

Appendix 1 – Consolidated Scientific Evidence and Opinion

1. Specified Risk Material

1.1. General

KEY SCIENCE	EFSA/SSC ¹	SEAC ²	OTHER
<p><i>Ongoing Health Canada study, due for full report by March 2006. Should indicate:</i></p> <p><i>a) when positive animals can be detected using ELISA (BioRad), IHC or WB relative to clinical onset</i></p> <p><i>b) when positive animals can be detected using ELISA (BioRad), IHC or WB relative to exposure i.e. stage in incubation; and possibly relative to dose (100g v 1g)</i></p> <p><i>Will help in more accurately deciding on age for SRM removal and testing.</i></p>	<p>EFSA Opinion on a Quantitative Assessment of the Risk Posed to Humans by Tissues of Small Ruminants in case BSE is present in these animal populations, 8 June 2005</p> <p>Low risk related to consumption of goat meat and products, for goats born after 2001 feed ban</p>	<p>SEAC 87, April 2005: Reducing Age Limit for Vertebral Column from 30 months to 12 months</p> <p>Change in classification of vertebral column as SRM from 30 months to 12 months would make a very small to negligible difference in risk to consumers.</p>	
<p><i>Experimental challenge of red deer with 25g of BSE infected brain in progress. No evidence of transmission of BSE to red deer at 12 month interim kill. Parenteral challenge in progress will determine whether resistance is absolute or relative.</i></p>	<p>EFSA Opinion on Assessment of Age Limit for SRM Removal in Cattle, 27-28 April 2005</p> <p>Assumes infectivity of CNS appears at ¾ of incubation period.</p> <p>Minimum age of EU BSE cases increasing.</p> <p>30 month age limit for SRM (excluding tonsils and intestine) removal would not cover small number of young animals.</p> <p>21 month age limit would cover youngest animal since 2001 (28 months).</p> <p>Recommends establishing likelihood of infectivity in SRM derived from infected cattle at different age groups, by back calculation modelling with further assessment of experimental and epidemiological data.</p>	<p>SEAC 86, March 2005: SRM in Small Ruminants</p> <p>No evidence of BSE in current goat herds. Risk of consumption of goat meat and meat products very low. Recommend watching brief.</p>	
<p><i>Japanese National Institute for Animal Health has detected WB positives in peripheral nerves in a</i></p>	<p>EFSA Advice on “OIE-facilitated consultation between EU and USA on the Interpretation and</p>	<p>SEAC 75, Sept 2002: Ox Tongue and Associated Tonsils</p> <p>Noted uncertainty in risk</p>	

