A microscopic image of E. coli O157 bacteria, showing a large, circular, textured structure with a bright, glowing edge, set against a dark blue background with faint, intersecting lines.

The Public Inquiry into the September 2005 Outbreak of *E.coli* O157 in South Wales

Chairman: Professor Hugh Pennington
March 2009

Outbreak of *E.coli* O157 in South Wales in 2005

- Primary Case(s) in School ▲
- Abercynon Infants School ▲
- Local Authority Boundary —
- City/Towns/Villages ■



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The Public Inquiry into the September 2005 Outbreak of *E.coli* O157 in South Wales

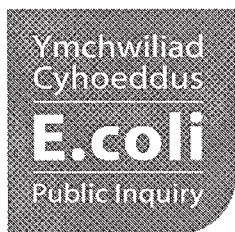
Chairman: Professor Hugh Pennington

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Post: Ymchwiliad Cyhoeddus E.Coli / E.coli Public Inquiry
Rhif Blwch Post 503 / PO Box 503
Caerdydd / Cardiff
CF11 1EN

Ffôn/Tel: 029 2082 1889 / 1840

E-bost/E-mail: ecolipublicinquiry@wales.qsi.gov.uk

Rt Hon Rhodri Morgan AM
First Minister for Wales
Welsh Assembly Government
Cardiff Bay
Cardiff
CF99 1NA

March 2009

Dear First Minister

***E.coli* PUBLIC INQUIRY**

You appointed me to hold a public inquiry into the Outbreak of *E.coli* O157 in South Wales in September 2005.

I was asked to investigate the circumstances that led to the Outbreak and how it was handled. I was also asked to consider my findings and make recommendations accordingly.

I have now completed the Inquiry and enclose my report.

Yours sincerely

Professor Hugh Pennington

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The Inquiry has lasted much longer than I had originally hoped. Principal reasons have been the necessity to wait for the conclusions of criminal proceedings before moving into the public aspects of our work, and the breadth and depth of our investigations. I thank the families affected by the Outbreak for their forbearance. In particular, I commend those of them who gave evidence not only for their willingness to appear in public but for the quiet dignity with which they relived harrowing and tragic events.

The conclusions and recommendations of this report are mine but the Inquiry has been a team effort. I am grateful to the whole team. The Inquiry Secretary, Ceri Breeze, has been a tower of strength, not only as administrative leader but also in tendering advice throughout. He has been ably assisted by the other members of the team. I thank John Hall, Rhian Thompson and Elin Wyn for the support they have provided. On the legal side, I thank the Inquiry's Solicitors Duncan Henderson and Dafydd Huw Davies, and Counsel James Eadie QC, Richard Cole and Emma Sutton for all their help. I am particularly grateful to James Eadie and Richard Cole for their visible contribution to the elicitation of evidence at the oral hearings and I owe a particular debt to James Eadie for his advice throughout the Inquiry.

Professor Hugh Pennington

The Outbreak

1. The Outbreak of *E.coli* O157 in South Wales in September 2005 was the largest outbreak caused by this organism in Wales and the second largest to date in the UK.
2. A total of 157 cases were identified, of which 118 were confirmed microbiologically as *E.coli* O157. Of those, 109 were of a strain unique to the Outbreak.
3. Most cases were children in 44 schools across four local authority areas. Thirty-one people were admitted to hospital. Tragically, Mason Jones aged five, died.

The Inquiry

4. The Inquiry's terms of reference were: "To enquire into the circumstances that led to the Outbreak of *E.coli* O157 infection in South Wales in September 2005 and into the handling of the Outbreak; and to consider the implications for the future and make recommendations accordingly".
5. Progress was affected by a criminal investigation and subsequent proceedings but the Inquiry was able to work in parallel with both.
6. The Inquiry considered a substantial volume of written and oral evidence. All relevant evidence and transcripts of proceedings can be accessed on the Inquiry's web site www.ecoliinquirywales.org

E.coli O157

7. Many types of bacteria live harmlessly in the digestive systems of people and animals. *E.coli* is one of them. But some types of it, such as *E.coli* O157, produce toxins that can cause serious illness.
8. *E.coli* O157 is a particularly nasty organism. It is highly infectious; only a few organisms can cause a potentially fatal infection.
9. The effect on some people can be mild but on others can be very serious and sometimes fatal. Some people are left with permanent kidney or brain damage.
10. Children under 5 and elderly people over 75 are particularly vulnerable. They are more likely to develop complications, which in themselves are not preventable and for which there are no specific treatments, only good supportive care.

Preventing Infection

11. The main source of *E.coli* O157 is the intestines of cattle and sheep. Infected animals show no symptoms but shed bacteria, most of which are found on the surface of their faeces.

12. Abattoirs must take steps to prevent an animal's flesh becoming contaminated with *E.coli* O157 in the first place. The organism is killed by cooking so action to prevent the cross-contamination of ready-to-eat foods is an essential food safety measure. In both abattoirs and butchers, food safety is delivered by Hazard Analysis Critical Control Point (HACCP), a system developed many years ago for the US Space Programme but now used worldwide.
13. Because *E.coli* O157 can also be transmitted between people, good personal hygiene practices are vital to prevent its spread. This is particularly important for elderly people in residential care homes, for children and young people in schools, and for people in hospital.
14. Food safety measures are underpinned by legislation, operated by businesses, and enforced by inspectorates. The regulatory systems in force at the time of the Outbreak had been reformed throughout the UK in the years before it. So the measures that were in place in 2005 were modern.
15. One of the measures, Butchers' Licensing, had even been introduced as a result of the 1996 outbreak of *E.coli* O157 in Scotland. All this makes the Outbreak particularly shocking.

Source of the Outbreak

16. The Outbreak was caused by food, cooked meats in this case, that had been contaminated with *E.coli* O157.
17. Extensive microbiological testing and typing revealed that the strains of *E.coli* O157 in people who were infected were indistinguishable from those found on cooked meats recovered from schools, in a sample of raw meat recovered from the premises of John Tudor & Son, a catering butcher business, and in samples of cattle faeces taken from a farm.
18. Cattle from the farm were slaughtered at the abattoir of J.E. Tudor & Sons Ltd, which supplied meat to John Tudor & Son
19. The Outbreak occurred because of food hygiene failures at the premises of John Tudor and Son. The responsibility for it falls squarely on the shoulders of William Tudor, the Proprietor.
20. William Tudor pleaded guilty to seven food hygiene offences. He was sentenced to twelve months imprisonment and banned from participation in managing any food business.
21. There were serious, and repeated, breaches of Food Safety Regulations. He failed to ensure that critical procedures, such as cleaning and the separation of raw and cooked meats, were carried out effectively. He also falsified certain records that were an important part of food safety practice.
22. The business's Hazard Analysis Critical Control Point (HACCP) plan was not valid. In some respects it was positively inaccurate and misleading.

- 23. William Tudor misled, and lied to, Environmental Health Officers on some issues, such as the use of the vac packing machine and a machine being away for repair.
- 24. There is no evidence that there was a sudden decline in food safety practice just before the Outbreak. Deficiencies had been there for a long time before.
- 25. William Tudor had a significant disregard for food safety and thus, for the health of people who consumed meats produced and distributed by his business.

The Inspections of John Tudor & Son

- 26. Bridgend County Borough Council was responsible for the inspection of John Tudor & Son.
- 27. The inspections undertaken by Environmental Health Officers were made less effective by William Tudor's dishonesty. Even so, the inspections did not assess or monitor the business's management of food safety as well as they could, or should, have done.
- 28. Clues were missed. Those that were spotted were lost in the system because there was no way of alerting other Environmental Health Officers to issues or concerns for subsequent inspections.
- 29. Failures around the Hazard Analysis Critical Control Point (HACCP) approach were the most important. The fundamental flaws in John Tudor & Son's HACCP plan could, and should, have been picked up.
- 30. There was insufficient focus on identifying and assessing working practices and procedures to ensure that the HACCP plan was being applied in practice.
- 31. The inspections failed systematically to assess the accuracy and effectiveness of the underlying HACCP documentation. Even when there is some indication that the underlying records were checked, inconsistencies and problems were not picked up.

The Food Standards Agency's Audit

- 32. Bridgend County Borough Council was audited by the Food Standards Agency in February 2004, some 18 months prior to the Outbreak.
- 33. Although feedback was provided at the end of the Audit in February 2004, the draft report was not sent to Bridgend until 17 June 2005, well over a year later.
- 34. The audit found little systemically wrong with Bridgend's team and methods of working.
- 35. The audit was systems-based. It was not designed to examine the techniques of an effective inspection.

School Meals

36. Schools were supplied with meats by John Tudor & Son under a contract with Rhondda Cynon Taf, Bridgend, Caerphilly and Merthyr Tydfil County Borough Councils.
37. The process by which the contracts were awarded in 1998 and 2002 was seriously flawed in relation to food safety.
38. The arrangements for the joint contract were inadequate, with a particular lack of clear and agreed roles and responsibilities between the organisations and key individuals.
39. The system for contract monitoring was not operated properly and the system for recording complaints was seriously flawed.
40. Better arrangements might have thrown more light on weaknesses in John Tudor & Son's approach to food hygiene and raised questions about his practices.
41. If anything was likely to have encouraged William Tudor to get his act together on food hygiene, it would have been the direct threat of failing to secure, or losing, what was a very significant contract.

The Abattoir

42. On the balance of probability, the *E.coli* O157 that caused the Outbreak entered the premises of John Tudor & Son on meat from the J.E. Tudor and Sons Ltd abattoir.
43. The likelihood of meat becoming contaminated with *E.coli* O157 at the Abattoir would have been significantly reduced if the Meat Hygiene Regulations that were in force in 2005 had been followed and enforced. There were big shortcomings in relation to both.
44. Over a prolonged period, the Meat Hygiene Service failed to perform effectively its overall enforcement function in relation to the Abattoir. Despite knowledge of longstanding, repetitive, failures, the Abattoir was allowed to continue functioning in breach of legislative requirements.
45. The limited enforcement action taken was demonstrably ineffective to achieve compliance with legislative requirements. For J.E. Tudor & Sons Ltd, the "light touch" enforcement was wrong.
46. Hygiene problems at the Abattoir had not been missed. The signals that the premises and its practices were unsafe were strong. They passed up lines of management in the Meat Hygiene Service. But it was allowed to continue in business without significant improvement.
47. There would have been a substantial increase in the risk of *E.coli* O157 on meat coming out of the Abattoir. As a result, the risks of unsafe food being produced and supplied into the food chain were considerably higher than they should have been.

Outbreak Control

48. The Outbreak was handled well. Importantly, the Outbreak Control Team identified a common link between cases at a very early stage. They reacted quickly, which led to the early removal of cooked meats from the food chain.
49. The Outbreak Control Team and many others who were also involved in action to control the Outbreak put in considerable time and effort to tackle the Outbreak, including extra hours and out-of-hours working.
50. But for the quality of the analysis and control measures, the Outbreak would have been considerably more severe and prolonged.

