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The TSE Road map II *(rev.10)*

A Strategy paper on Transmissible Spongiform Encephalopathies for 2010-2015

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WORKING DOCUMENT OF THE COMMISSION

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Subject: TSE Road map II - A Strategy paper on Transmissible Spongiform Encephalopathies for 2010-2015

1. INTRODUCTION

The first TSE[1] Roadmap, a reflection paper adopted by the Commission on 15 July 2005 (COM(2005) 322 FINAL), provided an outline of possible future changes to EU measures on TSEs in the short, medium and long-term while still making food safety and consumer protection the highest priority. The majority of short and medium term actions envisaged in the first TSE Roadmap have been achieved and the positive trend already observed in 2005 in the BSE epidemic has continued since then. At the same time, the impact of BSE on human health appears to be more limited than initially feared.

The goal for the coming years is to continue the review of the measures while assuring the highest level of food safety. Amendments to the TSE rules are and will continue to be taken following a stepwise approach supported by a solid scientific basis. In this respect, the scientific advices provided by the European Food Safety Authority (EFSA) should continue to play a crucial role to consider future policy options. It is also of paramount importance to continue research in those areas where information is lacking or gaps exist which do not allow firm decisions to be taken.

The aim of this paper is to further reflect and initiate discussions on future amendments allowing a review of the measures to align them with the situation where the EU is finally on the last pathway to eradicate BSE within its cattle population However vigilance should be ensured in order to continue to monitor the situation in case of potential re-emergence of BSE or emergence of a new TSE agent in cattle population.

This review should take into account the environmental, economic and social impacts of our policies on the EU sustainable development objectives.

[1] TSE = Transmissible Spongiform Encephalopathy (see definition in glossary on page 16)

2. OVERVIEW OF 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 (see glossary on page 16 for definition of technical terms or acronyms).

2.1. 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 advice. Following updated scientific evidence, 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.

2.2. UK embargo

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

2.3. 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 Resolutions.

2.4. 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.

2.5. Monitoring programme for bovine animals

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

2.6. 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 tests. The Commission initiated legislative actions to align the legislation with EFSA recommendations.

2.7. Eradication measures in small ruminants (sheep and goats)

In July 2007, a proportionate risk-based approach was introduced for 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 EFSA, 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.

2.8. 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.

2.9. 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.

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

In 2007 and according to EFSA recommendations, 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.

3. AMENDMENTS ENVISAGED FOR THE PERIOD 2010 – 2015

3.1. Further revision of the list/age limit for specified risk materials (SRM)

Strategic goal:

To ensure and maintain the current level of consumer protection by continuing to assure safe removal of SRM but modify list/age based on new & evolving scientific opinions.

3.1.1. Current legislation

Removal of specified risk materials is the most important public health protection measure. The list of SRM is established based on the scientific knowledge and a high level of precaution. The restrictions on the use of SRM include a prohibition to use such products for the production of derived products for use in food and feed such as tallow, gelatine, collagen and dicalcium phosphate.

3.1.2. Future policy options

Any amendment of the current list of specified risk material should be based on new evolving scientific knowledge while maintaining the existing high level of consumer protection within the EU. Any future revision however should take into account the epidemiological situation based on the data gained from BSE surveillance. The EFSA is currently conducting a reassessment of the pertinence of the SRM list in small ruminants and the final opinion should be available by the end of 2010. Since it is impossible, however, to consider the complete elimination of risk as a realistic objective for any risk management decision, the scientific advice should aim for a quantitative or a semi-quantitative approach taking into account the favourable epidemiological situation regarding BSE in the European Union. The alignment of the EU SRM list with the international standards of OIE should be sought (in particular for bovine intestines) as long as it is scientifically justified and the current obligation for Member States benefiting from an OIE negligible risk status to continue removing SRM could be reviewed if an increasing number of Member States reaches the negligible status..

3.2. Further revision of the feed ban

Strategic goal:

To review certain measures of the current total feed ban when certain conditions are met.

3.2.1. Current legislation

A ban on the feeding of mammalian meat and bone meal (MBM) to cattle, sheep and goats was introduced as of July 1994. In order to manage the risk of presence of prohibited material in ruminant feed through cross-contamination, this partial ban

was extended to a total EU wide suspension on the use of processed animal proteins (PAP) in feeds for any animals farmed for the production of food on 1 January 2001 with some exceptions like the use of fish meal for non ruminants. Any presence of prohibited constituents of animal origin in feed is considered as a breach of the feed ban i.e. the zero-tolerance.

The table below illustrates the current provisions of the feed ban:

	Farmed animals other than fur animals			**Pets and fur animals**
	Ruminants	**Non ruminants (except fishes)**	**Fishes**	
Processed animal proteins except blood meal and fish meal	NA	NA	NA	A
Blood meal from ruminants	NA	NA	NA	A
Blood products from ruminants	NA	NA	NA	A
Gelatine from ruminants	NA	NA	NA	A
Hydrolysed proteins other than those derived from non ruminants or from ruminant hides and skins	NA	NA	NA	A
Blood meal from non ruminants	NA	NA	A	A
Fishmeal	NA[2]	A	A	A
Blood products from non ruminants	NA	A	A	A
Di and tricalcium phosphate of animal origin	NA	A	A	A
Hydrolysed proteins from non ruminants or from ruminant hides and skins	A	A	A	A
Non ruminant gelatine	A	A	A	A
Egg, egg products, milk, milk products, colostrum	A	A	A	A
Animal proteins other than the above-mentioned ones	NA	A	A	A

[2] Milk replacers containing fishmeal and intended only for unweaned ruminants are authorised

A = authorised

NA = not authorised

3.2.2. *Ongoing Research*

As part of its annual work programme, the Community Reference Laboratory for animal proteins (CRL-AP) in feed investigated the strength of the microscopic method regarding the quantitative determination of animal constituents in feedingstuffs (to estimate the total amount of animal proteins in feed which is needed to allow the introduction of any tolerance level in feedingstuffs). The evaluation revealed that the current method is not reliable for the purpose of quantification.

In addition, the CRL-AP is investigating the performance of different new diagnostic methods which may identify the species (ruminant, pig or poultry) of traces of MBM found in feed. Indeed, the mandatory treatment of mammalian proteins at 133°C, 3 Bars during 20 minutes results in very small fragments of animal proteins which are hard to detect by the current analytical methods. The results of this evaluation should be available during the second half of 2010.

3.2.3. *Future policy options*

The starting point when revising the current feed ban provisions should be risk-based but at the same time taking into account the control tools in place to evaluate and ensure the proper implementation of this revised feed ban.

- Tolerance level for PAP in feed for farmed animals

Based on the results of the updated quantitative risk assessment on the risk linked to small amounts of processed animal proteins in feed initiated by EFSA, an introduction of a tolerance level with regard to a very small presence of PAP in feed may be proposed without jeopardising the current eradication measures.

- Lifting feed ban provisions for non-ruminants (pigs, poultry, fishes)

Currently, PAP forbidden for feeding purposes are used mainly to produce fertilizers, compost or carburant for cement works. However, PAP from non-ruminants may be a source of high quality proteins for non-ruminant farmed animals and the current ban provisions could be seen nowadays as a wasted opportunity considering that the transmission risk of BSE from non ruminants to non-ruminants is very unlikely. It is environmentally much more sustainable to use such protein for animal feed than for energy generation. Moreover, the replacement of PAP requires the import of alternative sources of proteins from third countries (namely soya, and in particular genetically modified soya). The reintroduction of PAP in non-ruminant feed may enable the EU to decrease its dependence on external sources of protein, to reduce the negative economic and environmental effects entailed by the total feed ban and to boost the competitiveness of the livestock and the meat processing industries.

Further progress in the development and the validation of analytical techniques to determine the species origin of PAP may result in an amendment of the provisions

with regard to the reauthorisation of non-ruminant proteins in feedingstuffs intended for non ruminants (including fishes) while taking into account the existing prohibition on intra-species recycling (e.g. poultry MBM could be fed to pigs and pig MBM to poultry). However, considering the limitation inherent on any control method, correct channelling of PAP from different species will be an important part of any review of the current feed ban provisions. It will be left to the stakeholders to decide if the valorisation of PAP for feeding purposes would level out the investments needed to comply with the channelling requirements.

3.3. Further revision of BSE surveillance

Strategic goal:

To continue to adapt the BSE monitoring system in bovine animals with a better targeting of the surveillance activity while keeping the capacity to monitor the evolution of the epidemiological situation and to assess the effectiveness of the protective measures in place.

3.3.1. Current legislation

The goal of the surveillance is to monitor and assess the effectiveness of control measures taken such as the feed ban and SRM removal by following the evolution of BSE prevalence over the years.

According to TSE legislation, each Member State shall carry out an annual monitoring programme for BSE including a screening procedure using rapid tests approved for that purpose. This programme shall cover as a minimum all bovine animals above 30 months of age slaughtered normally for human consumption (healthy slaughtered animals) and all bovine animals above 24 months of age which have died/been killed or been sent for emergency slaughter (risk animals).

However, a Member State which can demonstrate, based on epidemiological criteria, the improvement of the BSE situation on its territory may send an application to the Commission with a view to being authorised to revise its monitoring programme. Since 2009, 17 Member States have been authorised to review their monitoring programmes and to raise the age limit for testing to 48 months based on their favourable epidemiological situation and following positive EFSA opinions.

This increase in age limit for testing has led to a diminution of roughly 30 % of the number of tests performed annually in the EU in 2009 compared to 2008 (see Chart 1 in Annex) while keeping the same capacity to provide a reliable insight into the prevalence and evolution of BSE in the Member States. The same diminution can be observed for the costs associated to the detection of one BSE case in slaughterhouse (they have dropped from 14,15 M€ in 2008 to 9,91 M€ in 2009, see Chart 3 in Annex).

3.3.2. *Future policy options*

Depending on the results of the ongoing monitoring programmes, a further revision of the BSE monitoring programmes may be envisaged for Member States complying with epidemiological criteria. Such options could include:

- the continuation of the gradual increase in the age limits for testing of all healthy slaughtered animals and risk animals;
- testing of a statistical sample size of bovine animals above a certain age in each subpopulation (healthy slaughtered and risk animals);
- testing of bovine animals in each subpopulation based on their date of birth and the effective implementation of the feed ban.

Any future option should allow the continuous detection of an increase in BSE epidemic or an emergence of new TSE strains. In particular, since atypical BSE cases were detected over the last few years in animals older than 8 years old in the EU, any revision of BSE surveillance should not impair the detection of these cases. In addition, due to the single market and the free movement of bovine animals between Member States, the practical aspects in terms of control should not be disregarded and any new system put in place should remain easily manageable. Finally, in the mid-term, the revision of BSE surveillance should not prevent Member States to maintain their OIE status as regards BSE risk.

3.4. Further revision of scrapie eradication measures

Strategic goal:

To adapt the current eradication measures in TSE infected flocks to bring them in line with the latest scientific knowledge and to develop sustainable tools to control TSE in small ruminant flocks in the EU.

3.4.1. Current legislation

The current provisions for the eradication of TSEs in small ruminant flocks are based on a combination of different tools (total or partial culling in infected flocks based on genetic sensitivity of animals, breeding programmes to select for resistance to TSEs in high genetic merit sheep flocks, restocking with resistant animals and reinforced surveillance in infected flocks). Furthermore the molecular discriminatory testing in force since January 2005 allows the distinction between BSE and other TSEs to be made and may exclude the presence of BSE within a few weeks in most TSE cases. Special measures are also in place for atypical scrapie cases in order to take into account their limited spread of infection within a flock.

In goats, unlike sheep, there is no clearly identified genetic resistance or susceptibility to TSEs. In 2008, the final results of an EU funded pilot project study conducted in Cyprus and aimed at the identification of the effect of certain genes on scrapie resistance/susceptibility in goats seemed to indicate that some genes could be associated with resistance/susceptibility to classical scrapie in goats in CY. In view of the importance for the EU eradication policy in the goat population, EU funds have been allocated for the design and implementation of a protocol for additional studies in order to supplement the initial findings of the Cypriot pilot study. This protocol, finalised in September 2009, aims to collect data to gain further knowledge about genetic resistance to scrapie in goats. First results should be available in 2011.

3.4.2. Future policy options

The high complexity of TSEs in small ruminants (due mainly to the existence of different strains of prions), the current uncertainties as regards their zoonotic potential and the great diversity of factors influencing the transmission and maintenance of scrapie within and between flocks make it necessary to continue the reflection on the future legislative actions to take in order to control TSE in small ruminant flocks in the EU. The following actions could be considered:

- to establish the conditions for small ruminants herd certification as regards TSE based on results of rapid tests and on OIE guidelines in order to avoid the inadvertent spread of scrapie through infected preclinical animals;

- to further adapt measures for atypical scrapie if scientific data confirms that this scrapie strain is not contagious;

- to take advantage of genetic resistance in goats if further research indicates genetic resistance of certain genotypes within the goat population;

– to continue to encourage genetic control of scrapie in sheep through breeding programmes (while avoiding inbreeding or genetic drift) as these programmes appear to be effective at controlling the disease.

In any case, future research results and scientific advices concerning TSE in small ruminants will be the key elements influencing future policy options. In this respect, the results of the ongoing scientific assessment jointly performed by the EFSA and the European Centre for Disease Prevention and Control (ECDC) on any possible association between the TSEs in animals and humans could be of a great interest.

3.5. Cohort culling in bovine animals

Strategic goal:

To review the culling policy in BSE infected herds

3.5.1. Current legislation

In the case of confirmation of a BSE case in a holding, the current rules foresee the killing and complete destruction of bovine animals belonging to the "cohort" of the BSE case (i.e. bovine animals born in the same herd as the case within 12 months preceding or following the date of birth of the case and which may have consumed the same contaminated feed as the case). By way of derogation, it is possible to allow a Member State to defer the killing and complete destruction of cohort animals until the end of their productive lives. Only Germany applied for this derogation so far and was authorised to use it in 2007. Furthermore, where the BSE case is a female, its progeny born within two years prior to, or after, clinical onset of the disease shall be destroyed.

3.5.2. Future policy options

As the number of positive animals detected within the cohort animals in the EU is now very low (2 in 2008, 0 in 2009), a proposed alternative could be to stop the systematic cohort culling and to authorise the slaughtering of these animals for human consumption provided that animals are tested with negative results before entering the food chain. However, as the costs of cohort culling may be very low (very few animals may belong to the cohort in affected herds and have to be destroyed), the maintenance of the destruction of the cohort may be the preferred option, in particular in Member States where BSE is absent or very rare. The potential consequences for the export markets should also be taken into consideration.

3.6. Ante-mortem and post-mortem rapid tests

Strategic goal:

To continue to promote the development of the best rapid tests available for detecting TSEs

3.6.1. *Current legislation*

The European Commission completed the first evaluation of rapid diagnostic tests for BSE in cattle in 1999. Further evaluations of rapid diagnostic tests for TSEs in ruminants have subsequently been carried out. In 2007, the Commission, aware that developmental work on other tests had continued, decided to launch a new open call for expression of interest intended to cover ante and post-mortem tests for the detection of TSE in large (cattle) and small (sheep and goats) ruminants. This call was launched for a 5 year period and its objectives are to identify new tests and to select those that are suitable for inclusion in an evaluation programme based on EFSA scientific protocols. The call allows test manufacturers which have tests already at an advanced stage to apply in order to have their test evaluated for their suitability to use in the EU TSE surveillance programmes.

3.6.2. *Future policy option*

The option to test live animals if validated ante-mortem tests become available could be envisaged. The usefulness of this option for controlling BSE in bovine animals is limited nowadays. This option would however be of great help for herd certification in small ruminants' herds.

4. ALTERNATIVE SCENARIOS IF THE POSITIVE TREND DOES NOT CONTINUE IN ALL MEMBER STATES AT THE SAME PACE.

Although a full harmonisation of the measures should be our key objective and remain the preferred option, the epidemiological situation between the different Member States may lead to the situation that, where certain Member States would be eligible for further amendments, the basis for such amendments would not be strong enough to support similar modifications in another Member State. However due to the common market with trade of live animals and products between Member States, the practical implementation and practices will force the adoption of certain amendments limited to certain Member States. The amendment of the BSE surveillance system was an example where only 17 Member States were allowed to amend the BSE monitoring programme.

Even if all indicators regarding the prevalence of BSE in bovine animals suggest that a future increase of BSE cases is unlikely, alternative scenarios should be envisaged if the positive trend is not confirmed in certain Member States.

In that case, more stringent measures regarding SRM removal compared to the other Member States could be envisaged. At the last stage a temporary embargo might be envisaged which will allow the situation in the individual Member State to be addressed without penalising the other Member States where the negative trend is not confirmed.

5. CONCLUSION

The review of the measures related to TSE must be based on an appropriate assessment of the possible risks for human and animal health and must, taking into account existing scientific evidence and innovation, maintain or, if scientifically justified, increase the level of protection of human and animal health. It is impossible, however, to consider the complete elimination of risk as a realistic objective for any risk management decision in matters regarding food safety, where the cost and benefits of risk-reducing measures have to be carefully weighed in order to ensure the measure's proportionality. It is the role and responsibility of the risk manager to decide the acceptable level of risk, taking into account all the elements present in a scientific risk assessment. In addition the evaluation of the socio-economic impact on the competitiveness of the industries and farmers involved within the European Union should be an integral part in any review of the measures, as well as aspects related to the proportionality and sustainability of the policies envisaged.

Since any amendment will be supported by solid scientific advice, it is of paramount importance to continue research in those areas where information is lacking or gaps exist which do not allow firm decisions to be taken.

In addition, experience over the past two decades has demonstrated that BSE has been used abusively for protectionist ends. A strong and credible international framework is therefore of paramount importance to ensure that trade can take place under safe and fair conditions. The EU must take the lead in international standard setting bodies to promote European standards and policies, and align its legislation with international standards as far as possible.

In setting our future strategy it is also important not to lose sight of other threats to animal and public health which have emerged in recent years, such as Salmonella and antimicrobial resistance. The balance of evidence is increasingly pointing towards the need to better prioritise actions towards diseases which may have a bigger impact then TSEs in terms of public health, economy or society, and to set out EU funding accordingly. The encouraging trends in relation to BSE merit a considered review of the opportunities to focus on and securing money for these new threats.

6. ANNEXES

6.1. Glossary

What are TSEs?

Transmissible Spongiform Encephalopathies (TSEs) are a family of diseases occurring in man 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 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 specific risk materials (SRM)?

SRM are the organs considered to harbour the BSE infectivity in an animal affected by BSE and which can consequently posed 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 animal 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 term 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 of 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 EU, in addition to those tested as BSE suspects. The number of positive cases in 2009 (59 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 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.

6.2. Evolution of BSE epidemiological situation since 2001

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

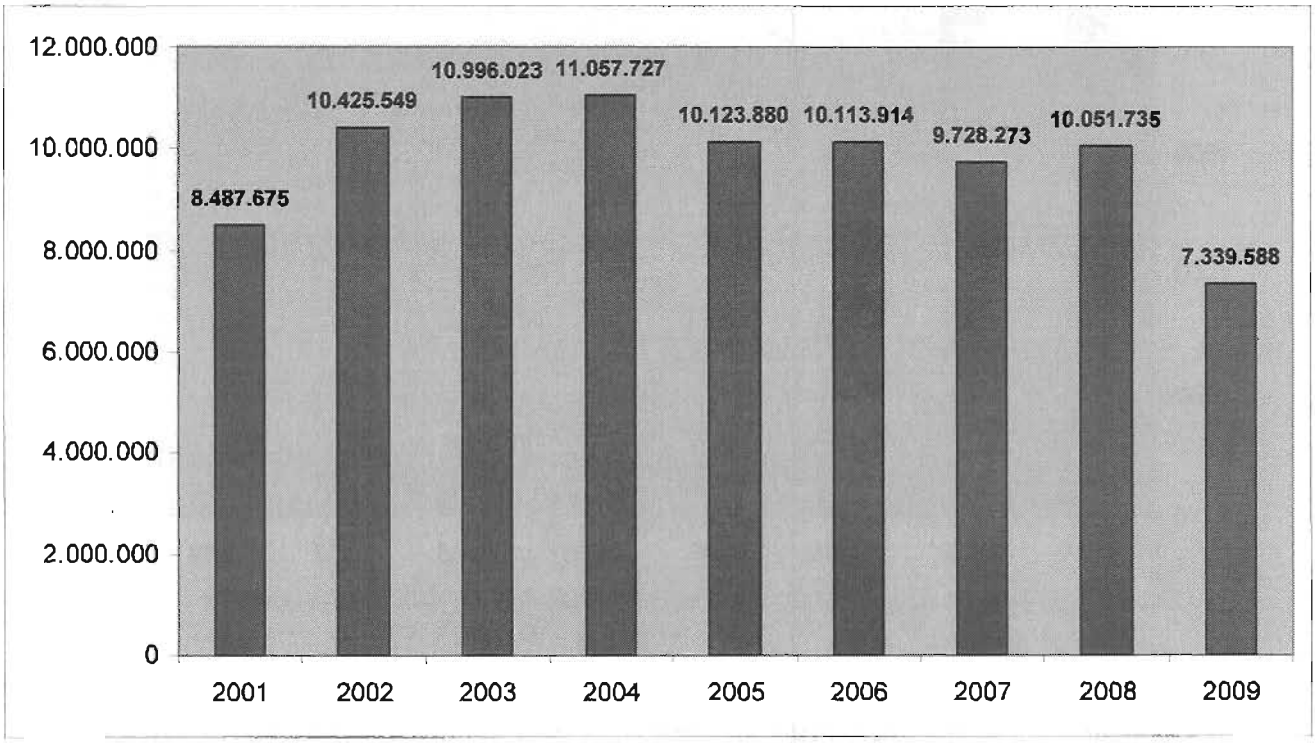


Chart 2: Evolution of the number of BSE positive cases in the EU since 2001

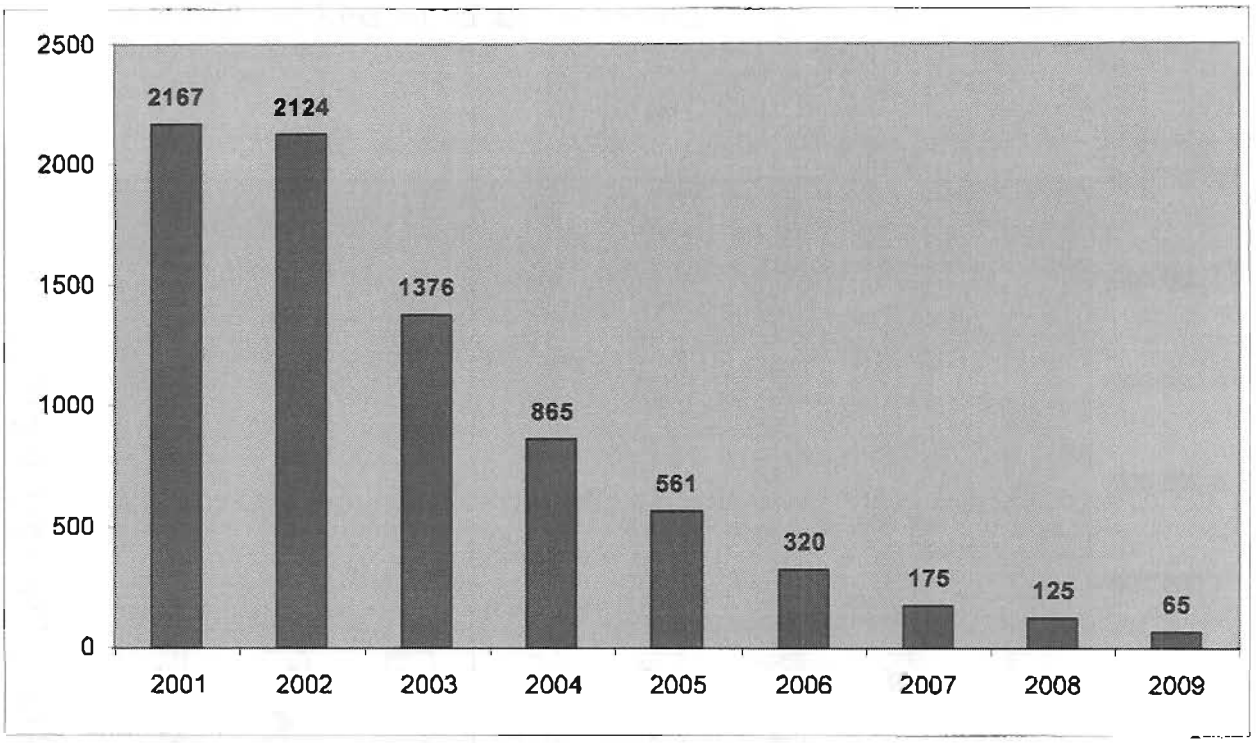
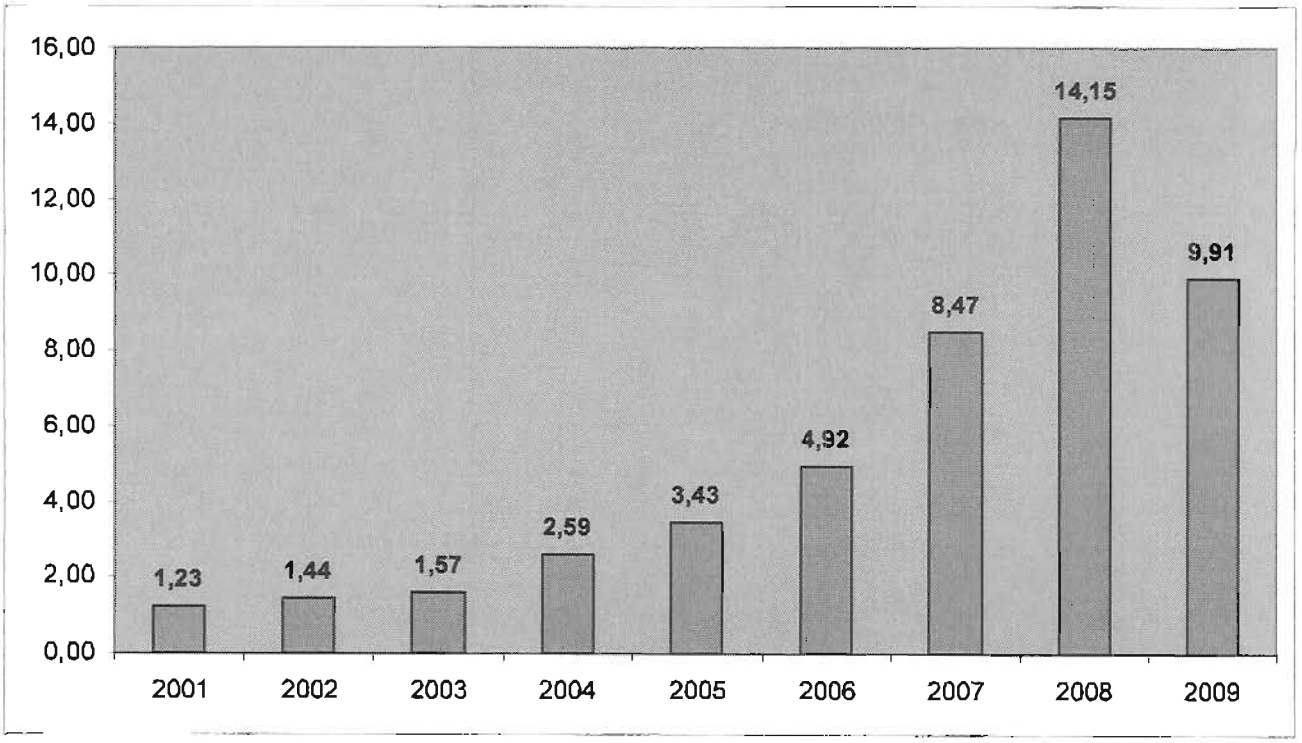


