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REPORT OF THE MEETING OF THE OIE AD HOC GROUP ON BOVINE SPONGIFORM ENCEPHALOPATHY SURVEILLANCE[1]

Paris, 3 – 5 October 2018

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The OIE *ad hoc* Group on bovine spongiform encephalopathy (BSE) surveillance (hereafter the Group) met from 3 to 5 October 2018 at the OIE Headquarters to provide independent analysis and advice to the OIE on the surveillance provisions applicable for the initial recognition and maintenance of controlled and negligible BSE risk status.

1. Opening

Dr Matthew Stone, Deputy Director General of the OIE, welcomed the Group convened to revise the provisions of the *Terrestrial Animal Health Code* (*Terrestrial Code*) Chapter 11.4. pertaining to BSE surveillance.

Dr Stone emphasised that the revision of the BSE standards was considered a priority for the OIE and its Members as the current standards may not be appropriate to the current BSE risk. Indeed, as a result of the successful implementation of effective control measures to mitigate the risk of infection, recycling and amplification of the prion, the incidence and global importance of classical BSE have markedly decreased over the past years. Within-country epidemics are clearly in decline and there is a need to revise OIE's standards pertaining to BSE surveillance accordingly.

Dr Stone insisted that whilst BSE might be a sensitive and political issue, the Group's proposals should be scientifically driven and risk-based. He also encouraged the Group to capture the rationale supporting its proposals and recommendations in its meeting report for the consideration of Members.

Dr Stone noted that this Group articulates with another BSE *ad hoc* Group focusing on BSE risk assessment which met in July 2018 and will meet again in November 2018, and that some experts participate in the two Groups to ensure a consistent revision of the overall BSE framework.

Dr Neo Mapitse, Head of the Status Department, thanked the experts for having signed the forms for undertaking of confidentiality and declaration of conflicts of interest, and noted that no conflict of interest had been declared.

2. Adoption of the agenda and appointment of chairperson and rapporteur

Dr Noel Murray was appointed Chair and Dr Mark Stevenson was the rapporteur with the support of the OIE Secretariat. The Group endorsed the proposed agenda for the meeting.

The terms of reference, agenda and list of participants are provided as Appendices I, II and III respectively.

[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 February 2019 report of the Scientific Commission for Animal Diseases because this report provides its considerations and comments. It is available at: http://www.oie.int/en/international-standard-setting/specialists-commissions-groups/scientific-commission-reports/meetings-reports/

3. Considerations of the current provisions for BSE surveillance

The Group discussed the current provisions for BSE surveillance defined in Articles 11.4.20. to 11.4.22. of the *Terrestrial Code*.

3.1. Current provisions

The design prevalence for achieving and maintaining an official BSE risk status is set at either 1 per 50,000 cattle for negligible BSE risk status or 1 per 100,000 cattle for controlled BSE risk status.

Four subpopulations of cattle are identified for surveillance purposes: routine (or healthy) slaughter, fallen stock, casualty slaughter and clinical suspects. Samples should be collected from at least three of them.

A surveillance point value is assigned to each sample based on the age of the animal and the subpopulation from which it was collected. Specific surveillance point values were defined based on the likelihood of detecting infected cattle in a particular subpopulation within a certain age class as estimated by a statistical model (BSurvE Prattley *et al*. 2007[2]) that was developed with data from the European Union (EU) at the peak of the BSE epidemic.

A minimum number of points to be collected (i.e., the surveillance points target) is determined based on the size of the adult (>24 months old) cattle population. The required number of surveillance points should be achieved over a maximum of seven consecutive years to substantiate a claim that the prevalence of BSE is at 1 per 100,000 or 1 per 50,000 design prevalence, or below, in support of the official recognition and maintenance of a controlled or negligible BSE risk status.

3.2. Historical perspective of the current provisions

The current surveillance provisions for BSE were developed at a time of great uncertainty regarding the global distribution of BSE and its prevalence within a country's cattle population. Furthermore, although initial studies had indicated that control measures such as a ban on feeding ruminants with meat-and-bone meal or greaves should be effective, just how effective they might be in controlling or eliminating BSE was yet to be demonstrated.

