AUSTRALIAN VETERINARY EMERGENCY PLAN

AUSVETPLAN

1998

Disease Strategy

Bovine spongiform encephalopathy (BSE)

AUSVETPLAN is a series of technical response plans that describe the proposed Australian approach to an emergency animal disease incursion. The documents provide guidance based on sound analysis, linking policy, strategies, implementation, coordination and emergency-management plans.

Agriculture and Resource Management Council of Australia and New Zealand

This Disease Strategy forms part of:

AUSVETPLAN Edition 2 1996

[AUSVETPLAN Edition 1 was published in 1991]

This strategy will be reviewed regularly. Suggestions and recommendations for amendments should be forwarded to the AUSVETPLAN Coordinator (see Preface).

Record of amendments to this manual:

[AUSVETPLAN Edition 2 was published in 1996]

[AUSVETPLAN Version 2.1 Final Document was published in 1998]

ISBN 0 642 24506 1

PREFACE

This **Disease Strategy** for the control and eradication of **bovine spongiform encephalopathy** (BSE) is an integral part of the **Australian Veterinary Emergency Plan**, or AUSVETPLAN (Edition 2). AUSVETPLAN structures and functions are described in the **Summary Document**.

This strategy sets out the disease control principles that were approved by the Agriculture Resource Management Council of Australia and New Zealand (ARMCANZ) out-of-session in January 1996, for use in a veterinary emergency caused by the introduction of BSE to Australia. This document has been amended to take into account developments that have occurred over the past few years.

BSE is designated as a List B disease by the Office International des Epizooties (OIE). List B diseases are 'Communicable diseases which are considered to be of socioeconomic and/or public health importance within countries and which are significant in the international trade of animals and animal products'. The principles contained in this document for the diagnosis and management of an outbreak of BSE conform with the **OIE International Animal Health Code 1997** (OIE Code; see Appendix 3).

BSE is not included in the Commonwealth/States cost-sharing agreement for the eradication of certain emergency animal diseases.

Detailed instructions for field implementation of the strategies are contained in the AUSVETPLAN **Operational Procedures Manuals** and **Management Manuals.** Cross-reference to strategies, manuals and other AUSVETPLAN documents are expressed in the form:

> Document Name, Section no.
> For example, **Decontamination Manual, Section 3**.

In addition, *Exotic Diseases of Animals: A Field Guide for Australian Veterinarians* by W.A. Geering, A.J. Forman and M.J. Nunn, Australian Government Publishing Service, Canberra, 1995 (**Exotic Diseases Field Guide**) is a source for some of the information about the aetiology, diagnosis and epidemiology of the disease and should be read in conjunction with this strategy.

This strategy will be reviewed regularly. Suggestions and recommendations for amendments should be forwarded to:

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The writing group was responsible for drafting this strategy. However, the text may have been amended at various stages of the consultation/approval process and the policies expressed in this version do not necessarily represent the views of all members of the writing group. Contributions may also have been made by other people not listed above and the assistance of all involved is gratefully acknowledged.

CONTENTS

1 NATURE OF THE DISEASE

Bovine spongiform encephalopathy (BSE) is a progressive neurological disease of adult cattle, characterised by a long incubation period followed by progressive degenerative disease and eventual death. The disease was first recognised in 1986, and probably arose because changed practices in processing meatmeal permitted transmission of the agent to numerous cattle. The disease in cattle has been sensationally referred to in the media as 'mad cow disease'.

1.1 Aetiology

BSE is caused by an unconventional agent, a *prion* that consists of an arrangement of an altered host protein, which can cause modification of the same protein when it is produced by the host, thus increasing the amount of pathogenic protein present in the host cells. Characteristic of these diseases is an accumulation of a protease-resistant form of a host cell membrane amyloid protein called PrP. The agent is extremely resistant to heat, irradiation and many chemical disinfectants.

In affected animals, the analogy of scrapie suggests that significant infectivity is likely to be present only in the central nervous system, and certain tissues in the lymphoreticular system. Experiments, although incomplete, suggest that the distribution of infectivity in BSE cases is no more widespread than in scrapie and probably is more restricted.

1.2 Susceptible species

BSE was first recognised in cattle in the United Kingdom in 1986. Spongiform encephalopathies were subsequently detected in zoo antelopes and both large and domestic felids. Cattle, sheep, goats, pigs, mice, mink and marmosets (but not chickens) have succumbed to a spongiform encephalopathy after experimental inoculation with large doses of brain from BSE-confirmed bovines. Oral transmission to sheep, goats and mink has been achieved, but pigs and chickens showed no evidence of spongiform encephalopathy four years after being fed brain from confirmed cases of BSE (Ministry of Agriculture, Fisheries and Food, UK 1994).

Spongiform encephalopathies occur naturally in humans at a rate of about 0.1 per 100000 per year. Recent evidence suggests that it is highly likely that the agents of BSE and new variant CJD are one and the same and that new variant CJD is acquired by consumption of central nervous system products derived from cattle infected with BSE (Blanchfield - IFST 1997).

1.3 World distribution and occurrence in Australia

Although isolated cases have occurred elsewhere (some possibly from imported feed), BSE is essentially confined to the United Kingdom and Ireland at present.

Table 1 Number of Reported Cases of BSE Worldwide

Country	**1987 and before**	**1988**	**1989**	**1990**	**1991**	**1992**	**1993**	**1994**	**1995**	**1996**	**1997**	**1998**
United Kingdom	442	2 514	7 228	14 407	25 359	37 281	35 090	24 436	14 560	8 150	4328	564
France					5		1	4	3	12	6	6
Ireland (Rep) *			15	14	17	18	16	19	16	73	77	29
Portugal*				1	1	1	3	12	14	29	30	34
Switzerland				2	8	15	29	64	68	45	38	4
Netherlands											2	...
Luxembourg											1	...
Belgium											1	3

* Includes imported animals

(OIE Data June 1998)

One case of spongiform encephalopathy was diagnosed in 1992 in a cheetah imported from the United Kingdom to a zoo in Western Australia.

1.4 Diagnostic criteria

Laboratory examination of tissues collected at postmortem examination is essential to confirm a diagnosis. However, affected animals have characteristic clinical signs. The long incubation period results in clinical signs usually appearing when animals are between two and five years of age.

It is advised that persons handling suspect animals or tissues take precautions to minimise the risks of exposure (see Section 2.2.5).

1.4.1 Clinical signs

The most frequent signs are apprehension, incoordination of hindquarters and excessive sensitivity to stimuli. Cows may paw the ground or constantly lick their nostrils. They develop a swaying gait, sometimes with high stepping of the feet, especially with the hind limbs. Cows may become aggressive and kick in the milking parlour. Weakness and loss of condition generally lead to slaughter before the animals succumb. The most common signs of disease in the initial stages (in decreasing order of frequency) are:

- nervous disposition
- kicking
- locomotor difficulty
- loss of condition
- loss of weight, reduced milk yield and abnormal behaviour

The Australian Animal Health Laboratory (AAHL) video, *A Tale of Transmission*, provides a clear demonstration of the clinical signs of BSE.

1.4.2 Pathology

There are no characteristic gross pathological changes but histopathology reveals spongiform changes in the brain and characteristic structures called scrapie-associated fibrils (SAFs) can be identified in the brain by electron microscopy.

1.4.3 Laboratory tests

Animal specimens should initially be sent to the State or Territory diagnostic laboratory from where they will be forwarded to the Australian Animal Health Laboratory (AAHL), Geelong for disease testing after obtaining the necessary clearance from the chief veterinary officer (CVO) of the State or Territory of the disease outbreak and informing the CVO of Victoria (for transport of the specimens to Geelong).

Specimens required/transport

The whole brain with the brainstem intact is removed from the skull of animals killed by intravenous barbiturate injection as soon as possible after death. A sample (3-10gm) of cervical spinal cord and/or medulla caudal to the obex, is frozen for possible detection of PrP^{Sc} by Western blotting or as scrapie-associated fibrils (SAFs) by transmission electronmicroscopy. The rest of the brain, after appropriate microbiological sampling, is fixed in neutral buffered 10% formol saline for histological examination.

