

# Bovine spongiform encephalopathy: is it time to relax BSE-related measures in the context of international trade?

D. Matthews\* & A. Adkin\*\*

Centre for Epidemiology & Risk Analysis, Veterinary Laboratories Agency, Woodham Lane, Addlestone, Surrey, KT15 3NB, United Kingdom

\* Retired

\*\* Corresponding author

## Summary

Bovine spongiform encephalopathy (BSE) has presented serious challenges to both the World Organisation for Animal Health and national governments, in defining and implementing appropriate national control measures, and in agreeing trade rules that permit safe trade in cattle and bovine products. Precautionary trade rules were initially necessary, based upon the science of sheep scrapie, but research into BSE later enabled BSE-specific trade rules to be developed. As a result, current rules on trade are underpinned by a sound body of knowledge on BSE. Declining epidemics in most affected countries confirm the appropriateness of current precautions. Nevertheless, risk is primarily dependent on the prevalence of infection with BSE. In the face of low prevalence scenarios, certain precautionary measures in the *Terrestrial Animal Health Code* may now be considered excessive. A thorough review is therefore deemed appropriate.

## Keywords

Bovine spongiform encephalopathy – BSE risk – Commodities – Infectivity – Surveillance – Trade.

## Introduction

At the time of writing it is 23 years since the first diagnosis of bovine spongiform encephalopathy (BSE) in the United Kingdom (UK). The announcement in 1996 that a disease of humans, variant Creutzfeldt-Jakob disease (vCJD), had most probably arisen from exposure to BSE via food triggered a global crisis with respect to food safety. It changed attitudes and approaches to ensuring food safety in many countries.

Declining epidemics in affected countries serve to confirm that BSE can be brought under control. A combination of surveillance, prohibitions and compliance audits provide evidence that consumer safety can also be assured. The standards of the World Organisation for Animal Health (OIE) on BSE and trade in cattle and bovine products have always aimed to take into account known science. Early precautionary rules were modified as scientific findings

allowed, subject to the agreement of OIE Members. Here the authors review the current situation, and consider whether or not there is now scope for the relaxation of rules relating to international trade.

## Situation report

A total of 27 countries have reported confirmed cases of BSE since 1989 (37). Two have detected BSE in imported cattle only. Of the 25 countries with indigenous cases, in two only were case numbers in 2008 greater than in 2007, and these numbers were small (Canada, 4; Portugal, 18). Indeed, in 2009, only four countries reported ten or more cases (France, Portugal, Spain and the UK – range 10 to 25). The statistics emphasise that confirmation of BSE does not immediately condemn a country to a significant epidemic. Case numbers in nine countries with indigenous cases did not reach double figures.

The overall picture strongly suggests that the application of corrective measures works. The long incubation period of BSE means that the delay between full compliance with regulatory measures and the last case of BSE may extend beyond the average lifespan of cattle alive when controls were introduced. There is no quick fix that will either prevent BSE if exposure has already occurred, or instantly eliminate it once cases are detected.

Most cases are currently classified as classical BSE (cBSE) to distinguish them from the small numbers that present with different post-mortem characteristics, referred to as atypical

BSE. The small numbers of atypical BSE (25) preclude meaningful epidemiological investigation. For cBSE, however, it is clear that prevention of exposure via feed will either prevent an epidemic or bring it under control. The challenges presented in ensuring the effectiveness of controls are, however, significant. Table I summarises the authors' assessments of the risks posed by various potential pathways for the transmission of BSE before and after the introduction of national regulatory controls. Although based primarily on the epidemiology of BSE in the UK, investigations in other countries have confirmed the consistency of risk factors arising from non-compliance.

**Table I**  
**Bovine spongiform encephalopathy transmission risks in pre- and post-regulatory scenarios**

These risks have led to the introduction of extreme prohibitions with regard to the production and use of feed

