PREVENTIVE MEASURES AND EXISTING REGULATIONS FOR BSE

Ray Bradley

Private BSE Consultant
Guildford UK

raybradley@btinternet.com

A presentation at the international conference 10-11 September 2003
Fort Collins, Colorado:
TSE in animal populations – Fact and Fiction
Session C – Management of TSE risk
GENERIC APPROACH

Based principally upon:

• Natural BSE in cattle
• Situation and experience in the EU and UK
• The main principles
ZERO RISK

A zero risk cannot be proved

therefore

the aim is to achieve effective

RISK REDUCTION
PRINCIPAL TSE OF MAN AND FOOD ANIMALS

Man
- Creutzfeldt-Jakob disease (CJD) sporadic form
- Variant CJD (vCJD)

Sheep and Goats
- Scrapie

Cattle
- Bovine spongiform encephalopathy (BSE)

Deer and Elk
- Chronic Wasting Disease (CWD)
TSE AGENTS

Single major strain of agent causes BSE

Several strains of scrapie agent, all different from BSE agent

Sporadic CJD agent(s) different from BSE and scrapie agents

vCJD agent different from scrapie and sporadic CJD agents
  BUT indistinguishable from the BSE agent

Conclusion and resulting concern:
  BSE is a zoonosis
  vCJD is caused by (dietary) exposure to the BSE agent
BOVINE MATERIALS ARE USED IN:

Human food

Animal feed

- Biologicals
- Pharmaceuticals
- Medical devices
- Cosmetics
- Plastics
- Fuel
- Building (cement, paint)
- Clothes (leather)

There is thus a theoretical BSE risk in these products if derived from BSE-infected starting materials. Measures are required to manage the risk.
MAJOR FACTORS DETERMINING SAFETY

Source
Process
Use

Principles can be applied to rendering, gelatine and tallow derivative manufacture
CATTLE TISSUES IN WHICH INFECTIVITY HAS BEEN FOUND BY BIOASSAY IN MICE AND/OR CATTLE

BRAIN

Trigeminal ganglia (not tested in natural BSE)

SPINAL CORD

Dorsal root ganglia (not tested in natural BSE)

RETINA, third eyelid (not tested in experimental BSE)

Distal ileum, Tonsil

Bone marrow (clinical phase only)

- **NATURAL BSE**
- **NATURAL and Experimental BSE**
- **Experimental BSE**
BOVINE SPONGIFORM ENCEPHALOPATHY

Cause: Increased exposure to a scrapie-like agent
Associated with: Concentrate feeding
Vehicle: Meat-&-bone-meal (MBM)
Because of: Changes in rendering and Inclusion of MBM in calf feed from 1970s (Horn, 2001)

But, MBM was recommended in calf diets even in 1952

(Miller and Robertson Practical Animal Husbandry (1952) p 405)
Horizontal and vertical transmission cannot be completely excluded though no plausible means of such transmission has been identified, particularly in the absence of a feed borne source.

Feed is the major, if not only source of natural infection for cattle.
PUBLIC HEALTH CONTROLS

Consumer Protection

AUG 1988
CARCASES OF SUSPECTS DESTROYED
Southwood

NOV 1989
NO SPECIFIED BOVINE OFFAL (SBO) TO HUMANS
MAFF

MAR 1996
DEBONE MEAT
Trimmings SBM
Vertebral column SBM
Head SBM
SEAC

Note: PFMA Members introduced SBO ban in June 1989

OTMS - MAFF/EC
MECHANICALLY RECOVERED MEAT (MRM)

Advanced Meat Recovery (US)

United Kingdom

• 1995 - not from bovine vertebral column

Precautionary principle (SEAC)

• 1998 - not from ruminant vertebral column

European Union

• April 2001- not from any ruminant bones
ANIMAL HEALTH CONTROLS

JUL 1988
RUMINANT FEED BAN
MAFF
EC 1994. Mammalian protein ban to ruminants
SEAC 1996. MMBM feed ban to all farmed species
EC 2001 Processed Animal Protein ban to all food animal species

AUG 1988
CARCASES OF SUSPECTS DESTROYED
Southwood

SEP 1990
NO SPECIFIED BOVINE OFFAL (SBO)
To animals
MAFF

Note: PFMA Members introduced SBO ban in June 1989
TEMPORARY EU FEED BAN FOR ALL FARMED ANIMALS KEPT, FATTENED OR BRED FOR FOOD

(Council Decision 2000/766 /EC)

No Processed Animal Protein* shall be fed to any farmed animal species kept, fattened or bred for food
From 1 Jan 2001

* MBM, bone meal, blood meal, dried plasma and blood products, hydrolysed proteins, hoof meal, horn meal, poultry offal meal, feather meal, dry greaves, fishmeal, dicalcium phosphate, gelatine and similar products.

No within species recycling of animal products or processed products. Reg 1774/2002
HUMAN FOOD AND ANIMAL FEED

Prepare animal feed from materials that are passed as fit for human consumption (CATEGORY 3 MATERIAL)

In particular include no processed or unprocessed experimental, laboratory, pet, zoo or circus animals, TSE-infected or suspected animals and material, animals killed for TSE elimination reasons, SRM, catering waste from international transport and certain other contaminated materials (CATEGORY 1 MATERIAL – Specific disposal required)

Or, digestive tract content, materials containing drug residues, import inspection failures, fallen stock of other domestic and wild animal species and parts of such animals and material not passed fit for human consumption (CATEGORY 2 MATERIAL – Specific disposal required)
MAJOR BSE RISKS
(worst-case scenario)
FROM
Clinical cases
Central nervous tissue
Distal ileum (Intestine)

Restricted tissue distribution of BSE infectivity in cattle compared with sheep with scrapie
SOLUTION

• Continuous awareness (OIE Code)
  Veterinarians, Farmers, livestock handlers
• Compulsory notification (Passive surveillance) (OIE Code)

• Compulsory slaughter

• Complete destruction (OIE Code)

In the EU this means:
  Incinerate or render by one of five approved methods including
  133°C, 3 bar, 20 minutes followed by incineration or co-incineration

• Laboratory confirmation (OIE Code and Manual) by State Veterinary Service
BSE RISKS IN FOOD PRODUCTS FROM:

- Live, healthy cattle
- Slaughtered cattle
FOOD PRODUCTS FROM LIVE, HEALTHY CATTLE

Milk

Milk products

Colostrum

WHO, OIE, EC, FDA agree that Milk has a negligible BSE risk and can be safely traded and used.

Precautionary Principle: Milk from cattle clinically suspected to have BSE must not be used for consumption except by the dam’s own calf.
BSE RISKS IN INFECTED, HEALTHY CATTLE

Brain, eyes and trigeminal ganglia
Spinal cord
Tonsil
Dorsal root ganglia
Distal ileum (intestine + mesentery) +
Any tissue contaminated with these
SRM

Render
133°, 3 bar 20 min
Incinerate

Stain with a heat-resistant dye

Landfill
SRM DEFINITION

Determined by:

Country risk level (Geographical BSE Risk Assessment - GBR)

Age of animal (all ages, > 6m, > 1 year, > 30 months)
Species (cattle, small ruminants = sheep and goats)

List of tissues to be removed (CNS, lymphoreticular, other)

Exclusions (e.g., in UK, vertebral column from cattle < 30 m)
SPECIFIED RISK MATERIAL (SRM)

Cattle

ALL MEMBER STATES

Cattle of all ages:

INTESTINES (duodenum to rectum) + mesentery

Cattle >12 months:

SKULL    BRAIN    EYES    TONSIL    SPINAL CORD

VERTEBRAL COLUMN (Excluding tail & TP of the thoracic/lumbar vertebrae & wings of the sacrum) + DRG - In UK Portugal & Sweden > 30 months

ADDITIONALLY IN UK & PORTUGAL #

Cattle >6 months:

HEAD (Excluding tongue)    BRAIN    EYE    TRIGEMINAL GANGLIA

TONSILS    THYMUS    SPLEEN    SPINAL CORD


# EXCEPT AUTONOMOUS REGION OF AZORES
FOOD PRODUCTS FROM
Slaughtered, healthy cattle

Meat
Blood
Fat
Offal
Processed products
MEAT, fat, blood and offal except SRM:

- Are inherently devoid of detectable infectivity
- BUT
- Could become infected by cross contamination from infected SRM if meat hygiene is poor or, from use of risk methods of stunning
STUNNING METHODS FOR CATTLE

HALAL/KOSHER

ELECTRICAL

NON-PENETRATIVE STUN

CARTRIDGE OPERATED CAPTIVE BOLT

PITHING

PNEUMATIC STUN GUN injects air under pressure into cranial cavity (Hantover)

LOWEST RISK

PITHING ROD

HIGHEST RISK

Air Compressor
CROSS-CONTAMINATION SOLUTIONS

• Effective *ante mortem* inspection
• Prohibition of risk methods of stunning
• Enforced high quality meat hygiene following HACCP principles

Additionally:
• OTMS (UK only). Recommended to abandon for animals born after 1 Aug 1996
• BAS (UK only)
• Rapid PrP Testing of cattle > 30 months old (Rest of EU). If the OTM rule is abandoned in UK testing will be substituted
GEOGRAPHICAL BSE RISK ASSESSMENT (GBR)

In the absence of a GBR it is difficult to ensure the BSE safety of imported cattle and cattle products because:

• Incubation period for BSE is long
• No operational test for BSE in the live animal or bovine products
Enables risk management criteria to be applied in a:

- Scientific manner
- Variable way related to the geographical risk

Anticipates possible future occurrence of BSE in a currently BSE-free country

e.g., Germany, Poland, Japan
The GBR is a:

**Qualitative indicator** of the likelihood of one or more cattle in a country being infected or affected with BSE at a given point in time

**Quantitative indicator** of the level of infection in a country where BSE has already been identified
THE GBR MODEL

Assumes an interaction between two factors:

Challenge  (By the BSE agent from imported or internal sources)

Stability  (Existence of, compliance with and enforcement of the measures)
THE GBR MODEL

EXTERNAL CHALLENGE

INTERNAL CHALLENGE

Native-born cattle

Measures (Stability)

SRM

MBM

Imported live cattle

Imported Feed

Imported MBM

Imported SRM

Imported Risk products
ASSESSING THE GBR OF A COUNTRY

Receive and analyse a complete dossier of epidemiological data and information showing:

• Structure and dynamics of ruminant populations
• Import data for live cattle, cattle products including MBM
• Cattle feeding practices
• Notification, MBM and SRM bans
• Measures to detect BSE + awareness
• Rendering practices and disposal of animal waste
• BSE-related culling

• Results of TSE active and passive surveillance
EC GBR RISK CATEGORIES

Category

I - Highly unlikely
II - Unlikely but not excluded
III - Likely but not confirmed or, confirmed at a lower level
IV - Confirmed at a higher level
<table>
<thead>
<tr>
<th>EC</th>
<th>OIE</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Highly unlikely</td>
</tr>
<tr>
<td>II</td>
<td>Unlikely but not excluded</td>
</tr>
<tr>
<td>III</td>
<td>Likely but not confirmed or confirmed at a lower level</td>
</tr>
<tr>
<td>IV</td>
<td>Confirmed at a higher level</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>OIE</th>
</tr>
</thead>
<tbody>
<tr>
<td>BSE-free country or zone</td>
</tr>
<tr>
<td>Provisionally free country or zone</td>
</tr>
<tr>
<td>Country or zone with a minimal BSE risk</td>
</tr>
<tr>
<td>Country or zone with a moderate BSE risk</td>
</tr>
<tr>
<td>Country or zone with a high BSE risk</td>
</tr>
</tbody>
</table>
GEOGRAPHICAL BSE RISK ASSESSMENT BY THE EC SSC

CATEGORY
I  Argentina, Australia, Botswana, Brazil, Chile, Costa Rica, Iceland, Namibia, New Caledonia Nicaragua, Norway, New Zealand, Panama, Paraguay, Singapore, Swaziland, Uruguay, Vanuatu  18

II  Canada, Colombia, Kenya, India, Mauritius, Nigeria, Pakistan, Sweden, USA  9

III  Andorra, Albania, Austria, Belarus, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Lithuania, Luxembourg, Netherlands, Poland, Romania, San Moreno, Slovak Republic, Slovenia, Spain, Switzerland, Turkey  29

IV  United Kingdom, Portugal  2
ANIMAL IDENTIFICATION

Newborn calves

Two eartags
Country, Unique herd No., individual No.
e.g., UK AG6279 00104
Tag within 36 hours (dairy) 30 days (beef)
Farm Register recording:
Date of birth
Breed
Sex
Dam ear No.
(Sire identification if known)
In UK submit details to British Calf Movement Service
(BCMS) within 15 days to receive PASSPORT
MOVEMENT AND PASSPORTS

Purpose
To record the life history from birth to slaughter or death

Agency
BCMS - >20 millions of movements pa

Responsibility
Seller
Purchaser

Record
Movement, slaughter, death
FARMS, PREMISES, HERDS AND HOLDINGS

Farm: Land and buildings used for agriculture

Premises: Any place where cattle are grazed, handled, held or kept

Herd: A group of cattle managed and kept separately

Holding: Premises comprising a single herd

• Herd identified by a unique number
• Holding identified by address and communication details
• Premises located by a unique map reference and Parish number

Computerised records held centrally by DEFRA
SUBSIDIARY MEASURES

Herd And Offspring Slaughter

Horizontal and vertical (maternal) transmission are biologically unproven. BSE-infected feed is the only known source of infection.

Compulsory herd and offspring slaughter are therefore of limited value.
COHORT SLAUGHTER

Feed cohort slaughter has some scientific merit, but by the time the first case in an exposed cohort is confirmed most of the cohort will be dead. Therefore it is of limited value, particularly if other measures are enforced. It may not be cost effective.
**Risk Analysis** (OIE Code)

**Hazard Identification**
The BSE agent

**Risk Assessment**
Largely complete but requires constant review

**Risk Management**
Largely complete but requires review as the risk assessment changes, new data and research comes forward and when the risk reduces
More stringent *versus* more relaxed

**Risk Communication**
Ongoing and vital to consumer confidence and understanding and international consensus
RISK COMMUNICATION IS VITAL

Openness, transparency, involvement (stakeholders)

**Upwards**
(with suppliers, researchers and Food Safety Agencies to gain information and establish the Farm to Fork principle)

**Laterally**
(to exchange information & enable co-decisions to establish consistency of approach within and between companies)

**Downwards**
(with consumers directly and by clear, accurate labelling of products to establish confidence in the safety, traceability and the Farm to Fork approach)
SOME PRINCIPLES OF RISK COMMUNICATION

Be open and consistent
Consult widely
Communicate uncertainties
Explain reasons for scientific advice
Keep simple and accurate
Respond quickly

Source: Joint WHO/FAO/OIE Technical Consultation on BSE Paris 11-14 Jun 2001
ROLE OF THE OIE

Fourfold Mission:

• Receive and rapidly disseminate animal disease reports
• Disseminate veterinary scientific information
• Promote international solidarity for animal disease control

• To guarantee the sanitary safety of world trade by developing sanitary rules for international trade in animals and animal products by providing normative documents such as the *Code* and *Manual* relating to rules that Member Countries can use to protect themselves from diseases, without setting unjustified sanitary barriers.
OIE Terrestrial Animal Health Code 2003

Chapter 3.2.13.

Provides the framework for safe international trading in cattle and cattle products

OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals

Provides information on approved diagnostic techniques
COMPLEXITY
BOVINE SPONGIFORM ENCEPHALOPATHY - BSE

BSE is a complex disease

BSE Measures are also complex

They may differ in:

- substance between countries
- relation to the BSE risk in the country
- the timing of introduction between countries
- the date of effective enforcement

From mid 1997-2003 in the EU, 42 legal documents have been issued
COMMUNITY LEGISLATION ON BSE SINCE MID-1997, REFERRING TO SCIENTIFIC OPINIONS - LEGAL TEXT

D 97/534/EC of 30 July 1997 Prohibition of the use of SRM (mainly brain, eyes and spinal cord)
D 98/272/EC of 23 April 1998 Epidemi-surveillance for all animal TSEs
Rec. 98/477/EC of 22 July 1998 Information necessary to support applications for the evaluation of TSE status
D 98/653/EC of 18 November 1998 Total ban on dispatch of live cattle and all cattle products from Portugal (Portugal embargo)
D 98/692/EC of 25 November 1998 Amendment of the UK embargo – Principles of the second step towards lifting the ban under the DBES in UK
D 99/881/EC of 14 December 1999 Postponement to 30 June 2000 of the date of application of D 97/534/EC(SRM)
D 99/724/EC of 28 October 1999 Health rules on gelatine
D 2000/418/EC of 29 June 2000 Prohibition of the use of SRM (Repeals D 97/534/EC)
D 2000/766/EC of 4 December 2000 Temporary ban on use of MBM
D 2001/25/EC of 27 December 2000 Prohibition of the use of dead animals in the production of animal feed
R 999/2001 of 22 May 2001 Prevention, control and eradication of certain TSE
R 1248/2001 of 22 June 2001 Amendment of R 999/2001 – Surveillance and testing
R 1328/2001 of 29 June 2001 Amendment of R 999/2001 – Transitional measures
R 270/2002 of 14 February 2002 Amendments of R 999/2001 – SRM, surveillance, animal feeding and placing on the market of ovine and caprine animals and products thereof
D 2002/670/EC of 20 August 2002 Amendment of D 98/256/EC – Adaptation of some DBES conditions
R 1494/2002 of 21 August 2002 Amendment of R 999/2001 – continuing of BSE testing in fallen stock Deletion of the restrictions on trade of bovine embryos – Clarifications of some SRM rules
D 2002/1003/EC of 18 December 2002 Survey of prion protein genotypes in sheep breeds
D 2003/100/EC of 13 February 2003 Breeding programmes for sheep
COMMUNITY LEGISLATION ON BSE SINCE MID-1997
REFERRING TO SCIENTIFIC OPINIONS - LEGAL TEXT  Continued

R 650/2003 of 10 April 2003 Import rules for live ovine and caprine animals
R 808/2003 of 12 May 2003 Incineration of animal by-products, treatment of wastewater from establishments handling animal by-products, treatment of mammalian processed animal protein
R 809/2003 of 12 May 2003 Processing standard for composting of animal by-products
R 810/2003 of 12 May 2003 Processing standard for biogas production using animal by-products
R 811/2003 of 12 May 2003 Intra-species recycling in fish, burial and burning of animal by-products
D 2003/321/EC of 12 May 2003 Processing standards for mammalian blood
D 2003/322/EC of 12 May 2003 Feeding of necrophagous birds with SRM
D 2003/324/EC of 12 May 2003 Intra-species recycling in fur animals
R 1053/2003 of 19 June 2003 Approval of new rapid tests
R 1128/2003 of 16 June 2003 Extending the transitional measures under the TSE Regulation
R 1139/2003 of 27 June 2003 Adding ileum to the list of SRM for small ruminants, new rules on the use of tongue and head meat of bovine animals

SOURCES:

Overview of the BSE risk assessments of the European Commission’s Scientific Steering Committee (SSC) and its TSE/BSE ad hoc Group
SIMPLICITY
MAJOR CRITICAL CONTROL POINTS

Feed ban
Destruction of clinical suspects
SRM ban
Rendering and other controls
  Starting materials - SOURCE
  Processing parameters - PROCESS
  End products - USE
Awareness of clinical signs & OIE Code
Active surveillance using ’Rapid’ tests
Meat hygiene regulations using HACCP principles
SUMMARY

Measures - Compulsory slaughter, Feed and SRM bans

Background - BSE a zoonosis, Feed is only significant route
Infected tissues are known and easily removed

Herd, cohort and offspring slaughter – limited value

Affected cattle and SRM - Incinerate or render and incinerate

Communication – Very important with all those in contact
with animals and risk products

Role of OIE – Crucial for animal health and trade
Terrestrial Code and Manual vital
ACKNOWLEDGEMENTS

DEFRA – Mr M Prince, Mr P Soul

EC DG SANCO – Dr AK Hakulin, Dr K van-Dyck, Dr P Vossen

Prosper de Mulder – Dr S Woodgate

Sedecon – Dr DM Taylor

VLA – Dr D Matthews, Mr SAC Hawkins, Mr GAH Wells