APPENDIX 1

RISK ASSESSMENT

The likelihood that bovine spongiform encephalopathy (BSE) established in the Australian herd as a result of the importation of cattle from North America (1996 to 2004)

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Executive summary

This paper presents results of an investigation of the likelihood that BSE established within the Australian cattle herd as a result of the importation of cattle from the United States and Canada between 1996 and 2004.

This investigation was carried out in two phases.

1. **Release assessment**

   A *qualitative* assessment of the likelihood that at least one infected animal entered Australia, and was subsequently slaughtered. This assessment was based on the published scientific literature on the epidemiology of BSE in the UK and Europe and on quarantine station records; surveillance records; and stud records; describing the origin, importation details, management and (where relevant) disposal of imported animals.

2. **Exposure assessment**

   A *qualitative* assessment of the likelihood that the BSE infective agent would have established in the Australian cattle herd, if at least one BSE-infected animal had been imported and sent to slaughter before the ban. This assessment was based on an examination of the 'pathway' of steps, or events, necessary for infection to have been disseminated undetected from the carcass of an infected imported animal to the Australian cattle herd and is as discussed in the report "*Risk assessment: 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)*".

From the release assessment, it was concluded that the likelihood that one or more infected animals were imported and sent to slaughter is qualitatively interpreted as a 'negligible' likelihood.

From the exposure assessment as previously reported, it was concluded that the likelihood that BSE would have established undetected in the Australian cattle herd, had at least one infected animal been sent to slaughter before the ban, was 'negligible'.

When the results of the two assessments were combined, the overall likelihood that BSE became established within the Australian cattle herd as a result of the importation of cattle from North America was considered 'negligible'.

BSE has never been observed in Australia and, despite the importation of cattle from the UK, Europe, Japan (via the United States), Canada and the United States, it is clear that Australia remains free from this important trade-limiting animal disease.

Introduction

In December 1993 a cow in Alberta Canada, imported from the United Kingdom in 1987, was diagnosed with BSE and subsequently destroyed along with the herd of origin. On May 20, 2003, BSE was confirmed in a 6 year old indigenous downer cow in Alberta, that was born in Saskatchewan in March 1997. On December 29, 2003, in Washington State, USA, a second case of BSE was confirmed in a downer dairy cow. This cow was born in Alberta in April 1997 and exported to the USA on September 4, 2001.

In the years 1996 to 2004, 328 and 21 cattle were imported from the United States and Canada respectively. The objective of this study was to investigate the likelihood that BSE became established undetected within the Australian cattle herd as a result of the importation of these 349 cattle. After the report of BSE in a Canadian cow in May 2003, all imported cattle still alive were placed under quarantine surveillance in accordance with Section 55A, Regulation 36 of the Quarantine Act. This section of the Act prohibits the unauthorised movement of these cattle, or their sale for slaughter, and ensures that their carcasses will be disposed of in a manner that meets with the approval of the Australian Quarantine and Inspection Service (AQIS).

It was assumed that for BSE to become established in the Australian cattle herd, infective agent would need to be recycled through the feeding of meat and bone meal (MBM) derived from infected imported animals. Subsequent recycling of infected Australian cattle through the same system might then have led to amplification of the disease and its possible establishment in the cattle population. There is some observational epidemiological evidence to suggest that BSE may also be transferred vertically from dam to calf (SEAC, 1997), although this route has only been documented in the situation where the dam is *clinically* affected (Taylor et al, 1995). As there is no evidence of clinical disease in imported cattle (live or dead), this was not considered further. No evidence exists to suggest that the BSE infective agent may be transferred through the semen or embryos (Wrathall et al, 1990) of infected cattle or *in utero* (Middleton and Barlow, 1993; European Commission, 1999).

It was also reasoned that imported animals, falling into the following categories could not have been infected with BSE or could not have been incorporated in the MBM that was fed to Australian cattle:

- animals still alive or re-exported
- animals known to have died and disposed of outside the commercial slaughter / MBM system
- animals born after the adoption, in August 1997, of the ban on inclusion of ruminant-derived material in ruminant feed in North America
- animals known to have been slaughtered commercially after the adoption, in October 1997, of the ban on inclusion of ruminant-derived material in ruminant feed in Australia
- animals known to have been more than 10 years of age at the time of death

The exclusion criteria are discussed individually below. The numbers of animals removed from the analysis at each step are shown in Table 1. In cases where information was inadequate to confirm that an animal had satisfied one or other criterion, a conservative stance was taken and the animal retained in the analysis.