For information on the collection of specimens see Geering et al 1995. For further information see the **Laboratory Preparedness Manual, Section 6 and Appendix 3**.

Laboratory diagnosis

AAHL tests: Laboratory diagnosis is based on histological changes in the brain (see Section 1.4.1, above). These tests can only be undertaken on tissues taken after death or euthanasia. Table 2 shows the tests for BSE that are currently available at AAHL.

Table 2 Diagnostic tests currently available at AAHL for BSE

Test	Specimen required	Test detects	Time taken to obtain result
Histopathology	formalin-fixed brain tissue	characteristic spongiform changes	2 days
Electron microscopy	fresh brain tissue	scrapie-associated fibrils	2 days
Isolation of agent by intracerebral inoculation into mice	fresh brain tissue	BSE agent	upwards to and beyond 1 year

Notes: As brain material is required for diagnosis, animals should preferably not be shot through the head. Brain material should still be submitted, however, even if the animal has been shot through the head.
Source: Information provided by AAHL, 1995 [refer to AAHL for the most up-to-date information].

1.4.4 Differential diagnosis

The following diseases must be considered in the differential diagnosis of BSE:

- acetonaemia and other metabolic disorders such as hypocalcaemia and hypomagnesaemia
- hepato-encephalopathy
- polioencephalomalacia

- perennial ryegrass staggers
- *Swainsonia* (Darling pea) toxicity
- other plant toxicities
- rabies
- lead poisoning
- bacterial encephalitis (eg listeria)
- space occupying lesions

It is expected that an occurrence of BSE would be associated with imported livestock. However contaminated veterinary therapeutics must also be considered a potential source of infection, along with contaminated surgical instruments. Where a contaminated therapeutic agent is the source of an outbreak, the disease would initially become much more widespread than if the source was imported livestock.

1.5 Resistance and immunity

1.5.1 Innate and passive immunity

The genetic effects on susceptibility to BSE are still under investigation in cattle. There is no evidence for passive immunity playing any part in resistance to BSE.

1.5.2 Active immunity

There is no acquired immunity to the BSE agent.

1.5.3 Vaccination

Vaccination is not applicable to this disease.

1.6 Epidemiology

The epidemiology of BSE is determined principally by the long incubation period and the mode of transmission. It is important to recognise that exposed animals may be infected with the agent for an unknown period before the onset of clinical signs.

1.6.1 Incubation period

The incubation period is prolonged. The peak incidence of BSE following exposure during calfhood has been among 4–5 years olds, with most cases occurring between 3 and 7 years of age. The OIE Code for BSE (see Appendix 3) states that BSE has a long incubation period measured in years.

1.6.2 Persistence of agent

Environment

The infectivity of the scrapie agent can persist for very long periods in the environment, up to 30 months having been recorded. The BSE agent is presumed to be similarly resistant (see Kimberlin 1992 for further details). Some infectivity remains after exposure to dry heat for 24 hours at 160°C and steam sterilisation is required (see Animal products/by-products, below).

Most common disinfectants, including ethanol, formaldehyde, iodophors and phenolics, are *not effective* against the agent (see Section 2.2.8). (Absolute decontamination might be almost

impossible. This may not be critical because it is unlikely that a sufficient quantity of the agent would be ingested from the environment compared to the higher concentration encountered during maternal transmission or by injection of a veterinary product.)

Live animals

Animals infected with spongiform encephalopathy agents have infective material principally in central nervous system tissues and lymphoreticular system. There is no immune response to eliminate the agent, and because the disease has a long incubation period, live clinically normal animals in the incubation period have been the principal source of introduction of disease into countries.

Animal products and by-products

The scrapie agent survives carcase decomposition and many of the procedures involved in the processing of product. Thermal processing requires steam heating at 134–138°C for 18 minutes to inactivate the agent (Kimberlin 1992). Refer to Appendix 5 for more data.

1.6.3 Modes of transmission

Live animals

There is no significant evidence for spread between cattle, either horizontally or vertically, although there is some evidence of direct transmission from dam to calf, but at a level insufficient to perpetuate the disease in the United Kingdom (Hoinville 1995). It also may be due to a common genetic predisposition. Spongiform encephalopathies have also been reported in antelopes in British zoos, where spread from dam to offspring may have occurred, and also in domestic cats in the United Kingdom. Recognition of these diseases was coincident with the appearance of BSE in cattle.

Artificial breeding

The agent is not known to be transferred in semen or embryos, however preliminary work is still in progress.

Animal products

BSE was first recognised in 1986, and epidemiological investigations suggest the disease occurred as a result of ingestion of meatmeal contaminated with high concentrations of the scrapie agent. Most cases were the result of calfhood exposure to the agent. An increase in the incidence of infections was probably caused by further increases in the concentration of the infective agent in meatmeal, as carcases of infected cattle were processed and entered the food chain via rendering plants. In addition, there may have been an increase in the infectivity of the agent for cattle after passage through this species.

Since the 1988 ban on feeding meatmeal in the United Kingdom there has been a progressive decline in BSE in the 1990s. This is illustrated in Figure l.

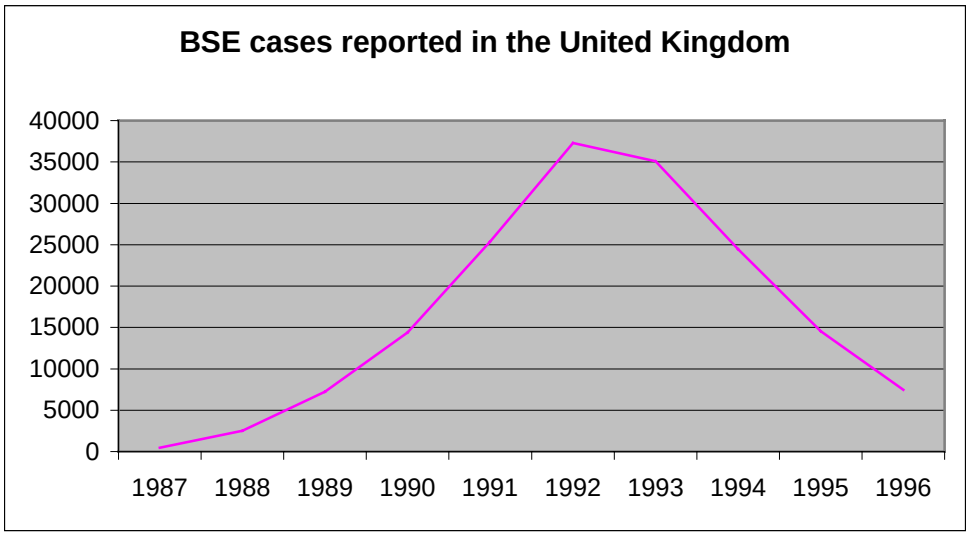

Figure 1

Biological products

Spongiform encephalopathy agents can be spread by inoculation of biologically derived therapeutic products (iatrogenic spread) such as:

- biological products derived from central nervous system extracts (in the same way as human pituitary gland extracts were contaminated with the agent for a human spongiform encephalopathy known as Creutzfeldt-Jakob disease agent); it is unlikely such a product would be legally imported and used;
- a therapeutic agent that has incorporated a contaminated ingredient in manufacture (for example contaminated brain heart infusion broth used as a substrate for a bacterial vaccine). While this poses a theoretical threat, there is no epidemiological evidence to suggest that this has been a source of BSE elsewhere.

Fomites

Transmission by fomites should not be a real concern. However, consideration should be given in particular to avoiding transmission by instruments used for veterinary applications and surgery.

Vectors

There is no documented evidence for transmission by insect or arthropod vectors.

1.6.4 Factors influencing transmission

The principle factor influencing the transmission of BSE is the feeding of meat and bone meals contaminated with the scrapie/BSE agent. Production practices in Australia generally mitigate against transmission of the agent. Australia has prohibited the feeding of meat and bone meal and compounded feeds containing ruminant materials to ruminants. Inoculation of a contaminated veterinary product has the potential to spread the infection more efficiently (see Section 1.7, below).