The Group acknowledged that BSE surveillance to date has generated a wealth of valuable information, particularly from the EU and Japan where much more extensive surveillance programs have been implemented than those recommended in Articles 11.4.20. to 11.4.22. of the *Terrestrial Code*. Essentially, all animals from each of the respective subpopulations above a certain age threshold including routine (or healthy) slaughter have been tested for BSE. Modifications have been made over the years, progressively increasing the minimum age of testing as the epidemic has declined. These programs have convincingly demonstrated the effectiveness of the various control measures as evidenced by a rapid and sustained decline in the incidence of classical BSE. Time series analysis carried out over the last 10-year period (2008–2017) showed a significant decreasing trend in the occurrence of classical BSE in the EU with an annual decrease of 38% in the proportion of cases per tested animals[3]. In a recently published study[4], a similar rate of decline was reported for the cases born after the "total[5]" feed ban (BARB) across EU. The consistent implementation of surveillance during a 17-year period (2001-2017) has allowed the year-by-year comparison and overall trend analysis of the incidence of BSE in the EU, showing a constant decline on the number of clinical cases of classical BSE, as illustrated in Figure 1.

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2 Prattley D, Cannon R, Wilesmith J, Morris R, Stevenson M. (2007). A model (BSurvE) for estimating the prevalence of bovine spongiform encephalopathy in a national herd. Preventive Veterinary Medicine 80:330-343. Doi: 10.1016/j.prevetmed.2007.03.007

3 European Food Safety Authority (2017). Scientific report on the European Union summary report on surveillance for the presence of transmissible spongiform encephalopathies (TSE) in 2016. EFSA Journal 15(11):5069, 68 pp.

4 Arnold ME, Simons RR, Hope J, Gibbens N, Adkin AL. (2017) Is there a decline in bovine spongiform encephalopathy cases born after reinforced feed bans? A modelling study in EU member states. Epidemiology & Infection 145(11):2280-2286.

5 Under the total feed ban the feeding of all processed animal proteins (PAPs) was banned from feeding to all farmed animals.

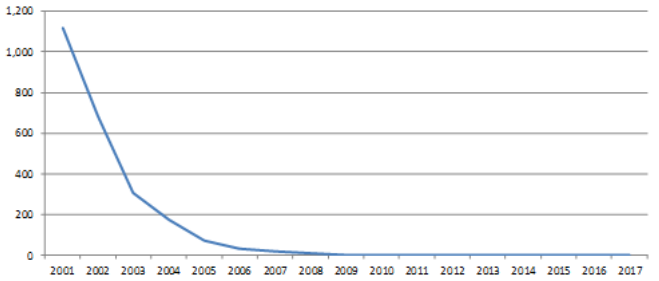

Figure 1: Number of clinical cases of classical BSE confirmed in the EU in the period 2011-2017[6]

When Canada reported its first case of classical BSE in 2003, the first report of an indigenous case of classical BSE had not occurred in any country worldwide in over 15 years. In the intervening years, although several Members have reported cases for the first time, they were all atypical BSE cases. Worldwide, 2017 was the first year in which no indigenous cases of classical BSE were reported. As stated in Article 11.4.1. of the *Terrestrial Code*, atypical BSE is a condition believed to occur spontaneously in all cattle populations at a very low rate and is excluded for the purposes of official recognition of a country's BSE status. Its detection in Members previously unaffected by classical BSE provides a surrogate indicator that they have been sampling at a sufficient intensity to detect classical BSE if it was actually present.

3.3. Lessons learned and implications for the future

The Group identified and discussed a number of issues that have arisen over the years that point to a need to review current BSE surveillance provisions, in particular:

- Surveillance has emerged as a significant roadblock for some low and middle-income Members in attaining an official BSE-risk status. As outlined in Section 3.1. of this report, for an official BSE risk status to be recognised by the OIE, a country must not only demonstrate through a risk assessment that appropriate measures have been taken to manage identified risks, but they must also demonstrate that they have met the relevant surveillance points target. For example, some Members may have been able to demonstrate that appropriate BSE control measures have been taken, but have failed to qualify for an official BSE risk status since they have not met their points target. This reflects a potential misalignment between the outcome from a risk assessment and the final categorisation of the BSE risk status of a country or *zone*. In such circumstances, BSE surveillance provisions arguably pose an artificial obstacle. Attempts to meet the surveillance points target can result in a disproportionate allocation of scarce resources as well as significant delays in achieving a particular status.

