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COMMISSION STAFF WORKING DOCUMENT

accompanying the

Communication from the Commission to the European Parliament and the Council

on the TSE Roadmap 2

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1. GENERAL INTRODUCTION

This working document accompanies the Communication of the Commission to the European Parliament and the Council on the TSE Roadmap 2.

The working document provides background information on certain aspects developed in the Communication. In particular:

- it gives a glossary of the technical terms used in the Communication;
- it provides an overview of the main achievements of the first TSE Roadmap over the period 2005-2009;
- it shows the evolution of the BSE epidemiological situation in the EU since 2001;
- it provides the full list of TSE legislation adopted following the first TSE Roadmap.

2. ANNEX I: GLOSSARY

What are TSEs?

Transmissible Spongiform Encephalopathies (TSEs) are a family of diseases occurring in human and animals and are characterised by a degeneration of brain tissue giving a sponge-like appearance leading to death. The family includes diseases such as Creutzfeldt Jakob Disease (CJD) in humans, Bovine Spongiform Encephalopathy (BSE) in cattle, Scrapie in small ruminants (sheep and goats), Chronic Wasting Disease (CWD) in cervids. The commonly accepted cause of the TSE disease is a transmissible agent called a prion which is an abnormal form of a protein.

What is BSE?

Bovine Spongiform Encephalopathy (BSE) is a TSE disease of cattle. BSE was first diagnosed in the UK in 1986, and reached epidemic proportions due to cattle being fed with processed animal protein, produced from ruminant carcasses, some of which were infected. BSE is considered to be transmissible to humans by the oral route causing variant Creutzfeldt-Jacob Disease (vCJD).

What are the specified risk materials (SRM)?

SRM are the organs considered to harbour the BSE infectivity in an animal affected by BSE and which can consequently pose a risk to human health if consumed. For bovines the list includes: the skull excluding the mandible and including the brain and eyes, and the spinal cord of animals aged over 12 months, the vertebral column including the dorsal root ganglia of animals aged over 30 months, the tonsils, the intestines from the duodenum to the rectum and the mesentery of animals of all ages. According to EU rules, all SRM are removed from the food and feed chains in EU Member States and destroyed. SRM removal is the most important measure in terms of protection of public health against BSE.

What is the feed ban?

The feed ban is a preventive measure laid down against TSE and consists of a ban on the use of processed animal protein (PAP) in feed for farmed animals in order to avoid spreading BSE. Findings by the scientific committees linked the spread of BSE to the consumption of feed contaminated by the infected ruminant protein in the form of PAP. In other words PAP produced from ruminant carcasses, some of which were infected, was assumed to be the transmission route of BSE. Based on these findings a ban on the feeding of mammalian processed animal protein to cattle, sheep and goats was introduced in July 1994. The ban was expanded in January 2001 with the feeding of all processed animal proteins to all farmed animals being prohibited, with certain limited exceptions. This is to ensure that there is no cross-contamination between feed containing PAP intended for species other than ruminants and feed intended for ruminants. Only certain animal proteins considered to be safe (such as fishmeal) can be used, and even then under very strict conditions.

What are processed animal proteins (PAP)?

PAP are animal proteins derived from animal by-products and which have been treated so as to render them suitable for direct use as feed material or for any other use in feedingstuffs, including pet food, or for use in organic fertilisers or soil improvers; however, it does not include blood products, milk, milk-based products, colostrum, gelatine, hydrolysed proteins and dicalcium phosphate, eggs and egg-products, tricalcium phosphate and collagen.

What is TSE monitoring/testing?

Adequate surveillance forms the basis for successful detection, control and eradication of TSEs. Since May 1998, EU-wide measures on surveillance have been in place. Each Member State has to carry out an annual monitoring programme for TSEs based on active surveillance (testing without previous suspicion) and passive surveillance (testing of clinical suspects identified by veterinarians/farmers) which applies to both bovine animals and ovine and caprine animals. The monitoring programme provides a reliable insight into the prevalence and evolution of TSEs in the Member States and at the same time ensures that no BSE cases are being slaughtered for human consumption.