This systematic exclusion process left 27 animals from 6 farms of origin in the analysis, 18 of which were Wagyu cattle from one farm.

Animals still alive or re-exported. Animals still alive will be disposed of outside the commercial slaughter system as a result of quarantine restrictions imposed on animals imported from North

America. Animals that have been re-exported are no longer relevant to Australia's BSE status, although the group were nevertheless free from clinical disease at the time of export.

Animals known to have died and been disposed of outside the commercial slaughter / MBM system. The premise underlying this investigation was that in order to become established within the Australian cattle herd, the BSE infective agent was recycled through the feeding of meat and bone meal (MBM) derived from infected imported animals. Subsequent recycling of infected Australian cattle through the same system might then have led to amplification of the disease and its possible establishment in the cattle population. Given this, it is clear that animals known to have died and to have been disposed of outside the commercial slaughter/MBM system were not relevant to the investigation.

Animals born after the adoption, in August 1997, of the ban on inclusion of ruminant-derived material in ruminant feed in North America. This criterion is an extension of the above — that is, cattle born after the adoption of the feed ban could not have been fed with MBM and could not therefore have been infected with the disease within the North American cattle herd.

Animals known to have been slaughtered commercially after the adoption, in October 1997, of the ban on inclusion of ruminant-derived material in ruminant feed in Australia. This criterion is an extension of the above — that is, cattle slaughtered after the adoption of the feed ban could not have been recycled in MBM to other cattle and could not, therefore have led to amplification of the disease within the Australian cattle herd.

Animals that are known to have been more than 10 years of age at the time of death. The incubation period for BSE is thought to range between 3 and 8 years (Wilesmith et al 1988, Anderson et al 1996). Since infection of UK and European cattle is believed to have occurred through the feeding of MBM to calves less than 6 months old (Wilesmith et al 1998), imported cattle more than 10 years of age that satisfied ante-mortem abattoir inspection were not considered a potential source of the BSE infectious agent. However none of the imported cattle fell into this category.

Table 1 Cattle imported from North America

Breed	Reason for removal from analysis					No of cattle remaining in analysis	No of farms of origin of risk cattle
	Number imported	Currently alive or re-exported.	Died on farm	Born after MBM ban in 8/97	Slaughtered after 10/97		
Angus	8	3	1	1	1	2	2
Beefalo	3	3	0	0	0	0	0
Brahman	86	72	2	9	1	2	1
Braunvieh	1	1	0	0	0	0	0
Dexter	10	9	1	0	0	0	0
Holstein	3	1	1	0	0	1	1
Jersey	6	5	0	1	0	0	0
Mini Hereford	11	7	0	0	0	4	1
River buffalo	2	2	0	0	0	0	0
Senepol	6	4	2	0	0	0	0
Shorthorn	1	0	0	0	1	0	0
Wagyu	211	159	4	2	29	17	1
Not specified	1	1	0	0	0	0	0
Total	**349**					**26**	**6**

The investigation was carried out in two phases.

The *first* (termed the 'release assessment') provided an estimate of the likelihood that the BSE infective agent would have entered Australia undetected in cattle imported from North America, and subsequently sent to slaughter, before the ban on ruminant-derived material in ruminant feed.[1]

The *second* phase of the investigation (termed the 'exposure assessment') provided an estimate of the likelihood that the BSE infective agent would have established undetected within the Australian cattle herd, if at least one BSE-infected animal had been imported and sent to slaughter before the ban. The exposure assessment was based on an examination of the 'pathway' of steps, or events, necessary for infection to have been disseminated from the carcass of an infected imported animal to the Australian cattle herd.

The results obtained from the release and exposure assessments were subsequently combined to provide an overall risk estimate. This two-stage approach enabled factors relevant to each of the assessments to be considered independently, but within the framework of the overall pathway of events necessary if BSE were to have established undetected in Australia.

[1] This is abbreviated hereafter as 'entry into the Australian cattle slaughter system'.

Release assessment

Data for the release assessment were obtained from two key sources:

- the published scientific literature on the epidemiology of BSE.
- a data base compiled for cattle imported from the United States and Canada - these data were compiled from a variety of sources, including quarantine station records, surveillance records on file and stud records supplied by owners and breed societies in Australian.

Correlation of risk factors identified in the scientific literature with the characteristics of imported animals enabled the identification of sub-populations for which the incidence of BSE is known to be markedly lower than that generally reported.

