参考資料３－１

厚生労働省発生食１２１８第１号
平成２７年１２月１８日

食品安全委員会
委員長　佐藤　洋　殿

厚生労働大臣　　塩崎　恭久

食品健康影響評価について

食品安全基本法（平成１５年法律第４８号）第２４条第１項第１号、第６号及び第１３号並びに同条第３項の規定に基づき、下記事項に係る同法第１１条第１項に規定する食品健康影響評価について、貴委員会の意見を求めます。

記

牛海綿状脳症（ＢＳＥ）対策について、以下の措置を講ずること。具体的に意見を求める内容は別紙の２のとおり。

（１）　と畜場におけるＢＳＥ検査について、牛海綿状脳症対策特別措置法（平成１４年法律第７０号）第７条第１項の規定に基づく検査の対象となる牛の月齢の改正。
（２）　特定部位について、牛海綿状脳症対策特別措置法第７条第２項並びにと畜場法（昭和２８年法律第１１４号）第６条及び第９条の規定に基づき、衛生上支障のないように処理しなければならない牛の部位の範囲の改正。
（３）　牛のせき柱を含む食品等の安全性確保について、食品衛生法（昭和２２年法律第２３３号）第１１条及び第１８条に基づく規格基準の改正。

（別紙）

１　諮問の背景及び趣旨

（１）牛海綿状脳症（ＢＳＥ）国内対策については、平成２４年１０月及び平成２５年５月の食品安全委員会の食品健康影響評価を踏まえ、平成２５年２月及び７月にと畜場におけるスクリーニング検査の対象月齢及び特定危険部位（ＳＲＭ）の範囲を見直した。

（２）世界的にＢＳＥリスクが減少している状況等を踏まえ、上記措置と平行して米国産牛肉等の輸入条件の見直しを行ったほか、その後も欧州産牛肉の輸入再開、ゼラチン及びコラーゲンの取扱いを見直してきた。

（３）現在の国内措置の根拠の一つである平成２５年５月の食品安全委員会の食品健康影響評価では、以下のとおり記述されている。

○　２００９～２０１５年にはＢＳＥの摘発頭数はほぼ０となり、以降、日本において飼料等を介してＢＳＥが発生する可能性は極めて低くなるものと推定。

○　当面の間、検証を継続することとし、将来的には、より長期にわたる発生状況に関するデータ及びＢＳＥに関する新たな科学的知見の蓄積を踏まえて、検査対象月齢のさらなる引き上げ等を検討するのが適当であると判断した。

（４）平成２５年７月から本年１１月末までに食用としてと畜された４８か月齢超の牛４８１，２０７頭は、ＢＳＥスクリーニング検査の結果が全て陰性であり、ＢＳＥ感染牛は発見されておらず、２０１５年末を迎えるため、現在のリスクに応じてリスク管理措置を見直す必要がある。

（５）また、ＯＩＥ基準よりも高い水準の措置を維持する場合には科学的な正当性を明確化する必要がある。

なお、欧州連合においては、近年、と畜場でのＢＳＥスクリーニング検査の対象やＳＲＭの範囲を見直している。

２　具体的な諮問内容

（１）検査対象月齢

食用にと畜される健康牛のＢＳＥ検査について、現行基準を継続した場合と廃止した場合のリスクを比較。なお、と畜場での検査は、生体検査において運動障害、知覚障害、反射又は意識障害等の神経症状が疑われたもの及び全身症状を呈する２４か月齢以上の牛のみを検査対象とする。

（２） ＳＲＭの範囲

現行の「全月齢の扁桃及び回腸遠位部並びに３０か月齢超の頭部（舌、頬肉、皮及び扁桃を除く。）、脊髄及び脊柱」から「３０か月齢超の頭部（舌、頬肉、皮及び扁桃を除く。）及び脊髄」に変更した場合のリスクを比較。

