoc* Group clarified that based on the outcomes of its assessment and if agreed by the Specialist Commissions, notification would only be mandatory for high pathogenicity avian influenza. Nonetheless, it highlighted that immediate notifications as emerging diseases as described in Article 1.1.4. would apply upon detection of a sudden and unexpected increase in virulence of low pathogenicity avian influenza viruses in poultry, or infection of domestic and captive wild birds with low pathogenicity avian influenza viruses that had been proven to be naturally transmitted to humans associated with severe consequences.

Annex 30 (contd)

The *ad hoc* Group also reaffirmed that occurrences of avian influenza viruses of high pathogenicity in birds other than poultry including wild birds should continue to be notified to the OIE in accordance with Article 1.3.6. In this regard the *ad hoc* Group considered that the current name in Chapter 1.3. ‘Infection with influenza A viruses of high pathogenicity in birds other than poultry including wild birds’ should be amended to ‘infection with avian influenza viruses of high pathogenicity in birds other than poultry including wild birds’.

The *ad hoc* Group did not agree with a comment opposing the addition of text stating that vaccination would not affect the status of a country or zone. The *ad hoc* Group reiterated that the absence of the disease and infection could be effectively demonstrated, even after vaccination, by adequate surveillance in accordance with Chapter 1.4. and relevant articles in this chapter of the *Terrestrial Code* and the corresponding chapter in the *Terrestrial Manual*.

The *ad hoc* Group agreed with a comment suggesting to replace ‘vaccination against high pathogenicity avian influenza’ with ‘vaccination against avian influenza viruses of H5 and H7 subtypes’, and amended the text to clarify that the vaccination against any avian influenza viruses may be recommended under specific conditions.

Article 10.4.2. Country or zone free from high pathogenicity avian influenza

The *ad hoc* Group did not agree with a comment claiming that monitoring of H5 and H7 LPAI in poultry is not justified in all situations to support freedom from high pathogenicity avian influenza, and reiterated its rationale noted under ‘General comments’ section above. Nevertheless, the *ad hoc* Group deleted text relating to monitoring of LPAI from this article and included cross-reference to relevant articles.

Article 10.4.2bis. Compartment free from high pathogenicity avian influenza

Although the *ad hoc* Group did not completely agree with the rationale provided by some Members suggesting that a compartment should be free from all influenza viruses, the *ad hoc* Group amended the text of point 1 of Article 10.4.22. to add a sentence stating that surveillance is aimed at ensuring that biosecurity and control measures are fit for purpose.

Article 10.4.2quater. Recovery of free status

In response to a comment requesting to provide a rationale to support reducing the minimum recovery period to less than 3 months, the *ad hoc* Group emphasised that two flock-level incubation periods, i.e. 28 days, should be considered as a minimum to recover free status if supported by surveillance to demonstrate the absence of infection, in accordance with provisions in Chapter 1.4. and the relevant articles in this chapter.

Article 10.4.3. Recommendations for importation from a country, zone or compartment free from high pathogenicity avian influenza – for live poultry (other than day-old poultry)

In response to a comment seeking clarification on the scope of vaccination referred to in this article, the *ad hoc* Group clarified that it covers vaccination against any subtypes of avian influenza virus. The *ad hoc* Group agreed there was no need to amend the text and noted that this would also apply to similar references in other articles.

The *ad hoc* Group agreed with a comment questioning the reference to a “flock free from infection with any H5 or H7 influenza A viruses” as it was not defined in the draft chapter. The *ad hoc* Group amended the text to refer to a flock of origin that should have been monitored for avian influenza viruses, with negative results. The same change was applied to other relevant articles. This response also addressed similar comments raised in other articles.

The *ad hoc* Group did not agree with a comment requesting to add text stating that “an exporting country must provide evidence to an importing country showing the absence of infection when vaccination is applied”, as it considered that this was addressed in Article 10.4.22. This response also addressed similar comments raised in other articles.

Annex 30 (contd)**Article 10.4.4. Recommendations for importation of live birds other than poultry**

In response to a comment querying whether, in point 3, the wording ‘a diagnostic test for influenza A viruses’ means only virological testing, the *ad hoc* Group clarified that it includes both serological and virological testing for avian influenza viruses, and consequently amended the text to improve clarity.

Article 10.4.6. Recommendations for importation of day-old live birds other than poultry

The *ad hoc* Group agreed with a comment requesting to include reference to “a statistically valid sample” in point 3, to ensure consistency with Article 10.4.4. The *ad hoc* Group also agreed with a comment suggesting that the parent flock should be tested negative for any avian influenza virus and modified the text accordingly.

Article 10.4.11. Recommendations for importation from a country, zone or compartment free from high pathogenicity avian influenza – for eggs for human consumption

The *ad hoc* Group did not agree with a comment requesting the reinstatement of the previous point 2 that read ‘the eggs have had their surfaces sanitized (in accordance with Chapter 6.5.)’. The *ad hoc* Group explained that this article was intended to provide measures to mitigate the risk of international spread of the disease via importation of eggs for human consumption, and not for food safety *per se*, and that the risk of disease transmission arising from unwashed eggs for human consumption was deemed negligible. The *ad hoc* Group also noted that Chapter 6.5. addressed sanitisation of hatching eggs only.

Article 10.4.12. Recommendations for importation of egg products of poultry

The *ad hoc* Group did not agree with a comment requesting to delete the reference to ‘high pathogenicity’ in the context of virus inactivation given that procedures required for inactivation of avian influenza viruses are the same irrespective of their pathogenicity. The *ad hoc* Group noted that this chapter is to mitigate the risks posed by high pathogenicity avian influenza and therefore this should be clearly addressed in this chapter.

Article 10.4.13. Recommendations for importation from a country, zone or compartment free from high pathogenicity avian influenza – for fresh meat of poultry

In response to a comment referring to the absence of provisions regarding the status of the exporting country for H5 and H7 low pathogenicity avian influenza in poultry, the *ad hoc* Group noted that this chapter is to mitigate the risks posed by high pathogenicity avian influenza and therefore this should be clearly addressed in this chapter. Furthermore, the *ad hoc* Group reiterated that H5 and H7 LPAI posed a lower risk than HPAI for spread through fresh meat, which was strongly supported by the risk assessment undertaken by the European Food Safety Authority (see the ‘assessment of low pathogenic avian influenza virus transmission via raw poultry meat and raw table eggs’ at <https://www.efsa.europa.eu/en/efsajournal/pub/5431>).

This response also addressed similar comments raised in other articles.

Article 10.4.18. Procedures for the inactivation of high pathogenicity avian influenza viruses in egg products of poultry

In response to a comment the *ad hoc* Group reviewed and amended the text accompanying the table to improve clarity.

The *ad hoc* Group did not agree with a comment to modify the presentation of the target reference for the reduction of avian influenza virus infectivity as it considered that log reduction was a mathematical term that could be widely used to quantify virus infectivity in any commodities.

Article 10.4.19bis. Procedures for the inactivation of high pathogenicity avian influenza viruses in scientific specimens and skins and trophies

In response to a request to share scientific literature that supports the specific parameters in this article, the *ad hoc* Group explained that they were developed based on parameters used in other disease-specific chapters such as foot and mouth disease, classical swine fever and African swine fever, and taking into consideration the characteristics of the pathogenic agent. The *ad hoc* Group also noted that this kind of extrapolation was often done, when deemed appropriate, in the *Terrestrial Code*.

Article 10.4.20. Principles of surveillance for avian influenza

Taking into consideration comments regarding the content and scope of this article, the *ad hoc* Group emphasised that this article addresses “Principles of surveillance for avian influenza” and was intended to be considered together with provisions provided in the following articles on surveillance and monitoring. In addition, the *ad hoc* Group amended the title and some text to improve clarity and to highlight the possibility for Members to adapt these provisions to their local context when demonstrating the absence of infection. The *ad hoc* Group also amended the text to clarify the relevance of monitoring of H5 and H7 low pathogenicity avian influenza viruses in poultry.

In response to a comment highlighting the importance of a monitoring system for LPAI in poultry, the *ad hoc* Group noted that monitoring activities for LPAI were extremely unlikely to detect infection, on a single establishment, in time for control measures to be taken to avoid mutation to high pathogenicity avian influenza on that single establishment. The *ad hoc* Group considered that the key goal to adequately manage the risk of spread of LPAI would be to detect clusters of infected poultry establishments where H5 and H7 low pathogenicity viruses spread between poultry establishments.

The *ad hoc* Group also added a new paragraph highlighting the value of the application of sequencing technologies and phylogenetic analyses to enhance the evidence for surveillance and disease prevention and control.

Article 10.4.22. Surveillance for demonstrating freedom from high pathogenicity avian influenza

The *ad hoc* Group did not agree with a comment to include an additional reference to the level of confidence, as this was already addressed in the cross-referenced Article 1.4.6.

The *ad hoc* Group did not agree with a comment that considered it contradictory to include a reference to monitoring of H5 and H7 LPAI in this article. The *ad hoc* Group considered that monitoring of these low pathogenicity viruses was important as described in Article 10.4.20. The *ad hoc* Group also highlighted that a “free status” depends not only on demonstrating freedom through surveillance, but also requires the implementation of effective biosecurity and sanitary measures to prevent the introduction of the disease. The *ad hoc* Group amended the text to improve clarity.

The *ad hoc* Group also added new text throughout this article to provide more details on transparency in the application of surveillance methodologies, some important variables for surveillance, different sampling strategies and overall surveillance sensitivity.

In response to a comment, the *ad hoc* Group agreed to revise the text of point 3 ‘Additional requirements for the recovery of free status’, by deleting ‘moved from or’ from the text as there was no need to include such a subpopulation of poultry under the surveillance programme for recovery of free status.

Article 10.4.22bis. Surveillance of wild bird populations

The *ad hoc* Group deleted the first generic paragraph agreeing that this was broadly addressed elsewhere in the chapter.

In response to a comment requesting to clarify whether active surveillance in wild birds included sampling of live and apparently healthy birds, the *ad hoc* Group amended the text accordingly to clarify this point.

Annex 30 (contd)

The *ad hoc* Group did not agree with a comment suggesting to add a sentence stating that regular testing of sentinel ducks in contact with wild waterfowl was recommended as active surveillance, as there was not strong evidence to support such a method for wild birds.

Previous Article 10.4.27. Surveillance for the avian influenza free establishments

In line with the amendments to delete the term 'avian influenza free establishment' from the draft chapter, and in response to a comment, the *ad hoc* Group deleted this article from the draft chapter as it was no longer considered necessary.

Diagnostic diagrams in the existing chapter

The *ad hoc* Group noted that the Biological Standards Commission did not support moving the diagnostic diagrams in Article 10.4.33. to the *Terrestrial Manual*. The *ad hoc* Group supported the approach proposed by the Code Commission to publish them, after updating if necessary, on an OIE webpage, once the revised chapter is adopted.

5. Any other business

The *ad hoc* Group agreed to develop a scientific paper which reviewed the global epidemiology of avian influenza and which would provide Member Countries with relevant technical advice on a range of issues such as surveillance methodologies, to support them in the implementation of the chapter, once adopted.

.../Annexes

Annex 30 (contd)

Annexe I

**REPORT OF THE MEETING OF THE OIE AD HOC GROUP ON AVIAN INFLUENZA
Paris (France), 11–13 June 2019**

Adopted agenda

- 1) Introduction
 - 2) Welcome
 - 3) Assessment of ‘H5 and H7 low pathogenicity avian influenza’ against the criteria for the inclusion of diseases, infections and infestations in the OIE list in Chapter 1.2. of the *Terrestrial Code*
 - 4) Consideration of comments received on the revised draft Chapter 10.4. ‘Infection with avian influenza viruses’
 - 5) Any other business
-

Annex 30 (contd)Annexe II**REPORT OF THE MEETING OF THE OIE AD HOC GROUP ON AVIAN INFLUENZA****Paris (France), 11–13 June 2019****List of participants****MEMBERS OF THE AD HOC GROUP****Dr David Swayne (Chair)**

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**ASSESSMENT OF H5 AND H7 LOW PATHOGENICITY AVIAN INFLUENZA
AGAINST THE LISTING CRITERIA IN CHAPTER 1.2.
OF THE TERRESTRIAL ANIMAL HEALTH CODE**

Overall assessment

The OIE *ad hoc* Group on avian influenza (the *ad hoc* Group) assessed H5 and H7 low pathogenicity avian influenza (LPAI) against the criteria for the inclusion of a disease, infection or infestation in the OIE list in accordance with Article 1.2.2. of the *Terrestrial Code*. The *ad hoc* Group noted that the criteria, in particular criteria 4(a) and 4(b), were difficult to interpret and apply to H5 and H7 LPAI because of the complexities of assessing a group of viruses where the characteristics of different strains or lineages/genotypes vary and the diversities of poultry sector and avian species involved. Taking into account the difficulty of interpretation of criteria 4(a) and 4(b) and the caveats documented in their assessment (see below), as well as the outcomes of assessments for the other criteria, the *ad hoc* Group agreed that H5 and H7 LPAI viruses did not meet the criteria for inclusion in the OIE list. Nonetheless, notification of events involving viruses in this category with specific characteristics indicating a significant risk to animal or public health should continue to be encouraged.

Table 1. Summary of assessment of H5 and H7 low pathogenicity avian influenza

	Listing criteria						Conclusion
	1	2	3	4a	4b	4c	
H5 and H7 LPAI	+	+	+	+/-	+/-	-	Taking into account the caveats noted under criteria 4(a) and 4(b), the <i>ad hoc</i> Group concluded that H5 and H7 LPAI does not meet the criteria for listing

Background

At the request of the Code Commission at its September 2018 meeting, the *ad hoc* Group undertook an assessment of 'H5 and H7 low pathogenicity avian influenza viruses' against the criteria in Article 1.2.2. of Chapter 1.2. 'Criteria for the inclusion of diseases, infections and infestations in the OIE list' of the *Terrestrial Code*.

The disease assessed was infection with the 'low pathogenicity avian influenza viruses' as defined in point 1(b) of Article 10.4.1, i.e. 'low pathogenicity avian influenza viruses are all influenza A viruses of H5 and H7 subtypes that are not high pathogenicity avian influenza viruses' of the 2018 edition of Chapter 10.4. 'Infection with avian influenza viruses' of the *Terrestrial Code*.

In advance of the meeting, members of the *ad hoc* Group were provided with detailed information on the assessment process and were requested to undertake assessments against each criterion based on the scientific evidence available. During the meeting, the *ad hoc* Group considered all of the assessments made for each criteria and reached an agreed position which is documented below.

Criteria for the inclusion of a disease, infection or infestation in the OIE list (Article 1.2.2.)

Criterion No. 1

International spread of the pathogenic agent (via live animals or their products, vectors or fomites) has been proven.

Annex 30 (contd)Annex III (contd)Assessment

H5 and H7 LPAI has moved beyond geographic boundaries by both wild bird movement and human activity, mostly by trade of infected live birds which shed LPAI viruses in their respiratory secretions and faeces. International spread of H5 and H7 LPAI has been proven in numerous outbreaks with these viruses, although extensive transboundary spread has not necessarily occurred. Nevertheless, international spread of the pathogenic agent should be considered a pathway. Spread via poultry products is not a specified pathway for most strains. The trade of live birds is the major risk with the best evidence being the movement of: 1) H5N2 LPAI in poultry in the late 1990s from Mexico to Guatemala, El Salvador and some Caribbean Islands; 2) a single episode of H5N2 LPAI between Canada and the USA in domestic ducks; and 3) H7N1 and H7N8 LPAI in global pet bird trade [1], as described below.

The H5N2 LPAI virus is highly adapted to chickens and not to migratory waterfowl, and the lack of virus in surveillance samples from the wild waterfowl populations, and the endemicity of the virus in Mexican chickens over much of central and southern Mexico, provided indirect evidence of the source being movement of live chickens across the porous national borders with appearance of the virus in poultry of neighbouring countries.

In the second example, domestic ducks infected with H5N2 LPAI virus were exported from Ontario, Canada to New York state, USA without spread beyond the importing premise. In the third example, during the 1990s, H7 LPAI were moved between countries via unregulated trade in live pet/captive passerine/psittacine birds [1].

The movement of H5 and H7 LPAI virus by wild birds is well documented for Canada-USA and European countries within numerous surveillance programmes [2,3], but the *ad hoc* Group did not use such information in assessing Criterion 1. The *ad hoc* Group only acknowledged the factualness of the spread within wild bird populations, but the assessment was focused only on spread through human activity.

On rare occasions, H5 or H7 LPAI viruses have been detected in illegally imported raw poultry meat [4] or eggs of turkeys or chickens, but the systemic spread required to produce the virus in such products appears to be virus strain specific and host species specific, and of much lower titers than seen with high pathogenicity avian influenza virus (HPAI) infections. These rare detections of H5 and H7 LPAI virus have not been associated with onward transmission and infections in poultry.

Conclusion

The criterion is met.

AND

Criterion No. 2

At least one country has demonstrated freedom or impending freedom from the disease, infection or infestation in populations of susceptible animals, based on the provisions of Chapter 1.4.

Assessment

The global distribution of avian influenza viruses is widely accepted in wild aquatic birds with demonstration of virus or antibodies against the virus on all seven continents. The spillover of these viruses into domestic poultry can be problematic as most such infections fail to cause disease, especially in domestic waterfowl, and surveillance for freedom is only able to be demonstrated in countries with well-developed active surveillance programmes. The declaration of freedom from H5 and H7 LPAI has some potential problems as surveillance for H5 and H7, especially in small holder poultry, is often inadequate to demonstrate freedom, and reporting of infection for the most part is done by those doing active surveillance; i.e. negative surveillance results allows some countries to declare H5 and H7 LPAI freedom, but surveillance system design requires careful evaluation to ensure such results are supportable.

Annex 30 (contd)

Annex III (contd)

In support of this position above, Member States of the European Union have carried out and reported results of active surveillance for avian influenza in poultry flocks using serology for H5 and H7 subtypes. Details of the surveillance and results of each year are available online [5]. During 2004–2010 (inclusive), the following countries carried out the required surveillance and did not detect any seropositive holdings to H5 or H7 avian influenza viruses in the poultry sampled: Austria, Cyprus, Estonia, Greece, Hungary, Latvia, Lithuania, Luxembourg, Slovenia and Slovakia. The data available through the reports to the European Commission provide evidence of freedom from H5 and H7 LPAI in the poultry populations of these countries.

As a separate point, most countries provide sufficient surveillance data for the self-declarations of freedom from H5 and H7 LPAI that have been reported to the OIE. Also in support of this position is the self-declaration of the recovery of country freedom from avian influenza provided by Denmark and reported to the OIE. The self-declaration covers the whole country and describes the two outbreaks of LPAI reported in May and June 2018 [6].

Conclusion

The criterion is met.

AND

Criterion No. 3

Reliable means of detection and diagnosis exist, and a precise case definition is available to clearly identify cases and allow them to be distinguished from other diseases, infections or infestations.

Assessment

Specific and sensitive serological, virological and molecular methods exist to identify the H5 and H7 LPAI virus or their infections in domestic poultry [7,8]. There are very precise case definitions that require underpinning laboratory diagnosis which enables the safe distinction between LPAI and HPAI [9], and allow differentiation of H5 and H7 LPAI from other diseases. The methodology currently used will reliably detect infection at flock level if present, and then subsequent differentiation of pathogenicity. However, the clinical case definition is not pathognomic given there are a number of pathogenic agents that can cause similar presentation, including infections with non-H5 and H7 LPAI virus. Laboratory diagnosis is essential.

The primary methods for screening for virus or infections are sensitive and specific and identify type A influenza viruses; e.g. matrix RRT-PCR, ELISA and AGP serological tests. The secondary tests are slightly less sensitive methods that are used to differentiate the infections or the viruses of H5 and H7 from those of non-H5/H7; e.g. H5 and H7 RRT-PCR tests and hemagglutination inhibition test. The methods are not in question, but the lack of capacity for diagnosis and surveillance to detect and differentiate the H5 and H7 from non-H5/H7 LPAI virus infections that are for the most part asymptomatic infections is still a challenge in some countries.

Conclusion

The criterion is met.

AND

Criterion No. 4 (a)

Natural transmission to humans has been proven, and human infection is associated with severe consequences.

Assessment

The *ad hoc* Group agreed that the complexity of the H5 and H7 group of viruses as being genetically and phenotypically heterogeneous presented challenges for a conclusive unambiguous assessment for this criterion. The *ad hoc* Group agreed that in order to reach consensus a series of underpinning caveats needed to be noted and should be taken into account when considering its recommendations, i.e.

