#### Questions and Answers on BSE updated 28 September 2007

#### What is BSE?

Bovine spongiform encephalopathy (BSE) is a brain disease in cattle. The commonly accepted cause of the disease is a misshaped prion (PrPres). Common symptoms of BSE include behavioural changes, lack of coordination, difficulty walking or standing up, decreased milk production and weight loss. However, the disease has also been detected in animals showing no symptoms or atypical signs of the disease.

BSE was first diagnosed in the UK in 1986, and reached epidemic proportions due to meat-and- bone meal, produced from animal carcasses, being fed to cattle. To date (up to August 2007), there have been about 184,600 BSE cases in the UK and about 5,250 cases elsewhere in the European Union. Most of the infected cattle were born in 1994, 1995 or 1996, before the measures taken from 1996 were implemented.

#### What impact can BSE have on human health?

BSE is assumed to be linked with the human disease Variant Creutzfeldt-Jacob Disease (vCJD). vCJD was first diagnosed in 1996, and up to July 2007, there have been 195 confirmed or suspected cases in the EU, mostly in young people. Most cases have occurred in the UK (163), although cases were also diagnosed in France (22), Ireland (4), Italy (1), The Netherlands (2), Portugal (2) and Spain (1).

Estimates of the future number of vCJD cases vary widely, as too little is known about the incubation period between exposure to the infective agent and the emergence of symptoms. However, it is assumed that any cases which may emerge in the future will be due to exposure to infected material before the current stringent control measures against BSE were implemented.

#### What is the current state of play regarding BSE in the EU?

Over the last five years, the number of positive BSE cases has been declining steadily in the EU. There has been about a 35% reduction in positive cases since 2002, with figures falling from 2129 BSE cases in the EU-15 in 2002 to 320 in the EU-25 in 2006. This downward trend, which is largely thanks to the stringent EU measures laid down against BSE, looks set to continue in the coming years.

#### What is the incidence of BSE by Member State?

Currently, the overall incidence of BSE is falling throughout the EU. In the UK the incidence has fallen sharply from over 37,056 cases in 1992 (at the peak of the epidemic) to 129 cases in 2006. The number of positive BSE cases has also dropped in most other Member States.

When analysing the evolution of positive BSE cases, it should be kept in mind that, before 2001, active monitoring of BSE was limited. The expanded active monitoring only became fully applicable in July 2001, and the number of tests performed annually was about 25 % higher in the period 2002-2005 than in 2001. Nonetheless, despite this increased testing, the reported number of cases and prevalence of BSE has still fallen since 2002.

Member States submit their figures on BSE testing and positive cases found to the Commission, which compiles them in monthly and annual reports.

Click <a href="http://ec.europa.eu/food/food/biosafety/bse/monitoring\_en.htm">http://ec.europa.eu/food/food/biosafety/bse/monitoring\_en.htm</a> for details on BSE monitoring and the Commission reports.

#### What is the expected future evolution of the disease?

The average incubation period of BSE in cattle is 4-6 years, but in certain cases it can be much longer. Therefore BSE cases will probably continue to occur until 2010 or later. However, the downward trend in the number of positive BSE cases shows no sign of stopping.

#### What EU legislation is in place with regard to BSE?

The main body of legislation covering BSE in the EU is Regulation (EC) No 999/2001. This gathers together all BSE measures adopted over the years into a single, comprehensive framework, consolidating and updating them in line with scientific advice and international standards. In addition, the Regulation sets out the instruments to manage the risk of BSE and other similar diseases such as scrapie in all animal species and relevant products. Regulation 999/2001 has been amended many times over the years in response to the evolution of the BSE situation, new or updated scientific advice and/or technological developments. (See below for EU measures against BSE)

All Community measures are based on sound, independent scientific advice from leading experts. These scientific opinions were initially provided and updated by the EU Scientific Steering Committee and other scientific committees focussed on BSE-related issues. Since May 2003, the European Food Safety Authority (EFSA) has taken over the role of providing scientific advice to the Commission in this area (<a href="http://www.efsa.eu.int/EFSA/efsa\_locale-1178620753812\_home.htm">http://www.efsa.eu.int/EFSA/efsa\_locale-1178620753812\_home.htm</a>)

#### What measures are in place in the EU protect the public against BSE?

The European Commission's top priority is to protect animal and public health, and to ensure that food is safe from farm to fork. To that end, the Commission has introduced a comprehensive and stringent set of BSE measures which apply throughout the EU.

#### These measures include:

- Veterinary inspections: All animals presented for slaughter must undergo a veterinary inspection, to ensure that suspected cases do not enter the food and feed chain (since 9 April 1990);
- **SRM removal**: Specified risk materials (SRMs), such as the spinal cord, brain, eyes, tonsils (see full list below), must be removed from cattle, sheep and goats before they enter the food and feed chain (since 1 October 2000).

