

Food Safety No. 1015001 from the Ministry of
Health, Labour and Welfare
Consumer Safety No. 5410, 2004
October 15, 2004

To: Mr. Masaaki Terada, Chairman
Food Safety Commission

Hidehisa Otsuji
Minister of Health, Labour and Welfare

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Minister of Agriculture, Forestry and Fisheries

About Food Health Impact Assessment

We ask for the opinion of your Commission, as to food health impact assessment as stipulated under Section 1, Article 11 of the Food Safety Basic Law (Law No. 48 in 2003) concerning the following matters, based on the provisions of Item 13, Section 1, and Section 3 of Article 24 of the same law.

Reviewing the following matters, based on the “, concerning countermeasures against Bovine Spongiform Encephalopathy (BSE) in Japan (Notice from Food Safety Commission, September 9, 2004):

- (1) Reviewing bovine age in months to be tested in the BSE tests at abattoirs, based on the provisions of Section 1, Article 7 of the Law on Special Measures Against Bovine Spongiform Encephalopathy, and promotion of research and development concerning related testing technologies;
- (2) Ensuring removal of Specified Risk Materials (SRM);
- (3) Bolstering effectiveness of feed regulations; and
- (4) Further promotion of BSE-related research and studies.

I BSE Tests at Abattoirs (MHLW-related)

1 Present situations

(1) Regulatory situations

Article 14 of the Abattoirs Law requires pre-slaughter and post-slaughter inspections by livestock inspectors, who belong to prefectural governments or municipalities that operate health centers, for slaughtering and dressing animals for meat. Article 16 of the Abattoirs Law prohibits slaughtering or dressing of bovine suspected of BSE infection in the pre-slaughter inspection, e.g. indicating nervous system symptoms. Scope for BSE-related tests among post-slaughter inspections is stipulated as bovine of 0 month old or older (i.e. cattle of all ages), in Section 1, Article 7 of the Law on Special Measures Against Bovine Spongiform Encephalopathy, and Article 1 of the MHLW-related Implementation Rules for the Law on Special Measures Against Bovine Spongiform Encephalopathy.

Article 16 of the Abattoirs Law also stipulates that BSE-infected bovine shall not be used for food, and that bovine diagnosed as BSE-infected shall be incinerated, and facilities and equipment of abattoirs that handled such bovine must be disinfected.

(2) Testing organization at prefectures, etc.

On October 18, 2001, BSE tests were incorporated in carcass inspection at all abattoirs that handle slaughtering and dressing of bovine. Cumulative 3551910 bovines were tested until August 31, 2004.

Bovines tested positive in BSE screening tests are referred to the National Institute of Infectious Diseases, Obihiro University of Agriculture and Veterinary Medicine, or Hokkaido University for confirmatory tests, based on which results the Expert Committee for the Testing of Bovine Spongiform Encephalopathy, established at the MHLW, issues definitive diagnosis.

2 Future tasks and actions

(1) Reviewing age scope for BSE tests

“About Countermeasures against Bovine Spongiform Encephalopathy (BSE) in Japan (Interim Summary)” (Notice from the Food Safety Commission, September 9, 2004; hereafter referred to as “Interim Summary”) points out in ‘4 Conclusion (2)’ as follows:

‘Even though bovines below the detection limit are excluded from the test scope, risks of vCJD are not considered to increase unless SRM-removing measures are changed from the present status, targeted at all month ages. However, we yet only have fractional facts, as to in what stage of incubation period BSE- infected bovines can be identified, with abnormal prion protein about the level of detection limit accumulated in their medulla oblongata obex, and in what month ages they should be. Considering the fact that two BSE-infected bovines have been found, aged 21 and 23 month old respectively, among

total nine BSE-infected bovines identified in the BSE tests in Japan, which have covered approximately 3.5 million bovines altogether, the existence of BSE prion may be identified in bovines aged 21 months or older with the present testing technology.

The amounts of abnormal prion protein contained in the medulla oblongata obex of the two BSE-infected bovines aged 21 and 23 months were much smaller than other infected bovines in the Western Blotting, at about 1/500 to 1/1000. This fact, combined with the absence of BSE-infected bovines aged under 20 months old, according to the tests in Japan that have covered approximately 3.5 million bovines, should be taken account of in the examination of future BSE-related measures in Japan.’