1.7 Manner and risk of introduction

Any occurrence of BSE in Australia can be reasonably expected to be an isolated event, the greatest risk being through the importation of infected livestock. It is possible that infected

cattle could have been imported from the United Kingdom before a ban was placed on importation and still be incubating the disease. However, since the ban was placed in 1988, it is now becoming most unlikely that clinical cases will occur in such stock which are maintained under government veterinary surveillance.

Transmission from contaminated biological products (iatrogenic spread) would require the source of the product to be outside Australia (unlikely to be approved), or for some contaminated material to be inadvertently included in a formulation (possible if the ingredient has passed through several suppliers).

Theoretically a sporadic instance of a form of spongiform encephalopathy could arise in an animal 'de novo' in Australia (or elsewhere).

2 PRINCIPLES OF CONTROL AND ERADICATION

The principles of eradication are:

- to slaughter all clinically-affected animals; and
- conduct a thorough risk assessment, including tracing of all high risk contacts.

The key consideration is whether the disease is associated with imported animals, has been introduced with biological products (iatrogenic transmission) or has spontaneously occurred (see section 1.7). In conjunction with an outbreak control program, there would need to be an increased level of surveillance of the national herd. Such a surveillance program would be designed to accommodate probabilities of the agent infecting other properties on a local, regional, state or national level.

Difficulty in achieving complete inactivation of the agent raises some particular concerns. There is a very low risk of horizontal transmission from contaminated carcases or fomites, except when large quantities are ingested, as in meatmeal. However, it is necessary to carry out intensive clean-up of areas identified as potentially heavily contaminated, eg necropsy sites and laboratories, because of the persistence of the agent in the environment. Efforts should be restricted to these areas.

2.1 Risk assessment

The risk assessment process aims to:

- determine the source of the outbreak;
- identify animals of equivalent risk status to the confirmed case(s); and
- classify the risk of infection in other groups of stock.

The following classifications are based on the assumption that the outbreak involves imported animals.

- *Affected* animals — those showing clinical signs of BSE.
- *Equivalent risk* animals — any imported cattle originating from the same property as affected animals, and the siblings (by the same dam) of affected animals.
- *Exposed* animals — the progeny of affected cattle that have been reared in close contact with those cattle (ie not resulting from artificial insemination or embryo transfer on other properties). Calves in contact (ie housed husbandry systems) with placenta of cattle later showing signs of BSE. from Appendix 1
- *Low risk* animals — the dams of affected animals; any recipient of semen or ova from affected animals; the progeny resulting from artificial insemination or embryo transfer from affected animals and those animals on the same premises which have not been in direct or indirect contact with affected animals .

The risk assessment process will be dynamic and adjusted according to the results of monitoring of equivalent risk, exposed and low risk groups (suspect animals). Different classes of animals would need to be individually identified.

Based on this risk assessment, the eradication strategy would include:

- establishing adequate security on identified premises (see Section 2.2.1);

- monitoring all deaths and regular surveillance (see Sections 2.2.2 and 2.2.3); and
- selective slaughter of stock (see Section 2.2.5).

2.2 Methods to prevent spread and eliminate pathogens

2.2.1 Quarantine and movement controls

Infected premises (IPs; containing affected animals) and suspect premises (SPs; containing equivalent risk, exposed or low risk animals) should be placed under quarantine in the first instance. Further quarantine and movement controls depend on the outcome of risk assessment. Long-term or lifelong quarantine of some groups may be considered necessary (see Appendixes 1 and 2).

Zoning

It is not anticipated that zoning is likely to be appropriate for BSE. It would be expected that, when first detected, disease would be confined to one property or a few foci that could be readily isolated.

2.2.2 Tracing

Tracing must be undertaken to establish the source of infection and to determine the presence of other potentially-infected herds. The order of priority should reflect the order of the risk categories listed above.

A major problem could arise in the event of implication of a therapeutic agent as the source of the disease. It is virtually impossible to confirm the contamination of a particular batch of the therapeutic agent, especially because of the long incubation period of the disease. Considerable industry cooperation would be required to determine the extent of the problem and to trace risks.

2.2.3 Surveillance

Suspect animals should be carefully examined at regular intervals to determine the presence of any characteristic clinical signs. Animals that develop clinical signs suggestive of BSE must be subject to laboratory examination of the central nervous system. When animals over 2 years old are slaughtered, a statistically valid sample must be monitored for evidence of BSE. Surveillance should be maintained for a prolonged period, bearing in mind the average incubation period of four years, and may need to be lifelong. Heightened monitoring of the national herd should occur. Active surveillance will be necessary to instil confidence in overseas markets. BSE is a notifiable disease and owners and veterinarians are obliged to notify animal health authorities of any illness, death or impending movement of suspect animals. BSE is a target disease under the National Animal Health Information System (NAHIS).

[Australia currently has a national Transmissible Spongiform Encephalopathy (TSE) surveillance program in place monitoring those animals developing suspect clinical signs.]

2.2.4 Treatment of affected animals

Treatment of animals is not possible.

2.2.5 Destruction of animals

Affected animals:

- Animals with the disease should be promptly slaughtered and incinerated or buried (see Section 2.2.7). This will remove real or perceived disease risks and allow a definitive diagnosis.

As brain material is required for diagnosis, animals should not be shot through the head. Shooting will also increase the risk of dissemination of the agent in the environment. It is recommended that any animal being destroyed for diagnosis be killed by the administration of intravenous barbiturate or any other acceptable method that do not damage the brain (see the (**Destruction Manual, Section 3.6**). Animals should be necropsied as close to the disposal site as possible.

Exposed or equivalent risk animals:

- As the number of these animals will only be small, suspect animals ('exposed' or 'equivalent risk') shall be slaughtered, brains collected and carcases disposed of by burial or incineration

Low risk animals:

- Animals may be slaughtered through domestic abattoirs and released for human consumption subject to negative results of histopathological monitoring.
- A protocol for inspection of carcases and removal and disposal of potentially infective offal such as abdominal viscera would need to be agreed upon.
- For animals of less than 2 years of age the carcases can be boned out. Appropriate eye and hand protection for abattoir and boning room workers should be provided.

2.2.6 Treatment of products

Regardless of treatment, because of the difficulty of ensuring complete inactivation of the BSE agent, it is largely impractical to treat products in order to decontaminate them. Products assessed as being a significant risk should be disposed of by incineration (see Section 2.2.7).

In 1996 SCARM banned the feeding of ruminant protein to ruminants.

2.2.7 Disposal

The OIE Code requires that affected cattle are slaughtered and completely destroyed (see Appendix 3, Article 3.2.13.4??).

Wherever possible, carcases should be burned. The burning of carcases must be under the supervision of disease control authorities to ensure that it is performed appropriately and that all contaminated material is completely burned. In selecting a site, consideration should be given to the future use of the area.

Where burning is not practical, carcases and other materials that cannot be adequately decontaminated should be buried in a site that will never be used for agricultural purposes (see the **Disposal Procedures Manual**). Consideration has to be given to the future use of the burial site, as the agent will remain in the soil for many months.

Some experimental work has been conducted in the United Kingdom, to determine criteria for rendering carcases that would ensure inactivation of the spongiform agent. The experiments

are protracted and expensive and may never reach a satisfactory conclusion due to lack of sufficient infective material. It is unlikely that rendering would be an acceptable means of disposal in Australia because the temperatures and pressures used would not be high enough to completely inactivate the disease agent (see Section 1.6.2, Appendix 5 and the **Red Meat Enterprises Manual)**.

2.2.8 Decontamination

Decontamination procedures should be undertaken on any materials that are contaminated through close contact with infected carcases. It is not necessary, however, to impose farm gate disinfection of materials leaving an infected or suspect premises (see Appendix 2).

