

This is provisional English translation of an excerpt from the original full report.

## **Risk Assessment Report (DRAFT)**

### **Consideration of risk variations in Japan derived from the proposed revisions of the current countermeasures against BSE**

Food Safety Commission of Japan (FSCJ)  
October 2012

#### **Executive Summary**

Food Safety Commission Japan (FSCJ) conducted assessments on human health risks associated with the Bovine Spongiform Encephalopathy (BSE) agent, in response to requests from the Ministry of Health, Labour and Welfare (MHLW). See detail of the MHLW's requests in box below.

In the process of this risk assessment, FSCJ utilized reference materials and documents provided by MHLW regarding BSE situation in the following five countries: Japan, the United States of America (USA), Canada, France and the Netherlands. FSCJ also used all scientific knowledge on BSE that had been collected so far throughout the FSCJ's work on assessment of BSE risks. Based on the latest scientific information on the BSE prevalence situation, BSE laboratory studies, BSE infection in cattle population, removal of specific risk materials (SRMs), meat processing process, atypical BSE, variant Creutzfeldt-Jacob Disease (vCJD, a human transmissible spongiform encephalopathy disease) and others, FSCJ thoroughly considered the human health risks arisen from consumption of edible parts of cattle.

A narrative brief description on BSE cases in the world is as follows: Mainly in the United Kingdom (UK), and also in other European countries, many cases of BSE had been detected. The number of BSE cases peaked in the early 1990's. According to relevant reports issued by World Health Organization (WHO) and others, a possible link between vCJD and BSE was first reported in 1996. As of July 2012, a total of 190,614 cases of BSE have been reported worldwide. The number of BSE cases peaked at 37,316 in 1992 and has fallen down sharply to 45 cases in 2010 and 29 cases in 2011, as a result of imposing more stringent regulations on feed control and other necessary measures against BSE. For eight years after the birth of the latest-born case in August 2004, no BSE case has been detected to date in the five countries listed above. .

Detail of the requests from MHLW is as follows:

1. The MHLW has proposed to change the present countermeasures against BSE by revising relevant regulations and/or requirements as follows, to be applied either to domestic cattle or cattle imported from USA, Canada, France and the Netherlands.
  - 1) Countermeasures applied to domestic cattle (hereinafter referred to as "the domestic measures")
    - a) To change an age limit required for domestic cattle to undergo BSE testing at slaughterhouses based on the Article 1, paragraph 7 of the Law on Special Measures against Bovine Spongiform Encephalopathy (Act No. 70 of 2002);
    - b) To revise standards for hygienic removal of specified materials as required by the Act on Special Measures concerning Measures against Bovine Spongiform Encephalopathy, Article 2, paragraph 7 and Abattoirs act Article 2, paragraph 7, 1953; and
    - c) To amend relevant requirements as required by the Food Sanitation Law (Articles 11

- and 18) to ensure safety of cattle meats including vertebral column.
- 2) Countermeasures applied to cattle imported from the USA, Canada, France and the Netherlands (hereinafter referred to as “the border measures”)
    - a) To revise current import requirements applied to cattle meat and offal imported from the USA and Canada; and
    - b) To revise current import requirements applied to cattle meat and offal imported from France and the Netherlands.
  2. In the context of the proposal above, specifically the MHLW requested the FSCJ to address the following points:
    - 1) For the domestic measures:
      - a) Age limit for BSE testing  
To examine potential variation of BSE risks to human health in association with the change in the age limit for BSE testing at slaughter from the current 20 months to 30 months of age.
      - b) Age limits for removal of specified risk materials (SRMs)  
To examine difference in risk levels between cattle of all ages and over 30 months of age in removal of SRMs including skull (excluding tonsils), spinal cord and vertebral column.
    - 2) For the border measures:
      - a) Age restriction on beef import  
To examine potential variation of BSE risks to human health when the age restriction on cattle meat and offal is changed from the current 20 months to 30 months of age.
      - b) Age limits for removal of specified risk materials (SRMs) in cattle  
To examine difference in risk levels to human health between cattle of all ages and over 30 months of age in removal of SRMs including skull (excluding tonsils), spinal cord and vertebral column.

Note: As for cattle of France and the Netherlands, the request was to examine changes in risk levels between the following two cases: i) ban of importing cattle at any month of age as currently applied to these two countries; and ii) allowing import of cattle at over 30 months of age under condition that SRMs including skull (excluding tonsils), spinal cord and vertebral column are removed.

