Network on BSE-TSE
Minutes of the 12th meeting

Held on 16-17 October 2017, Parma

(Agreed on 4 December 2017)

Participants

- **Network Representatives of Member States (including EFTA Countries):**

Country	**Name**[1]
Austria	Hermann Schildorfer
Belgium/Luxemburg	Stefan Roels
Bulgaria	Ilian Boykovski
Croatia	Branko Sostaric, Karmen Branovic
Cyprus	Penelope Papasavva-Stylianou
Czech Republic	Pavel Vodrážka
Denmark	Tim Kaare Jensen
Estonia	Olga Piirik
Finland	Tapani Lyytikäinen
France	Thomas Maignien
Germany	Anne Balkema Buschmann
Greece	Vaia Palaska
Hungary	Eszter Kanyorszky
Ireland	Michael Horan
Italy	Giuseppe Ru, Romolo Nonno, Daniela Meloni
Lithuania	Kristina Stakyte
The Netherlands	O.F.J. (Olaf) Stenvers
Poland	Miroslaw Pavel Polak
Romania	Theodora Chesnoiu Vasile
Slovakia	Martin Mojzis
Slovenia	Polona Juntes
Spain	Soledad Collado Cortés
Sweden	Maria Nöremark
United Kingdom	John Spiropoulos
Norway	Michael A. Tranulis
Switzerland	Peter Braam

1 Indicate first full name and them surname (John Smith) all throughout the document

- **Hearing Experts**

Stefanie Czub, Sandor Dudas (Canadian & OIE Reference Laboratories for BSE, Canadian Food Inspection Agency – web-conference, for point 4.5)

Takateru Daikai (Food Safety Commission of Japan – web-conference, for point 6.1)

- **European Commission:**

Lucie Carrouée (DG-SANTE)

- **EFSA:**

BIOCONTAM Unit (Pietro Stella – chair; Angel Ortiz Pelaez – secretariat; Yves Van Der Stede)

- **Others:**

Anna-Maria Baka (OIE)

16 October 2017

1. Welcome and apologies for absence

Pietro Stella, the Chair, welcomed the participants. Apologies were received from Sigrún Bjarnadóttir (Iceland), Edvins Olsevskis (Latvia) and Maria Jose Pinto (Portugal). Due to flight delays, the representatives of Bulgaria (Ilian Boykovski) and Norway (Michael Tranulis) were not present at the beginning of the meeting but they joined during.

2. Adoption of agenda

The agenda was adopted without changes.

3. Review the minutes of the 11th meeting of the Network on BSE-TSE held on 5-6 October 2016, Parma.

The minutes were agreed by written procedure on 2 December 2016 and published on the EFSA website on 23 December 2016.

4. Topics for discussion

4.1. Round-the-table on activities of Network Members in the TSE field since the last meeting

The Members of the Network provided an update on TSE-related scientific activities, with special interest on Chronic Wasting Disease (CWD), including risk assessments and other initiatives, which had been undertaken in their respective countries since the previous Network meeting. Belgium reported testing for CWD in cervids with no positive results. Cyprus had still many cases of scrapie in goats and expects changes in the EU legislation with regards the breeding for resistance in goats. Estonia reported a suspect case of CWD in moose shown behavioural changes, but resulted negative. Finland reported a forthcoming

publication on the analysis of surveillance data for scrapie. France lost the BSE negligible risk status in 2016 due to a case of classical BSE, published a risk assessment on SRM in small ruminants and asked for feedback from other countries about the efficiency of disinfection methods applied in farms affected with scrapie. Greece reported the lack of resources the reason why not all test results for TSE surveillance are uploaded into the database and reported. Lithuania reported the preparations for the implementation of the surveillance programme for CWD, and so did Poland. Romania highlighted that more than 2,000 wild/hunted cervids were tested in 2016 for TSE. The National Scrapie Plan of Slovenia was approved by the EC in 2016 and the network member reported the participation in the BTSF trainings for TSE during the last three years, funded by the EC. Sweden informed about the lack of funding to conduct CWD active surveillance. Spain is not planning any CWD surveillance and scrapie showed no changes in the trend. United Kingdom had no cases of BSE for the first year ever since BSE was described. Bulgaria would like the EC to allow the increase in the age of testing of healthy slaughtered cattle to 72 months.