Annex 30 (contd)Annex III (contd)

- The complexity and understanding of influenza A virus characteristics contrast to other pathogens (e.g. *Brucella* spp.) where either all strains cause zoonotic infection, or the genetic correlates/nuances are not understood at all at strain level.
- The occurrence of zoonotic infections with the H7N9 Chinese lineage LPAI virus since 2013 with severe outcomes (i.e. 40% case fatality rate) [10-12] could not be discounted; however the *ad hoc* Group agreed that this related to a single strain or 'virus lineage/genotype'. On this point alone all *ad hoc* Group members agreed the answer to the question under criterion 4(a) is yes: However the following caveats must accompany this assessment.
 - This 'unique virus lineage' was restricted in its range being limited to China to date.
 - Consistent with the genetic characteristics not all strains of H7N9 subtype are zoonotic.
 - Occurrences of infection of humans with other H5 and H7 LPAI viruses have been reported infrequently (e.g. H7N2 UK, H7N3 Canada and UK [noting of different genetic characteristics]) [13]. In most cases these did not cause 'severe consequences', rather typically being characterised by mild infection i.e. conjunctivitis or mild uneventful respiratory illness (also including some immunocompromised patients) with recovery.
 - Increased awareness in the last 15 years has resulted in more surveillance (avian-human interface).
- The *ad hoc* Group agreed that given the complexity of these viruses and difficulties in interpreting the criterion, its assessment for this criterion was inconclusive when applied to all H5 and H7 viruses of low pathogenicity for poultry.

Conclusion

The assessment for this criterion was inconclusive.

OR

Criterion No. 4 (b)

The disease has been shown to have a significant impact on the health of domestic animals at the level of a country or a zone taking into account the occurrence and severity of the clinical signs, including direct production losses and mortality.

Assessment

The *ad hoc* Group recognised that the reason for including H5 and H7 LPAI viruses in Chapter 10.4. of the *Terrestrial Code* was because of the potential for some of these viruses to mutate to a highly pathogenic form. However, the *ad hoc* Group also acknowledged that infection of poultry with the majority of H5 and H7 LPAI viruses as well as non-H5 and H7 viruses does not result in significant disease in the absence of co-factors that include secondary pathogens. This is supported by results from experimental infections of specific pathogen free chickens where no or only mild clinical disease has been observed. That being said, infection with some H5 and H7 LPAI viruses can cause production losses in specific poultry sectors. Examples of this include moderate to severe drops in egg production in breeder turkeys and to a lesser extent broiler breeders [14]. For these reasons the *ad hoc* Group's assessment of this criterion was inconclusive.

Conclusion

The assessment for this criterion is inconclusive.

OR

Annex 30 (contd)Annex III (contd)**Criterion No. 4(c)**

The disease has been shown to, or scientific evidence indicates that it would have a significant impact on the health of wildlife taking into account the occurrence and severity of the clinical signs, including direct economic losses and mortality, and any threat to the viability of a wildlife population.

Assessment

The natural reservoir for H5 and H7 LPAI viruses is in wild birds. In these populations the virus generally has a benign or subclinical affect and therefore probably has no impact on the biodiversity of wildlife associated with infection [15, 16].

Conclusion

The criterion is not met.

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Annex 31

Original: English
July 2019

REPORT OF THE MEETING OF THE OIE AD HOC GROUP ON VETERINARY SERVICES³ Paris (France), 3–5 July 2019

The OIE *ad hoc* Group on Veterinary Services (the *ad hoc* Group) met at OIE Headquarters from 3–5 July 2019.

The agenda and the list of participants are presented in Annex I and II.

1. Welcome and introduction

Dr Monique Eloit, Director General of the OIE, welcomed members of the *ad hoc* Group and the representative from the Terrestrial Animal Health Standards Commission (Code Commission) and thanked them for their continued support for this important OIE work.

Dr Eloit noted the importance of the topics to be discussed by the group, as they have a serious impact on the quality of Veterinary Services, which is essential to achieve the OIE objectives. She also encouraged the members of the group to take into consideration their broad experience to develop quality standards that could be useful to all OIE Member Countries, without prescribing any particular governance model.

Dr Eloit also emphasised that the same considerations should be had in mind while reviewing the definitions of the terms ‘Competent Authority’, ‘Veterinary Authority’ and ‘Veterinary Services’, as they are key for the whole *Terrestrial Animal Health Code (Terrestrial Code)*, and that special attention should be paid to Member Country comments to understand the challenges for the understanding of these definitions at the national level.

Dr John Weaver, Chair of the *ad hoc* Group, welcomed the experts and thanked them for their commitment to this work. He also commended the Secretariat’s preparatory work for this meeting.

The Secretariat delivered a short presentation to provide the context of *ad hoc* Group work within the OIE’s mandate and the OIE standard-setting process, with particular emphasis on the roles and responsibilities of *ad hoc* Groups, Specialist Commissions and the OIE Secretariat.

2. Background

2.1. Summary of recent work of the *ad hoc* Group on Evaluation of Veterinary Services on Chapters 3.1. and 3.2.

The Secretariat explained that, as presented in the Terms of Reference, their task should be based on the outputs of the *ad hoc* Group on the Evaluation of Veterinary Services and briefly summarised

³ Note: This *ad hoc* Group report reflects the views of its members and may not necessarily reflect the views of the OIE. This report should be read in conjunction with the September 2019 report of the Terrestrial Animal Health Standards Commission because this report provides its considerations and comments. It is available at <http://www.oie.int/en/international-standard-setting/specialists-commissions-groups/code-commission-reports/meetings-reports/>

Annex 31 (contd)

the work done by that group. The *ad hoc* Group on the Evaluation of Veterinary Services had met in May 2018, primarily to update the OIE PVS Tool, but also to consider the need to review *Terrestrial Code* Chapters 3.1. and 3.2. As a consequence of this work, it recommended that these chapters be revised to ensure they reflect the contemporary activities and responsibilities of the Veterinary Services and be better aligned with other chapters in the *Terrestrial Code*. It was noted that almost all the text was drafted approximately 20 years ago. The Code Commission, at its September 2018 meeting, supported this proposal and recommended that the *ad hoc* Group be reconvened to develop proposed changes to Chapters 3.1. and 3.2. The *ad hoc* Group met in November 2018 to progress this work. As a result of that meeting, preliminary drafts of Chapters 3.1 and 3.2 were presented to the Code Commission in February 2019. The Code Commission provided feedback on the proposal and requested that revision of the chapters be continued.

The Terms of Reference are presented in Annex III.

2.2. Brief on previous Code Commission's discussions relevant to the work of the *ad hoc* Group on definitions

The Secretariat informed the *ad hoc* Group of previous work and discussions of the Code Commission on definitions that preceded this meeting. In May 2018, a revised Chapter 6.2. - The role of the Veterinary Services in food safety systems was proposed for adoption in the 86th General Session, and during the discussion of this chapter, United States of America (USA), Canada, Australia and New Zealand commented on the use of the terms 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services'.

Following up on this intervention, the Code Commission discussed this issue further in its September 2018 meeting and responded to the countries' comments. To improve the understanding, the Commission agreed to revise the definitions of the three terms and proposed amendments that were circulated for Member Country comments.

In February 2019, the Code Commission considered comments received on the proposed amendments to the Glossary definitions for 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services'. Taking into consideration the different views expressed by Member Countries, and the importance of these definitions not only in the *Terrestrial Code* but also in the *Aquatic Animal Health Code (Aquatic Code)* and other OIE activities such as the PVS Pathway, the Code Commission requested that an *ad hoc* Group provide support to address the issue of definitions, together with proposed revisions of Chapters 3.1. and 3.2.

3. Definitions of Competent Authority, Veterinary Authority and Veterinary Services in the *Terrestrial Code* Glossary

The *ad hoc* Group considered comments from Australia, Canada, Chile, India, New Zealand, Switzerland, USA and the EU member countries, and discussed in depth these definitions and their interplay. To aid the discussion, the use of the definitions across the *Code* and the previous work of the *ad hoc* Group on Evaluation of Veterinary Services were carefully reviewed.

The *ad hoc* Group agreed that the current definitions lacked clarity and led to contradicting interpretations among Member Countries. Significant discrepancies in the understanding of each of the terms Veterinary Authority, Competent Authority and Veterinary Services were noted.

Following discussions, the *ad hoc* Group provided specific feedback to OIE Headquarters on each of the three terms. Considering that these definitions are closely related with other OIE standards, as well as with many OIE activities, OIE Headquarters will seek further advice from the Specialist Commissions, among others, before proposing modifications to the *Code* glossary.

4. Revision of Chapters 3.1. and 3.2. of the *Terrestrial Code*

The Secretariat updated the *ad hoc* Group on discussions held during the February 2019 meeting of the Code Commission. The Code Commission suggested modifying the structure of Chapters 3.1. and 3.2. of the *Terrestrial Code*, and stressed that the main reason for Veterinary Services to apply provisions in Chapters 3.1. and 3.2. was to be able to fulfil their duties and to implement provisions in the *Terrestrial Code*, and not for the purposes of evaluation. Therefore, presenting the standards in terms of how Veterinary Services should be evaluated should not be the main focus of the text. The Code Commission requested that a separate chapter deal with the evaluation aspects including objectives and types of evaluation.

Following these directions, the *ad hoc* Group undertook a thorough revision of Chapters 3.1. and 3.2. The main proposals for the structure and content of the new chapters are presented below.

4.1. Chapter 3.1. Quality of Veterinary Services

The *ad hoc* Group proposed to change the title of the Chapter to “*Quality of Veterinary Services*”, to better reflect the content.

The proposed draft chapter describes the key elements of quality Veterinary Services including the fundamental operating principles that should be considered for any activity of the Veterinary Services, and the major quality components, structured under ten titles, four on governance and six on technical aspects.

Each component contains an introductory description of the recommendation and a list of recommended elements to consider.

4.2. Chapter 3.2. Evaluation of Veterinary Services

As requested by the Code Commission, this short chapter provides contextual information on the evaluation of Veterinary Services, notably the main objectives and types of evaluation. Three types of evaluation are covered; self-evaluation, external evaluation by another Member Country, and external OIE evaluation.

Taking into consideration the development of the quality principles in Chapter 3.1, the *ad hoc* Group agreed to remove the detailed Evaluation Criteria described in Articles 3.2.3. to 3.2.12. of the current chapter, as well as much of the text detailing requirements for the self-evaluation or evaluation of the Veterinary Services of a country described in current Article 3.2.14.

In consideration of the proposals of the *ad hoc* Group on Evaluation of Veterinary Services and the Code Commission’s feedback, the *ad hoc* Group recognised the value of some generic content that would be applicable to several chapters in Section 3 and proposed to include a new introductory Chapter 3.X. The proposed title for the new introductory Chapter 3.X is “Introduction to Veterinary Services”. This would align with some other sections of the *Terrestrial Code* which start with a short introductory or background chapter. The *ad hoc* Group proposed a chapter that incorporates the concept of Veterinary Services, their role and importance, and summarises the overall structure of Section 3, to be considered once proposed changes to the definitions of Competent Authority, Veterinary Authority and Veterinary Services have been finalised.

The revised draft Chapters 3.1. and 3.2. are attached as Annexes IV, and V, respectively.

5. Next steps

The *ad hoc* Group was informed that its report, including the amended draft Chapters 3.1. and 3.2., will be considered by the Code Commission at its next meeting in September 2019.

.../Annexes

Annex 31 (contd)Annex I

**REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP ON VETERINARY SERVICES
Paris (France), 3–5 July 2019**

Agenda

- 1) Introduction from the OIE Headquarters
 - 2) Welcome (Chair Dr John Weaver)
 - 3) Background
 - a) Summary of the last work of the *ad hoc* Group on Evaluation of Veterinary Services
 - b) Brief on previous Code Commission's discussions relevant to the work of the *ad hoc* Group.
 - 4) *Terrestrial Code* Glossary definitions for 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services'
 - a) Consideration of the use of these terms throughout the *Terrestrial Code*: context, meaning, ease of understanding, inconsistent or inappropriate use;
 - b) Review and answer to Member comments received on the proposed revised definitions circulated in the Code Commission's September 2019 report; and amendment of texts if deemed necessary
 - 5) Chapters 3.1. Veterinary Services and 3.2. Evaluation of Veterinary Services
 - a) Review of Code Commission's feedback on the revised texts drafted by the *ad hoc* Group on Evaluation of Veterinary Services (November 2018);
 - b) Analysis of the structure and organisation of the two chapters;
 - c) Revise the text drafted by the *ad hoc* Group on Evaluation of Veterinary Services (November 2018).
 - 6) Report
 - 7) Any other business
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Annex 31 (contd)Annex II

**REPORT OF THE MEETING OF THE OIE AD HOC GROUP ON VETERINARY SERVICES
Paris (France), 3–5 July 2019**

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Annex 31 (contd)Annex III**REPORT OF THE MEETING OF THE OIE AD HOC GROUP ON VETERINARY SERVICES****Paris (France), 3–5 July 2019****Terms of Reference****Purpose**

The purpose of the *ad hoc* Group on Veterinary Services is to review and revise *Terrestrial Code* Chapters 3.1. Veterinary Services and 3.2. Evaluation of Veterinary Services, and to provide advice on the *Terrestrial Code* Glossary definitions for ‘Competent Authority’, ‘Veterinary Authority’ and ‘Veterinary Services’.

Background

Section 3 of the *Terrestrial Code* Quality of Veterinary Services consists of four chapters: Chapter 3.1. Veterinary Services first adopted in 1998; Chapter 3.2. Evaluation of Veterinary Services first adopted in 2002; Chapter 3.3. Communication first adopted in 2011 and Chapter 3.4. Veterinary Legislation first adopted in 2012. All chapters have only had minor amendments since adoption.

The *ad hoc* Group on the Evaluation of Veterinary Services met in May 2018, primarily to update the OIE PVS Tool, but also to consider the need to review *Terrestrial Code* Chapters 3.1. and 3.2. As a consequence of this work, it recommended that these chapters be revised to ensure they reflect the contemporary activities and responsibilities of the Veterinary Services and are better aligned with other chapters in the *Terrestrial Code*.

The Code Commission, at its September 2018 meeting, supported this proposal and recommended that the *ad hoc* Group be reconvened to develop an outline of proposed changes to Chapters 3.1. and 3.2. The *ad hoc* Group met in November 2018 to progress this work.

In February 2019, the Code Commission considered the recommendations of the *ad hoc* Group regarding a revised structure for the two chapters and recommended that the *ad hoc* Group continue its work, and at the same time assist with the ongoing revision of the Glossary definitions for Veterinary Services, Veterinary Authority and Competent Authority.

Following the recommendations of the Code Commission OIE Headquarters decided to create a new *ad hoc* Group to address this work, noting that although this work was linked to evaluation of Veterinary Services using the PVS Tool, it required a broader profile and competencies in its membership.

Specific issues to be addressed

- 1) Provide advice as to whether the *Terrestrial Code* Glossary definitions for ‘Competent Authority’, ‘Veterinary Authority’ and ‘Veterinary Services’ are fit for purpose and/or require any amendments taking into consideration:
 - a) the use of these terms throughout the *Terrestrial Code*: context, meaning, ease of understanding, inconsistent or inappropriate use;
 - b) Member comments received on the proposed revised definitions circulated in the Code Commission’s September 2019 report; and propose amendments if deemed necessary, with supporting rationale, considering the impact of any modification on the implementation of the OIE standards.
- 2) Prepare revised draft Chapters 3.1. and 3.2., taking into consideration:
 - a) the revised texts of Chapters 3.1. Veterinary Services and 3.2. Evaluation of Veterinary Services, drafted by the *ad hoc* Group on Evaluation of Veterinary Services (November 2018);
 - b) the advice of the Code Commission on the November 2018 *ad hoc* Group report, i.e.

Annex 31 (contd)Annex III (contd)

- i) Chapters 3.1. and 3.2. should be aligned with and support the other chapters of the *Code* including the use of cross-references, as appropriate.
- ii) Chapter 3.1. should be focused on standards for the establishment, maintenance, and improvement of Veterinary Services to meet their animal health and welfare, and veterinary public health objectives, and should be written as recommendations that can be implemented by Member Countries, instead of requirements or criteria to be assessed in evaluations.

Suggested the chapter addresses:

- General Considerations on Veterinary Services
 - General Considerations on quality standards, considering its context, use, and importance
 - Standards for Quality Veterinary Services:
 - Fundamental principles
 - Specific recommendations (e.g. Policy and Management, Personnel and Resources, Veterinary Profession, International Trade, Animal Health, Animal Production Food Safety, among others).
- iii) Chapter 3.2. should be focused on standards for how the evaluation of Veterinary Services should occur, recognising the different approaches and contexts for such evaluations.

Considerations

Ad hoc Group members should be familiar with the structure of the *Terrestrial Code*, and the use of Glossary definitions.

The significant progress made by the *ad hoc* Group on Evaluation of Veterinary Services in drafting Chapters 3.1 and 3.2, and as acknowledged by the Code Commission, should be taken into account. The Chair and some of the membership are being retained between the two *ad hoc* Groups to ensure this continuity of work.

Report

The *ad hoc* Group will finalise its report prior to 31 July 2019 for consideration by the Code Commission at its September 2019 meeting.

Annex 31 (contd)

Annex IV (contd)

[Note: this Annex has been replaced by Annex 20 to the report of the meeting of the OIE Terrestrial Animal Health Standards Commission which was held on 10–19 September 2019.]

Annex 31 (contd)

Annex V

[Note: this Annex has been replaced by Annex 21 to the report of the meeting of the OIE Terrestrial Animal Health Standards Commission which was held on 10–19 September 2019.]



Organisation
Mondiale
de la Santé
Animale

World
Organisation
for Animal
Health

Organización
Mundial
de Sanidad
Animal

Annex 32

Original: English
June 2019

**OIE AD HOC ON THE REVISION OF
CHAPTER 7.5. "SLAUGHTER OF ANIMALS" AND
CHAPTER 7.6. "KILLING OF ANIMALS FOR DISEASE CONTROL PURPOSES" ⁴**

Paris, 25–27 June 2019

1. Welcome and introduction

The OIE *ad hoc* Group on the revision of Chapter 7.5. "Slaughter of animals" and Chapter 7.6. "Killing of animals for disease control purposes" (the *ad hoc* Group) met for their third meeting at the OIE Headquarters on 25–27 June 2019.

The agenda and *ad hoc* Group participants are presented in Annexes I and II, respectively.

Dr Francisco D'Alessio, Deputy Head, Standards Department, welcomed participants and thanked them for their continued commitment to this important work, noting that this was the third meeting of the *ad hoc* Group convened to continue its work on the revision of Chapters 7.5. and 7.6.

Dr Leopoldo Stuardo, Chargé de mission, Standards Department, recalled that this *ad hoc* Group had been convened at the request of the Terrestrial Animal Health Standards Commission (Code Commission) to undertake a thorough review of Chapters 7.5. and 7.6. of the OIE *Terrestrial Animal Health Code (Terrestrial Code)* given that these chapters had not been reviewed extensively since 2005. The main issues to address in this review included the inconsistencies between the chapters, gaps with the current scientific knowledge and syntax and formatting issues in both chapters.

Dr Stuardo noted that the Code Commission will review the *ad hoc* Group's report at its next meeting in September 2019 and, if considered appropriate, will circulate the draft chapter for the first round of Member Country comments.

Dr Antonio Velarde, Chair of the *ad hoc* Group, welcomed participants and thanked them for their commitment to this work, in particular undertaking significant work between meetings. He also welcomed Dr Awis Qurni Sazili as a new member of this *ad hoc* Group.

2. Update on the February 2019 Code Commission meeting

The Secretariat provided a summary of the discussions held during the February 2019 meeting of the Code Commission regarding the *ad hoc* Group's previous meeting report of November 2018 noting that the Code Commission agreed with the proposed revised structure and format for the two chapters and the *ad hoc* Group's proposal to develop a draft definition for 'outcome/animal-based measurables'.

The *ad hoc* Group also noted the Code Commission's support to continue its work to review and amend definitions for slaughter, euthanasia, stunning and death.

⁴ Note: This *ad hoc* Group report reflects the views of its members and may not necessarily reflect the views of the OIE. This report should be read in conjunction with the September 2019 report of the Terrestrial Animal Health Standards Commission because this report provides its considerations and comments. It is available at <http://www.oie.int/en/international-standard-setting/specialists-commissions-groups/code-commission-reports/meetings-reports/>

Annex 32 (contd)**3. Development of a new draft Chapter 7.5. "Animal welfare during slaughter"**

The *ad hoc* Group considered draft texts developed by its members in advance of its meeting and continued Chapter 7.5. "Slaughter of animals". The *ad hoc* Group noted that the scope of the draft chapter would address animal welfare aspects of free moving animals and those arriving in containers or crates, from arrival through to slaughter at the slaughterhouse/abattoir.

The *ad hoc* Group agreed to propose a new title for Chapter 7.5. "Slaughter of animals" by "Animal welfare during slaughter" as they considered the revised title better reflected the contents of the chapter which addresses animal welfare aspects of throughout slaughter operations.

The *ad hoc* Group also noted that due to the very extensive nature of the proposed changes to this chapter, the text would only be presented as clean text and not in the usual strikeout/double underline format.

