Tentative Translation

Food Safety Risk Assessment of Beef and Beef Offal Imported to Japan

(From: Australia, Mexico, Chile, Costa Rica, Panama, Nicaragua, Brazil, Hungary)

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Food Safety Commission of Japan

Expert Committee of Prions.

Summary

Food Safety Commission has its own initiative to conduct risk assessments on food stuffs, namely 'self-tasking assessment'. It was within this framework that the current assessment 'Risk assessment of beef and beef offal imported to Japan' was conducted.

The current assessment employed models and methodologies previously used for the assessments of Japanese domestic beef, and beef imported from US/Canada. The latter assessment was also used to review Japanese domestic anti-BSE control measures of that time. Other organizations' methods, such as methods used for BSE status risk assessment of OIE and EFSA's GBR, were also consulted when developing the current risk assessment methodology. Total assessment was the combination of (1) risk of live cattle in the assessed country (temporal risks of BSE invasion and domestic propagation, with the assessment results validated by surveillance data) and (2) risk of beef and beef offal (cumulative BSE risk by types of slaughtered animals, slaughtering processes, etc.) based on the currently available scientific knowledge given by a certain period of time.

The summary of each assessed country is as follows;

<1. Australia>

Domestic BSE exposure/propagation risk was evaluated to be 'negligible', with the risk reduction effects at the meat processing lines to be 'high' to 'very high'. Therefore, the risk of BSE contamination on beef and beef offal imported from Australia was considered to be 'negligible'.

<2. Mexico>

Domestic BSE exposure/propagation risk was evaluated to be 'low', with the risk reduction effects at the meat processing lines to be 'very high'. Therefore, the risk of BSE contamination on beef and beef offal imported from Mexico was considered to be 'negligible'.

<3. Chile>

Domestic BSE exposure/propagation risk was evaluated to be 'negligible', with the risk reduction effects at the meat processing lines to be 'high' to 'very high'. Therefore, the risk of BSE contamination on beef and beef offal imported from Chile was considered to be 'negligible'.

<4. Costa Rica>

Domestic BSE exposure/propagation risk was evaluated to be 'negligible', with the risk reduction effects to at the meat processing lines be 'very high'. Therefore, the risk of BSE contamination on beef and beef offal imported from Costa Rica was considered to be 'negligible'.

<5. Panama>

Domestic BSE exposure/propagation risk was evaluated to be 'negligible', with the risk reduction effects at the meat processing lines to be 'very high'. Therefore, the risk of BSE contamination on beef and beef offal imported from Panama was considered to be 'negligible'.

<6. Nicaragua>

Domestic BSE exposure/propagation risk was evaluated to be 'negligible', with the risk reduction effects at the meat processing lines to be 'very high'. Therefore, the risk of BSE contamination on beef and beef offal imported from Nicaragua was considered to be 'negligible'.

<7. Brazil>

Domestic BSE exposure/propagation risk was evaluated to be 'very low', with the risk reduction effects at the meat processing lines to be 'very high'. Therefore, the risk of BSE contamination on beef and beef offal imported from Brazil was considered to be 'negligible'.

<8. Hungary>

Domestic BSE exposure/propagation risk was evaluated to be 'low', with the risk reduction effects at the meat processing lines to be 'very high'. Therefore, the risk of BSE contamination on beef and beef offal imported from Hungary was considered to be 'negligible'.

I. Background

Food Safety Commission Japan (FSCJ) conducts risk assessments by requests from risk managers, or alternatively it can also conduct assessments on its own initiative, termed as 'self-tasking assessment'.

The process of hazard selection for self-tasking assessment involves the following steps. The Expert Committee for Planning collects information and screens the possible assessment subjects based on their degrees of public's concern in Japan, or demands of information collection either due to the increasing necessity in developing hazards, or otherwise the items that are heavily requested for the assessments. Selected subjects are then discussed for their potential assessment at the Commission's opinion exchange meetings, and finally FSCJ officially adopts the hazards of choice to be the next subject of self-tasking assessment.

Currently, Japan imports beef and beef offal from the United States and Canada, the two countries that have previously experienced BSE cases, and for which FSCJ has already completed the assessments for BSE risks of their beef and beef offal. Besides those two, Japan also imports beef and beef offal from other countries where no BSE cases have been so far reported. However, some of these countries were categorized as level III of the Geographical BSE Risk (GBR) by the European Food Safety Agency (EFSA). According to EFSA's definition, countries were designated as GBR category III either because the country was estimated to be with a reasonably high possibility of having BSE cases but were not detected, or because the country had a few confirmed cases of BSE. There were also countries that were simply not assessed by EFSA GBR among exporters to Japan.

Japanese risk managers presently request importers of beef and beef offal from those countries to submit official health certificates confirming that their origin of cattle as healthy, and also ask to refrain from importing specified risk materials (SRM). Although the validity of health certificates has been confirmed at the quarantine stations, currently no measures are installed to clarify the exclusion of SRM among beef products imported. There is also uncertainty over potential risks of imported beef and beef offal due to insufficient availability of data related to BSE prevalence and anti-BSE countermeasures in these countries.

Risk assessment of beef and beef offal imported to Japan was among the most requested items during the public meetings and other occasions hosted by FSCJ. Behind those requests seem to be the public's concerns over uncertainty about BSE risks in beef and beef products imported from countries other than the United States

and Canada.

With this situation, FSCJ decided to conduct 'Risk assessment of beef and beef offal imported to Japan' as its self-tasking assessment.

Presently, the world-wide BSE prevalence is in the trend of decline. This risk assessment is essentially different from the rest of the BSE-related risk assessments previously conducted by FSCJ, in that the assessed countries are only those that have not previously reported BSE cases. Previous risk assessments on beef and beef products from the United States and Canada were made by comparison with the same risk in Japanese beef and beef products so that the assessment would be based on the relativity. In contrast, the current assessment is 'self-tasking' initiated by FSCJ, thus it was foreseen to be based on the data submitted by each assessed country on voluntary-basis. Subsequently, assuming that there may be a certain limitation to the data availability and submission, the Commission has decided to largely conduct this assessment on qualitative-basis, but still strive to have it as much quantitative as possible.

It was with this background that the Commission firstly developed a new assessment method suited to the current situation, and then carried BSE risk assessment for imported beef and beef offal according to this new method.

II. Assessment subject and method of gathering information

1. Assessment objective

The objective of present assessment was to evaluate the risk of beef and beef offal imported to Japan based on their potentials of BSE prion contamination per each subjected country.

2. Surveyed countries

14 countries are surveyed out of 16 countries from where Japan imported beef and beef offal from fiscal 2003 to 2006. United States of America and Canada are excluded. They are Commonwealth of Australia: New Zealand: United Mexican States: Republic of Chile: Republic of Vanuatu: Republic of Costa Rica: Republic of Panama: Republic of Nicaragua: Federative Republic of Brazil: Republic of Honduras: People's Republic of China: Kingdom of Norway: Republic of Hungary: Argentine Republic.

Table 1 and Table 2 show the import volume of beef and beef offal by country since fiscal 2003.

Table 1 Import volume of beef by country

(Amount of subprimal cuts/ Unit: Ton)

Country/Fiscal Year	2003	2004	2005	2006	2007
Australia	294,601.8	410,218.7	406,218.3	409,869.8	380,221.0
U.S.A.	201,052.3	0.0	661.7	12,236.3	36,548.3
New Zealand	21,251.9	34,819.0	39,778.6	35,224.0	33,633.6
Canada	2,573.7	0.0	114.6	2,516.8	3,478.1
Vanuatu	494.1	436.2	574.6	543.6	383.4
China	34.0	21.7	36.9	53.4	75.8
Chile	60.6	1,015.8	2,679.7	416.3	415.9
Mexico	7.9	2,759.6	7,426.2	5,887.2	7,858.9
Brazil	13.0	960.6	165.5	133.2	120.5
Nicaragua	6.7	6.7	0.0	0.2	2.1
Costa Rica	0.0	14.3	185.0	116.4	160.0
Argentina	0.0	96.0	11.4	0.0	0.0
Panama	0.0	13.8	188.0	236.8	240.7
Norway	0.0	0.0	60.5	0.0	0.0
Hungary	0.0	0.0	1.7	2.7	2.6
Sum	520,096.1	450,362.5	458,102.7	467,236.7	463,141.1

Numbers from Trade Statistics of Japan by the Ministry of Finance

Note 1: Import volume includes chilled meat, frozen meat, boiled/steamed meat, cheek meat and meat from the head.

Note 2: Breakdowns do not coincide with the Sum because of rounding up or dropping fractions.

Note 3: Along with above mentioned volume of beef, processed beef products which contain not less than 20 % of beef and material from cow in total weight have been imported; according to the record of 2005, 10,248 tons was imported from China and 5,250 tons out of the volume included hamburger steaks and cooked items for beef-on-rice dish (*Gyudon*,); 7,775 tons of these food products was imported from Australia.

Table 2 Import volume of beef offal by country

(Unit : Ton)

Country/Fiscal Year	2003	2004	2005	2006	2007
Australia	12,937.3	19,982.4	20,415.7	19,960.9	18,850.5
U.S.A.	59,993.5	82.8	77.2	1,946.5	6,071.6
New Zealand	3,569.5	4,823.6	4,756.6	4,387.7	4,085.4
Canada	753.3	0.0	11.9	436.7	794.6
Vanuatu	8.6	7.9	14.1	14.3	8.8
China	0.0	2.0	0.0	0.0	3.0
Chile	290.3	626.0	881.5	761.5	767.1
Mexico	1.9	603.3	1,240.5	1,865.6	1,946.1
Nicaragua	10.2	170.7	221.2	204.1	215.9
Costa Rica	0.0	49.9	137.7	149.2	216.5
Panama	3.0	54.3	104.6	134.7	109.1
Norway	54.8	32.3	37.5	24.8	43.0
Hungary	5.1	0.0	14.6	5.6	6.1
Honduras	0.0	5.6	20.8	25.6	84.4
Sum	77,627.5	26,440.8	27,934.0	29,917.1	33,202.0

Numbers from Trade Statistics of Japan by the Ministry of Finance

Note 1: Breakdowns do not coincide with the Sum because of rounding up or dropping fractions.