4.2. TSE activities of EFSA BIOHAZ Panel and BIOCONTAM Unit

Angel Ortiz Pelaez from the EFSA BIOCONTAM Secretariat presented the EFSA activities on TSE completed and ongoing since the 2016 Network meeting. Completed activities include three Scientific Opinions of the BIOHAZ Panel of EFSA: on BSE cases born after the reinforced ban (BARB); on the genetic resistance to TSE in goats; on chronic wasting disease (CWD) in cervids (opinion I). Another completed work is a procurement activity on an experimental study on the infectivity of sheep embryos. Ongoing activities of the BIOHAZ Panel include two mandates for Scientific Opinions: a) on chronic wasting disease (CWD) in cervids (opinion II); b) on the request for a scientific opinion on an updated Quantitative Risk Assessment (QRA) of the BSE risk posed by Processed Animal Proteins (PAP).

6.2 EU TSE annual report 2016: preliminary results and update on future data reporting

As per Regulation (EC) No 999/2001, as amended, EFSA is producing the European Union summary report on surveillance for the presence of transmissible spongiform encephalopathies (TSE) in 2016. Yves van der Stede, from the EFSA BIOCONTAM unit, presented the preliminary results of the surveillance data collected through the testing of cattle, sheep, goats, cervids and species other than ruminants in the reporting countries (28 member states plus Switzerland, Iceland and Norway) in 2016. The report will be published by the end of November 2017. The new EFSA data collection tool for TSE will be implemented next year. In preparation, the first meeting of the Scientific Network for Zoonoses Monitoring Data - Data Subgroup on TSE - will take place on 13-14 November 2017, at EFSA headquarters in Parma. Hands-on training on the SSD2 data model and usage for the TSE data collection will be provided during the meeting, targeted to the competent authorities' officials responsible for collating and submitting the TSE data at national level.

4.4 TSE EURL Guidelines for the detection of CWD in cervids

John Spiropoulos, representative of the United Kingdom, gave a presentation on the factors underpinning a successful strategy to detect CWD in Europe, the sample type (both obex and medial retropharyngeal lymph nodes from each animal should be sampled) and the testing strategy (Bio-Rad TeSeE SAP rapid test, using the CWD addendum and the IDEXX HerdChek Chronic Wasting Disease Antigen Test Kit, EIA fulfil the TSE EURL criteria). The TSE EURL has recommended compulsory proficiency testing for the laboratories in the 6 countries where CWD surveillance is targeted by the EC proposal, and optional for the rest of the countries. Confirmatory testing can be performed by National Reference Laboratories (NRL) or referred to the EURL and should include Western Blot and immunohistochemistry, depending on the existence of suitable fixed material. Cervid prion disease (CPD) in Europe is a novel situation and, ideally, there should be available test/s that would detect the disease with maximum sensitivity and specificity, which may not be possible at the moment. However the cases detected in Norway gives a degree of confidence that the approach proposed by the EURL is a good starting point. The representative of the United Kingdom stressed the fact that prion cases in cervids cannot be discriminated with scrapie nor can be confirmed as CWD with the current diagnostic methods, and that the only method to differentiate is by strain typing using rodent models.

4.5 CWD zoonotic potential and other ongoing TSE research in Canada

Stefanie Czub from the Canadian Food Inspection Agency (Canada) presented the results of the first evidence of intracranial and oral transmission of CWD in Cynomolgus macaques. A total of 21 macaques were inoculated through different routes (intracranial, oral, skin scarification and intravenous) with CWD positive material from white-tailed deer and elk. So far five animals have resulted positive, two intra-cranially challenged and three via oral route. In the five cases, histopathology, immunohistochemistry, Western Blot and RT-QuIC were able to detect PrP^{Sc} deposits or amyloid seeding (spinal cord, brain), even in the only animal that did not show clinical signs. The pattern of CWD observed in the macaques is different from BSE in macaques. There are still eleven inoculated macaques available for assessment, ten of them without showing any clinical signs after 4.7-8.4 years post inoculation. In a second presentation, Sandor Dudas, Stefanie Czub's collaborator, presented a summary of a number studies addressing different aspects of atypical BSE. The assessment of rapid tests approved for classical BSE for the detection of atypical BSE resulted successful. Equally the intra-cranial inoculation of the three types of BSE into transgenic mice (bovinized, humanized and wild type) resulted in the successful detection of PrP^{Sc} in the same tissues: brain, spinal cord, eyes, trigeminal ganglia and peripheral nerves. In a separate study, three and 15-month old cattle were inoculated orally with 100g of C, H and L-type BSE brain. One of three H-type-inoculated animals showed clinical signs at 17 months post-inoculation and had PrP^{Sc} detected, and so were two of the three C-type-inoculated ones. The study of the intra-cranial inoculation of five cattle with material from two anomalous Swiss BSE cases is still ongoing.

