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Swiss Expert Committee for Biosafety SECB

Recommendation of the Swiss Expert Committee for Biosafety on BSE diagnostics:

classification and safety measures

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1 Purpose and field of application

This SECB Recommendation is intended to support users in classifying and deciding upon safety measures in BSE diagnostics in contained systems. It is based on the provisions of the Ordinance of 9 May 2012 on the Contained Use of Organisms (Containment Ordinance, ContainO)[1] and the Ordinance on the Protection of Employees from Dangerous Microorganisms (PEMO)[2].

2 General provisions of the Containment Ordinance (ContainO; SR814.912)

The ContainO regulates the handling of organisms in contained systems and specifies, among other things, the allocation of organisms to groups (Article 6) and the allocation of activities to classes (Article 7). It also stipulates that a risk assessment should be carried out for work involving genetically modified or pathogenic organisms (*Annex 2.1 and 2.2*).

For the allocation of an activity to a class, the Containment Ordinance states that, when work involves a natural organism, the class of an activity normally corresponds to the group to which the organisms have been assigned (ContainO, Annex *2.2*, para. 2.1).

2.1 Clinical microbiological diagnostics

Analyses of clinical material (i.e. clinical microbiological diagnostics) can generally be assigned to class 2 if the diagnostic procedures involved do not represent an increased risk to people or the environment (ContainO, Annex *2.2*). If Group 3 pathogenic organisms have been enriched for diagnostic purposes and if this results in an increased risk to human beings, animals or the environment, or to biological diversity and its sustainable use, this activity must be assigned to Class 3.

One of the reasons for special regulation of the classification of clinical microbiological diagnostics is that the samples are analysed without prior enrichment and in contained test kits.

[1] Ordinance of 25 August 1999 on the Contained Use of Organisms (Containment Ordinance, ContainO) SR 814.912, https://www.fedlex.admin.ch/eli/cc/2012/329/en

[2] Ordinance on the Protection of Employees from Dangerous Microorganisms (PEMO) SR 832.321, https://www.fedlex.admin.ch/eli/cc/1999/445/de (in German)

The Swiss Expert Committee for Biosafety (SECB) has been instrumental in regulating clinical microbiological diagnostics in this special way and advocates the following decision-making tree for the classification of such work:

Decision-making tree for the classification of clinical microbiological diagnostics

Are Group 3 microorganisms being tested? ⇒ **No** ⇒ **Class 2**

⇓

Yes

⇓

Are Group 3 microorganisms capable of airborne transmission being tested? ⇒ **No** ⇒ **Class 2**

⇓

Yes

⇓

Does the method for testing Group 3 microorganisms capable of airborne transmission involve enrichment, including ⇒ **No** ⇒ **Class 2**

- Cultivation of reference strains
- Serotyping
- Resistance testing?

⇓

Yes

⇓

Class 3

2.2 Classification of reference laboratories

Samples from clinical microbiological diagnostic procedures are generally sent to a reference laboratory for detailed special analyses, such as serotyping and resistance testing. Activities in reference laboratories are assigned to **Class 3**. Reference laboratories regularly handle Group 3 microorganisms, and are involved in method validation and development. They also analyse positive samples from routine diagnostics to verify the test results. The number of positive samples they process, the enrichment of cultures, the cultivation of reference strains, and the development of analytical methods confer on them a status equivalent to research laboratories.

3 BSE diagnostics

3.1 Allocation of the BSE pathogen to a risk group

Pathogens of bovine spongiform encephalopathy (BSE) are allocated to Group 3**.

Group 3** pathogens are not normally transmitted aerogenically. As airborne transmission of Allocation of the BSE pathogen to this risk group (limited risk of infection for laboratory staff) is justified because its airborne transmission is not possible under natural conditions. However, oral uptake is possible. The SECB also discussed this classification in its Recommendation on the classification of work with prion genes and prion proteins of January 2013[3].

[3] https://www.efbs.admin.ch/en/recommendations/recommendations-of-the-secb/

3.2 Classification of BSE diagnostics

In BSE diagnostics, test kits approved in Switzerland are used to detect pathological prion proteins, which are allocated to Group 3**. The method does not require the prion proteins to be propagated. Samples for validating the test method are supplied by the manufacturer of the test, and contain non-infectious prion proteins. The diagnostic laboratories carry out routine analyses as part of animal disease monitoring, and rarely receive BSE-positive samples. By analogy with the decision-making tree for the classification of clinical microbiological diagnostics, therefore, BSE diagnostics is assigned to **class 2**. Activities involving BSE pathogens in reference laboratories, on the other hand, are assigned to class 3** (see 2.2).

3.3 Duty of notification

Work involving BSE pathogens for diagnostic purposes must be notified to the Federal Coordination Centre for Biotechnology and requires approval from the Federal Food Safety and Veterinary Office (FSVO).

4 Safety measures for diagnostics involving BSE pathogens

The general safety measures detailed in Annex 4, para. 1 of the Containment Ordinance (ContainO) and Annex 3, para. 1 of the Ordinance on the Protection of Employees from Dangerous Microorganisms (PEMO; SR 832.321), and the additional containment level 2 safety measures defined uniformly in the ContainO (Annex 4, para. 2.1) and PEMO (Annex 3, para. 2) apply to class 2 activities. These safety measures apply to all types of class 2 activities. Some of these measures need to be made more specific and supplemented by additional measures for BSE diagnostics (see also the WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies; Report of a WHO Consultation, Geneva, 23-26 March 1999; WHO/CSR/APH/2000.3[4]).

