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A test of Rasmussen's risk management framework in the food safety domain: BSE in the UK

A.L. Cassano-Piche[a]*, K.J. Vicente[b] and G.A. Jamieson[b]

[a]*Healthcare Human Factors Group, Centre for Global eHealth Innovation, University Health Network, Toronto, Canada;* [b]*Cognitive Engineering Laboratory, Department of Mechanical and Industrial Engineering, University of Toronto, Toronto, Canada*

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In 1986, bovine spongiform encephalopathy (BSE) was identified in the UK. Millions of BSE-infected cows were slaughtered and over 150 people contracted variant Creutzfeldt–Jakob disease, an inevitably fatal human form of BSE. Tragic incidents such as this provide valuable opportunities to understand and improve the safety of complex socio-technical systems. By studying accidents, knowledge can be gained that can improve system safety. The purpose of this article is to test the usefulness of Rasmussen's risk management framework for explaining how and why accidents occur in the food production domain. This was accomplished by using the framework to retrospectively investigate how and why BSE was transmitted through the human and animal food supply in the UK from 1986 to 1996. More specifically, an AcciMap and Conflict Map were constructed to represent contributing factors of the epidemic according to the structure of Rasmussen's framework. These factors were used to test the seven predictions made by the framework. All seven predictions were supported by the evidence, indicating that Rasmussen's risk management framework shows promise as a theoretically driven explanation of how and why accidents happen in complex socio-technical systems, particularly in the food production domain.

Keywords: risk management; Rasmussen's risk management framework; BSE; public health; public policy; socio-technical systems analysis; food safety

1. Introduction

In 1986, the beef production system in the UK became contaminated with bovine spongiform encephalopathy (BSE). Ten years later, despite the efforts of regulators to protect against BSE's potential risks, over 160,000 infected cows had been slaughtered and 10 young people had confirmed cases of the inevitably fatal disease variant Creutzfeldt–Jacob disease (vCJD), the human form of BSE thought to be transmitted through the consumption of contaminated beef. As of 2006, approximately 150 people have died from vCJD and more than 3 million cows have been slaughtered in the UK (National Creutzfeldt–Jacob Disease Surveillance Unit 2006). Along with the tragic loss of human and animal life, BSE delivered a forceful economic blow. Within 12 months of the discovery that vCJD was linked to BSE, the loss of exports and reduced domestic demand for British beef amounted to the total cost of GBP 1.15 billion (DTZ Pieda Consulting 1998). In April 2000,

*Corresponding author. Email: andrea.cassano-piche@uhn.on.ca

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it was estimated that the total net cost of the BSE crisis on the UK government would be GBP 3.7 billion by the end of the 2001/2002 financial year (Phillips *et al*. 2000).

Tragic incidents such as this provide valuable opportunities to understand and improve the safety of complex socio-technical systems. By studying accidents, knowledge can be gained that can improve system safety. However, the quality of the knowledge attained depends, in part, on the theoretical and methodological frameworks chosen to guide the analysis. The purpose of this article is to test the usefulness of Rasmussen's risk management framework for explaining how and why accidents occur in the food production domain by using the framework to retrospectively investigate how and why BSE was transmitted through the human and animal food supply in the UK from 1986 to 1996. This paper does not compare the results of this analysis with results garnered by applying other models to the same data. This would be an interesting topic to explore but is not within the immediate scope of this paper. Similarly, this paper does not attempt to generalise the findings to other domains. Subsequent research is required for this purpose. The Rasmussen framework was selected for two reasons. First, the explanatory adequacy of the framework has previously been investigated, showing that the framework has promise as a theoretically driven way of explaining how and why accidents occur (Vicente and Christoffersen 2006). Second, several case studies have used the framework to investigate accidents in transportation, water distribution, public health and space shuttle launch systems (Rasmussen and Svedung 2000, Cassano-Piché and Vicente 2005, Vicente and Christoffersen 2006, Johnson and de Almeida 2008), but this study marks the first application of Rasmussen's framework in the food production domain.

2. Risk management in a dynamic society

Rasmussen's (1997) framework – which has its basis in systems thinking – is motivated by the dramatically changed types of models needed to understand the structure and behaviour of complex socio-technical systems. Factors such as the rapid pace of technological change, the high degree of coupling enabled by computerisation and communication technologies and the volatility of economic and political climates each contribute to an environment in which the pressures and constraints that shape work practices are constantly shifting. Traditional modelling methods such as task analysis are inadequate as referents for understanding actual work practices because they depend on the assumption of a stable, tightly constrained environment (Vicente 1999). To fully appreciate how such systems work or why they sometimes fail, modelling tools are needed that provide an integrated view of the various contextual factors that directly and indirectly define how they operate.

2.1. *Structure*

Rasmussen's (1997) framework for modelling risk management has two components. The first is a structural hierarchy describing the actors – individuals and organisations – in a system. The structure of a socio-technical system involved in managing risk is provided in Figure 1. This figure provides a representative example of a system, although the precise number of levels and their labels can vary across industries. To understand how factors at each level contribute to accidents, knowledge from a variety of different academic disciplines is required. Factors at the work level reveal conditions associated with the particular process being controlled (e.g. nuclear power plant, healthcare system,

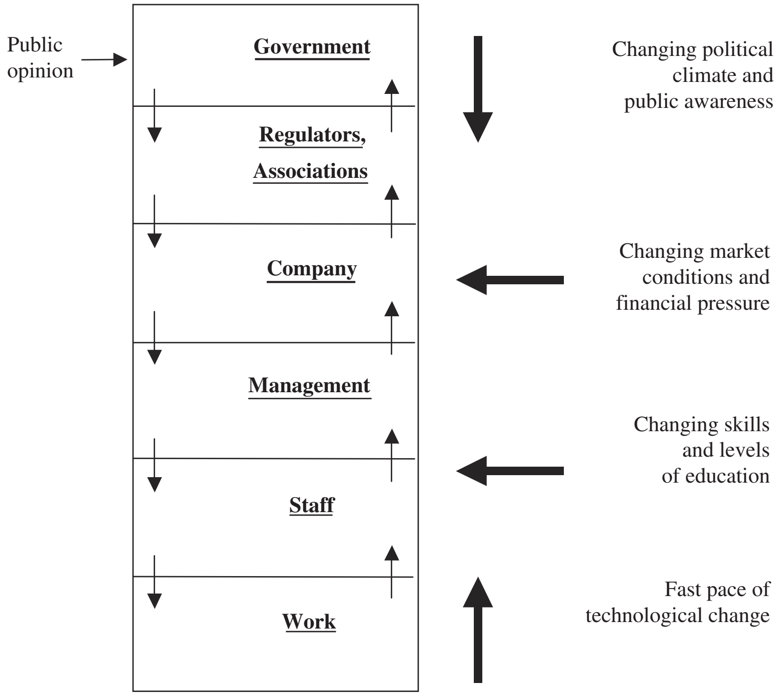

Figure 1. Various levels of a complex socio-technical system involved in risk management. Adapted from Rasmussen (1997) and reprinted from Vicente (2002), with permission from BMJ Publishing Group.

commercial aviation). Understanding accident factors at this level usually requires knowledge of science or engineering principles that underlie the system. Factors at the next level are the activities of the individual staff members who interact directly with the process being controlled (e.g. control room operators, front line hospital staff, airplane pilots). Knowledge of human factors engineering is usually helpful for understanding contributing factors at this level. Factors at the management level are attributed to the activities of the management that supervises the staff. They are best understood by individuals with a background in management theory and industrial-organisational psychology. Company-level factors stem from the activities of the company as a whole; however, several investigations of public health systems have modelled factors relating to local government at this level (Woo and Vicente 2003, Cassano Piché and Vicente 2005, Vicente and Christoffersen 2006). Understanding the factors at the company level usually requires knowledge of economics, organisational behaviour, decision theory and sociology. When local government is represented at this level, an understanding of political science and law is also necessary. Factors at the next level are the activities of the regulators or professional associations that are responsible for constraining the activities of companies in that particular sector. Factors at the government level are related to the activities of government (both civil servants and elected officials), who are responsible for setting public policy. At both of these levels, individuals with knowledge of political science, law, economics and sociology are required to understand the relevant factors.