The *ad hoc* Group agreed to amend the scope of the chapter to cattle, buffalo, bison, sheep, goats, horses, pigs, rabbits and poultry, as the *ad hoc* Group considered that there was not sufficient scientific information to develop robust recommendations for the slaughter of species such as camelids, deer and ratites. However, the *ad hoc* Group noted that they had developed some text that indicated that species other than those listed in the scope should be killed using the same overarching principles included in the revised chapter and also the basic principles described in Chapter 7.1. "Introduction to animal welfare" (except for reptiles, for which a specific chapter is being developed).

The *ad hoc* Group agreed that while the chapter addresses the slaughter of animals in slaughterhouses/abattoirs, the general principles could be applied to slaughter of animals in other places such as on farm.

The *ad hoc* Group agreed to develop the recommendations articles of the new draft chapter using a structure that addressed four aspects: animal welfare hazards, animal-based and other measures, recommendations and species-specific recommendations.

Regarding the use of the term "animal-based and other measures", the *ad hoc* Group agreed that this term should also include resource and management-based measures, which can be helpful when assessing animal welfare, especially when animal-based measures are not applicable.

The *ad hoc* Group proposed not to develop a specific article defining all the relevant criteria or measurables, as it was considered that it would be easier for the reader to have the specific measures listed immediately after the determination of "animal welfare concerns" and before the "recommendations".

Due to time constraints, the *ad hoc* Group decided to postpone discussions on the development of a definition for "outcome/animal-base measurable" until its next meeting.

The *ad hoc* Group proposed that the Code Commission consider seeking feedback from Members on the new approach being proposed for Chapter 7.5. even though the draft is incomplete, and articles still need to be drafted that address animals that arrive at the slaughterhouse/abattoir in containers or crates. The *ad hoc* Group considered that general feedback on the work done to date would be useful for future work on this chapter and to develop the revised Chapter 7.6.

The proposed revised Chapter 7.5. "Animal welfare during slaughter" that addresses free-moving animals, is presented as Annex III.

Annex 32 (contd)

4. Revised definitions for slaughter, euthanasia, stunning, death, and new definitions for distress, pain and suffering

The *ad hoc* Group agreed to modify the existing definitions for slaughter, euthanasia, stunning and death in order to ensure that they are aligned with their use in the proposed new Chapter 7.5. as well as ensuring consistency with other uses of these terms throughout the *Terrestrial Code*. The *ad hoc* Group also developed new definitions for pain, suffering and distress to be included in the Glossary noting that these terms are extensively used throughout the *Terrestrial Code* and not only in other chapters of Section 7. They will also be used in the revised Chapters 7.5. and 7.6.

The revised Glossary definitions for slaughter, euthanasia, stunning, death, and new definitions for distress, pain and suffering are presented in Annex IV.

5. Next steps

The *ad hoc* Group agreed to set its fourth meeting date for October 2019 to continue work on Chapter 7.5. and commence work on the revision of Chapter 7.6., pending feedback from the Code Commission.

.../ Annexes

Annex 32 (contd)

Annex I

**OIE AD HOC ON THE REVISION OF
CHAPTER 7.5. "SLAUGHTER OF ANIMALS" AND
CHAPTER 7.6. "KILLING OF ANIMALS FOR DISEASE CONTROL PURPOSES"**

Paris, 25–27 June 2019

List of participants

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Annex 32 (contd)

Annex II

**OIE AD HOC ON THE REVISION OF
CHAPTER 7.5. "SLAUGHTER OF ANIMALS" AND
CHAPTER 7.6. "KILLING OF ANIMALS FOR DISEASE CONTROL PURPOSES"
Paris, 25–27 June 2019**

Adopted agenda

- 1) Welcome and introduction
 - 2) Outcomes of the February 2019 Code Commission meeting discussions
 - 3) Development of the draft Chapter 7.5. "Animal welfare during slaughter" and related definitions
 - 4) Revised definitions for slaughter, euthanasia, stunning, death, and new definitions to include in the Glossary for distress, pain and suffering
 - 5) Next steps
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Annex 32 (contd)

Annex III

[Note: this Annex has been replaced by Annex 23 to the report of the meeting of the OIE Terrestrial Animal Health Standards Commission which was held on 10–19 September 2019.]

Annex 32 (contd)

Annex IV

[Note: this Annex has been replaced by Annex 18 to the report of the meeting of the OIE Terrestrial Animal Health Standards Commission which was held on 10–19 September 2019.]

CHAPTER 1.8.

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

Article 1.8.1.

Guidelines

In accordance with Article 11.4.2., the bovine spongiform encephalopathy (BSE) risk status of the cattle (*Bos indicus* and *Bos taurus*) population of a country, zone or compartment is determined on the basis of a *risk assessment* that evaluates the likelihood of the BSE agents (classical and atypical) being recycled within the cattle population, the ongoing implementation of a *surveillance* programme, and the history of occurrence and management of BSE cases.

In this chapter, "BSE" refers to both classical and atypical forms, unless otherwise specified.

The information specified in Articles 1.8.2. to 1.8.6. should be provided by OIE Member Countries in support of their application for official recognition of BSE risk status in accordance with Chapter 11.4. of the *Terrestrial Code*. The structure of the dossier should follow guidelines provided in the "Standard Operating Procedure for official recognition of disease status and for the endorsement of national official control programmes of Member Countries" (available on the OIE website).

Each element of the core document of the dossier provided to the OIE, should be clearly and concisely addressed with an explanation, when relevant, of how each one has been implemented in accordance with the provisions of the *Terrestrial Code* for the BSE risk status for which the Member is applying. The rationale leading to the conclusions reached for each section needs to be clearly explained and as appropriate, figures, tables and maps should be provided. The core document of the dossier should include the following sections:

- the history of occurrence and management of BSE cases in the country or zone (Article 1.8.2.),
- legislation (Article 1.8.3.),
- veterinary system (Article 1.8.4.),
- BSE *risk assessment* (Article 1.8.5.),
- BSE *surveillance* (Article 1.8.6.).

The terminology defined in the *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in the dossier. The dossier and all of its annexes should be provided in one of the OIE official languages.

Article 1.8.2.

History of occurrence and management of BSE cases in the country or zone

Describe the history of occurrence and management of BSE cases by providing the following documentary evidence:

- 1) If a case of BSE has ever been diagnosed in the country or zone, indicate the total number of BSE cases, and provide a table to indicate, for each case, the year of occurrence, the origin (indigenous or, if imported, the country of origin), the type (classical or atypical), and the year of birth of each indigenous case of classical BSE.

Annex 33 (contd)

- 2) If there have been cases of BSE, confirm that they were excluded from the *feed* chain and describe how this was achieved. In the table under Article 1.8.3. provide details of the national legislation, regulations and *Veterinary Authority* directives that describe these procedures.

Article 1.8.3.

Legislation

Provide a table listing all relevant legislation, regulations, *Veterinary Authority* directives, legal instruments, rules, orders, acts, decrees, etc., related to BSE. For each, provide the date of promulgation and implementation as well as a brief description of the relevance to mitigating against the risks associated with BSE. The table should include the legislation, regulations and directives referred to in the core document of the dossier. These instruments may be provided as annexes or as weblinks to supporting documents.

Article 1.8.4.

Veterinary system

The quality of the *Veterinary Services* of a Member is important to the establishment and maintenance of confidence in its *international veterinary certificates* by the *Veterinary Services* of other Members (Article 3.1.1.). It also supports an evaluation of the BSE risk status of the cattle population of a country or *zone*.

- 1) Describe how the *Veterinary Services* of the country have implemented the provisions of Chapters 1.1., 3.1. and 3.2.
- 2) The applicant Member may provide information on any recent (not older than five years) OIE PVS evaluation conducted in the country and follow-up steps within the PVS Pathway, and highlight the results relevant to BSE.
- 3) Describe how the *Veterinary Services* supervise, control, enforce and monitor all BSE-related activities.
- 4) Provide a description of the involvement and the participation of industry; producers; farmers; herdsmen; private *veterinarians*; *veterinary paraprofessionals*; transporters; workers at livestock *markets*, auctions and *slaughterhouses/abattoirs*; and other relevant non-governmental stakeholders in the control of BSE.
- 5) Describe the official cattle identification, registration, *traceability* and movement control system. Provide evidence of its effectiveness. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic. Indicate if there are any industry associations or organisations involved in cattle identification, registration, *traceability* and movement control systems that provide guidance, set standards or provide third party audits; include a description of their role, membership and interaction with the *Veterinary Services* or other *Competent Authority*.

Article 1.8.5.

BSE risk assessment1. Entry assessment

As described in Article 11.4.2., an entry assessment evaluates the likelihood that the classical BSE agent has been introduced into the country or *zone* via imported *commodities*.

For the purposes of undertaking an entry assessment, the period of interest is the preceding eight years (Articles 11.4.3. and 11.4.4.).

The *commodities* to be considered in the entry assessment are:

- cattle,
 - ruminant-derived protein meal,
 - *feed* (not intended for pets) that contains ruminant-derived protein meal,
 - fertilizers that contain ruminant-derived protein meal,
 - any other *commodity* that either is or could be contaminated by *commodities* listed in Article 11.4.14. E.g., over 30 months old cattle carcass or half carcass from which the spinal cord and vertebral column were not removed, originating from a country, *zone* or *compartment* posing a controlled or undetermined BSE risk.
- a) For each *commodity* listed above indicate if they were imported in the preceding eight years, and if so, from which countries.

For each *commodity* listed above describe the import requirements applied by the applicant country or *zone* and how they are related to the BSE risk status of the *exporting country* or *zone* and whether or not they are consistent with, or provide an equivalent level of assurance with, the recommendations laid out in Chapter 11.4. for the importation of such a *commodity*. When the import requirements are not consistent with the recommendations in Chapter 11.4. but are considered to provide an equivalent level of assurance, provide an explanation outlining the rationale and supporting evidence. In situations where an import requirement does not provide an equivalent level of assurance to the relevant measure in Chapter 11.4., provide an explanation of how this is likely to impact the entry assessment.

Describe the importation process for these *commodities* and how are they controlled, regulated and monitored by the *Competent Authority* with references as appropriate to the relevant legislation in the table under Article 1.8.3. Provide supporting evidence of the importation process including, when relevant, import permits or their equivalent, and examples of *international veterinary certificates* issued by *exporting countries*.

Describe the intended end use of the imported *commodities*, for example: cattle may be imported for breeding or immediate *slaughter*; rendered products may be imported for incorporation into *feed* for non-ruminant species such as pigs or *poultry*. Provide information on any systems in place and their results to monitor or track imported *commodities* to ensure they are used as intended.

Describe the actions available under national legislation to prevent illegal introduction of the *commodities* considered above and provide information on any illegal introductions detected and the actions taken.

- b) Conclusions for the entry assessment.

Given the sanitary measures applied (if any), what was the likelihood that, during the preceding eight years, any of the *commodities*, in the form that they were imported, harboured or were contaminated by the classical BSE agent?

Clearly and concisely describe the rationale leading to the conclusions reached.

Annex 33 (contd)2. Exposure assessment

As emphasised in Article 11.4.1., atypical BSE is a condition that occurs at a very low rate and is assumed to occur spontaneously in any cattle population. Although uncertainty remains regarding the potential transmissibility of atypical BSE through oral exposure to contaminated *feed*, this is the main route of transmission of classical BSE. Considering that atypical BSE may potentially be capable of being recycled in a cattle population if cattle were to be exposed to contaminated *feed*, it is necessary to undertake an exposure assessment regardless of the outcome of the entry assessment.

As described in Article 11.4.2., an exposure assessment evaluates the likelihood of cattle being exposed to the BSE agents either through imported *commodities* (classical BSE) or as a result of the presence of BSE agents (classical or atypical BSE) in the indigenous cattle population of the country or *zone*.

For the purposes of undertaking an exposure assessment, the period of interest is the preceding eight years (Articles 11.4.3. and 11.4.4.). At its discretion, the applicant Member may provide the information requested for a different period (i.e., longer than eight years for those applying for a negligible risk status, or for the time they have the information if applying for a controlled risk status) to establish the period when the likelihood of the BSE agents being recycled in the cattle population has been demonstrated to be negligible (i.e., to determine the period of time to be attested in point 2) of Articles 11.4.7. and 11.4.13., and point 3) of Article 11.4.10.).

As indicated in point 1 of Article 11.4.3., the final determination of the likelihood that the BSE agents have been recycled in the cattle population through the feeding of cattle with cattle-derived protein meal is the result of either point a) livestock industry practices or point b) effective and continuous mitigation of each identified risk.

Regardless of which pathway the overall conclusion of the *risk assessment* is based on, the first step in the exposure assessment involves an evaluation of livestock industry practices. Depending on the outcome from this step, an evaluation of mitigation measures specifically targeting BSE may also need to be considered.

a) Livestock industry practices

Because oral exposure to contaminated *feed* is the principal route of transmission of the BSE agents, the exposure assessment begins with a detailed description of the cattle population and associated industry practices with a particular emphasis on feeding practices; disposal of dead stock and waste from slaughtered animals; rendering; and production, distribution and storage of *feed* that may lead to cattle being exposed to potentially contaminated *feed*.

The intent of this section is not to describe the implementation and enforcement of measures specifically targeting the exposure of the cattle population to BSE agents (such as a legislated *feed* ban) as they will be considered when relevant in Section 2 b) *An evaluation of BSE specific mitigation measures*. The intention here is to evaluate the likelihood and extent of exposure of the cattle population to the BSE agents, given the ongoing livestock industry practices in a country or *zone*.

i) Demographics of the cattle population and production systems

Describe the composition of the cattle population and how the cattle industry is structured in the country or *zone* considering the types of production systems, including all that apply, such as dairy, beef, feedlot, fattening and finishing, intensive, extensive, semi intensive, transhumant, pastoral, agropastoral, and mixed-species farming.

ii) Feeding practices

For each type of production system, describe the rearing and production practices related to feeding ruminants of various ages, including the types of *feed* and *feed ingredients* (animal or plant based). When animal based ingredients are used, describe whether or not they are derived from rendered products of ruminant or non-ruminant origin as well as the respective proportions used.

Provide an indication of the proportion of the national *feed* production prepared commercially (including local mills) or mixed on farm using either imported or domestically produced ingredients.

Describe whether or not fertilizers containing ruminant-derived protein meal, composted materials derived from fallen stock (i.e., cattle of any age which were found dead or were killed on a farm, during transportation or at a *slaughterhouse/abattoir*), *slaughterhouse/abattoir* waste or animals condemned at *ante mortem* inspection or any other materials derived from or that incorporate ruminant protein are applied to land where cattle graze or where forage is harvested for feeding to cattle. When such fertilizers or composted materials are used, provide information on the extent and frequency of use.

Describe, for mixed-species farms that include ruminants, the number and size of such farms and whether or not there are any practices in place to ensure that ruminants are not likely to be fed with *feed* meant for non-ruminant species or that ruminant *feed* is not likely to be cross-contaminated with *feed* intended for non-ruminants that may contain rendered products of ruminant origin.

iii) Slaughtering and waste management practices

Describe the practices for fallen stock 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.

Describe the places where cattle are slaughtered (for example, on farm, at a *slaughterhouse/abattoir* or *market*) together with the respective proportions and associated ages.

Describe whether or not places where animals are slaughtered are required to be registered or approved by the *Veterinary Services* or other *Competent Authority* and if they are subject to official veterinary supervision. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic.

Describe how animals condemned at *ante mortem* inspection and waste declared as unfit for human consumption from slaughtered animals are processed, disposed of or destroyed, including composting, burial, rendering, incineration or other industrial uses such as salvaging and crushing bones for use in animal *feed*. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic.

iv) Rendering practices

Rendering is a process by which animal material is transformed into products such as protein meal that may be used in animal *feed*. It provides the pathway for the introduction of the BSE agents (classical or atypical) into the animal *feed* chain.

Annex 33 (contd)

Describe whether or not there are any rendering facilities in the country or *zone*, if they are required to be registered or approved by the *Veterinary Services* or other *Competent Authority* and if they are subject to official veterinary control or supervision. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic.

Using tables as appropriate, for each of the preceding eight years, provide a breakdown of the number of rendering facilities operating, indicating for each facility:

- the source and types of raw materials handled;
- whether or not they receive and process material from a particular species or process mixed materials including those derived from ruminants;
- whether or not ruminant waste is segregated from non-ruminant waste and if so how segregation is maintained to avoid potential cross-contamination of non-ruminant rendered materials during processing, storage and transport of rendered products, for example through dedicated lines, storage bins or silos, transport vehicles or *establishments*;
- the parameters of the rendering process (time, temperature, pressure, etc.);
- the type and intended end use of rendered products produced. If available, provide the amount of rendered products produced annually by type and intended end use.

If materials derived from imported cattle are managed differently, describe the process.

Indicate if there are any industry associations or organisations involved in the rendering industry that provide guidance, set standards or provide third party audits in relation to Hazard Analysis and Critical Control Points (HACCP) programmes, *good manufacturing practices*, etc. Include a description of their role, membership and interaction with the *Veterinary Services* or other *Competent Authority*.

v) Feed production, distribution and storage

When rendered products are used as ingredients in the production of animal *feed* the exposure of cattle to the BSE agents (classical and atypical) may arise as a result of the use of rendered products containing materials of ruminant origin as ingredients in cattle *feed* or as a result of cattle *feed* being cross-contaminated when such products are used in the production of *feed* for other species.

Describe whether or not facilities producing *feed* for ruminant or non-ruminant livestock as well as for pets are required to be registered or approved by the *Veterinary Services* or other *Competent Authority* and if they are subject to official veterinary control or supervision. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic.

For each of the preceding eight years, provide a breakdown using tables as appropriate of the number and types of operating facilities producing *feed*, indicating for each facility:

- excluding those listed in Article 11.4.1.bis, whether or not rendered ruminant products were used as ingredients in *feed* for ruminants, non-ruminants and pets;
- whether or not each facility was dedicated to manufacturing *feed* for a particular species or manufactured *feed* for multiple species including ruminants;

Annex 33 (contd)

When facilities manufactured *feed* for multiple species including ruminants, indicate whether or not there were any practices in place to avoid ruminant *feeds* from being contaminated with rendered ruminant products during *feed* manufacture, storage and transport.

Indicate if there are any industry associations or organisations involved in *feed* production, distribution and storage that provide guidance, set standards or provide third party audits in relation to HACCP programmes, *good manufacturing practices*, etc. Include a description of their role, membership and interaction with the *Veterinary Services* or other *Competent Authority*.

vi) Conclusions for livestock industry practices

- Given the livestock industry practices described above, is the likelihood that the cattle population has been exposed to either classical or atypical BSE during the preceding eight years negligible or non-negligible?
- Clearly and concisely describe the rationale leading to the conclusion reached.
- When the likelihood estimate is negligible, proceed to Section 4) *Risk estimation*.
- When the likelihood estimate is non-negligible, proceed to Section 2 b) *An evaluation of BSE specific mitigation measures*.

b) An evaluation of BSE specific risk mitigation measures

For those countries that have reported classical BSE cases in indigenous cattle, it is apparent that their historic livestock industry practices did not prevent the recycling of the BSE agent in their cattle population. These countries, together with others whose livestock industries practices would have been conducive to recycling may have implemented specific measures, such as through a legislated *feed* ban to ensure that the likelihood of recycling would be negligible. To qualify for official recognition of a BSE risk status, these countries need to demonstrate that the measures specifically targeting BSE have been and continue to be effectively implemented and enforced.

i) The nature and scope of a feed ban

Indicate if there is a ban on feeding ruminants with protein meal derived from ruminants.

When a *feed* ban has been implemented, clearly and concisely describe the date it was introduced, its nature and scope and how it has evolved over time.

In addition, if the *feed* ban has been implemented through national legislation, provide pertinent information in the table under Article 1.8.3. and a summary of any relevant legislation with references as appropriate.

ii) Commodities with the greatest BSE infectivity

Indicate whether or not any of those *commodities* listed in points 1) a) and 1) b) of Article 11.4.14. are removed from the carcass at the time of *slaughter* or subsequent fabrication or processing.

If so, also:

- Describe how they are disposed or destroyed through burial, composting, rendering, alkaline hydrolysis, thermal hydrolysis, gasification, incineration, etc.
- Describe any measures in place that ensure *slaughter* waste declared as unfit for human consumption that is rendered is not cross-contaminated with these *commodities*.

Annex 33 (contd)

- Describe whether these *commodities* from fallen stock and animals condemned at *ante mortem* inspection are excluded from rendering and how this is done.
- When these *commodities* are not excluded from *slaughter* waste declared as unfit for human consumption, describe the final disposal of this waste, and how it is handled and processed.
- Describe whether or not all these processes and methods are subject to approval and oversight by the *Veterinary Services* or other *Competent Authority*.