3. Method of gathering information

Necessary information for assessment was collected from answers to the Questionnaire items from the chosen countries: the Questionnaire was made and sent by FSCJ. In the survey program of FSCJ (Ref 1) trade statistics data of those countries were examined as well. And additional question were sent about more detailed information and uncertain points on answers for the Questionnaire in the process of assessment. In this paper reliability of data was sought by verifying the data from Trade Statistics of Japan with the answers from the countries.

III. Risk assessment methodology

1. Principle of the current risk assessment

Methodology for the current risk assessment was developed based on the previously used models in risk assessments of (1) Japanese domestic beef, and (2) US/Canadian beef imported to Japan, with the former having been used as a reference to review Japan's domestic BSE measures previously. OIE's risk assessment criteria for BSE status and EFSA GBR method were also referred to. The committee for the current assessment aimed at delivering overall conclusion as a science-based comprehensive assessment defined by time periods and based on the combination of the following risk aspects;

1) Periodic BSE risk status among the cattle population of a country:
   - External challenge: combined risks of invasion by imported live cattle and MBM
   - Domestic stability (inversed risk of BSE propagation) : Implementation of feed ban and installation of preventive measures against cross-contamination, etc.
2) Present risks of beef and beef offal processing lines:
   - Risks based on types of slaughtered animals and stages of meat processing, etc.

The current assessment was conducted on qualitative-basis rather than quantitative-basis because of the data restriction regarding BSE risks. In case the data were insufficient, assessment was done based on the worst-case scenario.

In addition, a few cases of irregular BSE (atypical) have been recently found in Europe, Japan, US, and among other countries. Those cases were regarded different from the classical type by band patterns of PrP^{Sc} proteins demonstrated by western blotting. The origin of atypical BSE is still unknown to this date, and information about BSE infectivity distribution in ruminant tissue is scarce (Ref 2).

Due to the above-mentioned situation, therefore, the current risk assessment was conducted with the assumption that:

1. The first case of BSE has occurred in UK for an unknown reason, then BSE agents were propagated through MBM recycling from BSE-infected cattle,
2. BSE infection was spread to other countries by exportation and utilization of BSE-infected live cattle and BSE-contaminated MBM for animal feeds.

2. Periodic BSE risk status among the cattle population of a country

(1) Assessment of External Challenge

For the purpose of analysis in this section, the Committee defined 'BSE risk country' as (1) a country of categories III or IV by EFSA GBR, and (2) a country with at least one BSE positive case reported among its domestic cattle in the past. External Challenge was assessed based on their records on live cattle, MBM and animal oil/fat importation from BSE risk countries defined by this description.

The risk countries are more specifically classified by the level of BSE contamination as follows,

(1) The determined BSE risk countries were further divided into following sub-groups;

UK,

European countries with moderate contamination,

European countries with low contamination2,

US,

Canada,

Others (Japan, Mexico, Chile, etc.).

Accordingly, each assessed country (beef and beef offal exporter to Japan) was requested to submit data regarding imports of live cattle and MBM from those BSE risk countries. Portugal had been categorized as level IV country by FESA GBR together with UK, thus should not be grouped with other moderate-risk European countries. Nevertheless, such distinction was not made because no assessed exporting country had a record showing importation from Portugal.

(2) Submitted information was analyzed for possible use of those imported live cattle and MBM for animal feed production in the assessed country.

(3) In case the record submitted by the assessed country indicated any degree of possibility for live cattle and MBM imports from BSE risk countries to have been used for animal feed, the degree of external challenge in the assessed country was estimated based on weighting factor of each BSE risk country. The assessment was based on a 5-year period as this was considered to be the general term for BSE incubation.

Risks of animal oil and fat varied depending on the products' grades (e.g. yellow grease, fancy tallow, etc.), but their risks were generally regarded as low compared to that of live cattle or

MBM. Thus the information associated with animal oil/fat and their usages were taken into consideration only when an importation of large quantity was recorded from BSE risk countries. Otherwise, those data were used as supplementary information.

Assessment of imported live cattle and MBM use for animal feed

All the imported live cattle and MBM in principle have a potential to be used for animal feed manufacturing, but when a country could provide feasible explanation for not utilizing any of those imported live cattle or MBM for animal feed, they could be determined as carrying no risk thus excluded from consideration of risks.

When the track record of those imported live cattle and MBM in the assessed country showed any of the following destinies, those were regarded as adding no risk to the assessed country;

(1) Imported live cattle; already dead and disposed by burial or incineration,

(2) Imported live cattle; still alive at the time of investigation so that they were excluded from potential use for animal feed manufacturing beforehand.

(3) Imported live cattle and MBM, recorded to have been re-exported to other countries.

Estimation of invasive BSE risk

In this assessment, the Committee defined the external challenge as combined invasion risks of imported live cattle and MBM. Its assessment was to be calculated based on the assumption that 1 ton of MBM was equivalent of 1 live bovine animal, as has been stated in GBR by Scientific Steering Committee and EFSA (Ref 3, 4).

Definition of weighting factor

Risks of imported live cattle and MBM from BSE risk countries were variable depending on country and timing of importation. To reflect this variation, this assessment employed weighting factor for live cattle and MBM of each BSE risk country.

Record showed that BSE prevalence in UK's live cattle was 5% at its peak period of 1988–1993, therefore, weighting factor of 1 was set as the risk of 1 live bovine animal importation from UK during this period (Ref 3).

Weighting factor of UK

Probability related point of UK was set as in the following, based on the values indicated by SSC's GBR and years of complete feed ban implementation in Europe (Ref 4, 5);

Live cattle	MBM
1987 and years before:0.1	1986-1990: 1
1988-1993: 1	1991-1993: 0.1
1994-1997: 0.1	1994-2005: 0.01
1998-2005: 0.01	2006 and years after: 0.001
2006 and years after: 0.001	

Weighting factor of European countries

European countries except for UK were divided into two categories, namely countries of 'moderate contamination' and 'low contamination'. Probability related points for live cattle and MBM were set up based on SSC's GBR and years of complete feed ban implementation in European countries (Ref 4, 5).

Countries such as France, the Netherlands, Belgium, and Italy were likely countries to have re-exported MBM from UK, thus were given the probability related point of 0.1 until UK has banned exportation of MBM (years of 1986 – 1996, Ref 3).

European countries;	
Moderate contamination	1986 - 2005: 0.01
	2006 - : 0.001
Low contamination	1986 - 1990: 0.001
	1991 - 2005: 0.01
	2006 - : 0.001

Weighting factor of US and Canada

In the previous risk assessments done by Prion Expert Committee of Food Safety Commission on US/Canadian beef imports to Japan, the surveillance-based BSE prevalence of US and Canadian cattle were estimated to be 1 case and 5-6 cases per one million cattle in US and Canada, respectively. Accordingly, probability related point of live cattle and MBM for those two countries were set as in the following (Ref 6). The values were given for the periods defined by estimated year of birth among BSE positive cattle (Ref 7, 8).

US	1993 -: 0.00002
Canada	1989 -: 0.0001

Weighting factor for Japan

In the previous risk assessment done by Prion Expert Committee of Food Safety Commission on US/Canadian beef imports to Japan, the surveillance-based BSE prevalence of Japanese cattle were estimated to be 5-6 cases per one million cattle. Birth years of BSE-positive cattle and the year of feed ban implementation were also taken into account to set the following probability related point for live cattle and MBM of Japan (Ref 6, 9).

Japan 1992 – 2006: 0.0001
2007 - : 0.00001

Weighting factor for countries with no reported BSE and in GBR category III (Mexico, Chile, etc.)

Probability related point for countries with no BSE cases were unable to be set by the above-mentioned BSE prevalence-based method. Since those countries were generally considered to have low BSE risks compared to countries with BSE positive cases, probability related point was not determined for these countries. Only in case an assessed country has imported a large quantity of live cattle and/or MBM from those BSE negative and GBR III countries, then the information were taken into consideration as a supplementary factor for the assessment.

Assessment for external challenge

Based on the principles above, external challenge (a sum of the invasion risks from imported live cattle and MBM) was estimated for each assessed country by 5-year of period. The assessment was given in 5 levels; high, moderate, low, very low, and negligible (Table 3).

Table 3 External Challenge

Levels for risk of invasion	UK equivalent（N）[1)]
High	100≦N
Moderate	20≦N＜100
Low	10≦N＜20
Very low	5≦N＜10
Negligible	0≦N＜5

1) Calculated based on the assumption of 1 ton of MBM equals to 1 live bovine animal

(2) Assessment of Domestic Stability (BSE propagation risk of a country)

Major countermeasures against BSE exposure/propagation consisted of (1) implementation of feed ban, (2) control over SRM use, (3) optimization of rendering conditions, and (4) installing preventive measures against cross-contamination. Previous epidemiological analyses indicated that the most effective measure implemented in Europe was feed ban, especially the real feed ban (prohibition of mammalian animal protein recycling to ruminants) followed by the general feed ban (prohibition of recycling ruminant protein among ruminants). Other measures that were also indicated as important for BSE control in these analyses included exclusion of SRM from rendering materials, optimization of rendering conditions (not less than 133C for a minimum of 20 min at an absolute pressure of 3 bar), dedication of feed mill to a single species, and production line separation (Ref 10). For assessment of domestic stability, the information submitted from each assessed country was firstly analyzed for the extent of feed ban implementation, then other aspects such as use of SRM, rendering conditions, and preventative measures against cross-contamination were evaluated.