Third countries exporting meat and meat products to the EU must also meet these requirements, except for countries with a negligible BSE risk status. (These negligible risk countries are set out in Commission Decision 2007/453/EC of 29 June 2007 establishing the BSE status of member states or third countries or regions thereof according to their BSE risk)

 MBM ban: There is a ban on the feeding of mammalian meat-and-bone meal (MBM) to cattle, sheep and goats (since July 1994). This ban was introduced following findings by the scientific committees, which linked the spread of BSE to the consumption of feed contaminated by ruminant protein in the form of MBM.

This ban was extended in January 2001 and now no farmed animals can be fed with processed animal protein. This is to ensure that there is no cross-contamination between feed for other species containing MBM and the feed intended for ruminants. Only certain animal proteins which are considered to be safe (such as fishmeal) can be used, and even then, it is under very strict conditions.

- Treatment of ruminant waste: There are strict processing standards for the treatment of ruminant animal waste (since 1 January 1995). These standards, which were re-enforced on 1 April 1997, require all mammalian waste used for the production of MBM to be pressure-cooked (133 °C/3 bars/20 minutes). This helps to minimise the risk of infectivity and avoid any infectious agent that could be present in animal cadavers from being recycled.
- Culling potentially infected animals: Any animals considered likely to have received the same potentially-infected feed as an animal infected with BSE must be culled and destroyed (since July 2001). Animals of the same age from the same herd (cohort animals) are most likely to have received the same feed and therefore must always be culled. Depending on the epidemiological situation and the traceability of animals, it may also be necessary to cull other animals from the same herd. In addition, the most recent offspring of female BSE cases must be culled, due to potential maternal transmission.
- Monitoring and surveillance: There are strong surveillance measures for the detection, control and eradication of BSE (since 1 May 1998), involving passive monitoring by veterinarians/farmers (identification of clinical suspects) and active monitoring through tests;

#### **Full SRM list**

#### (a) for bovine animals

- (i) the skull excluding the mandible and including the brain and eyes, and the spinal cord of animals aged over 12 months;
- (ii) the vertebral column excluding the vertebrae of the tail, the spinous and transverse processes of the cervical, thoracic and lumbar vertebrae and the median sacral crest and wings of the sacrum, but including the dorsal root ganglia of animals aged over 24 months; and
- (iii) the tonsils, the intestines from the duodenum to the rectum and the mesentery of animals of all ages.

#### (b) for ovine and caprine animals

- (i) the skull including the brain and eyes, the tonsils and the spinal cord of animals aged over 12 months or which have a permanent incisor erupted through the gum, and
- (ii) the spleen and ileum of animals of all ages

## What is the current testing programme for BSE in the EU?

In addition to the compulsory examination of all animals showing signs suggestive of BSE, rapid post mortem testing for BSE must be carried out on certain animals (since January 2001). Over 61 million cattle have been tested in the EU since 2001, and the Commission co-finances the testing programme (currently 6 Euro per test).

The animals to which these additional testing requirements apply are:

- Animals sent for emergency slaughter or showing signs of any kind of illness at the ante-mortem inspection in the slaughterhouse. From January 2001 to June 2001, this applied to all animals over 30 months of age. Since 1 July 2001, this requirement covers all animals over 24 months of age
- All bovine animals over 30 months of age which are slaughtered in the normal manner for human consumption.
- Cattle which have died or been killed on the farm or in transport, but not slaughtered for human consumption (fallen stock). From January 2001 to June 2001, only a random sample of such animals over 30 months of age had to be tested. However, since 1 July 2001, all fallen bovine stock over 24 months of age must be tested.

Until mid-2000, the majority of detected BSE cases were found through traditional passive surveillance, i.e. the examination and mandatory reporting of animals suspected of showing signs or clinical symptoms of BSE.

It became evident, however, that active monitoring was very important for picking up BSE cases in animals with non-typical symptoms (e.g. kicking, lameness, loss of weight and reduced milk yield). In addition, BSE cases have also been found through active monitoring in slaughtered animals without any previous signs of illness.

Systematic active monitoring started in January 2001 in target groups such as fallen stock and healthy slaughtered cattle without any previous signs of BSE. In the period 2001-2006, more than 70% of all BSE cases were detected in this way. When the systematic active monitoring was intensified in July 2001, it was expected that the result would be an increase in the number of detected BSE cases. However, on the contrary, the number of positive cases detected per month has steadily decreased in most Member States. In addition to the reduction of positive cases per month, the age structure of the positive BSE cases is shifting towards older animals in all Member States. This is a positive signal and shows that the measures taken from 1996 onwards are having an effect.