Since the start of an expanded monitoring programme on BSE in 2001, more than 87 million cattle have been tested in the EU, in addition to those tested as BSE suspects. The number of positive cases in 2009 (67 cases) has continued to decrease compared to previous years: 2008 (125), 2007 (175), 2006 (320), 2005 (561), 2004 (865), 2003 (1376), 2002 (2124) and 2001 (2167). This consistent fall proves the effect of the strict EU measures put in place. However, a complete eradication of BSE will still take years, given its long incubation period.

What is the OIE?

The OIE is the World Organisation for Animal Health. It is the intergovernmental organisation responsible for improving animal health worldwide. The need to fight animal diseases at global level led to the creation of the Office International des Epizooties (OIE) through the international Agreement signed on January 25th 1924. In May 2003 the Office became the World Organisation for Animal Health but kept its historical acronym OIE. It is recognised as a reference organisation by the World Trade Organization (WTO) and in 2010, had a total of 175 Member Countries and Territories. The OIE maintains permanent relations with 36 other international and regional organisations and has regional and sub-regional offices on every continent.

What is EFSA?

The European Food Safety Authority (EFSA), set up in January 2002 following a series of food crises in the late 1990s, is an independent source of scientific advice and communication on risks associated with the food chain. As a risk assessor, EFSA produces objective and independent scientific opinions and advice to provide a sound foundation for European policies and legislation and to support the European Commission, European Parliament and EU Member States in taking effective and timely risk management decisions. EFSA's remit covers food and feed safety, nutrition, animal health and welfare, plant protection and plant health.

3. ANNEX II: OVERVIEW OF THE FIRST TSE ROADMAP'S ACHIEVEMENTS OVER THE PERIOD 2005-2009

Since the adoption of the first TSE Roadmap in 2005, major steps have been taken as regards the following domains.

– Specified risk materials

The first step was an increase in the age limit for the removal of the vertebral column from 12 to 24 months on 1 January 2006 based on scientific advice¹. Following updated scientific evidence², a further increase in the age limit for the removal of the vertebral column as specified risk material in cattle from 24 to 30 months was adopted in April 2008.

– UK embargo

A second major step, unanimously supported by all Member States, was the lifting of the restrictions on the trade of live bovine animals and products thereof originating from the UK which entered into force on 2 May 2006.

– Categorisation of countries according to their BSE risk

In June 2007, Member States and third countries or regions thereof were classified into three risk categories as regards BSE (negligible risk, controlled risk and undetermined risk) according to OIE standards. The categorisation is updated every year based on OIE Resolutions³.

– Monitoring programme for small ruminants (sheep and goats)

In July 2007 the monitoring was reduced to a level similar to the situation before the increased monitoring programmes in small ruminants decided in 2005 following the detection of BSE in a goat. No new BSE cases were detected in the small ruminant population following this increased surveillance.

– Monitoring programme for bovine animals

Based on their favourable BSE situation (i.e. their clearly declining or consistently low BSE prevalence), 17 Member States have been authorised to increase the age limit for their BSE monitoring programmes (EU-15 MS as from 1st January 2009, then Slovenia as from November 2009 and Cyprus as from April 2010).

¹ The EFSA Journal (2005) 220, 1-7. Opinion on the assessment of the age limit in cattle for removal of certain specified risk materials (SRM).

² The EFSA Journal (2007) 476, 1-47. Opinion of the Scientific Panel on Biological Hazards on a request from the European Commission on the infectivity in SRM derived from cattle at different age groups estimated by back calculation modelling.

³ http://www.oie.int/eng/Status/BSE/en_BSE_free.htm

– Rapid tests approved for TSE monitoring

In 2008, the Community Reference Laboratory (CRL) for TSEs assessed the analytical sensitivity of all the currently approved TSE rapid tests against the same sample sets for the three main types of ruminant TSEs: BSE, classical scrapie and atypical scrapie. Subsequently, EFSA provided a scientific evaluation of the CRL study and recommended certain modifications regarding the approval of the current rapid tests⁴. The Commission initiated legislative actions to align the legislation with EFSA recommendations.