Screening of all cattle for BSE at abattoirs was introduced in October 2001, when the identification of bovine ages was still difficult, and when there was strong public concerns of mixed distribution of tested and non-tested beefs, shortly after the identification of the first BSE-infected bovine in Japan. Three years since then, based on the above suggestion in the “Interim Summary,” which has been submitted as verification results of BSE-related measures by the Food Safety Commission, in accordance with scientific progress in the meantime, the scope of BSE tests at abattoirs shall be revised to 21 months old and older (revision of Article 1 of the MHLW-related Implementation Rules for the Law on Special Measures Against Bovine Spongiform Encephalopathy).

Transitional measures shall be taken as necessary for the above reviewing.

(2) Development of BSE testing methods

‘4 Conclusion (3)’ of the “Interim Summary” points out, ‘Further improvements shall be made in the testing methods, and research shall be further promoted, on such issues as more adequate detection limits, and development of ante-mortem testing methods using tissues and blood derived from live bovine. Quantitative assessment of risks derived from bovines aged 20 month or under shall be further examined.’

Many achievements have been made by scientific research of the MHLW, including development of screening test methods, and increase in sensitivity of confirmatory tests. Based on the above suggestion, further research shall be made to evolve these technologies to detect abnormal prion protein, while collecting overseas information contributing to future BSE testing scheme.

II Removal of Specified Risk Materials (SRM) (MHLW-related)

1 Present situations

(1) Regulatory situations

Since October 18, 2001, slaughterers are required to treat bovine head (excluding tongue and cheek), spinal cord and distal ileum (two meters from connection to appendix), so as to prevent contamination of dressed carcass or viscera to be eaten, based on Article 9 of the Abattoirs Law, and Article 7 of the Implementation Rules for the same law. Details for the above treatment are indicated in “Management Guideline for Specified Risk Materials in Meat Processing” (Notice No. 308 from the Department of Food Safety, dated October 17, 2001, issued by Director-General of the Department of Food Safety, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare).

Also since October 18, 2001, abattoir founders/managers are required to put bovine head (excluding tongue and cheek), spinal cord and distal ileum (two meters from connection to appendix) in dedicated waste containers, and incinerate them, based on Article 6 of the Abattoirs Law, and Article 3 of the Implementation Rules for the same law.

Since July 4, 2002, the above measures have been stipulated in Sections 2 and 3, Article 7 of the Law on Special Measures against Bovine Spongiform Encephalopathy.

Furthermore, since February 16, 2004, use of bovine spinal column by meat processors, etc., has been prohibited based on Section 1, Article 11 of the Food Sanitation Law.

(2) Supervisory organization at prefectures, etc.

At abattoirs, removal, disposal and incineration of SRM are conducted in conformity with the Abattoirs Law, under the supervision of permanent stationing of livestock inspectors, who belong to prefectural governments, etc.

At meat processing/selling facilities, food sanitation monitors from prefectural governments, etc. regularly conduct on-site inspections in conformity with the Food Sanitation Law, to confirm the compliance situations.

2 Future tasks and actions

(1) Verification of SRM removal and prevention of cross-contamination

‘4 Conclusion (4)’ of the “Interim Summary” points out, ‘Prevention of cross-contamination through implementation of adequate slaughtering and dressing at abattoirs, etc. is important in reducing risks of BSE infection to humans. For this purpose, instructions shall be continued for adequate SRM removal and prevention of cross-contamination, as well as establishing mechanism to ensure adequate implementation, including regular verification of implementation status.’

At abattoirs, removal, disposal and incineration of SRM are conducted under the control of sanitation managers and operation sanitation managers of the abattoirs, under the supervision of livestock inspectors. At meat processing/selling facilities, food sanitation

monitors from prefectural governments, etc. regularly conduct on-site inspections to confirm the compliance situations. Based on the above suggestion, the following measures shall be added to these present situations, to ensure more appropriate verification of SRM management status:

- 1) To confirm compliance status of legislation and notification related to SRM management, surveillance of SRM management at abattoirs shall be conducted regularly, in which stunning methods; implementation of pithing; documentation status of SOP for SRM removal and incineration, relevant confirmation methods, and their implementation records; implementation of pre-split removal of spinal cord, SRM incineration method, post-split removal method of spinal cord; washing method of dressed carcass; and other issues are checked. Results of these checks shall be published.
- 2) Develop evaluation methods for SRM contamination prevention measures for dressed carcass, etc. in the carcass processing, and promote their application to abattoirs, through scientific research of the Ministry of Health, Labour and Welfare.