In addition, if there is specific national legislation concerning the definition, identification, removal and disposal or destruction of those *commodities* listed in points 1) a) and 1) b) of Article 11.4.14., provide pertinent information in the table under Article 1.8.3. and a summary of any relevant legislation with references as appropriate.

iii) Parameters of the rendering process

Describe whether or not the parameters of the rendering process are described in legislation and if they are consistent with, or provide an equivalent level of assurance to, the procedures for the reduction of BSE infectivity in ruminant-derived protein meal as described in Article 11.4.17. Provide details of the legislation, if applicable, in the table under Article 1.8.3.

iv) Cross-contamination

Describe the measures in place to prevent cross-contamination during rendering, *feed* production, transport, storage and feeding such as dedicated facilities, lines and equipment, as well as measures to prevent misfeeding, such as the use of warning labels. Provide information as to whether any of these measures are described in legislation and if facilities involved in rendering and *feed* production are required to be registered or approved under the *feed* ban by the *Veterinary Services* or other *Competent Authority*.

v) Awareness programme

Provide information on the existence of any ongoing awareness programmes or other forms of guidance given to all those stakeholders involved in rendering, *feed* production, transport, storage, distribution, sale and feeding under the scope of the *feed* ban. Provide examples of communication materials including publications, brochures and pamphlets.

vi) Monitoring and enforcement

Describe how the *feed* ban, if implemented, has been and continues to be monitored and enforced. Provide information on:

- official oversight from the *Veterinary Services*, other *Competent Authority* or a third party;
- training and accreditation programmes for inspectors;
- the planned frequency of inspections, the procedures involved including manuals and inspection forms;
- sampling programmes and *laboratory* testing methods used to check the level of implementation of the *feed* ban and avoidance of cross-contamination;
- options available to deal with infractions (non-compliances) such as recalls, destruction and monetary penalties.

Annex 33 (contd)

Provide information on the ongoing results of the official inspection programme for each of the preceding eight years using tables as appropriate:

- planned *versus* actual delivery inspections at rendering facilities, *feed* mills, farms, etc., with an explanation of any significant variance and how they may have impacted the programme;
- number and type of samples taken during inspections to verify that ruminant *feed* does not contain or is not cross contaminated with rendered products containing ruminant material (excluding those listed in Article 11.4.1.bis). Provide information by year, by source (rendering facility, *feed* mill or farm), indicating the *laboratory* test(s) used and the results obtained;
- the types of infractions (non-compliance) that occurred and corrective actions undertaken;
- any infractions (non-compliances) that were likely to have led to cattle being exposed to *feed* contaminated with ruminant material (excluding those listed in Article 11.4.1.bis) and how they were resolved.

vii) Conclusions for the evaluation of BSE specific risk mitigation measures

- In evaluating the effectiveness of a *feed* ban, if implemented, for each of the preceding eight years, consideration needs to be given to:
 - the management of *commodities* listed in points 1) a) and 1) b) of Article 11.4.14., and the associated likelihood that these materials, or other materials cross contaminated by them, may have entered the animal *feed* chain;
 - the rendering industry and the associated likelihood that rendered products containing ruminant material may retain BSE infectivity;
 - the *feed* industry, and the associated likelihood that *feed* for cattle may contain or has been cross-contaminated with ruminant-derived protein meal.
- Given the evaluation of BSE specific risk mitigation measures and their enforcement as described above, is the likelihood that the cattle population has been exposed to either classical or atypical BSE negligible or non-negligible during the preceding eight years?

Clearly and concisely describe the rationale leading to the conclusion reached.

- When the likelihood estimate is negligible, proceed to Section 4) *Risk estimation*.
- When the likelihood estimate is non-negligible, proceed to Section 3) *Consequence assessment*.

3. Consequence assessment

While uncertainty remains regarding the potential transmissibility of atypical BSE through oral exposure to contaminated *feed*, it is reasonable to assume for the purposes of a consequence assessment, that the likelihood of cattle becoming infected would be similar to classical BSE.

As described in Article 11.4.2., a consequence assessment evaluates the likelihood of cattle becoming infected following exposure to the BSE agents (classical or atypical) together with the likely extent of any subsequent recycling and amplification.

Annex 33 (contd)

For the purposes of undertaking a consequence assessment for the evaluation of BSE risk status, the period of interest is the preceding eight years.

Considering that, for all practical purposes, oral exposure to contaminated *feed* is the principal, if not the only route of transmission of the BSE agents, to initiate a cycle of BSE infectivity within a cattle population the following series of events would need to unfold:

- *commodities* listed in points 1) a) and 1) b) of Article 11.4.14. from an infected animal are included in raw materials that are rendered into ruminant-derived protein meal;
- the rendering process does not destroy infectivity of the BSE agent(s);
- the ruminant-derived protein meal is incorporated as an ingredient in cattle *feed*, or cattle *feed* is cross-contaminated during *feed* production, distribution and storage, or cattle are incorrectly fed with *feed* intended for non-ruminant species that includes the ruminant-derived protein meal as an *ingredient*;
- one or more animals that ingest contaminated *feed* become infected;
- the infected animal survives long enough to reach the later stages of a protracted incubation period when the levels of the BSE agent in those *commodities* listed in points 1) a) and 1) b) of Article 11.4.14. would begin to rise dramatically;
- *commodities* listed in points 1) a) and 1) b) of Article 11.4.14. are then included in raw materials that are rendered into ruminant-derived protein meal, completing one cycle.

Recycling arises when this cycle is repeated one or more times. Any level of recycling within a given period is sufficient to conclude that the consequences of exposure to contaminated *feed* for that period within the cattle population are non-negligible.

a) Factors to consider when evaluating the likely extent of recycling of the BSE agents within a cattle population:

i) Age at exposure

Animals less than 12 months of age are considered to be much more susceptible to *infection* than older animals, which are likely to be increasingly refractory to *infection* as they mature.

ii) Type of production system

- Calves reared as replacement animals for the breeding herd

Cattle exposed to BSE agents at less than 12 months of age and destined to enter the breeding *herd* are much more likely to become infected and survive long enough to reach the later stages of a protracted incubation period when the levels of the BSE agent in those *commodities* listed in points 1) a) and 1) b) of Article 11.4.14. would begin to rise dramatically. If these materials were rendered and subsequently contaminated cattle *feed*, it is highly likely that some level of recycling would occur.

- Feedlot cattle

Even if cattle reared in a feedlot that were destined to be slaughtered within the next two to six months were to become infected after consuming contaminated *feed*, the likelihood that they would have reached the later stages of a protracted incubation period (when the levels of the BSE agent in those *commodities* listed in points 1) a) and 1) b) of Article 11.4.14. would begin to rise dramatically) would essentially be negligible.

Annex 33 (contd)

Considering that mature cattle are likely to be much more refractory to *infection* than animals within their first year of life, even if they were to consume contaminated *feed*, it is highly unlikely that those *commodities* listed in points 1) a) and 1) b) of Article 11.4.14. would pose a threat if they were rendered and subsequently contaminated cattle *feed*.

iii) The impact of livestock industry practices or the implementation of measures under a feed ban

When evaluating the potential for the recycling of the BSE agents in the cattle population where an infraction (non-compliance) has occurred that may have led to *feed* being cross-contaminated, it is important to consider the impact of both the livestock industry practices and the ongoing measures under a *feed* ban. Even if an infraction that arose several years ago led to susceptible young animals becoming infected, in evaluating the likelihood of recycling in future years, consideration would need to be given to the effectiveness of the *feed* ban in subsequent years or whether or not any changes to livestock industry practices may have influenced the exposure risk.

b) Conclusions for the consequence assessment

When the outcome of the evaluation of livestock industry practices or the evaluation of BSE specific mitigation measures, that include the nature and scope of the *feed* ban and its enforcement, has concluded that there was a non-negligible likelihood that the cattle population has been exposed to the BSE agents, what is the likelihood that they have been recycled within the cattle population during the preceding 8 years?

Clearly describe the rationale leading to the conclusions reached.

4. Risk estimation

As described in Article 11.4.2., risk estimation summarizes the results and the conclusions arising from the entry, exposure and consequence assessments.

- a) Provide a summary of the entry and exposure assessments and the conclusions reached.
- b) If applicable, provide a summary of the consequence assessment and the conclusion reached.
- c) Indicate whether or not the condition of point 1) a) of Article 11.4.3. has been met, that is, if the likelihood that the BSE agents have been recycled in the cattle population has been negligible for at least 8 years. Indicate which of the two pathways is applicable: either livestock industry practices or the effective and continued mitigation of each identified risk.
- d) When the condition of point 1) a) of Article 11.4.3. has not been met, that is, it cannot be demonstrated that for at least eight years the likelihood that the BSE agents have been recycled in the cattle population has been negligible, provide an explanation for the period of time within the preceding eight years for which it can be considered that the likelihood has been negligible. Clearly describe the rationale leading to the conclusions reached.

Article 1.8.6.

BSE surveillance

Article 11.4.18. describes the criteria that underpin a credible *surveillance* programme together with an overview of the range of clinical signs that cattle affected by BSE are likely to exhibit.

The Delegate of the Member applying for recognition of a negligible or a controlled BSE risk status should submit documentary evidence that the provisions of point 1) of Article 11.4.18. have been effectively implemented.

Annex 33 (contd)

Documentary evidence detailing the results of the ongoing *surveillance* programme is also required.

1. Compulsory notification and investigation (Article 11.4.18. point 1) a))

To ensure the detection and follow-up of any suspected BSE cases, appropriate legislation, policies and incentives to support compulsory notification, investigation and verification should be in place.

- a) Describe the criteria for raising a suspicion of BSE including the range of clinical signs considered and how the clinical history is taken into account.
- b) Describe the guidance given to all stakeholders involved in the rearing and production of livestock including farmers, herdsmen, *veterinarians*, transporters, workers at livestock *markets*, auctions and *slaughterhouses/abattoirs* in terms of the criteria that would initiate the investigation of an *animal* suspected as being a case of BSE. Have these criteria evolved and, if so, how? What mechanisms are in place to ensure that these guidelines reach those stakeholders?
- c) Describe the reporting framework for suspected BSE cases including the sampling logistics to ensure suitable samples reach an approved BSE *laboratory* for examination.
- d) What was the date of implementation of any supporting legislation and associated policies making notification of suspected cases of BSE compulsory? Do they include a definition for a "suspect BSE case"? If appropriate, outline relevant legislation in the table under Article 1.8.3.
- e) Describe the measures in place to facilitate notification, such as compensation payments or penalties for not notifying a suspected case.
- f) Provide information on the occurrence of other diseases with neurological clinical signs compatible with BSE.

2. Awareness programme (Article 11.4.18. point 1) b))

An awareness programme is essential to ensure that all stakeholders are familiar with clinical signs suggestive of BSE as well as their reporting obligations.

- a) Describe the type(s) of awareness or training programme(s) implemented for specific target audiences including the recognition of clinical signs by farmers and others involved in the rearing and production of livestock, as well as the protocols for sample collection and submission by *veterinarians* and animal health technicians.
- b) Describe when the awareness or training programme(s) were implemented and their ongoing application and geographical coverage including the number and types of stakeholders involved.
- c) Provide a description including examples of the types of materials used in the awareness programme including training manuals, supporting documents such as publications in local newspapers and farming magazines, pamphlets and videos (weblinks to supporting documents in one of the official languages of the OIE may also be provided, when they exist.).
- d) Provide details of any contingency or preparedness plans to deal with an occurrence of BSE.

3. Laboratory investigations and follow-up field investigation (Article 11.4.18. point 1) c))

Provide documentary evidence that the relevant provisions of Chapter 3.4.5. of the *Terrestrial Manual* are applied, including the following:

Annex 33 (contd)

- a) If BSE samples are submitted to a *laboratory* in the country or *zone* for testing provide an overview of how many are involved in testing BSE samples, how they are approved or certified, their number, location and diagnostic procedures and the time frame for reporting results.
- b) If the BSE samples are not submitted to a *laboratory* in the country or *zone* for testing or suspicious or positive samples are referred to a *laboratory* outside the country, provide the names of the *laboratories* in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results;
- c) Describe the diagnostic protocol and tests used for processing samples for classical and atypical BSE and how they may have evolved over time, indicating: what is the primary test used?; what would be the series of secondary tests performed, if any, depending on the results of the primary test (i.e., negative, positive and inconclusive)?; and what test would be undertaken if discordant results between primary and secondary tests arise (e.g., primary positive result followed by a secondary negative result)?
- d) Describe the methods applied to assess the ages of animals such as individual identification or dentition.
- e) In a table (see below), provide details for all cattle that have been reported as having clinical signs suggestive of BSE (see Article 11.4.18. point 2)) for the preceding eight years.

Year notified	Laboratory identification number	Age (Years)	Type of production system (dairy, beef, etc.)	Description of observed clinical signs	Point of detection (farm, market, slaughterhouse, etc.)	Final diagnosis (if BSE, specify the strain)	Origin of the case (indigenous, imported)

Article 1.8.7.

Recovery of BSE risk status

Members applying for recognition of recovery of BSE risk status for a country or *zone* should implement the provisions of Article 11.4.3. or 11.4.4. and provide detailed information as specified in Article 1.8.5. of this application. Information in relation to other sections need only be supplied if relevant.

Following the occurrence of an indigenous case of classical BSE in an animal born within the preceding eight years, the outcome of subsequent investigations together with any additional measures implemented that confirm or ensure that the likelihood of BSE being recycled within the cattle population continues to be negligible should be provided with reference to the provisions in Article 1.8.5. as appropriate.

CHAPTER 1.8.

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

Article 1.8.1.

Guidelines

In accordance with Article 11.4.2., the bovine spongiform encephalopathy (BSE) risk status of the cattle (*Bos indicus* and *Bos taurus*) population of a country, zone or compartment is determined on the basis of a risk assessment that evaluates the likelihood of the BSE agents (classical and atypical) being recycled within the cattle population, the ongoing implementation of a surveillance programme, and the history of occurrence and management of BSE cases.

In this chapter, "BSE" refers to both classical and atypical forms, unless otherwise specified.

The following information specified in Articles 1.8.2. to 1.8.6. should be provided by OIE Member Countries to support applications of their application for official recognition of BSE risk status for bovine spongiform encephalopathy (BSE) in accordance with Chapter 11.4. of the *Terrestrial Code*. The Delegate of the Member Country submitting documentation of the legislation under which the Veterinary Services are mandated structure of the dossier should provide a description of the content of the relevant legal acts (in one of the three official languages of OIE), as well as the dates of follow guidelines provided in the "Standard Operating Procedure for official recognition of disease status and for the endorsement of national official publication and implementation control programmes of Member Countries" (available on the OIE website).

The dossier provided to the OIE should address concisely all the topics under the headings provided to describe the actual situation in the country and the procedures currently applied, explaining how these comply with the *Terrestrial Code*.

Each element of the core document of the dossier provided to the OIE, should be clearly and concisely addressed with an explanation, when relevant, of how each one has been implemented in accordance with the provisions of the *Terrestrial Code* for the BSE risk status for which the Member is applying. The rationale leading to the conclusions reached for each section needs to be clearly explained and as appropriate, figures, tables and maps should be provided. The core document of the dossier should include the following sections:

- ≡ the history of occurrence and management of BSE cases in the country or zone (Article 1.8.2.),
- ≡ legislation (Article 1.8.3.),
- ≡ veterinary system (Article 1.8.4.),
- ≡ BSE risk assessment (Article 1.8.5.),
- ≡ BSE surveillance (Article 1.8.6.).

The terminology defined in the OIE *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier. The dossier and all of its annexes should be provided in one of the OIE official languages.

Annex 34 (contd)Article 1.8.2.**History of occurrence and management of BSE cases in the country or zone**

Describe the history of occurrence and management of BSE cases by providing the following documentary evidence:

- 1) If a case of BSE has ever been diagnosed in the country or zone, indicate the total number of BSE cases, and provide a table to indicate, for each case, the year of occurrence, the origin (indigenous or, if imported, the country of origin), the type (classical or atypical), and the year of birth of each indigenous case of classical BSE.
- 2) If there have been cases of BSE, confirm that they were excluded from the feed chain and describe how this was achieved. In the table under Article 1.8.3, provide details of the national legislation, regulations and Veterinary Authority directives ~~may be that~~ describe these procedures.

Article 1.8.3.**Legislation**

Provide a table listing all relevant legislation, regulations, Veterinary Authority directives, legal instruments, rules, orders, acts, decrees, etc., related to BSE. For each, provide the date of promulgation and implementation as well as a brief description of the relevance to mitigating against the risks associated with BSE. The table should include the legislation, regulations and directives referred to and annexed as appropriate in one of the OIE official languages in the core document of the dossier. These instruments may be provided as annexes or as weblinks to supporting documents in one of the official languages of the OIE may.

Article 1.8.4.**Veterinary system**

The quality of the Veterinary Services of a Member is important to the establishment and maintenance of confidence in its international veterinary certificates by the Veterinary Services of other Members (Article 3.1.1.). It also be provided, where they exist supports an evaluation of the BSE risk status of the cattle population of a country or zone.

All annexes should be provided in one of the OIE official languages.

The Delegate of the Member Country applying for official recognition of BSE risk status must submit documentary evidence that the provisions of Article 11.4.2. and Article 11.4.3. or Article 11.4.4. have been properly implemented and supervised.

1) Introduction

Provide a general description of the bovine (*Bos taurus* and *B. indicus*) husbandry and slaughtering practices in the country. Provide figures and tables as appropriate.

2- Veterinary system

a) Describe how the Veterinary Services of the country have implemented ~~comply with~~ the provisions of Chapters 1.1., 3.1. and 3.2. ~~of the Terrestrial Code;~~

b) The applicant Member may provide information on any recent (not older than five years) OIE PVS evaluation conducted in the country and follow-up steps within the PVS Pathway, and highlight the results relevant to BSE.

- 3) Describe how the *Veterinary Services* supervise, control, enforce and monitor all BSE-related activities;
- 4) Provide a description of the involvement and the participation of industry; producers; farmers; herdsmen; private veterinarians; veterinary paraprofessionals; transporters; workers at livestock markets, auctions and slaughterhouses/abattoirs; and other relevant non-governmental stakeholders in the control of BSE.
- 5) Describe the official cattle identification, registration, *traceability* and movement control system. Provide evidence of its effectiveness. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic. Indicate if there are any industry associations or organisations involved in cattle identification, registration, *traceability* and movement control systems that provide guidance, set standards or provide third party audits; include a description of their role, membership and interaction with the *Veterinary Services* or other *Competent Authority*.

Article 1.8.25.

BSE risk status requirements: Section 1 – risk assessment (see point 1) of Article 11.4.2.

Article 11.4.2. of the *Terrestrial Code* Chapter on BSE prescribes the criteria to determine the BSE risk status of the cattle population of a country or zone. The Delegate of the Member Country applying for recognition of a claim for negligible risk status (Article 11.4.3.) or controlled risk status (Article 11.4.4.) must demonstrate compliance with the *Terrestrial Code*. That is, the Delegate must submit documentary evidence that the provisions of Article 11.4.3. or Article 11.4.4. have been properly implemented and complied with.

1. Introduction

The Delegate of the Member Country applying for official recognition by the OIE of BSE risk status of the cattle population of the country or zone should submit documentary evidence demonstrating that a *risk assessment* based on Section 2 and Chapter 11.4. of the *Terrestrial Code* has been carried out.

2- Entry assessment

- a) The potential for the As prescribed described in Article 11.4.2., an entry of the assessment evaluates the likelihood that the classical BSE agent through importation of meat and bone meal or greaves (including of non-ruminant origin)

Knowledge of the origin of *meat and bone meal, greaves* or *feed ingredients* containing either *meat and bone meal* or *greaves*, is necessary to assess the risk of entry of classical BSE agent. *Meat and bone meal* and *greaves* originating in countries of undetermined or controlled BSE risk pose a higher likelihood of entry than that from negligible risk countries.

Has *meat and bone meal, greaves* (including of non-ruminant origin) or *feed ingredients* containing either, been has been introduced into the country or zone via imported within the past eight years? If not, provide documentary evidence, including supporting legislation, where relevant:

- i) to support claims that *meat and bone meal* (including of non-ruminant origin), *greaves* or *feed ingredients* containing either *meat and bone meal* or *greaves* have not been imported, OR

If *meat and bone meal, greaves* (including of non-ruminant origin) or *feed ingredients* containing either, has been imported within the past eight years, provide documentary evidence of the following:

- ii) official statistics on annual volume, by country of origin, of *meat and bone meal* (including of non-ruminant origin), *greaves* or *feed ingredients* containing them;
- iii) the species composition of the *meat and bone meal, greaves* or *feed ingredients*;
- iv) the method used to reduce BSE infectivity complies with Article 11.4.19.