Schools and Hygiene

51. In 2004, the Children's Commissioner for Wales highlighted a problem with school toilets. He recommended that the Welsh Assembly Government should assist schools and governing bodies to undertake audits.
52. Few of the local authorities appear to have been aware of the Commissioner's report. The Assembly Government was aware of the report but did not bring it to the attention of local authorities.
53. As a result, and notwithstanding ongoing programmes of school improvements, the sort of action envisaged by the Children's Commissioner was triggered by the Outbreak itself.
54. Fortunately, the problems with toilet and hand washing facilities do not appear to have caused or contributed to the spread of the Outbreak. However, the provision of adequate facilities in schools is a basic requirement and it takes on a particular importance in terms of preventing the spread of an infection.

Treatment and Care

55. In-patient hospital care was as effective as it could be in the face of an infection that produces severe complications.
56. Some communications difficulties were experienced in the very early stages of the Outbreak. There was not a robust system for contacting Local Health Boards out-of-hours. The system for communications by Local Health Boards to front-line care professionals had weaknesses.
57. The communications difficulties did not have any adverse effects as far as outbreak control is concerned.
58. The Outbreak was a very real test of communications on a serious public health issue. It exposed some weaknesses and potential weaknesses in systems, which are likely to be relevant in most health incidents and/or outbreaks of a communicable disease, not just *E.coli* O157.

Learning Lessons

59. The only systems that worked well were outbreak control and clinical care. There were system failures everywhere else. Issues around HACCP were the most important. Wherever it should have been applied, there was insufficient appreciation of its power to deliver safe food.
60. I had hoped that the lessons from the shocking events in 1996 would stay in people's minds. But comparison of the failures that led to this Outbreak in South Wales with those in the outbreak in Scotland shows that this has not been the case.
61. We owe it to the memory of Mason Jones to learn the lessons from this Outbreak and to remember them.

Recommendations

The requirements for food hygiene that were in place at the time of the Outbreak should have been sufficient to prevent it. My recommendations therefore reflect what needs to be improved, tightened up or reinforced.

Food Safety Practice

1. All food businesses must ensure that their systems and procedures are capable of preventing the contamination or cross-contamination of food with *E.coli* O157.
2. Food businesses must get to grips with food safety management based very clearly on the seven key HACCP principles, ensuring it is a core part of the way they run their business.
3. Additional resources should be made available to ensure that all food businesses in Wales understand and use the HACCP approach and have in place an effective, documented, food safety management system which is embedded in working culture and practice.
4. The principles underpinning the Butchers' Licensing Scheme, which was introduced in response to the 1996 *E.coli* O157 outbreak, should guide food hygiene measures in businesses processing raw meat and unwrapped ready-to-eat foods.
5. The Food Standards Agency should review its current guidance and should be proactive in generating new guidance where needs are identified.
6. The Food Standards Agency should remove the confusion that exists among food business operators about what solution(s) should be used to prevent cross-contamination from surfaces and equipment.

Food Hygiene Inspections

7. Regulatory and enforcement bodies should keep the choice of “light touch” enforcement for individual food businesses under constant review.
8. The inspection of HACCP plans must be audit-based.
9. Training provision should be developed to ensure that all officers in Wales who check HACCP and HACCP-based plans, including those responsible for overseeing the work of those officers, have the necessary knowledge and skills.
10. Environmental Health Officers should obtain a copy of a business’s HACCP/food safety management plan at each inspection, which should be held on the business’s inspection file.
11. A system of logging issues, concerns or potential problems, whether by “red flagging” specific documents or by file notes, should be standard practice.
12. Decisions about confidence in a business’s management of food safety should be evidence-based.
13. All inspections, primary and secondary, must be unannounced unless, exceptionally, there are specific and justifiable circumstances or reasons why a pre-arranged visit is necessary.
14. Discussion with employees must be a standard part of food hygiene inspection visits.
15. The Food Standards Agency should develop, as part of its Audit Scheme or as an adjunct to it, a means of assessing how food hygiene inspections are undertaken by local authorities, including the assessment of HACCP and HACCP-based plans.

Procurement

16. Businesses contracting for the supply of high-risk foods, such as raw and cooked meats, to public sector organisations must be subject to independent food hygiene audits.

Health and Care Services

17. All health and care organisations should have an effective means of contacting key personnel during and outside normal working hours and for disseminating important information.

School and Hygiene

18. Every local authority should have a programme of audits to ensure that all schools have adequate toilet and hand washing facilities.

Learning Lessons

19. All local authorities in Wales should review their policies, procedures and systems against issues raised by this report.
20. The National Assembly for Wales should consider my recommendations and monitor and report progress on implementation.
21. A substantial review of food hygiene enforcement in Wales should take place approximately five years after the publication of this report.
22. Good practice advice and guidance issued by public bodies should be subject to follow-up and/or more detailed evaluation.

Learning More

23. Variable Number Tandem Repeat (VNTR) should be validated as a standard method for the typing of *E.coli* O157.
24. The feasibility of identifying “supershedder” cattle on farms should be explored as a potential means of reducing the likelihood of spreading *E.coli* O157 to other cattle.

The Outbreak

- 1.1 In September 2005, a major outbreak of *E.coli* O157 occurred in South Wales. It was the largest outbreak of its type ever seen in Wales and the second largest in the United Kingdom.
- 1.2 The Outbreak was declared on Friday, 16 September 2005. An Outbreak Control Team was formed. The first public announcement was made that weekend.
- 1.3 A total of 157 cases were identified during the Outbreak, of which 118 were microbiologically confirmed as positive for *E.coli* O157. Of those, 109 were of a strain identified as unique to the Outbreak.
- 1.4 Most cases were children in 44 schools in the Rhondda Cynon Taf, Caerphilly, Bridgend and Merthyr Tydfil areas, although there were also three cases in the Vale of Glamorgan. Thirty-one people, mainly children, were admitted to hospital. Tragically, on 4 October 2005 Mason Jones, aged five, died.
- 1.5 The Outbreak Control Team identified cooked sliced meats in school meals as the likely source of the infection. The meats were supplied by John Tudor & Son, a catering butchers' business based in Bridgend.
- 1.6 The Outbreak was formally declared over on 20 December 2005.

Calls for an Inquiry

- 1.7 Given the scale of the Outbreak, on 5 October 2005 the National Assembly for Wales set up a cross-party committee to consider the terms of reference for a public inquiry.
- 1.8 The Committee met for the first time on 7 November 2005. It took legal advice on the powers of the National Assembly for Wales to set up an inquiry. It noted that the Inquiries Act 2005 ("the 2005 Act") allowed the Assembly to set up an inquiry where particular events caused public concern, to set terms of reference, and to appoint a Chair.
- 1.9 The 2005 Act required the Assembly to consult the person it proposed to appoint as Chair about the terms of reference. I was approached after the Committee's first meeting and, having confirmed my interest, was invited to attend its second meeting on 17 November 2005.
- 1.10 At its second meeting, the Committee noted that a number of investigations were underway, including one by the police, and that a public inquiry would need to have regard to those. The Committee considered oral and written evidence. After consulting me, its Members decided that the terms of reference should be drafted broadly to ensure that I was not prevented from pursuing issues that might emerge from evidence. I considered this to be a sensible and helpful approach.

- 1.11 The Committee's report was laid before the Assembly on 30 November 2005[1]. It recommended:
- (i) That the National Assembly for Wales cause an inquiry to be held under the Inquiries Act 2005;
 - (ii) The Terms of Reference should be:
"To enquire into the circumstances that led to the Outbreak of *E.coli* O157 infection in South Wales in September 2005 and into the handling of the Outbreak; and to consider the implications for the future and make recommendations accordingly";
 - (iii) My appointment to Chair the Inquiry;
 - (iv) That, for the purpose of the Inquiry, functions under the Inquiries Act 2005 should be delegated to the First Minister.
- 1.12 The Committee's recommendations were agreed by the Assembly on 7 December 2005. Action was then taken to set up the Inquiry. The Inquiry's formal start date was 13 March 2006. It was the first in the UK to be established under the 2005 Act.

This Report

- 1.13 The Inquiry was a means of seeking out the facts in a way that would not be possible in, for example, a court case in which one party wins and another loses. My task was neither to decide in favour of one side or another nor to determine criminal or civil liability. The purpose of the Inquiry was to get to the bottom of the matters in question, something to which I was deeply committed. Through the Inquiry, I sought to answer the following questions:
- (i) What were the circumstances behind the Outbreak and why did it happen?
 - (ii) What happened after the Outbreak occurred and how was it managed?
 - (iii) What is needed by way of recommendations to try and prevent this from happening again?
- 1.14 The structure of the report follows the above logical sequence. It sets out in detail the relevant evidence under the key themes of my investigation, my findings and conclusions, and the recommendations I judge necessary as a result. The following paragraphs provide a more detailed guide to the structure of the report. I have produced a separate, bilingual, summary document that highlights the key messages from this report.
- 1.15 **Chapter 2** provides the background to the Inquiry and its approach. **Chapter 3** is an explanation of *E.coli* O157 and the features that make it such a threat to people's health.

- 1.16 **Chapter 4** provides the context for the Outbreak. It considers the incidence of *E.coli* O157 and previous outbreaks, including the major outbreak in Scotland in 1996. As is well known, I led the Review of that. Given the similarities between the Outbreak in South Wales and the Scottish outbreak, I thought it sensible to review what action was taken in Wales after the publication in 1997 of my Group's Report[2].
- 1.17 The Outbreak and the pattern of spread is described in **Chapter 5**. This is the foundation for the report. It is hard scientific evidence that shows very clearly the reach of the infection and its source. It is the result of detailed epidemiological work and substantial amounts of microbiological testing and typing that took place during the management of the Outbreak and the additional, more extensive, typing that I commissioned during the Inquiry.
- 1.18 **Chapter 6** describes the working practices of the business at the centre of the Outbreak, John Tudor & Son in Bridgend, which supplied raw and cooked meats for school meals.
- 1.19 Food businesses are subject to regulations designed to protect people's health. Environmental Health Officers from local authorities inspect premises to check compliance with food hygiene regulations. **Chapter 7** reflects a detailed examination of Bridgend County Borough Council's history of inspections of John Tudor & Son from 1997 to the time of the Outbreak.
- 1.20 **Chapter 8** examines the Food Standards Agency's role, in particular its audit scheme, which is one of the ways in which it discharges its responsibility for enforcing food safety law. The Agency undertook an audit of Bridgend's food law enforcement service in February 2004.
- 1.21 While during the Outbreak the major focus was, understandably, the business of John Tudor & Son, I considered it important to look back down the food chain to check if there was anything else that could have contributed to the Outbreak. What I saw led to the inspection regime of an abattoir becoming a substantial element of the Inquiry's investigation. This is the subject of **Chapter 9**.
- 1.22 The fact that the infection was transmitted through school meals meant that it was also important for me to consider the way in which meat for schools was purchased by local authorities. **Chapter 10** examines the procurement arrangements that were in place, looking back to contracts that were awarded to John Tudor & Son from 1998 to 2005.
- 1.23 Moving on to the management of the Outbreak, **Chapter 11** looks at how it was identified and how quickly, and what was done to control it. It examines the work of the Outbreak Control Team. **Chapter 12** focuses on communications activities that were undertaken to disseminate information about the Outbreak to health service providers while **Chapter 13** examines the provision of toilet and hand washing facilities in schools, which is an important measure to control the spread of infection.
- 1.24 The treatment and care of those who were infected is considered in **Chapter 14**, which focuses on the case of young Mason Jones, who tragically died as a result of the Outbreak, and **Chapter 15**, which examines the treatment and care of a sample of serious cases of infection.