According to the National Agricultural Statistics Services, there were 109.5 million cattle, of which 47.9 million cows and heifers have had calves, in USA and Canada on January 1, 2004. Given only two cases of BSE have been reported in cattle in North America and that none of farms of origin of imported cattle have been implicated in the intensive and extensive investigations of the BSE cases in North America, the likelihood that one or more infected animals were imported and sent to slaughter is qualitatively interpreted as a ‘negligible’ likelihood.

Given that one indigenous cases of BSE was born in Alberta (where the imported case of BSE was detected in 1993) and the other in Saskatchewan, it is likely that cattle originating from this region may be considered to be at higher risk of BSE infection than cattle from elsewhere in North America. Four Mini-Herefords imported into Australia originated from Alberta and were born before the meat and bone meal ban came into effect in North America, may have been slaughtered before meat and bone meal ban came into effect in Australia in October 1997 and entered the food chain (slaughter dates unknown). Considering that there were 5,675,000 cattle in Alberta on 1 January 2004, and that none of farms of origin of imported cattle have been implicated in the intensive and extensive investigations of the BSE cases in North America, the likelihood that one or more infected animals were imported and sent to slaughter remains qualitatively interpreted as a ‘negligible’ likelihood.

Exposure assessment

The objective of the exposure assessment was to estimate the likelihood that the BSE infective agent would have established undetected within the Australian cattle herd, had at least one BSE-infected animal been imported from North America and sent to slaughter before the Australian ban on the inclusion of ruminant derived materials in ruminant feed.

In Scientific Steering Committee (SSC) parlance, this phase of the investigation equated loosely to an investigation of Australia's 'stability'. Stability is defined by the SSC as '*... the ability of a BSE/cattle system to prevent the introduction and to reduce the spread of the BSE agent within its borders ...*', and relies on '*... the avoidance of processing of infected cattle and the avoidance of recycling of the BSE agent via the feed chain ...*'. Under this terminology, the SSC maintain that '*a stable system would eliminate BSE over time*', and '*an unstable system would amplify it*'.

The SSC consider a country's 'stability' to be derived from several key factors, including practices or regulations regarding:

- the feeding of MBM to cattle
- the rendering of cattle-derived tissues
- the exclusion of particular tissues/organs from rendering.

The SSC also considered practices or regulations regarding the slaughter of 'fallen stock'[2], and characteristics of a country's surveillance for TSEs important to a country's 'stability'.

With these factors in mind, the exposure assessment was based on the following sequence of questions;