For the system to function safely, vertical integration is required. That is, decisions at higher levels of the system should propagate down the hierarchy and be reflected in the decisions and actions at the lower levels, whereas information about the current state of affairs should propagate up the hierarchy and inform the decisions and actions at the higher levels. These interdependencies across levels of the hierarchy are critical to the successful functioning of the system as a whole. If instructions from above are not formulated or carried out at the lower levels, system states they intend to safeguard will not be protected. Additionally, if information from below is not collected or conveyed to decision-makers at higher levels, decisions made cannot reflect the available capacity, ability or goals of the system. The result is that the system can become unstable and start to lose control of the hazardous process that it is intended to control.

From this perspective, safety can be viewed as an emergent property of a complex socio-technical system. It is impacted by the decisions of all the actors – politicians, CEOs, managers, safety officers and work planners – not just the front-line workers alone. Consequently, threats to safety usually result from a loss of control caused by a lack of vertical integration (i.e. mismatches) across levels of a complex socio-technical system, not just from deficiencies at any one level alone. All layers play a critical, albeit different, role in maintaining safety.

The lack of vertical integration is frequently caused, in part, by a lack of feedback across levels of a complex socio-technical system. Actors at each level cannot see how their decisions interact with those made by actors at other levels, so the threats to safety are not obvious before an accident occurs because nobody has a global view of the entire system.

As shown on the right of Figure 1, the various layers of a complex socio-technical system are subject to external forces that stress the system. Examples of such perturbations include changing political climate and public awareness, changing market conditions and financial pressures, changing competencies and levels of education or changes in technological complexity. In this dynamic society, these external forces are stronger and change more frequently than ever before. Therefore, vertical alignment is more difficult to achieve.

2.2. *Dynamics*

The second component of the Rasmussen framework, shown in Figure 2, considers the dynamic forces that can cause a complex socio-technical system to modify its structure and behaviour over time. On the one hand, there are financial pressures that result in a cost gradient pushing the actors in the system to work in a more fiscally responsible manner. On the other hand, there are psychological pressures that result in an effort gradient pushing the actors in the system to work in a more mentally or physically efficient manner. People are frequently searching for easier ways to get a job done. Although this effort gradient is sometimes interpreted negatively as a sign of human laziness, given the proper conditions it can serve a positive role because it allows people to seek out new ways of getting the job done. This exploratory process can be particularly important when people are being asked or required to take on more responsibilities with fewer resources – the proverbial 'do more with less' that is so common in a dynamic society.

As a result of these two gradients, work practices will be subject to a form of Brownian motion, an exploratory but systematic migration over time. These financial and psychological forces inevitably cause people to find the most economic ways of performing their job. Moreover, the migration of work practices can occur at multiple levels of a complex socio-technical system and not just one level alone.

Over time, this migration causes people to cross the official boundary of work practices, shown on the near left in Figure 2. People are forced to deviate from procedures and cut

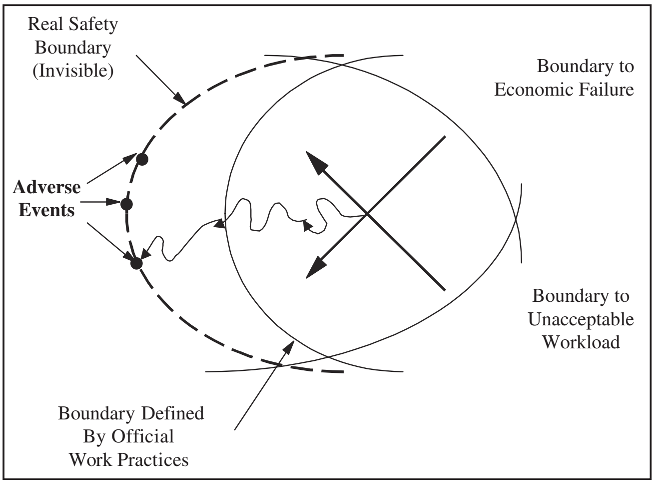

Figure 2. 'Brownian motion' model showing how financial and psychological forces can create behaviour gradients that cause work practices to migrate systematically toward the boundary of safety. Adapted from Rasmussen (1997). Copyright (2003), Kim J. Vicente.

corners because they are responding to requests or demands to be more cost-effective. As a result, the system's defences in depth degrade and erode gradually, not all at once.

One might think that a lack of procedural compliance and the resulting degradation in safety would raise an immediate warning flag, but this does not happen for two reasons. First, the migration in work practices is required to get the job done, given the stresses that the system is undergoing. That is why 'work to rule' campaigns, where people do their job strictly by the book, can cause complex socio-technical systems to come to a grinding halt. Second, the migration in work practices does not usually have any visible, immediate negative impact. The threats to safety are not obvious before an accident because the violation of procedures does not immediately lead to catastrophe. At each level in the hierarchy, people are working hard, striving to respond to cost-effective measures, but they do not see how their decisions interact with those made by other actors at different levels of the system. Yet, the sum total of these uncoordinated attempts at adapting to environmental stressors is slowly but surely 'preparing the stage for an accident' (Rasmussen 1997, p. 189).

As a result, the migration of work practices continues. People try harder and harder to work in more efficient ways and, with each new innovation, they are coming closer and closer to the real boundary of safety on the far left of Figure 2. However, because that boundary is usually invisible, people do not have any idea whether the system as a whole is close to or far away from disaster. Migrations from official work practices can persist and evolve for years without any breach of safety until the real safety boundary is reached. After an accident, workers will wonder what happened because they did not do anything differently than they had been doing in the recent past. In other words, accidents in complex socio-technical systems do not usually occur because of an unusual action or an entirely new, one-time threat to safety. Instead, they result from a combination of a systematically induced migration in work practices and an odd event that winds up revealing the degradation in safety that had been occurring all the while.

The second column of Table 1 summarises the predictions made by Rasmussen's (1997) framework. The remaining columns in Table 1 are described later. Note that, for each prediction, there is (at least) one alternative prediction. Thus, accidents need not have this set of characteristics, so Rasmussen's framework is falsifiable.

Table 1. Tool characteristics providing criteria for interpreting the findings.