- 1.25 **Chapter 16** examines the Review that was undertaken by the Chief Medical Officer for Wales, who was asked by the Minister for Health and Social Services at the time of the Outbreak to determine the need for any urgent action to protect people's health.
- 1.26 **Chapter 17** brings together my findings and conclusions and is the basis for the recommendations I make in **Chapter 18**.

The Inquiry's Web Site

- 1.27 The considerable body of evidence considered relevant to matters investigated by the Inquiry, including witness statements, exhibits, source documents and transcripts of proceedings, can be accessed through the Inquiry's web site www.ecoliinquirywales.org.
- 1.28 Copies of this report and the bilingual summary document can be downloaded from the web site.

The Inquiry Team

- 2.1 I was provided with a team to assist me in my task. The Secretary to the Inquiry was Ceri Breeze. He was responsible for all the arrangements for the Inquiry to take place. He was assisted by John Hall, Deputy Secretary, Rhian Thompson, Inquiry Support Officer and Elin Wyn, Media Consultant.
- 2.2 The Solicitor to the Inquiry was Duncan Henderson. He was responsible for instructing Counsel to the Inquiry, for gathering documentary and witness evidence, and for liaising with Core Participants and witnesses for the programme of hearings. The Deputy Solicitor was Dafydd Huw Davies. He covered the role of Inquiry Solicitor from 21 July 2008.
- 2.3 I appointed James Eadie as Senior Counsel to the Inquiry. He advised me on matters of law, assisted me in my investigation of the facts by presenting evidence to the Inquiry, and questioned witnesses on my behalf. He was assisted by Junior Counsel to the Inquiry, Richard Cole, and Assistant Junior Counsel, Emma Sutton.

Support

- 2.4 The National Assembly for Wales provided office accommodation for my team in its building in Cardiff Bay. It also allowed the Inquiry to hold its public hearings in the building.
- 2.5 I wish to put on record my sincere thanks to the Assembly, the Presiding Officer and Clerk to the Assembly for hosting the Inquiry. It made a significant contribution to the smooth running of the Inquiry and a substantial saving to the public purse. I also record my thanks to the many Assembly staff that provided support to my team throughout the Inquiry. It was much appreciated.
- 2.6 I am also grateful to the Welsh Assembly Government for the assistance given to me to set up the Inquiry and for support services provided to my team.

Procedures and Protocols

- 2.7 The Inquiries Act 2005 allows rules to be made for dealing with evidence and procedure. As my Inquiry was established relatively soon after the Act was passed, no rules were in place in Wales or elsewhere in the UK. I therefore determined the procedures in line with my powers under the 2005 Act. The procedures were published on the Inquiry's web site.
- 2.8 The 2005 Act also allowed me to make awards of costs for legal representation and compensation for financial loss and/or expenses to someone who was required to attend the Inquiry. Costs and expenses protocols were published on the Inquiry's web site.

The Inquiry's Approach

- 2.9 From the outset, I was mindful of the fact that a criminal investigation into the death of Mason Jones was underway. It was vital that the Inquiry's work did not risk prejudice to the outcome of any criminal investigation or eventual proceedings. An inevitable consequence was that the Inquiry could not move forward to a detailed public examination of all issues until the criminal investigation and proceedings had ended.
- 2.10 The criminal investigation concluded on 27 February 2007. The Crown Prosecution Service issued a public statement, which included the following paragraph:
- "After a lengthy and thorough investigation by the South Wales Police into the death of Mason Jones through *E.coli* food poisoning, the Crown Prosecution Service (CPS) has advised South Wales Police that there is insufficient evidence to provide a realistic prospect of conviction in respect of an offence of manslaughter. The CPS have also advised the police that a prosecution under the Health and Safety Act 1974 is not appropriate."
- 2.11 Following the CPS decision not to prosecute William Tudor, the owner and manager of John Tudor & Son, for manslaughter, the three local authorities most affected by the Outbreak, Bridgend, Caerphilly and Rhondda Cynon Taf, started a joint prosecution against him for food hygiene offences. Those proceedings concluded at a sentencing hearing on 7 September 2007 at Cardiff Crown Court. Mr Tudor had earlier pleaded guilty to six offences of placing unsafe food on the market and one offence of failing, as the proprietor of a food business, to protect food against the risk of contamination.
- 2.12 The six offences of placing unsafe food on the market related to meat distributed to Deri Primary and Hendre Junior Schools (Caerphilly), and Oaklands Primary, Glantaf Infants, Ton Pentre Junior and Newtown Primary Schools (Rhondda Cynon Taf), which was contaminated with *E.coli* O157 and was thereby injurious to health.
- 2.13 The other offence was that, as the proprietor of the business, he failed to ensure that raw and cooked meat during handling, storage, packaging, display and transportation was protected against contamination likely to render it unfit for human consumption, injurious to health or contaminated in such a way that it would be unreasonable to expect it to be consumed in that state.
- 2.14 Mr Tudor was sentenced to 12 months imprisonment. He also received an Order under Section 11(4) of the Food Safety Act 1990 prohibiting him from participating in the management of any food business in the future.
- 2.15 Inevitably, the Inquiry's progress was affected by the criminal proceedings but the approach adopted allowed it to obtain and analyse evidence in a way that did not risk interfering with those proceedings. This meant that on 7 September 2007, when the constraints imposed by criminal proceedings were removed, the Inquiry was able to move forward very quickly to its public hearings.

Core Participants

- 2.16 Individuals or organisations close to issues being investigated by an inquiry may be designated as “Core Participants”. Core participants play an active role in the Inquiry and are given access to documents and information. I decided the following should be Core Participants:
- The Individuals and Families affected by the Outbreak
 - Bridgend County Borough Council
 - Caerphilly County Borough Council
 - Merthyr Tydfil County Borough Council
 - Rhondda Cynon Taf County Borough Council
 - Bridgend Local Health Board
 - Caerphilly Local Health Board
 - Merthyr Tydfil Local Health Board
 - Rhondda Cynon Taf Local Health Board
 - Vale of Glamorgan Local Health Board
 - The Food Standards Agency (including the Meat Hygiene Service)
 - The National Public Health Service for Wales
 - The Welsh Assembly Government
- 2.17 In addition to those above, the Inquiry heard from others, principally healthcare providers, involved in the care and treatment of the more serious cases of infection that were selected for detailed investigation.
- 2.18 For reasons explained in more detail in Chapter 6, I did not designate Mr William Tudor of John Tudor & Son as a Core Participant. On grounds of fairness, I did invite him to make a statement to the Inquiry. He declined the opportunity to provide a statement.
- 2.19 I did not designate J.E. Tudor & Sons Ltd, the abattoir operator, as a Core Participant because the focus of my investigation was the inspection of the abattoir by the Meat Hygiene Service and because the abattoir ceased operations on 1 February 2006. Mr Jonathan Tudor was provided with a copy of relevant documents provided to the Inquiry by the Meat Hygiene Service in advance of the oral hearings, but the Inquiry did not receive a response.
- 2.20 The legal representatives of Core Participants are listed in Appendix 4.

Gathering Information

- 2.21 At an early stage, I met informally with some of the families affected by the Outbreak and listened to their views and concerns.
- 2.22 Core Participants were asked to provide information in the form of documents and witness statements. The Inquiry sought, and was provided with, evidence collected by South Wales Police during its investigation and evidence collated by the local authorities for their prosecution. This avoided the need for the Inquiry to start some of its investigations from scratch. I am grateful to those organisations for their co-operation.
- 2.23 The Inquiry also sought disclosure of the outbreak control database, which was held by the National Public Health Service for Wales. Steps were taken to obtain people's consent for the information to be disclosed to the Inquiry. I am grateful to the National Public Health Service for its help in facilitating that process.
- 2.24 The Inquiry received a total of 258 statements from 191 witnesses. These figures exclude witness statements obtained by South Wales Police as part of its criminal investigation.
- 2.25 In all, the Inquiry obtained and reviewed more than 45,000 pages of evidence.

Hearings

- 2.26 The Inquiry started its hearings on 12 February 2008. Between then and 19 March 2008, 63 witnesses were called to give oral evidence. The main purpose of the hearings, which were held in public, was to assist me in areas where facts were not clear or where there was controversy.
- 2.27 I held another public hearing on 14 May 2008, when Core Participants made oral submissions to supplement their written submissions.
- 2.28 I wished to ensure that evidence given to me was as full and helpful as possible. Mindful of the pressure this could put on witnesses, I decided not to allow photography or live broadcasting by radio or television during the sessions. However, recognising the media's important role in reporting the Inquiry's work, I did allow filming of the Inquiry's Preliminary Hearing and the opening and closing submissions of the hearings.
- 2.29 On 11 July 2008, the Inquiry published a Note of Emerging Issues, the purpose of which was to inform people of points that were of particular interest to me in considering possible recommendations. I asked Core Participants to provide me with a comprehensive and up-to-date picture of any changes that had been made to systems and procedures since the Outbreak and any that were planned.
- 2.30 I have considered in detail all submissions made to the Inquiry, irrespective of whether or not I refer to them in this report. In it, I set out my views on only those issues I consider to be most relevant to the specific matters in question.

Access to Evidence

- 2.31 Witnesses' statements and exhibits were published on the Inquiry's web site on the day they gave evidence. Full transcripts of proceedings were also published on the site, on average approximately two hours after the end of each session. This enabled members of the public and others across Wales and beyond to follow the proceedings in detail.
- 2.32 With the exception of documents that were subject to an order restricting publication, all other relevant evidence was published on the Inquiry's web site. By the beginning of January 2009, all of it could be accessed through the site. It will remain accessible after the publication of this report.
- 2.33 Before publishing my report, I gave individuals and organisations notice of potential criticism and/or adverse comments, and allowed them the opportunity to make representations to me.

The Cost of the Inquiry

- 2.34 Information on the cost of the Inquiry is available on the Inquiry's web site.

What is *E.coli*?

- 3.1 "*E.coli*", or to give it its full name "*Escherichia coli*", is a common bacterium. Many types of bacteria live harmlessly in the digestive systems of people and animals. *E.coli* is one of them. The average human gut contains approximately 10 million million bacteria. They weigh about one kilogram. The body needs these intestinal bacteria, because among other benefits, they synthesise vitamins and metabolise food components.
- 3.2 "*Escherichia*" is named after Theodor Escherich, a paediatrician. He discovered *E.coli* in 1885 when studying the intestinal bacteria of newborn babies. He was the first to investigate in detail the harmless bacteria of humans; a very appropriate study because the vast majority of the hundred billion billion *E.coli* living in the world at any one time are in the intestines of healthy humans and animals. But among the very large number of genetic types of *E.coli* are a few that cause disease. The most virulent are the Verocytotoxin producing *E.coli* ("VTEC"). Another widely used designation for VTEC is "EHEC", which is short for "*Enterohaemorrhagic E.coli*".