Stage	Transmission pathway	Risk	
		Pre-regulation	Post-regulation <sup>a)</sup>
Infected animal	Healthy infected cattle (undetected) moved between farms or exported	✓	✓ Culling of cohort controls marginally reduces this risk after detection of index case; exported risk reduced by OIE rules
	Dead (fallen) cattle directed for processing into animal by-products, including MBM	✓	✓ Highlights need for controls on processing to eliminate downstream risk
Abattoir	Healthy infected cattle slaughtered for human consumption	✓	✓
	Waste products (including infected tissues) not segregated and directed for processing into animal by-products, including MBM	✓	✓ May occur accidentally or fraudulently if compliance not complete
Rendering plant	No segregation of bovine wastes into high and low risk	✓	✓ May occur accidentally or due to inadequate segregation
	Processing standards incapable of inactivating BSE	✓	✓ Processing modified in some countries to maximise inactivation, but not guaranteed to be absolute
	MBM sold to feed manufacturers, used as fertiliser and exported	✓	✓ Potential for infectivity to enter feed manufacturing premises. Exports usually prohibited
Feed manufacturer	MBM derived from ruminants regularly, occasionally or accidentally included as ingredient in feed for cattle	✓	No May occur accidentally or due to inadequate segregation unless regulatory controls eliminate the risk
	Cross-contamination of feed intended for ruminants (can occur if ruminant MBM is still included in pig/poultry feed that is manufactured or stored in the same facility)	✓	No Regulatory controls must anticipate and prevent this risk
Farm	Infected feed received and fed to cattle	✓	No Low probability if stringent controls in place at manufacture
	Infected feed for pigs/poultry or pets is accidentally fed to cattle, or cross-contaminates cattle feed while handled or stored	✓	✓ Low probability if stringent controls in place
	MBM received for use as fertiliser contaminates feed (theoretical risk not identified from epidemiological analyses)	✓	✓ Low probability if stringent controls in place
	Feed produced before regulations are introduced is still in use on farm or residue contaminates newer batches		✓

a) dependent on specific national regulatory controls implemented in individual countries

MBM: meat-and-bone meal

OIE: World Organisation for Animal Health

The published oral ID<sub>50</sub> (median infective dose) for the infection of cattle with BSE is 0.2 g (33). This is not an absolute. It is dependent on infectivity levels in the brain of the donor animal, which will vary according to the stage of incubation at time of death. Most importantly it highlights the dangers of feed contamination with amounts that are undetectable and untraceable by available tests. Contamination of storage facilities with such trace amounts may continue beyond the point when feed controls are considered to be effectively enforced. Consequently, if ruminant feed is manufactured, stored or transported in a facility that also handles protein of ruminant origin there is a real risk of cross-contamination. Feed bans based upon OIE guidelines (ruminant to ruminant) require extensive risk management measures to ensure compliance.

Bovine spongiform encephalopathy proved a real challenge to the OIE and its Member Countries. In the absence of a test to detect infection in live animals, it was difficult to predict the scale of the early British epidemic. Furthermore, the extent to which BSE had spread before it was first diagnosed, both within and from the UK, by the movement of infected animals or contaminated feed ingredients, was seriously underestimated.

The appearance in the UK of BSE in cattle born after the initial ban on the use of ruminant-derived protein in ruminant feed suggested the possibility of routes of transmission other than feed. It took until the late 1990s before there was general acceptance that horizontal and vertical transmission could be ignored. Epidemiological and audit inspections at feed mills highlighted cross-contamination of feed as a major problem in the continuing transmission of BSE (3, 19, 20, 21, 22, 23, 26, 27, 35). Audits of compliance at abattoirs, rendering plants and feed companies, together with additional research evidence that identified infective tissues that had previously not been excluded from the feed chain, showed that it was vital to tighten controls further.

## The evolution of the *Terrestrial Animal Health Code*

The impact of such uncertainty on OIE procedures was that initial measures focused on establishing rules for safe trade in individual commodities, subject to certain guarantees. From the outset there was a belief that commodities such as semen, milk, milk products, hides and skins were safe irrespective of source country. Scientific uncertainty hindered the adoption of risk assessment approaches to the categorisation of countries.

The focus of the *Terrestrial Animal Health Code* (*Terrestrial Code*) shifted as a result of the 1996 global crisis. By then, BSE had been confirmed in several countries and this led to attempts by regulators to categorise countries, beginning with those considered to be of 'negligible risk' or 'BSE-free'. At that stage, where indigenous BSE cases were detected, they were recognised solely as a result of passive surveillance. It became clear, however, that clinical incidence alone was not a sufficiently robust indicator for the categorisation of countries affected by BSE. Additionally, the recognition of a single case frequently precipitated the application of disproportionate trade barriers, significantly beyond those recommended by the OIE. This was a major disincentive to the establishment of surveillance programmes and the reporting of cases.