- The clinical suspect surveillance subpopulation is assigned a much higher point value than the other surveillance subpopulations. In an attempt to maximise the number of accumulated surveillance points, some Members have claimed more animals as clinical suspects than would appear to be reasonably justified. For example, cattle may be claimed as clinical suspects based solely on an ante-mortem inspection at slaughter without supporting evidence that the animals were affected by an illness that was refractory to treatment and displaying progressive behavioural changes or neurological signs.

- While the current provisions require that cattle be sampled from three of the identified four subpopulations, based on the reports on the annual reconfirmation assessments for maintenance of official status, not all Members have been doing so[7]. Historically, stratification into four subpopulations was based on European experiences, with point values based on age and subpopulation as elaborated

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6 European Commission TSE surveillance database. The 2001-2015 annual reports are available at https://ec.europa.eu/food/safety/biosafety/food_borne_diseases/tse_bse/annual-reports_en . The 2016 annual report is available at https://efsa.onlinelibrary.wiley.com/journal/18314732

7 Annex 17 of the Report of the Scientific Commission for Animal Diseases in February 2017, and Annex 18 of the Report of the Scientific Commission for Animal Diseases in February 2018.

in BSurvE. While such an approach might be suitable for those Members where cattle are intensively reared and subjected to regular observation, in more extensive systems where cattle are not monitored closely, it may be difficult to stratify cattle into these streams. Situations would inevitably arise where an animal might be considered to be a clinical suspect, yet if it was not observed for a period of time it may well be seen for the first time as a downer (non-ambulatory) or found dead (fallen stock). Under such circumstances assigning an animal to a particular surveillance subpopulation is highly dependent on when it was first observed in the continuum of a progression from clinical suspect to downer to fallen stock.

- It is apparent that Members with small cattle populations continue to struggle to reach their surveillance points target. It is also evident from the reports on the annual reconfirmation assessments for maintenance of official status[7] that some Members are having difficulty in maintaining their points target. These Members have been cautioned of the shortfall in surveillance points and requested to rectify the situation in future years.

- An implicit assumption embedded in the current surveillance provisions is that the exposure risk in a cattle population of a country is essentially homogenous across and within cohorts. As a result, the relative value of an animal in terms of detecting BSE is simply weighted by its age and corresponding surveillance subpopulation. Depending on the particular local circumstances, some sectors of the cattle population may not have been exposed, such as those reared under extensive pastoral conditions, but they still remain as candidates for surveillance. Ideally, based on the results from an exposure assessment and assuming that contaminated feed is the only or the most likely source of the classical BSE agent, those sectors of the cattle population that have not been potentially exposed to feed potentially contaminated with ruminant meat-and-bone meal (MBM) should not be targeted for surveillance. Including cattle from unexposed sectors is not only inefficient, but inferences regarding the "standing" cattle population may also result to be uninformative.

- The surveillance point values in the current provisions are derived from BSurvE, which draws on estimates of the incubation period of BSE from the United Kingdom (UK) as well as data on the respective subpopulations from the EU in the early to mid-2000s. Concerns have been expressed that they may no longer reflect the likelihood of detecting infected cattle today, particularly in those Members on the tail end of an epidemic where the age of the few remaining BSE cases is progressively increasing and fewer animals are identified as clinical suspects. In addition, it is unlikely that they have ever been broadly applicable for many non-European countries, especially those with significantly different production systems.

- The implementation of the current surveillance provisions with a focus on achieving and maintaining a surveillance points target can be extremely costly. For example, in the EU, the average cost of detecting one BSE case between 2001 and 2004 was estimated to be 1.56 million Euros for the routine slaughter surveillance subpopulation and 0.07 million Euros for the risk animal surveillance subpopulations (fallen stock, casualty slaughter, and at *ante mortem* inspection)[8]. In the EU in 2008, the cost of detecting a single BSE case was 14.1 million Euros for cattle processed at abattoirs[9] and in 2014 the cost of detecting a single case of BSE for the fallen stock surveillance subpopulation was 13 million Euros[10]. This has posed, and continues to pose, a significant barrier for Members where resources are limited and other more urgent animal health priorities predominate. Surveillance is, after all, just one of many pieces of evidence that should be taken into account in evaluating a BSE risk status. An important objective in defining surveillance requirements is to ensure that they are both achievable and implemented to the extent that is reasonably necessary without imposing an undue burden on Members.