The assessment also focused on the degree of legal obligation bound to each regulation. The data regarding compliance to those preventative regulations were also evaluated whenever the data were available.

Status of feed ban

The essential part of BSE exposure/propagation prevention was to abolish feeding of cattle with possibly BSE-contaminated MBM through animal feeds. It is in this context that the feed ban has been implemented in countries as a preventive measure against BSE. As for the pragmatic level of conceptual description, the most effective way was to ban recycling of animal proteins regardless of animal types among mammals, followed by less but still effective measures such as ban on protein recycling from mammals to ruminants, then from ruminants to ruminants (Ref 4, 5).

Use of SRM

It has been stated that 99% or more of infectivity in BSE-positive bovine animal distributed to the bodily regions called SRM (e.g. brain, spinal cord, etc.) (Ref 4). Removal of SRM from rendering materials was considered to be important, and the best way to realize this measure was implementation of a legally-bound feed ban that prohibited the use of SRM and fallen stocks for animal feed. Even diversion of SRM use from feed production to human consumption was considered to provide a certain degree of protection against BSE exposure/propagation, when coupled with avoidance of fallen stock use for animal feed.

Table 4　Estimated infectivity of bodily parts in clinical case of BSE

Tissue		Total weight（g）	Titer of infectivity（$CoID_{50}$/g）	Total infectivity（$CoID_{50}$）
Specified-risk material (SRM)	Brain	500	5	2,500（60.1%）
	Trigeminal ganglia	20	5	100（2.4%）
	Spinal cord	200	5	1,000（24.0%）
	Dorsal root ganglia	30	5	150（3.6%）
	Distal ileum	800[1)]	0.5	400（9.6%）
Other tissues		548,450	Below detection limit	（＜0.5%）
Total		550,000[2)]		～4,160 $CoID_{50}$

1) 800 g appeared to be excessively large for the anatomically-defined region for ileum (excluding intestinal contents). Commonly, the ileum of adult bovine animal is approximately 1 m of the intestine.
2) Volumes differ depending on the type of animal, age, and breed. Wide variation also exists from geographical regions.

Rendering condition

Rendering under proper conditions could provide effective reduction in BSE infectivity. For example, heat treatment (126 C for 30 min.) of prion strain (301V strain) after passage using mice resulted in reduction of infectivity by log1.9 (ID50/g) and log 2.7 (ID50/g) (Ref 11). The scientific opinion by EFSA estimated the heat treatment of BSE prion by a certain condition (133 C for a minimal of 20 min at bar 3) effectively reduced its infectivity by 1000 times (Ref 3), although the same rendering condition may not be as effective as indicated above when the subject was a mixture of SRM and bones originating from BSE-infected cattle (Ref 12). Drawn from those data was the indication that, although heat treatment recommended by OIE appeared to be effective in reducing risks to certain extent, other measures should be combined with this rendering policy to completely prevent BSE exposure/propagation.

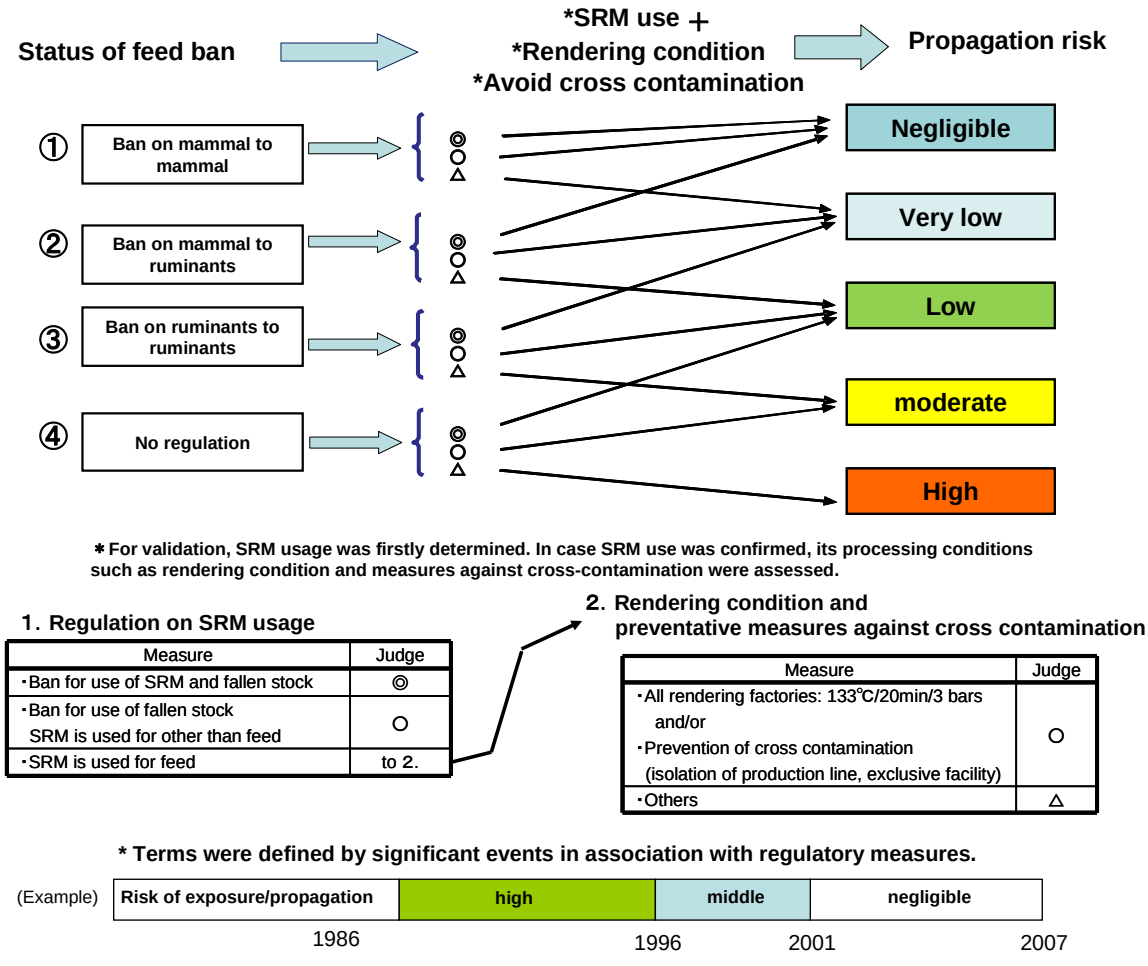
Preventive measures against cross-contamination

The previous study reported that the oral administration of BSE-infected cattle brain by 0.1g, 0.01g, and 0.001g was capable of transmitting BSE at the rate of 7 in 15 cattle, 1 in 15 cattle, and 1 in 15 cattle, respectively (Ref 14). These data were consistent with the European field observation that even a trace amount of animal protein was enough to infect bovine animals through contaminated feeds. Therefore, simply washing of the processing lines was not sufficient to prevent cross-contamination; implementation of more advanced measures such as dedication of feed mills to a certain species and line separation were required (Ref 10).

Assessment of domestic stability

Based on the assessment principle described above, domestic stability of each country was assessed by categorizing them to one of the following 5 ranks; BSE propagation risk is negligible, very low, low, moderate, and high, based on a certain period defined by significant events such as regulatory modification.

Figure 1. Assessment of domestic stability



(3) Assessment of Internal Challenge

Countries with high BSE propagation risks were thought to bear high risk of domestic BSE exposure/propagation upon entrance of BSE agents into the country. Thus, when the submitted data indicated a high risk of domestic BSE exposure/propagation (namely, combined risks of external challenge and domestic stability), this aspect was taken into consideration as a additional factor aside from external challenge.

(4) Verification by surveillance, etc.

Surveillance is the essential method for scientific validation of risk assessment output. In the current assessment, surveillance data were used to validate the result of assessment. The actual validation process was constructed based on the OIE point system, as any other alternatives were not available at that time.

3. Beef and beef offal

Ensuring the removal of SRM can remarkably reduce the risk of variant Creutzfeldt-Jakob disease (vCJD) in human, therefore, this measure is currently at the center of preventive policies regarding human and cattle health protection from BSE. The current risk assessment on beef and beef offal firstly evaluated the extent of 'SRM removal' done by each country, followed by combined assessment of items such as 'inspection at slaughterhouses' and 'stunning/pithing' to evaluate the risk-reducing efficiency of meat processing lines.

(1) SRM removal

In a BSE-positive bovine animal, 99% or more of its infectivity is attributed to SRM (Ref 2), thus exclusion of these materials from food chain ensures reduction in most of the vCJD-associated risks in human. To reflect these SRM-related aspects, the current assessment also took into consideration factors such as implementation of SRM removal or any other measures in preventing beef and beef offal from being contaminated by BSE agent. This part of assessment was ultimately designed to determine whether cross-contamination preventive measures and their efficacy-validating systems were installed in each country.

The definition of SRM in this assessment was adopted from OIE's SRM definition for 'controlled risk country' based on the following reasons:

The currently assessed countries were all with no BSE-positive reports.

There were however some countries that were categorized in GBR III of EFSA.

In addition, the definition and handling of SRM were variable among the assessed countries.

When the SRM definition of assessed country happened to be largely different from that of OIE, the assessment would be conducted separately from this general principle and handled in case-by-case manner.

