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

RAPID ADVICE 17-2014

Subject: Evaluation of the risk for public health of casings in countries with a "negligible risk status for BSE" and on the risk of modification of the list of specified risk materials (SRM) with regard to BSE (Dossier SciCom 2014/22)

Rapid advice approved by the Scientific Committee on 22nd October 2014.

Summary

The Scientific Committee was asked to answer two questions in regard to a proposal from the European Commission to no longer obligate Member States with a negligible BSE risk status to remove and dispose the specified risk materials as specified in Annex V to 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. The aim of this modification of the Regulation is to ensure that conditions for imports of commodities from third countries are not more favorable than the conditions applying to Member States with the same OIE BSE negligible risk status.

More specifically it was asked to the Scientific Committee:

- If there is a difference in public health risk between the casings imported from third countries with a "negligible risk status for BSE" and casings that come from the 18 EU Member States with a "negligible risk status for BSE"?

- If there is a significantly increased public health risk if, in the EU Member States with a "negligible risk status for BSE", the intestines are no longer removed as SRM and if the other risk materials for BSE (the skull including the brains and eyes, the spinal cord, the tonsils and the spine) are indeed considered as SRM?

Due to lack of availability of data on true prevalence and tissue infectivity of BSE (classical as well as atypical BSE) the Scientific Committee was not able to thoroughly investigate the questions.

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

The Scientific Committee is of the opinion that, taking into consideration the uncertainties in regard to the true prevalence of BSE (classical as well as atypical BSE) in countries with a "negligible risk status for BSE" and given the problems related with the early detection of asymptomatic BSE and given the zoonotic significance of atypical BSE, that stopping with the routine removal of specified risk materials during bovine slaughter will increase the risk for public health.

The Scientific Committee is not able to compare the public health risk of casings from third countries and from the 18 EU Member States, both with a negligible risk status for BSE, because of lack of data on true BSE prevalence and BSE tissue infectivity (classical BSE and atypical BSE) in the considered countries.

The Scientific Committee is also not able to properly answer the second question if there is a significantly increased public health risk if, in the EU Member States with a "negligible risk status for BSE", the intestines are no longer removed as SRM due to lack of quantitative data on tissue infectivity of different specified risk materials in slaughtered bovines in these countries. There is also no information on tissue infectivity of atypical BSE cases. It is known however that intestines are the portal of entry of prions and that they are already infective before the prions reach the central nervous system.

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

Samenvatting

Sneladvies over de risico's voor de volksgezondheid van worstenvellen in landen met een "verwaarloosbaar risicostatuut voor BSE" en over de risico's van wijziging van een lijst van gespecifieerde risicomaterialen (GRM) voor BSE.

Het Wetenschappelijk Comité is gevraagd om twee vragen te beantwoorden die verband houden met een voorstel van de Europese Commissie om de Lidstaten met een "verwaarloosbaar risicostatuut voor BSE" niet langer te verplichten om het gespecificeerd risicomateriaal te verwijderen en te vernietigen, zoals gespecificeerd in bijlage V bij Verordening (EG) nr 999/2001 van het Europees Parlement en de Raad van 22 mei 2001 houdende vaststelling van voorschriften inzake preventie, bestrijding en uitroeiing van bepaalde overdraagbare spongiforme encefalopathieën. Het doel van deze wijziging van de Verordening is ervoor te zorgen dat de voorwaarden voor de invoer van basisproducten uit derde landen met hetzelfde OIE BSE verwaarloosbaar risicostatuut niet gunstiger zijn dan de voorwaarden die van toepassing zijn voor de lidstaten.

Meer in het bijzonder werd gevraagd aan het Wetenschappelijk Comité:

- of er een verschil in risico is voor de volksgezondheid tussen de worstenvellen die worden ingevoerd vanuit derde landen met een "verwaarloosbaar risicostatuut voor BSE" en de worstenvellen die afkomstig zijn uit de 18 EU-lidstaten met een "verwaarloosbaar risicostatuut voor BSE"?

- of er een significant gestegen risico is voor de volksgezondheid indien in de EU-lidstaten met "een verwaarloosbaar risicostatuut voor BSE" de darmen niet langer worden verwijderd als GRM en de andere risicomaterialen voor BSE (de schedel inclusief de hersenen en de ogen, het ruggenmerg, de tonsillen en de wervelkolom) wel als GRM beschouwd blijven?