¹ European Food Safety Authority/ Scientific Steering Committee

² Spongiform Encephalopathy Advisory Committee

<p><i>fallen bovine. Vagus and adrenal subsequently submitted by VLA to Japanese – some positive. Additional nerves from same animals being tested by Japanese. If positive, will try to provide material from second VLA pathogenesis study to confirm timing of positivity. Further results expected by end 2005/early 2006.</i></p>	<p>Implementation of the OIE Standard on BSE, May 2004</p> <p>No conclusive evidence to enable definition of precise time, relative to incubation period or age, at which CNS becomes infected</p> <p>Cattle/Human species barrier unknown</p> <p>Previous precautionary approach (for CNS SRM) removal has been ½ age of youngest cases; where age used as surrogate for incubation period</p>	<p>assessment, particularly in relation to tonsillar infectivity. Potential risk of infectivity from consumption of ox tongue likely to be very small</p>	
<p>Pathogenesis of Experimental BSE: Preclinical Infectivity in Tonsil & Observations on the Distribution of Lingual Tonsil in Slaughtered Cattle, Wells et al. 2005 (Vet. Rec. 156 (401-407))</p> <p>Low level of infectivity in tonsil of cattle killed 10 months after exposure. Cattle pathogenesis study demonstrates early infection of distal ileum followed by later detection of infectivity in CNS, dorsal root ganglia and trigeminal ganglia.</p>	<p>EFSA Opinion on BSE Risk from Bovine Tonsil and Consumption of Bovine Tongue, 4 March 2004</p> <p>Tonsils of bovines of any age should be considered a risk. Tongues should be harvested to exclude lingual tonsil</p>		
<p>Experimental Transmission of Chronic Wasting Disease Agent from Mule Deer to Cattle by Intracerebral Route, Hamir et al. 2005, J Vet Diagn Invest 17(3)276-81</p> <p>Suggests CWD transmission in cattle could have long incubation period (5 years) and require a high dose orally.</p>	<p>SSC Opinion on Chronic Wasting Disease and Tissues that might carry a Risk for Human and Animal Feed Chains, 6-7 March 2003</p> <p>Cannot exclude transmission risk to humans and animals. Early widespread tissue distribution – difficult to define SRM</p> <p>No evidence of CWD in Europe but further surveillance necessary</p>		
<p>Full References contained in SSC Update of the Opinion on TSE Infectivity Distribution in Ruminant Tissues, Adopted 10-11 January 2002, Amended 7-8 November 2002</p>	<p>SSC Opinion on BSE Risk of Autonomic Nervous System, 6-7 March 2003</p> <p>Recommends further pathogenesis studies, but no justification for further removal of autonomic and peripheral nerves</p>		
<p>Full References contained in SSC Opinion on TSE Infectivity Distribution in Ruminant Tissues, State of Knowledge, December</p>	<p>SSC Update of the Opinion on TSE Infectivity Distribution in Ruminant Tissues, Adopted 10-11 January 2002, Amended 7-</p>		

2001	8 November 2002 Updated summary of current state of knowledge of infectivity in bovine, ovine and caprine tissues		
	SSC Opinion & Report Assessment on Human BSE Risk posed by Bovine Vertebral Column including Dorsal Root Ganglia, 16 May 2002 Risk from consumption of vertebral column and DRG depends on country consumption patterns and BSE incidence.		
	SSC Opinion on Safe Sourcing of Small Ruminant Materials (Should BSE in Small Ruminants Become Probable: Genotype, Breeding, Rapid TSE Testing, Flocks Certification and Specified Risk Materials), 4-5 April 2002 Summary of the distribution of infectivity in experimentally infected BSE-susceptible sheep. Tissues/organs that may contain BSE infectivity include head, spinal cord and dorsal root ganglia, spleen, peripheral nervous system, other lymphoid tissue, liver, pancreas, placenta and the alimentary tract including its lymph nodes and nerves.		
	SSC Opinion on TSE Infectivity Distribution in Ruminant Tissues, State of Knowledge, December 2001 Summary of current state of knowledge of infectivity in bovine, ovine and caprine tissues		

1.2. Tallow – see 2.3

1.3. Collagen

KEY SCIENCE	EFSA/SSC	SEAC	OTHER
	EFSA Opinion on Safety of Collagen and a Processing Method for Production of Collagen, 26 January 2005 Hydrolysis-based process		

	that has a conservatively estimated TSE inactivation capacity of 5 logs (currently used for pig/poultry bones which run a small risk of contamination with low-risk bovine bones).		
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1.4. Gelatine

KEY SCIENCE	EFSA/SSC	SEAC	OTHER
<p>Inactivation of the BSE agent by the heat and pressure process for manufacturing gelatine. Grobber et al. 2005 Vet.Rec. 157, 277-281</p> <p>Investigated whether autoclaving process used in industrial manufacture of gelatine (3 bar, 133°C, 20 minutes) inactivates the BSE agent. Crushed bovine bones and vertebral column spiked with the brains of mice infected with the 301V strain of BSE, subjected to simulated industrial gelatine-extraction process. No infectivity detected by intracerebral inoculation of mice with the extracted gelatine. Process calculated to reduce infectivity by at least 10 E6.5 ID50.</p>	<p><i>EFSA Opinion due in 2005</i></p>		
	<p>SSC Updated Opinion with regard to TSE Risks of Gelatine Derived from Ruminant Bones or Hides, 6-7 March 2003</p> <p>Three major factors – source material, effectiveness of inactivation process, end use.</p> <p><i>Processes which are guaranteed to eliminate all infectivity have so far not been described for products such as gelatine, tallow, MBM and dicalcium phosphate.</i></p> <p>Parts of bovine hides used for gelatine production do not present a TSE risk, provided contamination avoided.</p> <p>Risk of TSE contamination with TSE infectivity is much</p>		