(2) Inspection, stunning, and pithing at slaughterhouses

Elimination of high risk cattle such as downer cows is an important protocol in protecting human health from BSE risks, and for this reason OIE code requires proper antemortem inspection before slaughtering (Ref 13). However, it is also known that the clinical observation for possible symptoms alone is not enough to distinguish BSE-infected cattle from other diseases. Therefore, both the provisions of (1) effective elimination of downer cows at the antemortem inspection, and (2) BSE testing at slaughterhouses were evaluated in the current assessment.

Pithing of animals at slaughterhouse is linked to an increased risk of BSE contamination via brain and spinal tissue spillage from the stunning hole onto the processed meat and slaughtering facilities. It also increases the risk of high-risk tissue (brain and spinal cord) leakage into the blood stream. Likewise, stunning method with intracranial air/gas pressuring may also bring about similar manner of contamination (Ref 15). Therefore, the current assessment took into consideration of slaughtering process such as implementation of pithing or air/gas injection stunning in each assessed country.

(3) Others (mechanically recovered meat; MRM, etc.)

MRM (including advanced meat recovery, AMR) is the meat of secondary recovery by mechanical measures from bones, after the primary removal of major meat blocks was completed. This method carries a certain risk of SRM inclusion, thus the same assessment method of primary beef meat blocks cannot be adapted to MRM for the evaluation of risk-reducing efficacy of BSE measures.

Accordingly, the commission requested the countries known for MRM production to submit information regarding SRM exports to Japan, then these data were assessed separately from general beef and beef offal exports.

Additionally, total number of livestocks and their traceability were also requested as supplementary data because those matters were related to sensitivity and precision of antemortem inspection at slaughterhouse or estimation of animal's age in months.

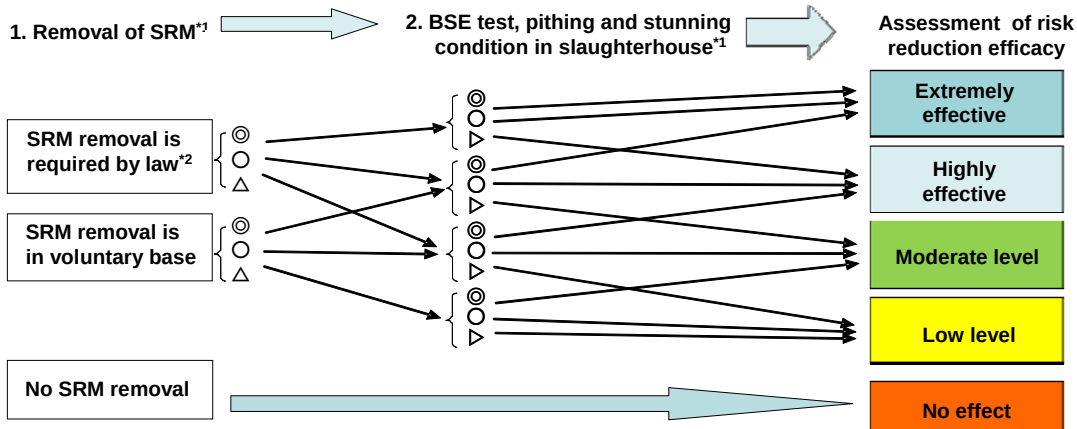
(4) Risk-reducing measures at meat processing lines

Based on the abovementioned principle, each assessed country for efficacy of its risk-reducing measures was categorized by 5 grades, namely 'very low', 'low', 'moderate', 'high', and 'very high' (Fig.2). Since the current assessment subjected only the meat products of Japanese import, the scope of evaluation was also on the criteria of beef product preparation and BSE-preventive measures intended to each country's exportation to Japan.

Presently, all the beef and beef offal importers in Japan are requested to voluntarily refrain from importing SRM from any foreign country. Some exporting countries even have their own specific

regulation on exclusion of SRM from beef and beef offal exports to Japan under the Animal Health Requirement. Therefore, these risk control measures were also taken into the assessment along with the information obtained from each country upon the commission's request through questionnaire.

Figure 2. Assessment for efficacy of risk reduction during meat processing



*1 Judgment basis for condition of SRM removal and procedures at slaughterhouse
(If available, data over the actual compliance was to be also taken into consideration.)
*2 Removal by domestic regulation, or by additional condition required for exportation to Japan

1. SRM removal

Measures	Judge
① Confirmation by meat inspector ② Washing by high pressure water (carcasses) ③ Washing of saw between carcasses ④SSOP and HACCP regulation 3~4 measures above are conducted	◎
Two of above measures are conducted	○
Others	△

2. BSE test, stunning, pithing procedures at slaughterhouse

Measures	Judge
・Health inspection to eliminate downers and BSE test in slaughterhouse and ・Ban for air pressure stunning and pithing	◎
One of above measures is conducted	○
Others	△

Note: Assessment is to be done on beef and beef offal exported to Japan based on the additional conditions required for Japanese exportation. Since all the currently assessed countries were known for no case of positive BSE report, SRM definition hereby adapted those set for 'controlled BSE risk' countries by OIE standard. When SRM definition widely differed from such a definition, the case was to be assessed separately in case-by-case manner.

4. Conclusion of risk assessment

For conclusion of this assessment, periodic BSE risk status of a country (the sum of external challenge and domestic stability) and efficacy of present BSE risk-reducing measures at meat processing lines were combined to be used as an indicator of comprehensive potential likelihood of BSE prion contamination in the beef and beef offal imported from the respective assessed country to Japan. Surveillance data were used to validate the reliability of assessment. Finally, the summary of each country was expressed in schematic figure to enhance the understanding as a reference.

2. Others

(1) Risk of mechanically recovered removed meat (MRM), etc.

Among the countries that have submitted replies to Japan's inquiry, Australia and Brazil reported domestic production of MRM, with the former country having exported 81.6 kg of MRM (head parts not included in raw materials) to Japan in 2008 while the latter had no such record.

The key structure of current risk assessment was the evaluation of imported beef and beef offal to Japan consisted of combination of multiple aspects such as risk of live cattle and risk-reducing measures at slaughterhouse and meat fabrication plant processing lines. Accordingly, any commodities factors that do not fall into these categories, such as MRM, should be taken into consideration separately. As shown in III. 3. (3), there is so far no ground to negate MRM contamination with SRM through meat processing lines, thus, at least MRM from those countries that have potentially had exposure to and/or propagation of BSE in immediate past of data collection should be regarded as carrying certain risks. However, MRM from countries that are regarded as having negligible possibility of BSE exposure/propagation may be considered as carrying negligible risk as well, provided the precondition of current assessment, namely classical BSE originating from the UK, is appropriately met.

Recently, there have been a few cases of irregular forms of BSE (atypical BSE) reported apart from classical BSE in Europe, Japan and the US. Those reports of atypical BSE indicated variation in molecular sizes of abnormal prion proteins (PrP^{Sc}) among cases, and eventually two major sizes of proteins were designated as H- and L-types.

Most of the atypical BSE cases were found in aged cattle over 8 years old, but a remarkable exception exists in Japan, where a steer of only 23 months old was reported to have been infected with atypical BSE (the 8th BSE case in Japan). When this exception was excluded, the detection ages of atypical BSE cases ranged from 6.3 to 18 years old. The average detection ages for H-type and L-type were 11.8 yr and 11.6yr, respectively. (Ref 36)

To the authors' best knowledge, there have been some 40 cases of atypical BSE reported world-wide, yet OIE does not require distinction between classical and atypical BSE cases in member countries for their reports while EFSA only recently referred to case reporting by classical/atypical recognition in its 2009 scientific opinion. Those situations seem to further obscure the clear number of atypical BSE cases occurring in the world.

The origin of atypical BSE is not yet determined. According to EFSA's scientific opinion published in 2008, all the cases of atypical BSE were reported with birth dates before the real feed ban in January 2001 in Europe. Therefore, the possibility of those atypical cases attributing to the contaminated feeds, just as in classical BSE, cannot be completely denied. On the other hand, data of atypical BSE cases (both H- and L-types) in France did not show any reasonable correlation between birth years and frequency of occurrence, as was indicated in classical BSE cases, thus

raising possible interpretation of atypical BSE as being sporadic isolated cases of prion disease (Ref 36).

Based on the data accumulated in France, the frequency of BSE atypical BSE cases per 1 million tested adult cattle were estimated to be 0.41 and 0.35 cases for H- and L-types, respectively. (1.9 and 1.7 cases for H- and L-types, respectively, when limiting the sampling to tested cattle of over 8 years old.)

In Japan, a total of 10 million cattle including fallen stocks and slaughtered cattle were tested for BSE, and the results showed no positive case for H-type and 2 positive cases (case 8; a 23 months old steer, case 24; a 169 months old beef) for L-type of atypical BSE. Those data put Japan to have prevalence frequency of atypical BSE estimated to be none for H-type and 0.2 cases for L-type per 1 million cattle including tested fallen stocks and slaughtered cattle. (Zero and approximately 1.5 cases for H- and L-type, respectively, when limiting the sampling to tested slaughtered cattle of over 8 years old.)