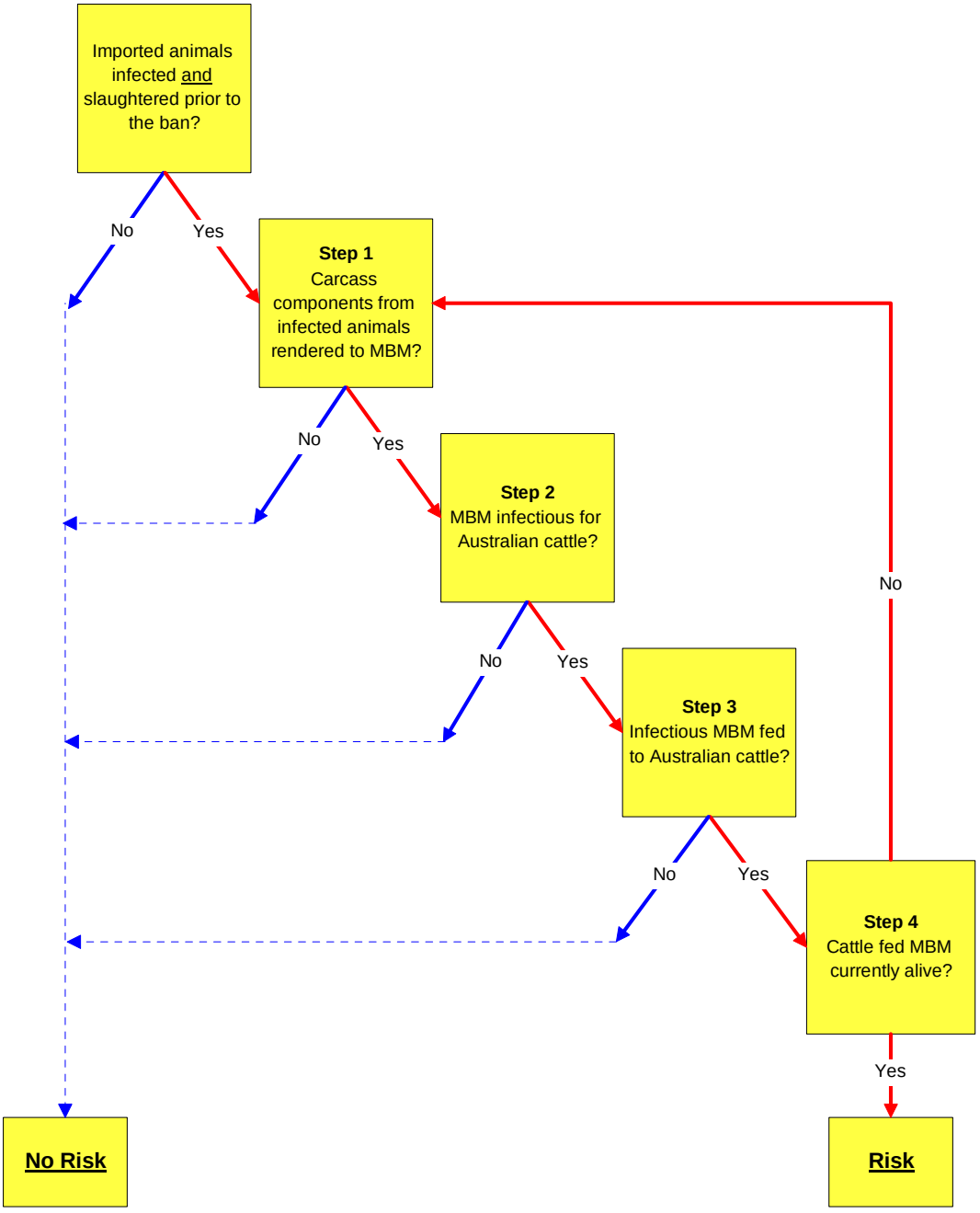
- would carcass components from a slaughtered infected (i.e. incubating or clinically affected) animal have been rendered to MBM?
- would MBM thus derived have been infectious for Australian cattle?
- would infectious MBM have been fed to Australian cattle?
- would Australian cattle fed infectious MBM remain alive and incubating the disease, or clinically affected but undetected by Australia's passive and active surveillance for BSE?

These questions, or steps, were viewed as risk-reducing factors, each of which would have contributed in a 'multiplicative' sense to final likelihood the BSE infective agent established within the Australian cattle herd, were an infected (incubating or clinically affected) animal imported and sent to slaughter (Figure 1).

The four steps are discussed individually.

[2] 'Fallen stock' are recumbent or seriously debilitated animals.

Figure 1 Steps in the exposure assessment



Step 1 - Would carcass components from a slaughtered infected North American animal have been rendered to MBM?

It can be assumed that at least some of the carcass components from any animal that was slaughtered in Australia would have been rendered to MBM.

Step 2 - Would MBM derived from a North American animal have been infectious for Australian cattle?

Three issues were considered relevant to this question;

1. the efficacy of Australian rendering systems as regards inactivation of the BSE infectious agent
2. the carcass components commonly rendered to MBM
3. the titre of BSE infectious agent in rendered carcass components

The efficacy of rendering in Australia. Processes employed by the 119 registered Australian rendering establishments are summarised below (European Commission, 2000; AFFA, 2000a);

- *Batch dry rendering*. Sixty of the Australian establishments use batch dry rendering, with conditions differing in accordance with the type of material to be processed. Typically, the lowest temperature for mixed raw material (including soft material) is approximately 120^0C, while the highest is approximately 145^0C. Cooking time ranges between 70 and 140 minutes.
- *Continuous dry rendering*. Forty of the Australian establishments use continuous dry rendering, with conditions differing in accordance with the type of material to be processed. Typically, the lowest temperature for mixed raw material (including soft material) is approximately 125^0C, while the highest is approximately 136^0C. Cooking time ranges between 35 and 90 minutes.
- *Continuous wet rendering*. Nineteen of the Australian establishments use various continuous wet rendering systems. The highest temperature for tallow is approximately 100^0C. Cooking time varies with the configuration of particular system and, in particular, with the addition of steam under pressure.
- *Processing in accordance with the EU standard*. Eight of the Australian establishments can transform ruminant material into MBM in accordance with the EU standard (batch conditions at 133°C, 3bar, 20min). Three of these are approved to export to the EU.

