

Scientific Network for Zoonoses Monitoring Data Minutes of the 1st specific meeting on TSE data reporting

**Held on 13-14 November 2017, Parma, Italy
(Agreed on 01 December 2017)**

Participants

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

Country	Name
Austria	Alexandra Bastian and Georg Nossek
Belgium	Benedicte Verhoeven
Bulgaria	Martin Vaskov Hristov
Cyprus	Georgia Aparin
Croatia	Tihana Miškić
Czech Republic	Petr Hedbávný
Denmark	Hanne Christensen and Thomas Lysgaard
Estonia	Olga Piirik
Finland	Sirkka-Liisa Korpenfelt
France	Jean-Philippe Amat
Germany	Nicolai Denzin
Ireland	Margaret Murray
Italy	Giuseppe Ru and Francesco Ingravalle
Latvia	Edvīns OļševskiS
Lithuania	Kristina Stakytė
Luxembourg	Manon Bourg
Malta	Lucia Strhanova
Netherlands	Vincent Hendriks
Poland	Malwina Lisiecka
Portugal	Renata CarvalhO
Romania	Theodora Chesnoiu
Slovakia	Martin Mojžiš
Slovenia	Ivan Ambrozic
Spain	Soledad Collado
Sweden	Kristina Mieziowska and Sandra Ögren
United Kingdom	Julia Thomas
Norway	Berit Heier
Switzerland	Michael Binggeli

- **Hearing Experts**

NA

- **European Commission:**

NA

- **EFSA:**

Biological Hazards and Contaminants (BIOCONTAM) Unit: Yves Van der Stede, Ortiz Pelaez Angel, Valentina Rizzi*.

Evidence Management (DATA) Unit: Mario Monguidi (Chair), Anca-Violeta Stoicescu (Scientific secretary), Davide Gibin, Mary Gilsean*.

(* attended for specific items)

1. Welcome and apologies for absence

The Chair welcomed the participants to the 1st specific meeting on transmissible spongiform encephalopathies (TSE) of the Scientific Network for Zoonoses Monitoring Data. Apologies were received from the representatives of Iceland, Greece and Hungary. The representative of Austria participated in agenda points 3.1–3.6 via teleconference.

2. Adoption of agenda

The agenda was adopted without changes. No further items were added.

3. Topics for discussion (first day)

3.1 Objectives of the training

The Chair presented the main objectives of the training. It was underlined that, starting from 2018 onwards, Member States (MSs) will be requested to submit TSE surveillance data to EFSA using the tools made available by EFSA. It was explained to the Network what role the Network members have. An important task of Network members is to liaise with the national experts and laboratories involved in sample analysis, data collection, data collation and data reporting.

3.2 Surveillance of TSE and reporting requirements

Yves Van der Stede presented the current surveillance of TSE and the reporting requirements as requested by the European Commission (EC) Regulation No 999/2001.¹ The rationale for setting up the Network sub-group on TSE data collection was briefly presented. Technical specifications² for TSE data reporting were prepared by an EFSA working group in 2016 and it was concluded that the new data submission on TSE should be performed according to the existing tools in EFSA. It was clarified that the data model is based on the Standard Sample Description version 2 (SSD2) and data reporting should follow the Guidance on

¹ Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies. OJ L 147, 31.5.2001, p. 1–40.

² EFSA (European Food Safety Authority), 2016. Technical specifications on the collection, management and analysis of data on the surveillance of transmissible spongiform encephalopathies (TSEs) in ruminants in the EU. EFSA supporting publication 2016:EN-1153. 101pp. doi:10.2903/sp.efsa.2016.EN-1153.

Data Exchange version 2.0 (GDE2). Data will be reported to EFSA in eXtensible Markup Language (XML) format via the Data Collection Framework (DCF). To support reporting countries in TSE data submission using XML data transfer, EFSA developed a data submission tool. Scientific clarifications were provided on additional information required in the new data model compared with the one reported to the EC. It was stressed that EFSA aims to improve the structure of the database as well as the quality of the data (in particular for small ruminants) as it is important for future risk assessments on TSE to have scientifically valid data. The testing schemes (including analytical methods) for Bovine spongiform encephalopathy (BSE), scrapie and Chronic Wasting Disease (CWD) were explained, according to the submission tool to be used.

The representative of Germany asked if the due date of data reporting will be still the 15th of the following month for which data are reported. EFSA clarified that this deadline is rather a reporting guideline than a legal requirement. The only legal requirement is the 31st of March of the following year for the annual report submitted by the MSs to the EC.

3.3 SSD2 Data Model and usage in TSE data collection

Mario Monguidi presented the SSD2 data model, which is a harmonised model for the collection of a wide range of analytical results in several domains of EFSA's remit. The SSD2 data model will also be used also for TSE data reporting. The sections and the data elements of the data model were briefly described. It was underlined that the controlled terminologies are used in the data model to guarantee the unambiguity of the received data, whereas the business rules are used to ensure that data quality criteria are met.

The Croatian representative mentioned that they have implemented already the SDD2 model in order to report data on zoonoses. As the data reporting according SSD2 is directly linked to their LIMS (Laboratory Information Management System) Croatia asked if this system can be used also to report TSE data. EFSA answered that the data model used for TSE is SSD2, but specific requirements were defined according the needs specified for TSE and that these should be followed.

3.4 Data Collection Framework: main functionalities and errors report

Davide Gibin presented the DCF, that is a secure web portal that supports the submission and validation of datasets transmitted to EFSA. The DCF supports the collection and storage of data. Data uploaded into the DCF are automatically checked against the catalogues and validated against business rules.