What is *E.coli* O157?

- 3.3 VTEC produce toxins that are lethal for cultured African green monkey (Vero) cells. They are also called "Shiga toxins" because of their close relationship to toxins produced by a bacterium that causes severe dysentery "*Shigella dysenteriae*". VTEC also have special genes whose products enable the bacteria to stick very firmly to the inner surface of the intestine. The commonest VTEC is *E.coli* O157:H7.
- 3.4 *E.coli* O157 is called an "emerging pathogen" because it is relatively new and because it is evolving quickly. It first came to notice abruptly and dramatically in 1982 in the USA, when it caused two outbreaks of bloody diarrhoea linked to the hamburgers from a chain of fast food restaurants. The first recorded outbreak in England and Wales was in 1983.
- 3.5 There have been increasing reports of *E.coli* O157 infection worldwide. This may be due in part to improved surveillance and methods of detection but it is generally accepted that the increase is real as opposed to being simply the result of increased awareness and assessment.
- 3.6 *E.coli* O157 is a particularly nasty organism because:
- (i) It is highly virulent; ingesting only very few organisms can cause illness.
 - (ii) It can survive for quite long periods on steel e.g. knives, and other surfaces.
 - (iii) It can survive refrigeration and is quite tolerant of acid, salt and dry conditions.
 - (iv) Although the effects of *E.coli* O157 toxins on some people can be mild, the impact on others can be very serious and sometimes fatal. Even after recovery from infection, some cases are left with permanent kidney or brain damage. The young (notably the under 5's) and the elderly (notably the over 75's) are particularly vulnerable.

- (v) Apart from good supportive care, including monitoring and close attention to hydration, there is no specific treatment for *E.coli* O157 infection. Once an infection has started, it is not possible to prevent the onset of complications.
- 3.7 *E.coli* O157 is highly infectious. A very small number of organisms, possibly between 10 and 100, can cause people to become ill.
- 3.8 Because the illnesses can be severe and sometimes fatal, particularly in infants, young children and the elderly, it is potentially much more dangerous than other forms of food poisoning such as *Salmonella*.
- 3.9 A diagnosis of an *E.coli* O157 infection is made by growing the bacterium in the laboratory. Special culture media are used on which colonies of the bacterium can be identified provisionally by their colour. Confirmation is done using special tests on the bacteria. The whole process takes about a day. In the UK, isolates are sent to a reference laboratory for sub-typing ("fingerprinting") and final confirmation. In an outbreak, it would be expected that all the *E.coli* isolates would have the same fingerprint. Sub-typing tests usually take about a week.

Sources of *E.coli* O157

- 3.10 The source of *E.coli* O157 extends back to the farm. It has been found in a range of wild animals, farm animals and domestic animals, and even in birds, mainly gulls. The main source is the intestines of cattle and sheep. It is more prevalent in cattle, although both can be a significant source of possible infection for people.
- 3.11 Approximately 9% of cattle may carry the organism. Infected animals do not show any clinical symptoms of *E.coli* O157 infection and do not appear to suffer any adverse effects, save perhaps for transient diarrhoea in very young animals. This means that it isn't possible for farmers to identify animals that are infected and there is no pressing reason for them to do so.
- 3.12 *E.coli* O157 bacteria live towards the end of the animal's gut and in its rectum. Infected animals shed the bacteria in their faeces. Most bacteria are found on the surface of the faeces.
- 3.13 Cattle vary considerably in the amount of *E.coli* O157 bacteria they shed. Factors affecting it may include age, fasting, diet, stress, and probably, the time of the year. Because bacteria can be present in animal manure, soil and grass and water courses can be contaminated. Contamination may be intermittent but when it occurs, it can last from a few weeks to approximately two months.

- 3.14 The level of *E.coli* O157 found in cattle faeces varies but is often very low. However, some animals excrete relatively large amounts of bacteria and have become known as “supershedders”. The presence of such animals increases significantly the potential for the spread of *E.coli* O157. They pose a significant risk of contaminating the environment or other animals within the herd. Other members of the herd or flock can quickly become colonised by Verocytotoxin producing *E.coli*.
- 3.15 *E.coli* O157 can survive for months in, or on the surface of, animal faeces, in soil and in freshwater. So anyone who comes into contact with infected faeces risks becoming a physical carrier and a potential source of infection for others, either directly or by contaminating other surfaces.
- 3.16 Normal abattoir processes aim to prevent meat becoming contaminated by the gut contents during slaughter, but contamination from hides, skins and fleeces is more challenging. The need for cleanliness of livestock presented for slaughter is also relevant. Dirty hides, skins or fleeces of animals can contaminate carcasses either through direct contact or through contact with workers’ hand tools, clothes or equipment. Bacteria that contaminate the surface of raw meat can be transferred to work surfaces. Research has shown that the organism can live on surfaces for at least 48 hours, thus posing a risk for cross-contamination. Given that relatively few organisms are needed to cause infection, this is a very real risk to people’s health. Hygiene measures to prevent cross-contamination are therefore vital.
- 3.17 “Supershedding” cattle are, if presented for slaughter, an increased risk to the food chain from the contamination of carcasses and the abattoir environment. In slaughterhouses, lairage is a likely source of contamination with *E.coli* O157 for animals and their hides.

How can People become Infected?

- 3.18 People can become infected through food and other sources. For both, infection is through a person’s mouth. This may occur by swallowing contaminated food or drink or by contact between the mouth and hands, which may have become infected through contact with other surfaces.
- 3.19 *E.coli* O157 spread through food is usually the result of well-recognised lapses in food handling, notably a failure to achieve adequate cooking temperatures or through cross-contamination of ready-to-eat products[3]. Products made from minced beef, such as burgers for example, present particular problems because any *E.coli* O157 bacteria on the surface of meat used to make the mince will be spread from its surface into the burger when it is made. Because mince is often prepared from the carcasses of several animals, a single infected carcass can contaminate a large batch of mince. Unless the centre of the burger is well cooked, it may not reach the required temperature to kill the bacteria.
- 3.20 Cross-contamination can occur when raw meat carrying *E.coli* O157 is allowed to contaminate other foods directly or via knives, other equipment or work surfaces.

- 3.21 Because *E.coli* O157 can also be transmitted between people, good personal hygiene is vital, as is meticulous attention to procedures designed to prevent cross-infection. This is particularly important for elderly people in residential care homes, for children and young people mixing in schools or places where pre-school children gather, and for people in hospital. Poor hygiene practices that allow faecal-oral contact result in person-to-person spread.
- 3.22 A variety of foods have been implicated in past outbreaks, including milk, cooked meats, salads, meat pies, dry cured salami, faecally-contaminated raw vegetables, cheese, yoghurt, apple juice, and water.
- 3.23 Infection can also occur through direct contact with infected animals and by contact with land contaminated with animal faeces. People whose job brings them into contact with farm animals are at increased risk. There are also risks associated with visitors, especially children, to farm centres.

What Happens when Someone becomes Infected?

- 3.24 While *E.coli* O157 causes no adverse effects in infected animals, in people it is a very different matter altogether. The young and the elderly are particularly at risk of serious consequences.
- 3.25 Knowledge of precisely how *E.coli* O157 produces disease, and why the young and elderly are so much more vulnerable to it, is still developing. Some people are affected minimally or not at all, while others develop serious illnesses sometimes with complications. Age apart, there is little to indicate who is likely to develop such complications.
- 3.26 After being taken in through the mouth, *E.coli* O157 bacteria travel to the stomach and then to the intestines, where they attach themselves to the inside surface of the large intestine. Toxins cause inflammation of the wall of the intestine and can also be absorbed and cause damage elsewhere in the body. The toxins may damage the walls of small blood vessels, which causes internal bleeding, so organs with many small blood vessels such as the kidneys and the brain are particularly susceptible.
- 3.27 The incubation period for infection with *E.coli* O157; that is, the period between infection with the organism and the onset of symptoms such as diarrhoea, is usually between 2 - 12 days and most commonly about three days.
- 3.28 Symptoms of infection include diarrhoea, headaches, abdominal pain, nausea and vomiting. The infection can cause:
 - (i) Mild diarrhoea.
 - (ii) Haemorrhagic colitis, which is caused by inflammation of the large bowel, with bloody diarrhoea.

- (iii) Haemolytic uraemic syndrome (“HUS”), which usually occurs in children and which is thought to be the major cause of kidney failure.
 - (iv) Thrombotic thrombocytopenic purpura (“TTP”).
- 3.29 Typically, infection causes 1-3 days of non-bloody diarrhoea after which in many cases diarrhoea becomes bloody. It is generally the appearance of blood in diarrhoea that prompts a person or family to seek medical help.
- 3.30 In most people, the symptoms last about a week and resolve themselves without any long-term problems. Research suggests that between 2-7% of people with *E.coli* O157 will develop HUS, which is a severe, potentially life-threatening complication. The incidence of this is higher in children than adults[4]. The risk that a child under the age of ten will develop HUS is about 15%.
- 3.31 HUS is a complex syndrome. Its characteristics include haemolytic anaemia, which is the destruction of red blood cells, and thrombocytopenia, which indicates the destruction of the cells (platelets) that are responsible for the clotting of blood, and acute kidney failure. HUS typically develops 5-13 days after the onset of diarrhoea.
- 3.32 TTP, which usually occurs in adults, is a clinical condition with the characteristics of HUS but also fever and complications of the skin and central nervous system.
- 3.33 A person who does not show any symptoms of *E.coli* O157 infection is termed “asymptomatic”. Such cases can cause difficulties as infection may not be diagnosed, which means that not everyone infected might be identified. Because people with asymptomatic infection may still excrete the *E.coli* O157 organism, they could still pass the infection on to others and therefore be a potential source of person-to-person infection. However, it is generally accepted that asymptomatic people pose less of a risk than those with diarrhoea. Some with an asymptomatic infection have gone on to develop HUS.

Treatment

- 3.34 Early identification of infection is vital. Provided it is recognised as a possibility by healthcare professionals, samples can be taken and appropriate and timely care considered.
- 3.35 There is no cure or antidote for *E.coli* O157 infection and therefore, treatment and care can only be supportive. It cannot deal directly with, or kill, the *E.coli* O157 bacteria or prevent the onset of complications.

- 3.36 The most effective ways of managing serious cases of infection are still far from certain:
- (i) Intravenous rehydration is important.
 - (ii) The administration of antibiotics is less clear. There is some evidence that they might increase the risk of HUS in children and adults. The current consensus is that they should not be administered.
 - (iii) Evidence relating to any possible harmful effects of the use of anti-motility or pain-relief agents is even less clear.
- 3.37 During the Outbreak, the National Public Health Service for Wales advised doctors that they should be aware that antibiotics are contraindicated in the community treatment of *E.coli* O157 as they may increase the risk of HUS. I have no reason to disagree with that advice.