Annex 34 (contd)

- b) ~~The potential for the entry of the classical BSE agent through the importation of potentially infected live cattle~~

~~The likelihood of entry is dependent on:~~

- ~~- the BSE status of the country or zone of origin;~~
- ~~- dairy versus meat breeds, where there are differences in exposure in the country or zone of origin because feeding practices result in greater exposure of one category;~~
- ~~- age of animals imported for slaughter;~~
- ~~- the effective implementation of the ban on feeding of ruminants with meat and bone meal and greaves derived from ruminants in the country or zone of origin before the birth of the imported animals.~~

~~Have live cattle been imported within the past seven years? Provide documentary evidence of the following:~~

- ~~i) to support claims that live cattle have not been imported including supporting legislation, OR~~
 - ~~ii) the country or zone of origin and volume of imports, official statistics, where relevant, in table form, and evidence of compliance with the requirements of Articles 11.4.6. to 11.4.9.~~
- e) ~~The potential for the entry of the classical BSE agent through the importation of potentially infected products of ruminant origin~~

~~The likelihood of entry is dependent on:~~

- ~~- the BSE status of the country or zone of origin and whether these products contain tissues known to contain BSE infectivity (Article 11.4.13.);~~
- ~~- dairy versus meat breeds, where there are differences in exposure in the country or zone of origin because feeding practices result in greater exposure of one category;~~
- ~~- age at slaughter.~~

~~What products of ruminant origin have been imported within the past seven years? This includes all products of ruminant origin that are not considered as safe commodities in Article 11.4.1., in particular products listed in points 1 a) v), vi) and vii) of Article 11.4.2. Provide documentary evidence of the following:~~

- ~~i) the country or zone of origin and volume of imports, in table form, of all products of ruminant origin that are not considered as safe commodities in Article 11.4.1.;~~
- ~~ii) evidence of compliance with the requirements of Article 11.4.26.~~

For the purposes of undertaking an entry assessment, the period of interest is the preceding eight years (Articles 11.4.3. and 11.4.4.).

The commodities to be considered in the entry assessment are:

- = cattle.
- = ruminant-derived protein meal.
- = feed (not intended for pets) that contains ruminant-derived protein meal.

- = fertilizers that contain ruminant-derived protein meal.
- = any other commodity that either is or could be contaminated by commodities listed in Article 11.4.14. E.g., ~~the~~ over 30 months old cattle carcass or half carcass from which the spinal cord and vertebral column were not removed, originating from a country or zone of origin and volume of imports, in or compartment posing a controlled or undetermined BSE risk.
- a) For each commodity listed above indicate if they were imported in the preceding eight years, and if so, from which countries

For each commodity listed above describe the import requirements applied by the applicant country or zone and how they are related to the BSE risk status of the exporting country or zone and whether or not they are consistent with, or provide an equivalent level of assurance with, the recommendations laid out in Chapter 11.4. for the importation of such a commodity. When the import requirements are not consistent with the recommendations in Chapter 11.4. but are considered to provide an equivalent level of assurance, provide an explanation outlining the rationale and supporting evidence. In situations where an import requirement does not provide an equivalent level of assurance to the relevant measure in Chapter 11.4., provide an explanation of how this is likely to impact the entry assessment.

Describe the importation process for these commodities and how are they controlled, regulated and monitored by the Competent Authority with references as appropriate to the relevant legislation in the table under Article 1.8.3. Provide supporting evidence of the importation process including, when relevant, import permits or their equivalent, and examples of international veterinary certificates issued by exporting countries.

Describe the intended end use of the imported commodities, for example: cattle may be imported for breeding or immediate slaughter, rendered products may be imported for incorporation into feed for non-ruminant species such as pigs or poultry. Provide information on any systems in place and their results to monitor or track imported commodities to ensure they are used as intended.

Describe the actions available under national legislation to prevent illegal introduction of the commodities considered above and provide information on any illegal introductions detected and the actions taken.

- b) Conclusions for the entry assessment

Given the sanitary measures applied (if any), what was the likelihood that, during the preceding eight years, any of the commodities, in the form that they were imported, harboured or were contaminated by the classical BSE agent?

Clearly and concisely describe the rationale leading to the conclusions reached.

2. Exposure assessment

As emphasised in Article 11.4.1., atypical BSE is a condition that occurs at a very low rate and is assumed to occur spontaneously in any cattle population. Although uncertainty remains regarding the potential transmissibility of atypical BSE through oral exposure to contaminated feed, this is the main route of transmission of classical BSE. Considering that atypical BSE may potentially be capable of being recycled in a cattle population if cattle were to be exposed to contaminated feed, it is necessary to undertake an exposure assessment regardless of the outcome of the entry assessment.

As described in Article 11.4.2., an exposure assessment evaluates the likelihood of cattle being exposed to the BSE agents either through imported commodities (classical BSE) or as a result of the presence of BSE agents (classical or atypical BSE) in the indigenous cattle population of the country or zone.

Annex 34 (contd)

For the purposes of undertaking an exposure assessment, the period of interest is the preceding eight years (Articles 11.4.3. and 11.4.4.). At its discretion, the applicant Member may provide the information requested for a different period (i.e., longer than eight years for those applying for a negligible risk status, or for the time they have the information if applying for a controlled risk status) to establish the period when the likelihood of the BSE agents being recycled in the cattle population has been demonstrated to be negligible (i.e., to determine the period of time to be attested in point 2) of Articles 11.4.7. and 11.4.13., and point 3) of Article 11.4.10.).

As indicated in point 1) of Article 11.4.3., the final determination of the likelihood that the BSE agents have been recycled in the cattle population through the feeding of cattle with cattle-derived protein meal is the result of either point a) livestock industry practices or point b) effective and continuous mitigation of each identified risk.

Regardless of which pathway the overall conclusion of the risk assessment is based on, the first step in the exposure assessment involves an evaluation of livestock industry practices. Depending on the outcome from this step, an evaluation of mitigation measures specifically targeting BSE may also need to be considered.

a) Livestock industry practices

Because oral exposure to contaminated feed is the principal route of transmission of the BSE agents, the exposure assessment begins with a detailed description of the cattle population and associated industry practices with a particular emphasis on feeding practices; disposal of dead stock and waste from slaughtered animals; rendering; and production, distribution and storage of feed that may lead to cattle being exposed to potentially contaminated feed.

The intent of this section is not to describe the implementation and enforcement of measures specifically targeting the exposure of the cattle population to BSE agents (such as a legislated feed ban) as they will be considered when relevant in Section 2 b) An evaluation of BSE specific mitigation measures. The intention here is to evaluate the likelihood and extent of exposure of the cattle population to the BSE agents, given the ongoing livestock industry practices in a country or zone.

i) Demographics of the cattle population and production systems

Describe the composition of the cattle population and how the cattle industry is structured in the country or zone considering the types of production systems, including all that apply, such as dairy, beef, feedlot, fattening and finishing, intensive, extensive, semi intensive, transhumant, pastoral, agropastoral, and mixed-species farming.

ii) Feeding practices

For each type of production system, describe the rearing and production practices related to feeding ruminants of various ages, including the types of feed and feed ingredients (animal or plant based). When animal based ingredients are used, describe whether or not they are derived from rendered products of ruminant or non-ruminant origin as well as the respective proportions used.

Provide an indication of the proportion of the national feed production prepared commercially (including local mills) or mixed on farm using either imported or domestically produced ingredients.

Annex 34 (contd)

Describe whether or not fertilizers containing ruminant-derived protein meal, composted materials derived from fallen stock (i.e., cattle of any age which were found dead or were killed on a farm, during transportation or at a slaughterhouse/abattoir), slaughterhouse/abattoir waste or animals condemned at ante mortem inspection or any other materials derived from or that incorporate ruminant protein are applied to land where cattle graze or where forage is harvested for feeding to cattle. When such fertilizers or composted materials are used, provide information on the extent and frequency of use.

Describe, for mixed-species farms that include ruminants, the number and size of such farms and whether or not there are any practices in place to ensure that ruminants are not likely to be fed with feed meant for non-ruminant species or that ruminant feed is not likely to be cross-contaminated with feed intended for non-ruminants that may contain rendered products of ruminant origin that are not considered as safe commodities in Article 11.4.1.;

iii) Slaughtering and waste management practices

Describe the practices for fallen stock 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.

Describe the places where cattle are slaughtered (for example, on farm, at a slaughterhouse/abattoir or market) together with the respective proportions and associated ages.

Describe whether or not places where animals are slaughtered are required to be registered or approved by the Veterinary Services or other Competent Authority

3. Exposure assessment

a) The origin of ruminant carcasses, by products and slaughterhouse/abattoir waste, and if they are subject to official veterinary supervision. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic.

Describe how animals condemned at ante mortem inspection and waste declared as unfit for human consumption from slaughtered animals are processed, disposed of or destroyed, including composting, burial, rendering, incineration or other industrial uses such as salvaging and crushing bones for use in animal feed. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic.

iv) Rendering practices

Rendering is a process by which animal material is transformed into products such as protein meal that may be used in animal feed. It provides the pathway for the introduction of the BSE agents (classical or atypical) into the animal feed chain.

Describe whether or not there are any rendering facilities in the country or zone, if they are required to be registered or approved by the Veterinary Services or other Competent Authority and if they are subject to official veterinary control or supervision. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic.

Using tables as appropriate, for each of the preceding eight years, provide a breakdown of the number of rendering facilities operating, indicating for each facility:

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- ≡ the source and types of raw materials handled;
- ≡ whether or not they receive and process material from a particular species or process mixed materials including those derived from ruminants;
- ≡ whether or not ruminant waste is segregated from non-ruminant waste and if so how segregation is maintained to avoid potential cross-contamination of non-ruminant rendered materials during processing, storage and transport of rendered products, for example through dedicated lines, storage bins or silos, transport vehicles or establishments;
- the parameters of the rendering processes process (time, temperature, pressure, etc.);

The overall risk of BSE in the cattle population of a country or zone is proportional to the potential for recycling and amplification of the infectivity through rendering practices. For the *risk assessment* to conclude that the cattle population of a country or zone is of negligible or controlled BSE risk, it must have demonstrated that appropriate measures have been taken to manage any risks identified. If potentially infected cattle or contaminated materials are rendered, there is a risk that the resulting *meat and bone meal* could retain BSE infectivity.

Rendering is a process by which inedible animal by-products and *slaughter* waste, including bones and fallen stock, are transformed into *meat and bone meal*.

How have ruminant carcasses, by-products and *slaughterhouse/abattoir* waste been processed over the past eight years? Provide the following:

- i) - A description of the collection and disposal of fallen stock, inedible animal by-products, and materials condemned as unfit for human consumption. If by the type and intended end use of rendered products produced. If available, provide the amount of rendered products produced annually by type and intended end use.
- If materials derived from imported cattle are managed differently, describe the process.
- ii) A description of the definition, collection and disposal of material listed in Article 11.4.14. iii) A description of the rendering industry and processes and parameters used to produce ruminant *meat and bone meal* and *groaves*.
- iv) Documentation describing monitoring and enforcement of the above.
- v) Information in a table (see below), including the audit findings in rendering plants processing material of ruminant origin (including mixed species containing ruminant material) and only material of non-ruminant origin (e.g., fish, *poultry*, pig, horse), related to the prohibition of the feeding to ruminants of *meat and bone meal* and *groaves*. The sampling objectives to detect whether material of non-ruminant origin could have been contaminated with ruminant material.

Year (information should be provided for each of the eight years for which effectiveness is claimed)	Type of renderers	Number of plants	Number of plants in (A) inspected under Competent Authority supervision	Number of inspections in (B) in total	Total number of plants in (B) with infractions	Total number of plants in (B) inspected under Competent Authority supervision with sampling	Total number of plants in (E) with positive test results
		(A)	(B)	(C)	(D)	(E)	(F)
Year 1	Material of ruminant origin (or mixed species)		(e.g.: < or = to A)	(e.g.: > or = to B)	(e.g.: < or = to B)	Not applicable for the purpose of the dossier	Not applicable for the purpose of the dossier
	Only material of non-ruminant origin		(e.g.: < or = to A)	(e.g.: > or = to B)	(e.g.: < or = to B)	(e.g.: < or = to B)	(e.g.: < or = to E)
Year 2, etc.	Material of ruminant origin (or mixed species)					Not applicable for the purpose of the dossier	Not applicable for the purpose of the dossier
	Only material of non-ruminant origin						

Annex 34 (contd)

- vi) Information in a table (see below) on each rendering plant referred to above processing material of ruminant origin (including mixed-species containing ruminant material) and only material of non-ruminant origin (e.g., fish, poultry, pig, horse) with infractions, specifying the type of infraction (columns D and F of the table above) and the method of resolution.

Year (information should be provided for each of the eight years for which effectiveness is claimed)	Type of renderers	Plant ID	Nature of infraction	Method of resolution	Follow-up results
Year 1	Material of ruminant origin	ID 1			
	(or mixed species)	ID 2			
		ID 3, etc.			
	Only material of non-ruminant origin	ID 1			
		ID 2			
		ID 3, etc.			
Year 2, etc.	Material of ruminant origin (or mixed species)				
	Only material of non-ruminant origin				

- b) ~~The potential for the exposure of cattle to the classical and atypical BSE agents through consumption of meat and bone meal or greaves of ruminant origin~~

~~The overall risk of BSE in the cattle population of a country or zone is proportional to the level of known or potential exposure to BSE infectivity. If cattle have not been fed products of ruminant origin (other than milk or blood) potentially containing meat and bone meal or greaves of ruminant origin within the past eight years, meat and bone meal and greaves can be dismissed as a risk. Where meat and bone meal is utilised in the production of any ruminant feed, a risk of cross-contamination exists.~~

~~Countries applying for negligible risk status will be required to demonstrate that the ruminant feed ban has been effective for at least eight years.~~

~~Feed mills are processing plants where different feed ingredients are mixed and processed together to produce compound feed for animals. This should include on-farm feed producers that keep cattle.~~

~~Has meat and bone meal or greaves of ruminant origin been fed to cattle within the past eight years (Articles 11.4.3. and 11.4.4. in the Terrestrial Code)? Describe the following:~~

- ~~i) the feed industry, including repartition between feed mills producing feed for ruminant only, feed for non-ruminant only and feed for both;~~
- ~~ii) methods of animal feed production, including details of ingredients used, the extent of use of meat and bone meal (including of non-ruminant origin) in any livestock feed;~~
- ~~iii) the use of imported meat and bone meal and greaves (including of non-ruminant origin), their country or zone of origin, including the feeding of any animal species;~~

Annex 34 (contd)

- iv) ~~the use made of meat and bone meal and grooves produced from ruminants, including the feeding of any animal species;~~
- v) ~~the measures taken to control cross-contamination of ruminant feed ingredients with the meat and bone meal and grooves including the risk of cross-contamination during production, transport, storage and feeding;~~
- vi) provide details in a table, on the audit findings in feed mill processing feed for ruminant only, for non-ruminant only and for both, related to the prohibition of the feeding to ruminants of *meat and bone meal* and *grooves*. The sampling aims to detect whether material of ruminant origin could have contaminated feed intended to ruminant;

Year (information should be provided for each of the eight years for which effectiveness is claimed)	Type of feed mill	Number of feed mills	Number of feed mills in (A) inspected under Competent Authority supervision	Number of inspections in (B) in total	Total number of feed mills in (B) with infractions	Total number of inspected feed mills in (B) with sampling	Total number of feed mills in (E) with positive test results
		(A)	(B)	(C)	(D)	(E)	(F)
Year 1	For ruminant only						
	For non-ruminant only					Not applicable for the purpose of the dossier	Not applicable for the purpose of the dossier
	For both						
Year 2, etc.	For ruminant only						
	For non-ruminant only					Not applicable for the purpose of the dossier	Not applicable for the purpose of the dossier
	For both						

- vii) details in a table, on each feed mill processing feed for ruminant only, for non-ruminant only and for both, with infractions, specifying the type of infraction (columns D and F of the table above) and the method of resolution;

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Year (information should be provided for each of the eight years for which effectiveness is claimed)	Type of feed mills	Feed mills ID	Nature of infraction	Method of resolution	Follow-up results
Year 1	For ruminant only	ID 1			
		ID 2			
		ID 3, etc.			
	For non-ruminant only	ID 1			
		ID 2			
		ID 3, etc.			
	For both	ID 1			
		ID 2			
		ID 3, etc.			
Year 2, etc.	For ruminant only				
	For non-ruminant				

- viii) why, in light of the findings displayed in the preceding four tables (of Sections 4 and 5), it is considered that there has been no significant exposure of cattle to the BSE agent through consumption of *meat and bone meal* or *greaves* of ruminant origin;
- ix) husbandry practices (multiple species farms) which could lend themselves to cross-contamination of ruminant feed with *meat and bone meal* and *greaves* destined to other species.

Indicate if there are any industry associations or organisations involved in the rendering industry that provide guidance, set standards or provide third party audits in relation to Hazard Analysis and Critical Control Points (HACCP) programmes, good manufacturing practices, etc. Include a description of their role, membership and interaction with the Veterinary Services or other Competent Authority.

- v) Feed production, distribution and storage

When rendered products are used as ingredients in the production of animal feed the exposure of cattle to the BSE agents (classical and atypical) may arise as a result of the use of rendered products containing materials of ruminant origin as ingredients in cattle feed or as a result of cattle feed being cross-contaminated when such products are used in the production of feed for other species.

Describe whether or not facilities producing feed for ruminant or non-ruminant livestock as well as for pets are required to be registered or approved by the Veterinary Services or other Competent Authority and if they are subject to official veterinary control or supervision. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic.

Annex 34 (contd)

For each of the preceding eight years, provide a breakdown using tables as appropriate of the number and types of operating facilities producing feed, indicating for each facility:

- ≡ excluding those listed in Article 11.4.1.bis, whether or not rendered ruminant products were used as ingredients in feed for ruminants, non-ruminants and pets;
- ≡ whether or not each facility was dedicated to manufacturing feed for a particular species or manufactured feed for multiple species including ruminants;

When facilities manufactured feed for multiple species including ruminants, indicate whether or not there were any practices in place to avoid ruminant feeds from being contaminated with rendered ruminant products during feed manufacture, storage and transport.

Indicate if there are any industry associations or organisations involved in feed production, distribution and storage that provide guidance, set standards or provide third party audits in relation to HACCP programmes, good manufacturing practices, etc. Include a description of their role, membership and interaction with the Veterinary Services or other Competent Authority.

vi) Conclusions for livestock industry practices

- ≡ Given the livestock industry practices described above, is the likelihood that the cattle population has been exposed to either classical or atypical BSE during the preceding eight years negligible or non-negligible?
- ≡ Clearly and concisely describe the rationale leading to the conclusion reached.
- ≡ When the likelihood estimate is negligible, proceed to Section 4 Risk estimation.
- ≡ When the likelihood estimate is non-negligible, proceed to Section 2b) An evaluation of BSE specific mitigation measures.

b) An evaluation of BSE specific risk mitigation measures

For those countries that have reported classical BSE cases in indigenous cattle, it is apparent that their historic livestock industry practices did not prevent the recycling of the BSE agent in their cattle population. These countries, together with others whose livestock industries practices would have been conducive to recycling may have implemented specific measures, such as through a legislated feed ban to ensure that the likelihood of recycling would be negligible. To qualify for official recognition of a BSE risk status, these countries need to demonstrate that the measures specifically targeting BSE have been and continue to be effectively implemented and enforced.

i) The nature and scope of a feed ban

Indicate if there is a ban on feeding ruminants with protein meal derived from ruminants.

When a feed ban has been implemented, clearly and concisely describe the date it was introduced, its nature and scope and how it has evolved over time.

In addition, if the feed ban has been implemented through national legislation, provide pertinent information in the table under Article 1.8.3. and a summary of any relevant legislation with references as appropriate.

ii) Commodities with the greatest BSE infectivity

Indicate whether or not any of those commodities listed in points 1) a) and 1) b) of Article 11.4.14. are removed from the carcass at the time of slaughter or subsequent fabrication or processing.

If so, also:

- = Describe how they are disposed or destroyed through burial, composting, rendering, alkaline hydrolysis, thermal hydrolysis, gasification, incineration, etc.
- = Describe any measures in place that ensure slaughter waste declared as unfit for human consumption that is rendered is not cross-contaminated with these commodities.
- = Describe whether these commodities from fallen stock and animals condemned at ante mortem inspection are excluded from rendering and how this is done.
- = When these commodities are not excluded from slaughter waste declared as unfit for human consumption, describe the final disposal of this waste, and how it is handled and processed.
- = Describe whether or not all these processes and methods are subject to approval and oversight by the Veterinary Services or other Competent Authority.

In addition, if there is specific national legislation concerning the definition, identification, removal and disposal or destruction of those commodities listed in points 1) a) and 1) b) of Article 11.4.14., provide pertinent information in the table under Article 1.8.3. and a summary of any relevant legislation with references as appropriate.

iii) Parameters of the rendering process

Describe whether or not the parameters of the rendering process are described in legislation and if they are consistent with, or provide an equivalent level of assurance to, the procedures for the reduction of BSE infectivity in ruminant-derived protein meal as described in Article 11.4.17. Provide details of the legislation, if applicable, in the table under Article 1.8.3.

iv) Cross-contamination

Describe the measures in place to prevent cross-contamination during rendering, feed production, transport, storage and feeding such as dedicated facilities, lines and equipment, as well as measures to prevent misfeeding, such as the use of warning labels. Provide information as to whether any of these measures are described in legislation and if facilities involved in rendering and feed production are required to be registered or approved under the feed ban by the Veterinary Services or other Competent Authority.

v) Awareness programme

Provide information on the existence of any ongoing awareness programmes or other forms of guidance given to all those stakeholders involved in rendering, feed production, transport, storage, distribution, sale and feeding under the scope of the feed ban. Provide examples of communication materials including publications, brochures and pamphlets.