  - 3) In addition, following the assessments on points 1) and 2) above, an assessment is to be conducted to determine as to whether risk variation would arise from further changes to the existing domestic and/or border measures, i.e. 1)a) and 2)a), in line with international standards for mitigating BSE risks.

The result of the risk assessment is summarized below.

Assuming that the proper implementation of the present feed control measures are maintained in Japan, the USA, Canada, France and the Netherlands, FSCJ evaluated a possible link between BSE and vCJD taking into account; the current BSE infection risks in cattle in these countries; and interspecies barrier between cattle and humans in BSE transmission risks. Consequently, FSCJ concluded that in these countries, development of vCJD would be highly unlikely to be linked with BSE prions through consumption of meat and offal (excluding the tonsils and distal ileum) from cattle at or under 30 months of age.

Accordingly, FSCJ adopted the following conclusions on the domestic measures and the border measures:

1) Domestic measures

a) Age limits for BSE testing

Variation in BSE risks to human health would be very small, if it arises, hence an effect of the variation on human health is negligible, in association with the change in the age limit for BSE testing is changed from the current 20 months to 30 months of age.

b) Age limits for removal of specified risk materials (SRMs) in domestic cattle

Difference in risk levels between all ages and over 30 months of age would be very small, if it exists, hence an effect of the difference on human health is negligible, in removal of SRMs, including skull (excluding tonsils), spinal cord and vertebral column.

2) Border measures

a) Age restriction on cattle meat and offal import

Difference in potential BSE risks to human health would be very small, if it arises, hence an effect of the variation on human health is negligible, in association with the change in the age restriction on cattle meat and offal import from the USA and Canada from the current 20 months to 30 months of age and lifting the current ban on import of cattle meat and offal from France and the Netherlands to allow cattle aged 30 months or under.

b) Age limits for removal of specified risk materials (SRMs) in cattle

Difference in risk levels of cattle between all ages and over 30 months of age would be very small, if it exists, hence an effect of the difference on human health is negligible, in removal of SRMs, including skull (excluding tonsils), spinal cord and vertebral column.

**Risk assessment (extracted from Part XIII of the original risk assessment report)****1. The current BSE infection and/or prevalence in cattle population in the five countries: Japan, USA, Canada, France and the Netherlands.**

## 1) Japan

Since the first BSE case detected in 2001, 36 cases of BSE cattle in total have been confirmed to date. After an existing feed control regulation was tightened in October 2001, no BSE incidence by cohort has been confirmed except one cattle born in January 2002. It is necessary to continuously monitor infection/prevalence of BSE. It was confirmed that the current feed regulation is effective throughout an ongoing surveillance program.

## 2) USA

Four cases of BSE have been confirmed so far. Of the four cases, one was atypical BSE case imported from Canada while other three were atypical BSE cases. As of September 2012, 35 months have passed since an existing feed regulation was tightened in October 2009. Noting that the BSE incubation period is about 5 to 5.5 years, it is deemed necessary to continuously monitor infection/prevalence of BSE so as to ensure efficacy of the existing feed regulation. A US surveillance program for BSE cattle was designed to detect a disease infection of one in one million adult cattle, which was sufficient to meet a level of the OIE point system for detection of BSE at least one per 100,000 adult cattle.

## 3) Canada

So far 18 cases of BSE have been confirmed, excluding one imported from the UK. Since July 2007 when an existing feed regulation was tightened, no BSE case has been detected among cattle born in and after September 2004. As of September 2012, 62 months have passed since an existing feed regulation was tightened in July 2007. Noting that the BSE incubation period is about 5 to 5.5 years, it is necessary to continuously monitor infection/prevalence of BSE so as to ensure efficacy of the existing feed regulation. A BSE surveillance program in Canada was designed to detect at least one BSE positive cattle at a confidence level in 95% where two per one million adult cattle were infected. The surveillance programme meets the level of the OIE point system for detection of BSE at least one per 100,000 adult cattle.

## 4) France

So far 1,023 cases of BSE have been confirmed. Since a domestic feed regulation was tightened in November 2000, no BSE incidence by cohort has been confirmed except for two cattle born in 2001 and one cattle born in April 2004. It is necessary to continuously monitor infection/prevalence of BSE. It was confirmed that the current feed regulation was effective throughout ongoing surveillance program. The BSE surveillance level in France fulfills the BSE surveillance requirements implemented in EU legislation, thus meets the level of the OIE point system for detection of BSE at least one per 100,000 adult cattle.