- 4.1 This outbreak in Wales came nearly ten years after my involvement in the review of the major outbreak in Scotland in 1996. As the second largest outbreak of *E.coli* O157 in the UK, comparisons have inevitably been made between the two. Worryingly, there are many similarities.
- 4.2 The last chapter described *E.coli* O157 and its characteristics. This chapter sets the Outbreak in context. As background to the circumstances surrounding the Outbreak, it considers my review of the Scottish outbreak and what was done in Wales afterwards.

How Common is *E.coli* O157?

- 4.3 *E.coli* O157 infection is still relatively rare but because the illnesses it can cause can be severe and even fatal, it is a serious public health issue. The fact that it is rare is no reason at all for complacency.
- 4.4 Wales and Scotland are not alone in suffering major outbreaks of *E.coli* O157.

Previous Outbreaks of Note

- 4.5 Between November 1992 and February 1993, the American “Jack-in-the-Box” outbreak (burgers) resulted in 477 confirmed cases of *E.coli* O157 or Haemolytic Uraemic Syndrome (“HUS”), and four deaths, in four States; Washington, Idaho, California, and Nevada. This stimulated the US Department of Agriculture Food Safety and Inspection Service to declare *E.coli* O157 an adulterant in raw beef and it began a sampling programme to test for it in Federally inspected establishments and retail stores.
- 4.6 To date, the largest ever outbreak of *E.coli* O157 occurred in Sakai City, Osaka, Japan in July 1996, just before the outbreak in Scotland. There were 2,764 microbiologically confirmed cases but many more people had symptoms of infection. Of the confirmed cases, 2,345 were school children in 47 schools. There were 121 cases of HUS and three deaths. The source was traced to radish sprouts served at school meals.
- 4.7 In May 2000, an outbreak in Walkerton, Ontario, Canada, which was also the subject of a public inquiry, was traced to a contaminated public water supply. More than 2,300 people fell ill, of which 163 cases were confirmed microbiologically. Twenty-seven people had HUS. Four people died from the infection and it contributed to the death of three others.

Incidence and Pattern of *E.coli* O157 Outbreaks

- 4.8 The incidence of *E.coli* O157 is significantly higher in UK compared to most other European countries.

Table 4.1: Number of Cases of *E.coli* O157 in European Countries, 2005

Country	Number of Cases
England & Wales	950
Scotland	166
Ireland	108
France	74
Germany	73
The Netherlands	54

Source: Enter-Net Annual Report, 2005, European Commission

- 4.9 In 2005 in the UK, the rate of *E.coli* O157 infection was 2.0 per 100,000 population, which is closer to the USA figure of 1.05 cases. However, the foods that transmit the infection in the USA are substantially different, as are some of the control measures. In 2006, the UK accounted for 78% of all *E.coli* O157 cases in Europe
- 4.10 Between 1982 and 2002, 350 outbreaks of *E.coli* O157 were recorded in the USA. The total number of cases was 8,598 in 49 States[5]. Approximately half of the outbreaks (52%) were put down to food sources. Sixteen (9%) were in schools. The table below provides more information on the foods involved.

Table 4.2: Outbreaks of *E.coli* O157 attributed to Food Sources, USA, 1982 - 2002

Vehicle for Transmission	Number of Outbreaks	% of Food Outbreaks
Ground beef	75	41
Unknown	42	23
Produce	38	21
Other beef	11	6
Other food	10	5
Dairy	7	4
Total	183	100

Source: Rangel et al (2005) [5]

- 4.11 It is difficult to obtain comparable figures for the UK. Between 1989 and 1991, there were 17 outbreaks in the UK, 9 of which were in Scotland[6]. Of the total of 165 probable cases, 143 were confirmed by microbiological testing. In most of the outbreaks, no food source could be identified. The only outbreak in 1989 was put down to “ox roasting”. Of the others, one outbreak was associated with a beefburger restaurant chain and another outbreak was associated with locally produced yoghurt.
- 4.12 Between 1992 and 2002, there were 44 foodborne outbreaks in England and Wales[7]. Of 625 cases, *E.coli* O157 was confirmed microbiologically in 409. Ten of the outbreaks were associated with butchers’ shops. Nine were associated with milk and or milk products, of which four were linked with unpasteurised milk and three with milk sold as pasteurised.
- 4.13 Between 1996 and 2000 there were 11 outbreaks of *E.coli* O157 in Scotland[8]. The total number of cases was 651 with 382 confirmed microbiologically. Of the food sources identified, three of the outbreaks were caused by meat from butchers, including Barr’s, the source of the 1996 outbreak in Lanarkshire. Two outbreaks were caused by raw milk, two by cheese and one was attributed to salad.
- 4.14 The UK has a relatively high incidence of *E.coli* O157 compared to the rest of Europe (Ireland apart) and the United States. The incidence of different serogroups is strikingly different and there is also a very different pattern of infection. As far as I can ascertain, the UK is the only place with a history of butcher-associated outbreaks occurring on a regular basis. Figures from the Food Standards Agency[9] make this point very clearly.

Table 4.3: General outbreaks on Infectious Intestinal Disease associated with Butchers’ Premises, England and Wales, 1995 to 2004

Year	Number of Outbreaks
1995	8
1996	3
1997	4
1998	2
1999	4
2000*	5
2001	3
2002	0
2003	0
2004**	1

Source: Food Standards Agency

Note: * Butchers’ Shops Licences required from 1 November 2000

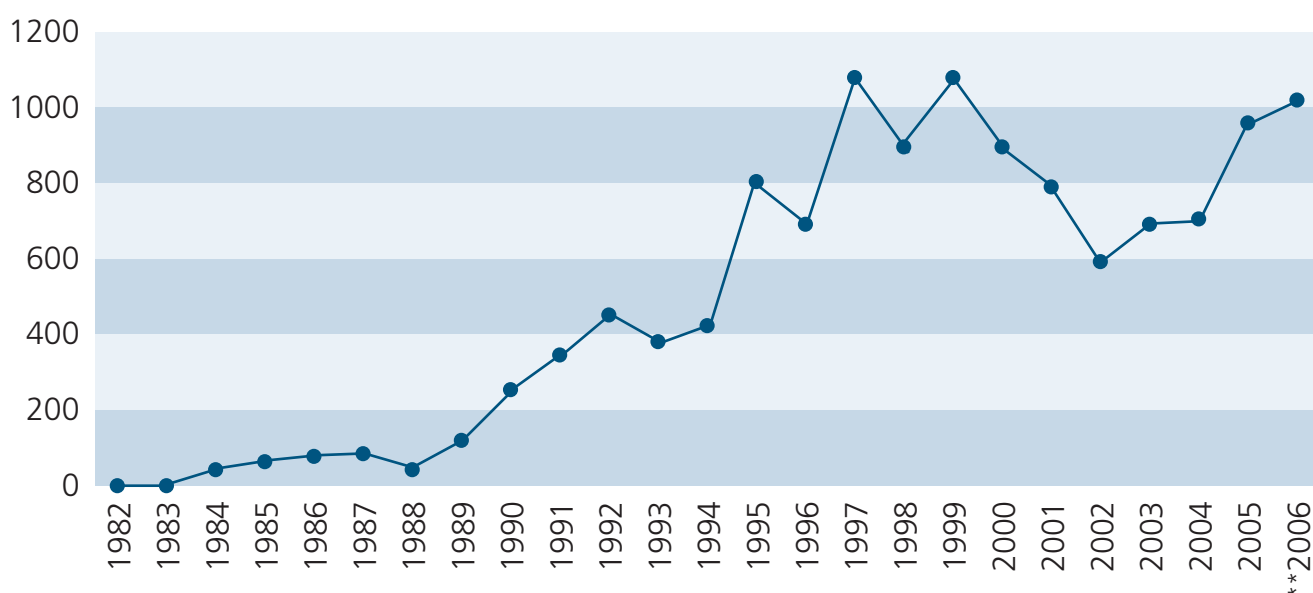
** Provisional

- 4.15 Outbreaks in the UK are nearly all local whereas many in the USA have been continent-wide. For example, the 2006 spinach outbreak originated in produce from the Salinas Valley in California but affected 205 people in 26 States. Thirty-five people contracted HUS and there were three deaths.
- 4.16 It is reasonable to suppose that the distribution of outbreaks in the UK reflect the small to medium size of the businesses that were responsible for them. This is also the case for outbreaks caused by milk. The largest milk outbreak in the UK was in North Cumbria in 1996 with 114 cases. Eighty-eight were confirmed microbiologically and three people developed HUS[10]. The source was a two-man farm that pasteurised approximately 1,920 pints of their own milk each week.
- 4.17 Before 2005, the last outbreak of *E.coli* O157 in Wales was in 2000, with eight cases confirmed microbiologically. The largest outbreak in Wales before 2005 was in 1995 in North Wales with 49 cases.
- 4.18 A small community outbreak in Wales in 1993 is also worthy of mention[11]. It was the first report in Britain of *E.coli* O157 being isolated from a beef product (beefburger). The report states "Six (patients) had consumed meat or meat products from a single retail butcher in the town. Inspection of the premises revealed procedures that might permit contamination of cooked products by raw meat."

England and Wales

- 4.19 In England and Wales, the trend on infection is upward. Contaminated food is the source of around half the cases.

Diagram 4.1: Vero Cytotoxin-Producing *E.coli* O157 Strains Examined by the Laboratory of Enteric Pathogens: Isolations from Humans in England and Wales, 1982 – 2006



Source: Health Protection Agency, Laboratory of Enteric Pathogens

Note: 2006 data is provisional

- 4.20 More than 80% of cases of *E.coli* O157 in England and Wales are sporadic; that is, cases that are not apparently linked to other cases. In Wales, around 30 sporadic cases are confirmed every year. In just over half, the source is never identified.
- 4.21 Most cases tend to occur between July and September of each year. This is consistent with research that has shown that animals shed higher concentrations of the bacteria in summer months. However, *E.coli* O157 is a year-round threat that requires continual attention to hygiene procedures.

Preventing Infection

- 4.22 The most important line of defence is to prevent *E.coli* O157 from getting into the food chain in the first place. In 1995, as a result of concerns about the emergence of *E.coli* O157, measures were recommended by the Advisory Committee for the Microbiological Safety of Food. These included:
- (i) Action to minimise the contamination of carcasses of animals at slaughter.
 - (ii) The adoption by the food industry of a Hazard Analysis Critical Control Point ("HACCP") approach to prevent contamination.
 - (iii) The prevention of cross-contamination from raw to cooked food.
 - (iv) Reconsideration of the sale of raw cow's milk in England and Wales.
 - (v) Advice on the cooking of beefburgers to kill *E.coli* O157 thus reducing risks of infection through undercooked food.
 - (vi) Control measures at all levels in the food chain given that the eradication of *E.coli* O157 in cattle is unlikely.
- 4.23 The above are fundamental to preventing *E.coli* O157 infection and form the basis of hygiene regulations. Abattoirs, food processors and retailers all have a part to play. The presence of *E.coli* O157 in cattle is a given. Without being able to tell which animals are carrying it and which are not, it must be assumed that all raw meat could be contaminated.
- 4.24 The slaughter process is the key first stage. Therefore:
- (i) the animal's hide must be removed with care to prevent it coming into contact with its raw flesh; and:
 - (ii) the gastro-intestinal tract, which hosts the *E.coli* O157 organism, must also be removed with care in order to prevent the contents contaminating the surface of the carcass.
- 4.25 *E.coli* O157 can survive on the surfaces of knives, tables, scales and other equipment, and on plastic packaging. Effective cleaning and disinfection procedures are therefore vital to preventing cross-contamination.