Because the BSE pathogen is assigned to Group 3**, application may be made to the SFOA to replace or omit particular safety measures.

4.1 Safety measures for laboratories involved in BSE diagnostics

Particular attention should be paid to the following safety measures ((No.) gives the number of the particular safety measure under the ContainO and PEMO):

Restricted entry to the work area – only individuals involved in BSE diagnostics (No. 2);

- Access to work area through an airlock (separate room) (No. 4), in accordance with Art. 12 para 3b;
- Biohazard warning signs (No. 8);
- Surfaces resistant to acids, alkalis, solvents and disinfectants (No. 19);
- Microbiology safety cabinets (No. 21);
- Prevention of aerosol formation. The following tasks must be carried out in a microbiology safety cabinet: opening sample containers, cutting samples, homogenization, preparation of proteolysis and centrifugation in an Eppendorf centrifuge (No. 22);
- Special clothing for the work area and its removal on leaving the laboratory (No. 27);
- Personal protective equipment, in particular gloves, to be worn (No. 28);
- Regular disinfection of workplaces with 2N NaOH for 1 hour and covering of workplaces with impermeable material (No. 29);
- Observation of special inactivation measures for BSE pathogens in contaminated material and waste and on contaminated equipment (No. 33), see Chapter 4.4 below.

[4] https://apps.who.int/iris/handle/10665/66707

4.2 Safety measures for handling sample material outside the laboratory

In addition, specific instructions must be established covering the safety measures to be observed when taking samples in an abattoir or rendering collection, and for the transport of samples. Chapter 4.4 below lists the safety measures that the SECB believes to be necessary for BSE diagnostics, from sampling at the abattoir to final disposal; generally applicable rules should be followed for handling at abattoirs in particular.

4.3 Protection of workers

In addition to the safety measures already mentioned, the PEMO requires additional measures to be taken to protect workers and detailed instructions/training to be given to personnel who handle BSE pathogens (Article 11 PEMO).

4.4 Handling sample material

Activity	**Specific safety measures**
Extraction of brain samples at the abattoir	- Observe measures for sampling and inactivation specified in the *Technical instructions of the FSVO:* o Taking of samples from emergency slaughtered cattle and their examination for BSE (in German)[5] o Taking of samples from fallen stock and euthanized bovines for BSE testing (in German)[6] - Labelling of samples: e.g. according to the guideline “Safe transport of biological material” from the Institute of Virology and Immunoprophylaxis, Mittelhäusern[7]
Transport of routine samples	- Exempt animal specimen by post or courier
Transport of suspicious samples Transport of positive controls to validate the BSE test Transport of positive samples to a reference laboratory for verification	- Hazardous-goods transport (UN3373) by post or courier
Receipt of samples at laboratory	- Unpack packages on a laboratory bench in a level 1 laboratory
Analysis of samples at the laboratory	- Labelling sample containers, opening sample containers, cutting the sample, homogenization and preparation of proteolysis in a class II MSC in a level 2 laboratory

[5] Entnahme von Proben bei Krankschlachtungen zur Untersuchung auf BSE https://www.blv.admin.ch/dam/blv/de/dokumente/tiere/tierkrankheiten-und-arzneimittel/technische-weisung/technische-weisung-entnahme-proben-krankschlachtungen.pdf.download.pdf/TW%20BSE%20Krankschlachtungen.pdf

[6] Entnahme von Proben bei umgestandenen oder nicht zur Fleischgewinnung getöteten Tieren der Rindergattung und deren Untersuchung auf BSE https://www.blv.admin.ch/dam/blv/de/dokumente/tiere/tierkrankheiten-und-arzneimittel/technische-weisung/technische-weisung-probenahme-umgestandene-rinder-bse.pdf.download.pdf/TW%20BSE%20Umgestandene%20Tiere%20de.pdf

[7] Safe transport of biological material https://www.ivi.admin.ch/dam/ivi/de/dokumente/ivi/infomaterial/Sicherer%20Transport%20von%20biologischem%20Material_E.pdf.download.pdf/Sicherer%20Transport%20von%20biologischem%20Material.pdf

Activity	Specific safety measures
	- Electrophoresis, Western blot, ELISA in a level 2 laboratory
Disposal of BSE-negative and positive sample material and solid and liquid waste	Possible means of disposal: incineration as hazardous waste is the safest form of inactivation according to the current state of knowledge. - Solid and liquid waste: Hazardous-goods transport in UN-certified disposable containers for incineration at a waste incineration facility licensed for hazardous waste (high temperature) - Solid waste: Autoclave at 134 °C for at least 1 h, 3 bar (EU Standard) - Liquid waste: - Autoclave at 134 °C for at least 1 h, 3 bar or - Incubate for 1 h with NaOH (final concentration 2N) and subsequently neutralize - Animal waste: must be incinerated in accordance with the Epizootic Diseases Ordinance (EzDO, SR 916.401)
Decontamination of workplaces and equipment	Treat with 2N NaOH (wipe with paper towels soaked in 2N NaOH or immerse equipment in it) for at least 1 h