– Eradication measures in small ruminants (sheep and goats)

In July 2007, new rules were introduced as regards the eradication measures applicable in flocks where scrapie was detected and specific measures were adopted for flocks affected by atypical scrapie because, even if the knowledge of this disease is still limited, it has been scientifically recognised that atypical scrapie differs in terms of risk and epidemiology from classical scrapie. In February 2009, following the publication of a scientific opinion from EFSA⁵, animal health protective measures in relation to milk and milk products coming from classical scrapie infected flocks were adopted in order to prevent the spread of classical scrapie to other ruminant flocks through feeding.

– Eradication measures in bovine animals

The legal basis was introduced in 2006 to defer the killing and complete destruction of cohort animals until the end of their productive lives following an application from the Member States. Only Germany applied for this derogation and was authorised to use it in 2007.

– Feed ban

A tolerance on the presence of bone fragments originating from unavoidable environmental contamination has been introduced in 2005 for beet pulp. This derogation was extended to all feed materials of plant origin in 2009. In September 2008, the possibility to use fishmeal in milk replacers destined for young ruminants has been introduced.

On 23 May 2006, the European Commission appointed the Centre Wallon de recherches agronomiques (CRA-W) in Gembloux (Belgium) as Community Reference Laboratory for the detection of animal proteins (AP) in feedingstuffs.

⁴ The EFSA Journal 2009; 7(12):1436 [32 pp.]. Scientific Opinion on Analytical sensitivity of approved TSE rapid tests.

⁵ The EFSA Journal (2008) 849, 1-37. Opinion of the Scientific Panel on Biological Hazards on a request from the European Commission on the human and animal exposure risk related to Transmissible Spongiform Encephalopathies (TSEs) from milk and milk products derived from small ruminants.

– Chronic wasting disease in cervids (e.g. deer, reindeer)

In 2007 and according to EFSA recommendations⁶, a survey was launched in order to detect the possible presence of TSEs in wild and farmed cervids in the EU. This survey, which was based on statistical planning, has now been completed. About 13,000 tests were performed on wild and farmed cervids and no positive case was detected.

⁶ The EFSA Journal (2004) 70, 1-7, Opinion on a surveillance programme for Chronic Wasting Disease in the European Union.

4. ANNEX III: EVOLUTION OF BSE EPIDEMIOLOGICAL SITUATION SINCE 2001

Chart 1: Total tests performed in bovine animals during the period 2001–2009 in the EU