３　今後の方針

食品健康影響評価の結果を踏まえて、必要な管理措置の見直しを行う。

各国の特定危険部位（SRM）

第97回プリオン専門調査会
資料2より抜粋

日本	・全月齢の扁桃及び回腸（盲腸との接続部分から２メートル までの部分に限る。）並びに30か月齢超の頭部（舌、頬肉、皮及び扁桃を除く。）及び脊髄 （と畜場法施行規則、厚生労働省関係牛海綿状脳症対策特別措置法施行規則） ・30か月齢超の脊柱（背根神経節を含み、頸椎横突起、胸椎横突起、腰椎横突起、頸椎棘突起、胸椎棘突起、腰椎棘突起、仙骨翼、正中仙骨稜及び尾椎を除く。） （食品衛生法に基づく食品、添加物の規格基準）
ＥＵ	**（無視できるリスクの国、管理されたリスクの国、不明の国）** ・12か月齢超の頭蓋（下顎を除き脳、眼を含む）及び脊髄 **（管理されたリスクの国、不明の国）** ・30か月齢超の脊柱（尾椎、頸椎・胸椎・腰椎の棘突起及び横突起並びに正中仙骨稜・仙骨翼を除き、背根神経節を含む） ・全月齢の扁桃、小腸の後部４メートル、盲腸及び腸間膜
米国	・30か月齢以上の脳、頭蓋、眼、三叉神経節、脊髄、脊柱（尾椎、胸椎及び腰椎の横突起並びに仙骨翼を除く）及び背根神経節 ・全月齢の扁桃及び回腸遠位部 （9 CFR Part 310）
カナダ	・30か月齢以上の頭蓋、脳、三叉神経節、眼、扁桃、脊髄及び背根神経節 ・全月齢の回腸遠位部 (Health of Animals Regulations C.R.C., c. 296)
OIE(管理されたリスクの国)	・30か月齢超の脳、眼、脊髄、頭蓋骨及び脊柱 ・全月齢の扁桃及び回腸遠位部 （OIE Terrestrial Animal Health Code 2014 CHAPTER11.4.14）

COMMISSION REGULATION (EU) 2015/1162

of 15 July 2015

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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard 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 ([1]), and in particular the first paragraph of Article 23 thereof,

Whereas:

(1) Regulation (EC) No 999/2001 lays down rules for the prevention, control and eradication of transmissible spongiform encephalopathies (TSEs) in animals. It applies to the production and placing on the market of live animals and products of animal origin and, in certain specific cases, to exports thereof.

(2) Point 1 of Annex V to Regulation (EC) No 999/2001 designates as specified risk material ('SRM') certain bovine, ovine and caprine tissues if they come from animals whose origin is in a Member State or third country, or in one of their regions, with a controlled or undetermined Bovine Spongiform Encephalopathy ('BSE') risk status. Point 2 of that Annex extends the list of tissues designated as SRM to Member States with a negligible BSE risk status, but not to third countries with the same status. As a consequence, Member States with a negligible BSE risk status are to remove and dispose of SRM, while imports into the Union of such tissues from third countries with a negligible BSE risk status are allowed.

(3) The World Organization for Animal Health ('OIE') only recommends the exclusion from international trade of SRM derived from bovine animals originating in countries with a controlled or undetermined BSE risk, while no such exclusion is recommended for bovine animals originating from countries with a negligible BSE risk status ([2]).

(4) The Commission Strategy Paper on Transmissible Spongiform Encephalopathies for 2010-2015 ([3]) envisages the possibility to review the current obligation for Member States with a negligible risk status to remove SRM from the food and feed chain if an increasing number of Member States reach such status. With the adoption on 20 October 2014 of Commission Implementing Decision 2014/732/EU ([4]), which is based on the World Animal Health Organisation (OIE) Resolution No 18 of May 2014 ([5]), seventeen Union Member States have been recognised as having a negligible BSE risk status.

(5) Authorising all bovine tissues currently classified as SRM to be used in the food chain in Member States with a negligible BSE risk status is considered premature at this stage due to certain remaining scientific uncertainties linked to Atypical BSE.

([1]) OJ L 147, 31.5.2001, p. 1.
([2]) Article 11.4.14 of the OIE Terrestrial Animal Health Code, Edition 2014 (OIE — Terrestrial Animal Health Code — V 8 — 15.7.2014).
([3]) Communication from the Commission to the European Parliament and the Council — The TSE Road map 2 — A Strategy paper on Transmissible Spongiform Encephalopathies for 2010-2015; COM(2010)384 final.
([4]) Commission Implementing Decision 2014/732/EU of 20 October 2014 amending Decision 2007/453/EC as regards the BSE status of Bulgaria, Estonia, Croatia, Latvia, Luxembourg, Hungary, Malta, Portugal and Slovakia (OJ L 302, 22.10.2014, p. 58).
([5]) Resolution No 18, 'Recognition of the Bovine Spongiform Encephalopathy Risk Status of Member Countries', adopted by the World Assembly of Delegates of the OIE on 27 May 2014 (82 GS/FR — Paris, May 2014).