Atypical BSE of both H- and L-types was confirmed to be transmissible by intracerebral inoculation in transgenic mice expressing alleles of bovine or ovine PrP genes and of inbred mice (Ref 41, 42, 43, 44, 45). However, for transgenic mice expressing human prion protein, only L-type but not H-type could be transmitted according to the previously published reports (Ref 46, 47). There have been also reports of glycosylation pattern transformation from L-type BASE PrP^{Sc}-like type to more of the classical BSE PrP^{Sc} type. This phenomenon was observed when passage using inbred and TgVRQ2 mice (Ref 42, 44). As for the atypical cases of BSE confirmed in Japan, the 24th case of BSE was determined to have had atypical L-type at the detection age of 169 month-old, and its sample was successfully transmitted to Tg mice expressing bovine prion protein (Ref 45). However, the other case of atypical L-type BSE confirmed in Japan (the 8th case at the age of 23 month-old) was reported to be unsuccessful in transmission to Tg mice expressing bovine prion protein. The reason for this inconsistency is not clear at this time, although the possible presence of limitation in amount of prion protein accumulated in the sampled brain subject or in the inoculated volume to reach to the detection limit may not be out of consideration (Ref 48).

A recent report has shown that atypical L-type of BSE has a potential of higher degree of pathogenicity than that of classical counterpart, because incubation periods are shorter in atypical BSE by transmission to Tg mice expressing human prion protein, suggesting possibly higher degree of pathogenicity possessed by atypical BSE when compared to its classical counterpart (Ref 46, 49, 37).

In contrast to classical BSE, the systemic distribution of abnormal prion protein in atypical BSE is barely known, therefore it is unclear whether the brainstem is truly the optimal part of sampling and testing in H/L type detection (Ref 50). Likewise, information regarding infectivity

distribution of atypical BSE is scarce in bovine peripheral tissues and body fluid. All together, lack in those essential data raises a certain hindrance to evaluating relative risk-reducing effects of various SRM removal measures from the cattle (Ref 2).

Based on those currently available data on potential risk for humans for L-type BSE and prevalence of atypical BSE prevalence, it may be too far reaching to deny the risk of MRM, especially in those derived from aged cattle. However, the degree of influence by the presence of atypical BSE on our concept of the MRM risk will be limited to a certain extent at a low level under the circumstances with presently available knowledge and our discussion. In the mean time, one must also be reminded of the fact that only a limited amount of data is currently available for atypical BSE. A proper amount of discretion should be accompanied when interpreting those data to avoid unnecessary confusion. Further research and accumulation of data will bring additional insight into the mechanism, pathogenicity and transmission potential of atypical BSE, for which further assessment may become necessary in the future.

(1)Australia

①Live Cattle

a. Risk of BSE Invasion

Import of Live Cattle from BSE Risk Countries

Data on imported live cattle to Australia are shown in Table 5. Figures in the table are taken from the Questionnaire response by the Australian authority and the data of cattle exports from BSE risk countries to Australia (Source: the World Trade Atlas. Trade statistics published by state governments are also used for some figures). Table 5 shows the numbers of cattle imported from the BSE risk countries only during the period for which weighting factors are set.

According to the Questionnaire response, Australia banned importation of live cattle from the UK and Ireland in 1988, from Europe in 1991, from Japan in 2001, and from Canada and the USA in 2003. The numbers of live cattle imported to Australia from BSE risk countries between 1986 and 2007 included 38 from the UK, 186 from European countries with moderate contamination (Ireland and France), 128 from European countries with low contamination (Denmark), 651 from the USA, 1,223 from Canada, and 24 from Japan.

Meanwhile, the numbers of live cattle exported to Australia by BSE risk countries are recorded in the World Trade Atlas. Those numbers include 228 from European countries with low contamination (Poland, Denmark, and Austria), 1,864 from the USA and 237 from Canada. However, it should be noted that the export from Poland was not documented in the Working Group Report on the Assessment of the Geographical BSE Risk (GBR) of Australia (2004) published by EFSA, and that there was no actual export of live cattle from Austria to Australia, it, in fact, was exportation from Austria to Ukraine; but the number was mistakenly printed due to the wrong quotation of country code, UA (Ukraine) for AU (Australia) (Ref. 32). It should be also noted that the USA pre-export inspection office recorded only 493 head of live cattle that were exported from USA to Australia between 1993 and 2001.

Import of MBM from BSE Risk Countries

Data on imported MBM to Australia are shown in Table 6. The figures in the table are taken from the Questionnaire response by the Australian authority and the data on MBM exports from BSE risk countries to Australia (Source: the World Trade Atlas. Trade statistics, published by state governments, are also used for some figures). Table 6 shows the amount of MBM imported from the BSE risk countries during the period when weighting factors are set.

According to the Questionnaire response, Australia has banned importation of animal feeds containing MBM from all countries except for New Zealand. Accordingly, there is no import of MBM from BSE risk countries to Australia.

Meanwhile, the World Trade Atlas recorded 26 tons of MBM imported from European counties with moderate contamination (Germany and the Netherland), 43 tons from Europe countries with low contamination (Denmark), 862 tons from the USA, and 163 tons from Canada. It should be noted, however, that in Working Group Report on the Assessment of the GBR of Australia (2004), EFSA points out that 22 tons exported from Germany in 2002 was exempted from the risk MBM category, because the exportation of processed animal protein had been banned from EU members in 2001; in addition, exportation from Canada and USA was also excluded based on the declarations by the chief veterinary officers of both countries(Ref. 32).

Import of Animal Oil/Fat from BSE Risk Countries

The Questionnaire response from Australia shows import of animal oil/fat from BSE risk countries, including the UK. From 2001 through 2005 alone, approximately 280,000 tons of animal oil/fat was imported to Australia from Canada. However, use of imported oil/fat for ruminant animal feed is banned in Australia. The oil/fat was imported for human food staff, cosmetics, or for other industrial purposes.

Assessment of the Use of Imported Live Cattle and MBM for Animal Feed

To assess the possible source of exposure among the imported cattle, the previously available risk assessment by Australian government (Ref. 33 and 34) and EFSA's Working Group Report on the Assessment of the GBR of Australia 2004 were reviewed (Ref. 32). Based on the assessment, animals applicable for the following criteria were exempted from consideration as risk animals because they were not intended for animal feed:

(1) Live Cattle imported from UK but born before June 1976:

(2) Cattle that was alive at the time of inspection:

(3) Cattle that has not been rendered.

The numbers of live cattle shown in the table 5 indicate those of possible source of exposure, and they were estimated under the assumption that the rate of cattle with no potential risk stayed the same throughout the years of importation. This assumption was adopted because the Questionnaire response included only the number of cattle for each birth cohort year, therefore lacking of the number of cattle needed to be dealt with for each importation year.

Based on the described condition above, the numbers of imported cattle with a potential of being a source of exposure for the period between 1986 and 1990 were regarded as: 13 out of 38 head of imported cattle from the UK, 74 out of 158 from European countries with moderate contamination, and 15 out of 33 from European countries with low contamination. For the cattle imported from Canada, all 1,030 cattle were considered to have had a possibility of being a source of exposure.

From 1991 through 1995, 13 out of 28 cattle imported from European countries with moderate contamination, and 56 out of 71 imported from European countries with low contamination were regarded as carrying the possibility of being a source of exposure. For the cattle imported from the USA and those imported from Canada, all 301 and 186 head of cattle, respectively, were regarded as having the possibility of being a source of exposure.

From 1996 through 2000, all 24 head of cattle imported from European countries with low contamination were regarded as carrying the possibility of being a source of exposure, in addition to 56 out of 276 from the USA and 5 out of 24 from Japan.

From 2001 through 2005, 15 out of 74 head of cattle imported from the USA and 1 out of 7 imported from Canada were regarded as carrying the possibility of being a source of exposure.

In regard with animal oil/fat, even though a rather large amount of those materials was imported from Canada, Australian government has adopted the ban on importation of animal oil/fat for intended use of ruminant animal feed, therefore, the risk was evaluated to be negligible.

Table 5. Import of Live Cattle from BSE Risk Countries experienced by Australia

			1986-1990	1991-1995	1996-2000	2001-2005	2006-2007	**Total**
			Number of imported cattle	Number of imported cattle	Number of imported cattle	Number of imported cattle	Number of imported cattle	**Number of imported cattle**
Import data[1]	UK	Questionnaire	38	0	0	0	0	**38**
		Trade statistics	0	0	0	0	0	**0**
	Europe [4] (Countries with moderate contamination)	Questionnaire	158	28	0	0	0	**186**
		Trade statistics	0	0	0	0	0	**0**
	Europe (Countries with low contamination)	Questionnaire	33	71	24	0	0	**128**
		Trade statistics	6	0	24	198	0	**228**
	USA	Questionnaire		301	276	74	0	**651**
		Trade statistics		1,052	777	35	0	**1,864**
	Canada	Questionnaire	1,030	186	0	7	0	**1,223**
		Trade statistics	229	0	1	7	0	**237**
	Others (Japan)	Questionnaire	0	0	24	0	0	**24**
		Trade statistics	0	0	0	0	0	**0**
	Total	**Questionnaire**	**1,259**	**586**	**324**	**81**	**0**	**2,250**
		Trade statistics	**235**	**1,052**	**802**	**240**	**0**	**2,329**

		1986-1990		1991-1995		1996-2000		2001-2005		2006-2007		**Total**
		Number of imported cattle	UK Equivalent	Number of imported cattle	UK Equivalent	Number of imported cattle	UK Equivalent	Number of imported cattle	UK Equivalent	Number of imported cattle	UK Equivalent	**Number of imported cattle**
Number of imported cattle with a potential of being a source of exposure [2]	UK	13	7.17	0	0.00	0	0.00	0	0.00	0	0.00	**13**
	Europe (Countries with moderate contamination)	74	0.74	13	0.13	0	0.00	0	0.00	0	0.00	**87**
	Europe (Countries with low contamination)	15	0.02	56	0.56	24	0.24	0	0.00	0	0.00	**95**
	USA			301	0.01	56	0.00	15	0.00	0	0.00	**372**
	Canada	1,030	0.10	186	0.02	0	0.00	1	0.00	0	0.00	**1,217**
	Others (Japan)	0	0.00	0	0.00	5	0.00	0	0.00	0	0.00	**5**
	Total	**1,132**	**8.03**	**556**	**0.72**	**85**	**0.24**	**16**	**0.00**	**0**	**0.00**	**1,789**
		Negligible		**Negligible**		**Negligible**		**Negligible**		**Negligible**		

(Reference) Numbers calculated using the figures in the trade statistics.