(2) Others

‘3-3-2-3 Risk Reduction through SRM Removal’ of “Interim Summary” points out, ‘Further examination is required as to pithing, including its abolition in the future.’

Based on the above suggestion, the Ministry of Health, Labour and Welfare shall organize cases at abattoirs that have already abolished pithing, and provide relevant information to prefectures, etc., to promote instructions toward the abolition of pithing at abattoirs, while promoting further examination toward general abolition, taking account of actual statuses at abattoirs.

III Bolstering Effectiveness of Feed Regulations (MAFF-related)

1 Present situations

- (1) As for feed, feeding of ruminant-derived proteins to ruminants shall be eliminated, as it has been the cause for prevalence of BSE. At the same time, from the perspective of preventing contamination of feed by ruminant-derived proteins through cross-contamination, feed for ruminants shall not contain mammal-derived, poultry-derived or fish and shellfish-derived proteins (hereinafter referred to as “mammal-derived proteins”), as stipulated in the ingredient standards based on Section 1, Article 3 of the Law Concerning Safety Assurance and Quality Improvement of Feed (hereinafter referred to as “Feed Safety Law”).
- (2) To ensure the effectiveness of the above ingredient standards, Section 1, Article 3 of the Feed Safety Law stipulates on manufacturing, storage, indication and use of feed as follows:
 - a As for manufacturing of feed, mammal-derived proteins shall not be used in the manufacturing of feed for ruminants.
 - b As for storage of feed, feed containing mammal-derived proteins shall be stored so as not to contaminate feed for ruminants.
 - c As for indication of feed, feed containing mammal-derived proteins shall bear the indication that it should not be used for ruminants.
 - d As for use of feed, feed containing mammal-derived proteins shall not be used for ruminants.
- (3) To ensure compliance with these feed-related standards, the Fertilizer and Feed Inspection Services Incorporated Administrative Agency (hereinafter referred to as “Fertilizer and Feed Inspection Services”), prefectural governments, etc. shall conduct monitoring based on the Feed Safety Law, over the businesses dealing in importation, manufacturing, marketing, use, etc. of feed, as well as giving them instructions in accordance with “Guidelines concerning Prevention of Contamination of Feed for Ruminants by Animal-derived Proteins” (Notice from Director-General of Food Safety and Consumer Affairs Bureau, Ministry of Agriculture, Forestry and Fisheries, dated September 16, 2003).

2 Future tasks and actions

‘4 Conclusion (5)’ of the “Interim Summary” points out, ‘Although risk of BSE occurrence is considered minimal, given the current feed regulations as countermeasures against BSE, it is important to conduct continued checks by the administration to ensure effectiveness of feed regulations, taking account of the identification of BSE in young cattle.’

As for feed regulations, the above regulatory measures have been implemented to prevent feeding of ruminant-derived proteins to ruminants, with an eye to the prevention of cross-contamination. Focused tests have been conducted to ensure the effectiveness of these

measures, in the stages of feed manufacturing in Japan, and importation of animal protein feed into Japan, in which risk of cross-contamination rises.

However, to prevent transmission of abnormal prion as factor for BSE infection, and eliminate BSE in Japan, considering the past BSE identification in Japan, it is necessary to further bolster the testing and guiding organization concerning compliance with feed regulations, in the stages of: 1) importation of feed from overseas, 2) marketing of feed in Japan, and 3) use of feed in Japan.

For this purpose, the following measures shall be introduced afresh, to bolster effectiveness of feed regulations.

(1) Prevention of cross-contamination concerning imported feed

Testing and analysis of imported feed shall be reinforced to ensure compliance with ingredient standards, and the following measures shall be taken:

- a As for fish meal, etc. as animal protein, import tests by the Animal Quarantine Service shall be continued appropriately. In case of violation, suspension of import and/or other measures shall be taken, to ensure prevention of contamination of fish meal, etc. by ruminant-derived proteins.
- b As for other feed, the Fertilizer and Feed Inspection Services shall conduct testing and analysis, based on identified materials for the imported feed, in accordance with the expanded submission data from importers (revision of Article 70, Implementation Rules for the Feed Safety Law). In case of violation of ingredient standards, such measures as recall/disposal shall be taken, to ensure prevention of contamination of other imported feed by ruminant-derived proteins.