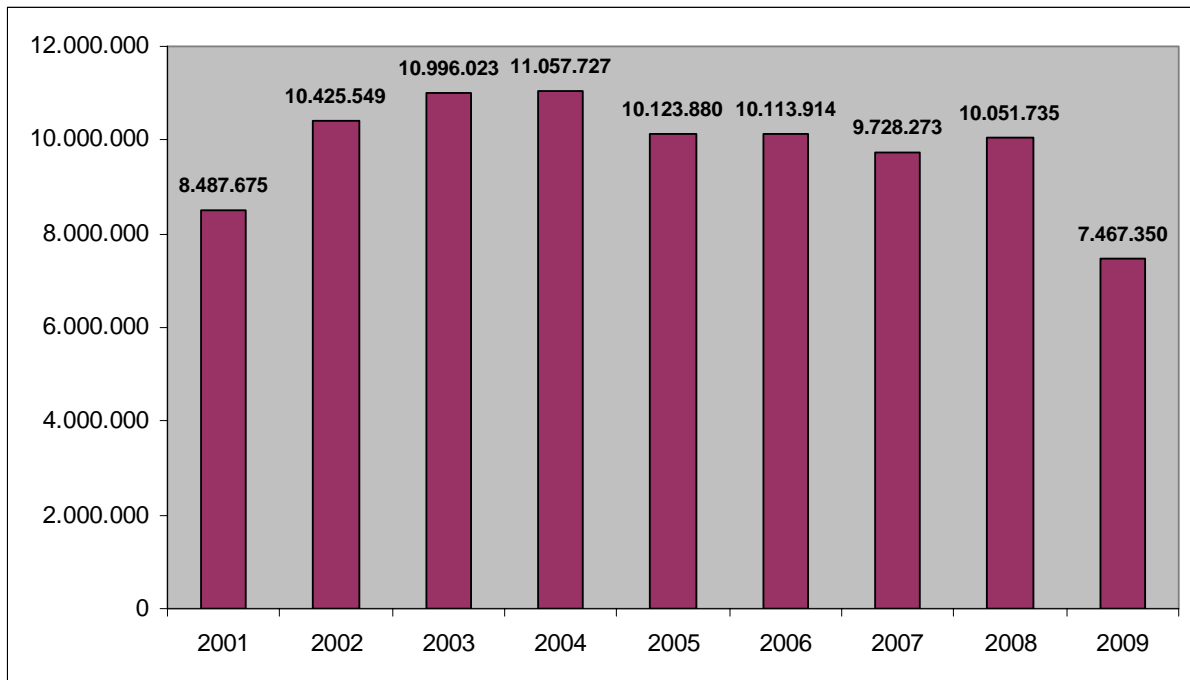


Chart 2: Evolution of the number of BSE positive cases in the EU since 2001

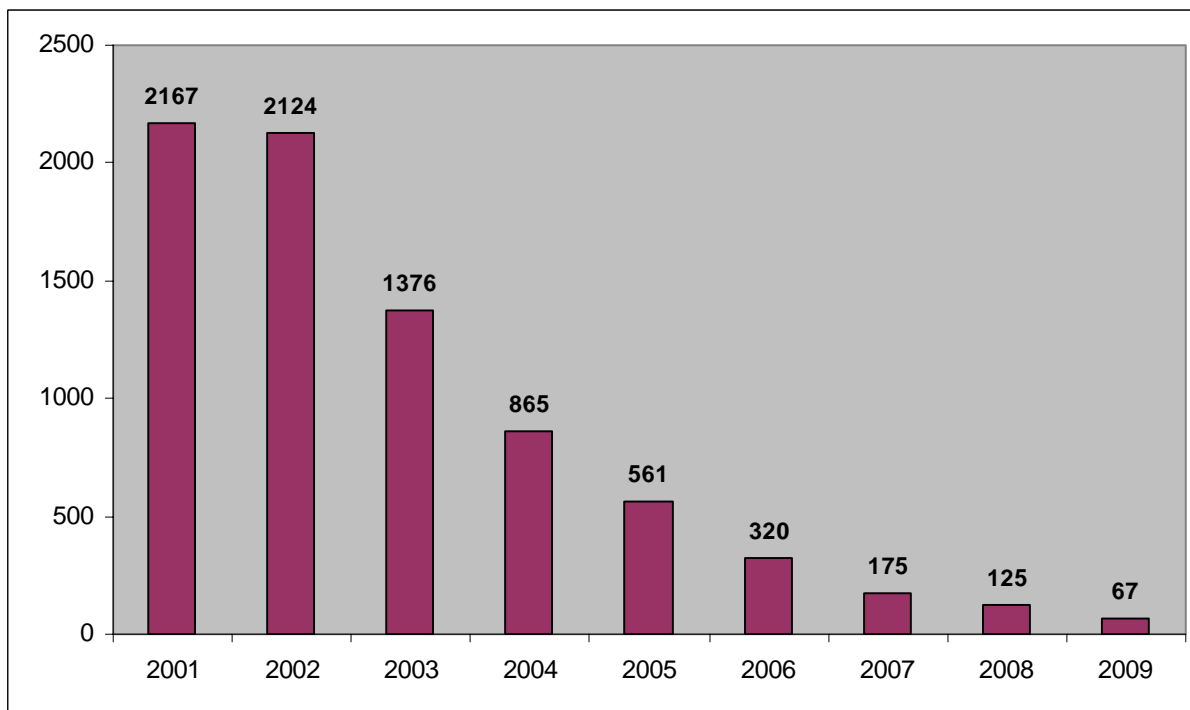
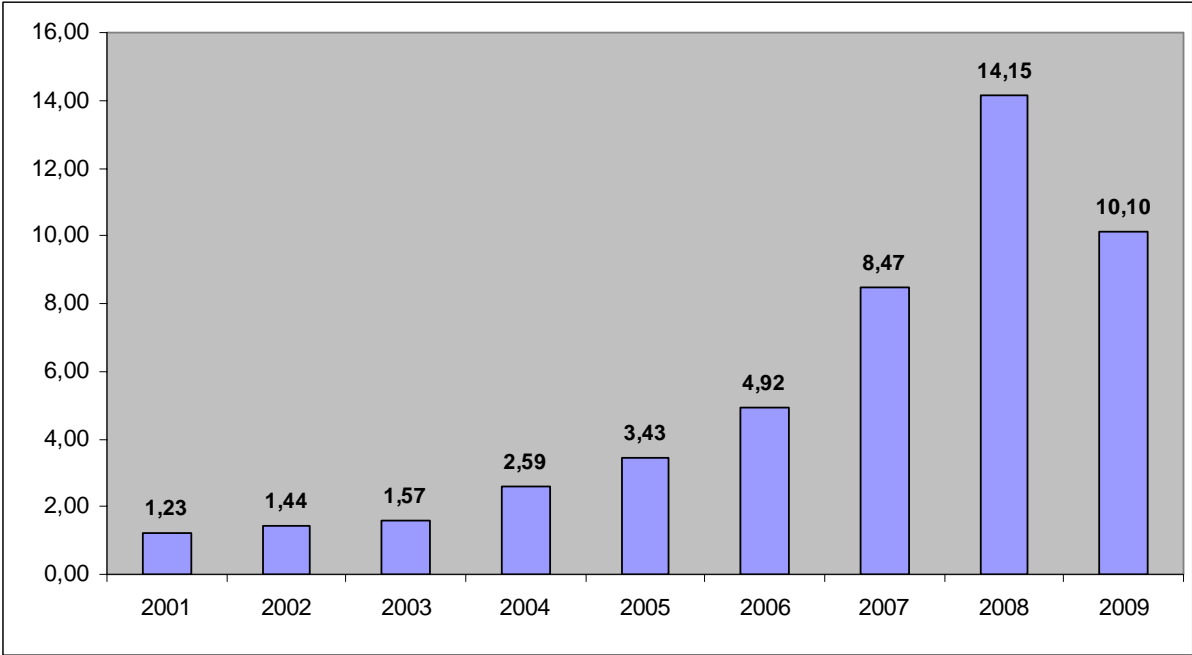


Chart 3: Evolution of the costs (M€) per BSE case detected in slaughterhouse since 2001



5. ANNEX IV: CHRONOLOGICAL LIST OF TSE LEGISLATION ADOPTED FOLLOWING THE FIRST TSE ROADMAP

2005

Legal text	Contents
Commission Regulation (EC) No 1974/2005 of 2 December 2005 amending Annexes X and XI to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards national reference laboratories and specified risk material (OJ L 317, 3.12.2005, p. 4)	Amendment of R 999/2001 as regards national reference laboratories and Specified Risk Materials – modification of the age limit for vertebral column in bovines