In 1998, the European Commission (EC) asked its Scientific Steering Committee (SSC) to begin a process of assessing the BSE risk status (referred to as Geographical BSE Risk – [GBR]) of European Union (EU) member countries (10). This was based primarily on the assumption that exposure arose from the importation of infected animals or contaminated meat-and-bone meal from the UK. The outcome was subsequently reinforced by the results of active surveillance, based on post-mortem testing with rapid tests. Active surveillance established a mechanism by which prevalence of infection could be determined more effectively, and enabled trends to be followed, giving earlier evidence of success or failure of feed controls.

Research and audit evidence soon indicated that it was possible to identify tissues and products that were inherently safe, and to which no BSE-related conditions should be attached (29, 31, 32, 34, 36). Furthermore, evidence from affected countries suggested that, despite the presence of BSE, risk to consumers and to animal health could be controlled with effective, and fully enforced, measures (1). It was therefore no longer necessary to create arbitrary divisions between affected countries based upon case numbers. After all, case numbers reflected infections acquired four to eight years earlier rather than risk in the country at the time of detection. The analysis of surveillance data and compliance audits confirmed the effectiveness of regulatory measures (3, 20, 21, 22, 23, 26, 27, 35).

The *Terrestrial Code* has now evolved to a point where surveillance is encouraged, but in a manner that is proportionate and enables trends in prevalence, and thereby compliance, to be monitored. The *Terrestrial Code* also provides standards for trade with countries classified as being of 'undetermined risk', by virtue of not being categorised as 'negligible risk' or 'controlled risk'.

## Scope for further revision

The BSE chapter (38) in the current edition (2010) of the *Terrestrial Code* provides a framework for a short review of current knowledge, concentrating on key factors and broad principles. The ultra-cautious approach to risk still adopted by some countries, supposedly based on continued uncertainty, is no longer supported by current scientific evidence. Although there continue to be individual knowledge gaps, the majority of current OIE standards are now supported by a substantial amount of data, based specifically on BSE in cattle and the analysis of risks to humans conducted over the past two decades (1, 2, 4, 5, 6, 7, 8, 9, 11, 12, 13, 14, 15, 16, 17, 24, 28, 29, 30, 31, 32, 33, 34, 36). It is time for perceptions of risk, and misconceptions regarding sources of infectivity, to take account of firm scientific evidence.

Epidemiological investigations into cases of vCJD support past decisions on the definition of risk tissues. It is clear that the biggest, and possibly only, risk to consumers was infectivity within bovine central nervous system (CNS) tissue that was incorporated into food products before prohibitions were introduced (5, 6, 36). While lower levels of infectivity have been detected in other tissues, which were not designated as 'specified risk materials' (SRM), they are unlikely to have caused significant numbers of human infections in the UK, if any. Tissue infectivity data have been compiled and published on a regular basis by the World Health Organization (36).

### General provisions and safe commodities

Where the *Terrestrial Code* permits certain commodities to be exported without BSE-specific conditions, irrespective of source country status, the exemptions are determined by a combination of specific negative bioassay transmission results, epidemiological analyses, and compliance with specific conditions. Table II summarises the commodities that, at the time of writing, can be traded with and without BSE-specific conditions.

Bioassays and/or prion protein (PrP) detection methods have not detected evidence of infectivity in bovine milk (and therefore milk products), semen, embryos, hides, skins, muscle or blood (or blood products). In the case of milk, semen and embryos epidemiological investigations have supported bioassay results, and ruled out their involvement in the natural transmission of BSE (36). Only one equivocal result is reported with respect to muscle, where a single mouse out of ten died following inoculation of semitendinosus muscle samples collected from a naturally infected clinical case of BSE (2). This result was uninterpretable, does not concur with other assay results, and could have arisen due to the presence of traces of peripheral nervous tissue or laboratory contamination.

A fully negative result was obtained with longissimus dorsi muscle, which has a closer association with the spinal column and hence spinal nerves.

As peripheral somatic nerves have only been found to be infected after the onset of clinical signs, when the CNS is infectious (17), the exclusion of clinical cases from the food chain is key to ensuring the safety of meat.

There is no evidence for the presence of infectivity in skin. It is therefore inevitable that commodities produced from skin, such as gelatine and collagen, are deemed to be safe provided that production methods do not give rise to contamination. Bone appears to be free of infectivity, but in this instance a risk of contamination of bone with CNS, in particular the vertebral column at the time of carcass splitting, has generated greater concern about the safety of tallow, gelatine or dicalcium phosphate (DCP) produced from bone. Risk assessments conducted on behalf of the EC (7, 8, 9) attempted to quantify that residual risk, although the production processes are inherently difficult to evaluate by experimental approaches. The processes are, however, expected to produce substantial inactivation, and published studies have confirmed this for gelatine (12, 14) and DCP (13) and at least one risk assessment has concluded that gelatine is safe regardless of the source of raw material used (18).