- 4.26 Personal hygiene is important. Hand washing can prevent infection in the first place, not only from food but from other sources including the farm, farm animals and farm environments. It can also help to prevent the spread of infection from person-to-person. For the latter, good hygiene practices and adequate toilet and hand washing facilities in places such as schools are also vital.
- 4.27 People who are, or who may be, infected with *E.coli* O157 and who handle food as part of their job, and people who work as carers or nurses, should be temporarily excluded from work. Similar restrictions on children attending school or nursery can also help prevent the spread of infection.

My Report on the 1996 Outbreak in Scotland

- 4.28 The outbreak in Scotland was, and still is, the largest outbreak of *E.coli* O157 in the UK. In November 1996, the Secretary of State for Scotland asked me to chair an Expert Group to examine the circumstances that led to the Outbreak, to advise on the implications for food safety, and to identify lessons to be learnt. We presented an interim report to the Secretary of State on 31 December 1996 and a final report on 8 March 1997[2].
- 4.29 A Fatal Accident Inquiry commenced in April 1998. In his Determination, Sheriff Cox QC said:
“The Pennington recommendations when implemented along with the establishment of the Food Standards Agency should reduce the risk of another tragedy of similar size, but unless the lessons are learned by everyone in the butchery trade – and indeed by every person with responsibility for handling raw meat and cooking it – the safety of the meat on the plate, as it were, cannot be guaranteed”.
- 4.30 My Group was committed to identifying measures to help reduce the possibility of future *E.coli* O157 infections. The overarching principle that guided our work was the need to tackle the dangers it presented and to reinforce public health considerations in food safety.
- 4.31 We did not describe or debate in any detail the causes of the Outbreak or the individual roles and actions involved in its occurrence, management and control. That was for the Fatal Accident Inquiry and the criminal proceedings.

The Outbreak

- 4.32 The possibility of an outbreak was identified on a Friday afternoon in November 1996. By that evening, a common factor had been identified amongst those suspected of being infected or confirmed with the infection. Nearly all had consumed food obtained directly or indirectly from J.Barr and Son, Butchers, of Wishaw.

- 4.33 Barr's premises comprised two retail units; a butcher's and a baker's. At the rear of the butcher's unit was the manufacturing area. The premises had modern chillers, equipment and work surfaces but had been extensively converted and extended. It was similar to others of its age. Its layout and design constrained measures that could be taken to ensure effective product flows and separation of raw and cooked products.
- 4.34 The Outbreak extended across local authority boundaries. There were 17 deaths either caused by *E.coli* O157 or in which infection with it was a significant contributory factor. The total number of confirmed cases was 279 but more than 2,500 people were investigated in connection with the Outbreak. The Outbreak was declared over on 20 January 1997.

Issues Examined

- 4.35 We considered how and why fresh meat becomes contaminated with *E.coli* O157 in the first place and the likely distribution in the food chain. We reviewed measures that could, and should, be taken to minimise contamination and cross-contamination, and how the measures are regulated and enforced. We also considered the steps that needed to be taken to manage and control outbreaks, and the adequacy of systems and arrangements for that. Our report was structured around key themes, of which the following are particularly relevant to this Inquiry into the South Wales Outbreak.

Hazard Analysis and Critical Control Point

- 4.36 As the overarching system that governs the UK's approach to tackling food safety issues, we spent much time considering the Hazard Analysis and Critical Control Point ("HACCP") system as a structured approach to identifying the potential hazards in a business. HACCP is both a philosophy and a practical approach.
- 4.37 From what we heard, there was confusion about the application of HACCP in both a practical and legislative senses. "HACCP", "HACCP principles", "Hazard analysis" and "risk assessment" were terms that seemed to be used interchangeably and could be misinterpreted.
- 4.38 We felt the need to raise the level of awareness of, and expertise in, tackling the hazards involved in food handling and production. The most effective way was to influence the attitudes of all those involved throughout the food production process and to ensure that they take personal responsibility for the adoption of good practice in food handling and hygiene. The successful application of HACCP requires the full commitment of management and the workforce, and knowledge, understanding and expertise in identifying the hazards and assessing the risks involved in an operation. We had several concerns including:
- (i) The reliance on businesses, albeit with external advice and assistance as appropriate, to identify potential hazards and critical control points in their own operations.
 - (ii) Businesses required expertise and training for successful implementation.

- (iii) The concept was sound but relatively new and consequently it was insufficiently known about or understood.
- (iv) The period over which HACCP principles could be introduced effectively was lengthy; Senior Environmental Health Officers (“EHOs”) suggested it would take five years or even longer regardless of the risks inherent in a particular business.
- (v) We believed enforcement had, at the request of central Government, been generally pursued with a “light touch” based on a graduated approach. Indeed a 12 month period of grace had been set out in the statutory Codes of Practice for enforcement of the hazard analysis requirements of the 1995 Regulations. I believe that that approach could no longer be considered appropriate or acceptable.
- (vi) The enforcement procedures of the 1995 Regulations were not totally effective.
- (vii) If public health was at risk due to defects in the hazard analysis system, emergency action needed to be taken under the Food Safety Act 1990.

4.39 We concluded that measures were needed to reinforce legislation to strengthen the implementation and enforcement of HACCP principles in the short-term and to promote food safety pending its full implementation. Our report recommended:

- (i) Improved guidance on risk assessment in Codes of Practice.
- (ii) Accelerated implementation of HACCP for high-risk premises.
- (iii) Review of existing guidance on cross-contamination.
- (iv) Better targeting of environmental health department resources including more frequent inspections of high-risk premises.
- (v) Amending the definition of the health risk condition in section 11 (2) of the Food Safety Act 1990 to permit food authorities to have greater confidence to take enforcement action if they felt they had reasonable evidence that particular food premises represented a risk to public health.
- (vi) Separation of raw meat and cooked foods in target premises.
- (vii) The introduction of selective licensing for high-risk premises to permit more detailed conditions to be set to minimise health risks and enforcement. This was seen as a short-term measure while HACCP systems were being introduced.

4.40 We understood the Government’s general policy against prescription in favour of deregulation to reduce the regulatory burden in small businesses. However, we felt that the need to promote safety in food production and safeguarding public health had to be accepted as a special case where the balance required a greater degree of prescription.

- 4.41 The recommendations particularly pertinent to this Inquiry into the South Wales Outbreak were “Practice and Hygiene in Slaughterhouses”, “Practice and Hygiene in Meat Products Premises and Butchers’ Shops”, and “Enforcement”.

Practices and Hygiene in Slaughterhouses

- 4.42 We noted that the position on general standards in abattoirs across Scotland was mixed, as it appeared to be in other parts of the UK. We were clear that the MHS was acutely aware of the need for high standards to be achieved and maintained in all abattoirs and was taking steps actively to tackle the issue. We supported and encouraged the MHS in its efforts to raise overall standards in abattoirs. We suggested that, as for broader enforcement activity, resources should be targeted on poor performers and there should be rigorous encouragement and enforcement of the standards to be achieved.
- 4.43 Among other recommendations, we said that in line with the approach recommended for more general enforcement, the efforts and resources of the MHS should be targeted at higher-risk premises, especially those abattoirs with Hygiene Assessment Scores of under 65.

Practices and Hygiene in Meat Products Premises and Butchers’ Shops

- 4.44 The potential for cross-contamination highlights the critical nature of meat production and butchers’ premises within the food chain. It is inevitable that some raw meat contaminated with *E.coli* O157 will enter premises. Raw meat therefore needs to be treated as potentially contaminated and appropriate hygiene standards adopted.
- 4.45 We accepted fully that HACCP should be the universal approach and the need to renegotiate the EU directives made this a longer-term aim. But we had reservations in the short-term, even about those HACCP principles that were already in domestic legislation. We considered the regulatory position and issues surrounding implementation and enforcement in considerable detail.
- 4.46 Recognising the need for a framework of actions which would improve the protection of public health and minimise the risk of infection with *E.coli* O157 from cooked meats and meat products, and reflecting our support for the general policy approach involving the application and implementation of HACCP, we recommended among other things:
- (i) That the HACCP approach and all seven of its principles should be adopted by all food businesses to ensure food safety. While this was being negotiated into EU and domestic legislation, implementation and enforcement of the principles in existing legislation required acceleration.
 - (ii) Pending HACCP implementation, selective licensing arrangements for premises not covered by the Meat Products (Hygiene) Regulations 1994 (“the 1994 Regulations”) should be introduced.

- (iii) That licensing arrangements should include appropriate requirements for the documentation of hazard analysis, labelling and record-keeping to facilitate product recall, and temperature control and monitoring. All food handlers should be required to have at least basic food training and all supervisory staff, and those who run small, one-person operations, trained to at least intermediate level. In addition, licensing should cover matters relating to the suitability of premises, equipment and hygiene practices to a level equivalent to that required by the 1994 Regulations.

4.47 In relation to the physical separation requirements of licensing, we recommended:

- (i) That there should be separation, in storage, production, sale and display, between raw meat and unwrapped cooked meat/meat products and other ready to eat foods. This should have included the use of separate refrigerators and production equipment, utensils and wherever possible, staff.
- (ii) That where the use of separate staff cannot be achieved, alternative standards, such as the completion and implementation by the operator of a HACCP or the provision and use of additional facilities e.g. for hand washing in the serving area, might be regarded as sufficient to permit the award of a licence. It was thought that central Government departments would have wished to give further thought as to precisely how this arrangement might operate.
- (iii) Where neither (i) nor (ii) above was achievable, the premises should not be permitted to sell both raw and unwrapped cooked meat/cooked meat products, although they could be permitted to sell pre-wrapped cooked/ready-to-eat meat products prepared elsewhere and brought in for that purpose.

Enforcement

4.48 We examined where responsibility for enforcement lay and the competence of those charged with enforcement practice. We also considered the changes in the structure of Environmental Health Departments and changes in Government policy on food safety enforcement as a result of implementing EU single market measures and deregulation initiatives. We recognised that this had created uncertainty amongst Environmental Health Officers about the overall approach. It seemed to us unacceptable that EHOs should be in any doubt about the need for anything other than rigorous enforcement of food safety standards, which should be clear and unambiguous.

4.49 Recommendations set out in our interim report and in our final report were designed to strengthen the position on enforcement, particularly in relation to high risk premises. These included:

- (i) The accelerated implementation of HACCP for high-risk premises.
- (ii) The proposed selective licensing arrangements.