Annex 34 (contd)vi) Monitoring and enforcement

Describe how the *feed* ban, if implemented, has been and continues to be monitored and enforced. Provide information on:

- ≡ official oversight from the *Veterinary Services*, other *Competent Authority* or a third party;
- ≡ training and accreditation programmes for inspectors;
- ≡ the planned frequency of inspections, the procedures involved including manuals and inspection forms;
- ≡ sampling programmes and *laboratory* testing methods used to check the level of implementation of the *feed* ban and avoidance of cross-contamination;
- ≡ options available to deal with infractions (non-compliances) such as recalls, destruction and monetary penalties.

Provide information on the ongoing results of the official inspection programme for each of the preceding eight years using tables as appropriate:

- ≡ planned *versus* actual delivery inspections at rendering facilities, *feed* mills, farms, etc., with an explanation of any significant variance and how they may have impacted the programme;
- ≡ number and type of samples taken during inspections to verify that ruminant *feed* does not contain or is not cross contaminated with rendered products containing ruminant material (excluding those listed in Article 11.4.1.bis). Provide information by year, by source (rendering facility, *feed* mill or farm), indicating the *laboratory* test(s) used and the results obtained;
- ≡ the types of infractions (non-compliance) that occurred and corrective actions undertaken;
- ≡ any infractions (non-compliances) that were likely to have led to cattle being exposed to *feed* contaminated with ruminant material (excluding those listed in Article 11.4.1.bis) and how they were resolved.

vii) Conclusions for the evaluation of BSE specific risk mitigation measures

- ≡ In evaluating the effectiveness of a *feed* ban, if implemented, for each of the preceding eight years, consideration needs to be given to:
 - ≡ the management of *commodities* listed in points 1) a) and 1) b) of Article 11.4.14., and the associated likelihood that these materials, or other materials cross contaminated by them, may have entered the animal *feed* chain;
 - ≡ the rendering industry and the associated likelihood that rendered products containing ruminant material may retain BSE infectivity;
 - ≡ the *feed* industry, and the associated likelihood that *feed* for cattle may contain or has been cross-contaminated with ruminant-derived protein meal.
- ≡ Given the evaluation of BSE specific risk mitigation measures and their enforcement as described above, is the likelihood that the cattle population has been exposed to either classical or atypical BSE negligible or non-negligible during the preceding eight years?

Clearly and concisely describe the rationale leading to the conclusion reached.

- = When the likelihood estimate is negligible, proceed to Section 4) *Risk estimation*.
- = When the likelihood estimate is non-negligible, proceed to Section 3) *Consequence assessment*.

3. Consequence assessment

While uncertainty remains regarding the potential transmissibility of atypical BSE through oral exposure to contaminated *feed*, it is reasonable to assume for the purposes of a consequence assessment, that the likelihood of cattle becoming infected would be similar to classical BSE.

As described in Article 11.4.2., a consequence assessment evaluates the likelihood of cattle becoming infected following exposure to the BSE agents (classical or atypical) together with the likely extent of any subsequent recycling and amplification.

For the purposes of undertaking a consequence assessment for the evaluation of BSE risk status, the period of interest is the preceding eight years.

Considering that, for all practical purposes, oral exposure to contaminated *feed* is the principal, if not the only route of transmission of the BSE agents, to initiate a cycle of BSE infectivity within a cattle population the following series of events would need to unfold:

- = *commodities* listed in points 1) a) and 1) b) of Article 11.4.14. from an infected animal are included in raw materials that are rendered into ruminant-derived protein meal;
- = the rendering process does not destroy infectivity of the BSE agent(s);
- = the ruminant-derived protein meal is incorporated as an ingredient in cattle *feed*, or cattle *feed* is cross-contaminated during *feed* production, distribution and storage, or cattle are incorrectly fed with *feed* intended for non-ruminant species that includes the ruminant-derived protein meal as an *ingredient*;
- = one or more animals that ingest contaminated *feed* become infected;
- = the infected animal survives long enough to reach the later stages of a protracted incubation period when the levels of the BSE agent in those *commodities* listed in points 1) a) and 1) b) of Article 11.4.14. would begin to rise dramatically;
- = *commodities* listed in points 1) a) and 1) b) of Article 11.4.14. are then included in raw materials that are rendered into ruminant-derived protein meal, completing one cycle.

Recycling arises when this cycle is repeated one or more times. Any level of recycling within a given period is sufficient to conclude that the consequences of exposure to contaminated *feed* for that period within the cattle population are non-negligible.

- a) Factors to consider when evaluating the likely extent of recycling of the BSE agents within a cattle population:
 - i) Age at exposure

Animals less than 12 months of age are considered to be much more susceptible to *infection* than older animals, which are likely to be increasingly refractory to *infection* as they mature.

Annex 34 (contd)ii) Type of production system= Calves reared as replacement animals for the breeding herd

Cattle exposed to BSE agents at less than 12 months of age and destined to enter the breeding herd are much more likely to become infected and survive long enough to reach the later stages of a protracted incubation period when the levels of the BSE agent in those commodities listed in points 1) a) and 1) b) of Article 11.4.14. would begin to rise dramatically. If these materials were rendered and subsequently contaminated cattle feed, it is highly likely that some level of recycling would occur.

= Feedlot cattle

Even if cattle reared in a feedlot that were destined to be slaughtered within the next two to six months were to become infected after consuming contaminated feed, the likelihood that they would have reached the later stages of a protracted incubation period (when the levels of the BSE agent in those commodities listed in points 1) a) and 1) b) of Article 11.4.14. would begin to rise dramatically) would essentially be negligible.

Considering that mature cattle are likely to be much more refractory to infection than animals within their first year of life, even if they were to consume contaminated feed, it is highly unlikely that those commodities listed in points 1) a) and 1) b) of Article 11.4.14. would pose a threat if they were rendered and subsequently contaminated cattle feed.

iii) The impact of livestock industry practices or the implementation of measures under a feed ban

When evaluating the potential for the recycling of the BSE agents in the cattle population where an infraction (non-compliance) has occurred that may have led to feed being cross-contaminated, it is important to consider the impact of both the livestock industry practices and the ongoing measures under a feed ban. Even if an infraction that arose several years ago led to susceptible young animals becoming infected, in evaluating the likelihood of recycling in future years, consideration would need to be given to the effectiveness of the feed ban in subsequent years or whether or not any changes to livestock industry practices may have influenced the exposure risk

b) Conclusions for the consequence assessment

Where the outcome of the evaluation of livestock industry practices or the evaluation of BSE specific mitigation measures, that include the nature and scope of the feed ban and its enforcement, has concluded that there was a non-negligible likelihood that the cattle population has been exposed to the BSE agents, what is the likelihood that they have been recycled within the cattle population during the preceding 8 years?

Clearly describe the rationale leading to the conclusions reached.

4. Risk estimation

As described in Article 11.4.2., risk estimation summarizes the results and the conclusions arising from the entry, exposure and consequence assessments.

a) Provide a summary of the entry and exposure assessments, and the conclusions reached.b) If applicable, provide a summary of the consequence assessment and the conclusion reached.

Annex 34 (contd)

- c) Indicate whether or not the condition of point 1) a) of Article 11.4.3. has been met, that is, if the likelihood that the BSE agents have been recycled in the cattle population has been negligible for at least 8 years. Indicate which of the two pathways is applicable: either livestock industry practices or the effective and continued mitigation of each identified risk.
- d) When the condition of point 1) a) of Article 11.4.3. has not been met, that is, it cannot be demonstrated that for at least eight years the likelihood that the BSE agents have been recycled in the cattle population has been negligible, provide an explanation for the period of time within the preceding eight years for which it can be considered that the likelihood has been negligible. Clearly describe the rationale leading to the conclusions reached.

Article 1.8.36.

BSE risk status requirements: Section 2 – other requirements (see points 2) to 4) of Article 11.4.2.)

BSE surveillance

Article 11.4.18. describes the criteria that underpin a credible *surveillance* programme together with an overview of the range of clinical signs that cattle affected by BSE are likely to exhibit.

The Delegate of the Member applying for recognition of a negligible or a controlled BSE risk status should submit documentary evidence that the provisions of point 1) of Article 11.4.18. have been effectively implemented.

Documentary evidence detailing the results of the ongoing *surveillance* programme is also required.

21. ~~Compulsory notification and investigation (see point 3) of Article 11.4.2.)~~18. point 1) a)

~~In order to ensure appropriate the detection and follow-up of any suspected BSE cases, appropriate legislation, policies and incentives to support BSE control and eradication and effective regulatory controls compulsory notification, investigation and verification should be in place.~~

~~The socioeconomic implications of BSE require that there be incentives and obligations to notify and investigate suspected cases.~~

~~a) a) Describe the criteria for raising a suspicion of BSE including the range of clinical signs considered and how the clinical history is taken into account.~~

~~b) Describe the guidance given to farmers, all stakeholders involved in the rearing and production of livestock owners, animal handlers including farmers, herdsmen, veterinarians, transporters, workers at livestock markets or, auctions, workers at and slaughterhouses/abattoirs, etc. in terms of the criteria that would initiate the investigation of an *animal* suspected as being a case of BSE. Have these criteria evolved and, if so, how? What mechanisms are in place to ensure that these guidelines reach those stakeholders?~~

~~b) c) Describe the reporting framework for suspected BSE cases including the sampling logistics to ensure suitable samples reach an approved BSE laboratory for examination.~~

~~d) What was the date of implementation of any supporting legislation and content of the legal act associated policies making notification of suspected cases of BSE compulsory? Do they include a definition for a "suspect BSE case"? If appropriate, outline relevant legislation in the table under Article 1.8.3.~~

Annex 34 (contd)

~~e) e) Describe the measures in place to stimulate/facilitate notification, such as compensation payments or penalties for not notifying a suspected case.~~

~~f) Provide information on the occurrence of other diseases with neurological clinical signs compatible with BSE.~~

2. ~~Awareness programme (see Article 11.4.18, point 2) of Article 11.4.2.) 1) b))~~

~~An awareness programme is essential in ensuring detection to ensure that all stakeholders are familiar with clinical signs suggestive of BSE as well as their reporting obligations.~~

~~a) Describe the type(s) of awareness or training programme(s) implemented for specific target audiences including the recognition of clinical signs by farmers and reporting of BSE, especially in countries of low prevalence; others involved in the rearing and competing differential diagnoses. Provide documentary evidence of the following: production of livestock, as well as the protocols for sample collection and submission by veterinarians and animal health technicians.~~

~~a/b) Describe when the awareness or training programme was(s) were implemented and its continuous/their ongoing application and geographical coverage;~~

~~b) including the number and occupation of persons who have participated in the awareness programme (farmers, livestock owners, animal handlers, veterinarians, workers at livestock markets or auctions, workers at slaughterhouses/abattoirs, etc.); types of stakeholders involved.~~

~~c) Provide a description including examples of the types of materials used in the awareness programme (the manual, supportive including training manuals, supporting documents, or other teaching materials) such as publications in local newspapers and farming magazines, pamphlets and videos (weblinks to supporting documents in one of the official languages of the OIE may also be provided, where when they exist.);~~

~~d) Provide details of any contingency plans or preparedness plans to deal with an occurrence of BSE.~~

3. ~~Examination in an approved laboratory of brain or other tissues collected within the framework of the surveillance system described above (see point 4) of Article 11.4.2.) Laboratory investigations and follow-up field investigation (Article 11.4.2018, point 1) c))~~

~~Provide documentary evidence that the relevant provisions of Chapter 23.4.5. of the Terrestrial Manual are applied, including the following:~~

~~a) If BSE samples are submitted to a laboratory diagnosis carried out in the country or zone for testing provide an overview of the approved laboratories where samples of cattle tissues from how many are involved in testing BSE samples, how they are approved or certified, their number, location and diagnostic procedures and the time frame for reporting results.~~

~~b) If the BSE samples are not submitted to a laboratory in the country or zone for testing or suspicious or positive samples are examined for BSE;~~

~~b) if BSE referred to a laboratory diagnosis is not carried out in outside the country, provide the names of the laboratories in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results;~~

Annex 34 (contd)

- e) ~~that these diagnostic procedures and methods have been applied through the entire surveillance period~~
- c) Describe the diagnostic protocol and tests used for processing samples for classical and atypical BSE and how they may have evolved over time, indicating: what is the primary test used?; what would be the series of secondary tests performed, if any, depending on the results of the primary test (i.e., negative, positive and inconclusive)?; and what test would be undertaken if discordant results between primary and secondary tests arise (e.g., primary positive result followed by a secondary negative result)?
- d) Describe the methods applied to assess the ages of animals such as individual identification or dentition.
- e) In a table (see below), provide details for all cattle that have been reported as having clinical signs suggestive of BSE (see Article 11.4.18, point 2)) for the preceding eight years.

<u>Year notified</u>	<u>Laboratory identification number</u>	<u>Age (Years)</u>	<u>Type of product on system (dairy, beef, etc.)</u>	<u>Description of observed clinical signs</u>	<u>Point of detection (farm, market, slaughterhouse, etc.)</u>	<u>Final diagnosis (if BSE, specify the strain)</u>	<u>Origin of the case (indigenous, imported)</u>

Article 1.8.4.

Section 3: BSE surveillance and monitoring systems (see point 1 b) iv) and point 4) of Article 11.4.2.)

Articles 11.4.20. to 11.4.22. prescribe the number of cattle, by *subpopulation*, that need to be tested in order to ensure the detection of BSE at or above a minimal threshold prevalence.

- 4) ~~Does the BSE surveillance programme comply with the guidelines in Articles 11.4.20. to 11.4.22. of the Terrestrial Code? Provide documentary evidence of the following:~~
- a) ~~that the samples collected are representative of the distribution of the cattle population in the country or zone, including by age and subpopulations as described in Article 11.4.21.;~~
- b) ~~the methods applied to assess the ages of animals sampled and the proportions for each method (individual identification, dentition, other methods to be specified);~~
- c) ~~the means and procedures whereby samples were assigned to the cattle subpopulations described in Article 11.4.21., including the specific provisions applied to ensure that animals described as clinical met the conditions of point 1) of Article 11.4.21. and that at least three of the four subpopulations have been sampled.~~
- 2) ~~In a table (see below), provide details of all clinically suspected cases notified complying with the definition in point 1) of Article 11.4.21.~~

Laboratory identification number	Age	Description of observed clinical signs	Point of detection (farm, market channels, slaughterhouse)	Final diagnosis

Annex 34 (contd)

- 3) In a table (see below), provide details of the number of target points applicable to the country or zone and its BSE surveillance requirements (type A or type B surveillance as a result of the risk assessment of Section 4) are met as described in Articles 11.4.21. and 11.4.22.

SUMMARY TABLE FOR BSE SURVEILLANCE								
Year: (complete a separate table for each year of surveillance)								
Surveillance subpopulations								
	Routine slaughter		Fallen stock		Casualty slaughter		Clinical suspect	
	Samples	Points	Samples	Points	Samples	Points	Samples	Points
>1 and <2 years								
>2 and <4 years								
>4 and <7 years								
>7 and <9 years								
>9 years								
Subtotals								
Total points								

- 4) Provide the number of adult cattle (over 24 months of age) in the country or zone.

Article 1.8.5.

Section 4: BSE history of the country or zone (see Articles 11.4.3. and 11.4.4.)

//Contents of Current Article 1.8.5. were edited and moved to Draft Article 1.8.2.//

Article 1.8.6Z.

Recovery of BSE risk status

~~Member Countries~~Members applying for recognition of recovery of BSE risk status for a country or zone should ~~implement~~ comply with the provisions of Article 11.4.2. and Article 11.4.3. or Article 11.4.4. of the *Terrestrial Code* and provide detailed information as specified in Article 1.8.5. of this questionnaire application. Information in relation to other sections need only be supplied if relevant.

Following the occurrence of an indigenous case of classical BSE in an animal born within the preceding eight years, the outcome of subsequent investigations together with any additional measures implemented that confirm or ensure that the likelihood of BSE being recycled within the cattle population continues to be negligible should be provided with reference to the provisions in Article 1.8.5. as appropriate.

**RATIONALE FOR THE REVISION OF THE
CHAPTERS 11.4. AND 1.8. OF THE *TERRESTRIAL CODE***

Since July 2018, four *ad hoc* Groups on bovine spongiform encephalopathy (BSE) have been held to review Chapter 1.8. Application for official recognition by the OIE of risk status for bovine spongiform encephalopathy and Chapter 11.4. Bovine spongiform encephalopathy of the OIE *Terrestrial Animal Health Code (Terrestrial Code)*.

Purpose of this document

Given the extensive nature of this work this document has been developed to collate the rationales for the proposed amendments to Chapters 11.4. and 1.8. into a single document to facilitate their review by the OIE Terrestrial Animal Health Standards Commission (the Code Commission).

References are provided to the respective meeting reports where the discussion substantiating the proposed amendments can be found:

<i>Ah hoc</i> Group	Meeting dates	Reference to the report within this document
BSE risk assessment (first meeting)	3-5 July 2018	RA1
BSE surveillance	3-5 October 2018	Surv
BSE risk assessment (second meeting)	20-22 November 2018	RA2
BSE risk assessment and surveillance	18-21 March 2019	RA&Surv

1. Revised Chapter 11.4.

1.1. Article 11.4.1. General provisions

Revisions were made to ensure better alignment with the structure of other disease-specific chapters. Current Article 11.4.1. was split into two: Article 11.4.1. on General provisions, and Article 11.4.1.bis. on Safe commodities, and definitions of terms applicable to this chapter, including a case definition, were grouped at the beginning of the Article 11.4.1 (RA&Surv).

a) *Definitions of meat-and-bone meal (MBM) and greaves*

The *ad hoc* Group noted that based on the current definitions of MBM⁵ and greaves⁶ a) the rationale to differentiate MBM and greaves is unclear; b) greaves can potentially be considered intermediate protein products; and c) a common understanding in different countries of what greaves are, as well as a variety of practices as to how greaves they are used is lacking. The *ad hoc* Group therefore proposed to include both MBM and greaves in a single definition under the term '*protein meal*':

⁵ MBM means the solid protein products obtained when animal tissues are rendered, and includes any intermediate protein product other than peptides of a molecular weight less than 10,000 daltons and amino-acids".

⁶ Greaves means the protein-containing residue obtained after the partial separation of fat and water during the process of rendering.

Annex 35 (contd)

“means any final or intermediate solid protein-containing product, obtained when animal tissues are rendered, excluding blood, blood products, peptides of a molecular weight less than 10,000 daltons and amino-acids” (RA&Surv).

The *ad hoc* Group recommended that at this stage the proposed definition of “protein meal” should be included in Chapters 11.4. and 1.8. and the OIE Secretariat should explore whether this definition would also be relevant for the other disease-specific chapters where the terms MBM and greaves are used⁷. If considered relevant for other chapters, the proposed definition could ultimately replace the definitions of MBM and greaves in the Glossary of the *Terrestrial Code* (RA&Surv).

b) Atypical BSE

The *ad hoc* Groups considered how atypical BSE should be addressed in the *Terrestrial Code*.

Currently, Chapter 11.4. states in Article 11.4.1. that “For the purposes of official BSE risk status recognition, BSE excludes 'atypical BSE' as a condition believed to occur spontaneously in all cattle populations at a very low rate”. The *ad hoc* Group acknowledged that while the eradication of classical BSE might be feasible assuming its transmissibility via contaminated feed, the eradication of atypical BSE might remain elusive if cases occur spontaneously. However, the *ad hoc* Group highlighted the uncertainty associated with the origin of all BSE agents, including atypical BSE, the potential transmissibility of atypical BSE through contaminated feed and any zoonotic risk that might result from the recycling of atypical BSE agent in ruminant feed (RA2). For this reason, the *ad hoc* Group prepared an overview of relevant literature on the risk of atypical BSE being recycled in a cattle population and its zoonotic potential⁸ (provided as Appendix IV of RA&Surv).

With regard to the risk of recycling of atypical BSE, recently published research confirmed that the L-type BSE prion (a type of atypical BSE prion) can be orally transmitted to calves⁹. In light of this evidence, and the likelihood that atypical BSE could arise as a spontaneous disease in any country, albeit at a very low incidence, the *ad hoc* Group was of the opinion that it would be reasonable to conclude that atypical BSE is potentially capable of being recycled in a cattle population if cattle were to be exposed to contaminated feed. Therefore, the recycling of atypical strains in cattle and broader ruminant populations should be avoided (RA&Surv).

The *ad hoc* Group acknowledged the challenges in demonstrating the zoonotic transmission of atypical strains of BSE in natural exposure scenarios. Overall, the *ad hoc* Group was of the opinion that, at this stage, it would be premature to reach a conclusion other than that atypical BSE poses a potential zoonotic risk that may be different between atypical strains (RA&Surv).