	Prediction	Tool characteristic	How supported
1	Safety is an emergent property of a complex socio-technical system. It is impacted by the decisions of all of the actors – politicians, managers, safety officers and work planners – not just the front-line workers alone.	Boxes at many levels of the **AcciMap**	Show the contributing decisions of actors at multiple levels of the system
		Actors labelled on the **Conflict Map**	Show specifically the actors involved in the accident
2	Threats to safety or accidents are usually caused by multiple contributing factors, not just a single catastrophic decision or action.	Multiple boxes on the **AcciMap**	Show that accidents have multiple contributing factors
		Annotated text on the right-hand side of **Conflict Map**	Describes multiple contributing factors
3	Threats to safety or accidents usually result from a lack of vertical integration (i.e. mismatches) across levels of a complex socio-technical system, not just from deficiencies at any one level alone	Lines on the **Conflict Map** connecting actors in the system	Show instances of vertical misalignment. The lines are connected between the source of the mismatch and where the effects are felt
		AcciMap does not contribute	—
4	The lack of vertical integration is caused, in part, by a lack of feedback across levels of a complex socio-technical system. Actors at each level cannot see how their decisions interact with those made by actors at other levels, so the threats to safety are far from obvious before an accident.	Annotated text on the right hand side of **Conflict Map**	Describes specific instances of poor feedback across levels of the system
		AcciMap does not contribute	—

5	Work practices in a complex socio-technical system are not static. They will migrate over time under the influence of a cost gradient driven by financial pressures in an aggressive competitive environment and under the influence of an effort gradient driven by the psychological pressure to follow the path of least resistance.	Precondition (rounded) boxes on the **AcciMap**	Highlight financial and efficiency pressures that influence work practices
		Annotated text on the right-hand side of **Conflict Map**	Describes instances of decisions made by one actor that cause financial or efficiency pressures for other actors
6	The migration of work practices can occur at multiple levels of a complex socio-technical system, not just one level alone.	Boxes at many levels of the **AcciMap**	If a migration of work practices is described by the data source, specific poor work practices will appear as boxes on the AcciMap. Boxes at multiple levels will support this prediction.
		Annotated text on the right-hand side of **Conflict Map**	If a migration of work practices is described by the data source, the annotations may describe the reasons underlying the migration in work practices at multiple levels.
7	Migration of work practices causes the system's defences to degrade and erode gradually over time. Accidents are induced by a combination of this systematically induced migration in work practices and a triggering event, not by an unusual action or an entirely new, one-time threat to safety.	The connection between boxes on the **AcciMap**	The pattern connecting the boxes helps to identify the systematically induced pattern of migration as well as the triggering event
		Annotated text on the right-hand side of **Conflict Map**	Describe specific factors that contribute to the breakdown in a system's defences

3. BSE and the UK beef production domain

3.1. *Epidemiology*

Although the origin of BSE will likely never be certain, it is probable that the disease originated in the 1970s as a result of a sporadic gene mutation in a cow or other animal. BSE is a specific form of a transmissible spongiform encephalopathy (TSE), a disease type that is thought to be caused by an abnormally shaped prion protein and is known to affect a wide range of animals and humans. In their normal shape, prion proteins cause no harm, but the abnormally shaped mutation does not degrade like normal cells and contact between normal and abnormally shaped prion proteins causes the normal ones to convert to abnormal. Eventually, this leads to an accumulation of the abnormal form of the protein, which causes the death of nerve cells and leaves the brain with a sponge-like appearance. If deformed protein from an animal incubating a TSE enters another animal, transmission can occur. The most obvious means of entry is through food. The practice of using animal protein in ruminant feed facilitated BSE transmission among cows, since highly infective tissues from cows that were clinically affected by the BSE agent were rendered into animal protein for animal feed. By allowing 'the practice of feeding ruminant materials to herbivores, which are thus exposed to infective risks against which they have not evolved any defenses ... they open up new pathways for infection to the farmed animals and potentially from them to man via food and/or medicinal products' (Phillips *et al.* 2000, Vol. 5, p. 160). The consumption of food products containing highly infective cow tissues was also the most likely transmission route of BSE to humans (as vCJD). However, it is possible that some transmission from cows to humans could have occurred through the use of medicinal or cosmetic products (i.e. vaccines, sutures, face creams) derived from highly infectious bovine tissues or through direct contact with diseased animals or their tissues (occupational hazard of the agricultural industry), although there is no evidence to support that this was the case.

A number of TSEs have been identified in animals and humans, but prior to 1986 BSE and vCJD were unknown types of TSEs. Initially, BSE was thought to be transmitted from scrapie-infected sheep. This was reassuring to regulators and policy makers since scrapie has proven to be innocuous to humans for over 200 years. As years passed, accumulating evidence led to the determination that BSE was not to be a form of scrapie. Ten years after BSE was identified, its transmissibility to humans (in the form of vCJD) was established. CJD has been a known human TSE for many years. However, the clinical features and novel pathology of the cases that arrived during the BSE epidemic suggested that recent instances were a new variant of the disease, hence vCJD.

3.2. *The beef production industry*

Three major plant types make up the beef production industry: slaughterhouses, renderers and feed mills. An understanding of the roles of each of these is helpful for understanding the protection efforts described in the next section.

The slaughterhouse is, quite simply, where cattle are slaughtered. Meat sold for human consumption in the UK must come from a licensed slaughterhouse. Here, meat that is acceptable for human consumption is separated from that which is unfit. Acceptable meat is sent to be butchered; the rest is sent to renderers for processing but is first separated into material that can be incorporated into animal feed and material that is unfit (offal). Offal is either stained or sterilised by slaughterhouses before being sent to renderers.

Renderers process waste from carcasses into consumable materials including meat and bone meal (MBM), tallow and products used in pet foods. MBM is supplied to feed mills, where it is incorporated into the production of animal feed for ruminants, pigs and poultry.

3.3. *Regulatory structure of the beef production system*

The government and regulatory structure concerned with the safe operation of the beef production system in the UK is responsible for drafting laws and policies to protect animals and humans against harmful agents such as TSEs. During the time period of this research, the ministry within the central government responsible for all issues related to agriculture and animal health in all UK member countries was the Ministry of Agriculture, Fisheries and Food (MAFF). The ministry within the central government responsible for all issues related to human health is the Department of Health.

During the epidemic, MAFF took the lead responsibility on most BSE-related matters, especially BSE-related research. Although the minister contributed to final policy decisions, the Chief Veterinary Officer advised on veterinary policy for all of Great Britain and was the leading presenter of government policy decisions to the UK agricultural industry. The Chief Veterinary Officer was also a spokesperson to the media and public on behalf of the Government and was the main contact to other countries on veterinary matters.

The Department of Health's responsibility and interest with regard to the BSE epidemic was for the protection of human health against the possibility of BSE transmission via beef consumption, vaccines, cosmetics, occupational hazards and medical devices that use bovine-derived materials (e.g. sutures). Like the Chief Veterinary Officer, the Chief Medical Officer advised the Minister of Health and represented the UK on health-related matters.

During the epidemic, several expert committees were established to advise MAFF on a number of issues related to BSE. The two committees that were most influential were the Southwood Working Party (SWP), and the Spongiform Encephalopathy Advisory Committee (SEAC).

The SWP was established in April 1988 to advise health and agricultural ministers on the implications that BSE might have on human health. The motivation for its establishment was the Chief Medical Officer's request for guidance on the risks that BSE posed to human health so that the decision to implement a slaughter and compensation policy could be better informed. However, the formal terms of reference included advising on all matters related to BSE.