For items that will withstand steam sterilisation, and whose value justifies it, autoclaving at 134–138°C for at least 18 minutes is recommended (see Appendix 5). Steam sterilising at 121°C in the presence of 1 molar (M) sodium hydroxide (40g/L) is also effective (Taguchi et al 1991). Sodium hypochlorite at a concentration of 1.4% will achieve surface inactivation in 30 minutes (see also Geering et al 1995). The only other chemical decontamination that is acceptable is exposure to 1M sodium hydroxide (40g/L) for at least 1 hour[1]. This will not guarantee absolute inactivation but has been shown to reduce infectivity by at least 6 logs (Brown et al 1986). Recent data from the United States suggested that an acid phenolic compound called LpH is also very effective for surface decontamination (Ernst et al 1993). This product is no longer available but a similar product is presently under evaluation.

Note: sodium hydroxide at this concentration is highly caustic and may cause damage to items being treated. It is also a hazard for operators who should wear eye protection. Any splashing on the skin should be followed by immediate rinsing with clean water. In the case of splashing in the eye, it should be irrigated with saline and medical attention sought immediately. However 1M sodium hydroxide has been suggested as a skin wash and disinfectant for persons working with the materials derived from Creutzfeldt-Jakob disease cases. It has been stated that unbroken skin will tolerate this concentration for about 5 minutes (Brown et al 1984).

Formalin fixation of infected tissues stabilises scrapie agent so that it cannot then be inactivated by steam sterilisation under the conditions described above. Exposure of formalin-fixed tissues to 100% formic acid for 18 hours will allow safe processing for histopathology examination. Residues of formalin-fixed tissues should be disposed of by incineration.

[1]Refer to Laboratory preparedness manual, Appendix 6.

In a recent BSE incident in Canada in 1994, the following specific decontamination actions were taken on the infected property:

- all manure in barns, corrals and runways was removed and stockpiled;
- all fences, fenceposts in the corral area and all walls and partitions in the barns were scraped down and faecal material added to the manure stockpile;
- fences, fence posts in the corral area, chute, barn walls and partitions were sprayed with a 2% chlorine wash followed by whitewashing;
- all watering equipment was scrubbed and rinsed with 2% chlorine;
- lime was spread on the ground of the corral and runways and then harrowed;
- equipment used in spraying and clean-up was cleaned and washed with 2% chlorine before leaving the infected premises; and
- in the spring the stockpiled manure was spread on cropland.

2.2.9 Vaccination

Not applicable.

2.2.10 Grazing management

There is no evidence to support excretion of the agent of BSE into the environment. Unlike scrapie, grazing management is not a useful adjunct to the control of BSE.

2.2.11 Wild animal control

Carcases must be disposed of in such a way as to prevent access by wild carnivores and omnivores and by osteophagic cattle and sheep.

2.2.12 Vector control

Not applicable.

2.2.13 Public awareness

Advice to the media must be carefully considered. It is necessary to inform the public, especially those in the livestock industries, of the circumstances of the outbreak and any trade implications. It is likely that fears will be raised about human health issues related to consumption of meat, and media sources could draw parallels with concerns raised in the United Kingdom. Early discussions with human health authorities is essential, in order to ensure that a consistent public health position is developed. In addition, advice should be given that products regarded as a significant risk of containing the agent would not be allowed to enter the food chain. These assurances cannot be provided with surety if the source of the disease is a therapeutic agent that has been widely used for some time. There may be some additional concern if the ingredient implicated as the source of the disease has been used to prepare human therapeutics.

There is also likely to be a considerable level of public concern if major trading partners decline to accept Australian exports. A perception that the domestic market is being supplied with an unsafe product is likely to arise. Media liaison officers need to be prepared for this issue.

The key points are to identify key spokespeople for each industry group, establish knowns and unknowns, involve journalists in the development of statements, rehearse scenarios and ensure coordination occurs between groups. (Workshop proceedings 1996)

2.3 Safety precautions

While spongiform encephalopathies occur naturally in humans, there is some circumstantial evidence that the BSE agent may be transmissible to humans. (Moon 1996) Persons involved in handling potentially-infected material must take adequate precautions to avoid exposure to these agents. Veterinarians, laboratory workers and slaughterhouse workers should wear gloves and eye protection when handling tissues suspected of containing high levels of the agent.

Care should be taken to minimise environmental contamination during necropsy procedures. Carcases should be disposed of carefully and instruments thoroughly decontaminated. More extensive decontamination of the environment should not be necessary.

Meat and meat products from affected and equivalent risk animals must not enter the animal or human food chain.

2.4 Feasibility of control in Australia

If there is an occurrence of BSE in Australia that can be linked to an introduced animal, and if forward tracing can identify all other potentially-infected stock, eradication of the disease will almost certainly be achievable. If BSE is found to be widespread and occurrences cannot be linked to each other, control of the disease will be more difficult. A specific policy and prolonged program of surveillance will then be necessary to achieve control and eradication.

If cases of BSE occur in imported animals located in a quarantine station (ie a ‘quarantine incident’), there is the option of using either the Commonwealth *Quarantine Act 1908* or the relevant State disease control legislation to effect control measures.

3 POLICY AND RATIONALE

3.1 Overall policy for bovine spongiform encephalopathy

Bovine spongiform encephalopathy (BSE) is an OIE List B disease that is significant in the international trade in cattle and cattle products.

The policy is to eradicate the disease as quickly as possible using a combination of strategies including:

- ***a total management plan*** **to focus the action on risk animals and to maximise the efficiency of the eradication program;**
- ***slaughter and sanitary disposal*** **of all clinically-affected, exposed and equivalent-risk stock (note - these terms have been specifically defined in Section 2.1);**
- ***depopulation*** **(partial or complete) should be undertaken if doubt exists concerning the status of animals in the herd.**
- ***quarantine*** **of all cattle on infected and suspect premises;**
- ***tracing and surveillance*** **to define the limits of the incident and provide additional evidence to re-establish free status;**
- ***risk assessment*** **to identify stock that have had any opportunity to acquire infection because of contact or lineage with confirmed cases; and**
- ***an awareness campaign*** **to facilitate cooperation from industry and the community.**

BSE would not be expected to be found beyond the initially infected property. It is not necessary to establish a restricted or control area.

A case of BSE is likely to have an effect on export trade in cattle and cattle products, at least in the short term, and may cause disquiet in the domestic beef and milk markets.

BSE is not included in the Commonwealth/States cost-sharing agreement.

The CVO(s) in the State(s)/Territory(s) in which the outbreak(s) occurs will be responsible for implementing disease control measures (in accordance with relevant legislation), and will make ongoing decisions on follow-up disease control measures in consultation with the Consultative Committee on Emergency Animal Diseases (CCEAD), the State/Territory and Commonwealth governments, and representatives of the affected industries. The detailed control measures adopted will be determined using the principles of control and eradication (Section 2) and epidemiological information about the outbreak. For further information on the responsibilities of the State/Territory disease control headquarters and local disease control centre(s), see the **Control Centres Management Manual, Part 1, Section 3 and 4**.

3.2 Strategy for control and eradication

The general strategy will be to destroy and dispose of affected animals immediately, quarantine the infected premises, and undertake tracing and a risk assessment of the information obtained so that more detailed eradication planning decisions can be implemented. The strategy will be irrespective of whether the source is an infected biological product, an imported animal, some other source such as a contaminated veterinary instrument, or occurred 'de novo'.

BSE is not considered a contagious disease; and it is unlikely to be transmitted either horizontally or vertically (although possible means of agent transmission needs further clarification). As long as the infected and equivalent-risk animals are destroyed, and the infected premises quarantined, the total situation can be determined based on laboratory assessment, tracing and risk assessment of the animals involved. Suspect properties identified by tracing will need to be quarantined and an appropriate level of movement controls placed on animals and products.

As the presence of the disease will lead to national and international disruption to trade, regular and ongoing liaison with industry, the media, public health officials and the public is an integral part of the strategy for eradication.

3.2.1 Stamping out

Stamping out may be adopted for some groups to overcome long and costly ongoing surveillance and quarantine, or due to international and/or domestic pressure.