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8 The TSE roadmap. Brussels, 15 July 2005 COM(2005) 322 FINAL

9 The TSE roadmap 2. Brussels, 16 July 2010 COM(2010) 384 FINAL https://ec.europa.eu/food/sites/food/files/safety/docs/biosafety_food-borne-disease_tse_road-map2.pdf

10 Using the estimated cost per sample of fallen stock in 2014 for the UK by Wall BA, Arnold ME, Radia D, Gilbert W, Ortiz-Pelaez A, Stärk KD, Van Klink E, Guitian J. (2017) Evidence for more cost-effective surveillance options for bovine spongiform encephalopathy (BSE) and scrapie in Great Britain. Eurosurveillance 22(32):30594

Overall, the Group concluded that the goals of BSE surveillance needed to be redefined. A great deal of experience has been gained with BSE over the last several decades, which means that the uncertainties that historically existed no longer prevail. It is now evident that the various risk mitigation measures, including feed bans, have been effective. The Group emphasised that while the current surveillance provisions have served their purpose adequately, they also have significant drawbacks. As alluded to in the preceding paragraphs, a point-based surveillance system has led to a number of unintended consequences. It can be expensive to implement and maintain, and has led to significant and perhaps insurmountable delays in some Members achieving controlled or negligible BSE-risk status. These Members are likely to be discriminated against in the international trade environment; especially those that could reasonably claim on the basis of a risk assessment, that the BSE risks are being effectively mitigated. Some Members have manipulated the points system to their advantage by claiming more clinical suspects than would appear to be justified. For others with small cattle populations, meeting their points target is an ongoing struggle.

4. Proposed changes for BSE surveillance

The Group discussed at length the role that BSE surveillance plays in support of initial recognition and maintenance of an official BSE risk status, together with the surveillance strategy that would be the most appropriate for the later phase of BSE epidemics in Members.

4.1. Defining a surveillance strategy for the future

The Group noted that, according to Article 11.4.1. of the *Terrestrial Code*, "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 Group therefore emphasised that BSE surveillance in support of the initial recognition and maintenance of an official BSE risk status should focus on classical BSE in cattle.

As outlined in Article 11.4.20. of the *Terrestrial Code*, under the current surveillance provisions there are one or more goals depending on the risk category of a country or *zone*: to detect BSE at a pre-determined design prevalence, to monitor the evolution of BSE including the effectiveness of mitigation measures such as a feed ban, and to provide sufficient information to provide support for a claimed BSE status. As discussed in Section 3.2. of this report, surveillance programs implemented over many years in those Members with classical BSE have provided critical insights into the evolution of BSE and have convincingly demonstrated the effectiveness of mitigation measures, particularly those associated with a feed ban. As a result, the Group concluded that since the relevant control measures for BSE are well-established and that sufficient evidence has been accumulated, the goals associated with monitoring the evolution of BSE and demonstrating the effectiveness of mitigation measures through surveillance have been met. Given that BSE is a rare disease, monitoring the effectiveness of measures through testing of individual animals for the presence of infection can be extremely expensive. To satisfy statistical requirements, very large sample sizes are required. For example, it was estimated that, in the absence of testing of routine slaughter, Cyprus would need to test 98.7% of their total standing cattle population to detect at least 1 case per 100,000 animals with a 95% confidence level; that would require that almost all the cattle population of Cyprus would have to die on farm and be tested in a single year to meet the requirements[11]. As a result, ongoing efforts would be more appropriately channelled into maintaining and monitoring the rigorous and continuous implementation of the various mitigation measures in the field. Furthermore, monitoring their implementation indirectly through surveillance is not a strategy that can be recommended given the long lag times involved as a result of the protracted incubation period for BSE. This approach does not allow for the rapid implementation of corrective actions.