SEAC was established on 3 April 1990 to advise MAFF and the Department of Health on matters related to spongiform encephalopathies. SEAC provided policy advice to the government on nearly every decision that was made regarding BSE.

In addition to receiving support from advisory committees, MAFF (and the advisory committees) received support from the Neuropathogenesis Unit (NPU). The NPU is a research group jointly funded by the Agricultural Research Council and the Medical Research Council responsible for studying scrapie and other TSEs.

Local government also played an important role in the safe operation of the beef production system by enforcing legislation related to food safety and specifically BSE.

4. The BSE inquiry

The BSE Inquiry Report (Phillips *et al.* 2000) served as the main data source for this analysis. The report focuses on the events related to the emergence and identification of BSE and vCJD in the UK up to March 1996, when the link between BSE and vCJD was established. Given the complexity of the events surrounding the BSE outbreak, it may not be possible for any one account to be comprehensive. However, the BSE Inquiry Report is a very detailed and thorough data source comprising 5000 pages published in 16 volumes. Its contents include evidence from over 1000 witness statements from more than 630 individuals, 138 days of public verbal evidence from 333 witnesses and more than 3000 files from government departments, companies, trade associations and scientists.

A secondary data source was used to gain an alternate perspective on the decisions made by the UK Government. The chapter 'Mad cow disease 1980s–2000: how reassurances undermined precaution' from a European Environment Agency (EAA) report 'Late lessons from early warnings: the precautionary principle 1896–2000' (van Zwanenberg and Millstone 2001) highlights the deficiencies in the precautionary approach taken by the Government during the BSE epidemic.

4.1. *Methods*

A qualitative case study methodology (Yin 2003) was used to structure this research and enhance the construct validity and external reliability. According to Yin (2003), a case study comprises five components: its questions; its propositions; a unit of analysis; the logic linking data to the propositions; the criteria for interpreting the findings.

The research question for this study is: can Rasmussen's risk management framework describe how and why BSE (and later vCJD) entered and continued to be transmitted through the human and animal food supply in the UK from 1986 to 1996? The propositions of this case study are the seven predictions of Rasmussen's framework (Table 1). The unit of analysis is the release of BSE into the human and animal food chains in the UK from 1986 to 1996. The logic linking the data to the propositions can be thought of as the process of matching patterns in the data to the theoretical propositions. In this case study, the framework's tools – the AcciMap and the Conflict Map (see Woo and Vicente 2003) – help to highlight patterns in the data that are related to the seven predictions (propositions). The characteristics of these tools are helpful for providing criteria for interpreting the findings. An AcciMap (Figure 3) is a specific representation of the release of a hazard source mapped onto the structural hierarchy presented in Figure 1. The AcciMap is best understood by starting at the critical event and working backwards through the chains of contributing factors. A Conflict Map (Figure 4) is a representation of the potential conflicts between actors that may have helped set the stage for the hazard to be released. Table 1 shows how the characteristics of each tool relate the data to each proposition. Note that neither the AcciMap nor the Conflict Map is able to illustrate specific instances of a migration in work practices (i.e. predictions 5, 6 and 7) since neither tool represents the data with regard to time. However, if the data source is able to illustrate that such a migration has occurred (i.e. it specifically describes work practices over time), then the cause of the migration and the levels at which poor work practices are seen are indicated by these tools.

Yin's (2003) case study methodology provided several ways to enhance construct validity and external reliability. Three methods employed in this study enhance construct validity. The first was the use of multiple sources of evidence triangulated by the authors.

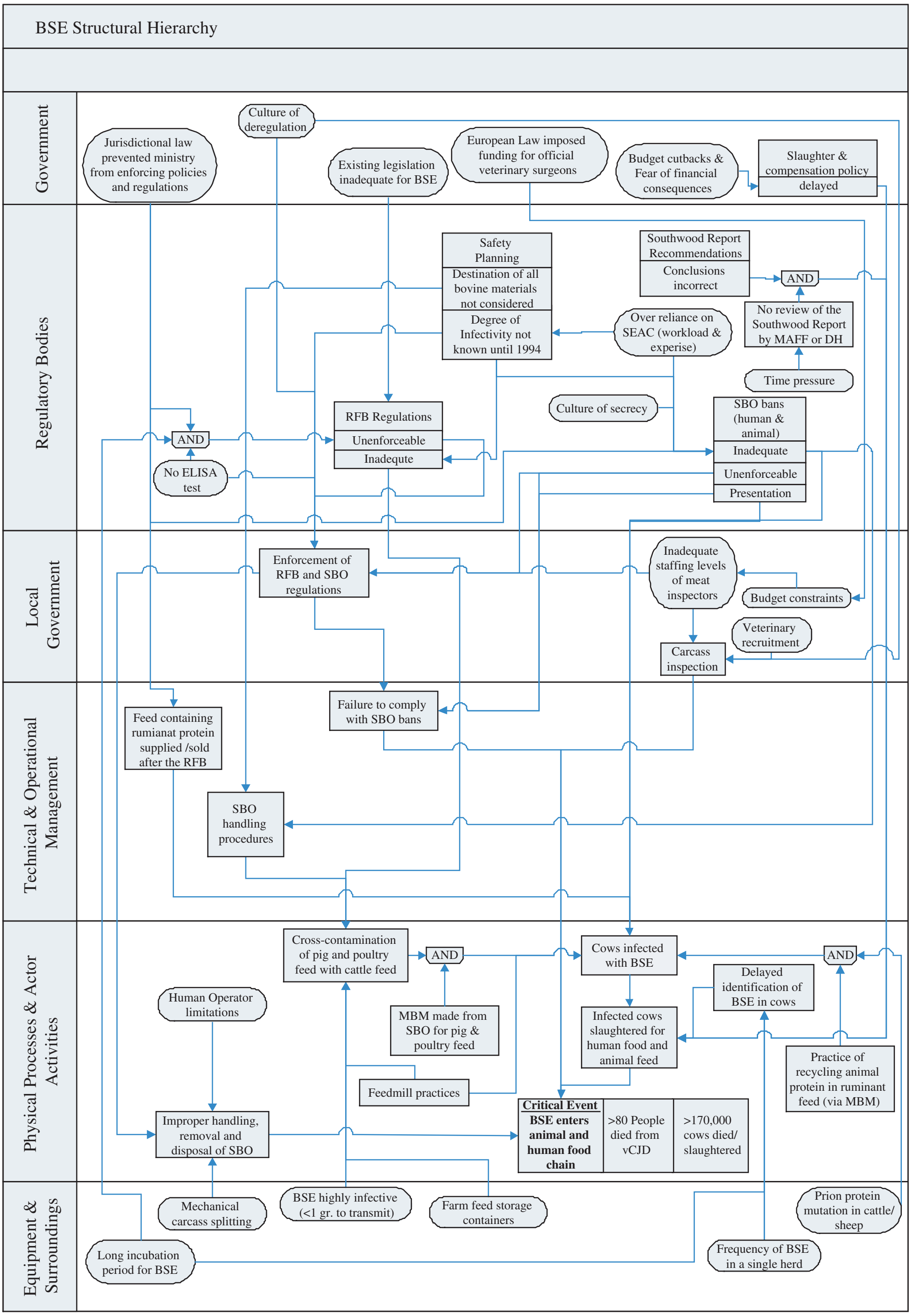

Figure 3. AcciMap of contributing factors to bovine spongiform encephalopathy (BSE) events. SEAC = Spongiform Encephalopathy Advisory Committee; MAFF = Ministry of Agriculture, Fisheries and Food; DH = Department of Health; RFB = ruminant feed ban; SBO = specified bovine offal; ELISA = enzyme linked immunosorbent assay; MBM = meat and bone meal.