- 4.50 We endorsed HACCP as the overarching policy and practical approach to ensuring food safety and recommended incremental steps to advance its implementation. We considered it unreasonable to expect EHOs to be the sole, or indeed the main, contributors towards taking forward education and awareness of HACCP principles and their implementation. Responsibility for that rests primarily with business. Nonetheless, we felt that EHOs had an important role to play. Not only do they have substantial experience and expertise to offer, but they will also be expected to make judgements about the appropriateness or otherwise of HACCP.

Action in Wales after The Pennington Report

- 4.51 In his Determination of the Fatal Accident Inquiry, Sheriff Cox referred to the importance of learning lessons. Given the circumstances and scale of the South Wales Outbreak, his words are indeed profound. "Lessons learnt" is highly relevant and led me to question what was done in Wales after the Outbreak in Scotland.

The Welsh Office's Role in Food Safety

- 4.52 The Welsh Office monitored local authorities' performance on food safety. Policy responsibility was vested in its Public Health Division. Professional advice was provided by Chief Environmental Health Adviser, Mr Ronald Alexander, and Deputy Chief Environmental Health Adviser, Mr David Worthington. Both provided written evidence to the Inquiry.
- 4.53 Liaison with local authorities was helped by the Panel of Chief Environmental Health Officers from District Councils. In 1996, this became the Society of Directors of Public Protection. Below it sat Technical Panels for subject-specific areas such as food safety.

Action after The Scottish Outbreak

- 4.54 The Government published its response to my report on 8 April 1997. Immediately upon publication, the Welsh Office distributed copies of it along with my report. The next day, it issued a Circular reminding local authorities that the inspection of butchers' shops dealing with raw and cooked meats was a high priority and to ensure the necessary hazard analysis plans were in place.
- 4.55 While my report's recommendations required action by central Government, several recommendations fell to the Welsh Office to implement. These included:
- (i) Additional funding for the HACCP approach.
 - (ii) Food hygiene training provided in the primary and secondary school curriculum.
 - (iii) Guidance and education about food handling and hygiene.
 - (iv) Non-registered premises should be encouraged to adopt HACCP principles.
 - (v) Good hygiene practice encouraged amongst those working with vulnerable groups.

(vi) Accelerated HACCP implementation and funding for local authorities.

(vii) Written reports of large or otherwise significant outbreaks and adequate numbers of personnel with appropriate skills to deal with outbreaks.

4.56 At that time, the Welsh Office did not have an internal group to consider food hygiene and safety issues so it reconvened its Food Safety Group.

Accelerated Implementation of HACCP

4.57 On 19 August 1997, The Secretary of State for Wales announced £1.2 million for local authorities to accelerate the implementation of food safety systems based on HACCP principles. A Circular was issued explaining revisions to Code of Practice No. 9 and enforcement of the hazard analysis requirement. It also explained that pending the introduction of selective licensing, the Food Safety (General Food Hygiene) Regulations 1995 could be used to enforce the physical separation of raw meat and unwrapped cooked meat/meat products where it was thought necessary to prevent cross-contamination.

4.58 By December 1997, funding had been given to local authorities to support HACCP implementation. Progress varied but each local authority had at least one officer trained in HACCP. A generic HACCP document was agreed to help butchers produce tailored systems.

4.59 In February 1999, the Food Safety Group reported that after some initial doubts, local authorities viewed accelerated HACCP favourably. It was seen as positive in building relationships with butchers.

Food Hygiene Training and Education

4.60 Difficulties in altering the National Curriculum were reported so action focused on other measures, including a food hygiene leaflet and associated materials. Guidance on school visits to farms was also issued. Guidance was issued to the NHS on the risks of cross-contamination of meat and the need for food handlers to be adequately trained.

Outbreak Control Plans

4.61 The requirement for reports of outbreaks was already incorporated in Welsh Office guidance and Welsh Office Circular (90)64 required local authorities to review annually their plans for managing food poisoning outbreaks. But the Food Safety Group thought it prudent to ask local authorities in Wales to review their outbreak control plans. All did so.

4.62 The idea of an all-Wales Model Outbreak Plan for managing food poisoning outbreaks was also being considered and subsequently, was produced.

Problems with Local Authority Food Law Enforcement

- 4.63 While progress was made on HACCP, some problems emerged in respect of low inspection rates in some local authorities. By June 1997, there was “very considerable cause for concern”. There were indications that the new authorities that had emerged after local government reorganisation had further reduced staffing in Environmental Health Departments. An extra £300,000 was found for increased inspections.
- 4.64 In December 1997, the South East Wales Food Liaison Group identified problems in the systems and practices of butchers’ shops and surprisingly poor awareness of the potential problems given the publicity on *E.coli* O157 and other food poisoning.
- 4.65 By March 1998, the position on inspections was considered extremely poor, with very few authorities undertaking enough inspections to meet the requirements of the Code of Practice. Officials had raised it with the authorities on several occasions. Mr Alexander recorded his grave concern at the level of food law enforcement. At a meeting of the Food Safety Group in July 1998, he said that Wales had been lucky to escape a serious outbreak of food poisoning and when such an outbreak occurred, the performance of Welsh local authorities might be viewed in a critical light.
- 4.66 As a result of the concerns, and in conjunction with the Welsh Local Government Association, a Task Force was set up to collaborate on food hygiene matters. It met for the first time in February 1999.

The Food Standards Agency

- 4.67 The Food Safety Group considered the role of the Food Standards Agency (“FSA”) in Wales, its powers, accountability, funding, and staffing. After January 1999, it became clear that the Agency would assume responsibility for food safety. The policy focus in the Welsh Office then became the Agency’s establishment and the transfer of functions to it. As far as Mr Worthington can recall, after 16 February 1999 there were no further meetings of the Task Force.
- 4.68 In May 1999, the Welsh Office became the National Assembly for Wales. The FSA became operational on 1 April 2000 as the Government’s statutory adviser on food safety.

Best Practice Recommendations

- 4.69 The Society of Directors of Public Protection in Wales was also proactive after the publication of my report in Scotland. Towards the end of 1997, one of its groups produced a document “Lessons to be Learned from the Fatal Accident Inquiry: Best Practice Advice”. The document was approved by the Society and circulated to all local authorities. It provided best practice notes for all officers involved in food safety.

- 4.70 Mr Worthington says that as far as he can remember, all local authorities accepted the recommendations, responded positively to them, and agreed to implement them. All recommendations are relevant to this Inquiry but some are worthy of particular note:

Competence of Environmental Health Officers

- All food safety officers to be suitably trained in relation to the principles of HACCP and HACCP auditing.

Inspection Systems

- A duty on managers to introduce systems and insist on standards that would result in adequate inspections.
- Individual premises files to have up-to-date records of inspection reports and issues associated with the premises or systems, and certain files to contain information such as product flow plans.
- All inspections must be hazard analysis audit-based.

Inspection Techniques

- The principal focus of inspections must be to check that managers and staff are properly trained in safe food production and that procedures are in place to prevent contamination.
- In seeing that the letter of the regulations is complied with, the EHO must not lose sight of the overall aim, which is the production of safe food. Until the principles of hazard analysis are fully implemented, inspections must include observing what is taking place, discussing procedures with staff, identifying weaknesses in systems and operations, assessing risks, and ensuring that staff know what to do, are doing it and know why they are doing it.
- During inspections, officers should discuss systems with employees to assess the true picture of training, their understanding of the role of critical control points, cross contamination, personal hygiene and fitness to work policies.
- Proprietors should be encouraged to sketch diagrams of premises, depicting flow patterns of raw and cooked foods as they are useful for identifying possible cross-contamination points, the dual use of surfaces for raw and cooked foods and personnel flow routes.
- Use of cleaning chemicals and techniques should be audited.
- Authorities should instil in officers a need for quality inspections not merely quantity.

Conclusions

- 4.71 The information on the incidence of *E.coli* O157 infection, the contextual information on past outbreaks, and the summary of key points of my Group's report speak for themselves. My review of action taken in Wales after the Scottish outbreak leads me to the following conclusions.
- 4.72 The Welsh Office acted promptly after the publication of my report into the Scottish outbreak. Appropriate steps were taken to minimise the chances of an outbreak in Wales. Action was taken in response to concerns about levels of inspections, but seems to have fallen away in the run up to the establishment of the FSA. In the context of the 2005 Outbreak, I do not consider this to be a significant issue.
- 4.73 The best practice advice produced by the South East Wales Task Force is a very good example of a proactive response to learning from the Scottish outbreak. As will be seen later in this report, some of the recommendations are evident in the inspection practices and procedures that have been examined during the Inquiry. In reality, this may be the result of changes to Codes of Practice and Regulations as opposed to the Best Practice Advice, of which there was very little awareness among witnesses.
- 4.74 Sadly, I could not see some of the recommendations on practice reflected in the inspection regime I have examined. It seems, therefore, that some learning from the experience of the Scottish outbreak in 1996 has been lost to Wales. The Best Practice Advice was a good idea. It was "advice" only of course, but it was said that all local authorities accepted the recommendations and agreed to implement them. Such action can help to ensure the continued development of practice and, importantly, that lessons are learned from past events.