As a result, DCP is considered safe provided it is free of traces of protein and fat. European Union risk assessments, using worst-case assumptions about the inclusion of CNS and vertebral column, and presuming that bone-derived DCP was fed to cattle (mineral-derived DCP is actually preferred), considered DCP to represent a genuine risk if fed to cattle. It was, however, clear that the exclusion of CNS and vertebral column and low BSE prevalence in source countries significantly reduced the dangers (9).

A small risk of transmission to cattle has been suggested for tallow (7, 19), but this risk is much smaller than the historical risk that tallow presented for humans in the UK. This risk is considered to be associated with contaminating protein rather than the tallow itself. It is for this reason that only tallow with levels of impurities below 0.15% can be traded freely, although it is recognised that protein only represents a small fraction of residual impurity (7). With respect to blood, contrary to the evidence from small ruminants, all efforts to detect infectivity in blood (and blood products) have failed (36). The absence of a detectable peripheral involvement in bovines is accepted and is in distinct contrast to small ruminants infected with scrapie, or cervids infected with chronic wasting disease.

### BSE risk status

The fundamentals of the assessment of risk from BSE are appropriately summarised in Article 11.5.2. of the

**Table II**  
**Bovine spongiform encephalopathy (BSE) and trade: commodities that can (✓) and cannot (✗) be traded and the BSE-specific conditions that apply (Terrestrial Animal Health Code, 2010)**

Traded commodities affected	Exporting country risk status			
	Negligible	Negligible (indigenous cases)	Controlled	Undetermined
<b>Free trade – safe commodities</b>				
Article 11.5.1.				
Milk and milk products	✓	✓	✓	✓
Semen and embryos	✓	✓	✓	✓
Hides and skins	✓	✓	✓	✓
Gelatine derived from hides and skins	✓	✓	✓	✓
Tallow with impurities max 0.15%	✓	✓	✓	✓
Dicalcium phosphate (DCP) – no protein or fat	✓	✓	✓	✓
Blood and blood products	✓ (a)	✓ (a)	✓ (a)	✓ (a)
Deboned meat	✓ (a, b)	✓ (a, b)	✓ (a, b)	✓ (a, b)
<b>Conditional trade – subject to BSE-specific rules</b>				
Articles 11.5.7.-11.5.9.				
Live cattle	✓	✓ (c, d)	✓ (c, d)	✓ (c, e, f)
Articles 11.5.10.-11.5.12.				
Other meat and meat products	✓	✓ (c, d)	✓ (a, b, g)	✓ (a, b, d, h)
Article 11.5.13.				
Ruminant-meat-and-bone meal (MBM) or greaves	✓	✗ <sup>(i)</sup>	✗	✗
Article 11.5.14.				
Risk tissues				
Tonsils, distal ileum (all ages)	✓	✓	✗	✗
Brains, eyes, spinal cord, skull and vertebral column	✓	✓	✗ (>30 months)	✗ (>12 months)
Article 11.5.15.				
Gelatine and collagen derived from bones	✓	✓	✓ (b, j)	✓ (b, j)
Articles 11.5.16. & 11.5.18.				
Tallow				
Other tallow <sup>(k)</sup>	✓	✓	✓ (b)	✗
Tallow derivatives	✓	✓	✓ (b or j)	✓ (j)
Article 11.5.17.				
Dicalcium phosphate				
Other DCP <sup>(k)</sup>	✓	✓	✓ (b, j, l)	✓ (b, j, l)

(a) Not stunned using compressed gas/air or pithing process and subject to ante- and post-mortem inspection

(b) Specified risk tissues excluded

(c) Cattle identification system in place

(d) Born after effective ruminant MBM feeding ban

(e) It must be demonstrated that cattle have not been fed MBM for 2 years

(f) Contemporary cattle in cohort or herd of birth controlled/slaughtered. Already implicit in definition of negligible risk and controlled risk countries

(g) No mechanically recovered meat from cattle >30 months of age

(h) No mechanically recovered meat from cattle >12 months of age

(i) Unless produced from cattle born after date of effective feed ban

(j) Specified processing conditions applied

(k) 'Other tallow' and 'Other DCP' refers to commodities that do not comply with the definitions in Article 11.5.1.