The key goal of the current surveillance provisions has been to detect BSE, if it were present in a country at predetermined design prevalence of either 1 in 100,000 cattle (Type A Surveillance) or 1 in 50,000 cattle (Type B Surveillance). A points target is laid out in Article 11.4.22. of the *Terrestrial Code* (Table 1) based on the design prevalence and the size of the adult cattle population. If a Member meets its points target,

[11] Source: European Food Safety Authority (2016). Evaluation of the revision of the BSE monitoring regime in Croatia. EFSA Journal 14(2):4399; 27 pp.

then it can be concluded that it is sampling at a sufficient intensity to detect BSE if it were present at the nominated design prevalence. This would in turn provide confirmation of the conclusions arising from the risk assessment by demonstrating the effectiveness of the risk mitigation measures. However, as discussed above, as a result of the prolonged incubation period for BSE, there is a considerable lag time involved. Furthermore, as discussed in Section 3.2. there are a number of challenges in implementing and maintaining these types of surveillance programs: they can be very expensive; it is difficult to justify the diversion of scarce resources to implement them in low and middle-income Members; the points system is subject to manipulation; and for a number of Members, particularly those with small cattle populations, it is an ongoing struggle to meet the points target.

Recognising these challenges, the Group considered two different options:

- Reduce the number of subpopulations from four to two: routine slaughter and a broad risk class by combining clinical suspects, casualty slaughter and fallen stock. This approach would address those issues identified in Section 3.2. associated with over-stratification and manipulation of the points system. Since the point value derived from BSurvE is simply a ratio of the probability that an infected animal would leave the population via subpopulation *j* at age *t* and test positive compared to the probability that an uninfected animal would leave via the same subpopulation at the same age, the various subpopulations can be readily combined. The Group considered the point values estimated by an expert of the Group based on an update of BSurvE taking into account these two subpopulations and data from the EU.

- Target only the risk groups, including clinical suspects, casualty slaughter and fallen stock. Indeed, the Group took note, based on data from the EU, that the likelihood of detection of BSE cases at routine slaughter is extremely low compared with other subpopulations. In 2004, 11 million cattle were tested in the EU and 864 cases of BSE were confirmed. The surveillance stream that had the largest probability of detecting cases was the clinical suspects (5.6% of all tested clinical suspects resulted positive), followed by the 'risk group' composed of fallen stock, casualty slaughter and with observations at *ante-mortem* inspection (with 0.03%). However, only 0.002% of the animals tested at routine slaughter resulted positive[12]. However, the Group pointed out that the prevalence of clinical cases is likely to be much lower nowadays than in 2004, and therefore considered that this approach would place too much emphasis on clinical suspects in the current epidemiological context. Furthermore, as emphasised in Section 3.3. of this report, experience has shown that higher points value for clinical suspects can result in manipulations of the points system by Members.

In addition to targeting certain subpopulations, further targeting of animals within those subpopulations could be considered by focussing on those sectors of the cattle population that are more likely to be exposed to feed potentially contaminated with ruminant MBM or greaves based on the outcome from a risk assessment that takes into account cattle husbandry, production, feeding and slaughter practices. For example, mature dairy or beef cattle reared as replacement heifer calves that were fed with commercially prepared milk replacer or starter rations, could be targeted for surveillance, whereas cattle reared exclusively on pasture would not. Under this scenario a risk-based surveillance strategy would be designed on a country-by-country basis in light of a thorough description of the cattle production system(s) present in each country and of the outcome of a risk assessment. Each Member would need to define a risk-based surveillance strategy fit for their purposes. This would address those concerns identified in Section 3.2. associated with testing animals, such as those raised in extensive pastoral systems that have never been exposed to potentially contaminated feed and would not yield any useful information.

Following extensive discussions of these options, including an analysis of the likely number of animals to test, the Group determined that these options would not resolve the underlying challenges associated with setting and meeting an overall points target that was both realistically achievable and did not have significant resource implications. The Group recognised that the points-based system has served its purpose reasonably well up to now, although there have been some difficulties and unintended consequences.