The occurrence of disease in one or a few herds should be addressed by slaughter of all the affected cattle. Risk assessment will then define further actions and strategies. This may include slaughter and laboratory assessment of high risk (*equivalent risk* and *exposed* animals; see Section 2.1) groups. Further actions would be defined by findings from these animals.

In the event of an outbreak of BSE not traceable to imported animals, the source of the infection should be determined and investigations conducted (including the slaughter of sufficient animals) with a view to establishing the distribution and prevalence of infection.

3.2.2 Quarantine and movement controls

Quarantine will be imposed on the infected premises and suspect premises and movement controls on animals and products will be introduced in the short term until the situation is defined. Further decisions can then be made based on data from the epidemiological investigations. There will be few ongoing restrictions for most animals or products. The declaration of restricted and control areas for BSE is not warranted.

Refer to Appendixes 1 and 2.

Zoning

It is most unlikely that zoning of geographic areas would be appropriate for BSE, unless a widespread but geographically-defined outbreak of BSE was discovered.

3.2.3 Treatment of affected animals

There is no treatment that is effective and affected animals must be destroyed.

3.2.4 Treatment of animal products and by-products

There is no treatment of animal products from affected animals that is effective for normal commercial operations. The release and movement of by-products, such as hides, should not be impeded but ruminants must not be used for rendering for meatmeal or bonemeal. The OIE Code (Appendix 3 Article 3.2.13.3) outlines the minimum procedures that should be adopted for international trade of animal products. These same procedures should be adopted for domestic trade.

Crops and grains will not need to be restricted.

3.2.5 Vaccination

There is no vaccine and vaccination is not applicable.

3.2.6 Tracing and surveillance

Tracing will be required to determine the source of the introduction of the disease. The trace-forward of suspect premises will be based on previous contact with the affected animals on the infected premises. Further action will depend on the risk classification of the animals involved. Trace-back will attempt to locate the possible source, which is most likely to be due to a live animal introduction or the use of a contaminated biological product or some other iatrogenic source.

If the disease is due to a single administration of a biological therapeutic agent it is likely that there may be more affected animals at a number of different locations, all at a similar stage of degenerative neurological change. Information about the attack rate will assist in risk assessment of the index herd and surveillance of other herds exposed to the same product.

Failure to identify a source will prevent immediate definition of the index herd and necessitate more widespread investigation and surveillance before developing a control/eradication strategy.

3.2.7 Media and public relations

Special attention will need to be paid to media and public relations. It is highly likely that a case or outbreak of BSE will be widely publicised by the media as a potential risk to human health, leading to unnecessary public alarm and a significant decrease in beef consumption. This needs to be countered by the provision of precise information, appointment of key spokespeople and clear coordination between the relevant organisations (see the **Public Relations Manual**).

3.3 Social and economic effects

A major implication following the occurrence of BSE in Australia would be the costs associated with restrictions on Australia's international trade in livestock and livestock products. The selected strategy must address the concerns of major trading partners. BSE has recently been reported in Denmark(July 1992), Canada (November 1993), Germany (1992, 1994 and 1997), and Italy (October 1994), and in all cases the disease occurred in cattle imported from the United Kingdom. The regulatory authorities took rapid and drastic action to isolate the outbreaks, including the destruction of other imported and in-contact stock. In the recent Canadian outbreak, for example, all susceptible animals on the IP were slaughtered. A similar approach will be necessary to convince our trading partners that the outbreak has been eradicated.

Domestic consumer markets could also have concerns about product safety. This could affect local sales of beef and dairy products. It is likely that beef processing industries will be affected, and flow-on effects could bring considerable hardship. When the UK scare occurred in March 1996, meat sales fell 20% and prices were 28% lower for three months in Japan. Beef consumption in Germany fell 33% (Workshop 1996). Programs to restore consumer confidence may be necessary. Examples are provided in the workshop proceedings. However, other livestock industries may benefit as consumers switch to white and other meats.

An isolated occurrence of the disease in an imported animal to which authorities responded promptly should have minimal impact.

3.4 Criteria for proof of freedom

Proof of freedom will require rapid action to dispose of affected animals, and possibly high risk animals, and a thorough investigation and surveillance of suspect animals over time (using NAHIS). If these are few in number it may be better to slaughter the animals and examine the brain at the beginning of the control operation rather than subject them to ongoing, and possibly lifetime, surveillance. It will be necessary to ensure that producers and veterinarians are reporting cases of neurological disorders for full laboratory examination.

[Australia currently has a national Transmissible Spongiform Encephalopathy (TSE) surveillance program in place monitoring those animals developing suspicious clinical signs.]

Minimum requirements for effective surveillance are provided in Article 3.2.13.1 of the OIE Code (1996). This is reproduced in Appendix 3.

3.5 Funding and compensation

As BSE is not included in the Commonwealth/States cost-sharing agreement for the eradication of certain emergency animal diseases, funds to pay the costs of eradication, including compensation, will have to be found from other sources. Possible sources are:

- State government funds;
- State disease compensation funds;
- Commonwealth government funds;
- special industry levies; and
- other agreed arrangements.

Alternatively, the costs and losses might have to be borne by individual owners.

3.6 Strategy if the disease becomes established

It is highly unlikely that BSE would become established in Australia and the nature of cattle farming in Australia might reduce the efficiency of transmission of the disease in the field. However, if widespread spread occurred due to inoculation of a contaminated therapeutic agent, a protracted program of monitoring would be required with a high level of industry cooperation to eliminate the disease. Eradication of the disease would require extensive record keeping by commercial farmers and a program of accreditation for studs might be helpful.

APPENDIX 1 Guidelines for classifying declared areas

Infected premises (IP)
A premises classified as an IP will be a premises (which may be a paddock or part of a property) on which a case of BSE has been confirmed or is believed to exist.

Dangerous contact premises (DCP)
Not applicable.

Suspect premises (SP)
Premises classified as SPs will be premises containing suspect animals of the following risk assessment categories (see Section 2.1):

- *Equivalent risk* animals — any imported cattle originating from the same property as affected animals, and the siblings (by the same dam) of affected animals.
- *Exposed* animals — the progeny of affected cattle that have been reared in close contact with those cattle (ie not resulting from artificial insemination or embryo transfer on other properties). Calves in contact (ie housed husbandry systems) with placenta of cattle later showing signs of BSE.
- *Low risk* animals — the dams of affected animals; any recipient of semen or ova from affected animals; the progeny resulting from artificial insemination or embryo transfer from affected animals and those animals on the same premises which have not been in direct or indirect contact with affected animals .

Restricted area (RA)
Not applicable.

Control area (CA)
Not applicable.

APPENDIX 2 Recommended quarantine and movement controls

Infected premises	Suspect premises
Movement out of susceptible animals: Movement dependent on risk assessment.	Movement dependent on risk assessment.
Movement in of susceptible animals: No restriction but advise owner of implications.	No restriction but advise owner of implications.
Movement out of specified products: May need to restrict — negotiate at the time.	
Movement out of other animals: Control movement of sheep and goats.	
Movement in and out of people: No restriction.	
Movement in and out of vehicles and equipment: No restriction apart from equipment that has been in contact with slaughtered animals. Equipment will require decontamination before movement out of infected premises.	
Movement out of crops and grains: No restriction.	

APPENDIX 3 OIE International Animal Health code for BSE [revised and adopted in May 1998]

BOVINE SPONGIFORM ENCEPHALOPATHY (BSE)

Preamble: For diagnostic tests, reference should be made to the *Manual*.

Article 3.2.13.1.

Bovine spongiform encephalopathy (BSE) is a progressive nervous disease of adult cattle. BSE has a long *incubation period* measured in years, and arose from the consumption of contaminated ruminant protein.