Wegens gebrek aan beschikbaarheid van gegevens over de werkelijke prevalentie en de weefselbesmettelijkheid van BSE (klassieke evenals atypische BSE) was het Wetenschappelijk Comité niet in staat was om de vragen grondig te onderzoeken.

Het verwijderen van gespecifieerd risicomateriaal bij slachting van rundvee verhindert dat geïnfecteerde materialen de voedselketen binnenkomen.

Het Wetenschappelijk Comité is van mening dat, gezien de onzekerheid met betrekking tot de werkelijke prevalentie van BSE (klassieke evenalsaAtypische BSE) in landen met een “verwaarloosbaar risicostatuut voor BSE”, gezien de problemen verbonden met de vroegtijdige detectie van asymptomatische BSE en gezien de zoönotische betekenis van Atypische BSE, dat het stopzetten van het routinematig verwijderen van de gespecifieerde risicomaterialen bij slachting van rundvee het risico voor de volksgezondheid zal verhogen.

Het Wetenschappelijk Comité is niet in staat om de risico's voor de volksgezondheid van worstenvellen uit derde landen en uit de 18 EU-lidstaten, beide met een “verwaarloosbaar risicostatuut voor BSE” te vergelijken, vanwege het gebrek aan gegevens over de werkelijke prevalentie van BSE en BSE weefselbesmettelijkheid (klassieke BSE en atypische BSE) in de beschouwde landen.

Het Wetenschappelijk Comité is ook niet in staat om naar behoren een antwoord te geven op de tweede vraag of er een significant verhoogd risico voor de volksgezondheid is indien in de EU-lidstaten met een "verwaarloosbaar risicostatuut voor BSE", de ingewanden niet langer meer verwijderd worden als GRM wegens gebrek aan kwantitatieve gegevens over weefselbesmettelijkheid van verschillende gespecificeerd risicomaterialen bij de geslachte runderen in deze landen. Er is ook geen informatie over de weefselbesmettelijkheid van atypische BSE-gevallen. Het is echter bekend dat ingewanden de ingangspoort vormen voor prionen en dat deze reeds geïnfecteerd zijn vooraleer de prionen het centraal zenuwstelsel bereiken.

De uiteindelijke beslissing met betrekking tot de noodzaak van het verwijderen van alle of een deel van het gespecificeerd risicomateriaal is een beslissing van risicobeheer en overstijgt de bevoegdheden van het Wetenschappelijk Comité.

Résumé

Avis rapide sur le risque pour la santé publique des boyaux naturels utilisés pour produire des saucisses dans les pays “de statut à risque négligeable pour l’ESB” et sur les risques inhérents à une proposition de modification de la liste des matériels à risque spécifiés (MRS) pour l’ESB

Il est demandé au Comité scientifique de répondre à deux questions relatives à une proposition de la Commission européenne de ne plus obliger les Etats membres possédant un statut à risque négligeable d’ESB à éliminer et détruire les matériels à risque spécifiés (MRS), comme cela était spécifié dans l’annexe V du Règlement (CE) N° 999/2001 du Parlement européen et du Conseil du 22 mai 2001 fixant les règles pour la prévention, le contrôle et l'éradication de certaines encéphalopathies spongiformes transmissibles. L’objectif de cette modification du Règlement est de veiller à ce que les conditions pour l’importation des produits de base à partir de pays tiers ne soient pas plus favorables que les conditions applicables aux pays membres, à statut OIE ESB identique, à savoir risque négligeable.

Plus précisément, il est demandé au Comité scientifique:

- s'il y a une différence de risque pour la santé publique entre les boyaux naturels utilisés pour produire des saucisses, importées à partir des pays tiers avec "un statut à risque négligeable d'ESB'' et les boyaux naturels provenant des 18 Etats membres de l'UE avec un statut à risque négligeable d'ESB ?

- s'il y a une augmentation significative du risque pour la santé publique si dans les États membres avec "un statut à risque négligeable d'ESB'', les intestins ne sont plus éliminés en tant que MRS, alors que les autres MRS (crâne y compris cerveau et yeux, moelle épinière, amygdales et colonne vertébrale) restent considérés comme MRS ?