The *ad hoc* Group concluded that while the occurrence of a case of atypical BSE, regardless of the origin (imported or indigenous), would not impact a country’s BSE risk status by itself, it was nevertheless important to consider the potential recycling of all BSE agents, not only of classical BSE, in the exposure assessment (section 3.2. of RA2). As a result, atypical BSE is considered in the recognition of a country’s BSE risk status as the existing Article 11.4.1. implies (RA2 and RA&Surv).

⁷ Chapters of the *Terrestrial Code* where the terms “meat-and-bone meal” and/or “greaves” are relevant: Chapter 8.1. on anthrax; Chapter 8.4. on infection with *Brucella abortus*, *B. melitensis* and *B. suis*; Chapter 8.11. on infection with *Mycobacterium tuberculosis* complex; Chapter 14.8. on scrapie; and Chapter 15.3 on infection with porcine reproductive and respiratory syndrome virus.

⁸ The overview has been referred to the OIE Biological Standards Commission in support of the update of Chapter 3.4.5. on BSE of the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*.

⁹ Okada H, Iwamaru Y, Imamura M, Miyazawa K, Matsuura Y, Masujin K, Murayama Y, Yokoyama T. Oral transmission of L-Type bovine spongiform encephalopathy agent among cattle. *Emerging Infectious Diseases*. 2017 Feb; 23(2):284.

Based on this information, the *ad hoc* Group proposed amendments to Article 11.4.1. and point 1(b) of Article 11.4.2. to emphasise the potential for atypical BSE to be recycled in a cattle population if cattle were to be exposed to contaminated feed, and to points 3(a) and 4. of draft Article 11.4.3. to clarify the impact and the way to address atypical BSE cases. As a consequence, the statement “*For the purposes of official BSE risk status recognition, BSE excludes 'atypical BSE' as a condition believed to occur spontaneously in all cattle populations at a very low rate*” was removed (RA2 and RA&Surv).

c) *Species of interest*

BSE primarily affects cattle. The *ad hoc* Group considered it relevant to include a paragraph clarifying that several animal species may be naturally (household cats, ruminant and feline species in zoos, goats) or experimentally (sheep) susceptible to BSE, but are not considered to be epidemiologically significant, particularly in the presence of an ongoing ruminant-to-ruminant feed ban (RA1).

d) *Scope (country, zone, compartment) for recognition of status*

The *ad hoc* Group noted that Article 1.6.1. states that the official recognition of BSE risk status by the OIE only applies to countries and zones, and that for compartments, the BSE risk of their cattle population may be claimed by Members on the basis of a self-declaration and their recognition should be based on bilateral negotiations between trading partners (RA1).

Considering that implying that a compartment can be recognised with a BSE risk status would be inconsistent with Article 1.6.1., the *ad hoc* Group amended those instances in the chapter where a risk ‘status’ is linked to a ‘compartment’, by removing the word ‘status’ (e.g. *the BSE risk status of the exporting country, zone or compartment*).

1.2. Article 11.4.1.bis. Safe commodities

With regard to safe commodities, the *ad hoc* Group took note of the definition provided in the Glossary of the *Terrestrial Code*, i.e. “*Safe commodities means a commodity that can be traded without the need for risk mitigation measures specifically directed against a particular listed disease, infection or infestation and regardless of the status of the country or zone of origin for that disease, infection or infestation*” and of the provisions of Chapter 2.2. Criteria applied by the OIE for assessing the safety of commodities (RA&Surv).

The *ad hoc* Group noted that for the commodities listed under point 1(g) of Article 11.4.1. (deboned skeletal muscle) and point 1(h) (blood and blood by-products), measures specifically directed against BSE to mitigate the risk of cross contamination by the BSE agent are currently explicitly stated. Considering that inclusion of these commodities in an article specifically listing safe commodities is no longer consistent with either the Glossary or Chapter 2.2., the *ad hoc* Group sought advice from the Code Commission and agreed with their recommendation that these commodities should not be listed as safe commodities and would need to be addressed in separate articles of Chapter 11.4. (i.e., Articles 11.4.9. to 11.4.11. and 11.4.13.) (RA&Surv)

The *ad hoc* Group pointed out that “semen and *in vivo* derived cattle embryos” should not necessarily only be “*collected and handled in accordance with the recommendations of the International Embryo Transfer Society*” as recommended in current point 1(b) of Article 11.4.1. but rather in accordance with relevant chapters of the *Terrestrial Code* (RA&Surv).

1.3. Article 11.4.2. The BSE risk of the cattle population of a country, zone or compartment

a) *Determination of a BSE risk status*

The *ad hoc* Group explained that the BSE risk status of a cattle population should be determined based on: (1) a comprehensive risk assessment, (2) the continuous implementation of a passive surveillance programme to detect the emergence or re-emergence of classical BSE, and (3) the history of occurrence and management of cases of classical or atypical BSE (RA&Surv). The *ad hoc* Group recommended to amend Article 11.4.2. to reflect this.

Annex 35 (contd)**b) Risk assessment**

The *ad hoc* Group noted that factors to be taken into consideration in the entry and the exposure assessments listed in Article 11.4.2. were duplicated -without being fully harmonised- in Articles 11.4.23. to 11.4.29. and in Chapter 1.8. Duplications within the *Terrestrial Code* increase the likelihood of inconsistencies. To address this issue, the *ad hoc* Group proposed to delete the details in Article 11.4.2. regarding the factors to be taken into consideration in the entry and the exposure assessments, and to only include them in Chapter 1.8. (RA1). Articles 11.4.23. to 11.4.29. were also removed (see section 1.23. of this document).

c) Entry assessment

The *ad hoc* Group noted that the entry assessment includes both local factors (points (i) and (ii); i.e., presence/absence of the BSE agent in the indigenous population, and production of MBM or greaves) and factors associated with the introduction of the BSE agent through importation (points [iii] to [vii]). The *ad hoc* Group suggested that, consistent with recommended approaches on risk assessment (i.e., Chapter 2.1. of the *Terrestrial Code*), the entry assessment should focus on the likelihood of imported commodities being infected or contaminated with the BSE agent, whilst local factors should be addressed in the exposure assessment. As a consequence, the *ad hoc* Group noted that Chapter 1.8. would have to be revised to mirror the proposed changes, and an exposure assessment would need to be performed regardless of the results of the entry assessment (RA1).

d) Exposure assessment

According to the current provisions of Article 11.4.2. point 1(b), an exposure assessment should be conducted if a risk factor is identified by the entry assessment (RA2). As explained in section 1.1.b. of this document, the *ad hoc* Group clarified that exposure to the atypical BSE agent should be taken into consideration. Indeed, because of the significant uncertainty regarding the likelihood of the recycling of the atypical BSE agent, an assessment of the likelihood of the cattle population being exposed to the BSE agents (classical or atypical) should be performed regardless of the outcome of the entry assessment (RA1 and RA2). The *ad hoc* Group noted that this represents another reason why an exposure assessment should be performed regardless of the outcome of the entry assessment (RA1).

The *ad hoc* Group clarified that the assessment should evaluate the likelihood of the classical BSE agent entering the country or zone and of the BSE agents (classical and atypical) being present and recycled in the cattle population leading to the exposure of indigenous cattle to the infectious agent, taking into consideration the impact of livestock industry practices or the measures that have been implemented to mitigate any identified risk factors (RA2).

e) Two additional steps

Consistent with Chapter 2.1. methodologies for conducting a risk assessment, the *ad hoc* Group proposed that two additional steps (a 'consequence assessment' and a 'risk estimation') should also be undertaken to complete the assessment of the BSE risk (RA1).

The *ad hoc* Group discussed whether there was a need to outline the different steps of the BSE risk assessment in Chapter 11.4. or if these steps could be covered by a cross-reference to Chapter 2.1. Considering that Chapter 2.1. focuses on import risk analysis, the *ad hoc* Group determined it was appropriate to list and define the steps to be undertaken to perform a comprehensive BSE risk assessment in Article 11.4.2. (RA1).

f) Prerequisites for the detection of BSE cases

The *ad hoc* Group noted that points 2 to 4 of current Article 11.4.2. (i.e., an ongoing awareness programme for BSE, compulsory notification and investigation, and examination of samples carried out in accordance with the *Terrestrial Manual*) were more related to the surveillance programme than to the risk assessment. Therefore, the *ad hoc* Group recommended that Article 11.4.2. should primarily focus on the determination of the BSE risk status and that the provisions related to the detection of BSE cases should be moved to Article 11.4.18. (RA1 and Surv).

1.4. Article 11.4.3. Negligible BSE risk

a) Duration to be covered by the risk assessment, surveillance, and risk mitigating measures

The *ad hoc* Group discussed the time period that the risk assessment, the surveillance programme, and the risk mitigating measures should cover to demonstrate a negligible BSE risk status. Consistent with previous *ad hoc* Groups on BSE, the *ad hoc* Group recommended that an eight-year period would be appropriate considering that the upper 95th percentile incubation period for classical BSE is estimated to be seven years, and that the risk should have been mitigated for more than an incubation period. It was noted that in countries at the tail of the BSE epidemic, the incubation period may (artificially) appear to be longer as a result of the control measures that have been implemented. However, this should not be considered to be a globally applicable trend and would not justify a revision of the time period to be covered by the risk assessment and the risk mitigating measures (RA2).

In accordance with the recommendation of the *ad hoc* Group on BSE surveillance, the *ad hoc* Group agreed it would be appropriate that the duration for which surveillance has been conducted prior to the official recognition of a BSE risk status be aligned with the duration for which the BSE risk should have been effectively mitigated (i.e., 8 years) (RA2).

b) Pathways to achieve a negligible likelihood of the BSE agent (classical or atypical) being recycled in the cattle population

The current provisions primarily place the emphasis on determination of whether or not a country has implemented appropriate measures, particularly through a feed ban, to mitigate against the risk factors associated with the recycling and amplification of the BSE agent. This pathway proved appropriate for countries that have reported indigenous cases of classical BSE in their cattle populations and for those whose import history indicated that there was a non-negligible likelihood that the BSE agent may have been introduced. However, the *ad hoc* Group acknowledged that the impact of local livestock industry practices on the likelihood of the BSE agent being recycled were insufficiently taken into account. This is particularly relevant for those countries whose cattle populations are reared either predominantly or exclusively under extensive pastoral systems, or where there is practically no animal rendering production (RA1).

The *ad hoc* Group determined that a negligible BSE risk status could result from either (RA1):

- a negligible likelihood of a cattle population being exposed to BSE agent due to the local livestock industry practices (e.g., extensive pastoral systems) for more than the 95th percentile of the incubation period (i.e., for at least 8 years);
- the appropriate mitigation of risk factors for recycling and amplification of the BSE agent for the same duration as defined above (i.e., at least 8 years).

The *ad hoc* Group recommended that these two pathways for achieving a negligible BSE risk status should be recognised and that provisions adequate to these distinct scenarios should be proposed (RA1).

Annex 35 (contd)

The *ad hoc* Group further determined that the details of livestock industry practices to be considered (i.e., feeding, slaughtering and rendering practices) should be described in the BSE questionnaire rather than in Chapter 11.4. (RA2).

c) *Ruminant-to-ruminant feed ban*

The *ad hoc* Group agreed that applicants should still demonstrate that ruminants have not been fed to ruminants, since (i) the presence of the atypical BSE agent in cattle populations is potentially ubiquitous, (ii) the oral route is the main route of transmission of at least classical BSE in cattle, and (iii) feed bans have proven to be effective in restricting BSE spread (RA2). The *ad hoc* Group therefore proposed to amend points 1(a) and 1(b) of Article 11.4.3. to clearly emphasise that protein meal derived from ruminants should not have been fed to ruminants regardless of the pathway for achieving a negligible BSE risk status (i.e., husbandry practices or effective and continuous mitigation of each identified risk) (RA&Surv).

The *ad hoc* Group agreed that a feed ban may not always need to be legislated to provide an appropriate level of assurance (RA1 and RA2).

d) *Impact of the occurrence of imported and of atypical BSE case(s)*

Considering that the occurrence of cases of atypical BSE and of imported cases (of classical or atypical) of BSE would not necessarily imply a change in livestock industry practices nor a breach in the effective mitigation measures of identified risks in the country or zone, the *ad hoc* Group recommended that these occurrences should not impact the official recognition or maintenance of a negligible BSE risk status, as long as those cases are managed to ensure they do not enter the animal feed chain. The *ad hoc* Group therefore amended points 3(a) and 4 of Article 11.4.3. (RA2 and RA&Surv).

e) *Impact of the occurrence of indigenous cases of classical BSE*

According to the current provisions of point 3(b) of Article 11.4.3., the occurrence of a single indigenous case of classical BSE born less than 11 years ago not only prevents the recognition, but also leads to the suspension, of a negligible BSE risk status. The *ad hoc* Group could not conclude that the occurrence of one or a few cases of classical BSE in animals born after a feed ban systematically reveals a breach in the effective enforcement of the feed ban. The *ad hoc* Group expressed that this requirement was neither proportionate to the risk nor supported by robust scientific evidence (RA1 and section 4.3.d. of this document).

Therefore:

- For the initial recognition of a negligible BSE risk status, it would be reasonable to require that indigenous cases of classical BSE have not been born within the preceding 8 years, which corresponds to at least 95% of the incubation period for classical BSE and ensures consistency with the time period recommend for surveillance and the implementation of risk mitigation measures (RA2).
- For the impact of the occurrence of an indigenous case of classical BSE in an animal born 8 or less years ago in a country or zone already recognised with a negligible BSE risk status, the *ad hoc* Group amended draft Article 11.4.3. point 3(b)(ii) and the last paragraph in draft Article 11.4.3. to clearly state that the Member could regain its negligible BSE risk status provided that a subsequent investigation (on the conditions of livestock industry practices or the measures for the effective and continuous mitigation of each identified risk), confirms that the likelihood of the BSE agent being recycled within the cattle population continues to be negligible. Pending the outcome of such an investigation following the confirmation of a diagnosis of classical BSE, the negligible BSE risk status would be suspended and the conditions for a controlled BSE risk status would apply. In accordance with the ‘OIE Standard Operating Procedures on suspension, recovery or withdrawal of official status’, the outcome of the investigation would have to be favourably assessed by the Scientific Commission, within a maximum of 2 years after the detection of the case, for the negligible BSE risk status to be re-instated (RA2 and RA&Surv).

f) Birth cohort animals of an indigenous case of classical BSE

The *ad hoc* Group studied robust surveillance data showing that the occurrence of BSE cases amongst cohorts is much lower than in other surveillance streams¹⁰. The *ad hoc* Group concluded that as long as measures including a feed ban and the removal and destruction of tissues listed in Article 11.4.14. had been continuously and effectively implemented, and an effective surveillance system for the detection and investigation of cases is in place, the complete destruction of all birth cohort animals would not provide a significant gain in risk reduction as any risks associated with cohort animals would have been effectively eliminated (RA1). The *ad hoc* Group therefore removed provisions regarding birth cohort animals.

g) Complete destruction or disposal of any cases of BSE

In accordance with the overview on atypical BSE (section 3 and Appendix IV of RA&Surv), and consistent with the previous recommendations of the OIE *ad hoc* Group on BSE which met in August 2016, the *ad hoc* Group re-affirmed the position that any cases of BSE, either classical or atypical, that have been detected should be completely destroyed (or disposed of in such a way that ensures they do not enter the animal feed chain) to prevent the recycling of BSE agents (RA2 and RA&Surv). The *ad hoc* Group therefore added point 4 to Article 11.4.3. (RA&Surv).

h) Maintenance

The *ad hoc* Group agreed that consistent with the provisions of the current Article 11.4.2., Members should review their BSE risk assessment annually (RA&Surv) and that documentary evidence on the implementation of the passive surveillance program and its results, and an update on the occurrence and management of BSE cases should be provided each year (Surv).

1.5. Article 11.4.4. Controlled BSE risk

If a country or zone can demonstrate compliance with the requirements listed in Article 11.4.3., but not yet for the preceding eight years, it would qualify to be recognised as having a controlled BSE risk status. As such, this status provides an intermediate step for Members as they work towards achieving negligible BSE risk status as well as ensuring the sanitary safety of exported commodities (RA1, RA2, and RA&Surv).

The *ad hoc* Group refined Article 11.4.4. to ensure consistency of wording with Article 11.4.3. (RA&Surv).

1.6. Article 11.4.5. Undetermined BSE risk

By default, the BSE risk of the cattle population of a country, zone or compartment not recognised as fulfilling the requirements of negligible or controlled BSE risk would be considered to be undetermined (RA1). As some Members have expressed confusion on the conditions associated with being identified as posing an undetermined BSE risk, the definition of an undetermined BSE risk was revised to improve clarity (RA2).

1.7. Current Article 11.4.6. Recommendations for importation of bovine commodities from a country, zone or compartment posing a negligible BSE risk

There are no remaining bovine commodities which are not already covered in the rest of the articles on recommendations for importation. Therefore, the *ad hoc* Group proposed to delete this article (RA&Surv).

¹⁰ All details in section 4.3.d. of RA1.

Annex 35 (contd)**1.8. Article 11.4.6. Recommendations for importation of cattle from a country, zone or compartment posing a negligible BSE risk**

Article 11.4.7. currently provides recommendations for the importation of cattle from a country, zone or compartment posing a negligible BSE risk but where there has been an indigenous case. The *ad hoc* Group considered that in light of the provisions of amended Article 11.4.3., which clearly defines the conditions related to the occurrence of an indigenous case, it was no longer relevant to provide such recommendations. The same recommendations would apply for the importation of live cattle from any country, zone or compartment posing a negligible BSE risk. The title of draft Article 11.4.6. was accordingly amended (RA&Surv).

Point 1 of current Article 11.4.7. requires measures to be taken on same feed cohort or birth cohort animals when an indigenous case of classical BSE has been identified. As the measures for cohort animals would not provide a significant gain in risk reduction as long as the likelihood of BSE being recycled within the cattle population continues to be negligible (see section 1.4.f. of this document), the *ad hoc* Group concluded that point 1 of Article 11.4.7. was no longer necessary (RA&Surv).

Point 2 of current Article 11.4.7. requires that cattle were born “*after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants had been effectively enforced*”. Consistent with revisions to point 1 of amended Article 11.4.3., the *ad hoc* Group proposed to amend the text referring to cattle born in the country, zone or compartment to “*during the period when the likelihood of the BSE agent being recycled in the cattle population has been demonstrated to be negligible*” (RA&Surv).

The *ad hoc* Group discussed the provisions for trade that should apply to cattle older than the period for which the likelihood of the BSE agent being recycled in the cattle population has been assessed to be negligible. The *ad hoc* Group noted that a country or zone applying for the official recognition of a negligible BSE risk status may be able to demonstrate that the likelihood of the BSE agent being recycled in the cattle population has been negligible for more than 8 years. In that case, this should be acknowledged in the report of the *ad hoc* Group on BSE Risk Status Evaluation of Members. This would allow countries or zones newly recognised as having a BSE negligible risk status to export cattle older than 8 years based on the provisions of amended Article 11.4.6. The BSE questionnaire was amended to allow an applicant Member to document the BSE risk assessment for a period of more than eight years (RA&Surv).

1.9. Article 11.4.7. Recommendations for importation of cattle from a country, zone or compartment posing a controlled BSE risk

Consistent with the approach proposed in amended Article 11.4.6., the *ad hoc* Group advised that the provisions on the permanent identification of cattle were no longer necessary and that the cattle selected for export should be born in the country, zone or compartment during the period when the likelihood of the BSE agent being recycled in the cattle population has been demonstrated to be negligible. Consequently, this period should be acknowledged in the report of the *ad hoc* Group on BSE Risk Status Evaluation of Members. The BSE questionnaire was amended to allow an applicant Member to document the BSE risk assessment for a different period to eight years (RA&Surv).

Editorial changes (e.g., “cattle selected for export”; “~~complies with the conditions referred to in Article 11.4.4.~~” changed to “posing a controlled BSE risk”) were made throughout amended Articles 11.4.6. to 11.4.18. to ensure consistency throughout the chapter.

1.10. Article 11.4.8. Recommendations for importation of cattle from a country, zone or compartment posing an undetermined BSE risk

Establishment and assessment of provisions listed in current Article 11.4.9. point 1 (“*the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants has been banned and the ban has been effectively enforced*”) and 3.b. (cattle selected for export “*were born at least two years after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants was effectively enforced*”) would be difficult considering that a feed ban may not have been implemented in countries, zones or compartments posing an undetermined BSE risk (RA&Surv).

The *ad hoc* Group therefore recommended that Article 11.4.8. should focus on the demonstration that an individual animal has never been fed with feed containing ruminant-derived protein meal (point 2). The *ad hoc* Group acknowledged that this would be difficult to certify and that a permanent individual identification, recording and traceability system from birth and throughout the lifetime of the animal prior to export would be a pre-requisite to allow such a demonstration to be made (hence point 1). This option would, however, allow for bilateral negotiations of such trade (RA&Surv).