The BSE status of a country or zone can only be determined on the basis of the following criteria:

1) risk analysis identifying all potential factors for BSE occurrence and their historic perspective, in particular:

   a) consumption by cattle of *meat-and-bone meal* of ruminant origin;

   b) importation of meat-and-bone meal potentially contaminated with a transmissible spongiform encephalopathy (TSE) or feedstuffs containing it;

   c) importation of animals or *embryos*/ova potentially infected with a TSE;

   d) epidemiological situation concerning all animal TSE in the country or zone;

   e) extent of knowledge of the population structure of cattle, sheep and goats in the country or zone;

   f) the origin of animal waste, the parameters of the rendering processes and the methods of animal feed production;

2) on-going education programme for veterinarians, farmers, and workers involved in transportation, marketing and slaughter of cattle to encourage reporting of all cases of neurological disease in adult cattle;

3) compulsory notification and investigation of all cattle showing clinical signs compatible with BSE;

4) a BSE surveillance and monitoring system with emphasis on risks identified in point 1) above, in conformity with the guidelines in Appendix 4.5.1.; records of the number and results of investigations should be maintained for at least seven years;

5) examination in an approved laboratory of brain or other tissues collected within the framework of the aforementioned surveillance system.

Article 3.2.13.2.

For the purpose of this *Code*, four categories of countries or zones with regard to BSE are defined according to the criteria listed in Article 3.2.13.1.:

BSE *free country* or *zone*

A country or zone may be considered free of BSE if:

1) a risk analysis, as described in point 1) of Article 3.2.13.1., has been conducted which demonstrates that appropriate measures have been taken to manage any risk identified;

2) a) the criteria in points 2) to 5) of Article 3.2.13.1. are complied with; or

b) the criterion in point 3) of Article 3.2.13.1. is complied with and it has been proven that for at least (period under study) no *meat-and-bone meal* has been fed to ruminants;

3) a) there has been no *case* of BSE; or

b) all cases of BSE have been clearly demonstrated to originate directly from the importation of live cattle or bovine *embryos*/ova, provided that suspect animals are slaughtered, investigated and, if disease is confirmed, completely destroyed; or

c) BSE has been eradicated (under study).

***Country* (or *zone*) that has not demonstrated a BSE free status and has not declared any indigenous cases of the disease** (definition under study)

A country or zone may be listed in this category if:

1) a) either no case of BSE has ever been confirmed; or

b) there has been no case of BSE for at least (period under study); or

c) all cases of BSE have been clearly demonstrated to originate directly from the importation of live cattle or bovine embryos/ova, provided that suspect animals are slaughtered, investigated and, if disease is confirmed, completely destroyed;

AND

2) at least one of the other requirements to be considered free is not met (under study).

***Country* or *zone with a low incidence* of BSE**

(definition under study)

***Country* or *zone with a high incidence* of BSE -** (definition under study)

Article 3.2.13.3.

Regardless of the status of the *exporting country*, *Veterinary Administrations* can authorise without restriction the import or transit through their territory, directly or indirectly, of the following commodities from healthy animals:

- milk and milk products;

- *semen*;

- protein-free tallow (maximum level of impurities of 0.15% in weight);

- dicalcium phosphate (with no trace of protein or fat);

- hides and skins, and

- gelatin and collagen prepared exclusively from hides and skins.

Article 3.2.13.4. (under study)

When importing from a *country* (or *zone*) that has not demonstrated a BSE free status and has not declared any indigenous cases of the disease, *Veterinary Administrations* should require:

<u>for cattle</u>

the presentation of an *international animal health certificate* attesting that:

1) the criteria listed in Article 3.2.13.1. have been applied;

2) the feeding of ruminants with *meat-and-bone meal* derived from ruminants has been banned and effectively enforced;

3) cattle selected for export are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin, and are not the offspring of BSE suspect or confirmed females.

Article 3.2.13.4bis.

When importing from *a country or zone with a low incidence* of BSE, *Veterinary Administrations* should require:

for cattle

the presentation of an *international animal health certificate* attesting that:

1) the criteria listed in Article 3.2.13.1. are complied with;

2) the affected cattle are slaughtered and completely destroyed;

3) the feeding of ruminants with *meat-and-bone meal* derived from ruminants has been banned and effectively enforced;

4) cattle selected for export:

   a) are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin and are not the offspring of BSE suspect or confirmed females;

   b) were born, raised and had remained in herds in which no case of BSE had been confirmed for at least (period under study); or

   c) were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal derived from ruminants has been effectively enforced; or

   d) originate from a country where all BSE infected cattle and herds are slaughtered and completely destroyed (under study).

Article 3.2.13.5.

When importing from a *country* or *zone with a high incidence* of BSE, *Veterinary Administrations* should require:

for cattle

the presentation of an *international animal health certificate* attesting that :

1) the criteria listed in Article 3.2.13.1. are complied with;

2) the affected cattle are slaughtered and completely destroyed;

3) the feeding of ruminants with meat-and-bone meal derived from ruminants has been banned and effectively enforced;

4) cattle selected for export:

   a) have never been fed ruminant meat-and-bone meal and were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal derived from ruminants was effectively enforced;

   b) are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin and are not the offspring of BSE suspect or confirmed females;

   AND

   c) either were born, raised and had remained in a herd in which no *case* of BSE had ever been confirmed, and which contains only cattle born on the farm or coming from a herd of equal status; or

   d) were born, raised and had remained in a herd in which no case of BSE had been confirmed for at least (period under study), and which contains only cattle born on the farm or coming from a herd of equal status.

Article 3.2.13.6. (under study)

When importing from a country (or zone) that has not demonstrated a BSE free status and has not declared any indigenous cases of the disease, *Veterinary Administrations* should require:

<u>for *fresh meat* (bone-in or deboned) and *meat products* from cattle</u>

the presentation of an *international sanitary certificate* attesting that:

1) the criteria listed in Article 3.2.13.1. have been applied;

2) the feeding of ruminants with meat-and-bone meal derived from ruminants has been banned and effectively enforced;

3) *ante mortem* inspection is carried out on all bovines;

4) fresh meat and meat products do not contain certain organs or tissues from cattle over thirty months of age that were born before the date from which the ban on the feeding of ruminants with meat-and-bone meal derived from ruminants was effectively enforced (under study)

Article 3.2.13.6bis.

When importing from *a country or zone with a low incidence* of BSE, *Veterinary Administrations* should require:

for *fresh meat* (bone-in or deboned) and *meat products* from cattle

the presentation of an *international sanitary certificate* attesting that:

1) the criteria listed in Article 3.2.13.1. are complied with;

2) the feeding of ruminants with *meat-and-bone meal* derived from ruminants has been banned and effectively enforced;

3) the affected cattle are slaughtered and completely destroyed;

4) *ante mortem* inspection is carried out on all bovines;

5) fresh meat and meat products do not contain brain, eyes, spinal cord or distal ileum from cattle over six months of age which were born before the date from which the ban on the feeding of ruminants with meat-and-bone meal derived from ruminants was effectively enforced.

Article 3.2.13.7.

(deleted)

Article 3.2.13.8.

When importing from *a country or zone with a high incidence* of BSE, *Veterinary Administrations* should require:

for *fresh* deboned *meat* and *meat products* from cattle

the presentation of an *international sanitary certificate* attesting that:

1) the criteria of Article 3.2.13.1. are complied with;

2) the affected cattle are slaughtered and completely destroyed;

3) the feeding of ruminants with *meat-and-bone meal* derived from ruminants has been banned and effectively enforced;

4) *ante mortem* inspection is carried out on all bovines;

5) the cattle from which the meat originates:

   a) were identified by a permanent identification system enabling them to be traced back to the dam and herd of origin;

   b) are not the offspring of BSE suspect or confirmed females; and either :

i) were born and had only been kept in herds in which no *case* of BSE had been recorded; or

ii) were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal derived from ruminants has been effectively enforced; or

iii) were born and had only been kept in herds in which no case of BSE had been confirmed for (period under study);

6) the tissues listed in Article 3.2.13.12. paragraph 1 are removed from all the cattle at slaughter and destroyed;

7) nervous and lymphatic tissues exposed during the cutting process have been removed and destroyed;

8) a system is in operation enabling the fresh meat and meat products destined for export to be traced back to the establishments from which they are derived.