	higher with bones than with hides. Method of production of safe gelatine specified.		
	<p>SSC Report on the Current State of Knowledge on the TSE Infectivity Clearance Capacity of Various Gelatine Production Processes, 5 September 2002</p> <p>A summary of methods, including four (inactivation capacity >4.5 logs) that when used with appropriate raw material sourcing, will reduce end product TSE risk close to zero.</p>		

2. Feed Ban

2.1 Environmental Contamination of Beet Pulp

KEY SCIENCE	EFSA/SSC	SEAC	OTHER
		<p>SEAC 80, November 2003: Infectivity in Bone Marrow</p> <p>The level of infectivity in sternal bone marrow is at most very low, but further study is recommended.</p>	<p>Bone Fragments in Beet Cossettes, Updated Expert Opinion No. 005/2005 of German Federal Institute for Risk Assessment (BfR) January 2005</p> <p>Genetic tests indicate rodent, pig and human bone. In the opinion of BfR there is no BSE risk associated with these beet cossettes contaminated with bone fragments.</p>

2.2 Fish meal/Lifting Feed Ban Provisions

KEY SCIENCE	EFSA/SSC	SEAC	OTHER
<p>Area-Level Risks for BSE in British Cattle Before and After the July 1988 Meat and Bone Meal Feed Ban, Wilesmith et al. 2005 Prev.Vet.Med. Jun 10;69 (1-2):129-44</p> <p>After July 1988 UK ban on feeding MBM to ruminants, the risk increased in areas with greater numbers of pigs relative to cattle indicating cross contamination.</p>	<p>SSC Opinion on the Feeding of Wild Fish meal to Farmed Fish and Recycling of Fish with Regard to TSE, 6-7 March 2003</p> <p>From the limited available research results, scientific literature on TSEs in fish and routine examination of fish brain, it can be concluded that there is no evidence that a natural TSE exists in fish and there are no indications of replication of scrapie or</p>		<p>Review of the Evidence for the Occurrence of BSE Cases in Cattle Born After the Reinforced Feed Ban in UK, Hill 2005⁴</p> <p>Exceptionally low doses (1mg) of BSE-infected neural tissue can infect calves</p> <p>Control of BSE requires complete elimination of BSE agent from cattle feed chain</p> <p>Feed controls should be</p>