(6) On 19 January 2011, the European Food Safety Authority (EFSA) published a joint opinion prepared with the European Centre for Disease Prevention and Control (ECDC) on any possible epidemiological or molecular association between Transmissible Spongiform Encephalopathies (TSEs) in animals and humans ('the joint EFSA and ECDC Opinion') ([1]). In this joint opinion, the EFSA and ECDC confirmed the identification of atypical forms of BSE in cattle and made the distinction between classical BSE, L-type atypical BSE and H-type atypical BSE.

(7) According to this joint opinion, several elements indicate that the L-type atypical BSE agent has the potential to be a zoonotic agent. By contrast, such elements are absent for the H-type atypical BSE agent. This joint opinion also stated that the unusually old age of all H-type atypical BSE and L-type atypical BSE identified cases and their apparent low prevalence in the population suggest that these Atypical BSE forms are arising spontaneously, independently of the animal feeding practices. The BSE surveillance system in the Union showed a very low prevalence and relative constant level of atypical BSE cases in recent years.

(8) On 11 January 2011, EFSA published a Scientific Opinion on the revision of the quantitative risk assessment of the BSE risk posed by processed animal proteins ([2]) ('EFSA's 2011 opinion'). This scientific opinion indicates that 90 % of the total infectivity amount in a BSE clinical case is associated with central and peripheral nervous system tissues. More precisely, this opinion estimated that 65 % of the total amount of infectivity in a clinical case of BSE is associated with the brain and 26 % is associated with the spinal cord.

(9) On 11 July 2014, EFSA published a scientific report on a Protocol for further laboratory investigations into the distribution of infectivity of Atypical BSE ([3]). According to that scientific report, collective data indicate that Classical BSE shares the same tissue distribution as the Atypical BSE cases, with the higher titres of infectious prion proteins and/or infectivity detected in the central and peripheral nervous systems.

(10) For all those reasons, the brain and the spinal cord of cattle over 12 months whose origin is in a Member State with negligible BSE risk status should remain in the list of SRM, pending further knowledge is gained on the risk linked to Atypical-BSE.

(11) Given the practical difficulties to ensure the absence of contamination of the bones of the skull with brain tissues, the skull of cattle over 12 months whose origin is in a Member State with negligible BSE risk status should also be maintained as SRM.

(12) The data examined by EFSA mainly refer to Europe, due to the very robust surveillance system in the EU. Discussions at OIE level are ongoing to review the BSE chapter of the OIE Terrestrial Animal Health Code in the light of recently acquired knowledge concerning Atypical-BSE. The Union rules as regards SRM in Member States and third countries with negligible BSE risk status should be reviewed in the light of the outcome of these discussions.

(13) The skull, the brain, the spinal cord and the eyes of bovine animals over 12 months are not known to be imported into the Union.

(14) In order to ensure more similar conditions for putting on the market commodities from the Member States compared to imports of commodities from third countries, while taking into account the possible remaining risk linked to the use in the food and/or feed chain of certain tissues, the additional requirement extending the prohibition of SRM of bovines to Member States with a negligible BSE risk should therefore be repealed except for the skull, the brain and spinal cord of bovine animals over 12 months.

(15) Regulation (EC) No 999/2001 should therefore be amended accordingly.

(16) Should future scientific evidence point out public health risks that are currently unknown, the Union rules as regards SRM in Member States and third countries with negligible BSE risk should be reviewed.

(17) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

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([1]) EFSA Journal 2011; 9(1):1945.
([2]) *EFSA Journal 2011*; 9(1):1947.
([3]) *EFSA Journal 2014*;12(7):3798.

HAS ADOPTED THIS REGULATION:

Article 1

In Annex V to Regulation (EC) No 999/2001, point 2 is replaced by the following:

'2. **Specific requirements for Member States with negligible BSE risk status**

Tissues listed in point 1.(a)(i) and 1.(b), which are derived from animals whose origin is in Member States with a negligible BSE risk, shall be considered as specified risk material.'.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 15 July 2015.

For the Commission
The President
Jean-Claude JUNCKER