Trade Statistics [3]	Total	**235**	**0.03**	**1,052**	**0.01**	**802**	**0.25**	**240**	**1.98**	**0**	**0.00**	**2,329**
		Negligible		**Negligible**		**Negligible**		**Negligible**		**Negligible**		

1: 'Number of cattle imported' and 'Number of imported cattle with a potential of being a source of exposure' are described only for the period when weighting factors are set.

2: The numbers of cattle that are exempted from the number of those to be treated as risk animals based on the information on the document attached to the Questionnaire response (risk assessment by Australian government) and other information.

3: We regard all the cattle as a source of exposure because the exact number is unknown from the trade statistics as to how many of imported cattle were as such.

4: In addition to this number, import of 38 tons of live cattle from countries with moderate contamination (France and Germany) is reported in the trade statistics. (When the volume of imported live cattle is indicated only in the weight and not in the number of animals, that volume is not included in the assessment.)

Table 6. Import of MBM from BSE Risk Countries experienced by Australia

			1986-1990	1991-1995	1996-2000	2001-2005	2006-2007	**Total**
			Volume of importation (ton)	Volume of importation (ton)	Volume of importation (ton)	Volume of importation (ton)	Volume of importation (ton)	**Volume of importation (ton)**
Import data[1]	UK	Questionnaire	0	0	0	0	0	**0**
		Trade statistics	0	0	0	0	0	**0**
	Europe (Countries with moderate contamination)	Questionnaire	0	0	0	0	0	**0**
		Trade statistics	0	0	0	26	0	**26**
	Europe(Countries with low contamination)	Questionnaire	0	0	0	0	0	**0**
		Trade statistics	0	0	43	0	0	**43**
	USA	Questionnaire		0	0	0	0	**0**
		Trade statistics		0	846	16	0	**862**
	Canada	Questionnaire	0	0	0	0	0	**0**
		Trade statistics	0	0	163	0	0	**163**
	Others	Questionnaire	0	0	0	0	0	**0**
		Trade statistics	0	0	0	0	0	**0**
	Total	Questionnaire	**0**	**0**	**0**	**0**	**0**	**0**
		Trade statistics	**0**	**0**	**1,052**	**42**	**0**	**1,094**

		1986-1990		1991-1995		1996-2000		2001-2005		2006-2007		**Total**
		Volume of Importation (ton)	UK equivalent	Volume of importation (ton)	UK equivalent	Volume of Importation (ton)	UK equivalent	Volume of importation (ton)	UK equivalent	Volume of importation (ton)	UK equivalent	**Volume of Importation (ton)**
Volume of Imported MBM with a potential of being a source of exposure	UK	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	**0**
	Europe (Countries with moderate contamination)	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	**0**
	Europe (Countries with low contamination)	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	**0**
	USA			0	0.00	0	0.00	0	0.00	0	0.00	**0**
	Canada	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	**0**
	Others	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	**0**
	Total	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**
		Negligible		**Negligible**		**Negligible**		**Negligible**		**Negligible**		

(Reference) Numbers calculated using the figures in the trade statistics.

Trade statistics[2]	Total	**0**	**0.00**	**0**	**0.00**	**1,052**	**0.45**	**42**	**0.26**	**0**	**0.00**	**1,094**
		Negligible		**Negligible**		**Negligible**		**Negligible**		**Negligible**		

1: 'Volume of MBM imported' and 'Volume of imported MBM that can be a source of exposure' are calculated only for the period when weighting factors are set.

2: We regard all of the MBM as a source of exposure because the exact number is unknown from the trade statistics as to how many of imported MBM were as such.

Assessment for external challenge

External challenge was evaluated based on the Questionnaire response by the Australian government. The level for risk of invasion between 1986 and 1990 was 8.03 in UK equivalent for live cattle and regarded 'very low'. The invasion risk level between 1991 and 2007 was regarded 'negligible' with even lower UK equivalents of 0.72 (1991–1995), 0.24 (1996–2000), 0.0004 (2001–2005), and 0 (2006–2007). (The UK equivalents obtained in evaluation of invasion risk levels using trade statistics were less than 2 for all periods between 1986 and 2007. The level of invasion risk for this period, therefore, was regarded 'negligible'.)

The UK equivalents for MBM were 0 for the all periods, and the invasion risk, therefore, was regarded 'negligible'. (The UK equivalents obtained in evaluation of invasion risk levels using trade statistics were less than 1 for all periods between 1986 and 2007. The invasion risk for this period, therefore, was regarded 'negligible'.)

The comprehensive invasion risk (combination of risks by imported live cattle and MBM) was regarded 'very low' for the period between 1986 and 1990 and 'negligible' for the period between 1991 and 2007 (Table 7). (Evaluation of invasion risk level based on trade statistics resulted in 'negligible' for all the periods. Even when the values in the Questionnaire response did not match the values in the trade statistics, the level of comprehensive invasion risk never exceeded the values in the Questionnaire response.)

Table 7. External challenge experienced by Australia

	1986-1990	1991-1995	1996-2000	2001-2005	2006-2007
Live cattle	**Very low**	**Negligible**	**Negligible**	**Negligible**	**Negligible**
MBM	**Negligible**	**Negligible**	**Negligible**	**Negligible**	**Negligible**
Overall Level	**Very low**	**Negligible**	**Negligible**	**Negligible**	**Negligible**

b. Domestic Stability (BSE propagation risk of country)

Feed regulations

In 1996, the Australian livestock industries implemented a voluntary ban on the feeding of ruminant-derived MBM to ruminants. In 1997, the feeding was legally banned. In 1999, amendments were made to extend the feed ban to MBM from specific mammals. In the period between 2001 and 2002, the scope of ban was further expanded to include feeding of ruminants with feed derived from all kinds of vertebrates. It is reported that the use of ruminant-animal-derived MBM for cattle feed had been very small even before the regulations were imposed.

Australian farmers feed their cattle mainly with grass, with supplementary use of hay, silage, grain and pees/beans. In the feedlots, where approximately 30% of the beef cattle finish their fattening periods, grains are used as a major feed.

While a small number of farmers raise cattle, pigs and chickens together, feeding ruminant animals with chicken litter is legally prohibited.

Compliance with feed regulations is verification by inspectors authorized by state and territory government at different stage of the distribution: rendering facilities, feed mills, feed retailers, and farms.

In a 2006 report of a farm-stage survey, noncompliance was found in seven farms out of a total of 8,328, including feedlots, dairies and cattle farms. In a survey for feed production/distribution stage in 2006, four out of 90 rendering facilities, 17 out of 237 feed mills, and 43 out of 258 retailers were found breaching the regulations. However, it should be noted these figures are not be taken literally. This was not a survey conducted with subjects selected randomly, but a survey carried

out only on the high-risk farms and facilities. In addition, some farms or facilities may be counted more than once for different items of noncompliance. The regulations not complied with these institutions included those for labeling and storage conditions of raw materials.

To investigate contamination of animal protein in feed, sample tests have been conducted with high risk facilities using polymerase chain reaction (PCR) analysis. In 2006, 56 tests were conducted and one case of contamination was found in cattle feed.

Use of SRM

Australia has been recognized as a 'negligible BSE risk country', and therefore the Australian government has not defined SRM, nor required domestic distributors to remove SRM from foodstuff or animal feed. Head, vertebral column, the spinal cord and distal ileum are used for human consumption (50%) and non-bovine animal feed including pet food (48%). The rest is apparently used for fertilizer or is disposed of. The Questionnaire response notes that these parts have rarely been used for cattle feed even before the feed ban (approximately 1%). Most (approximately 80%) of the fallen stock, emergency slaughter or bovines condemned at antemortem were buried or incinerated at the farm, while the rest (approximately 20%) were seemingly used for animal feed including pet food after the rendering.

Rendering Conditions

Six facilities, which account for about 3% of the national production, practice rendering subject to the conditions provided for in the OIE codes (at 133°C for a minimum of 20 minutes at absolute pressure of 3 bar pressure). The rest of the facilities carry out rendering at 102–136°C for 70–150 minutes under the atmospheric pressure.

Measures to Prevent Cross-contamination

According to the 2001–2005 data, there are about 122 feed mills in Australia, approximately 60% of which are 'dedicated facilities' (they produced feed for particular species) and the other 40% are 'mixed facilities' (they produced feed for both ruminant and non-ruminant animals). In the data taken in and after 2006, the ratios of dedicated facilities and mixed facilities among the 152 feed mills are about 70% and 30%, respectively. Among the mixed facilities using MBM, three facilities have separate lines for different kinds of feed, while other facilities wash the lines before changing the products.

The number of rendering facilities reported in 2001–2005 data is 102. Although there are no data to describe the ratio of dedicated and mixed facilities, many rendering facilities are seemingly involved in manufacturing of feed for a specific livestock due to the commercial reasons. Approximately 50 to 60% of the MBM produced in Australia is exported.

Others

Transmissible spongiform encephalopathy (TSE) cases have been reported in Australia. In 1952, scrapie was found in four out of 10 sheep imported from the UK. They were eradicated immediately and no case has been reported in Australia since then. TSE has been also found in one imported cheetah and one Asian golden cat, which were incinerated or buried. No other case of TSE has been confirmed in Australia.