The European Commission's *Report on the Assessment of the Geographical BSE Risk of Australia* concluded that since not more than 3% of Australian rendering complies with the current EU standard, and because much of this portion is subsequently exported, Australian MBM should be classified as potentially infective. This extremely conservative position is likely to underestimate the complexity of the situation in Australia, where rendering in accordance with the range of protocols outlined above would be expected to lead to a reduction in the titre of the BSE infective agent, if not its complete inactivation. Indeed, in the report of the British Government's Review Committee (Review Committee, 2001) it is explained that;

- no rendering system will completely inactivate the BSE infective agent in MBM
- alteration of rendering practices in the UK prior to the BSE outbreak (specifically, the switch from batch to continuous processing and the removal of solvent extraction of tallow[3]) was likely to have added an 'enabling' effect to the dynamics of infection - that is, that while rendering practices in the UK prior to, and during, the 1970s would not have been completely effective in inactivating the BSE infective agent, they would probably have reduced its titre below the 'threshold' required for infection of 'susceptible' animals.

The Review Committee further qualified this by citing experimental evidence (Taylor et al, 1997) that suggested that alterations to rendering in the UK would have led to a reduction in the inactivation of

[3] According to the Review Committee, it is a common misconception that reduction in temperature or failure to prescribe minimum holding times in the rendering of carcass waste led to the failure of inactivation of the scrapie agent and transmission across the species barrier to cattle.

the BSE infective agent of approximately the same magnitude as required mathematically to produce the rate of infection observed in the UK epidemic. Given that rendering practices in Australia prior to the ban were at least comparable to those in the UK prior to, and during, the 1970s, it is reasonable to assume that the conclusions of the Review Committee would apply equally to the Australian situation - *viz*, that such practices are likely to have provided a 'degree of inactivation' sufficient to prevent infection, should livestock have been fed MBM derived from a BSE-infected carcass.

The carcass components commonly rendered to MBM. It is known that the so-called specified risk materials (SRMs) such as central nervous system (CNS) tissue (e.g. brain, brainstem and spinal cord) and the intestine[4] are generally rendered in Australia. It is also known, however, that mixing of SRMs and low risk materials, and of the carcass materials from different animals, is an integral feature of the rendering process.

The impact of thorough mixing in the context of Australian rendering plants is not clearly understood. On the one hand, mixing may have resulted in the subsequent exposure of a larger number of cattle. Alternatively, however, mixing would have led to a substantial dilution effect, as the 'proportion' of infected animals (should they have existed) would have been extremely low. In fact, since the likelihood that more than a single infected animal would have been imported and slaughtered in Australia is virtually zero, this proportion would most probably have been 'one over the very large number of animals processed in any day or run in an Australian meatworks'. In view of this, and of the additional mixing of SRMs and low risk carcass components, it can be seen that a dilution in the titre of infected material of at least several orders of magnitude would be expected.

Dilution equates intuitively to a reduction in the amount of infectious agent in MBM likely to have been consumed by any one animal. Whether the amount fed may still have exceeded the 'threshold' for infection discussed by the Review Committee (see above) cannot be determined. What can be said, however, is that dilution of this magnitude was not a feature of the situation in the UK prior to the BSE epidemic, where (a) a much higher proportion of animals were infected, and, (b) carcass components from a much smaller number of animals were generally rendered into any one batch of MBM.

The titre of BSE infectious agent in rendered carcass components. Research carried out in the UK (Wells et al, 1994; Wells et al, 1998; Wells et a, 1999) showed that tissue extracts from the small intestine of calves were infective to mice within 6-18 months after oral inoculation. Extracts from the bone marrow were infective 38 months after inoculation. However, the same studies also showed that tissue extracts from the CNS tissues were *not* infective until the onset of clinical illness. In other words, the tissues most likely to be relevant in the Australian context and in incubating animals, are not from the nervous system, but from the small intestine, particularly, the distal ileum (Wells et al, 1998). All studies on infectivity are conveniently summarised in the report of the British Food Standards Agency (FSA, 2000),

While the titre of infective agent in the ileum of incubating animals is likely to vary amongst animals, and with the stage of the disease, it is also likely to be substantially lower than the titre of infective agent associated with the CNS tissues of clinically affected animals. Moreover, the intestinal tissue component of carcass materials rendered to MBM is likely to be a very small proportion of the overall rendered mass. These factors would lead to a substantial dilution effect, over-and-above that which was attributed to 'mixing' of carcass components from different animals (see above). While it cannot be determined whether the resulting titre might still exceed the 'threshold' for infection, it is clear that

[4] From January 1 2001, the entire intestine was added to UK national legislation regarding SRMs derived from cattle of any age.

rendering of incubating animals only was not a feature of the situation in the UK prior to the BSE epidemic.