3.5 Support provided by EFSA for the data reporting

Anca Stoicescu presented the support provided by EFSA for data collection and reporting. Any technical and scientific issue encountered in the process of data collection and reporting should be addressed to the functional mailbox: zoonoses_support@efsa.europa.eu. It was highlighted that, in order to receive an answer on a specific topic as soon as possible, the specific functional mail boxes should be used.

3.6 How to report data with the TSE submission tool: aggregated level, case level, random genotyping

Mario Monguidi presented the main functionalities of the newly developed TSE data submission tool. The installation of the tool and test connection was performed by all the participants following the steps presented. It was emphasized that all the documentation related to the functionalities of the reporting tool developed by EFSA is available on GitHub (<https://github.com/openefsa/TSE-data-reporting-tool/wiki>). GitHub is an open source application, acting as a client application for the DCF according to GDE2 specifications. All updates for the future will be available on GitHub. The data submission tool can be freely downloaded and adapted by MSs, if needed. Any issues related to the tool should be communicated using the GitHub's "Issues" form or directly to zoonoses_support@efsa.europa.eu.

3.7 Practical session: simulate a real data upload for TSE surveillance data with aggregated level, case level data and random genotyping data

Mario Monguidi, Davide Gibin, Anca Stoicescu and Yves Van der Stede helped the participants to perform a real data upload with test data for TSE surveillance (aggregated level, case level data and genotyping data).

Network members were requested to provide, directly on GitHub, feedback related to the reporting tool (catalogues and functionality) and on the provided instructions. EFSA will follow up on all aspects raised by the MSs representatives and will provide a fully functional submission tool and updated documentation prior to the opening of 2018 TSE data collection. The Network members highlighted that the tool needs modification in order to allow reporting of random genotyping data in a consistent way. The reporting of randomly-sampled sheep for genotyping purposes only will be further developed by EFSA and communicated to the Network. A new term was requested to be added in the age class category for BSE data reporting. After discussions, this proposal was agreed; however, a business rule will be put in place to restrict the use of "unknown" for the age class up to a maximum of 2% of the whole bovine reported.

14 November 2017 (second day)

4. Welcome and apologies for absence

The Chair welcomed the participants to the 1st Specific Meeting on TSE of the Scientific Network for Zoonoses Monitoring Data. Apologies were received from the representatives of Iceland, Greece and Hungary.

5. Topics for discussion

5.1 How to trigger inclusion of data in EFSA Data Warehouse (validation reports)

Anca Stoicescu showed the validation report available in the EFSA scientific Data Warehouse (DWH). The steps for the acceptance and rejection of a file already included in DWH were explained.

The Network members asked EFSA to provide documentation in the form of a flowchart which describes all necessary steps to be taken from submission (in the tool or directly in the DCF) to acceptance/rejection of submitted data in the DWH of EFSA.

5.2 How to amend data already included in the EFSA Data Warehouse

Mario Monguidi presented practical aspects on how to amend data already included in the DWH. The data with 'accepted' DWH status can be only amended, and the steps in performing the amendments were presented.

5.3 Practical session: amend data already included in the EFSA Data Warehouse

In this practical session participants performed amendments to the data included in the DWH.

5.4 Future perspectives about data reporting to EFSA and discussion

During a round table discussion, participants expressed their views on how to proceed with data submission in the long term, e.g. post 2020. The main concerns were related to the time and resources needed to adapt the national system for automated data transfer. The reporting tool developed by EFSA will be used by the majority of the Network members. EFSA stressed that in the long term it is beneficial to submit also the negative samples at sample level. EFSA underlined that it is up to the Network to propose improvements that are discussed within the Network.

The Network members were requested to check internally the availability of required data and to identify and fill data gaps, in order to be able to report TSE data according to the EFSA reporting requirements.

EFSA will offer on-line trainings on data transmission during 2018 for MSs that need additional help to submit their data.

6. Conclusions

An overview of the main discussions and agreements reached during the meeting was presented. Finally, the Chair requested the Network members to fill in the meeting evaluation form and to submit to EFSA ideas for Network discussion.

7. Closure of the meeting

The Chair thanked the Network members for their engagement and their constructive contributions to the discussions. The meeting was closed at 13.30.

Appendix: List of Action Points

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Draft list of the action points agreed at the meeting

Agenda Point	What	Agreement/Comment	Deadline
3.1	Network members to liaise with the national experts (from laboratories, competent authority etc.) involved in sample analysis, data reporting and validation.	Network members should ensure the communication between EFSA and all the national experts.	Continuously
3.5	Functional mail boxes should be used according to their purpose.	If you encounter any difficulty, or have any question about reporting, contact: zoonoses_support@efsa.europa.eu	Continuously
3.7	Reporting tool and related documentation.	Network members: Provide any issue noticed related to the reporting tool (catalogues and functionality), guidelines provided in GitHub.	27 November 2017
3.7	Reporting tool and related documentation.	EFSA: follow up of feedback and provide full functional submission tool for starting submitting from 2018 onwards and documentation (GitHub).	15 December 2017
5.1	How to trigger inclusion of data in EFSA Data Warehouse (DWH) (validation).	Provide simplified flowchart to describe steps from submission to rejection/acceptance of submitted data	15 January 2018
5.4	Propose on-line trainings in 2018 by EFSA (if needed by Member States).	Express the need for training via zoonoses_support@efsa.europa.eu	31 January 2018
7	To perform the evaluation survey: Scientific Network for Zoonoses Monitoring Data evaluation of 1st specific meeting on TSE data reporting	Member States are kindly requested to answer the online survey.	30 November 2017