2006

Legal text	Contents
Commission Regulation (EC) No 253/2006 of 14 February 2006 amending Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards rapid tests and measures for the eradication of TSEs in ovine and caprine animals (OJ L 44, 15.2.2006, p. 9)	Amendment of R 999/2001 as regards rapid tests and TSE eradication measures on small ruminants
Commission Regulation (EC) No 339/2006 of 24 February 2006 amending Annex XI to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the rules for importation of live bovine animals and products of bovine, ovine and caprine origin (OJ L 55, 25.2.2006, p. 5)	Amendment of R 999/2001- deleting Brazil, Chile, El Salvador, Nicaragua, Namibia, Botswana and Swaziland from the list of countries exempted from certain TSE-related trade conditions for live bovine animals and products of bovine, ovine and caprine origin
Commission Regulation (EC) No 546/2006 of 31 March 2006 implementing Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards national scrapie control programmes and additional guarantees and derogating from certain requirements of Decision 2003/100/EC and repealing Regulation (EC) No 1874/2003 (OJ L 94, 1.4.2006, p. 28)	Implementing R 999/2001 as regards national scrapie control programmes and additional guarantees and derogating from certain requirements as regards breeding programmes in certain Member States.
Commission Regulation (EC) No 657/2006 of 10 April 2006 amending Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the United Kingdom and repealing Council Decision 98/256/EC and Decisions 98/351/EC and 1999/514/EC (OJ L 116, 29.4.2006, p. 9)	Lifting of the embargo on the United Kingdom – Amendment of R 999/2001 as regards SRM, BSE monitoring and repeal of Commission Decision 98/256/EC and related measures

Commission Regulation (EC) No 688/2006 of 4 May 2006 amending Annexes III and XI to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the monitoring of transmissible spongiform encephalopathies and specified risk material of bovine animals in Sweden (OJ L 120, 5.5.2006, p. 10)	Amendment of R 999/2001 as regards BSE monitoring in Sweden
Commission Regulation (EC) No 1041/2006 of 7 July 2006 amending Annex III to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards monitoring of transmissible spongiform encephalopathies in ovine animals (OJ L 187, 8.7.2006, p. 10)	Amendment of R 999/2001 as regards TSE monitoring in sheep . Increased number of tests
Regulation (EC) No 1923/2006 of the European Parliament and of the Council of 18 December 2006 amending Regulation (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 404, 30.12.2006, p. 1)	Regulation of the European Parliament and of the Council. Amendment of R 999/2001 as regards categorisation of countries, specified risk materials, TSE surveillance , Import conditions

2007

Legal text	Contents
2007/182/EC: Commission Decision of 19 March 2007 on a survey for chronic wasting disease in cervids (OJ L 84, 24.3.2007, p. 37)	Laying down rules for a survey for Chronic wasting disease in cervids
2007/315/EC: Commission Decision of 30 April 2007 laying down specific measures to be applied by Cyprus with regard to scrapie (OJ L 118, 8.5.2007, p. 23)	Specific measures for Cyprus regarding Scrapie
Commission Regulation (EC) No 722/2007 of 25 June 2007 amending Annexes II, V, VI, VIII, IX and XI to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 164, 26.6.2007, p. 7)	Amendment of R 999/2001. End of transitional measures from 1 July 2007
Commission Regulation (EC) No 727/2007 of 26 June 2007 amending Annexes I, III, VII and X to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 165, 27.6.2007, p. 8)	Amendment of R 999/2001. modification of eradication measures for ovine and caprine animals and monitoring in ovine and caprine animals
2007/453/EC: Commission Decision of 29 June 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk (OJ L 172, 30.6.2007, p. 84)	Establishing the BSE status of Member States and certain third countries

<u>2007/667/EC: Commission Decision</u> of 15 October 2007 authorising the use of at risk bovine animals until the end of their productive lives in Germany following official confirmation of the presence of BSE (OJ L 271, 16.10.2007, p. 16)	BSE cohort culling in Germany
<u>Commission Regulation (EC) No 1275/2007</u> of 29 October 2007 amending Annex IX to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 284, 30.10.2007, p. 8)	Amendment of R 999/2001. Import conditions for products of animal origin from bovine, ovine and caprine animals
<u>Commission Regulation (EC) No 1428/2007</u> of 4 December 2007 amending Annex VII to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 317, 5.12.2007, p. 61)	Amendment of R 999/2001. Derogation: possibility to delay the destruction of animals in TSE affected flocks for 5 breeding years