1.11. Article 11.4.9. Recommendations for importation of fresh meat and meat products from a country, zone or compartment posing a negligible BSE risk

The *ad hoc* Group reviewed the recommendations listed in current Article 11.4.10., and, consistent with the proposed approach in the amended Article 11.4.6., the *ad hoc* Group recommended that fresh meat and meat products imported from a country, zone or compartment posing a negligible BSE risk should be derived from cattle that passed ante-mortem inspection and were born during the period when the likelihood of the BSE agent being recycled in the cattle population has been assessed to be negligible. The *ad hoc* Group proposed alternative provisions for meat and meat products derived from cattle that were not born during this period (RA&Surv).

The *ad hoc* Group emphasised that *post-mortem* inspection is not considered relevant for BSE and recommended any reference to *post-mortem* inspection be removed wherever currently used in the chapter. (RA&Surv).

The *ad hoc* Group suggested to amend the titles of Articles 11.4.9. to 11.4.11. to reflect that these correspond to fresh meat and meat products, as *fresh meat* is a glossary term.

1.12. Article 11.4.10. Recommendations for importation of fresh meat and meat products from a country, zone or compartment posing a controlled BSE risk

The *ad hoc* Group reviewed the recommendations listed in current Article 11.4.11. and proposed editorial changes for the sake of harmonisation with Article 11.4.11. and accuracy (RA&Surv).

In particular:

- Replace the sentence

“were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process” with the sentence

“were not subjected to a stunning process with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, prior to slaughter”.

- Commodities not to be traded:

Distal ileum, skull, brain, eyes, vertebral column and spinal cord are listed in points 1(a) and 1(b) of Article 11.4.14. When referring to these, the word “commodity” better describes them as a group, as these are not all tissues (tissue is a cellular organisation level between cells and a complete organ), organs or body parts.

Also, ‘brain’ should be in singular.

- Contamination with vertebral column:

Added “*from the*” to point 2(b) to clarify that it is the mechanically separated meat from the vertebral column (and not only the vertebral column) which should not contaminate fresh meat and meat products.

Annex 35 (contd)**1.13. Article 11.4.11. Recommendations for importation of fresh meat and meat products from a country, zone or compartment posing an undetermined BSE risk**

The *ad hoc* Group reviewed the recommendations listed in current Article 11.4.12. and agreed with the opinion of the *ad hoc* Group on BSE which met in August 2016 that point 2(b), should be removed. This point recommends that fresh meat and meat products should be produced and handled to ensure that such products do not contain and are not contaminated with nervous and lymphatic tissues exposed during the deboning process. The *ad hoc* Group agreed that these measures would have been implemented out of an abundance of caution based on a comparison with scrapie. Indeed, pathogenesis studies have subsequently confirmed that BSE in cattle amplifies almost exclusively in the CNS and the ileal Peyer's patches, with limited involvement of the peripheral nervous and lymphatic systems in the late stages of the disease following clinical onset. As a result, the *ad hoc* Group concluded that the removal of these tissues is not relevant to mitigate the BSE risk (references in RA&Surv).

The *ad hoc* Group noted that point 2© of current Article 11.4.12. required that fresh meat and meat products should be produced and handled in a manner which ensures that such products do not contain and are not contaminated with mechanically separated meat from the skull and from the vertebral column from cattle over 12 months of age. The *ad hoc* Group discussed the age limit of 12 months and agreed that it was originally implemented out of an abundance of caution in the early 2000s when there was significant uncertainty. However, experiences gained since then have confirmed that the occurrence of clinical cases in cattle less than three years of age is a rare event (references in RA&Surv). The *ad hoc* Group concluded that maintaining an age limit of 12 months would be disproportionate to the level of risk and recommended it be aligned with the age limit suggested for the importation of meat and meat products from a country, zone or compartment posing a controlled BSE risk (i.e., 30 months) (RA&Surv).

1.14. Article 11.4.12. Recommendations for importation of cattle-derived protein meal from a country, zone or compartment posing a negligible BSE risk

Current Article 11.4.13. was revised consistent with the change in definition presented in section 1.1.a. of this document (i.e., from "meat-and-bone meal or greaves" to "protein meal").

The *ad hoc* Group recommended revising the scope from "ruminant" to "cattle-derived protein meal". *Bos taurus* and *B. indicus* are the species of relevance for BSE as defined in Article 11.4.1. (RA&Surv). During a post-meeting discussion, the *ad hoc* Group re-affirmed their position, indicating that as stated in Article 11.4.1., the recommendations in this chapter are intended to mitigate the human and animal health risks associated with the presence of the BSE agents in cattle only. As a result, the recommendations in Articles 11.4.6. to 11.4.18. are all about mitigating the BSE risks associated with the trade of commodities derived from cattle. Including "ruminants" more broadly in Article 11.4.14. would be beyond the scope of the BSE Chapter. It's worth noting that Article 14.8.11., concerning scrapie, recommends to not trade MBM containing any sheep or goat protein from countries not considered free from scrapie, and does not impose restrictions for trade of ruminant-derived MBM.

Consistent with the revision proposed in Article 11.4.6., the *ad hoc* Group recommended revising point 1 of current Article 11.4.13. which provides recommendations for importation from negligible BSE risk countries where there has been an indigenous case of BSE. Indeed, provisions regarding the occurrence of an indigenous case of BSE, in a country, zone or compartment posing a negligible BSE risk were no longer considered relevant in light of the provisions of Article 11.4.3. The *ad hoc* Group emphasised that the age of the cattle should be taken into consideration to ensure that they were born during the period when the likelihood of the BSE agent being recycled in the cattle population was assessed to be negligible (RA&Surv).

As recommendations for the importation of cattle-derived protein meal from countries, zones or compartments posing a controlled or undetermined BSE risk (current Article 11.4.13. point 2) should not be developed (rationale for this in section 5.13. of RA&Surv) and would no longer apply to this Article 11.4.12., the *ad hoc* Group proposed to move this recommendation to Article 11.4.14. point 3 (RA&Surv).

1.15. New Article 11.4.13. Recommendations for importation of blood and blood products

Considering that the *ad hoc* Group recommended that blood and blood products should no longer be listed as safe commodities (see section 1.2. of this document), the *ad hoc* Group drafted a new article to provide recommendations for the importation of blood and blood products (RA&Surv).

The *ad hoc* Group clarified that the provisions in this Article relate to blood and to blood products rather than to blood by-products. A blood by-product refers to one that is not intended to be produced but that results from processing of blood when a different final product is intended (which would be a blood product). Blood product refers to derived product from blood, which, together with blood are the scope of this article.

The recommendations provided for blood and blood products derived from ruminants which were not born in a country, zone or compartment posing a negligible BSE risk during the period when the likelihood of the BSE agent being recycled in the cattle population has been demonstrated to be negligible ensure that cross contamination with nervous tissue is avoided (RA&Surv).

1.16. Article 11.4.14. Recommendations in relation to the trade of the commodities with the greatest BSE infectivity

The *ad hoc* Group considered the recommendation made by the *ad hoc* Group on BSE which met in August 2016 proposing that the restriction applicable to tonsils be removed and reviewed the scientific evidence showing that extremely low levels of prion infectivity are present in tonsils (details in RA&Surv). The *ad hoc* Group concurred with the *ad hoc* Group that the restriction applicable to tonsils should be removed.

Consistent with the rationale presented in section 1.14. of this document, the recommendation to not trade cattle-derived protein meal, or any commodities containing such products, which originate from a country, zone or compartment posing a controlled or undetermined BSE risk, was moved from point 2 of current Article 11.4.13. to point 3 of Article 11.4.14. (RA&Surv).

As emphasised in section 1.13. of this document, the *ad hoc* Group agreed that current scientific evidence does not support an age limit of 12 months. The *ad hoc* Group therefore recommended removing point 3) of current Article 11.4.14. (RA&Surv).

Editorial changes were proposed to clearly reflect the proposed provisions.

1.17. Current Article 11.4.15. Recommendations for importation of gelatine and collagen prepared from bones and intended for food or feed, cosmetics, pharmaceuticals including biologicals, or medical devices

After reviewing the steps that bones should be subjected to for the preparation of gelatine and collagen, and after considering scientific evidence (reference in RA&Surv), the *ad hoc* Group determined that the provision of exclusion in point 2(a) of current Article 11.4.15. (i.e., “*vertebral columns from cattle over 30 months of age at the time of slaughter and skulls have been excluded*”) could not be justified (RA&Surv).

Annex 35 (contd)

Furthermore, the *ad hoc* Group considered that the steps of the process described in point 2(b) were common industrial practices and were not specifically directed against BSE. Therefore, the *ad hoc* Group contemplated whether, in light of the definition of safe commodities provided in the Glossary and of the provisions of Chapter 2.2., gelatine and collagen prepared from bones and intended for food or feed, cosmetics, pharmaceuticals including biologicals, or medical devices could be considered safe commodities provided they are subjected to the processes currently described in point 2(b) of Article 11.4.15. After seeking advice from the Code Commission, the *ad hoc* Group remain uncertain whether or not this would be fully consistent with Chapter 2.2. As a result, the *ad hoc* Group proposed to maintain this provision in Article 11.4.15. at this stage and to refer the proposal to include it in the list of safe commodities to the Code Commission for further deliberation (RA&Surv).

The Code Commission agreed to include gelatine and collagen prepared from bones in the list of safe commodities. Current Article 11.4.15. was removed.

1.18. Article 11.4.15. Recommendations for importation of tallow (other than as defined in Article 11.4.1.bis) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

The *ad hoc* Group agreed that, based on the evidence available to date, the exclusion of those materials listed in point 1) of Article 11.4.14. in the preparation of tallow, ensures the effective mitigation of potential BSE risks regardless of whether the country, zone or compartment of origin has controlled or undetermined BSE risk status. As a result, the *ad hoc* Group proposed to remove the specific reference to controlled BSE risk in point 2) of current Article 11.4.15. With this change, tallow would be eligible for trade from a country, zone or compartment posing a controlled or undetermined BSE risk as long as it derived from cattle that passed *ante-mortem* inspection and had not been prepared using the commodities listed in point 1 of Article 11.4.14. (RA&Surv).

1.19. Article 11.4.16. Recommendations for importation of dicalcium phosphate (other than as defined in Article 11.4.1.bis) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

As dicalcium phosphate can be considered a co-product of bone gelatine, the *ad hoc* Group recommended that, dicalcium phosphate should either originate from a country, zone or compartment posing a negligible BSE risk, or from products compliant with the requirements of current Article 11.4.15. This is consistent with the opinion of the *ad hoc* Group on BSE which met in August 2016). Therefore, the *ad hoc* Group proposed edits to point 2 to prevent redundancy (RA&Surv).

Furthermore, the *ad hoc* Group clarified that dicalcium phosphate is rather a co-product than a by-product of bone gelatine as it is produced along with gelatine when the material of origin is bone. Both gelatine and dicalcium phosphate share the initial production steps (i.e., decreasing and demineralization) and are both intended outputs of the process.

1.20. Current Article 11.4.18. Recommendations for importation of tallow derivatives (other than those made from tallow as defined in Article 11.4.1.bis) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

The *ad hoc* Group considered the provisions of point 3 of current Article 11.4.18. which recommend that tallow derivatives should have been produced by hydrolysis, saponification or transesterification using high temperature and pressure. The *ad hoc* Group considered that these measures were common industrial practices and were not specifically directed against BSE. Therefore, the *ad hoc* Group contemplated if in light of the definition of safe commodities provided in the Glossary and provisions of Chapter 2.2., tallow derivatives could be considered safe commodities provided they are subjected to the process described in point 3 of current Article 11.4.18. However, after receiving preliminary advice from the Code Commission, the *ad hoc* Group proposed to maintain the corresponding provision at this stage, and to refer the proposal to include it in the list of safe commodities to the Code Commission for further consideration (RA&Surv).

The Code Commission agreed to include tallow derivatives in the list of safe commodities. Current Article 11.4.18. was removed.

1.21. Article 11.4.17. Procedures for the reduction of BSE infectivity in protein meal

No further revisions proposed.

1.22. Article 11.4.18. Surveillance, and Current Articles 11.4.21. and 11.4.22.

The *ad hoc* Group concurred that: (1) a points-based surveillance system could no longer be justified, (2) a baseline level of passive surveillance for BSE should be continuously implemented to identify cattle with a clinical presentation consistent with BSE, (3) the requirements to conduct active surveillance on the risk groups (i.e., fallen stock and casualty slaughter) and on animals from the healthy slaughter subpopulation destined for human consumption should be eliminated, (4) proper implementation of a sensitive passive surveillance program for BSE should be monitored and documented, (5) BSE surveillance should have been in place and documented for at least 8 years to achieve a negligible BSE risk status (details in Surv).

In accordance with the proposed amendments presented in section 1.3.c. of this document, the *ad hoc* Group moved points 2 to 4 of current Article 11.4.2. to points 1(a) to (c) of Article 11.4.18. The *ad hoc* Group recommended editorial changes to state that passive surveillance for BSE should rely on: (1) the compulsory notification of BSE in the whole territory, (2) an ongoing awareness programme maintained to encourage reporting of all suspected cases and to ensure the sensitivity of passive surveillance, and (3) the appropriate laboratory examination and follow-up of any suspect case in accordance with the recommendations defined in Chapter 3.4.5. of the *Terrestrial Manual* (Surv).

In point 2 of Article 11.4.18., the *ad hoc* Group updated the list of behavioural or clinical changes which should give raise to clinical suspicions of classical BSE currently stated in point 1 of Article 11.4.21. (Surv). Currently, BSE clinical suspects are restricted to those aged over 30 months. However, there are instances of field BSE cases being detected below this age limit. As a precautionary measure and with increased reliance on passive surveillance, the *ad hoc* Group proposed that cattle of any age displaying behavioural or clinical signs consistent with BSE should be regarded as clinical suspects (Surv).

For the sake of clarity, the *ad hoc* Group recommended removing general considerations on surveillance not specific to BSE as well as avoiding redundancies between the different articles pertaining to BSE surveillance. Therefore, the *ad hoc* Group recommended defining the provisions for passive BSE surveillance in Article 11.4.18., and deleting current Articles 11.4.21. and 11.4.22. (Surv).

1.23. Current Articles 11.4.23. to 11.4.29. BSE risk assessment

The *ad hoc* Group noted that while Articles 11.4.23. to 11.4.29. set out the requirements for an entry and exposure assessment together with the assumptions, the broad questions to be answered, and the supporting rationale and evidence required for key steps in the risk assessment, these are not fully harmonised with Chapter 1.8. (the 'BSE questionnaire'). As a result, there are a number of inconsistencies that potentially create confusion for Members requesting official recognition by the OIE. To address this issue, the *ad hoc* Group recommended that Articles 11.4.23. to 11.4.29. be deleted from Chapter 11.4. In this way, and to be consistent with the structure of other chapters of diseases that have official recognition, Chapter 11.4. would focus on defining the requirements applicable to the official recognition of BSE risk status, whereas Chapter 1.8. would provide a tool in the form of a questionnaire for Members to provide the relevant information and demonstrate how they fulfil the requirements set in Chapter 11.4. (RA1)

Annex 35 (contd)**2. Revision of Chapter 1.8.****2.1. General considerations**

Major edits in the structure of the BSE questionnaire were done to ensure consistency between relevant proposals in this document and those proposed in the revised draft Chapter 11.4. (RA&Surv)

Proposed amendments considered the experiences of the experts of the *ad hoc* Group that assess applications for official recognition, which identified areas that lack clarity and are commonly misinterpreted by applicants, that are not comprehensive enough to support a fully informed assessment, or, that are not relevant for an evaluation of the BSE risk status (RA2).

The *ad hoc* Group acknowledged that “questionnaires” for the official recognition of status for other diseases (i.e., Chapters 1.7. and 1.9. to 1.12.) do not justify why certain information is necessary nor offer detailed guidelines on how it should be provided. However, the *ad hoc* Group justified that the revised questionnaire should be comprehensive enough to support a fully informed assessment of compliance with the requirements for the recognition of a BSE risk status (RA2 and RA&Surv). This would greatly facilitate the assessment by the OIE as a consequence. Moreover, if this questionnaire is ever removed from the Code at some future point, it will be a well-positioned document to become a stand-alone guideline.

2.2. Article 1.8.1. Guidelines

Article 1.8.1. now provides guidelines for the application for official recognition of BSE risk status, including details of the structure of both the dossier and the core document.

The provisions related to the submission of all relevant legislation are proposed to be included in a dedicated Article 1.8.3. (RA&Surv)

A general description of bovine husbandry and slaughtering practices is currently requested in point 1. However, in accordance with the proposed revisions to Articles 11.4.2. and 11.4.3., the most appropriate place in the questionnaire to request information on all relevant practices related to livestock industry, would be in the exposure assessment (RA1).

The provisions related to the veterinary system are now included in a dedicated Article 1.8.4. (RA&Surv)

2.3. Article 1.8.2. History of occurrence and management of BSE cases in the country or zone

Evidence regarding the historic presence (or absence) of the BSE agent addressed in current BSE questionnaire (current Article 1.8.5.) should still be considered. However, the information on cohorts would no longer be relevant in the assessment in light of the revised provisions of draft Article 11.4.3. (RA1)

Moreover, given the revised provisions in points 3 and 4 of draft Article 11.4.3., details of each detected BSE case, as well as how they were handled should be provided.

2.4. Article 1.8.3. Legislation

Information on the relevant legislation should still be requested. However, having all relevant legislation in a single section of the dossier rather than scattered throughout several sections of the Questionnaire would facilitate the assessment the dossier.

2.5. Article 1.8.4. Veterinary system

Information on the veterinary services (current Article 1.8.1. point 2(a) to (e) should still be requested. However, also information on cattle identification, registration, traceability and movement control system should be provided.

2.6. Article 1.8.5. BSE risk assessment

Consistent with Article 11.4.2, explicit sections on consequence assessment and risk estimation were developed (points 1 to 4 of Article 1.8.5.).

Applicants, and not the OIE, should document the necessary body of evidence and undertake the risk assessment (RA&Surv).

The likelihood estimates, as well as the conclusions of the consequence assessment and the risk estimation should be presented consistent with and based on the guidance provided in the OIE *Handbook on Import Risk Analysis for Animals and Animal Products*¹¹ (RA&Surv).

a) Entry assessment

The *ad hoc* Group highlighted that detailed quantitative information (e.g., volume, statistics, etc.) on imported commodities was not informative for the entry assessment as long as either the commodities were imported under conditions consistent with the recommendations laid out in Chapter 11.4. or it can be demonstrated that an equivalent level of assurance was provided. The emphasis should be on documenting the measures applied to imported commodities depending on the BSE risk status of the country or zone of origin together with how the Competent Authority verifies compliance through supporting legislation, certification, and regulations (RA&Surv).

b) Exposure assessment

The determination of the pathway (i.e., either livestock industry practices or effective and continuous mitigation of each identified risk) to follow during the application for official recognition of its BSE risk status should be based on the conclusions arising from livestock industry practices and the associated likelihood that the cattle population has been exposed to either classical or atypical BSE agents (RA&Surv).

The applicant should provide information on livestock industry practices regardless of the pathway chosen as this provides indispensable background information. If the applicant Member concludes that the likelihood has been non-negligible, an evaluation of BSE specific mitigation measures should be performed. If an applicant Member concludes that the likelihood that the cattle population has been exposed to either classical or atypical BSE agents has been negligible as a result of its livestock industry practices, but the *ad hoc* Group on BSE Risk Status Evaluation of Members reaches a different conclusion, the application for a BSE risk status would be rejected. The applicant Member would then be invited to apply for the recognition of its BSE risk status based on the effective and continuous mitigation of each identified risk (RA&Surv).

See sections 1.8. and 1.9. of this document regarding the determination of the actual period when the likelihood of the BSE agent being recycled in the cattle population has been assessed to be negligible (RA&Surv).

¹¹ <https://doc.oie.int/seam/resource/directMedia/Zb-9qYZskLnFILt2I38xzS9KEFngaTIS?binaryFileId=16619&cid=432> and <https://doc.oie.int/seam/resource/directMedia/Zb-9qYZskLnFILt2I38xzeqTpRHNq5CT?binaryFileId=16620&cid=432>

Annex 35 (contd)**c) *Consequence assessment and risk estimation***

These sections were added to reflect the new provisions defined in draft Article 11.4.2. (RA&Surv).

The series of events that could initiate a cycle of BSE infectivity within a cattle population are explained (RA&Surv).

Any level of recycling within a given period will be sufficient to conclude that the consequences of exposure to contaminated feed within the cattle population was non-negligible for that period (RA&Surv).

2.7. Article 1.8.6. BSE surveillance

Current Article 1.8.4. on BSE surveillance was revised to reflect the new provisions for BSE surveillance defined in draft Article 11.4.18. (RA&Surv).

2.8. Article 1.8.7. Recovery of a BSE risk status

Guidance is given for Members applying for the recovery of a previously recognised negligible BSE risk status suspended following non-compliance with any of the 4 provisions of draft Article 11.4.3, including the occurrence of an indigenous case of classical BSE in an animal born within the preceding 8 years (RA&Surv).

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