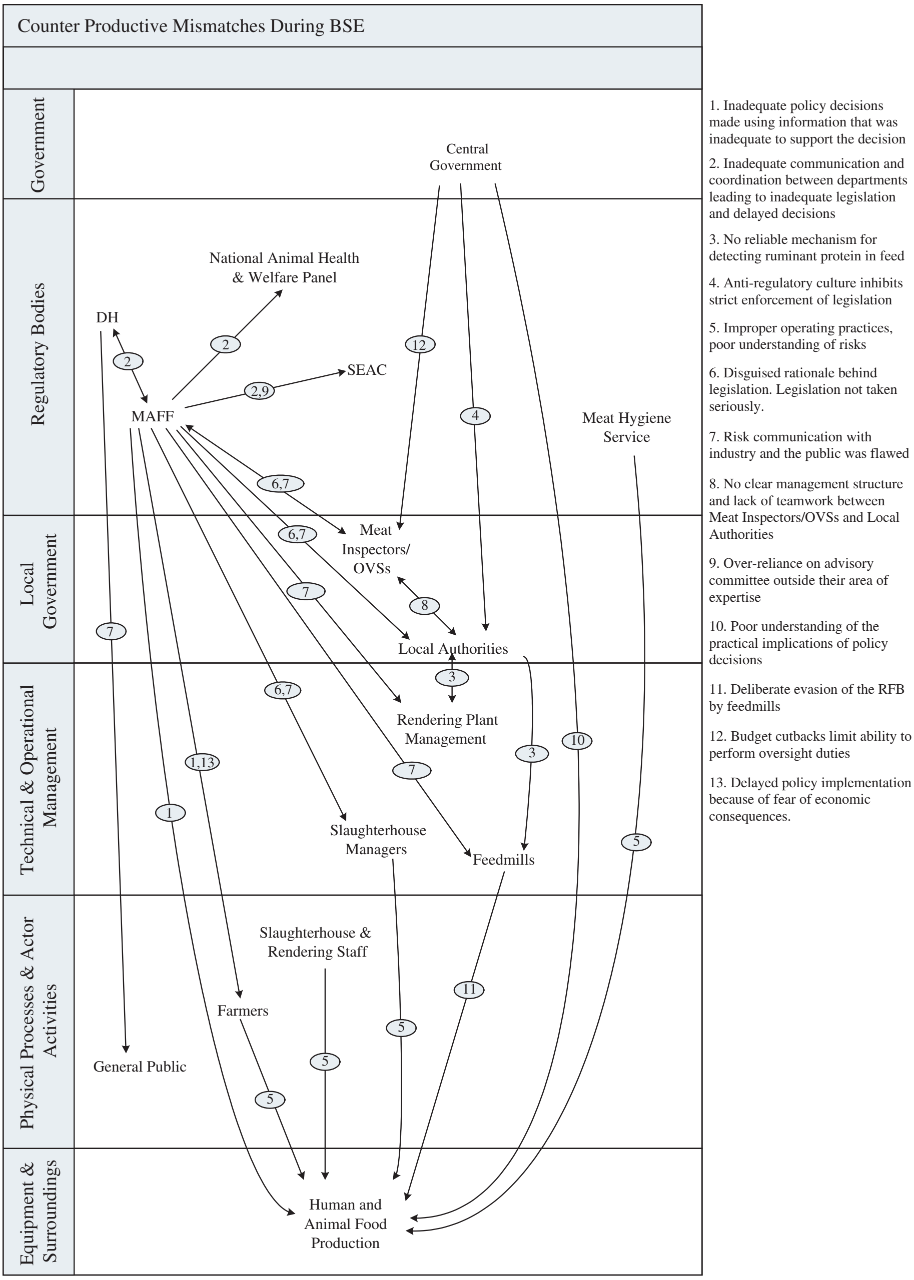

Figure 4. Conflict Map showing poor vertical integration during the bovine spongiform encephalopathy (BSE) epidemic. SEAC = Spongiform Encephalopathy Advisory Committee; MAFF = Ministry of Agriculture, Fisheries and Food; OVS = Official Veterinary Surgeon RFB = ruminant feed ban.

Data in the BSE Inquiry Report represents a triangulation of the multiple contributing sources of data described earlier. Additionally, the authors of this paper triangulated the data in the BSE Inquiry Report with the EAA report chapter. The second method used to enhance construct validity was establishing a chain of evidence that would allow an external observer to follow the derivation of the evidence presented in the study. The AcciMap and a Conflict Map allow an external observer to follow the derivation of the evidence presented in the study. The third method used to enhance construct validity was the use of key informants to review the analysis. Professor Erik Millstone, Professor of Science and Technology Policy at the University of Sussex and co-author of the EAA report chapter, and Dr Ron Rogers, Senior Scientific Advisor in the Bureau of Microbial Hazards at Health Canada, acted as key informants who reviewed the analysis.

In order to enhance experimental reliability, Yin (2003) recommends the creation of a database of case notes as a means of organising and documenting the data collected. The database for this case study consists of 224 case notes handwritten on index cards.

4.2. *Analysis*

This section compares the contributing factors of the BSE epidemic with the predictions of Rasmussen's risk management framework by testing the ability of the AcciMap (Figure 3) and Conflict Map (Figure 4) to represent the findings of the BSE Inquiry (Phillips *et al.* 2000). At the end of this section a summary is presented of how well the events of the BSE epidemic support the predictions of Rasmussen's risk management framework.

4.3. *Equipment and surroundings*

Several of the factors at this level relate to the nature of BSE, which was an unknown entity until November 1986. Previously, cows were not thought by medical scientists to be susceptible to TSEs. Identifying this new disease in cows was difficult because on many farms there was a pattern of only a single cow in a herd being affected. This factor, combined with the similarities between BSE clinical symptoms and other cattle diseases, delayed the identification of index cases. BSE's five-year incubation period introduced delays that made it difficult to identify a specific transmission source (i.e. cattle feed infected with the BSE agent). Even after the disease and its transmission source had been identified, the long incubation period made it difficult to assess the impact of disease 'control actions' intended to protect animal and human health. Control actions were less effective than anticipated because certain cow tissues, such as brain and spinal cord, have a high titre of the BSE agent in clinically affected cows. For example, ingestion of less than a gram of brain tissue from clinically affected animals is enough to transmit the disease to a calf. This degree of infectivity was not realised by MAFF until 1994. Because regulations developed early in the epidemic were made with incorrect assumptions about the amount of infective material a person would have to ingest to potentially become infected if the disease was transmissible to humans, they did not protect against small amounts of infected material entering the human and animal food chain.