2008

Legal text	Contents
<u>Commission Regulation (EC) No 21/2008</u> of 11 January 2008 amending Annex X to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the lists of rapid tests (OJ L 9, 12.1.2008, p. 3)	Amendment of R 999/2001. List of rapid tests
<u>Commission Regulation (EC) No 315/2008</u> of 4 April 2008 amending Annex X to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the lists of rapid tests (OJ L 94, 5.4.2008, p. 3)	Amendment of R 999/2001. List of rapid tests
<u>Commission Regulation (EC) No 357/2008</u> of 22 April 2008 amending Annex V to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 111, 23.4.2008, p. 3)	Amendment of R 999/2001. Modification of the age limit for vertebral column in bovines
<u>Commission Regulation (EC) No 571/2008</u> of 19 June 2008 amending Annex III to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the criteria for revision of the annual monitoring programmes concerning BSE (OJ L 161, 20.6.2008, p. 4)	Amendment of R 999/2001. Criteria for the revision of annual BSE monitoring programmes
<u>Commission Regulation (EC) No 746/2008</u> of 17 June 2008 amending Annex VII to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 202, 31.7.2008, p. 11)	Amendment of R 999/2001. modification of eradication measures for ovine and caprine animals

<u>2008/661/EC: Commission Decision</u> of 1 August 2008 amending Decision 2007/182/EC on a survey for chronic wasting disease in cervids (OJ L 215, 12.8.2008, p. 8)	Extending the survey for Chronic wasting disease in cervids
<u>Commission Regulation (EC) No 956/2008</u> of 29 September 2008 amending Annex IV to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 260, 30.9.2008, p. 8)	Amendment of R 999/2001. Authorisation for the use of fishmeal in of milk replacers intended for feeding to young animals of ruminant species
<u>Commission Decision (EC) 2008/829</u> of 30 October 2008 amending the Annex to Decision 2007/453/EC establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk (OJ L 294, 1.11.2008, p. 14)	Update of classification of countries according to their BSE risk
<u>Commission Decision (EC) 2008/908</u> of 28 November 2008 authorising certain Member States to revise their annual BSE monitoring programme (OJ L 327, 5.12.2008, p. 24)	Certain Member States may revise their annual BSE monitoring programme.

2009

Legal text	Contents
<u>Commission Regulation (EC) No 220/2009</u> of 11 March 2009 amending Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies, as regards the implementing powers conferred on the Commission (OJ L 87, 31.3.2009, p. 155)	Amendment of R 999/2001. Modification of the implementing powers conferred on the Commission.
<u>Commission Regulation (EC) No 103/2009</u> of 3 February 2009 amending Annexes VII and IX to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 34, 4.2.2009, p. 11)	Amendment of R 999/2001. Modification of eradication measures for ovine and caprine animals.
<u>Commission Regulation (EC) No 162/2009</u> of 26 February 2009 amending Annexes III and X to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 55, 27.2.2009, p. 11)	Amendment of R 999/2001. Modification of certain approved laboratory methods for the diagnostic of TSEs.
<u>Commission Regulation (EC) No 163/2009</u> of 26 February 2009 amending Annex IV to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 55, 27.2.2009, p. 17)	Amendment of R 999/2001. Modification of certain feed ban provisions.

<u>Commission Decision (EC) 2009/719</u> of 28 September 2009 authorising certain Member States to revise their annual BSE monitoring programmes (OJ L 256, 29.9.2009, p. 35)	Slovenia is included in the list of Member States that may revise their annual BSE monitoring programmes
<u>Commission Decision (EC) 2009/830</u> of 11 November 2009 amending the Annex to Decision 2007/453/EC as regards the BSE status of Chile, Colombia and Japan (OJ L 295, 12.11.2009, p. 11)	Update of classification of countries according to their BSE risk

2010

Legal text	Contents
<u>Commission Decision (EC) 2010/66</u> of 5 February 2010 authorising certain Member States to revise their annual BSE monitoring programmes (OJ L 035, 6.2.2010, p. 21)	Cyprus is included in the list of Member States that may revise their annual BSE monitoring programmes