³ EC 2002. Interim results (2002) of FAIR CT97 3308 Project

⁴ <http://defraweb/animalh/bse/pdf/hillreport.pdf>

	<p>BSE agent in experimental transmission studies. There is no evidence that the feeding of wild fish meal to farmed fish presents any TSE risk to human or animal health.</p> <p>However the transmission research³ is incomplete and other data sources are limited</p>		tightened up.
<p>Poultry, Pig and the Risk of BSE Following the Feed Ban in France – A Spatial Analysis, Abrial et al. 2005 Vet.Res. July-August;36(4):615-628</p> <p>After July 1990 French ban on feeding MBM to ruminants, the risk increased in areas with greater pig density indicating cross contamination.</p>	<p>SSC Statement on its Report and Scientific Opinion on Mammalian Derived Meat and Bone Meal forming a Cross-Contaminant of Animal Feedingstuffs adopted 24-25 September 1998, 26-27 October 2000</p> <p>In principle, the cross contamination of animal feed with mammalian meat and bonemeal (MMBM) is not acceptable.</p> <p>Feed contaminated above levels that can be reliably quantified should be condemned.</p>		<p>Update on Research into Detection of Mammalian Protein, Advisory Committee on Animal Feedingstuffs, 2002 & Defra Website 2004 & VLA Luddington 2005</p> <p>Microscopy Analysis Test (MAT) is only EU officially recommended test. Currently unable to reliably detect a 0.1% MMBM level in presence of 5% fishmeal in feed.</p>
	<p>Intra-Species Recycling – SSC Opinion on the Risks born by Recycling Animal By-Products as Feed with regard to Propagating TSE in Non-Ruminant Farmed Animals, September 1999</p> <p>Evidence that pigs susceptible to intra-cerebral TSE infection. No evidence of natural TSE in pigs, poultry or fish. However possibility cannot be excluded.</p> <p>Recycling increases risk of TSE cases or undetected pool of infection. Intra-species recycling worse because no species barrier.</p>		<p>Conclusions of Advisory Committee on Animal Feedingstuffs on the Feeding of Fish Meal to Farmed Animals, May 2001</p> <p>No specific risks to animal or fish health from the inclusion of fish meal in animal or fish feed.</p> <p>Cross contamination or adulteration of fish meal with meat and bone meal (MBM) unlikely when material arrives in UK direct from South America</p> <p>Risk of cross contamination of fish meal with MBM, would not warrant a ban providing existing rules on MBM use fully adhered to, and there is assured and protected production/ supply chain</p>
	<p>SSC Opinion on the Risks of Non-Conventional Transmissible Agents, Conventional Infectious Agents or Other Hazards such as Toxic Substances Entering the Human Food or Animal Feed Chains via Raw Material from Fallen</p>		

	<p>Stock and Dead Animals or via Condemned Materials, June 1999</p> <p>Recycling or disposal of condemned animals/materials should not lead to any direct human consumption. Also indirect human consumption by use of animals fed with condemned animals/materials should be avoided.</p>		
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2.3 Tallow

KEY SCIENCE	EFSA/SSC	SEAC	OTHER
<p>Unpublished Data from VLA, 2005</p> <p>Unpublished data from a pressure rendering study indicates that BSE infectivity <u>can</u> survive in tallow recovered by centrifugation and tallow recovered by solvent extraction.</p>	<p>EFSA Opinion on the Assessment of the Human and Animal BSE Risk Posed by Tallow with respect to Residual BSE Risk, 27-28 April 2005</p> <p>EFSA assessed the validity of the outcome of a quantitative risk assessment (QRA) of the residual BSE risk in tallow. The QRA supports the general conclusions of the 2001 SSC Opinion and Report on the safety of tallow. The estimates of risk for tallow production and use, as specified in the 2001 Opinion, are low. This may have implications for relaxation of the rules. In general the calculated exposure levels can be regarded as minimal.</p>	<p>SEAC 83, June 2004: BSE Infectivity of Tallow</p> <p>This relates to SEAC's consideration of an update on the findings of an experimental rendering study. The study showed some partitioning of infectivity into tallow. SEAC indicated that issues relating to tallow and infectivity could be considered again when EFSA published its conclusions.</p>	
<p>Rendering Practices and Inactivation of Transmissible Spongiform Encephalopathy Agents, Taylor 2003 (Rev.Sci.Tech.Int.Epiz. 22(1),297-310)</p> <p>133°C, 3 bar, 20 minute rendering method might not be robust under worst-case conditions. One study⁵ reported survival of some BSE infectivity when spiked raw material was subjected to the process.</p> <p>Solvent extraction can be used to enhance the yield of tallow and produce low-fat</p>	<p>SSC Opinion on the Safety of Tallow Derivatives from Cattle Tallow, April 2003</p> <p>Tallow derivatives safe with regards to BSE risk if derived from food or feed grade tallow and cross contamination prevented.</p> <p>Tallow derivatives safe with regards to BSE risk if they are derived from lowest risk categories (GBR-C I)¹⁰ and fallen stock excluded.</p> <p>For GBR-C II countries, tallow derivatives safe if fallen stock excluded,</p>		

