

Frequently asked questions about BSE-tests

What will a BSE-test look for?

The commonly accepted cause of BSE is a misshaped prion protein (PrPres). This misshaped protein causes other normal proteins to become misshaped. These proteins clump together to form sheets. There are other theories of the cause of BSE and some variations on the above theory. The presence of PrPres is regarded as a marker for the disease.

BSE tests will determine if a detectable level of PrPres (either the cause of BSE or a marker for the disease) is present in the tissue examined.

How many tests have been approved by the European Commission?

To date, the European Commission has approved five rapid tests:

- Bio-Rad TeSeE test
- Prionics AG Check LIA test
- Prionics-Check Western test
- Enfer test -InPro CDI-5 test

Following an open call for expressions interest in 2003, a third evaluation round of post-mortem rapid tests is ongoing.

How do the tests operate in practice?

All five tests operate by detecting the infectious agent or marker PrPres in the central nervous system. Following slaughter of the animal a sample of brain or spinal cord is taken from the animal using a special tool. This tissue is taken to the laboratory and tested for the presence of PrPres. Rapid tests are quick and reliable, and allow large numbers of samples to be tested.

What other methods are used to diagnose BSE?

Other laboratory techniques used to diagnose BSE include histopathological examination (detection of spongiform encephalopathy), examination of BSE fibrils (equivalent to scrapie associated fibrils), examination by immunohistochemistry or western blot.

For what purpose can the tests be used?

Tests may be used for surveillance and also to provide additional protection for the consumer.

1. Surveillance

Tests can be used to determine if BSE exists in a population and to obtain an indication of its prevalence. Used over time these can be used to monitor changes in the level of the disease.

In addition to the compulsory examination of all animals showing signs suggestive of BSE, rapid post mortem testing for BSE must, as of 1 January 2001, be carried out on:

- Animals slaughtered as emergencies or showing signs of any kind of illness at the ante mortem inspection in the slaughterhouse. From January 2001 to June 2001: all animals over 30 months of age. As of 1 July 2001: all animals over 24 months of age.
- All bovine animals over 30 months of age subject to normal slaughter for human consumption. By way of derogation, Sweden is allowed to test only a random sample.
- Fallen stock: cattle which have died or been killed on the farm or in transport, but not slaughtered for human consumption. January 2001 to June 2001: A random sample of bovine animals over 30 months of age. As of 1 July 2001: All bovine animals over 24 months of age
- In the UK, where the vast majority of bovine animals over 30 months of age are destroyed under the Over Thirty Months Scheme (OTMS), BSE testing must be carried out on the following animals slaughtered under that scheme: all bovine animals subject to casualty slaughter, all animals over 42 months of age born after 1 August 1996 and subject to normal slaughter and a random sample of bovine animals born before 1 August 1996 and subject to normal slaughter

2. Additional Health protection

BSE is a relatively rare disease. However, routine testing of animals prior to slaughter may detect animals presented for slaughter which may have unnoticed signs of BSE and also animals with the disease which are not yet showing signs. The identification and removal of these animals will be an additional protection for the consumer. However, the most important measure to protect the consumer is the removal of specified risk material like brain or spinal cord from every animal slaughtered. These tissues harbour almost all infectivity if there is any present. Removal of specific risk materials is obligatory in the EU since 1.10.2000.

How did the European Commission evaluate BSE tests?

Two evaluation rounds have been completed and a third evaluation round is ongoing.

The policy for approval of rapid tests has so far been as follows:

1. An open call for expressions of interest is published in the Official Journal. It calls upon potential producers to express their interest and to submit a technical dossier supporting their claim.

2. Submissions following the open call are scrutinised by a panel of independent experts, currently managed by the European Food Safety Authority (EFSA), whose task is to select tests for participation in a laboratory evaluation exercise.
3. Tests which have performed satisfactorily in the laboratory evaluation are further assessed in a field trial.
4. Based on the results of the field trial, the EFSA adopts an opinion on the performance of the tests and, if such performance proves satisfactory, recommends the test for approval.
5. Based on the opinion of EFSA the Commission makes a proposal to amend Annex X to Regulation 999/2001, where approved rapid tests are being listed. The proposal is submitted for an opinion to the Standing Committee on the Food Chain and Animal Health.

What were the results of the evaluations?

The reports of the previous evaluation rounds are available on the Commissions web site at:

[The evaluation of tests for the diagnosis of Transmissible Spongiform Encephalopathy in Bovines \(8 July 1999\)](#)

[Opinion of the Scientific Steering Committee on design of a field trial for the evaluation of new rapid BSE post mortem tests \(22 February 2002\)](#)

[The evaluation of five rapid tests for the diagnosis of transmissible spongiform encephalopathies in bovines \(2nd study 27 March 2002\)](#)

[Opinion of the SSC on the field trial evaluation of two new rapid BSE post mortem tests \(2nd study 3 March 2003\)](#)

What can the test do early in the infection?

No method will detect BSE early in the infection. BSE has an average incubation period of 4-6 years. Therefore the EU testing programmes are targeted at animals over 30 months. The PrPres has not been detected in bovine brain or other nervous tissue very early in the disease and infectivity has not been shown either. In experimental infection where very high doses were administered, infectivity has been found in the ileum, part of the intestine. This has not been detected in natural infections.

Why not use tissue from pre-clinical cows?

Such tissue is not available for routine use. This tissue can only be produced by experimentally infecting cows and then slaughtering them about three years later before they develop symptoms.

Have the tests detected pre-clinical animals?

The tests have identified BSE cases at normal slaughter without obvious signs of disease, but we cannot know how advanced the disease was.

Most cases of BSE have been identified by the tests in animals presented for emergency slaughter or found dead at the farm. These animals showed some disease signs but these signs had not been treated as suspicious for BSE.

How much do the tests cost?

Member States purchase following competitive tenders. The cost will depend on this and also factors such as size of order, whether items such as training are included etc. The Commission is co-financing the surveillance programmes to a maximum of 8€ per test for tests carried out in 2004.