(l) By-product of bone gelatine

*Terrestrial Code*, and are reinforced by the guidelines for conducting the assessment in Articles 11.5.23. to 11.5.29. Unfortunately they presume sufficient background knowledge to ensure that questions are answered both

accurately and truthfully. The key message, that risk management may require the exclusion of mammalian, rather than just ruminant, protein from ruminant diets, may not be sufficiently clear. Partial measures may still

significantly reduce risk, as seen in Europe in the 1990s, but may delay the decline of epidemics.

These fundamentals were thoroughly evaluated and modified by the EC/SSC BSE GBR approach, and its subsequent revisions (10). Their translation into OIE guidelines allows greater worldwide acceptability but does present a danger of failure, albeit partial, if the need for rigorous implementation is not recognised.

### Commodities that should not be traded

Article 11.5.14. primarily addresses trade, for food, feed and other purposes, of tissues that are designated by the EU as SRM in affected countries.

Although the subject of much debate in the past, rules have surprisingly not totally followed the progress of scientific findings, either in the *Terrestrial Code* or in specific country or regional legislation. High-risk tissues were initially designated by extrapolation from the known science of sheep scrapie. Furthermore, risk management decisions went beyond the limits of scientific knowledge and were taken on the basis of whether or not designating a certain tissue as risk material would facilitate auditing and compliance or implementation within abattoirs or rendering plants. For example, designating the whole head, rather than just the brain, as risk material meant the head could be discarded and there was no need for a time-consuming thorough inspection. The OIE position, however, has been to limit the tissues designated as risk materials to those where there was published scientific evidence of risk.

The detection of significant levels of infectivity in the distal ileum, brain and spinal cord has confirmed that the designation of these tissues as SRM was correct (5, 6, 36). Spleen and thymus were eventually removed from SRM lists following thorough investigation. With respect to tonsils, infectivity was only detected in trace amounts in experimentally infected cattle that had received a large oral inoculum of BSE-infected brain (4). Limited and equivocal results were obtained with bone marrow from experimentally infected cattle (24, 32), and nictitating membrane (36) and muscle (2, 36) of naturally infected cattle. None of the results were consistent with epidemiological evidence of risk, or sufficient to precipitate designation as SRM.

Meanwhile, infectivity has definitely been detected in peripheral (somatic and autonomic) nerves of experimentally infected animals, and in somatic nerves of naturally infected animals, but without triggering designation as SRM (15, 16, 17). Adrenal glands of naturally infected cattle were also positive (17). These anomalies arise partly because results became available at a time when prevalence levels had fallen significantly.

Moreover, the risks posed by these tissues were also considered to be largely dealt with by existing guidelines (which excluded clinically affected cattle from the food chain) or by the removal of tissues during the normal process of carcass dressing.

The key tissue where dispute remains, and regulatory inconsistencies continue, is the gastrointestinal tract. In cattle, in contrast to small ruminants, there is no evidence of infectivity throughout the gastrointestinal tract. Early experimental results for cattle, based on high-dose exposure, implicated the ileum (28, 30, 31), especially in association with the lymphoreticular structures referred to as Peyer's Patches. While this limited distribution was used in some countries as justification for the designation of only the ileum as SRM, others continued to destroy the intestine from pylorus to anus. This has therefore presented itself as a significant trade barrier. The absence of evidence for infectivity in duodenum and jejunum may have reflected the limitations of early investigations. Conversely, the interpretation of the positive data for the ileum also failed to appreciate the potential over-estimation of risk associated with high-dose exposure of cattle.

Two studies of relevance to this issue remain in progress and are due to be published. One uses bioassay in transgenic mice to examine duodenum and jejunum from cattle exposed to high doses of BSE by mouth. The other opportunistically took advantage of the presence of tissues (duodenum, jejunum and ileum) taken from cattle exposed to either low-dose or high-dose inocula, by mouth. Earlier immunohistochemical studies of ileal tissues from naturally and experimentally infected cattle suggested that PrP<sup>BSE</sup> concentrations, and implicitly infectivity levels, were significantly lower in naturally infected animals (28). This suggested that in cattle exposed to a low dose of BSE, presumed to be the case with naturally infected animals, the risk arising from ileum was potentially significantly lower than the presumed risk from the high-dose experiments. The opportunistic work (i.e. the tissues were not collected specifically for this study) supports this interpretation – that high-dose challenge results in a positive ileum but with traces of PrP<sup>BSE</sup> in the jejunum of some cattle, while a low dose makes abnormal PrP difficult to detect in the ileum, and apparently impossible in the jejunum (8). This demands cautious interpretation of data arising from high-dose studies, and does suggest that the OIE designation of only ileum as SRM is correct.