[12] https://ec.europa.eu/food/sites/food/files/safety/docs/biosafety_food-borne-disease_tse_ms-annual-report_2004.pdf

The Group was briefed on the outcomes of the first meeting of the *ad hoc* Group on BSE Risk Assessment from 3-5 July 2018, in particular about the categorisation of negligible BSE-risk status. Under the provisions proposed by this *ad hoc* Group, the BSE-risk status of a country would be determined from a detailed consideration of comprehensively documented risk assessment (entry assessment, exposure assessment, consequence assessment, and risk estimation). Two pathways were proposed for a country to demonstrate that the likelihood of the cattle population being exposed to the BSE-agent has been and continues to be negligible for at least 8 years: either, as a result of the husbandry and farming practices (e.g., extensive pastoral systems); or, based on the continuous and effective implementation of mitigation measures to prevent the recycling of the BSE-agent in the cattle population. Under these provisions, since the likelihood of the occurrence of classical BSE would have been determined to be negligible, the Group considered that a points-based surveillance system could no longer be justified as the level of investment required cannot be considered to be cost effective. It would also be disproportionate to the risk.

This position was further supported by a recent publication that estimated the time it would take for a surveillance program to detect a theoretical re-emergence of BSE in a cattle population. If both active and passive surveillance were implemented, it would take 15 years, whereas a system relying solely on passive surveillance would only be delayed by two more years[13]. Considering the likely investment required to implement an active surveillance program, it is apparent that the costs would by far exceed those of a passive program, for very little additional gain in the likely time to detect disease re-emergence.

The Group concurred that surveillance should always have played a secondary role in evaluating the BSE-risk status of a country. The primary focus should be on a transparently documented and comprehensive risk assessment that includes a detailed evaluation of husbandry and farming practices as well as the continuous and effective implementation of relevant mitigation measures with the ongoing results of a surveillance program taken into account.

Overall, the Group concluded that a baseline level of surveillance should continue with the focus being on cattle identified with a clinical syndrome consistent with BSE (refractory to treatment, displaying progressive behavioural changes or neurological signs). This would include animals on a continuum of a progression from clinical suspect to downer to fallen stock with an appropriate supporting history. Such animals should be subject to compulsory notification supported by an awareness program and examination of brain samples in a laboratory as outlined in Articles 11.4.2. and 11.4.3. Such a surveillance strategy, referred to as passive surveillance, would have the goal of detecting a potential emergence or re-emergence of classical BSE in the cattle population.

5. Proposals for revised provisions for BSE surveillance

The Group revised the provisions for the initial recognition and maintenance of negligible (Article 11.4.3.) and controlled (Article 11.4.4.) BSE-risk status, as well as the detailed provisions for BSE surveillance (Articles 11.4.20. to 11.4.22.), in light of the surveillance strategy defined in Section 4 of this report.

5.1. Surveillance in support of the initial recognition and maintenance of BSE negligible risk status (Article 11.4.3. of the *Terrestrial Code*)

The Group determined that an ongoing robust passive surveillance program for BSE should be in place. Consistent with the recommendation of the *ad hoc* Group on BSE risk assessment, the Group recommended that should an indigenous case of classical BSE be detected, a follow up field epidemiological investigation should be undertaken to identify potential sources of exposure.

Consistent with the current provisions for BSE surveillance, the Group recommended that BSE surveillance should have been in place and documented for at least 7 years to achieve a negligible BSE risk status.

For the maintenance of negligible BSE-risk status, documentary evidence on the implementation of the passive surveillance program and its results should be provided each year.

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[13] Simons R., Arnold M., Adkin A. (2017) Assessing the time taken for a surveillance system to detect a re-emergence of bovine spongiform encephalopathy in cattle. *Preventive Veterinary Medicine*, 13:48–54.

Article 11.4.3. (Negligible BSE risk) was revised to reflect these provisions.

The Group noted that revisions to the "BSE Questionnaire" (Chapter 1.8. of *Terrestrial Code*) and to the annual reconfirmation form for BSE would be needed to reflect the proposed changes in BSE surveillance in support, respectively, of the initial recognition and maintenance of an official negligible BSE risk status, and suggested this be addressed by the *ad hoc* Group on BSE risk assessment at its next meeting.

5.2. Surveillance in support of the initial recognition and maintenance of BSE controlled risk status (Article 11.4.4. of the *Terrestrial Code*)

The Group noted, that under the provisions proposed by the *ad hoc* Group on BSE risk assessment, countries and *zones* which can demonstrate compliance with the requirements for negligible BSE-risk status, but not yet for the relevant period of time, would qualify for recognition as having a controlled BSE risk. As such, controlled BSE-risk status would represent an intermediate step for Members as they work towards achieving negligible BSE-risk status. The Group fully supported this approach and therefore concurred that the nature of the surveillance provisions in support of the initial recognition and maintenance of a controlled BSE risk status should be similar to those in support of the initial recognition and maintenance of a negligible BSE risk status.