Summary

When the three issues associated with rendering were combined, it was considered very unlikely that MBM derived from an infected imported animal would have been infectious for Australian cattle.

Step 3 - Would infectious MBM derived from a North American animal have been fed to Australian cattle?

Table 2 summarises the production and utilisation of MBM in Australia between 1995/96 and 1997/98. Significantly, it can be seen that it was only in the 1995/96 year that a very small proportion (approx 2%) of MBM produced in Australia was utilised in cattle feed, whether directly or as a component of commercially produced feeds. The balance (approx 98%) was incorporated into pig, poultry and pet foods, or used as fertiliser.[5]

A voluntary ban on the use of ruminant material in ruminant feed was instigated in May 1996, prompting distributors of MBM and manufacturers of commercial cattle feeds to report zero utilisation for the 1996/97 year. It was reported in Australia's submission to the SSC that compliance with the ban was upheld rigorously by members of rendering, stockfeed and livestock associations. Any isolated instances of feeding of MBM to cattle ceased following the adoption of the official ban in October 1997.

Table 2 Production and utilisation of meat and bone meal in Australia in tonnes†

Year	Total	Dairy cattle	Beef cattle	Commercial cattle feed[6]	Total cattle (%)
1995 - 1996	423,500	< 5,000	< 1,000	< 1,000	< 7,000 (2%)
1996 - 1997	407,000	0	0	0	0
1997 - 1998	434,500	0	0	0	0

Source: Australian Stockfood Manufacturers Association

Summary

For the period of interest to this investigation before Australia adopted a ruminant feed ban, it would have been very unlikely for infective material, assuming that it entered the MBM system through the slaughter of an incubating animal, to have subsequently been fed to Australian cattle. Indeed, the odds of this event occurring are approximately one in fifty.

[5] Personal communication — Australian Stockfood Manufacturers Association, 2001.

[6] The term 'commercial cattle feed' is used to describe pelleted and other processed feeds. By comparison, the utilisation of MBM as food for 'dairy cattle' and 'beef cattle' implies its inclusion on-farm or in feedlots as a variable component of a ration.

Step 4 - Would Australian cattle fed infectious MBM derived from a North American animal remain alive and incubating the disease, or clinically affected but undetected by Australia's passive and active surveillance for BSE?

In order for cattle fed MBM that contained the BSE infective agent to affect Australia's BSE status they must currently be alive and, thus, a part of the national herd. Since BSE has not been diagnosed in Australia, these animals must also either; (a) be incubating the disease, or, (b) have become clinical cases but have eluded Australia's active and passive surveillance for BSE.

Three issues were relevant to this step in the assessment;

1. the survival profile of Australian cattle
2. the incubation period for BSE
3. Australia's passive and active surveillance for BSE

The survival profile of Australian cattle. Since the period of interest ran from 1 January 1996 to either May 1996 (voluntary feed ban) or October 1997 (legislated feed ban) (ie 6-8 years prior to the drafting of this report), it is apparent that most cattle fed MBM during that time will have been slaughtered or will have died on-farm. More specifically, *all* cattle that were in beef feedlots during that period will have been slaughtered (largely for export), while most dairy cattle will have exceeded the age of optimal productivity and economic return and are likely to have been culled. Some extensively farmed beef store cattle may remain alive, although the proportion slaughtered or otherwise dying each year will be increasing.

The incubation period for BSE. The incubation period for BSE appears to depend on a raft of poorly defined factors, but falls in most cases between 3 and 8 years (Wilesmith et al, 1988; Anderson et al, 1996). Thus, it is reasonable to expect that most animals infected during or before the period of interest and currently alive, would have developed clinical symptoms.

Australia's passive and active surveillance for BSE.

The chronology of Australian surveillance for BSE is summarised below.

- Before 1990, passive surveillance for BSE in Australia was based on the observations of skilled government and private veterinarians, as well as those of informed owners and handlers of stock. BSE was considered in the differential diagnosis of all bovine neurological disease. Brains submitted for histopathology were examined for evidence of BSE. No evidence of BSE was found.
- In 1990, an active surveillance program for BSE involving the examination of cattle brains was implemented. The number of cattle brains examined for histopathological evidence of BSE during various subsets of this period is shown in Table 3 below. During this time, passive surveillance through the differential diagnoses of veterinarians and the observations of the farming community continued. No evidence of BSE was found.

