

L.6.- Evaluation of rapid BSE and scrapie tests

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Transmissible spongiform encephalopathies (TSEs) comprise several fatal neurodegenerative diseases of mammals, including bovine spongiform encephalopathy (BSE) in cattle and scrapie in small ruminants. Testing for TSE in cattle and small ruminants populations is compulsory in the European Union since 2001 and 2002, respectively. Diagnostic methods to detect BSE and scrapie include the classical post mortem examination of central nervous tissue by histopathology or immunohistochemistry and, more recently, the use of rapid immunoassays. The difficulty in diagnosing TSE, however, is the early detection of abnormally folded prion protein (PrP^{Sc}) and the uneven distribution of PrP^{Sc} only in certain tissues. Both aspects require the use of highly sensitive tests to allow a detection. Nowadays, rapid tests for the diagnosis of BSE in cattle, and scrapie in small ruminants are used worldwide more than 12 million times per year. The Institute for Reference Materials and Measurements (IRMM) of the European Commission has evaluated in the past nine different rapid BSE tests, five of which have been formally approved for large scale testing under regulation EC 999/2001. During these evaluations many critical points for both, the design of evaluation schemes and quality control protocols could be identified and were considered for further evaluations of rapid TSE tests. In addition to BSE test evaluations in 1999, 2001 and 2004, IRMM has recently carried out an evaluation of rapid tests for the detection of scrapie in sheep. Data on the outcome of 20 BSE test 6 scrapie test evaluations as well as results on the development of reference materials for the quality control of rapid post mortem TSE tests will be presented.

Keywords

Bovine spongiform encephalopathy, scrapie, rapid test, diagnosis, evaluation