Soon after contaminated ruminant feed was identified as the transmission source, MAFF introduced the ruminant feed ban (RFB) – a ban on the inclusion of ruminant protein in ruminant feed. Despite this measure, contaminated feed may have continued to enter the animal feed supply from contaminated farm feed storage containers where pre-RFB feed may have remained clinging to the walls of hoppers and bulk feed containers.

The final factor at this level was the contamination of animal feed with small amounts of highly infective tissues (i.e. spinal cord and dorsal root ganglia) that were intended for removal during the process of mechanical carcass splitting. Although clinically infected animals were removed from the food production process before carcass splitting occurred, cows that were infected but not yet showing clinical symptoms (sub-clinicals), were not. The spinal cord and dorsal root ganglia of sub-clinicals are also highly infective. During the process of mechanical carcass splitting small pieces of spinal cord and dorsal root ganglia would remain attached to the spinal column. The spinal column was included in the process of harvesting mechanically recovered meat (MRM), a product that was included in food products for human consumption. There is still no direct evidence linking vCJD to particular types of food products that include MRM, but this is one of the likely ways in which the BSE agent came in contact with humans.

4.4. *Physical processes and actor activities*

Most of the factors that appear at this level of Figure 3 have already been described in the background section or at the previous level. The issue of cross-contamination between ruminant feed (subjected to the RFB) and non-ruminant feed (not subjected to the RFB) remains to be discussed here.

After the RFB, MAFF thought the direct flow of ruminant protein into ruminant feed was cut off. However, the flow was merely slowed down as a result of a combination of two factors. First, animal protein intended for pig and poultry feed (non-ruminant feed) was not subjected to the RFB, so it still contained MBM derived from bovine tissues called specified bovine offal (SBO). SBO tissues were known to be infective based on previous experience with sheep infected with scrapie. The second factor is the practices on mixed farms and in feed mills that allowed ruminant and non-ruminant feed to be cross-contaminated. To enhance human food safety, SBO was banned from all food products for human consumption in November 1989. This was not the case for animal feed until September 1990. Had SBO been banned from animal feed earlier, the effects of cross-contamination would have been diminished since the most infective tissues would have also been eliminated from pig and poultry feed.

4.5. *Technical and operational management*

Owners and managers of slaughterhouses, rendering plants and feed mills were responsible for translating the RFB and SBO ban legislation into new practices for their employees. All three contributing factors at this level of Figure 3 resulted predominantly from the failure of management to comply with regulations. In slaughterhouses, plant staff were unclear about what was considered SBO. This was in part because of a lack of supervision of plant staff by plant managers to ensure that SBO was being properly stained – a process that visually identified offal that is fit for consumption by humans or certain types of animals. The ignorance of plant staff resulted in widespread violations of the SBO regulations. Most concerning was that high-risk tissues (brain and spinal cord) were being mixed with other by-products and processed for animal consumption.

After the animal SBO legislation took effect, renderers were charged with processing SBO into MBM and safely disposing of it. This processing was done separately from non-SBO feed processing; however, the same equipment was used for each batch type. Efforts to prevent cross-contamination varied widely from steam cleaning and/or disinfecting equipment between batch types to no cleaning efforts at all. There was no legislation to ensure the separation of SBO and non-SBO material and the creation of such legislation was rejected for fear of drawing public attention to the BSE issue. Instead, a code of practice was drafted by MAFF's Meat Hygiene Veterinary Section that required a 'purging system' – running a line of non-SBO production but treating it as SBO – between lines. Given the small amount of BSE-contaminated material that can cause infection, this measure was not enough to eliminate cross-contamination, although these measures reduced the scope of the problem.

The final factor discussed at this level deals with the deliberate evasion of the RFB by owners and operators of feed mills. Some feed mills chose to continue selling their stocks of pre-RFB feed after the ban.

4.6. *Local government*

Local authorities (LAs) responsible for enforcing BSE-related regulations, such as the RFB and human and animal SBO bans, did so with a lack of assiduousness. Although the RFB was unenforceable by strict means (because no test existed to detect the presence of banned ruminant protein), an effort could have been made to enforce the ban by checking the records of feed mills for ingredients including ruminant protein. This effort was not made, possibly because LAs were under the impression that the RFB was not an important protective measure. Having neither received guidance on the order, nor been consulted before it was introduced, they felt it served 'face-saving' intentions and did not require strong enforcement.

Similar reasons led to the poor level of enforcement of the human and animal SBO bans. LAs could have exercised their authority over slaughterhouses that did not comply with the regulations; however, they were reluctant to be over-exacting with their enforcement. Where slaughterhouses were operating on the margin of financial stability, LAs were inclined to protect local employment and maintain the service to farmers that slaughterhouses provided. A lack of motivation also detracted from LA diligence, especially in jurisdictions that had only one plant to regulate and provided no prospects for promotion or job enhancement.

In slaughterhouses, meat inspectors were responsible for ensuring that parts not fit for human consumption were removed from carcasses before they left the slaughterhouse. As Figure 3 indicates, at least three factors contributed to the poor performance of meat inspectors. First, due to severe budget cuts, the staffing levels of meat inspectors were insufficient. Second, '[t]he speed of operations, and the speed of the slaughter itself put pressure on inspectors, [leaving them] without the ability to do the task properly' (Phillips *et al.* 2000, Vol. 6, p. 318). Third, LAs experienced difficulty recruiting Official Veterinary Surgeons to supervise slaughterhouses.

4.7. *Regulatory bodies*

During the epidemic, MAFF drafted three new regulations to reduce the risk posed by BSE to humans and/or animals. The first regulation was the RFB (described above). This ban had the potential to end the epidemic; however, the regulation was unenforceable by LAs since no enzyme linked immunosorbent assay (ELISA) test existed to detect the presence of animal protein in compound feed. Additionally, this measure was inadequate for protecting against cross-contamination in feed mills. At the time the RFB was introduced, the amount of contaminated material required for transmission to cattle was not known, nor were there experiments under way by MAFF to determine the attack rate of BSE.

The second regulation was the human SBO ban. Tissues that were recommended for inclusion in the ban were bovine tissues that were normally processed for human food and in scrapie-infected sheep showed significant infectivity levels. The human SBO ban was intended to protect against the risk from both sub-clinical animals and BSE-infected animals that may slip through the cracks and arrive at a slaughterhouse. This intention was not communicated to the public. Instead, they were told that the ban was a practical means of implementing the recommendation from an advisory committee to remove SBO from baby food (a recommendation that was given without justification). This presentation of the ban disguised its true purpose, not only from the public, but also from new MAFF ministers being briefed on the issue. The result was that the ban was seen as an unnecessary precaution, which contributed to the poor compliance of many slaughterhouse operators and meat inspectors. Additionally, the human SBO ban did not restrict for human consumption a comprehensive list of tissues that posed significant risk – particularly MRM.

The third regulation, the 1990 animal SBO ban, had similar inadequacies to the human SBO ban because it used the same initial definition of SBO that was established for the human SBO ban, which did not include MRM. Additionally, the ban did not require the separation of SBO from other unfit material, require staining SBO a different colour than other unfit meat and excluded fallen stock (cows that died on farms and were collected separately from healthy cows for incorporation into animal feed). Furthermore, the animal SBO order was unenforceable. The order made it an offence to knowingly sell or supply feed containing SBO. Neither feed compounders nor farmers had any means of knowing if the feed had been derived from SBO. The inadequacies of this order are the result of the culture of secrecy within MAFF that existed at that time. The order was developed without consulting those with knowledge about practical enforcement of the ban.