Vu le manque de disponibilité de données sur la prévalence réelle d'ESB et sur l'infectivité des tissus par l'ESB (aussi bien l'ESB classique que l'ESB atypique), le Comité scientifique n'était pas en mesure d'analyser en profondeur les questions.

Le retrait des MRS des bovins à l'abattage prévient l'introduction de tissus infectés par l'ESB dans la chaîne alimentaire.

Le Comité scientifique est d'avis que, vu l'incertitude concernant la prévalence réelle de l'ESB (aussi bien classique qu'atypique) dans les pays à risque négligeable d'ESB, vu les problèmes de détection précoce de l'ESB lorsqu'elle est asymptomatique et vu le caractère zoonotique de l'ESB atypique, l'arrêt de l'élimination en routine des MRS lors de l'abattage des bovins va augmenter le risque pour la santé publique.

Le Comité scientifique n'est pas en mesure de comparer les risques pour la santé publique de l'utilisation de boyaux naturels utilisés pour produire des saucisses provenant soit de pays tiers avec statut à risque négligeable pour l'ESB, soit des 18 Etats membres de l'UE, également avec statut à risque négligeable pour l'ESB, vu le manque de données sur la prévalence réelle de l'ESB et sur l'infectivité des tissus (ESB classique et atypique) dans les pays considérés.

Le Comité scientifique n'est pas non plus en mesure de répondre convenablement à la deuxième question, à savoir si le risque pour la santé publique est augmenté si, dans les Etats membres de l'UE avec un statut à risque négligeable pour l'ESB, les intestins ne sont plus éliminés comme MRS, vu le manque de données quantitatives sur l'infectivité des différents MRS chez les bovins abattus dans ces pays. Il n'y a non plus d'informations sur l'infectivité des tissus des cas d'ESB atypiques. Il est cependant bien connu que les intestins forment la porte d'entrée pour les prions et qu'ils sont infectés par les prions préalablement à leur atteinte du système nerveux central.

La décision finale concernant la nécessité d'éliminer l'entièreté ou une partie des matériels à risque spécifiés appartient au gestionnaire de risque et dépasse les compétences du Comité scientifique.

Key words

BSE - TSE – bovine – specified risk materials

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
(Sausage) casings	Material that encloses the filling of sausages. Natural casings are made of intestinal submucosa.
Negligible risk for BSE	Cfr. Chapter 11.4.3. of the OIE Terrestrial Code http://www.oie.int/fileadmin/Home/eng/Health_standards/tahc/2010/chapitre_bse.pdf

1.2. Context

During a TSE workgroup meeting on July 5th, 2013 DG SANCO has 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 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies would have to be abrogated. This proposal has not yet been approved by the Member States at present.

In regard to this proposal the Scientific Committee published a rapid advice (SciCom 16-2013) in which it was concluded that stopping, in Belgium, with the routine removal of specified risk materials during bovine slaughter would increase the risks for public health.

The European Commission (by DG SANCO) had the intention to resubmit on October 13th, 2014 the same proposal to the TSE workgroup with the aim to submit it to vote within the Standing Committee for Plants, Animals, Food and Feed on October 14th, 2014. The reasons for this are:

- that third countries with negligible BSE risk status do not remove the SRM from the food chain and their products (mainly sausage casings or casings) are allowed for import into the EU;

- that EU Member States with a negligible BSE risk status are up till now not allowed to apply more flexible measures in accordance with the OIE code and are not allowed to market the same products;

- that in the EU it is expected that, in a few years, classical BSE will be eradicated and that just a number of atypical BSE cases will remain.

The current situation is trade-distorting and maintains a crooked competitive situation of EU Member States relative to third countries with a negligible BSE risk status. The latter are indeed allowed to export sausage casings (casings) to the EU. According to the FASFC risk managers the solution that DG SANCO moves forward, in particular the complete lifting of all measures for SRM, seems too lax. A possible option, according to them, is to restrict the removal of SRM to the bovine central nervous system and the tonsils and to exclude the intestines from the list of SRM which signifies that they reenter the food chain.

1.3. Questions

In order to prepare the Belgian position, an advice is asked to the Scientific Committee using the accelerated procedure, with regard to the following questions:

- Is there a difference in public health risk between the casings imported from third countries with a “negligible risk status for BSE” and casings that come from the 18 EU Member States with a “negligible risk status for BSE”?

