



STATEMENT ON INFECTIVITY IN BOVINE TONSIL

Background

1. The views of the Committee were sought on unpublished results from an ongoing long-term study of the pathogenesis of BSE in cattle. This study is being carried out by the Veterinary Laboratory Agency and is funded by the Food Standards Agency (FSA).
2. In this study, cattle were orally dosed with 100g of BSE-infected bovine brain material. At various times after oral dosing, cattle were killed and different tissues tested for infectivity. In the first instance, the presence of infectivity was assessed by injection of various tissues into inbred mice ("mouse bioassay"). In this research infectivity was detected in:
 - distal ileum (the earliest infectivity was detected at 6 months after inoculation.)
 - brain and spinal cord and closely associated nervous tissue (infectivity was detected in the months just prior to the clinical onset of BSE in cattle)
 - at a single time point (around the time of clinical onset) bone marrow was also found to contain infectivity.

However, no infectivity was detected in the other tissues tested by the mouse bioassay.

3. It was recognised that assay of bovine material in mice involves crossing a species barrier, which may reduce the sensitivity of the assay to detect infectivity. Subsequent research showed that intracerebral injection in calves ("cattle bioassay") was several hundred-fold more sensitive than the mouse bioassay with respect to the detection of putative infectivity in bovine tissues. Therefore, starting about 6 years ago, a study was initiated to test a range of cattle tissues that had been tested in the mouse bioassay using the more sensitive cattle bioassay. The Committee was presented with recent results from this ongoing cattle bioassay.

Research Findings

4. Early results from the cattle bioassay study confirmed infectivity in the distal ileum, brain and spinal cord at certain times in the incubation period to those previously reported in the mouse bioassay. However, new findings show that one of five cattle that received pooled palatine tonsil tissue, taken 10 months after experimental inoculation with BSE, had shown clinical evidence of the onset of BSE at 45 months post-inoculation. At present, the 4 remaining animals are still alive (48 months after inoculation), without confirmed evidence of clinical onset of BSE. The equivalent result in the original mouse bioassay was negative.
5. The Committee considered that although at present only one of the five animals has shown evidence of transmission of BSE, the finding was significant and was unlikely to result from experimental artefact. The Committee noted that the significance of this finding would be strengthened if any of the other four animals in the experimental group developed BSE or if tonsil tissue sampled at 6, 18 or 26 months after inoculation also showed evidence of infectivity in this study. The Committee noted that these studies are ongoing.

Assessment of potential public health implications

6. The Committee noted that tonsils from cattle are Specified Risk Material (SRM) from 6 months of age in cattle from the UK and Portugal, and SRM from 12 months of age for other EU countries. Bovine tongue is not classified as SRM and therefore can be sold for human consumption. Although the location of palatine tonsil is such that it is unlikely to be removed with tongue, there is a possibility that some lingual tonsil, which is close to the root of the tongue, might be present in that part of the tongue removed and intended for human food consumption.
7. The Committee was informed by the FSA that a limited, preliminary examination of current practices of cutting and removal of the tongue indicated no visible lingual tonsil was present on tongue as removed. The Committee was informed that such tissue was not detectable if tongue was cut in a particular area. The Committee considered, nevertheless, that it would be prudent to conduct further examination of current practices of preparing bovine tongue and of the amount and distribution of any tonsil tissue in tongues prepared for human consumption.

8. Despite the paucity of data on current practices, the Committee considered that any potential risk was likely to be low as the long incubation period of the one animal that had developed BSE (45 months post-inoculation) in this experiment suggested that the level of infectivity was low. Additionally the Committee considered that the potential for exposure is limited given:

The number of BSE infected cattle entering the food chain is likely to be very small because of the decline of the BSE epidemic in the UK, existing feed controls and the over thirty month (OTM) rule.

Tonsil is SRM from the age of 6 months in the UK and Portugal and 12 months in other EU states.

Although the quantity of tonsil tissue attached to tongues is unknown, it is likely, at most, to be small.

9. On the question of whether tonsil should be made SRM from any age, the Committee acknowledged this was a risk management issue and thus is beyond their remit. However they considered that this option should be examined as part of the overall risk assessment.
10. With respect to bovine lymphatic tissue other than tonsil, the Committee noted that a previous study on pooled lymph nodes or spleen taken from naturally infected animals with clinical BSE had not shown evidence of infectivity by cattle bioassay. The Committee was informed that assay of specific lymph nodes were included in the ongoing experiment and at present have not shown evidence of infectivity, but the assay is incomplete.

Conclusions

11. The Committee concluded that although only one of the five animals inoculated with tonsil tissue has so far succumbed to BSE, this finding is significant and unlikely to be an experimental artefact. However, the significance of this finding would be strengthened by:
 - the pending results from the other four animals in the experimental group; which are currently not showing definite clinical signs of BSE
 - the results from other experimental groups of animals which received tonsil tissues sampled at 6, 18 or 26 months after inoculation. .
12. The Committee was not able to assess the magnitude of the potential risk, as insufficient information on current practices was available at the time of assessment. In view of this, the Committee made a number of recommendations.

Recommendations

13. The Committee recommended that a risk assessment be carried out to establish the potential level of exposure to BSE infectivity that the human population might be exposed to as a consequence of the possibility of infectivity in tonsil tissue. The Committee considered that further work was needed to establish the distribution of tonsillar tissue in tongues prepared for human consumption. The assessment should include risks associated with both UK and imported meats. The Committee recommended that it is also necessary to investigate the food uses of tongues and of tonsils from young animals that are not classified as SRM.
14. The Committee recommended that, in addition to cattle bioassay, further studies on lymphoid tissues from cattle should be carried out, using the most sensitive assays, as these become available. These should include validation of this interim finding by exploring all available techniques to detect PrP^{sc} on both the original tonsil tissue material collected, as well as any lymphoreticular tissue tested in the mouse bioassay that had not been included in the cattle bioassay.

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