⁵ Schreuder et al.1998 Studies on the efficacy of hyperbaric rendering procedures in inactivating BSE and scrapie agents. Vet.Rec.142,474-480

<p>MBM. Solvent extraction experiments⁶ on solid material derived from rendered BSE and scrapie infected tissue, demonstrated that, on average, the solvent extraction systems achieved approximately a ten-fold⁷ reduction in the titre of the TSE agents tested.</p> <p>Tallow has been considered generally to be relatively free from BSE risks because-</p> <p>i) Epidemiological studies⁸ have failed to find any association between occurrence of BSE and consumption of tallow.</p> <p>ii) In BSE-spiked rendering studies⁹, no infectivity was found in crude, unfiltered tallow produced by a rendering procedure that produced MBM with almost as much infectivity as was present in the untreated, BSE-spiked raw material.</p> <p>Unrealistic to consider that tallow could never become contaminated with BSE agent. Source material and levels of suspended solids affect risk.</p>	<p>animals are fit for human consumption, various other production standards are met (including filtration) and cross contamination prevented.</p> <p>For GBR-C III and IV countries, tallow derivatives safe if SRMs have been removed, in addition to the requirements for GBR-C II countries.</p>		
	<p>SSC Revised Opinion and Report on the Safety of Tallow obtained from Ruminant Slaughter By-Products, 28-29 June 2001</p> <p>No evidence that ruminant tallow constitutes a TSE risk. SSC considers that possible TSE risks associated with tallow will result from protein impurities in end product.</p>		

⁶ Taylor et al. 1998 Solvent extraction as an adjunct to rendering: the effect on BSE and scrapie agents of hot solvents followed by dry heat and steam. Vet.Rec. 143,6-9

⁷ Brown P. 2001 Bovine spongiform encephalopathy British Medical Journal 322, 841-844 - indicates that a one log reduction might have been sufficient for infectivity to survive the process and contaminate the MBM produced.

⁸ Wilesmith et al. 1988 BSE Epidemiological studies on the origin. Vet.Rec.128,199-203

⁹ Taylor et al. 1995 Inactivation of the BSE agent by rendering procedures. Vet.Rec.137,605-610

¹⁰ Geographical BSE Risk is qualitative indicator of the likelihood of the presence of one or more cattle being infected with BSE, at a given point in time in a country. GBR I = highly unlikely; GBR IV=confirmed at a higher level

	Cannot rely on infection reduction capacity of process, so need to set safety criteria based on geographical source of raw materials, individual animal source of by-products, presence of SRM, risk of cross contamination, level of residual impurities, and intended use.		
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2.4 Dicalcium Phosphate & Tricalcium Phosphate

KEY SCIENCE	EFSA/SSC	SEAC	OTHER
	<p>SSC Updated Opinion & Report on the Safety of Dicalcium Phosphate (DCP) and Tricalcium Phosphate (TCP) from Bovine Bones used as a Feed Additive or as a Fertiliser, 6-7 March 2003</p> <p>TCP and DCP derived from bovine and porcine bones.</p> <p>Residual BSE risk in DCP from bones sourced from higher risk countries is negligible providing animals fit for human consumption, SRM excluded, contamination avoided and production process has proven TSE infection reduction capacity</p> <p>TCP produced from bovine bones not a risk providing conditions for sourcing and production are similar to gelatine</p> <p>Risk from use of DCP and TCP as fertiliser is remote</p>	<p>SEAC 62, July 2000: Production of Dicalcium Phosphate for Poultry Feed</p> <p>Agreed that imported bovine bones and bones from UK cattle under 30 months with SRM removed, could be used to product DCP for poultry feed. However, only if prevention of intra-species recycling could be guaranteed</p>	