Click <a href="http://ec.europa.eu/food/food/biosafety/bse/monitoring\_en.htm">http://ec.europa.eu/food/food/biosafety/bse/monitoring\_en.htm</a> for details on the number of tests and detected cases.

#### How are BSE rules monitored and enforced?

Member States are responsible for ensuring that EU rules are properly enforced their respective territories. The Commission's Food and Veterinary Office (FVO) carries out inspections to verify the correct implementation, enforcement and control of EU legislation by the competent national authorities. When a breach of the legislation is reported, the Commission initiates infringement procedures against the Member State concerned. The FVO inspection reports are published on the Commission's website at: http://ec.europa.eu/food/fs/inspections/vi/reports/index\_en.html

#### What is the BSE situation in third countries?

BSE has also occurred in a number of non-EU countries. Click <a href="http://ec.europa.eu/food/biosafety/bse/third\_en.htm">http://ec.europa.eu/food/biosafety/bse/third\_en.htm</a> for the number of BSE cases in third countries.

Under EU rules, imports must meet the same safety standards as products produced in the Member States. Therefore, strict import requirements related to BSE are laid down in Regulation (EC) No 999/2001 (Annex IX). These include the requirements that the imported animals or the animal products are fully traceable and not from a BSE-infected herd/cohort; that the MBM ban is in place in the country of origin; and that no banned substances (such as mechanically re-covered meat) has been used in the animal products.

# How is the risk of BSE in third countries evaluated and how are they classified in BSE risk categories?

It is important to have a categorisation system to determine the BSE-risk of third countries, so as to allow trade rules to be established for each BSE-risk category, which will provide the necessary guarantees for protecting animal and public health.

Up until 1 July 2007, the EU categorised countries or regions according to 4 Geographical BSE Risk (GBR) groups:

- Level I BSE highly unlikely
- Level II BSE unlikely but not excluded
- Level III BSE likely but not confirmed, or confirmed at a lower level
- Level IV BSE confirmed at a higher level

These groups, and the metholodogy for deciding which countries should fall into which groups were developed based on solid scientific advice from the SCC.

On 1<sup>st</sup> July 2007, Regulation (EC) No 722/2007 entered into force, amending the TSE Regulation (EC) No 999/2001. Regulation 722/2007 brought the EU's system for categorising countries according to risk into line with that of the World Organisation for Animal Health (OIE). As such, countries are put into 3 groups: negligible BSE risk, controlled BSE risk or undetermined BSE risk. The determination of BSE status is based on a risk assessment and the implementation of a surveillance programme. Trade rules for each risk category were also introduced.

The BSE status of Member States or third countries or regions thereof are categorised according to their BSE risk in Commission Decision 2007/453/EC.

#### (http://eur-

lex.europa.eu/LexUriServ/site/en/oj/2007/I\_172/I\_17220070630en00840086.pdf)

### What are the rules for imports from third countries?

Regulation (EC) No 999/2001 (Annex IX) lays down the BSE-related import requirements for live bovine, ovine and caprine animals, and for the products of these animals. This Regulation provides additional protection against BSE in that it asks that the same guarantees be applied for imports of beef into the EU like they are required the EU. For example, it prohibits imports of specific risk materials (SRM) or meat products containing SRMs from third countries with a controlled or an undetermined BSE risk status, and third countries must ensure that the slaughter techniques of animals are in line with EU rules.

The import rules apply also to a list of bovine, ovine and caprine products (rendered fats, gelatine, petfood, bone and bone products, raw material for the manufacture of animal feedingstuffs) from third countries. For countries with a negligible BSE risk status, no BSE related import restrictions are foreseen.

BSE related import rules set out by the EU seek to minimise any disruption to, or other implications for, trade. For example, trade in beef carcasses is not interrupted, as there is provision for the removal of vertebral column (as SRM) in the EU rather than in the third country before export. However, most beef is traded in de-boned form and is therefore unaffected. Third countries must, however, ensure that the slaughtering techniques of animals do not include practices which are prohibited in the EU.

## What research activities on TSEs is the EU doing?

The European Commission has sponsored research into Transmissible Spongiform Encephalopathies (TSEs) since 1990.

The Seventh Framework Programme for research and technological development (FP7) is currently the European Union's main instrument for funding research into BSE (among many other issues). FP7, which will run from 2007-2013, was drawn up after extensive consultations with the scientific community, research and policy-making institutions and other interested parties.

FP7 has a budget of 53.2 billion euros over its seven-year lifespan, the largest funding allocation yet for such programmes. Click <a href="http://ec.europa.eu/research/fp7/">http://ec.europa.eu/research/fp7/</a> for more information on FP7

Further enquiries on BSE can be send to <a href="mailto:sanco-mailbox@ec.europa.eu">sanco-mailbox@ec.europa.eu</a> of the Health & Consumer protection Directorate-General: