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The TSE Road map 2

A Strategy paper on Transmissible Spongiform Encephalopathies for 2010-2015

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1. INTRODUCTION

The first TSE[1] Roadmap[2], 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 Bovine Spongiform Encephalopathy (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.

This Communication is complemented by a Commission Staff Working Document (CSWD) where Annexes referred to in the Communication can be found and which *inter alia* includes an overview of the achievements of the first TSE roadmap over the period 2005-2009.

The goal for the coming years is to continue the review of the measures while assuring a high 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 advice 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 Communication is to outline future possible 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 a potential re-emergence of BSE or emergence of a new TSE agent in cattle population.

This review should be primarily driven by scientific advice and technical issues related to the control and enforcement of the new measures.

[1] TSE = Transmissible Spongiform Encephalopathy (see definition in Annex I to CSWD).
[2] COM(2005) 322 FINAL of 15 July 2005.

2. ACTIONS ENVISAGED FOR THE PERIOD 2010 – 2015

2.1. 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.

2.1.1. Current legislation

Specified Risk Materials (SRM) are the organs considered to harbour the BSE infectivity in an animal affected by BSE. In the EU, the removal of SRM from the food and feed chains is mandatory since 2000. The removal of SRM is the most important public health protection measure. The list of SRM is established based on scientific knowledge and a high level of precaution. The restrictions on the use of SRM include a prohibition to use certain products for the production of derived products for use in food and feed such as tallow, gelatine, collagen and dicalcium phosphate.

2.1.2. Future policy options

Any amendment of the current list of SRM should be based on new evolving scientific knowledge while maintaining the existing high level of consumer protection within the EU. However, the list of SRM to be removed from the food and feed chains should also take into account the epidemiological situation based on the data gained from BSE surveillance. 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 World Organisation for Animal Health (OIE) should be sought (in particular for bovine intestines) if supported by solid scientific advice based on quantitative risk assessments. The current obligation for Member States benefiting from a negligible risk status according to the OIE Code[3] to remove SRM from the food and feed chain could be reviewed if an increasing number of Member States reaches the negligible status for which no SRM list has been established.

2.2. Further revision of the feed ban

Strategic goal:

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

[3] http://www.oie.int/eng/normes/mcode/en_chapitre_1.11.6.htm

2.2.1. 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 feed 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 breaches the feed ban since the legislation does not provide for any 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 fish)**	**Fish**	
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[4]	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

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

A = authorised

NA = not authorised

2.2.2. 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 preliminary results of this 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 difficult to detect by the current analytical methods. The results of this study should be available during the second half of 2010.

2.2.3. Possible gradual lifting of the feed ban

The starting point when revising the current feed ban provisions should be risk-based but at the same time should take into account the control tools in place to evaluate (i.e. the availability of a reliable test to identify the species of trace of MBM).

– Tolerance level for PAP in feed for farmed animals

In order to apply a risk-based approach in case prohibited PAP has been detected, a certain tolerance level may be established.

On December 2009, the Commission asked EFSA to provide an updated quantitative risk assessment on the risk linked to small amounts of processed animal proteins in feed. The EFSA opinion is expected by the end of 2010. Based on the EFSA conclusions, 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 may be a source of proteins for non-ruminant farmed animals which need to be fed with high quality proteins. Considering that the transmission risk of BSE from non ruminants to non-ruminants is very unlikely, a lifting of the ban on the use of PAP from non-ruminants in non-ruminant feed could be considered, but without lifting the existing prohibition on intra-species recycling (e.g. poultry MBM could only be fed to pigs and pig MBM to poultry). Moreover the reintroduction of PAP in non-ruminant feed may enable the EU to decrease the dependence on other sources of proteins.

Such a measure would however be acceptable only if validated analytical techniques to determine the species origin of PAP are available. In addition, considering the limitation

inherent in any control method, correct channelling of PAP from different species will be an important part of any review of the current feed ban provisions. The valorisation of PAP for feeding purposes will have to be compared to the investments needed to comply with the channelling requirements.

2.3. 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.

2.3.1. 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[5] 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 (Chart 1 in Annex III to CSWD) 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 Million in 2008 to € 10,1 Million in 2009, see Chart 3 in Annex III to CSWD).

2.3.2. 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:

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[5] Belgium, Cyprus, Denmark, Germany, Ireland, Greece, Spain, France, Italy, Luxembourg, Netherlands, Portugal, Austria, Slovenia, Finland, Sweden, United Kingdom.

– 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 from maintaining their OIE status as regards BSE risk.

2.4. Further revision of scrapie eradication measures

Strategic goal:

To adapt the current eradication measures in TSE infected flocks of sheep and goats 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.

2.4.1. Current legislation

The current provisions for the eradication of TSEs in sheep flocks are based on a combination of different tools (total or selective culling of susceptible animals in infected flocks, breeding programmes to select for resistance to TSEs in high genetic merit flocks, restocking with resistant animals and reinforced surveillance in infected flocks). For goat herds, total culling is the only option applicable if classical scrapie is detected.

Special measures are however in place for atypical scrapie cases in order to take into account their limited spread of infection within a flock: animals are exempted from culling but they shall be submitted to an intensified TSE surveillance during two breeding years without any possibility to be moved from their herd.

2.4.2. Past and on-going research

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.

Furthermore, a scientific assessment jointly performed by EFSA and the European Centre for Disease Prevention and Control (ECDC) on any possible association between TSEs in animals and humans is ongoing and the results of this work could be of great interest as regards the zoonotic potential of TSEs in small ruminants.

2.4.3. 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 advice concerning TSE in small ruminants will be the key elements influencing future policy options.

2.5. Cohort culling in bovine animals

Strategic goal:

To review the culling policy in BSE infected herds.

2.5.1. 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.

2.5.2. 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.

2.6. Ante-mortem and post-mortem rapid tests

Strategic goal:

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

2.6.1. Current legislation

Only the rapid tests which are listed in the TSE legislation can be used for the monitoring of TSE in the EU. Before being able to be listed, any rapid test has to be thoroughly evaluated as regards its analytical performances and has to be positively recommended to the Commission by EFSA.

2.6.2. On-going activities for the development of laboratory tests

The 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.

2.6.3. 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.

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

The level of protection of consumers should be the same across the EU. But the epidemiological situation between the different Member States justifies the situation that, where certain Member States would be eligible for further amendments, others would not. The practical implementation and practices will therefore 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 decline in BSE cases is not confirmed in all Member States.

In that case, more stringent measures regarding SRM removal could be envisaged for those Member States with a lower decline of BSE cases. As a final measure, a temporary embargo might be envisaged which would allow the situation in the individual Member State to be addressed without penalising the other Member States where the negative trend is not confirmed.

4. 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.

Since any amendment will have to 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, in particular by third countries. 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 than TSEs in terms of public health and to set out EU funding accordingly. The encouraging trends in relation to BSE merit a considered review of the opportunities to focus on these other threats.