3. Monitoring programmes

KEY SCIENCE	EFSA/SSC	SEAC	OTHER
	<p>EFSA Report on the BSE Surveillance Model (BSurvE) established by the Community Reference Laboratory for TSE, October 2004</p> <p>BSurvE model represents a major step forward in the analysis of BSE prevalence having regard to age distributions and surveillance streams and statistical uncertainty (confidence intervals), when compared to the use of the current OIE</p>	<p>SEAC 85, November 2004: Potential Public and Animal Health Risks of Chronic Wasting Disease (CWD)</p> <p>Endorsed EFSA opinion. Noted that there is no evidence of transmission of CWD to humans from venison consumption, but data are limited.</p> <p>There is no evidence to suggest that BSE is present in UK deer, but it is important to monitor</p>	<p>Annexes I and II of The TSE Roadmap, July 2005</p> <p>Provide statistical data on BSE surveillance since 2001. Assuming the effectiveness of the total feed ban, the number of younger cases will reduce, and the total cost of surveillance for detection of each positive younger case will increase.</p>

	thresholds for BSE prevalence that are crude prevalences.	findings of an on-going study to look at potential susceptibility of red deer to BSE	
	<p>EFSA Opinion on a Surveillance Programme for Chronic Wasting Disease in the European Union, June 2004</p> <p>Recommends initiation of an EU-wide experimental screening, targeting at-risk groups of animals, using rapid test and confirmatory methods. Should focus initially on farmed deer and fallen stock cervids >18 months. Should include all forms of TSE. Should match a cut-off prevalence of at least 0.5% (for risk populations) or at least 1% for other populations.</p>		<p>OIE Terrestrial Animal Health Code 2005, Appendix 3.8.4 – Surveillance for BSE</p> <p>Sets out surveillance goals, including detecting disease, monitoring disease, monitoring controls, supporting BSE status, or gaining a higher status for trade.</p> <p>Sets out target groups.</p> <p>Type A Surveillance - surveillance for supporting BSE status or gaining a higher status 1:100 000 (95%).</p> <p>Type B Surveillance - maintenance surveillance for negligible risk countries 1:50 000 (95%).</p>
	<p>EFSA Advice on “OIE-facilitated consultation between EU and USA on the Interpretation and Implementation of the OIE Standard on BSE, May 2004</p> <p>Purpose of BSE surveillance is to determine presence of BSE and, if occurrence of BSE is demonstrated, to estimate the prevalence and monitor the evolution of the epidemic and thus the efficiency of feed bans.</p> <p>Effective surveillance could influence SRM measures</p> <p>During the course of a surveillance programme, it may be possible to review SRM removal requirements</p>		
	<p>EFSA Opinion on the Interpretation of Results of EU Surveillance of TSEs in Ovine & Caprine Animals, Culling Strategies for TSEs in Small Ruminants and the TSE-Related Safety of certain Small Ruminant</p>		

¹¹ SSC Opinion on Safe Sourcing of Small Ruminant Materials (Should BSE in Small Ruminants Become Probable: Genotype, Breeding, Rapid TSE Testing, Flocks Certification and Specified Risk Materials), 4-5 April 2002

	<p>Products, November 2003</p> <p>Data obtained under current EU TSE surveillance programme in small ruminants would make it possible to estimate the prevalence of TSE in each Member State, but the reliability of the estimate would vary significantly between Member States.</p> <p>Recommend more sheep testing and validation of rapid post mortem BSE tests for TSEs in sheep.</p> <p>No need to revise previous opinions on the breeding for TSE resistance, culling strategies or safe sourcing of small ruminants. In comparison to previous opinion (2002¹¹) there is no significant new data on risks of products, or evidence for a higher probability of BSE being present under natural conditions.</p>		
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4. The categorisation of countries according their BSE risk.

