

Statement from TSE CRL 3rd July 2006 Use of Spinal Cord for BSE Surveillance

The first stage of TSE testing is sampling. In order to ensure the integrity of test results it is vital that the most appropriate tissue is obtained. Data from a recent unpublished experimental pathogenesis study at the VLA underlines our observations from field cases. The area which should be sampled is the tissue where abnormal PrP is most consistently deposited, and co-incidentally first detectable. For BSE, the pattern is remarkably consistent, with early changes appearing first in certain nuclei in the brainstem at the level of the obex (for more details please see the CRL sampling guidance document.)

<http://www.defra.gov.uk/corporate/vla/science/documents/science-tse-rl-samp-iss.pdf> .

In order to maximise the likelihood of detecting CNS positive cases, especially at the early pre-clinical stages, the CRL therefore recommends that surveillance programmes for BSE **must** be set up to target the brainstem at the level of the obex. Under no circumstances should a surveillance programme be based on sampling spinal cord or other central nervous system tissues as the tissue of choice. There are currently no rapid tests on the market approved for routine, large-scale use on spinal cord.

Nevertheless, there is frequently a conflict between sampling the most appropriate target site and failure to test because the sample received is unsuitable, such as when the sampling process has damaged the target areas, or the sample is severely autolysed. A balance has to be struck between maximising the sensitivity of testing, and maximising the sensitivity of the surveillance where significant numbers of no-test samples would rightly be criticised. There is no doubt that in animals that are clinically affected or showing early clinical signs, and where deposition of abnormal PrP is more widespread, a positive result can be achieved by testing brain stem or cervical spinal cord, and consequently there are opportunities to overcome deficiencies in sample quality by testing target areas other than the obex. In such circumstances positive results are always valid. It is negative results that may be questionable.

Accepting that this should be a secondary option **only** where the obex is not identifiable, other parts of the brain stem/cervical spinal cord can be tested using currently approved rapid tests, even though their approval is currently specific to testing of the obex. In this case a positive result is valid and should be reported as such. Negative results must however be reported with the caveat that optimal tissues were not available for testing. The alternative option is to report such tissues as "no test" i.e. un-testable as the target tissue is not available.