Article 11.4.4. (Controlled BSE risk) was revised to reflect these provisions.

The Group noted that revisions of the "BSE Questionnaire" (Chapter 1.8. of *Terrestrial Code*) and of the annual reconfirmation form for BSE would be needed to reflect the proposed changes in BSE surveillance in support, respectively, of the initial recognition and maintenance of an official controlled BSE risk status, and suggested this be addressed by the *ad hoc* Group on BSE risk assessment at its next meeting.

5.3. Detailed provisions for BSE surveillance (Articles 11.4.20. to 11.4.22. of the *Terrestrial Code*)

The Group revised Articles 11.4.20. to 11.4.22. of the *Terrestrial Code* pertaining to BSE surveillance.

For the sake of clarity, the 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 Group recommended defining the provisions for passive BSE surveillance in revised Article 11.4.20., and removing Article 11.4.21. and Article 11.4.22.

The Group recommended that passive surveillance for BSE should rely on the compulsory notification of any susceptible animal showing clinical signs suggestive of BSE in the whole territory, as well as the appropriate laboratory examination of any suspect case in accordance with the recommendations defined in Chapter 2.4.5. of the *Terrestrial Manual*. Furthermore, the Group stressed that a continuous awareness programme for BSE should be maintained to encourage reporting of all cases suggestive of BSE and to ensure the sensitivity of passive surveillance.

Regarding BSE clinical suspects, in light of the description of clinical signs usually associated with classical BSE cases as reported by the Animal & Plant Health Agency and others[14], the Group updated the list of behavioural or clinical changes which should give raise to clinical suspicions of classical BSE. Clinical suspects would be animals identified with a clinical syndrome consistent with BSE (i.e., displaying progressive behavioural changes or neurological signs that are refractory to treatment). This would include animals on a continuum of a progression from clinical suspect to downer (or non-ambulatory) to fallen stock with an appropriate supporting clinical history. Clinical signs may include *"progressive behavioural changes that are refractory to treatment such as increased excitability, depression, nervousness, excessive and asymmetrical ear and eye movements, apparent increased salivation, increased licking of the muzzle, teeth grinding, hypersensitivity to touch or/and sound (hyperaesthesia), tremors, excessive vocalization,*

[14] [1] Animal Health and Plant Agency (APHA). Clinical signs of bovine spongiform encephalopathy in cattle. February 2017. https://science.vla.gov.uk/tse-lab-net/documents/clinical-signs-bse--cattle-video.pdf, [2] Konold G, Bone S, Ryder S, Hawkins AC, Courtin F, Berthelin-Baker C. (2004) Clinical findings in 78 suspected cases of bovine spongiform encephalopathy in Great Britain T. Veterinary Record. 155: 659-666, [3] Saegerman C, Speybroeck N, Roels S, Vanopdenbosch E, Thiry E, Berkvens D. (2004) Decision support tools for clinical diagnosis of disease in cows with suspected bovine spongiform encephalopathy. Journal of Clinical Microbiology. 42(1):172–178, [4] Winter MH, Aldridge BM, Scott PR, Clarke M. (1989) Occurrence of 14 cases of bovine spongiform encephalopathy in a closed dairy herd. British Veterinary Journal. 145(2):191-194.

panic-stricken response, and excessive alertness; postural and locomotory changes such as abnormal posture (dog sitting), abnormal gait (particularly pelvic limb ataxia), low carriage of the head (head shyness), difficulty avoiding obstacles; inability to stand and recumbency; generalised non-specific signs such as reduced milk yield, loss of body condition, weight loss, bradycardia and other disturbances of the cardiac rhythm". The Group noted that cases may display only some of these signs, which may also vary in severity, and that such animals should still be investigated as BSE clinical suspects.

Furthermore, the Group suggested that cattle of any age displaying behavioural or clinical signs consistent with BSE should be regarded as clinical suspects. At the current time, BSE clinical suspects, as defined in Article 11.4.21. point 1, are restricted to those aged over 30 months. However, there are instances of field BSE cases being detected below this age limit. Based on the UK data (as of September 2018), 52 cases out of a total of 181,135 cases were aged below 31 months, with the youngest aged just 20 months. As a precautionary measure and with increased reliant on passive surveillance, the Group recommended there should be a broader index of suspicion of disease with the removal of any age limit.