### Gelatine and collagen prepared from bones, tallow and dicalcium phosphate

The exclusion of gelatine and collagen produced from bones from the list of products that can be traded freely, and of tallow containing greater than 0.15% insoluble

impurities, is precautionary and not based on direct scientific investigation of risk. The exclusions were certainly considered appropriate in Europe where the prevalence of BSE was relatively high. Theoretical estimations of risk cannot exclude the likelihood of transmission to cattle or humans via such products, especially if applied parenterally. Consequently, conditions for their trade are quite specific. Vertebral column from cattle over 30 months of age, which represents a high risk with respect to source bones, can only be imported from countries designated as being of negligible risk. Where the source bones arise from countries of controlled risk, the conditions put in place are those that are considered most likely to inactivate BSE. These are essentially industry standards and published studies have demonstrated that both the alkaline extraction of gelatine (12) and acid extraction alone (14), which are used to produce certain grades of gelatine, significantly reduce any BSE infectivity which might be present.

Two key factors influence these precautionary approaches, namely the prevalence of BSE in source cattle and industry standards for processing.

Firstly, if prevalence is zero, then precautionary rules for processing, and standards of contamination, become less relevant. Given that all products present challenges in terms of traceability, and verification that they are not derived from countries where BSE risk remains, one route to simplification would be to actually determine the scale of risk in those countries that are currently of 'undetermined risk' and wish to export such materials.

As an alternative to determining that the global prevalence of BSE no longer presents a risk, perhaps there is now scope for international industry standards to be agreed that guaranteed sufficient inactivation to enable trade? This has been a thorny subject for years, especially with respect to tallow. The setting of common international industrial standards is an approach that is already being followed with respect to some food and feed products, and could eliminate the need for country-specific conditions. The end product would guarantee minimal, but not necessarily zero, risk, but should generally be acceptable if the worldwide acceptance of BSE risk becomes more balanced.

## Surveillance

Current *Terrestrial Code* guidelines for the conduct of surveillance for BSE are the result of much debate, frequent frustration, and eventual political compromise. The desire for transparent rules that apply to all has inevitably brought the guidelines to the current point. Their basis, a model of BSE epidemiology (BSurvE) based upon what was known about BSE in the EU in 2000 (20, 26, 27, 35), was never intended to produce the one-size-fits-all guide

for surveillance that we now have. It was scientifically robust, but recognised that variations in industry practices in individual countries needed to be taken into account in evaluating the outcome for each. In other words, the model was intended to take into account variations in cattle industries before delivering an epidemiological assessment of risk, and recommendations for surveillance that would meet the needs of individual countries.

Nevertheless, coupled with the outcome of the SSC GBR assessment process, BSurvE has enabled the adoption of a more defensible transparent approach to surveillance in the *Terrestrial Code* than was previously possible. This new approach represents a step forward, but it should not necessarily be the last.

The BSurvE model was based on a snapshot of epidemiological data at a given point of time, and ideally required modification to take into account changes in prevalence and risks. Furthermore, as it was intended to be modified to suit individual countries, the one-size-fits-all approach adopted in the *Terrestrial Code* inevitably penalises some countries, such as those with small cattle populations. Modification of the chapter is therefore desirable if it is to remain current, but will inevitably become more difficult with time, and will be resource intensive. OIE Members may, therefore, prefer to accept the limitations of the current chapter in this context rather than undertake the complex process of updating it.

## Further change or status quo?

There should be no doubt that risk to both cattle and humans is now significantly less than it was a decade ago (1). Independent verification of risk status for countries categorised as being of 'negligible risk' or 'controlled risk' provides a sound basis with which to evaluate risk in general in the context of trade rules. The benefits of thorough re-evaluation of risk status were highlighted in 2007, when the European Food Safety Authority (which took over the responsibilities of the SSC when it was dissolved in 2003) assessed and updated the SSC GBR categories in line with OIE criteria; two countries (Chile and Finland), previously within SSC GBR category III (BSE likely, but not confirmed, or confirmed at a lower level), were re-categorised as 'negligible risk'. This confirms that there are grounds for optimism. Furthermore, where visible epidemics decline following official intervention, the results continue to support the scientific basis for the definition of control measures.