Article 3.2.13.9. (under study)

When importing from a country (or zone) that has not demonstrated a BSE free status and has not declared any indigenous cases of the disease, *Veterinary Administrations* should require:

for bovine *embryos*/ova

the presentation of an *international animal health certificate* attesting that:

1) the criteria of Article 3.2.13.1. have been applied;

2) the feeding of ruminants with *meat-and-bone meal* derived from ruminants has been banned and effectively enforced;

3) embryos/ova for export are derived from females which:

a) are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin;

b) are not the offspring of BSE suspect or confirmed females;

c) were not suspected of being affected by BSE at the time of embryo collection;

4) the embryos/ova were collected, processed and stored strictly in accordance with Appendix 4.2.3.1.

Article 3.2.13.9bis.

When importing from *a country or zone with a low incidence* of BSE, *Veterinary Administrations* should require:

for bovine *embryos*/ova

the presentation of an *international animal health certificate* attesting that:

1) the criteria of Article 3.2.13.1. are complied with;

2) the affected cattle are slaughtered and completely destroyed;

3) the feeding of ruminants with *meat-and-bone meal* derived from ruminants has been banned and effectively enforced;

4) embryos/ova for export are derived from females which:

   a) are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin, and are not the offspring of BSE affected females;

   b) are not affected with BSE;

   c) were not suspected of being affected of BSE at the time of embryo collection; and

   d) either were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal derived from ruminants was effectively enforced; or

   e) were born, raised and had remained in herds in which no case of BSE had ever been confirmed; or

   f) were born, raised and had remained in herds in which no case of BSE had been confirmed for at least (period under study);

5) the embryos/ova were collected, processed and stored strictly in accordance with Appendix 4.2.3.1.

Article 3.2.13.10.

When importing from *a country or zone with a high incidence* of BSE, *Veterinary Administrations* should require:

for bovine *embryos*/ova

the presentation of an *international animal health certificate* attesting that:

1) the criteria of Article 3.2.13.1. are complied with;

2) all affected cattle are slaughtered and completely destroyed;

3) the feeding of ruminants with *meat-and-bone meal* derived from ruminants has been banned and effectively enforced;

4) embryos/ova for export are derived from females which:

    a) are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin, and are not the offspring of BSE affected females;

    b) are not affected with BSE;

    c) were not suspected of being affected by BSE at the time of embryo collection; and

    d) either were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal derived from ruminants was effectively enforced; or

    e) have never been fed ruminant meat-and-bone meal and:

        i) either were born, raised and had remained in a herd in which no *case* of BSE had ever been confirmed, and which contains only cattle born on the farm or coming from a herd of equal status; or

        ii) were born, raised and had remained in a herd in which no case of BSE had been confirmed for at least (period under study), and which contains only cattle born on the farm or coming from a herd of equal status;

5) the embryos/ova were collected, processed and stored strictly in accordance with Appendix 4.2.3.1.

Article 3.2.13.11.

Ruminant-derived *meat-and-bone meal*, or any feedstuffs containing such meal, which originate from *countries with a high incidence* of BSE should not be traded between countries.

Ruminant-derived meat-and-bone meal, or any feedstuffs containing such meal, which originate from countries or zones not free from BSE should not be traded between countries for use in ruminant feed. For other uses, the meal should have been processed in plants which are approved and regularly controlled by the *Veterinary Administration* following validation that each plant can achieve the processing parameters described in Appendix 4.3.3.1.

Article 3.2.13.12.

Brains, eyes, spinal cord, tonsils, thymus, spleen, intestines, dorsal root ganglia, trigeminal ganglia and bones, and protein products derived therefrom, from cattle over six months of age originating from *countries with a high incidence* of BSE should not be traded between countries.

The following commodities should not be traded between countries, unless they comply with the conditions laid down in Article 3.2.13.11.: brains, eyes, spinal cord, distal ileum, and protein products derived therefrom, from cattle born before the date from which the ban on the feeding of ruminants with meat-and-bone meal derived from ruminants was effectively enforced, and were at the time of slaughter aged over six month, if they originate from a country or zone with a low incidence of BSE.

The following commodities should not be traded between countries, unless they comply with the conditions laid down in Article 3.2.13.11.: (list under study), and protein products derived therefrom, from cattle born before the date from which the ban on the feeding of ruminants with meat-and-bone meal derived from ruminants was effectively enforced, and were at the time of slaughter aged over thirty months, if they originate from a country (or zone) that has not demonstrated a BSE free status and has not declared any indigenous cases of the disease (under study).

Article 3.2.13.12bis.

Veterinary Administrations of *importing countries* should require:

<u>for gelatin and collagen prepared from bones</u>

the presentation of an *international sanitary certificate* attesting that:

1) the bones came from a BSE *free country* or *zone*;

OR

2) the bones came from a country (or zone) that has not demonstrated a BSE free status and has not declared any indigenous cases of the disease, or from a *country* or *zone with a low incidence* of BSE; and

3) skulls and vertebrae (excluding tail vertebrae) have been excluded; and

4) the bones have been subjected to a process including:

   a) pressure washing (degreasing),

   b) acid demineralisation,

   c) either acid (under study) or prolonged alkaline treatment,

   d) filtration,

e) sterilisation at ≥138°C for a minimum of four seconds,

or using other methods that reduce the infectivity by at least 5 $\log_{10}$ LD_{50}/g.

Article 3.2.13.12ter.

Veterinary Administrations of *importing countries* should require:

for tallow (other than protein-free tallow)

the presentation of an *international sanitary certificate* attesting that:

1) it originates from a BSE *free country* or *zone*;

OR

2) it originates from a *country* (or *zone*) that has not demonstrated a BSE free status and has not declared any indigenous cases of the disease, or from a *country* or *zone with a low incidence* of BSE; and

3) if prepared by fat melting, has not been prepared using the tissues listed in the second paragraph of Article 3.2.13.12.;

4) if prepared from defatted bones:

   a) skulls and vertebral columns have been excluded;

   b) it has been processed using a method that reduces the infectivity by at least 5 $\log_{10}$ LD_{50}/g;

for tallow derivatives (other than protein-free tallow derivatives) in cosmetics and in pharmaceutical products

the presentation of an international sanitary certificate attesting that:

1) they originate from a BSE free country or zone;

OR

2) they originate from a *country* (or *zone*) that has not demonstrated a BSE free status and has not declared any indigenous cases of the disease, or from a country or zone with a low incidence of BSE; and

3) they have been produced by hydrolysis using high temperature and pressure.

Article 3.2.13.13.

Careful selection of source materials is the best way to ensure maximum safety of ingredients or reagents of bovine origin used in the manufacture of medicinal products.

Countries wishing to import bovine materials for such purposes should therefore consider the following factors:

1) the BSE status of the country and herd(s) where the animals have been kept, as determined under the provisions of Article 3.2.13.1. and Article 3.2.13.2.;

2) the age of the donor animals;

3) the tissues required and whether or not they will be pooled samples or derived from a single animal.

Additional factors may be considered in assessing the risk from BSE, including:

1) precautions to avoid contamination during collection of tissues;

2) the process to which the material will be subjected during manufacture;

3) the amount of material to be administered;

4) the route of administration.

APPENDIX 4 Procedures for surveillance and proof of freedom

The OIE guidelines for surveillance and monitoring to establish country freedom, taken from the BSE Code, are provided below.

4.5. EPIDEMIOLOGICAL SURVEILLANCE SYSTEMS

APPENDIX 4.5.1.

BSE SURVEILLANCE AND MONITORING SYSTEM

Surveillance for BSE requires the laboratory examination of brains from clinically suspect animals by histopathology and, if necessary, other methods described in the *Manual* (i.e. western blot, scrapie associated fibril examination and detection of abnormal PrP by immunohistochemistry). Since the histopathology of BSE is well described and remarkably consistent based on the experience of affected countries, histopathology alone is sufficient for BSE surveillance.

