SCIENTIFIC COMMITTEE
OF THE BELGIAN FEDERAL AGENCY FOR THE SAFETY
OF THE FOOD CHAIN

RAPID ADVICE 16-2013

Subject: Evaluation of a proposal to stop with the routine removal of specified risk materials during bovine slaughter (Dossier SciCom 2013/22)

Advice approved by the Scientific Committee on 20 September 2013

Summary

Rapid advice on a proposal to stop with the routine removal of specified risk materials during bovine slaughter.

The Scientific Committee was asked to evaluate a proposal to stop with the routine removal of specified risk materials during bovine slaughter given the Belgian OIE status of 'negligible risk' with regard to BSE.

The Scientific Committee is of the opinion that the risk evaluation has to be done in the light of the European or even global factual sanitary situation in regard to BSE taking into account the uncertainties related to the topic.

Removal of specified risk materials from cattle at slaughter prevents infected materials from entering the food chain.

The Scientific Committee is of the opinion that, given the actual epidemiological BSE situation in the EU and taking into consideration the uncertainties in regard to early detection of asymptomatic BSE and the zoonotic significance and true prevalence of Atypical BSE, stopping in Belgium with the routine removal of specified risk materials during bovine slaughter will increase the risk for public health.

Key words

BSE - TSE – bovine – specified risk materials - slaughter – risk assessment

1. Terms of Reference

1.1. List of abbreviations

BSE	Bovine Spongiform Encephalopathy
TSE	Transmissible Spongiform Encephalopathies
Classical BSE case	a BSE case classified as such in accordance with the criteria laid down in the EU reference laboratory's method for the classification of bovine TSE isolates (adopted from EU 630/2013)
Atypical BSE case	a BSE case which cannot be classified as a classical BSE case in accordance with the criteria laid down in the EU reference laboratory's method for the classification of bovine TSE isolates (adopted from EU 630/2013)
SRM	specified risk materials for bovines: – the skull including the brain and eyes and the spinal cord of bovine animals aged over 12 months but excluding the mandible; – the vertebral column, excluding the vertebrae of the tail the spinous and transverse processes of the cervical, thoracic and lumbar vertebrae, the median sacral crest and the wings of the sacrum, but including the dorsal root ganglia of bovine animals aged over 30 months; – the tonsils, the intestines, from the duodenum to the rectum, and the mesentery of bovine animals of all ages.
OIE	World Organisation for Animal Health

1.2. Context

During a TSE workgroup meeting on July 5th, 2013 DG SANCO proposed that member states with a 'negligible BSE risk status' should no longer be obliged to remove the specified risk materials (SRM) from the food chain. Hereto annex V, 2. of regulation (EC) nr. 999/2001 has to be abrogated.

The reasons for this pending decision, as provided in the request for advice, are that :

- the OIE is asked to start a dossier with regard to the diagnostic differentiation of Classical BSE from Atypical BSE, implicating relaxed measures for controlling Atypical BSE in the future ;
- products (sausage skin, for example) are imported into the EC from third countries with a 'negligible BSE risk status' and which do not remove the SRM from the food chain ;
- it is prognosticated that within a couple of years in the EC, Classical BSE will be eradicated and that only Atypical BSE cases will be left over ;
- currently 8 EC member states have a 'negligible OIE BSE risk status' and in 2014 perhaps 10 other countries will obtain this same qualification. The European Commission therefore intends to apply the rules in the EC which match the international standards of the OIE;

- until now, the EC member states with a ‘negligible BSE risk status‘ were not allowed to apply more flexible measures in accordance with the OIE Code except for decreased surveillance of healthy slaughtered cattle. Now that this group of EC member states has become considerably larger, DG SANCO intends to introduce a more flexible regime.

The European Commission has asked the member states to express their views on this subject before the end of September 2013.

1.3. Legislation

REGULATION (EC) No 999/2001 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies.

COMMISSION REGULATION (EU) No 630/2013 of 28 June 2013 amending the Annexes 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.

1.4. Questions

In order to prepare the Belgian position, a rapid advice is asked to the Scientific Committee on August 20th, 2013 using the accelerated procedure with regard to the following questions:

- Given the Belgian OIE status 'negligible risk with regard to BSE', is it still necessary to continue to remove all SRM?

- Can the legislation on SRM removal be modified without compromising public health?