Table 3 Laboratory surveillance for BSE *prior to* the National TSE Surveillance Program (1998)

State / Territory	Period	Bovine brains examined
Tasmania	1992-1996	180
Western Australia	1990-1995	104
Victoria	1990-1995	600
New South Wales	1991-1995	1200
Queensland	1990-1996	957
South Australia	1991-1995	257
Northern Territory	Since 1/1/95	21
Total		**3319**

- Since 1994 BSE has been **compulsorily notifiable** in Australia.
- In 1998, a **National TSE Surveillance Program** (NTSESP) was implemented. The NTSESP is an integrated national program jointly funded by industry and governments and managed by the Australian Animal Health Council (AAHC). The NTSESP complies with the OIE Code chapter on BSE, which requires that countries claiming to be free of TSEs have in place a surveillance system to detect BSE and scrapie, should they occur.

The key outputs of the program are:

- examination of sufficient cases of nervous disease and chronic progressive disease or wasting in cattle and sheep through laboratory examination or treated and recovered reports to satisfy Australia's TSE surveillance targets
- an easily accessible and up-to-date national database of TSE surveillance information supported by detailed, eligible case records and laboratory specimens stored for at least 7 years — publication of results from TSE surveillance in Animal Health Surveillance Quarterly, the web site of the National Animal Health Information System (NAHIS) program and in Animal Health in Australia
- provision of information from TSE surveillance to support trade in Australia's livestock products and assure domestic consumers of beef and sheep meats of Australia's freedom from TSE in food animals.

Each State and Territory animal health agency, together with AQIS, participates in the NTSESP with a national coordinating role provided through the NAHIS (National Animal Health Information System) Coordination Group. Awareness and training programs on TSE surveillance are carried out through industry peak bodies, State and Territory animal health agencies and AQIS. A financial incentive scheme has been developed to increase reporting and investigation of eligible TSE cases by producers and private veterinarians.

Private veterinarians and officers of the State and Territory animal health agencies and AQIS, through existing networks, carry out clinical and/or post-mortem examination of eligible cases. Specimens are accompanied by a detailed case history. Initial histopathological examination of brains to specifically exclude a TSE is performed by pathologists trained in TSE diagnostic techniques — if required, further diagnostic investigations are undertaken by trained personnel located at Australian Animal

Health Laboratory. The TSE surveillance program complies with the current OIE International Animal Health Code, in which it is stated that the number of samples taken each year should be based on a 99% probability of detecting BSE, if the disease accounts for 1% of the cases of neurological disease in cattle.

The number of eligible cases of neurological disease in cattle and sheep requiring examination each year under the NTSESP is shown in Table 4 below. According to the OIE rationale, 400 cattle brains should be examined each year. Australia exceeds this number (459 cattle brains were examined in 2003) and targets specific sub-populations considered to be of a higher risk of BSE.

No evidence of BSE has been found in Australia.

Table 4 Number of eligible cases required to be examined each year under the National TSE surveillance program

State / Territory	Number of cases to examine each year	
	Cattle	**Sheep**
Queensland	156	40
New South Wales	100	153
Victoria	68	81
Tasmania	12	14
South Australia	16	50
Western Australia	24	112
Northern Territory	24	0
Total	**400**	**450**

- In addition to the NTSESP, passive surveillance through the differential diagnoses of government and private veterinarians, and the observations of the farming community, has continued. The level of training and awareness of both groups as regards neurological diseases of cattle and sheep has increased in step with the attention BSE has received internationally.

Summary

For cattle, fed MBM that contained the BSE infective agent, to affect Australia's BSE status they must be *alive*. Since BSE has not been diagnosed in Australia, these animals must also either; (a) be incubating the disease, or, (b) have become clinical cases, but have eluded Australia's active and passive surveillance for BSE.

From this, it was shown that:

- most animals fed MBM of ruminant origin between 1 January 1996 and the voluntary or legislated feed bans (1996 and 1997 respectively), would have died or been culled by the end of 2003
- *if* Australian cattle were infected during this period, it is very likely that most would have become clinical cases by the end of 2003

- *if* Australian cattle were infected and became clinical cases, they would almost certainly have been detected through ongoing passive and active surveillance for TSEs.