The arguments for keeping measures under constant review are strong. It is, however, important that individual *Terrestrial Code* conditions are not reviewed in isolation. This should ensure that inconsistencies do not arise. The

fact that some relaxation has already occurred within the *Terrestrial Code* suggests that OIE Members are becoming more comfortable about residual risk. Nevertheless, anomalies can arise if changes are not synchronised. The exportation of live animals from countries categorised as being of 'undetermined risk', in the absence of clearly defined surveillance requirements, is now accepted. Whether or not such a relaxation is scientifically sound, it suggests that the rules relating to commodities such as gelatine and tallow, for example, are now disproportionately rigorous.

The decline in BSE prevalence in Europe has had the disappointing consequence of reducing support for research on prion diseases. This means that relaxation of

rules cannot rely on imminent new scientific data to support future changes. Current scientific knowledge, coupled with evidence arising from the introduction of controls in affected countries, including the prevalence of vCJD, and the low prevalence of BSE in all affected countries, should provide a sound basis for establishing more proportionate rules for future trade.

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# Encéphalopathie spongiforme bovine : le moment est-il venu d'assouplir les mesures appliquées en matière d'ESB dans le cadre du commerce international ?

D. Matthews & A. Adkin

## Résumé

L'encéphalopathie spongiforme bovine (ESB) a représenté un défi majeur pour l'Organisation mondiale de la santé animale ainsi que pour les gouvernements nationaux qui ont dû concevoir et appliquer des mesures de lutte appropriées au niveau national, et se mettre d'accord sur les mesures sanitaires à appliquer pour sécuriser les échanges internationaux de bovins et de leurs produits. Dans un premier temps, le principe de précaution s'est imposé dans le cadre des échanges, basé sur les connaissances disponibles concernant la tremblante du mouton ; les progrès scientifiques concernant l'ESB ont ensuite permis de mettre au point des mesures spécifiques à l'ESB en matière de commerce. En conséquence, les mesures appliquées actuellement sont fondées sur un corpus raisonnable de connaissances relatives à l'ESB. L'affaiblissement des épidémies dans la plupart des pays affectés confirme que les mesures de précaution en vigueur portent leurs fruits. Toutefois, le risque d'ESB est surtout corrélé à la prévalence de l'infection par l'agent de l'ESB. Face à des scénarios de faible prévalence, certaines mesures de précaution décrites dans le *Code sanitaire pour les animaux terrestres* de l'OIE peuvent être considérées comme excessives. Il est donc souhaitable de procéder à une révision complète de ces mesures.

## Mots-clés

Commerce international – Encéphalopathie spongiforme bovine – Infectiosité – Marchandise – Risque d'ESB – Surveillance. ■

# Encefalopatía espongiforme bovina. ¿Ha llegado el momento de relajar las medidas de control de la enfermedad en el comercio internacional?

D. Matthews & A. Adkin

## Resumen

La encefalopatía espongiforme bovina (EEB) ha planteado grandes dificultades a la Organización Mundial de Sanidad Animal (OIE) y a las administraciones nacionales a la hora de definir y aplicar medidas nacionales de control adecuadas y de consensuar reglas comerciales que hagan posible un comercio seguro en bovinos y sus derivados. En un principio hubo que introducir en el comercio reglas cautelares, basadas en el conocimiento científico que se tenía del prurigo lumbar, pero más adelante las investigaciones sobre la EEB permitieron elaborar reglas comerciales adaptadas específicamente a la enfermedad. Las normas que rigen actualmente el comercio reposan así en un sólido acervo de conocimientos sobre la EEB. El declive de la epidemia en la mayoría de los países afectados confirma la idoneidad de las precauciones vigentes. Sin embargo, el riesgo depende sobre todo de la prevalencia de la infección. Ahora, ante la hipótesis de un descenso de los índices de prevalencia, cabría considerar excesivas algunas de las medidas cautelares que figuran en el *Código Sanitario para los Animales Terrestres*. Por ello los autores juzgan oportuno examinar exhaustivamente la cuestión.

## Palabras clave

Comercio – Encefalopatía espongiforme bovina – Infecciosidad – Mercancías – Riesgo de EEB – Vigilancia.



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