Over the course of the BSE epidemic, SEAC was asked to give advice on more issues than was possible to adequately consider, and on issues that fell outside their expertise. One of their tasks was the facilitation of the interchange between the various bodies responsible for BSE research. Because SEAC was so overloaded, they lacked the time necessary to review the adequacy of the research being carried out or identify gaps in the research. The result was the publication of a paper in 1992 expressing their satisfaction with the research progress made, even though key research issues, such as minimum infective dose, the infectivity of different tissues, understanding of the fate of bovine tissues and the development of the ELISA test for feed testing, were not yet addressed. The lack of knowledge as a result of outstanding research bears some responsibility for the inadequacy of BSE-related regulations and poor enforcement of the regulations.

The final factors at the regulatory bodies level are the erroneous conclusions made in the report of the SWP. The report was not thoroughly reviewed. If it had been, some of the potential risks born out of the report's rationale may have been revealed. The SWP published a report in February 1989 containing recommendations for protecting human and animal health. One of the conclusions of this report was that the risk to humans posed by sub-clinical animals did not justify any further protective measures. Had the report been reviewed by MAFF and the Department of Health, particularly representatives from MAFF's Central Veterinary Laboratory, they would likely have appreciated that this statement was based on 'analogies with slender scientific evidence related to Scrapie' (Phillips *et al.* 2000, Vol. 6, p. 110) and would have given the advice they later provided: to eliminate certain tissues from the food chain based on the fact that certain tissues in scrapie-infected animals in the later pre-clinical stage are likely to be highly infective.

4.8. *Government*

The factors presented at this level of Figure 3 are associated with policies and laws made at the central level of government in the UK and preconditions that affected their development.

The decision to implement a slaughter and compensation policy, whereby any cow showing symptoms consistent with BSE would be slaughtered and compensation for the loss of that cow paid to farmers, fell to MAFF's minister. The minister was reluctant to approve a slaughter and compensation policy drawing on public funds because of recent public expenditure cutbacks, fear of economic consequences from detrimental effects on exports arising from BSE and wanting to avoid setting a precedent that might generalise to other circumstances. Before making a final decision, he requested the advice of the Department of Health's Chief Medical Officer (CMO). At this time, the Department of Health had not been made aware of BSE and the CMO was not confident about the potential risks. He requested that a committee (i.e. the SWP) be set up to advise the Department of Health on the human health risks. Six months elapsed between MAFF's recommendation to the minister to implement a slaughter and compensation policy and its implementation following the recommendation of the SWP. During this delay, BSE-infected animals continued to enter the human food chain. Had MAFF informed the Department of Health of issues related to BSE earlier, this delay may have been averted.

The legislation in place at the time of BSE generally did not meet the legislative needs to protect the human and animal populations against BSE. 'Departments had to make do with existing primary legislation, although it was not often ideally suited to addressing the problems of BSE. New secondary legislation could be introduced, but this required clearance, consultations and time to introduce' (Phillips *et al.* 2000, Vol. 1, p. 30). An example of this is that MAFF had no power to enter and take samples at feed mills to ensure that the RFB was being implemented effectively. MAFF's lawyers gave confused and conflicting advice on this matter because the legislation had not been designed to meet the problem in question.

The jurisdictional divide between regulators and LAs proved to be a recurrent problem throughout the BSE epidemic. While the regulators (mainly MAFF) made policy decisions and drafted regulations, the LAs were responsible for enforcing these regulations. In the case of BSE, MAFF had no power to enforce either the RFB or the SBO bans even though they possessed more knowledge, expertise and laboratory facilities than LAs, which were not required to report to MAFF on their enforcement actions.

Decisions made at the government level subjected other levels of the system to economic pressure. The European Commission, of which the UK was a member, required that slaughterhouses employ Official Veterinary Surgeons to oversee meat inspectors. This put additional financial constraints on LAs, who were already assigned limited funds.

Overshadowing all the decisions and actions made at the top levels of Figure 3 is the deregulation initiative. At the time of BSE, a key aim of the Government was to lift the burden of state regulation on industry and small businesses. Any proposals for new measures had to be tested against their cost to industry; 'enforcement was expected to be done with a light touch' (Phillips *et al.* 2000, Vol. 1, p. 30). This initiative conveyed the message that it was not desirable to be over-demanding in insisting on compliance with regulations unless there was strong evidence that the objective of the regulation was not being achieved. This initiative negatively impacted the enforcement efforts of the LAs and the priority given to slaughterhouse supervision assigned by slaughterhouse management.

Table 2. Test of the predictions in Table 1 for the bovine spongiform encephalopathy (BSE) epidemic.

	Prediction
1.	The AcciMap shown in Figure 3 vividly shows how the involvement of actors at all levels of the system set the stage for the BSE epidemic.
2.	No one factor in Figure 3 is independently responsible for the BSE epidemic. Many factors are influenced by at least two other factors. For example, failure of the local authorities (LAs) to enforce ruminant feed ban (RFB) and specified bovine offal (SBO) regulations can be attributed to the absence of a test for ruminant protein, a lack of communication from the Ministry of Agriculture, Fisheries and Food (MAFF) about how the regulations should be enforced and the importance of their enforcement, too few inspectors and an incomplete understanding of the risks associated with BSE.
3.	Figure 4 shows some of the mismatches between individuals and organisations across the levels of the socio-technical system responsible for human and animal food production in the UK. These examples of vertical misalignment punctuate how the priorities or objectives of individuals and organisations at different levels of the system can conflict as a result of the specific pressures that each is operating under.
4.	MAFF's efforts to end the propagation of BSE were performed in isolation from the other levels of the system. Determining the success of their efforts was subject to a time lag because there were no established feedback mechanisms from the lower levels of the system. It was not until at least an incubation period of time passed (five years) that the inadequacy of, and lack of compliance with, their regulatory efforts was realised.
	At the time of the RFB provision, no test existed to determine if ruminant protein was still being included in ruminant feed. This feedback was necessary to determine the compliance of both slaughterhouses and renderers and would also indicate the level of enforcement being offered by LAs. It was not until BSE was detected in cows that were born after the ban that the inadequacies of the RFB and its implementation were identified.
5.	Both economic and efficiency pressures influenced the decisions and actions of actors. The effects of these actions and decisions resulted in a migration towards system instability. Economic pressures were felt predominantly by actors at the highest levels of the system while efficiency pressures had the greatest impact on actors at the local government and physical processes and actor activities levels.
	Budget constraints on LAs existed before the introduction of BSE. These constraints help to explain why some LAs did not employ sufficient staff to carry out slaughterhouse inspection duties satisfactorily. When BSE imposed additional requirements on inspectors they were unable to meet the new production demands.
	Financial pressures contributed to the poor compliance with the voluntary animal SBO ban. The temptation for slaughterhouses to pass off SBO as non-SBO material was considerable because slaughterhouses had to pay for its removal. Renderers were also tempted not to look too closely at the material because, should they have to treat it as SBO, they would have to pay the disposal cost. Disposal of SBO ranged from £40–200 a tonne.
	Efficiency pressures had the largest impact on meat inspectors. Staffing levels were such that meat inspectors had little time for enforcement of regulations. Inspectors who tried to achieve 100% compliance with spinal cord removal were under tremendous pressure. 'The speed of operations, and the speed of the slaughter itself put pressure on inspectors without the ability to do the task properly' (Phillips *et al.* 2000, Vol. 6, pp. 317–318).
6.	The migration of work practices occurred at three levels – regulatory bodies, local government and technical and operational management. Migration at all three of these levels was discussed in prediction 5.