After due deliberation during the work group meeting on August 27th, 2013 and the plenary session of the Scientific Committee on September 20th, 2013

the Scientific Committee emits the following advice:

2. Introduction: the facts

2.1 Zoonotic characteristics of BSE-forms in cattle

EFSA and ECDC published in 2011 a joint scientific opinion on any possible epidemiological or molecular association between TSEs in animals and humans. The conclusions state that, at that time (2011), the only TSE agent demonstrated to be zoonotic is the Classical BSE agent in cattle. The evidence that the same agent is involved in both BSE in cattle and vCJD in humans is based on biological and molecular strain typing studies demonstrating clearly the similarities between the BSE agent in cattle and the vCJD agent in humans (Collee *et al*., 2006), on epidemic curves of both diseases and their geographical occurrence and on transmission experiments to mice (Bruce et al., 1997).

Atypical BSE types with a PrP^{Sc} molecular signature different from Classical BSE have been identified by Western blot analysis meanwhile (Biacabe *et al.*, 2004, Buschmann *et al.*, 2006). These were termed H-type BSE and L-type (or BASE) BSE. Atypical BSE cases have been essentially detected in aged asymptomatic cattle during systematic testing at slaughterhouse. The joint opinion states also that, of the new forms of BSE in cattle which have been identified, laboratory transmission experiments to human PrP transgenic mice or primates suggest that L-type Atypical BSE has a significant zoonotic potential, which appears similar or even higher than that of the Classical BSE agent. In particular primates are highly susceptible to the L-type Atypical BSE, even by the oral route.

In Belgium no cases of Atypical BSE have been detected so far (2013).

2.2. The fundamentals of the BSE control program

The EU has laid down a comprehensive set of harmonized rules for the prevention, control and eradication of BSE. The fundamentals of the EU BSE control program are based on:

- a total ban on feeding of animal proteins to farmed animals to protect animal health,
- a compulsory removal and destruction of bovine specified risk materials containing the highest risk of BSE infectivity to protect public health,
- destruction of carcasses of positive BSE cases and culling strategies for herds with confirmed BSE cases to protect public health,
- a comprehensive risk based disease monitoring system to detect BSE cases and remove them from the food chain to protect public health and to study the epidemic evolution of BSE.

From a public health point of view, the most important measures are the destruction of carcasses of positive BSE cases and the compulsory removal and destruction of bovine specified risk materials.

2.3. Testing for BSE

The legal framework for the active monitoring of ruminants for the presence of TSE is laid down in Article 6 of the TSE Regulation EC N° 999/2001 and specified in its Annex III Chapter A.

The monitoring of bovine animals for the presence of BSE is divided into different target groups (fallen stock, emergency slaughtered animals, animals with clinical signs at ante mortem, healthy slaughtered animals, animals culled under BSE eradication and animals clinically suspected of being infected by BSE).

The BSE monitoring by the EU Member States has been subjected regularly to modifications in accordance to the evolution of the BSE epidemiological situation. According to information from the EC TSE working group of March 2013 no more testing of healthy slaughtered cattle is done in Belgium, Estonia, Ireland, Latvia, Luxembourg, the Netherlands, Finland and the United Kingdom. In other countries testing of healthy slaughtered cattle will stop at some point in 2013 or is reduced to certain age groups.

In general the total number of BSE tests in the EU has decreased since 2009 due to the increase of the age limit for testing in some Member States and the focusing of BSE monitoring to animals at risk (clinical signs at ante mortem inspection, fallen stock, emergency slaughter).

Originally discriminatory testing to identify Classical BSE from Atypical H- or L-type BSE was performed by Member States on a voluntary basis. Since 1 July 2013 this discriminatory testing has become mandatory (EU 630/2013 of 28 June 2013).

2.4. Prevalence of BSE

The coordinated European response to BSE has proven successful and the number of BSE positive cases has dropped significantly in the 27 EU Member States from 2166 cases in 2001 to 28 in 2011 (EU report on the monitoring of ruminants for the presence of Transmissible Spongiform Encephalopathies in 2011).

Out of the 28 BSE cases identified in the EU in 2011, 23 were (on a voluntary basis) further submitted to discriminatory testing with the following result: 17 cases of Classical BSE, 3 cases of Atypical H-type BSE and 3 cases of Atypical L-type BSE.

In 2012, 18 cases of BSE were detected in the EU of which 7 were Atypical BSE (Source: TSE Expert working group DG SANCO 5/7/2013). Further discriminatory testing revealed that from these 7 Atypical BSE cases 1 case was Atypical H-type BSE and 6 were Atypical L-type BSE (Source: draft EU TSE report 2012).

Since 2007 no BSE cases were found in Belgium. No H- and L-type Atypical BSE have been diagnosed in cattle with BSE (1999-2008) aged seven years and older in Belgium (Dobly et al., 2010).