The Group emphasised that since BSE causes no pathognomonic clinical signs, all Members with cattle populations will observe individual animals displaying clinical signs consistent with BSE. All clinical suspects reported should be documented when applying for the initial recognition of an official BSE risk status as well as in support of the maintenance of an official BSE risk status in order to demonstrate that a sensitive passive surveillance for BSE has been implemented.

6. Further considerations

The Group suggested that the Group on BSE risk assessment should complement draft Article 1.4.3. point 4 to define the impact of the occurrence of indigenous case(s) of BSE on negligible BSE risk status, and drafted a proposal for the consideration of this Group.

The Group advised that the Group on BSE risk assessment should reassess the time periods defined in Article 1.4.3. (i.e., eight years for the risk assessment and for the control of feed, and seven years for mitigation measures including surveillance) and align them, if deemed appropriate.

The Group recommended that consistency should be ensured between the list of behavioural or clinical signs related to BSE defined in the revised Article 11.4.20. of the *Terrestrial Code* and those listed in Chapter 2.4.5. of the *Terrestrial Manual*.

The Group noted that due to the nature of BSE, OIE standards are likely to require reassessment in the future in light of new scientific evidence and the evolution of the global situation of BSE.

The Group emphasised that training by the OIE on the procedures and requirements for the official recognition of the BSE risk status of a country or *zone* would be beneficial for Members once the revised provisions come into force.

7. Finalisation and adoption of the draft report

The Group reviewed and amended the draft report. The Group agreed that the report reflected the discussions.

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…/Appendices

Appendix I

MEETING OF THE OIE AD HOC GROUP

ON BOVINE SPONGIFORM ENCEPHALOPATHY SURVEILLANCE

Paris, 3 – 5 October 2018

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Terms of Reference

Purpose

The purpose of this *ad hoc* Group is to provide independent analysis and advice to OIE on the surveillance provisions applicable for the initial recognition and maintenance of controlled or negligible BSE risk status.

Functions

This *ad hoc* Group will report to the Director General of the OIE, and approved reports will be considered by the relevant Specialist Commissions (the Scientific Commission or the Terrestrial Animal Health Standards Commissions) when necessary, in accordance with the OIE Basic Texts.

In light of the recommendation of the BSE risk assessment *ad hoc* Group, the responsibilities of this *ad hoc* Group will be to review scientific evidence, provide guidance and draft recommendations on the provisions for BSE surveillance (Chapter 11.4., Chapter 1.8., and provisions for annual reconfirmation), in particular:

1. Define the purpose, the need for, and the type(s) of surveillance for initial recognition and maintenance of status, taking into account the outcome of the risk assessment;

2. Give special attention to the cost-effectiveness of the surveillance provisions as well as to their global applicability (i.e., including to countries with small cattle populations and countries with limited resources);

3. Review literature which could inform the revision of the surveillance requirements as well as refinements to the existing model for BSE surveillance or the development of a new model; and

4. The revision of the BSE Questionnaire (Chapter 1.8. of the *Terrestrial Code*) to ensure consistency with the proposed revisions to Chapter 11.4. of the *Terrestrial Code*.

The potential impact of updated surveillance requirements on the status of countries or *zones* already having an officially recognised BSE risk status will be carefully considered.

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Appendix II

MEETING OF THE OIE AD HOC GROUP
ON BOVINE SPONGIFORM ENCEPHALOPATHY SURVEILLANCE
Paris, 3 – 5 October 2018

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Agenda

1. Opening.

2. Adoption of the agenda and appointment of chairperson and rapporteur.

3. Review of the Terms of Reference (ToR) and definition of the work plan:

    - Considerations on the current provisions for BSE surveillance
    - Proposed change of paradigm for BSE surveillance
    - Proposals for revised provisions for BSE surveillance
    - Further considerations

4. Adoption of the report.

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Appendix III

MEETING OF THE OIE AD HOC GROUP

ON BOVINE SPONGIFORM ENCEPHALOPATHY SURVEILLANCE

Paris, 3 – 5 October 2018

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List of participants

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