Assessment of Domestic Stability

The domestic stability was assessed based on the Questionnaire response by the Australian government. Our assessment revealed that the "risk of exposure/propagation was high" (1986–1997), "risk of exposure/propagation was moderate" (1998–2002), and "risk of exposure/propagation is low" (2003–2007) in Australia (Table 8, Table 9).

Table 8. Domestic Stability in Australia

Item	Status
Feeding	1996: Ban on feeding of ruminant derived MBM to ruminants (voluntary) 1997: Ban on feeding of ruminant derived MBM to ruminants (legal obligation) 1999: Ban on feeding of specific mammal derived MBM to ruminants 2001–2002: Ban on feeding of all vertebrates derived MBM to ruminants
Use of SRM	【SRM】 ≈ 50% is used for human consumption, ≈ 48% for feed for non-bovine animals including pet food, and the rest is either used as fertilizer material or is disposed of. 【Fallen stock, emergency slaughter or bovines condemned at antemortem】 ≈ 80% is incinerated or buried in the farm, ≈ 20% is used for pet food or other animal feeds after the rendering.
Rendering conditions	Only at the facilities who produce 3% of the national production, the condition is set for 133°C/ 20 minutes/ 3 bar At most of facilities processed under the atmospheric pressure
Measures to prevent cross-contamination	【Feed mills】 ≈ 70% of the mills produce feed for particular species only. Other facilities either use separate lines or wash lines before switching the type of products. 【Rendering facilities】 Many facilities process materials from a particular species due to commercial reasons.

Table 9. Assessment of Domestic Stability in Australia

	Feeding	Use of SRM, Rendering Conditions, Preventive measure against cross-contamination, etc.	risk of exposure/propagation
1986–1997	No specific regulations	-	**High**
1998–2002	Ban on feeding of ruminant derived MBM to ruminants	-	**Moderate**
2003–2007	Ban on feeding of all vertebrates derived MBM to ruminants	-	**Low**

c. Verification by surveillance, etc.

Population Structure

The total cattle population in Australia in 2006 was approximately 22,190,000 made up of 6,130,000 of Beef cattle (1-year old or older bullocks); 13,460,000 of Beef cattle (1- year old or older female beef cattle or heifer); 1,880,000 of Dairy cows (mostly 14 months old or older); 720,000 of Breeding cattle (Those raised for a breeding purpose among uncastrated beef cattle or uncastrated male calves)

Surveillance Outline

Passive surveillance started in Australia in 1990, followed by active surveillance started in 1998 as part of (National TSE Surveillance Program) NTSESP. This program is designed to detect a case of BSE at the 1 per 1 million with a 99% of confidentiality, and this surveillance procedure was based on the guideline by OIE. Sampling is conducted with a main focus on 'animals sampled at the farm with the clinical conditions matching the definition' (or 'clinical suspect' by the OIE classification) with 'fallen stock' and 'casualty slaughter' also included. The animals categorized as 'routine slaughter' are excluded from the surveillance.

Screening tests are conducted using histopathological testing methods for 'animals with the clinical conditions matching the definition', the ELISA method or Western blotting method for 'fallen stock' and 'casualty slaughter'. To confirm the results, the immunohistochemical method is used mainly.

The surveillance was conducted for 3,310 animals between 1990 and 1997. Since the NTSESP was implemented in 1998, more than 10,000 animals are surveyed. No animal has diagnosed as BSE positive. When the results of the latest seven years were statistically analyzed based on the point system used by OIE, the standards to show the prevalence of less than 1 in 100,000 adult animals with a 95% confidentiality were considered to be satisfied (Table 10).

Table 10. Surveillance Point Calculation in Australia

Number of cattle population (2006): approximately 22,190,000* → 300,000 points are needed in 7years.

Number of Animals Surveyed					
Year	Routine slaughter	Fallen stock	casualty slaughter	Clinical suspect	**Total**
2001	802	438	81	502	**1,823**
2002				439	**439**
2003		150		460	**610**
2004		201	220	445	**866**
2005		718	1,587	482	**2,787**
2006		641	760	497	**1,898**
2007 (only partially available)		232		263	**495**
Total	802	2,380	2,648	3,088	**8,918**
Surveillance points	(x0.2) 160	(x0.9) 2,142	(x1.6) 4,237	(x750) 2,316,000	**2,322,539 (Goal achieved)**

Notes:

- Surveillance points were compared with the points needed by the OIE Type A Surveillance.
- Surveillance points were calculated under an assumption that all the animals are 4 years old or older and less than 7 years old.
- The cattle population in the Questionnaire response by the Australian government was used to calculate with an assumption that all the animals are 24 months old or older.

BSE Awareness Program and Mandatory Notification

Various organizations in Australia, including the federal government, state and territory authorities, livestock associations, veterinary medicine associations, universities, and agricultural/technical schools, conduct awareness programs for a wide variety of people in different stages of the food chain including farmers, veterinarians, transportation workers, meat processors, and retailer. Their typical way of activities include training sessions, publication and distribution of guidelines, videos and brochures, information given on the Internet.

In all the states and territories in Australia, BSE is designated as one of the diseases that require mandatory notification. Since 1989, when the clinical status was first recognized in the UK, report of suspect cases to animal hygiene authorities has been legally obligated. To support NTSESP, compensation has been paid to the farms that reported the animals applicable to the sampling as well as to the veterinarians.

② Beef and Beef Offal

a. SRM Removal

Methods of SRM Removal, etc.

In Australia, use of SRM for foodstuff is allowed if the animal is passed antemortem and postmortem inspection (except for tonsil, which cannot be used for foodstuff). SRM is removed from foodstuff items only required by trade contracts or organization of importing nations during slaughter process. The Questionnaire response states that head (including brain, skull, eye, trigeminal ganglia and tonsil, but excluding tongue and cheek meat) and spinal code are removed from all the meat intended for exporting to Japan regardless of the age. The vertebral column and distal ileum are not imported to Japan following a notice sent to importers, which instructs them to voluntarily restrain from SRM import.

Tonsil, which is not suitable for foodstuff, is processed in rendering. Spinal code, which is not suitable for foodstuff either, is rendered, buried or saved as pet food. Other parts of SRM are usually removed and sent to rendering processes, but in some cases, they are saved for human consumption for a specific market.

Split liner is a common practice in slaughter houses. Saws used for split liner are being washed with water spray while in use and sterilized after use (before the use for the next carcass). Spinal codes are removed either by hand or with a suction machine. When requested by the importing country, an official veterinarian or meat inspector conducts random inspection to see if no spinal code tissues reminded on the carcass. Most of fabrication plants do not wash the carcasses after removing the spinal code, but in some cases carcasses are washed with drinkable water at a low pressure. At a small number (2 or 3) of facilities, certain approved substances with antibacterial functions (e.g., lactic acid) are added to the washing water.

Tonsils are removed at slaughterhouses by authorized workers before head inspection is conducted by a meat inspector. The inspector checks the removal of tonsils at the time of head inspection.

When required by the importing country, authorized workers remove distal ileum by hand after the organ inspection is conducted by the meat inspector. The removal of distal ileum is checked by official meat inspectors or veterinarians.

Control based on (SSOP) and (HACCP)

Compliance of the Sanitary Standard Operation Procedure (SSOP) and Hazard Analysis Critical Control Point (HACCP) is required for all the exporting facilities. The Australian Quarantine and Inspection Service manage these procedures. Australia is designated as negligible BSE risk country, and therefore, BSE-related management procedures are not identified as CCP.

Additional Requirements, etc. for Export for Japan

Facilities that produce meat and meat products intended for export for Japan must meet the conditions stipulated in the 1982 Export Control Act, 2005 Multilateral Export Control Regimes, and Australian meat standards. Implementation of HACCP and SSOP are also required.

b. Slaughtering Processes

Antemortem inspection and BSE testing at the slaughter houses

Antemortem inspection is conducted by an official veterinarian or meat inspector. Any animals with abnormal behaviors, including downers, are identified as not applicable for slaughter and included in the BSE testing.

Currently, BSE test is not conducted for routine slaughter.

Stunning and Pithing

Stun guns are used in all slaughterhouses. The type of stun guns that sends the tip of the bolt into the skull is used at 95% of the facilities. The slaughter method of injecting pressured air or gas into the skull or the method using a hummer is not used in any slaughterhouses in Australia.

Pithing is not practiced in Australian slaughterhouses.

c. Others

Mechanically Recovered Meat (MRM)

Mechanically recovered meat (MRM) is produced in Australia using vertebral column. Head is not used for MRM in Australia. There is a record of MRM export for Japan in 2008, where 81.6 kg of frozen ground beef (bone and tendon removed) was exported by one facility.

Traceability

Since the 1960s, tail tags have been used at a state level as a measure to control diseases, such as bovine brucellosis and bovine tuberculosis.

As a national identification system, the National Livestock Identification System (NLIS) was introduced in 1999, which became obligatory in all the states in July 2005. Property Identification Codes (PICs) allocated to each farm, information on movements of cattle, ear tag number, registration dates, and other information items are registered for cattle identification.

Although cattle in Australia are classified based on the carcass weight, not the age of the animal in months, age (in months) of each bovine animal is determined based on its teeth for the purpose of BSE surveillance.

Number of Slaughterhouses and Number of Slaughtered Animals

AQIS conducts meat inspection in 82 slaughterhouses. In all of these facilities, meats are processed for domestic and export to other countries / Japan. The number of animals slaughtered was 7,387,509 in 2007 data. Since the slaughtered animals are classified based on the weight of carcass, detailed data on age (in months) structure of slaughtered animals is not available. However about 10% of the slaughtered animals are estimated to be 120kg or lighter as carcass weight, also 12 months old or younger.