According to OIE, the annual incidence rate of BSE (number of indigenous cases per million bovines aged over 24 months during the year) in 2012 was zero in Austria, Belgium, Brazil, Canada, Czech Republic, Denmark, Finland, Germany, Greece, Israel, Italy, Japan, Liechtenstein, Luxembourg, The Netherlands, Slovakia, Slovenia, Sweden and Switzerland. It

was different from zero in France (0.10), Ireland (0.99), Poland (0.98), Portugal (2.39), Spain (1,94), USA (0.03) and the United Kingdom (0.643).

2.5. Prevalence of vCJD

Variant Creutzfeldt-Jakob disease (vCJD) is a rare and fatal human neurodegenerative condition. vCJD was first described in the United Kingdom in March 1996 and has been linked with exposure to Classical BSE, which was first reported in the United Kingdom in 1986.

According to the WHO (http://www.who.int/mediacentre/factsheets/fs180/en/) from October 1996 to March 2011, 175 cases of vCJD have been reported in the United Kingdom, 25 in France, 5 in Spain, 4 in Ireland, 3 each in the Netherlands and the United States of America (USA), 2 each in Canada, Italy and Portugal, and one each in Japan, Saudi Arabia and Taiwan.

The number of annual human cases of vCJD has drastically decreased. The number of cases of vCJD in the United Kingdom peaked in 2000 with 28 deaths. It has since declined to about 2 diagnosed cases and 2 deaths per year in 2008.

As far as we know no vCJD cases have been reported in Belgium.

2.6. OIE BSE risk status

According to Chapter 11.5. of the OIE Terrestrial Animal Health Code the BSE risk status of the cattle population of a country is determined on the basis of various criteria such as the outcome of a risk assessment (entry and exposure assessment), the ongoing awareness program for professionals, the compulsory notification and investigation of all cattle showing clinical signs consistent with BSE, the diagnostic procedures, the BSE surveillance and monitoring systems and the BSE history of the country.

Countries, regions or zones are thus recognized as having a negligible BSE risk, a controlled BSE risk or an undetermined BSE risk.

According to Resolution No. 20 of the OIE (Paris, May 2013) the following OIE Member Countries are recognized as having:

- a negligible BSE risk in accordance with Chapter 11.5. of the *Terrestrial Code:*

  Argentina, Australia, Austria, Belgium, Brazil, Chile, Colombia, Denmark, Finland, Iceland, India, Israel, Italy, Japan, Netherlands, New Zealand, Norway, Panama, Paraguay, Peru, Singapore, Slovenia, Sweden, United States of America, Uruguay

- a controlled BSE risk in accordance with Chapter 11.5. of the *Terrestrial Code:*

  Bulgaria, Canada, Chinese Taipei, Costa Rica, Croatia, Cyprus, Czech Republic, Estonia, France, Germany, Greece, Hungary, Ireland, Republic of Korea, Latvia, Lichtenstein, Lithuania, Luxembourg, Malta, Mexico, Nicaragua, Poland, Portugal, Slovakia, Spain, Switzerland, United Kingdom.

3. Uncertainties

In regard to the evaluation of the public health risk of the proposal to stop with the routine removal of specified risk materials during bovine slaughter many uncertainties still exist such as:

- the uncertainty associated to the number of missed BSE cases in cattle which end(ed) up in the food chain. This uncertainty is related to the long incubation period of the disease (which certainly holds true for the Atypical BSE) and the difficulty of identifying infective asymptomatic animals,
- the uncertainty related to the infectivity of specified risk materials of missed BSE cases,
- the uncertainty related to the zoonotic risk of Atypical L-type BSE,
- the uncertainty related to the true prevalence and epidemic curve of Atypical BSE.

4. Advice

The Scientific Committee is of the opinion that the questions should be treated in the light of the European or even global factual sanitary situation in regard to BSE taking into account the uncertainties related to the topic.

The Scientific Committee notes that the proposal to no longer remove the specified risk materials from the food chain in member states with a 'negligible BSE risk status' is a fundamental operation affecting the basics of the harmonized EU rules for public health protection against BSE infection. This proposal not only affects Belgium but all member states.

It has to be recognized that the statistics of the epidemiological curve of BSE in the member states shows a very favourable and stable evolution. Further, in a number of member states (including Belgium) the annual BSE incidence rate per million bovines aged over 24 months in 2012 was zero; in other states the annual BSE incidence rate varied in 2012 from 0.10 to 2.39 indicating that in the EU not every member state has reached the same low level of BSE contamination of its cattle population. This is confirmed by the current OIE BSE risk status situation which is not equal for all member states. It should be noted however that the diagnostic sensitivity of BSE testing in healthy asymptomatic cattle is lower (Penders *et al*., 2005) than the test sensitivity originally determined on symptomatic cattle due to the long incubation period of the disease. The true prevalence of BSE can therefore be estimated as higher than the officially reported results. Therefore, in the case of Belgium, a reported annual BSE incidence rate of zero would still be in agreement with a true prevalence different from zero.