17 October 2017

5. Welcome and apologies for absence

The Chair welcomed the participants for the second day of the meeting.

6. Topics for discussion

6.1 TSE surveillance and TSE risk assessment activities in Japan

Takateru Daikai, Chief of Prions Section of the Food Safety Commission of Japan (FSCJ), after describing the organizational structure of the FSCJ and the risk assessment flow process, presented the recent activities of the related agencies in the TSE field. The testing of healthy slaughtered cattle for human consumption was discontinued in April 2017 following a risk assessment that concluded that risk to human health by ceasing the testing in this surveillance stream is negligible. The last BSE case confirmed in Japan was in 2009. No cases of BSE have been confirmed among cattle born after the last case was confirmed in the birth cohort of January 2002. Other risk assessments concluded that human prion disease including vCJD is highly unlikely to occur through consumption of bovine meat and offal (excluding SRM). Hence Ministry of Health, Labour and Welfare (MHLW) lifted the ban on the import of beef and bovine offal from a number of EU member states. There has only been on case of vCJD in Japan: a male who had stayed in the UK, Spain and France during a month on 1990. The FSCJ also concluded that the risk to human health arisen from ceasing screening testing for healthy slaughtered sheep and goats is negligible (January 2016). Hence MHLW lifted the ban on the import of ovine and caprine meat from France. With regards to CWD, no cases have been confirmed in Japan. However, and due to the recent occurrence in the world, the FSCJ collected relevant information and is planning to publish a fact sheet on CWD soon.

4.3 Update on CWD in Norway

Michael Tranulis, representative of Norway, updated the BSE/TSE Network on the epidemiological situation of the CWD outbreak in Norway. At the time of the Network meeting, ten cases of the disease in reindeer (7) and moose (3) have been detected since April 2016. The last moose case was detected in a region about 200 km from where the other two moose cases were detected, and about 10km of the border with Sweden, but both areas are considered to be a single epidemiological unit. The Norwegian Scientific Committee for Food Safety (VKM) published the second opinion on "CWD: state of emergency for the future of cervids (Phase II)", highlighting the distinction of the profiles presented by the cases in reindeer in moose. The major decision with regards the control of CWD in cervids is the cull of the entire population of wild reindeer in zone I of Nordjfella with approximately 2,200 animals, to be done by regular hunting, sharp-shooting and organized slaughter, until May 2018. This measure will be complemented by the partial fencing of the area, the prohibition of salt licks, the intensified sampling and surveillance in the area surrounding Nordjfella mountain and Selbu areas, and the split of Norway into two epidemiological

zones with movement restrictions applied. The measures are not popular and are having a strong echo in Norwegian media. So far a total of 10,889 cervids have been tested in Norway in 2017, including 2,655 moose, 3,403 semi-domesticated reindeer and 2,226 wild reindeer, outnumbering the 10,043 cervids tested in 2016. Studies including inoculation experiments, genetic analysis and novel diagnostic methods are ongoing.

6.3 TSE surveillance in small ruminants slaughtered for human consumption

Michael Horan, representative of Ireland, proposed this topic for discussion. The Chair stressed the importance of focussing this discussion on the pure scientific and epidemiological aspects of this proposal rather than on management issues. Following the discontinuation of the testing of healthy slaughtered for human consumption in cattle, given the latest EFSA considerations that scrapie is not a zoonotic disease and that still the SRM is removed in adult small ruminants, there is a case for the discontinuation of the testing at abattoirs of healthy small ruminants slaughtered for human consumption. In the case of a member state with a population of sheep or goats greater than 750,000, the requirements is 10,000 tested animals, which is perceived as a considerable burden. The floor was then opened for discussion. Representatives of Italy expressed their disagreement with this proposal and considered it premature, given the higher incidence of scrapie in the EU compared to BSE, the contribution of the healthy slaughtered surveillance stream to the unbiased estimation of the prevalence of disease and the disadvantages of focusing surveillance mainly on fallen stock, since it is easier to over/under-represent certain age groups when sampling fallen stock. Poland representative suggested that surveillance should be different for countries in which only atypical scrapie is present. The Swedish representative highlighted the importance of discussing these issues openly, of keeping the memory of the TSE epidemics in Europe and how to learn the lesson in order to prevent from occurring again. The possibility of contaminated feed still going around in Europe cannot be neglected as a potential source of re-emergence of TSE.