There are 107 fabrication plants in Australia, all of which process meat both for domestic consumption/export to other countries and for export to Japan.

d. Assessment of Risk-reducing Measures at Meat Processing Lines

Based on the Questionnaire response by the Australian government, the risk-reducing measures at meat processing lines in Australia were assessed. The risk-reducing efficacies of the measures were recognized either 'Extremely effective' or 'Highly effective' (Table 11).

Table 11. Summary of Assessment in Australia

<table>
<tr><th colspan="2"></th><th>Measure</th><th>Judge</th></tr>
<tr><td rowspan="5">Current Practice of SRM Removal</td><td>Definition of SRM</td><td>No national definition for SRM.</td><td rowspan="5">SRM is removed based on the regulations of the specific country (spinal column and distal ileum are removed based on the risk management measures at the time of import) (Methods of practice, etc.:◎)</td></tr>
<tr><td>Removal of SRM</td><td>【Meat exporting to Japan】
・Head, spinal code: removed regardless of age in months.

Other parts (vertebral column and distal ileum) are not exported to Japan following a notice sent to importers, which instructs them to voluntarily restrain from SRM import.</td></tr>
<tr><td rowspan="3">Methods, etc.</td><td>Split saw is washed between animals</td></tr>
<tr><td>Most of food processing factories do not wash the carcasses after removing the spinal code, but in some cases carcasses are washed with drinkable water at a low pressure.</td></tr>
<tr><td>When requested by the importing country, an official veterinarian or meat inspector conducts inspection to see if no spinal code tissues remained on the carcass.

Both HACCP and SSOP are practiced at exporting facilities.</td></tr>
<tr><td rowspan="3">Inspection at slaughter houses Stunning and pithing</td><td>Inspection at slaughterhouse</td><td>・Antemortem inspection is conducted either by an official veterinarian or meat inspector.
・Any animals with abnormal behaviors, including downers, are identified as not applicable for slaughter and included in sampling candidates for the BSE inspection.
・Currently, routine slaughter is not included in the subject to surveillance, and therefore BSE inspection is not carried out.</td><td rowspan="3">○</td></tr>
<tr><td>Stunning with injection of pressured air or gas into the skull</td><td>Not practiced.</td></tr>
<tr><td>Pithing</td><td>Not practiced.</td></tr>
<tr><td colspan="2">MRM</td><td>MRM is Produced.
Vertebral column is used for MRM. Head is not used.
MRM was exported to Japan in 2008 by one facility.
(frozen ground beef (bone and tendon removed): 81.6 kg)</td><td></td></tr>
<tr><td colspan="2">Additional requirements, etc. for export for Japan</td><td>・Exporting facilities must meet the conditions stipulated in the 1982 Export Control Act, 2005 Multilateral Export Control Regimes, and Australian meat standards.
・Implementation of HACCP and SSOP are required.</td><td></td></tr>
<tr><td colspan="2">Livestock Hygiene Requirements</td><td></td><td></td></tr>
<tr><td colspan="2">Administrative guidance on import of beef for human consumption, etc. by notice</td><td>Importing companies are instructed to withhold import of SRM for human consumption even from non-affected countries in order to prevent possible confusion in case BSE occurs in that country.</td><td></td></tr>
<tr><td colspan="2">Assessment of risk-reducing measures</td><td colspan="2">Efficacy of risk-reducing measures:
'Extremely effective' to 'Highly effective'</td></tr>
</table>

③ Conclusion

The evaluation of beef and beef offal imported from Australia to Japan, based on the Australia's responses, resulted in our consideration that the external challenge is "negligible to very low" (1986 to 1997) and "negligible" (1998 to 2007). In addition, the risk against domestic stability was considered that "risk of exposure/propagation was high" (1986 to 1997), "risk of exposure/propagation was moderate" (1998 to 2002), and "risk of exposure/propagation is low" (2003 to 2007).

Based on the results of assessments for external challenge and risk against domestic stability, the risk of BSE exposure/propagation in Australia is considered to be negligible.

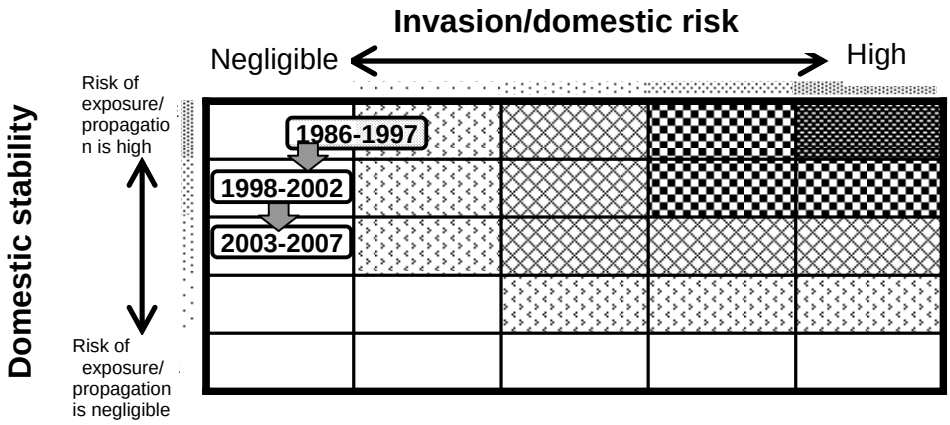
The surveillance so far has turned out to be with no BSE positive cattle. Whilst the surveillance outcome over the seven year period (2001 to 2007) was assumed enough to meet the standard which "will allow the detection of BSE around a design prevalence of at least one case per 100,000 in the adult cattle population, at a confidence level of 95%" as stipulated by OIE.

Risk-reducing efficacy at the meat processing lines was assumed as "Extremely effective" to "Highly effective".

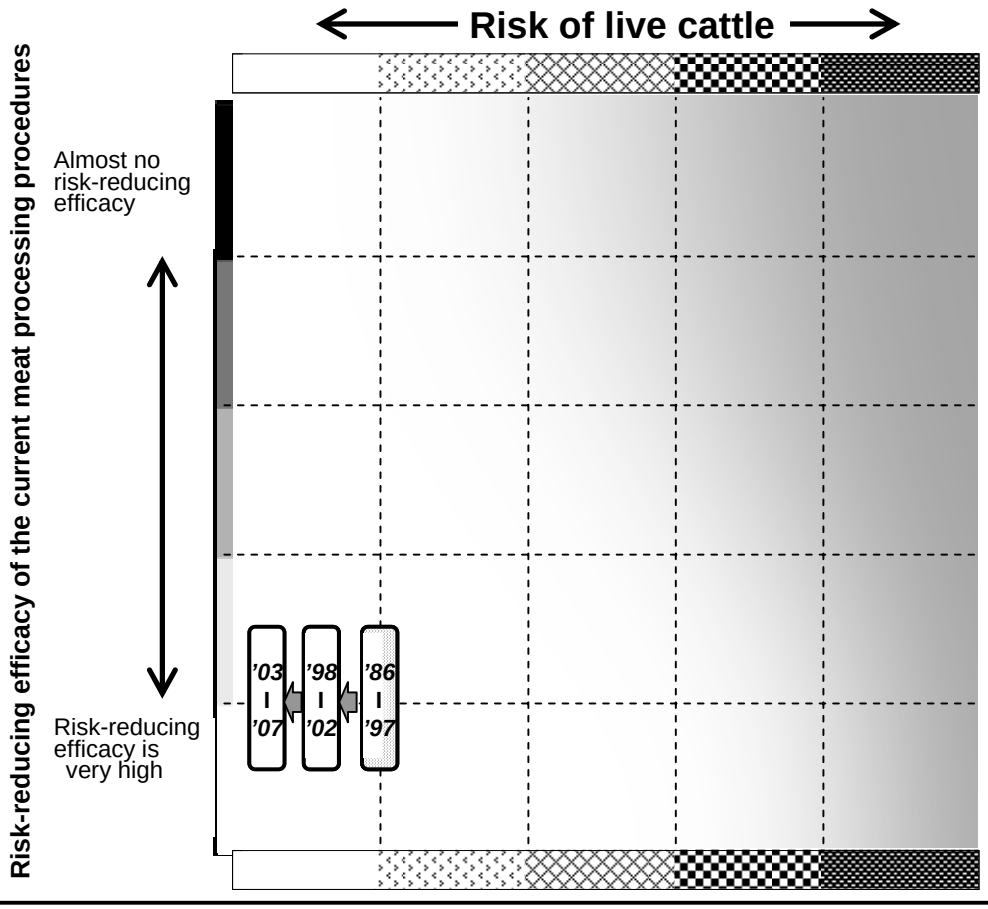
Judging from those presented above, the potential risk of BSE exposure/propagation in Australia is considered negligible, and the risk-reducing efficacy at the meat processing lines was assumed as "Extremely effective" to "Highly effective". Therefore, the risk of BSE prion contamination in beef and beef offal imported from Australia is considered to be negligible.

<Reference: Australia>

A. Risk of Live Cattle



B. Risk of Beef, etc. Imported to Japan



Periods show the birth cohort years (birth years of cattle)

<Reference>

32. EFSA, Working Group Report on the Assessment of the Geographical BSE-Risk (GBR) of AUSTRALIA 2004
33. National Health and Medical Research Council (NHARC) Special Expert Committee on the TSEs, The likelihood that bovine spongiform encephalopathy (BSE) established in the Australian herd as a result of the importation of cattle from the UK and Europe (1980 to 1991)
34. National Health and Medical Research Council (NHARC) Special Expert Committee on the TSEs, The likelihood that bovine spongiform encephalopathy (BSE) established in the Australian herd as a result of the importation of cattle from North America (1996 to2004)