Conclusions: exposure assessment

The objective of the exposure assessment was to estimate the likelihood that the BSE infective agent would have established undetected within the Australian cattle herd, if at least one BSE-infected animal had been imported from North America after 1 January 1996 and sent to slaughter before the ruminant feed ban was implemented. The assessment was based on the following four questions, each of which *must* have been answered affirmatively for establishment within the Australian cattle herd to have taken place:

1. would carcass components from a slaughtered, infected (incubating or clinically affected) North American animal have been rendered to MBM?
2. would MBM thus derived have been infectious for Australian cattle?
3. would infectious MBM have been fed to Australian cattle?
4. would Australian cattle fed infectious MBM be incubating the disease, or be clinically affected but undetected by Australia's passive and active surveillance for BSE?

In answer to the *first* question, it was explained that at least some carcass components from all animals slaughtered in Australia are rendered to MBM.

Three issues were considered in answering the *second* question;

- the efficacy of Australian rendering systems as regards inactivation of the BSE infective agent
- the carcass components commonly rendered to MBM
- the titre of BSE infectious agent in rendered carcass components

These issues were considered in the light of the report of the British Government's Review Commission, where 'enabling' factors were described as key issues in the epidemiology of the UK BSE epidemic. In particular, the report described a 'threshold' titre of BSE infective agent in MBM that was most probably breached by a combination of altered rendering practices. The effect of the increased titre was subsequently exacerbated by the enhanced feeding of MBM to (notably) dairy calves.

When carried into the Australian context, this assessment showed that the titre of BSE infective agent in MBM was likely to have been substantially lowered by; (a) each of the various rendering practices used in Australia, (b) the degree of dilution that would have occurred in Australia if carcass components a single infected animal had been combined with a large number of uninfected animal, and, (c) the additional dilution that would have resulted from localisation of infection within the small intestine of incubating animals. Overall, the likelihood that MBM derived from an infected animal would have been infectious to Australian cattle was considered very low.

In answering the *third question*, the pattern of consumption of MBM in Australia prior to the ban was used to show that had infectious MBM been obtained from imported animals, it is very unlikely to have subsequently been fed to Australian cattle.

The *fourth* question was addressed by considering the survival profile of Australian cattle, the incubation period for BSE and Australia's passive and active surveillance for BSE. Here it was shown that *if* Australian cattle had been infected through the feeding of infectious MBM prior to the ban, it is very unlikely that they would remain both alive and incubating the disease. Given this, it was also shown that clinical cases of BSE would almost certainly have been detected through the range of passive and active surveillance systems in place in Australia. Most recently, this includes the NTSESP,

which meets the requirements for certification of ongoing freedom from BSE outlined in the OIE Code.

When the responses to these four questions were viewed in the context of a pathway of 'necessary' steps, the overall likelihood that BSE would have established undetected in the Australian cattle herd, had at least one infected animal entered the cattle slaughter system was considered negligible.

Assessment of overall risk

The objective of this study was to investigate the likelihood that BSE became established within the Australian cattle herd as a result of the importation of 349 cattle from North America between 1 January 1996 and 1 January 2004. The underlying premise was that in order to become established, the BSE infective agent was recycled through the feeding of MBM derived from infected imported animals. Subsequent recycling of infected Australian cattle through the same MBM system might then have led to amplification of the disease and its possible establishment in the cattle population.

The investigation was carried out in two phases.

The release assessment

A *qualitative* assessment of the likelihood that at least one infected animal entered Australia, and was subsequently slaughtered prior to the instigation of a ban on the inclusion of ruminant materials in ruminant feed. This assessment was based on the published scientific literature on the epidemiology of BSE; and on quarantine station records; surveillance records; and stud records describing the origin, importation details, management and (where relevant) disposal of imported animals.

The exposure assessment

A *qualitative* assessment of the likelihood that the BSE infective agent would have established within the Australian cattle herd, if at least one BSE-infected animal had been imported and sent to slaughter before the ban. This assessment was based on an examination of the 'pathway' of steps, or events, necessary for infection to have been disseminated undetected from the carcass of an infected imported animal to the Australian cattle herd.

From the release assessment it was found that the likelihood that one or more infected animals were imported and entered the cattle slaughter system is qualitatively estimated as a negligible likelihood. From the exposure assessment it was found that the likelihood that that BSE would have established undetected in the Australian cattle herd, had at least one infected animal entered the cattle slaughter system, was negligible. When the two results were considered together, the overall likelihood that BSE became established within the Australian cattle herd as a result of the importation of cattle from North America was also described as negligible.

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