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Risk Assessment Report

Consideration of risk variations in Japan derived from the proposed revisions of the current countermeasures against BSE ~ Risks to human health from raising the limit for BSE testing age for domestic cattle ~ (Prions)

Food Safety Commission of Japan (FSCJ)

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ABSTRACT

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

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 the United States (US), Canada, France, and the Netherlands.
 - 1) Countermeasures applied to domestic cattle (hereinafter referred to as “the domestic measures”)
 - a) To change the age limit required for domestic cattle to undergo BSE testing at slaughterhouses based on 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 Article 2, Paragraph 7 of the Law on Special Measures Against Bovine Spongiform Encephalopathy, and Articles 6 and 9 of the Abattoirs Law (Law No. 114 of 1953); and
 - c) To amend relevant requirements as required by Articles 11 and 18 of the Food Sanitation Law (Law No. 233 of 1947) ensuring safety of cattle meat including vertebral column.
 - 2) Countermeasures applied to cattle meat and offal imported from the US, 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 US 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 MHLW requested 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 BSE testing at slaughter of cattle when 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)
To examine differences 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 cattle meat and offal import
To examine potential variations of BSE risks to human health when the age restriction on cattle meat and offal import is raised from the current 20 months to 30 months of age.
- b) Age limits for removal of specified risk materials (SRMs) in cattle
To examine differences 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.
- 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 age as currently applied to these two countries; and ii) allowing import of cattle at over 30 months of age under the 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.

FSCJ had completed first the risk assessment on 2.1) Domestic measures and 2.2) Border measures, using reference materials and documents provided by MHLW regarding the BSE situation in the following five countries: Japan, the US, Canada, France, and the Netherlands, as well as other publications dealing with scientific evidence on BSE. Subsequently, FSCJ conducted the risk assessment mentioned in 2.3), an assessment on BSE risks to human health from raising the limit for BSE testing age of cattle in Japan, but not on that from raising age restrictions on cattle meat and offal imports from the other four countries, because the method for risk assessment on BSE testing age had been developed by the FSCJ, focusing on domestic cattle as a model case.

Based on the findings obtained through the FSCJ's risk assessment for BSE that had been conducted before the risk assessment mentioned in 2.3), as well as the situation of implementation of BSE control measures, definition of specified risk materials (SRMs), the situation of slaughtering processes, and estimated prevalence of BSE in Japan, FSCJ thoroughly considered the human health risks arisen from consumption of edible parts of cattle when the rule of the age limit for BSE testing for domestic cattle is changed.

A large number of BSE cases were reported in European countries, mainly in the United Kingdom (UK), with a peak in the early 1990s. According to relevant reports issued by World Health Organization (WHO) and others, a possible link between vCJD and BSE was first pointed out in 1996. Until March in 2013, a total of 190,643 cases of BSE have been reported worldwide. The number peaked at 37,316 in 1992, but decreased extensively to 45 cases in 2010, 29 cases in 2011 and 21 cases in 2012, as a result of imposing more stringent feed restrictions and other control measures. As for the five countries listed above, regardless of the difference in the feed restrictions and the BSE epidemiological situation, no BSE case has been detected among cattle born in the past eight and a half years since the time when the last BSE case was confirmed in one cow that was born in August 2004.

Considering thoroughly the currently available evidence, FSCJ conducted the risk assessment on the above BSE risks to human health from raising the limit for BSE testing age for domestic cattle. The results are summarized below.

Based on (1) the current status of BSE in cattle, (2) the comprehensive implementation of control measures such as import restriction, feed restriction, and appropriate processing at slaughterhouses, and (3) interspecies barrier between cattle and human in transmission of BSE prion, development of vCJD is highly unlikely to occur through consumption of meat and offal (excluding SRM) derived from cattle born and raised in Japan.

As a result of comprehensive implementation of the BSE control measures, no BSE cases have been identified in cohorts born after January 2002 until May 2013. Taking into account the surveillance data of BSE in the European Union, it is assumed that most BSE infected cattle—approximately 97%—can be detected before the age of 11 years. Therefore, if no BSE cases have been detected among cattle borne in the last 11 years or more, BSE incidence in these birth cohorts is considered to be negligible under the continuously implemented countermeasures against BSE, including feed restrictions.

However, it would be difficult to assess BSE incidence of a birth cohort of age under 11 years, even if any of the cattle in this cohort were infected, because the time period passed after the birth would be insufficient to cover most of the infected cattle of this cohort. Therefore, FSCJ concluded that the age limit for BSE testing should be raised tentatively to the age defined below to continue verification, and that it is appropriate to consider a further lift of the age limit for BSE testing in future, based on the data of BSE prevalence for the longer time period and on new scientific findings on BSE accumulated by that time.

Regarding the age limit for BSE testing, FSCJ considers that BSE risk to human health is negligible even if the age limit for BSE testing at slaughterhouses is lifted to over 48 months, based on the following findings:

1. The age in months of the youngest animal confirmed to be infected with BSE in Japan.
2. The age in months of animals confirmed to be infected with BSE in the EU.
3. The age in months at which the deposit of BSE prions was detected in the cattle received experimental oral inoculation of the brain tissues from BSE-infected cattle.
4. The relationship between dose and incubation period that the higher the intake of BSE prions the longer the incubation period.