KEY SCIENCE	EFSA/SSC	SEAC	OTHER
	<p><i>EFSA have convened an Expert group to reconsider the GBR approach - meets 5 September 2005</i></p>		<p>OIE Terrestrial Animal Health Code 2005, Chapter 2.3.13</p> <p>Details conditions for categorisation and trade, as specified in The TSE Roadmap.</p> <p>There are three categories – negligible BSE risk; controlled BSE risk; undetermined BSE risk.</p> <p>Categorisation is based on a risk assessment, and if appropriate an exposure assessment covering presence or absence of TSE, and prevalence based on surveillance; use of MBM; import of cattle; import of feed; import of products of ruminant origin; recycling of BSE agent; use of ruminant carcasses in animal feed; feeding ruminants with MBM and level of surveillance. Other factors include awareness of passive surveillance, compulsory notification of TSE, use of approved laboratories, feed ban</p>

			monitoring, restriction of cohorts and offspring. There are two tiers of surveillance.
	<p>Update of the Opinion of the Scientific Steering Committee on the Geographical Risk of Bovine Spongiform Encephalopathy (GBR), January 2002</p> <p>Final Opinion of the Scientific Steering Committee on the Geographical Risk of Bovine Spongiform Encephalopathy (GBR), July 2000</p> <p>GBR is a qualitative indicator of the likelihood of the presence of one or more cattle being infected with BSE, pre-clinically as well as clinically, at a given point in time, in a country. Where the presence of BSE is confirmed, the GBR gives an indication of the level of infection. There are four levels: 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.</p> <p>The assessment is based on 8 factors – structure and dynamics of cattle population; BSE surveillance; BSE related culling; import of cattle and MBM; feeding; MBM-bans; SRM-bans; rendering.</p>		

5. Review of culling policy with regard to TSEs in small ruminants

KEY SCIENCE	EFSA/SSC	SEAC	OTHER
<p>Natural transmission of BSE between sheep within an experimental flock, Bellworthy et al. 2005. Vet.Rec. 157:7 p.206</p> <p>Indicates that experimental BSE in sheep can transmit either <i>in utero</i> or perinatally</p>	<p>EFSA Opinion on the Interpretation of Results of EU Surveillance of TSEs in Ovine & Caprine Animals, Culling Strategies for TSEs in Small Ruminants and the TSE-Related Safety of certain Small Ruminant Products, November 2003</p> <p>SEE 3</p>		<p>Commission Regulation (EC) No 36/2005 of 12/01/2005</p> <p>Amends Commission Regulation (EC) 999/2001 ("The TSE Regulation"), requiring primary discriminatory immuno-blot testing of all positive scrapie cases, and further discriminatory testing of any samples from which BSE cannot be excluded.</p>

			<p>BSE –Statements by the Royal Society 1996</p> <p>Spongiform encephalopathies are found in various forms in a variety of animals. The human form is CJD. The sheep form is scrapie, which is a common and long-standing sheep disease and in which the agent is not known to infect humans.</p>
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6. Cohort culling in bovine animals