## 5) The Netherlands

Eighty eight cases of BSE have been confirmed so far. Since a feed regulation was tightened in December 2000, no BSE incidence by cohort has been confirmed, except for one cattle born in February 2001. It is necessary to continuously monitor infection/prevalence of BSE. It was confirmed that the current feed regulation was effective throughout an ongoing surveillance program. The BSE surveillance level in the Netherlands fulfills the BSE surveillance requirements implemented in EU legislation, thus meets the level of the OIE point system for detection of BSE at least one per 100,000 adult cattle.

**2. Consideration on accumulation of abnormal prion proteins in bovine tissues and infection risks of the prion proteins to humans**

Considering the current BSE epidemic in the five countries, as mentioned in Section 1 above, it is presumed that potential exposure levels in cattle to BSE prion proteins through feed, if any,

may not exceed a level equivalent to 1g of brain material of cattle infected with BSE in the UK, interpreted by the experimental results.

In the experimental oral exposure study in cattle, in which cattle was exposed to 1 g of BSE infected brain tissues in the UK, the clinical signs of BSE and abnormal prion protein in its central nervous tissues were initially detected at 44 months post exposure. Abnormal prion protein in central nervous tissues was not detected in the cattle at 42 months post exposure, i.e. over 46 months of age (M.E. Arnold et al 2007; G.A.H. Wells et al 2007). Additionally, the results from the intracerebral inoculation of BSE materials in cattle indicated that the earliest detection of abnormal prion protein in the brainstem was 7-8 months before onset of clinical signs. Therefore, the possibility that the abnormal prion protein is detected in the central nervous tissues below the age of 30 months was considered to be very low.

The incidence of vCJD in the UK, in which the highest number of cases on vCJD have been reported, peaked in 2000, but has been gradually declining thereafter. BSE is assumed to be strongly linked with the occurrence of vCJD. The number of vCJD cases in the world has sharply dropped from its peak to only several cases a year. Therefore, BSE control measures such as the feed regulation and prohibition of the use of SRMs in food effectively reduced the risk for infection with the BSE agent not only for cattle but also for humans.

Human health risks of transmissible agents derived from atypical BSE cannot be ruled out. Most of the atypical BSE cases were found in cattle aged over 8 years excluding the one case in Japan that was found at the age of 23 months (The detection ages of atypical BSE cases ranged from 6.3 to 18 years, excluding the case in 23 months). Accumulation level of prion protein in medulla oblongata of this atypical BSE case was found to be very low, so that it was not even transmissible to highly BSE susceptible transgenic mice. Therefore, the risk associated with the consumption of atypical BSE prion, excluding that from relatively old cattle was assessed negligible.

### 3. Conclusion in the risk assessment

Assuming that the proper implementation of the present feed control measures are maintained in the five countries (Japan, the USA, Canada, France and the Netherlands), FSCJ evaluated a possible link between BSE and vCJD, taking into account the current BSE infection risks and/or prevalence in cattle; and interspecies barrier between cattle and humans in BSE transmission. Consequently, FSCJ concluded that in the five countries, development of vCJD is highly unlikely to be linked with consumption of BSE prions in cattle meat and offal (excluding the tonsils and distal ileum) from cattle under 30 months of age.

Accordingly, FSCJ adopted the following conclusions for the: 1) domestic measures; and 2) border measures:

#### 1) Domestic measures

##### a) Age limits for BSE testing

Variation in BSE risks to human health would be very small, if it arises, hence an effect of the variation on human health is negligible in association with the change in the age limit for BSE testing was changed from the current 20 months to 30 months of age.

##### b) Age limits for removal of specified risk materials (SRMs) in domestic cattle

Difference in risk levels between all ages and over 30 months of age would be very small, if it exists, hence an effect of the difference on human health is negligible, in removal of SRMs, including skull (excluding tonsils), spinal cord and vertebral column.

#### 2) Border measures

##### a) Age restriction on beef import

Variation in potential BSE risks to human health would be very small, if it arises, hence an effect of the variation on human health is negligible, in association with the change in age restriction on cattle meat and offal imported from USA and Canada from the current 20 months to 30 months of age and lifting the current ban on import of beef from France and the Netherlands to allow cattle aged 30 months or under.

b) Age limits for removal of specified risk materials (SRMs) in cattle

Difference in risk levels of cattle between all ages and over 30 months of age would be very small, if it exists, hence an effect of the difference on human health is negligible, in removal of SRMs, including skull (excluding tonsils), spinal cord and vertebral column.