(2) Ensuring regulations concerning feed storage at dealers

Compliance check for dealers shall be reinforced to ensure regulations concerning feed storage at dealers, and the following measures shall be taken:

- a Scope of monitoring by feed regulations shall be expanded in the feed selling stage, by requiring retailers that sell feed directly to farmers to fulfill reporting based on the Feed Safety Law (revision of Article 69, Implementation Rules for the Feed Safety Law).
- b Ensure prevention of contamination of feed for ruminants by ruminant-derived proteins in the feed selling stage, through bolstering awareness of feed storage regulations among retailers and other feed dealers, as well as bolstering of on-site inspections, etc. by prefectural governments.

(3) Ensuring regulations concerning feed use at cattle-raising farmers

To ensure regulations concerning feed use at cattle-raising farmers, bolster awareness of feed regulations among farmers through circuit inspection by the Agricultural Policy Planning Division and other opportunities, as well as bolstering on-site inspections of

farmers by prefectural governments, to prevent misuse and abuse of feed at the farmer stage.

(4) Others

As for traceability, a measure in the production stage was enforced in December 2004, concerning such issues as recording of information of animal identification. Furthermore, a measure is to be implemented from December of 2005 to indicate the animal identification number on beef in the distribution stage. Preparations shall be promoted for its secure implementation.

As for the testing of risk bovines, the scheme was just established in 2004 to implement dead bovine tests in all prefectures. Testing of risk bovines shall be continued to verify the effectiveness of BSE-related measures, as well as identifying the level of BSE contamination in Japan.

IV Further Promotion of BSE-related Research and Studies (MHLW and MAFF-related)

1 Present situations

Before the first BSE case in Japan was identified in September 2001, scientific research of the MHLW and project research of the MAFF had conducted examination of testing methods, surveillances, etc. Following the BSE occurrence in Japan, the two ministries have collaborated in research and studies necessary for BSE-related measures, including: development of high-sensitivity, rapid testing at abattoirs; implementation of direct injection of BSE agent to reveal the mechanism of BSE emergence; and examination of methods to prevent contamination of meats by abnormal prion.

2 Future tasks and actions

(1) Development of BSE testing methods

‘4 Conclusion (3)’ of the “Interim Summary” points out, ‘Further improvements shall be made in the testing methods, and research shall be further promoted, on such issues as more adequate detection limits, and development of ante-mortem testing methods using tissue, blood, etc. taken from live cattle. Quantitative assessment of risks derived from bovines aged below 20 months old shall be further examined.’

Many achievements have been made by scientific research of the MHLW, including development of screening test methods, and increase in sensitivity of confirmatory tests. Based on the above suggestion, further research shall be made to evolve these technologies to detect abnormal prions, while developing ante-mortem testing methods for BSE as project research of the MAFF.

(2) Development of evaluation methods for measures to prevent SRM contamination

‘4 Conclusion (4)’ of the “Interim Summary” points out, ‘Prevention of cross-contamination through implementation of adequate slaughtering and dressing at abattoirs, etc. is important in reducing risks of BSE infection to humans. For this purpose, instructions shall be continued for adequate SRM removal and prevention of cross-contamination, as well as establishing mechanism to ensure adequate implementation, including regular verification of the implementation status.’

Based on the above suggestion, the scientific research of the MHLW shall continue to examine the development of evaluation methods for measures to prevent contamination of dressed carcass, etc. by SRM.

(3) Continued injection experiments, etc.

“Interim Summary” reports as follows in respective sections:

- ‘3-3-4 Risk increase and decrease by management measure options’

“Attempts for quantitative risk assessment shall be continued in the future. Continued efforts shall be also made to collect and examine information concerning results of

oral intake experiments conducted overseas as well as in Japan, etc.”

- ‘4 Conclusion (2)’

“We yet only have fractional facts, as to in what stage of incubation period BSE-infected bovines can be identified, with abnormal prion protein about the level of detection limit accumulated in their medulla oblongata obex, and in what month ages they should be.”

- ‘5 Conclusion’

“The MHLW and the MAFF shall continue with further research and studies in the future, to reveal unknown facts of BSE scientifically. They also conduct quantitative risk assessment as necessary, based on new data and understanding obtained from the above efforts.”

Based on the above, BSE agent injection experiments and other BSE-related research project shall be continued as scientific research of the MHLW, while project research of the MAFF shall conduct oral intake experiments for bovines, to reveal the accumulation mechanism of abnormal prion.