For surveillance purposes, testing a part of the population is consistent with Chapter 1.4.5. on Surveillance and Monitoring of Animal Health. Options for selecting the part of the population for testing include in decreasing order of relevance:

- **Examination of native-born animals displaying clinical signs compatible with BSE:** Screening the cattle population for animals displaying compatible clinical signs is the best approach for increasing the ability to detect BSE if it occurs. With this approach, animals displaying neurological signs or moribund cattle without signs of infectious or traumatic illness are candidates for examination of brain. Since BSE causes no pathognomonic clinical signs, all countries with cattle populations will observe individual animals with compatible clinical signs. Examination of the brains of these cattle may identify alternative diagnoses such as cerebral listeriosis, rabies or brain tumor. Surveillance should primarily focus on cattle over 24 months of age displaying behavioural and neurological signs lasting for at least 15 days and resistant to treatment. In countries where the incidence of progressive neurological diseases is low, surveillance may be extended to cattle over four years of age presenting clinical signs of progressive diseases.

  Table 1 indicates the minimum number of clinical cases that should be investigated by neurohistological methods according to the total native-born cattle population over 24 months of age. As this sampling is not random, the numbers indicated in this table are a subjective interpretation rather than a strict statistical deduction.

Table 1

Minimum number of annual neurohistological investigations of animals showing clinical signs compatible with BSE required for effective surveillance according to the total native-born cattle population over 24 months of age

Native-born cattle population over 24 months of age	Minimum number of brains to examine
500,000	50
700,000	69
1,000,000	99
2,500,000	195
5,000,000	300
7,000,000	336
10,000,000	367
20,000,000	409
30,000,000	425
40,000,000	433

- **Examination of selected subpopulations of higher risk animals:** Increases the ability to detect BSE if it is present. Higher risk animals include animals imported from countries or zones not free from BSE, animals which have consumed potentially contaminated feedstuffs from countries or zones not free from BSE, offspring of BSE-affected cows and animals which have consumed feedstuffs potentially contaminated with other TSE agents. Surveillance needs to target mainly animals over 24 months of age.

The efficiency of the surveillance is increased by a combination of the two above approaches.

- **Random sampling of cattle brains:** Since BSE is rare, even in countries with the highest incidence of disease, microscopic examination of brains from a random sample of the national cattle population is unlikely to detect a disease prevalence of 1 in 1,000,000 or more unless huge numbers of brains are examined.

APPENDIX 5 Experimental Protocols Used to Mimic Commercial Rendering Processes

			End temperature (C°)			Inactivation
Process	**Code**	**Particle diameter**	**Planned**	**Achieved**	**Time (Min)**	**BSE**
Batch atmospheric	B	150	120	121	150	YES
Continuous atmospheric (natural fat)	C	30	100-125	112	50	NO
	D	30	125	123	125	YES
	E	30	100-140	122	50	NO
	F	30	140	139	125	YES
Continuous atmospheric (high fat)	G	30	140	136	30	YES
	H	30	140	137	120	YES
Continuous vacuum (high fat)	I	10	125	120	20	NO
	J	10	125	121	57	NO
Continuous wet rendering (natural fat)	K	20	100-120	101	120	YES
	L	20	120	119	240	YES
	M	20	70	72	240	YES
Batch pressure (natural fat)	Q	50	133	133	30	YES
	R	30	136	135	28	YES
	S	30	145	145	28	YES

[From information presented by Dr Kevin Taylor, Assistant Chief Veterinary Officer UK, at the Workshop on the implications of International Disease Emergencies — BSE a case study October 1996.]

GLOSSARY

Animal by-products	Products of animal origin destined for industrial use, eg raw hides and skins, fur, wool, hair, feathers, hooves, bones, fertiliser.
Animal products	Meat products and products of animal origin (eg eggs, milk) for human consumption or for use in animal feeding.
AUSVETPLAN	A series of documents that describe the Australian response to emergency animal diseases, linking policy, strategies, implementation, coordination and emergency management plans.
Biological products	Reagents of biological origin (eg, sera, hormones) for therapeutic use in the diagnosis or treatment of certain diseases.
Consultative Committee on Emergency Animal Diseases	A committee, chaired by the Commonwealth Government (DPIE), of State/Territory CVOs, AAHL and CSIRO, to consult in emergencies due to the introduction of an exotic disease of livestock, or serious epizootics of Australian origin.
Control area	A bigger area than a restricted area (possibly as big as a State) where restrictions will reduce the chance of the disease spreading further afield (not applicable for BSE; *see* Appendix 1).
Declared area	A defined tract of land for the time being subject to disease control restrictions under emergency disease legislation. Types of declared areas include *restricted area; control area; infected premises;* and *dangerous contact premises.*
Decontamination	Includes all stages of cleaning and disinfection.
De novo	The emergence of a new disease
Disposal	Sanitary removal of animal carcases and things by burial, burning or some other process so as to prevent the spread of disease.
Emergency animal disease	Includes exotic animal diseases and endemic diseases that warrant a national emergency response.
Fomites	Inanimate objects (eg surgical equipment) that can carry the emergency agent and spread the disease through mechanical transmission.
Iatrogenic disease	A disease caused by medical/veterinary procedures, usually occurring as a side effect of pharmacological agents.
Incubation period	The longest period which elapses between the introduction of the pathogen into the animal and the occurrence of the first clinical signs of the disease.
Index herd	The first or original herd in which a case of the disease has been diagnosed (also, index case; index property).
Infected premises	*see* Appendix 1.
Local disease control centre	An emergency operations centre responsible for the command and control of field operations in a defined area.

Movement controls	Restrictions placed on movement of animals, people and things to prevent spread of disease.
Premises	A defined area or structure, which may include part or all of a farm, enterprise or other private or public land, building or property.
Prevalence	The number of cases of a specific disease (or infection or positive antibody titre) occurring in a given population at a particular time (expressed as the proportion of sampled animals with the condition of interest at a given time).
Quarantine	Legal restrictions imposed on a place or tract of land by the serving of a notice, limiting access or egress of specified animals, persons or things.
Rendering (of carcases)	Processing by heat to inactivate infective agents. Rendered material may be used in various products, according to particular disease circumstances.
Restricted area	A relatively small declared area (compared to a control area) around an infected premises that is subject to intense surveillance and movement controls (not applicable to BSE; *see* Appendix 1).
Risk assessment	Assessment of the relative likelihood of an event, taking into consideration all relevant available and unavailable information.
Risk enterprise	Livestock-related enterprise with a high potential for disease spread or economic loss.
Sentinel animals	Animals of known health status monitored for the purpose of detecting the presence of a specific emergency disease agent.
Spongiform encephalopathies	A group of diseases affecting various animal species all of which involve non-inflammatory vacuolated (spongiform) degeneration of the grey matter areas of the brain and spinal cord.
Stamping out	Eradication procedures based on quarantine and slaughter of all infected animals and animals exposed to infection.
State/Territory disease control headquarters	The emergency operations centre that directs the disease control operations to be undertaken in the State/Territory.
Surveillance	A systematic program of inspection and examination of animals or things to determine the presence or absence of an emergency disease.
Susceptible animals	Animals that can be infected with the disease (for BSE — mainly cattle; see Section 1.2).
Suspect premises	*see* Appendix 1.
Tracing	The process of locating animals, persons or things that may be implicated in the spread of disease, so that appropriate action is taken.
Viraemia	The presence of viruses in the blood.
Zoning	Dividing a country into defined infected and disease-free areas. A high level of movement control between zones will apply.
Zoonosis	Disease transmissible between animals and people.

Abbreviations

AAHL	CSIRO Australian Animal Health Laboratory, Geelong
ARMCANZ	Agriculture and Resource Management Council of Australia and New Zealand
BSE	Bovine spongiform encephalopathy
CCEAD	Consultative Committee on Emergency Animal Diseases
CJD	Creutzfeldt-Jakob Disease
CSIRO	Commonwealth Scientific and Industrial Research Organisation
CVO	Chief veterinary officer
DPIE	Department of Primary Industries and Energy
IP	Infected premises
OIE	World Organisation for Animal Health [Office International des Epizooties]
NAHIS	National Animal Health Information System
PrP	Protease-resistant form of host cell membrane protein
SAF	Scrapie-associated fibrils
SCARM	Standing Committee on Agricultural and Resource Management
SP	Suspect premises

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