(*continued*)

Table 2. Continued.

	Prediction
7.	Some of the forces that set the stage for the BSE epidemic had been actively shaping the system long before the arrival of BSE. There was a history of poor general hygiene standards in licensed slaughterhouses as a result of sloppy work practices and poor enforcement with regard to the movement of unfit offal. The BSE Inquiry Committee was 'at first inclined to believe that poor standards of general hygiene would inevitably go hand in hand with poor standards of compliance with the SBO Regulations. So far as concerned the formalities of disposal of SBO once it had been removed from the carcass, we were proved right' (Phillips *et al*. 2000, Vol. 1, p. 135). Retrospectively, it is not surprising that a similar level of poor compliance with new BSE-related regulations was demonstrated. Flouting the regulations had not resulted in adverse outcomes in the past and the new regulations were not presented as an important measure for protecting human health.

4.9. *Assessing the predictions of Rasmussen's framework*

Table 2 summarises how well the predictions made by Rasmussen's risk management framework account for the factors that contributed to the BSE epidemic. There is good agreement between data and theory.

5. Discussion

The objective of this study was to test the ability of Rasmussen's risk management framework to explain how and why accidents occur in the food safety domain through the use of BSE and vCJD in the UK as a case study. This was accomplished by testing whether the BSE- and vCJD-related events that occurred in the UK from 1986 to 1996 supported each of the seven predictions of the framework. Indeed, evidence for each of the seven predictions was identified.

Using Rasmussen's approach to modelling accident causation is useful because it helps to identify ways to reduce the likelihood of accidents involving similar hazard sources. The framework accomplishes this by identifying the underlying factors at all levels of the system that contribute to unsafe decisions and actions, rather than focusing merely on the specific low level factors involved in a particular accident sequence.

Factors at the government and regulatory bodies levels highlight some of the outcomes of policy decisions that were made during the outbreak without the support of scientific evidence and that had serious economic implications. These outcomes included delayed, inadequate and unenforceable decisions that allowed BSE to continue to spread. These results point to the need for regulators and advisory committees to establish well-defined risk modelling techniques (Wilson 2005) to guide policy decisions when the degree of risk is uncertain and the decision has the potential to impact public health. A well-defined risk modelling technique would serve as a counter-gradient to the economic pressure, encouraging a more conservative, evidence-based and usually economical approach to managing risk.

Factors presented on the Conflict Map (Figure 4) have implications for identifying broken or missing feedback loops. Inadequate feedback prevents decision-makers from making decisions that accurately reflect the overall state of the system with regard to the boundary of safety and limits the information that operators receive about incorporating safety-related decisions made at higher levels (i.e. policies and procedures) into their work.

By addressing inadequate feedback across levels of a system, not only is the potential for a reoccurrence of the release of the same hazard source reduced, but there is a greater chance that the release of other hazard sources will also be averted since the system can be more tightly controlled.

The results of this study provide further support for the claim that Rasmussen's risk management framework shows promise as a theoretically driven explanation of how and why accidents happen in complex socio-technical systems (Vicente and Christoffersen 2006). Furthermore, this study shows that the framework may be useful for describing accidents that stem from the release of an unanticipated hazard source, not just well-defined hazard sources as is described in the original treatment of the framework (Rasmussen and Svedung 2000). While unanticipated hazard sources pose a difficult problem for prospective risk management, using Rasmussen's framework to guide retrospective studies of accidents caused by unanticipated hazard sources may prove useful for facilitating system redesign. The analysis may illustrate ways to protect against similar (now known) hazard sources and other unknown hazard sources that could be released as a result of the same system weaknesses in vertical integration.

There is one contributing factor in the BSE epidemic that the framework did not anticipate, namely MAFF's restraint from taking further precautionary measures even when a cheap, simple and risk-reducing measure was available (van Zwanenberg and Millstone 2001). After initial regulations were put in place and statements were made to the public about the safety of beef, MAFF avoided taking further precautionary measures because they were liable to undermine previous decisions and the Government's reassuring message to the public about the safety of beef. This action represents the Government's response to public opinion (or the fear of inviting negative public opinion). While public opinion is acknowledged by the framework as a factor having the potential to influence decisions and actions at the government level, the predictions of the framework do not anticipate the unsafe behaviour exhibited by MAFF in response to the fear of negative public opinion. If the tendency to avoid taking precautionary measures that may undermine previous decisions is shown to be a frequent contributor in other case studies using this framework, an addition to the framework, perhaps in the form of an additional gradient, may be warranted.

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About the authors

Andrea Cassano-Piché is a Human Factors Engineer and the Patient Safety Team Lead at the Centre for Global eHealth Innovation at the University Health Network, Toronto, Canada. She received a BASc and MASc in Industrial Engineering from the University of Toronto. Ms Cassano-Piché's research interests focus on proactive risk management in healthcare. She recently led the development of a hazard reporting system to help proactive identify latent failures at the University Health Network – the largest research hospital in Canada.

Kim J. Vicente is founding director of the Cognitive Engineering Laboratory at the University of Toronto, where he is Professor in the Department of Mechanical and Industrial Engineering. In 1991, he received a PhD in Mechanical Engineering from the University of Illinois at Urbana-Champaign. At the age of 34, he was promoted to full professor, the youngest in the 175-year history of the University of Toronto. Vicente has conducted extensive research in applications as diverse as aviation, infectious diseases, food management, medicine, network management, nuclear power, and petrochemical processes. Vicente's research has led to 1 patent, 2 books, 3 co-edited books, 178 refereed articles, 16 book chapters, 17 invited keynote addresses, and 54 technical reports. Professor Vicente also helped change the way a multinational Big Pharma corporation of 70,000 employees in 120 countries and $16 billion of annual sales does its business. Vicente has been presented the Premier's Research Excellence Award, valued at $100,000, and was the first engineer ever to receive the McLean Award, the University of Toronto's most prestigious award for basic research. Vicente also received the NSERC E.W.R. Steacie Memorial Fellowship, Canada's most prestigious prize for young academics in all areas of science and engineering. In 1999, he

was chosen by *TIME* magazine as one of 25 Canadians under the age of 40 who is a ‘Leader for the 21st Century who will shape Canada’s future’, and in 2002-2003, he was the 31st Jerome Clarke Hunsaker Distinguished Visiting Professor at the Massachusetts Institute of Technology.

Greg A. Jamieson is an Assistant Professor of Mechanical and Industrial Engineering at the University of Toronto. He received Bachelor of Science degrees in Mechanical Engineering and Psychology (with Distinction) from the University of Illinois at Urbana-Champaign, and Masters of Applied Science and Doctor of Philosophy degrees in Human Factors Engineering from the University of Toronto. His research and teaching centre on the design of cognitive artefacts for people working in complex systems. Professor Jamieson specialises in human-automation interaction and human-machine interface design with applications in process systems.