- Is there a significantly increased public health risk if, in the EU Member States with a “negligible risk status for BSE”, the intestines are no longer removed as SRM and if the other risk materials for BSE (the skull including the brains and eyes, the spinal cord, the tonsils and the spine) are indeed considered as SRM?

1.4. 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.

1.5. Work method

Due to time constraints it was only possible to consult experts electronically. A draft rapid opinion was discussed at the plenary session of the Scientific Committee on October 17th 2014 and electronically validated on October 22nd 2014.

The Scientific Committee gives the following rapid advice:

2. Introduction

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 surveillance 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.

The BSE surveillance by the EU Member States has been subjected regularly to relaxations in accordance to the evolution of the BSE epidemiological situation. In general the total number of BSE tests in the EU has decreased since 2009 due to the increase of the lower age limit for obligatory testing in some Member States and the focusing on 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).

The coordinated European response to BSE has proven successful and the apparent number of BSE positive cases has dropped significantly in the 28 EU Member States from 2,166 cases/year in 2001 to 18/year in 2012 (EU report on the monitoring of ruminants for the presence of Transmissible Spongiform Encephalopathies in 2012).

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. 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: EU TSE report 2012). No statistics are available for 2013. Since 2007 no BSE cases were found in Belgium.

In 2012, no BSE cases were found in Belgium, Bulgaria, Czech Republic, Denmark, Germany, Estonia, Greece, Croatia, Italy, Cyprus, Latvia, Lithuania, Luxembourg, Hungary, Malta, the Netherlands, Austria, Romania, Slovenia, Slovakia, Finland and Sweden. In Belgium no cases of Atypical BSE have been detected so far.

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 and 2013 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 in 2012; 0.19 in 2013), Ireland (0.99 in 2012; 0.32 in 2013), Poland (0.98 in 2012; 0.32 in 2013), Portugal (2.39 in 2012; 0 in 2013), Spain (1,94 in 2012; 0 in 2013), USA (0.03 in 2012 and 0 in 2013) and the United Kingdom (0.643 in 2012; 0.656 in 2013).

The OIE 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. 18 of the OIE (82nd General Session May 2014) the following OIE Member Countries are recognized as having:

- a negligible BSE risk in accordance with Chapter 11.4. of the *Terrestrial Code:*

  Argentina, Australia, Austria, Belgium, Bulgaria, Brazil, Chile, Colombia, Croatia, Denmark, Estonia, Finland, Hungary, Iceland, India, Israel, Italy, Japan, Korea (Rep. of), Latvia, Luxembourg, Malta, Netherlands, New Zealand, Norway, Panama, Paraguay, Peru, Portugal, Romania, Slovakia, Singapore, Slovenia, Sweden, United States of America, Uruguay

- a controlled BSE risk in accordance with Chapter 11.4. of the *Terrestrial Code:*

  Canada, Chinese Taipei, Costa Rica, Cyprus, Czech Republic, France, Germany, Greece, Ireland, Lichtenstein, Lithuania, Mexico, Nicaragua, Poland, 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 holds true even more for the atypical BSE), the low sensitivity of the available diagnostic methods 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 tissue infectivity distribution of atypical BSE in ruminants.

4. Advice

In its rapid advice SciCom 16-2013 on the evaluation of a proposal to stop with the routine removal of specified risk materials during bovine slaughter the Scientific Committee concluded that the proposal to no longer remove the specified risk materials from the food chain in Member States with a 'negligible OIE BSE risk status' is a fundamental operation affecting the basics of the harmonized EU rules for public health protection against BSE infection. This proposal affects the health of all consumers of bovine products.

The Scientific Committee recognizes that the statistics of the epidemiological curve of BSE incidence rates in the Member States show a favourable and steady evolution (EU TSE report, 2013). 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 (France) to 2.38 (Portugal) 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 OIE BSE risk status situation that is not equal for all Member States. According to OIE statistics incidence rates for BSE varied in 2013 from 0 to 0.32. In the United Kingdom OIE statistics show very low numbers of cases in 2013 (3) and 0 in 2014 (data as of October 2nd, 2014).

According to EFSA (2014) the impact and therefore the risk of BSE was very heterogeneously distributed among Member States. The temporal peaking of BSE prevalence varied between countries. In the past the BSE epidemic was different between Member States in terms of level of prevalence and temporal evolution. Currently, the tailing of the BSE epidemic allows the EU27 Member States to be considered as a single epidemiological entity.