Chart 3: Evolution of the costs (M€) per BSE case detected in slaughterhouse since 2001



6.3. Chronological list of TSE legislation adopted following 2005 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)	Amendment of R 999/2001 as regards BSE monitoring in Sweden

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)	
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**

2007/667/EC: Commission Decision 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**
Commission Regulation (EC) No 1275/2007 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
Commission Regulation (EC) No 1428/2007 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
Commission Regulation (EC) No 21/2008 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
Commission Regulation (EC) No 315/2008 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
Commission Regulation (EC) No 367/2008 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**
Commission Regulation (EC) No 571/2008 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
Commission Regulation (EC) No 746/2008 of 17 June 2008 amending Annex VII to Regulation (EC) No	Amendment of R 999/2001. **modification of eradication measures for**

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)	ovine and caprine animals
2008/661/EC: Commission Decision 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
Commission Regulation (EC) No 956/2008 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
Commission Decision (EC) 2008/829 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
Commission Decision (EC) 2008/908 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
Commission Regulation (EC) No 220/2009 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.
Commission Regulation (EC) No 103/2009 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.
Commission Regulation (EC) No 162/2009 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.

Commission Regulation (EC) No 163/2009 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**.
Commission Decision (EC) 2009/719 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**
Commission Decision (EC) 2009/830 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
Commission Decision (EC) 2010/68 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**