KEY SCIENCE	EFSA/SSC	SEAC	OTHER
<p>Implications of BSE Infection Screening Data for the Scale of the British BSE Epidemic and Current European Infection Levels, Donnelly et al. 2002 Proc.R.Soc.Lond. 269:27179-90</p> <p>Paper based on BSE survey and clinical incidence data, estimated maternal transmission at 0.5% (0-2.8%). When the effects of the offspring cull were taken into account, the estimate increased to 0.7% (0-4%). These represent the most recent estimates of the risk of maternal transmission replacing the 9.6% estimate in the 1997 cohort study.¹² Evidence derived from the 1997 cohort study also suggests that the risk for offspring declined as the feedborne risk declined. The low level of maternal transmission would not be sufficient to maintain the BSE epidemic alone.</p>	<p>EFSA Opinion on BSE-Related Culling in Cattle, April 2004</p> <p>In the light of current data, and absence or more sensitive <i>in vivo</i> tests, there is not enough evidence to modify the 2000 SSC opinion concerning the definition or application of birth cohort culling. If there is a risk of transmission from dam to offspring, by a mechanism that is not understood, it is not related to ova and embryos.</p> <p>Based on 2002 and 2003 testing data, it can be concluded that the prevalence of BSE in birth cohorts¹³ of affected cattle was about ten times higher than the prevalence of BSE in the overall healthy animal population (2.77 versus 0.31 in 2002, 3.70 versus 0.29 in 2003). [Cases per 10 000 tested]</p>	<p>SEAC 77, February 2003: Moving from culling all BSE Offspring born after July 1996, to culling all offspring born two years prior to, or after development of BSE in the dam.</p> <p>No scientific evidence to suggest that moving to the EU rule would increase the risk of human exposure to BSE infected animals</p>	<p>6.2. OIE Terrestrial Animal Health Code 2005, Chapter 2.3.13</p> <p>Includes the requirement for the progeny of female BSE cases, born within 2 years prior to or after onset of clinical disease, and all cattle reared with the BSE case during the first year of life and which consumed the same feed, and all cattle born in the same herd as, and within 12 months of the birth of the BSE case to be permanently identified, have their movements controlled, and be completely destroyed following slaughter or death.</p>
	<p>SSC Opinion on BSE-Related Culling in Cattle, September 2000</p> <p>Ideally all cattle exposed to the same feed should be culled.</p>		

¹²A cohort study to examine maternally associated risk factors for BSE. Wilesmith et al. 1997 Vet.Rec.141, 239-243; Analysis of the BSE maternal cohort study: evidence for direct maternal transmission. Donnelly et al.1997 App.Stats.46,(3) 321-344

¹³ In this context "birth cohort" refers to the group of bovine animals born in the same herd as the index case within 12 months before or after the birth of the affected animal

	<p>Data indicates that birth cohort culling has a similar effect to herd culling, and is more cost efficient.</p> <p>Up to 57% of the cases in the national UK birth cohort 1987/88 could have been eliminated by an early birth cohort cull. Not clear if a similarly significant effect can be expected in the later stages of an epidemic.</p> <p>BSE not horizontally transmitted. Only significant routes of transmission are feed, and much less importantly vertically from infected dam to calf.</p> <p>Infection normally takes place in first months of life. Incubation period is 2-14 years (mean 60 months), with the vast majority of clinical cases being 4-6 years at clinical onset</p> <p>Current diagnostic tools can diagnose BSE in asymptomatic animals in late stages of incubation, but not in early stages of incubation.</p> <p>BSE is a rare event.</p>		
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7. UK restrictions

KEY SCIENCE	EFSA/SSC	SEAC	OTHER
	<p>EFSA Statement on UK Application for Moderate BSE Risk Status, March 2005</p> <p>Confirmed that UK can be considered as a country with moderate risk status in terms of BSE for its whole cattle population (less than 200 cases of BSE per 1 million cattle aged over 24 months, over a 12 month period)</p>		
	<p>EFSA Opinion on UK Application for Moderate Risk BSE Status, April 2004</p> <p>The modelling methodology used to calculate the absolute incidence is statistically sound. On the basis of projected upper 95% confidence limits, UK has</p>		

	<p>made robust case for its whole cattle population to be considered as OIE moderate BSE risk status from a date intermediate between July and December 2004.</p> <p>Already UK is clearly moderate risk in respect of cattle born after July 1996</p>		
	<p>EFSA Opinion on the Scientific Justification for Proposing Amendments to the UK Date Based Export Scheme (DBES) and to the Over Thirty Months (OTM) rule, April 2004</p> <p>The prevalence of BSE in UK cattle born after 31 July 1996 is below 200 cases per million adult cattle (i.e. "OIE moderate risk"). The UK is likely to become OIE moderate risk in respect of its total cattle population in 2004.</p> <p>Removal of dam survival rule and lower (6 month) age limit for eligible cattle will not increase BSE risk to human health.</p> <p>If OTM is removed, a comprehensive testing programme identical to that in other Member States should replace it.</p>		