A closer analysis of the EU results of the differential diagnostics of BSE-types suggests that Atypical BSE forms become relatively more important. Especially the L-type of Atypical BSE is of zoonotic importance and its apparent 'emergence' should be closely observed, also in Belgium, because the lower sensitivity of the BSE routine surveillance program performed on healthy asymptomatic cattle may lead to false negative results. According to Dobly *et al.* (2010) this may be also related to the relatively small Belgian cattle population and to the relatively young age of the Belgian cohort. According to Malcolm *et al.* (2009), rare BSE mutations raise concerns over risks to public health, as they could occur in countries considered to be free from BSE and therefore could be missed in a routine surveillance program.

The diminished routine testing for BSE is a risk factor for early detection of new TSEs.

The Scientific Committee was surprised to learn that third countries with a ‘negligible BSE risk status‘ and which do not remove specified risk materials from the food chain are allowed to import certain animal products (such as sausage skin) into the EU. The Committee considers this practice at risk for importing BSE into the European food chain.

Given the many uncertainties in regard to the true BSE risk (cfr. chapter 3) it is impossible for the Scientific Committee to perform a quantitative risk assessment on the proposal to stop with the routine removal of specified risk materials during bovine slaughter.

The Scientific Committee is of the opinion however that, in general, the proposal to stop with the routine removal of specified risk materials during bovine slaughter will inherently increase the risk for public health to be exposed to BSE because of the uncertainty related to missed BSE cases and the apparent emergence of Atypical BSE. In the light of the current BSE prevalence situation in Belgium this risk is considered to be very low, but not nihil.

In regard to the situation of TSE contamination of small ruminants many more uncertainties exist which make it even more difficult to assess the risk. The Scientific Committee did not study this situation.

Answer to the questions

Given the Belgian OIE status 'negligible risk with regard to BSE', is it still necessary to continue to remove all SRM?

The Scientific Committee is of the opinion that stopping in Belgium with the routine removal of specified risk materials during bovine slaughter will increase the risk for public health to be exposed to BSE because of the uncertainty related to the detection of BSE. This uncertainty is the consequence of the long incubation period (especially in Atypical BSE types), the apparent spontaneous nature of Atypical BSE, the lack of a clear clinical picture of Atypical BSE cases, the difficulty associated with the differentiation between BSE types, and the reduction in number of tested healthy slaughtered animals.

The final decision pertaining the need of removal of all specified risk materials is a risk management decision and goes beyond the competencies of the Scientific Committee.

Can the legislation on specified risk materials removal be modified without compromising public health?

The Scientific Committee is of the opinion that the legislation on specified risk materials removal can only be modified without compromising public health if the following conditions are met:

- eradication of Classical BSE in all member states;

- existence of reliable differential diagnostic tests with a high sensitivity to guarantee timely detection of Atypical BSE cases and their removal from the food chain.

In addition, the Scientific Committee emphasizes (as in previous advices i.e. Advice 17-2012) the crucial importance to maintain the feed ban.

5. **Conclusion**

Removal of specified risk materials from cattle at slaughter prevents infected materials from entering the human food chain.

The Scientific Committee is of the opinion that, in the light of the actual BSE epidemiological situation in the EU and taking into consideration the uncertainties in regard to the early detection of asymptomatic BSE, the zoonotic significance and the true prevalence of Aspecific BSE, stopping in Belgium with the routine removal of specified risk materials during bovine slaughter will increase the risk for public health.

On behalf of the Scientific Committee,
The President

Prof. Em. Dr. Pharm. C. Van Peteghem (Sgd.)
Brussel, 20/09/2013

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Conflict of interest

No conflicts of interest were determined.

Expression of gratitude

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Legal framework of this advice

The Law of 4 February 2000, on the establishment of the Federal Agency for the Safety of the Food Chain, and in particular article 8 of said Law;

The Royal Decree of 19 May 2000, on the structure and operating procedures of the Scientific Committee, as established within the Federal Agency for the Safety of the Food Chain;

The Internal Rules as mentioned in Article 3 of the Royal Decree of 19 May 2000, on the composition and operating procedures of the Scientific Committee established within the Federal Agency for the Safety of the Food Chain, as approved by the Minister on 9 June 2011.

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The Scientific Committee reserves the right to modify or change this advice at all times in the event that new information or data may become available following the publication of this version.