A closer analysis of the results of the differential diagnostics of BSE-types in the EU suggests that Atypical BSE forms become relatively more important. Especially the L-type of atypical BSE is of zoonotic importance and its evolution should be closely observed. According to EFSA (EFSA 2014) the atypical BSE cases detected through the active surveillance do not show any particular trend between 2001 and 2012 (numbers of cases varying between 2 and 8 per year.

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

Answer to the questions:

1. Is there a difference in public health risk between the casings imported from third countries with a "negligible risk status for BSE" and casings that come from the 18 EU Member States with a "negligible risk status for BSE"?

According to Chapter 11.4. 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 (http://www.oie.int/en/animal-health-in-the-world/official-disease-status/bse/en-bse-carte/).

There is a difference in BSE surveillance systems between EU and third countries. According to EFSA (2014) the BSE surveillance system in the EU clearly surpasses the OIE BSE requirements.

It is not because countries belong to the same OIE BSE risk category that there may not be a difference in true BSE prevalence. It should be noted also that the diagnostic sensitivity of BSE testing in asymptomatic infected cattle is lower (Penders et al., 2005) than the test sensitivity originally determined on cattle with symptoms due to the long incubation period of the disease. The true prevalence of BSE is therefore higher than the officially reported results.

According to EFSA (2014) in BSE infected bovine, the relative distribution of the infectivity in the different portions of the intestines and in the mesenteric tissues varies with age, reflecting the stage of incubation of the disease.

In evaluating the risk of BSE transmission by casings it has also to be taken into account that a number of infected cattle enters the food chain because they are not detected by the diagnostic tests. According to EFSA (2014) it was estimated that in 2012 about 610 infected cattle entered undetected the food chain in the EU27.

In case of re-emergence of classical BSE the disease will be associated with infection of younger animals (Saegerman et al., 2006). It is at present not known whether the same age-dependent infection holds for Atypical BSE.

In its rapid advice SciCom 16-2013 the Scientific Committee stated that it 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 export certain animal products (such as sausage skin - casings) to the EU. The Committee considered this practice at risk for importing BSE into the European food chain.

In conclusion the Scientific Committee is not able to answer this question with an acceptable degree of uncertainty because of lack of data on true prevalence of BSE (classical as well as atypical forms of BSE) in the considered countries. It reiterates its concern regarding the import of certain animal products from third countries with a ‘negligible BSE risk status’ as stated in rapid advice SciCom 16-2013.

2. Is there a significantly increased public health risk if, in the EU Member States with a "negligible risk status for BSE", the intestines are no longer removed as SRM while the other risk materials for BSE (the skull including the brains and eyes, the spinal cord, the tonsils and the spine) are indeed considered as SRM?

Once again the Scientific Committee is not able to properly answer this question because of lack of quantitative data on tissue infectivity of different specified risk materials in slaughtered bovines in EU Member States with a "negligible risk status for BSE".

BSE infected animals may enter undetected the food chain due to the low sensitivity of the diagnostic tests. Further on the classical BSE agent accumulates from the first months post exposure in particular segments of the bovine intestines and persists till clinical onset. In addition no information is available about the infectivity of tissues by the atypical BSE agent, especially in the intestines.

If intestines from cattle in EU Member States with a "negligible risk status for BSE" are no longer removed as SRM and are allowed to enter the food chain the public health risk will be increased. The degree of rise in risk level cannot be determined. According to EFSA Journal 2014;12(2):3554, the TSEi model indicated that the removal of the last four meters of the small intestine and of the caecum from the food and feed chain would result in a major reduction of the Classical BSE exposure risk associated with intestine and mesentery in cattle.

Referring to its previous advice 16-2013 the Scientific Committee repeats that stopping with the routine removal of all specified risk materials during bovine slaughter will increase the risks of exposure of the population to BSE because of the uncertainty related to the detection of BSE. This uncertainty is the consequence of the long incubation period (especially in cases of atypical BSE), the low sensitivity of the available diagnostic methods, the apparent spontaneous nature of atypical BSE, the lack of a clear clinical picture of atypical BSE cases and the reduction in number of tests in healthy slaughtered animals.

The final decision pertaining the need of removal of all or part of the specified risk materials is a decision to be taken by the risk manager and goes beyond the competencies of the Scientific Committee.

