European Food Safety Authority

Scientific Panel on Biological Hazards

Parma, 16 March 2006

Statement of the Scientific Panel on Biological Hazards related to report of the EU TSE Community Reference Laboratory on the recent TSE cases in sheep.

Background

Based on discriminatory Western blotting results, concerns had been raised on three BSE-like cases in sheep (two French and 1 Cypriot animal). The EU TSE Community Reference Laboratory (CRL) with the support of the Strain Typing Expert Group (STEG) was asked to review the data from the testing carried out. After the CRL report was published and in the light of its ongoing work on the Quantitative Risk Assessment (QRA) on the BSE risk of sheep meat and sheep meat products, the Scientific Panel on Biological Hazards (BIOHAZ) reviewed this CRL report. A Working Group (WG) meeting was organised on March 14, 2006 and the report of the WG was discussed at the BIOHAZ Plenary meeting of 15-16 March 2006.

The findings of the Community Reference Laboratory (CRL) Strain Typing Expert Group (STEG).

As summarised in Table 1 (taken from the CRL/STEG Report).

Table 1.

Case no	05-0825 (Fr)	06-0017 (Fr)	204163425 (Cyp)
Discriminatory Western Blot (WB)	BSE-like[1]	BSE-like[1]	BSE-like[1]
ELISA	Intermediate scrapie[2]	Intermediate scrapie[2]	Not done[3]
Discriminatory Immunohistochemistry (IHC)	Not done[3]	Not done[3]	Intermediate[4]

[1] There are some minor discrepancies between the glycoform profiles obtained from these samples and those of experimental ovine BSE. However, it is the consensus of the group that glycoform profile alone is not a robust discriminatory criterion.

[2] The result does not fit the criteria for 'BSE-like' by this 'test', 05-0825 and 06-0017 isolates show intermediate resistance to PK treatment which is quite common in a population of "classical" scrapie.

[3] A full ring trial has not been possible for any of these cases.

Conclusions and recommendations

1. The BIOHAZ Panel concurred with the conclusions of the CRL/STEG[5] (in *italics* as follows) :

    1. *It is not possible to compare IHC, WB and ELISA results for each sample using the evaluated discriminatory methods, therefore the STEG cannot classify any of the samples conclusively as "BSE in sheep".*

    2. *Nevertheless, additional data from ELISA and IHC suggest that the samples may not be BSE in sheep, since they do not conform to our expectations based on currently available data from experimental ovine BSE. However there is insufficient evidence to definitively rule out the presence of BSE, since the actual sensitivity (negative predictive value) of ELISA and IHC alone are not known, and the current data differ from the great majority of classical scrapie isolates.*

    3. *All three samples appear to fit into a previously unrecognised/undefined category, similar to cases identified in France in 1996, and in the United Kingdom in 2004, that warrants further investigation by bioassay.*

2. The BIOHAZ Panel noted the press releases of the European Commission[6] (EC) and EFSA[7] on these cases. In particular the BIOHAZ Panel endorsed the Commission's intent to strengthen TSE monitoring programmes in sheep in order to provide sufficient and reliable data from all Member States (MS) to facilitate current and future risk assessments. The Panel further advised that this increase in

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- Fixed material was not collected from the French cases, thereby precluding discriminatory immunohistochemistry. Data has been reviewed from Western blot (AFSSA) and ELISA (CEA) testing.

- Insufficient fresh tissue was available from the Cypriot case to allow full molecular testing without compromising the availability of material for subsequent bioassay. Data has been reviewed from Western blot (VLA) and discriminatory immunostaining (VLA Lasswade).

- Absence of a full panel of test results in ring trial means that even if there had been total conformity of interpretation, unequivocal categorization of the isolates would not be possible at this stage. However, it is clear from the results available that they do not all concur with the 'BSE-like' outcome of the primary differential screening blot, and consequently would not have been categorized as BSE-like even if all test methods had been applied.

[4] The result does not fit the criteria for 'BSE-like' by this 'test', nor does it match those for classical scrapie isolates. It also does not share the properties of 'atypical' scrapie, as defined in the EFSA Opinion.

[5] http://europa.eu.int/rapid/pressReleasesAction.do?reference=MEMO/06/113&format=HTML&aged=0&language=EN

[6] http://europa.eu.int/rapid/pressReleasesAction.do?reference=IP/06/288&format=HTML&aged=0&language=EN

[7] http://www.efsa.eu.int/press_room/press_statements/1388/state_biohaz_bse_sheep_en1.pdf

surveillance be done in accordance with the recommendations as formulated in the earlier EFSA Opinion (EFSA, 2003).

3. The BIOHAZ Panel reviewed the previous opinions of the EC Scientific Steering Committee (SSC) and EFSA on this subject. They felt particular attention needed to be paid to a revision of the tissue distribution of infectivity in BSE-affected sheep and directed this consideration to the EFSA Working Group currently preparing an opinion answering to a mandate of the EC on the QRA for BSE related risk in sheep meat and sheep meat products ("EFSA QRA Sheep WG").

4. The BIOHAZ Panel recommends that the CRL/STEG clarifies its advice on the classification of TSE isolates in the particular case where not all confirmatory tests can be applied to samples of an animal (as happened in these French and Cypriot cases).

5. The BIOHAZ Panel further recommends that since the full range of discriminatory tests, *i.e.* IHC, ELISA and WB, are required to minimize the potential confusion of an "inconclusive" diagnosis, MS should ensure that the quality and quantity of the tissue collected as part of their surveillance programmes, is adequate for the requirements of this full range of tests.

6. The BIOHAZ Panel advises that the protocols of these discriminatory tests and the data obtained during their ring trial evaluation needed to be more widely available for peer-review so that their strengths and limitations can be more widely appreciated.

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References

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