6.4 ANSES opinion on SRM removal in small ruminants

Thomas Maignien, representative of France, presented the results of an opinion published by the French Agency for food, environmental and occupational health and safety (ANSES) on the public health risk that the proposal of the European Commission (EC) to reduce the list of specified risk materials (SRM) for small ruminants (limited to skull, brain and eyes) could pose. An urgent response was required by ANSES. The opinion concluded that it is appropriate to maintain and optimise all measures likely to reduce consumer exposure to the scrapie agent, given the recent evidence of transmission to human PrP transgenic mice and to macaques and the need to conduct quantitative risk assessments combining pathophysiology and epidemiology before such decision is applied. A related risk associated with this measure would be the classification of potentially-infective material as category 3 animal by-products that could end up in the environment (fertilisers) or in animal feed via cross-contamination with non-ruminant processed animal protein (PAP).

6.5 Update on the activities of the OIE in the TSE field

Anna-Maria Baka, representative of OIE (Status Department), updated the Network on the recent TSE-related activities carried out at the OIE, and future ones. One country and two zones were recognised as having a negligible BSE risk status by the World Assembly of OIE Delegates in 2017: Poland and two zones of the UK, namely Scotland and Northern Ireland. At the moment, there are 47 member countries and 3 zones in the world with negligible BSE risk status: 29 countries and 2 zones of them are in Europe. As the incidence and global importance of classical BSE have markedly decreased over the past years, the current BSE standards, i.e. Chapter 11.4. of the OIE *Terrestrial Code*, including the provisions for risk assessment and surveillance applicable to the categorisation of BSE risk status as well as trade requirements, are to be substantially revised in order to remain proportionate to the risk associated with BSE. An indicator of the need for this in depth revision is that countries submitting applications for BSE risk status recognition and maintenance express the difficulties to comply with the surveillance and risk assessment provisions, in a context of improved global situation of BSE. The OIE plans to set up two types of *ad hoc* groups (surveillance and risk assessment) to revise the BSE Chapter of the Terrestrial Code. With regards to CWD, this is not an OIE listed disease but some countries report regularly occurrence via WAHIS-Wild. The working group on wildlife (WGW) discussed in December 2016 the difficulties to demonstrate freedom from this disease. The potential inclusion in the OIE list should be reconsidered when more substantial and convincing scientific evidence is available.

6.6 Update on the activities of the European Commission in the TSE field

Lucie Carrouée, representative of the European Commission (DG SANTE – G), updated the Network on the recent TSE-related risk management activities in the European Commission, in relation to: i) feed ban (i.e. revision of the feed-ban for non-ruminants, review of the conditions for export of processed animal proteins from the EU to third countries, use of insect PAP in feed for acquaculture (1st step) and poultry (2nd step), and the use of starfish for the production of fishmeal destined to non-ruminant feed; ii) specified risk material (SRM) (i.e. adaptation of SRM list for small ruminants taking into account the limited BSE risk in those species); iii) BSE risk status classification: to align EU legislation on BSE classification of countries with the latest OIE classification; iv) BSE import requirements: to clarify EU BSE import requirements in case of triangular trade, and to align EU BSE import requirements for ruminant PAP with OIE; v) scrapie: explore if a similar approach for goats can be used as for sheep concerning eradication measures and breeding programmes, based on genetic resistance to TSEs, and approval of the Slovenian National Scrapie Control Programme (NSCP); vi) CWD: safeguard measures to protect the EU territory from CWD, following the detection of CWD cases in Norway, and to have better knowledge of the CWD epidemiological situation in EU/EEA countries with a reindeer and/or a moose population.

6.7 Round-the-table discussion on the EFSA Scientific Network on BSE-TSE

Network members were invited to provide, also after the meeting, suggestions for improvement of the functioning of the Network and for possible topics for future discussion in the Network. The Netherlands complimented the organizers for the interesting agenda. Ireland found the topics enjoyable for the practical implications of the scientific knowledge exposed in the meeting to risk management. Sweden praised the BSE/TSE network as a valuable forum where TSE topics can be discussed with experts and colleagues from other countries. Poland highlighted the participation of experts for other parts of the world. The chair invited all network members to share information with EFSA and the other Network members anytime during the year.

7. Any Other Business

No additional topics were discussed.

8. Closure of the meeting

The discussions held during the meeting will be summarised in the form of meeting minutes and an annual report, that will be circulated by EFSA Secretariat in due time to all participants for comments and agreement.

The next meeting of the EFSA Network on BSE-TSE will be organised during the third quarter of 2018.

The Chair thanked all speakers for their presentations, and all participants for attending the meeting and for their active participation in the discussions, and closed the meeting.