5. Conclusion

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

The Scientific Committee is of the opinion that, taking into consideration the uncertainties in regard to the true prevalence of BSE (including classical as well asaAtypical BSE) in countries with a "negligible risk status for BSE" and given the problems related with the early detection of asymptomatic BSE and given the zoonotic character of atypical BSE, stopping with the routine removal of all specified risk materials during bovine slaughter will increase the risk for public health.

The Scientific Committee is not able to compare the public health risk of casings from third countries and from the 18 EU Member States both with a negligible risk status for BSE because of lack of data on true BSE prevalence (classical BSE and atypical BSE) in the considered countries.

The Scientific Committee is not able to properly answer the question if there is a significantly increased public health risk if, in the EU Member States with a “negligible risk status for BSE”, the intestines are no longer removed as SRM due to lack of quantitative data on tissue infectivity of different specified risk materials in slaughtered bovines in these countries. There is also no information on tissue infectivity by the agent of atypical BSE.

On behalf of the Scientific Committee,
The President

Prof. Dr. E. Thiry (Sgd.)
Brussels, 06/11/2014

References

De Bosschere H, Roels S & Vanopdenbosch E. Atypical Case of Bovine Spongiform Encephalopathy in an East-Flemish Cow in Belgium (2004) Journal of Applied Research in Veterinary Medicine 2 (1), 52-54.

EFSA. Scientific opinion on BSE risk in bovine intestines and mesentery. EFSA Journal 2014;12(2):3554. http://www.efsa.europa.eu/en/efsajournal/doc/3554.pdf

EU. Report on the monitoring of ruminants for the presence of transmissible spongiform encephalopathies (TSEs) in the EU in 2012. Final version 9 October 2013.

Ferguson-Smith M., Richt J. Rare BSE mutation raises concerns over risks to public health. Nature, 457, 1079, 2009.

OIE, 2013. Terrestrial Animal Health Code, Bovine Spongiform Encephalopathy. Chapter 11.5. http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_1.11.5.htm

OIE. Annual incidence rate of bovine spongiform encephalopathy (BSE) in OIE Member Countries that have reported cases, excluding the United Kingdom. http://www.oie.int/?id=507

OIE. Annual incidence rate of bovine spongiform encephalopathy (BSE) in the United Kingdom. http://www.oie.int/animal-health-in-the-world/bse-specific-data/annual-incidence-rate-in-the-united-kingdom/

Penders J., Berkvens D., Saegerman C., Praet N., Dispas M., Verbraeken S., Roels S., Thiry E. Estimation de la prévalence réelle de l'encéphalopathie spongiforme bovine en Belgique en 2002 et 2003. Epidémiol. Santé Anim., 2005, 47, 113-121.

Rapid advice SciCom 16-2013: Evaluation of a proposal to stop with the routine removal of specified risk materials during bovine slaughter. http://www.favv-afsca.fgov.be/scientificcommittee/advices/_documents/RAPIDADVICE16-2013_EN_DOSSIER2013-22.pdf

Saegerman C., Speybroeck N., Vanopdenbosch E., Wilesmith J.W., Berkvens D. Trends in age at detection in cases of bovine spongiform encephalopathy in Belgium: an indicator of the epidemic curve. Vet Rec. 2006;159(18):583-587.

WHO. Variant Creutzfeldt-Jakob Disease. Factsheet N°180. Revised February 2012. http://www.who.int/mediacentre/factsheets/fs180/en/

Members of the Scientific Committee

The Scientific Committee is composed of the following members:

D. Berkvens, A. Clinquart, G. Daube, P. Delahaut, B. De Meulenaer, L. De Zutter, J. Dewulf, P. Gustin, L. Herman, P. Hoet, H. Imberechts, A. Legrève, C. Matthys, C. Saegerman, M.-L. Scippo, M. Sindic, N. Speybroeck, W. Steurbaut, E. Thiry, M. Uyttendaele, T. van den Berg, C. Van Peteghem†

Conflict of interest

No conflicts of interest were reported.

Expression of gratitude

The Scientific Committee wishes to acknowledge the scientific secretariat and the members of the work group for preparing this draft advice. The work group was composed of the following members:

Members of the Scientific Committee	D. Berkvens (reporter), C. Saegerman, E. Thiry
Invited experts	S. Roels (CODA), N. Korsak (ULg)

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.

Disclaimer

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.