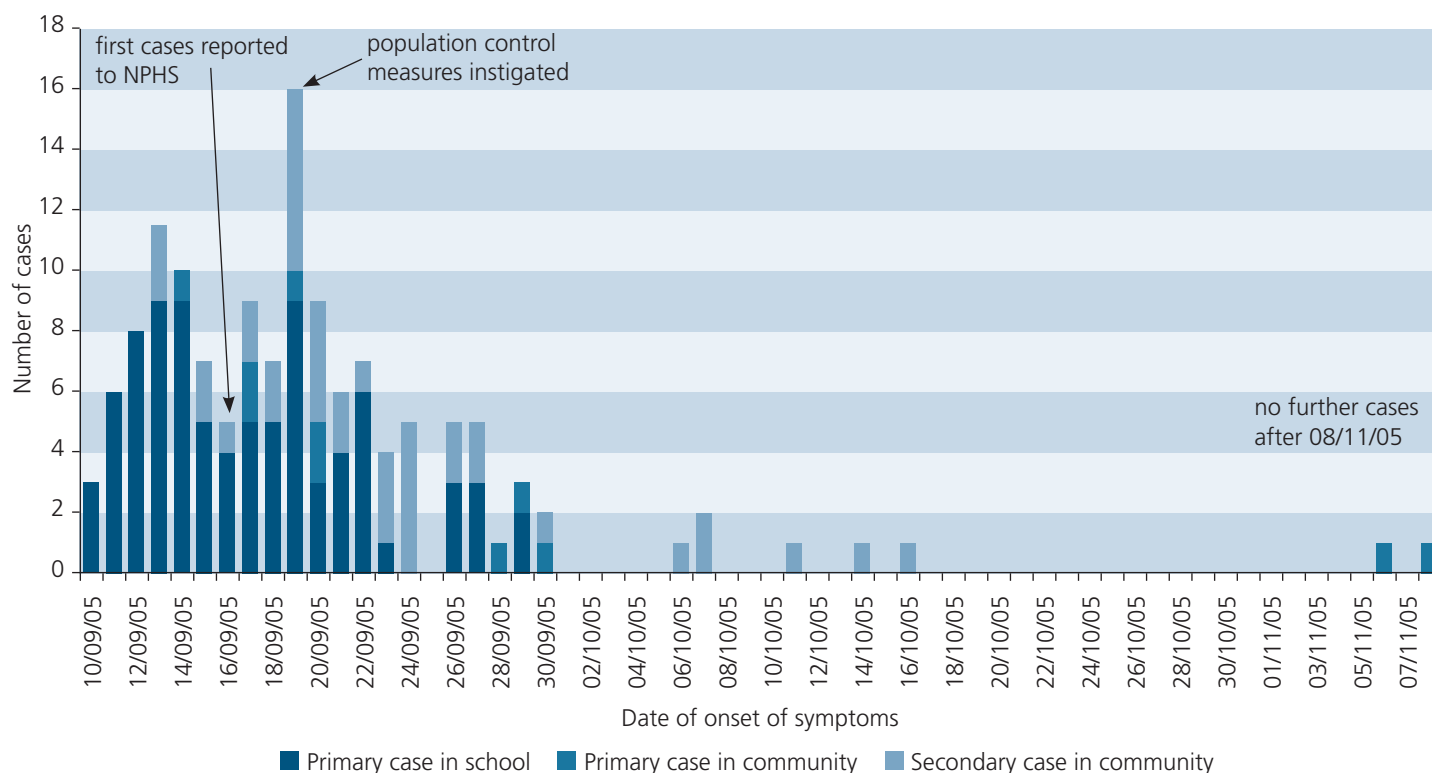
- 5.1 The Outbreak was the largest ever of *E.coli* O157 in Wales and the second largest in the UK. The work of the Outbreak Control Team, the police and local authority investigations and my Inquiry also means that it perhaps one of the most thoroughly investigated outbreaks caused by the organism.
- 5.2 This Chapter describes the pattern of the Outbreak and the microbiological evidence that underpins it. It is the foundation for the report. The testing and typing done as part of managing the Outbreak and the additional, more extensive, testing and typing I commissioned has confirmed without doubt that the same strain of *E.coli* O157 passed from the farm to food to the people who were infected. It has established the source of the infection and its reach.

Epidemiology

- 5.3 On the morning of Friday, 16 September 2005, a doctor at Prince Charles Hospital, Merthyr Tydfil, informed the National Public Health Service for Wales that in the previous two days, five children had been admitted with watery, blood-stained, diarrhoea. Three others with bloody diarrhoea had also been seen at the hospital's assessment unit. The same morning, a microbiologist reported that *E.coli* O157 had been identified in two samples. At a meeting that afternoon, an outbreak was declared and an Outbreak Control Team ("OCT") was formed.
- 5.4 There were two main strands of investigation by the Outbreak Control Team. The first was designed to ascertain epidemiologically the pattern of infection. The purpose of this investigation was to seek to identify and isolate the source of the Outbreak by identifying a common feature, or features, between those who were affected.
- 5.5 The results were that:
- (i) The majority of cases involved school children. Ultimately, 44 schools had at least one infection.
 - (ii) The cases were spread in the main across the four local authority areas of Bridgend, Caerphilly, Merthyr Tydfil and Rhondda Cynon Taf.
 - (iii) In Rhondda Cynon Taf, primary cases spread across 25 primary schools (including nursery and infants) and four secondary schools. In Merthyr Tydfil, cases were spread across two primary schools and in one secondary school. In Caerphilly, cases were spread across nine primary schools. In Bridgend, there were cases in three secondary schools.
- 5.6 The common feature linking the cases was the supply of cooked sliced meat from John Tudor & Son ("Tudors"). The business supplied the school meals services in the four local authority areas. At that time, all schools with a case where the onset of symptoms was before 17 September 2005 had been exposed to cold cooked meats supplied by Tudors during the first week of term.

- 5.7 The investigation identified three cases who reported that their symptoms of possible infection had started on 10 September 2005. For the vast majority of cases, the date of onset of symptoms was before the end of September 2005.
- 5.8 The OCT used the following definitions:
- (i) a probable case was any person presenting with bloody diarrhoea within the last fortnight resident in South Wales.
 - (ii) a confirmed case was a probable case with microbiological confirmation of *E.coli* O157. This was later modified to include any individual who was confirmed, microbiologically, positive for *E.coli* O157 even in the absence of symptoms.
 - (iii) a primary case is the first individual within a group or family to get the disease which, in this case, is those who were believed to have eaten the infected meat source. There may be several primary cases in a group if they are exposed to the same source of infection around the same time.
 - (iv) a secondary case was a person who had caught the disease from a primary case.
- 5.9 By the end of the Outbreak, 157 cases had met the case definition. Of these, 127 cases were aged 18 or under. Thirty-one cases were admitted to hospital of which two adults and nine children were transferred to other hospitals for specialist care and treatment.

Diagram 5.1: Epidemic Curve, Outbreak of *E.coli* O157, South Wales, 2005



Source: Outbreak of Verotoxin Positive *Escherichia coli* O157 infection in South Wales Autumn 2005;
Report of the Outbreak Control Team

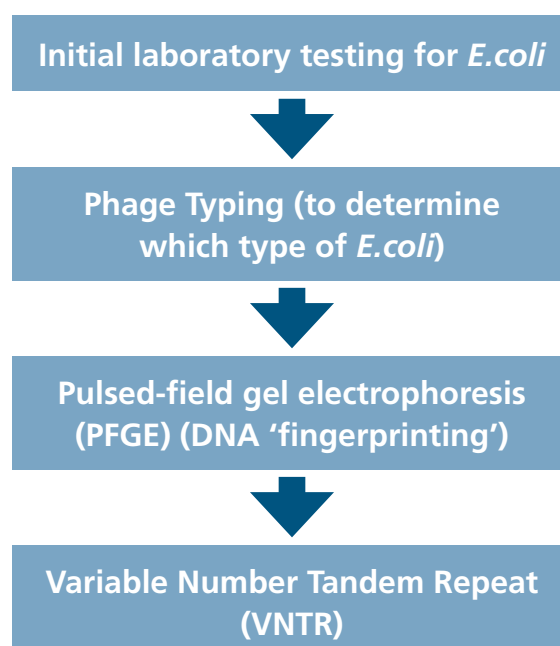
Microbiology

- 5.10 The second strand of investigation involved the microbiological testing of samples to identify the strain of *E.coli* O157. People who were suspected of being infected were asked to provide faecal specimens. Samples of food were also obtained as were environmental samples from the meat supplier in question and from premises linked to that business, including farms and an abattoir.
- 5.11 Samples submitted by suspected cases were tested at NHS or NPHS laboratories. In cases in which *E.coli* O157 was isolated, the samples were sent to the Reference Laboratory for England and Wales, the Laboratory of Enteric Pathogens at the Centre for Infections of the Health Protection Agency in Colindale, London ("Colindale"), for phage typing and other tests designed to identify with as much precision as possible the particular strain of *E.coli* O157 involved. The Colindale team produced a report dated August 2006.

Testing and Typing

- 5.12 The relatively low number of *E.coli* O157 organisms required to cause infection can make it more difficult to identify than other forms of food poisoning. And the ability to isolate it from someone's faeces is usually successful only if specimens are obtained within four days of the onset of symptoms. That said, when *E.coli* O157 is confirmed, microbiology has at its disposal a variety of powerful methods to identify the many different strains of *E.coli* O157. This contributes to outbreak control by confirming or denying links between people who are ill and food or other sources that are suspected of being the source of infection. The different levels of testing is outlined below:

Diagram 5.2: Hierarchy of Testing and Typing Initial Laboratory Testing for *E.coli*



- 5.13 The majority of VTEC that cause disease and illnesses in people is the O157:H7 type. The different types can be identified by the antibodies they produce through two molecules on their surface; the 'O' and 'H' molecules. There are more than 170 different 'O' groups ("serogroups") of *E.coli* bacteria and these can be subdivided into different 'H' types ("serotypes").
- 5.14 The strains of *E.coli* O157 can be broken down into even smaller groups using a process known as "phage typing". Phage typing is a way of distinguishing between closely related micro-organisms. It can recognise more than 80 different phage types. The most common in England and Wales is Phage Type (PT) 21/28.
- 5.15 The testing and typing can be taken further by pulsed-field gel electrophoresis ("PFGE"), which is a way of fingerprinting the organism's DNA. For many years, PFGE has been the method of choice for detailed comparison of VTEC O157 samples for epidemiological purposes so that any links between samples of food, samples from people and samples from the environment can be identified. Letters e.g. 'A', 'B', 'C' and so on, are usually used as a means of distinguishing different PFGE profiles that are identified. However, a complicating factor is that the *E.coli* O157 organism can mutate over time, weeks or months, which can lead to a variety of different profiles being identified around one outbreak. Some may clearly be closely linked while others may appear to be, or may indeed be, not linked at all.
- 5.16 Variable Number Tandem Repeat ("VNTR") was developed to provide a robust typing method that was more rapid than PFGE and one that was not reliant on the subjective interpretation of profiles that for technical reasons may vary between laboratories. The VNTR approach has been found to have epidemiological significance in that, generally, it is more discriminatory and less variable in terms of profiles of *E.coli* O157. It takes DNA fingerprinting to another level by examining sequences of the DNA directly. It has been used quite extensively in the USA but not here.

Links between Cases

- 5.17 Microbiological testing and typing confirmed the scale and spread of the Outbreak. One hundred and eighteen cases were confirmed microbiologically to be excreting verotoxin positive *E.coli* O157. Table 5.1 shows how the Outbreak developed from start to finish.

Table 5.1: Timeline of Confirmed Cases, South Wales Outbreak

Date of Meeting	Number of Confirmed Cases
16 September 2005	Outbreak declared
20 September 2005	11
23 September 2005	26
29 September 2005	81
3 October 2005	99
7 October 2005	101
11 October 2005	103
18 October 2005	111
27 October 2005	114
Total at end of the Outbreak	118

Source: Minutes of Meetings of the Outbreak Control Team

- 5.18 The number of primary cases per school varied. The majority, twenty five, had one case. The maximum, in two schools, was eleven.
- 5.19 Forty-eight people were considered to be cases of secondary infection.
- 5.20 There were clear microbiological links between the majority of cases. All produced VT (Verotoxin) 2, which is a particular type of toxin. Stools from 109 cases were *E.coli* O157 phage type ("PT") 21/28.
- 5.21 Further testing was done to differentiate the phage type. This identified pulsed-field gel electrophoresis ("PFGE") types. While in total there were 21 different PFGE profiles, the majority of cases were pulsed field types 'A' (33 cases), 'B' (6 cases), 'C' (43 cases), 'E' (9 cases) or 'M' (2 cases). These types are closely related, which Colindale concluded, provided powerful evidence of an identical source.
- 5.22 *E.coli* O157 was also isolated in six samples of food. Four were identified as cooked sliced lamb or turkey and one as 'poultry'. The other positive sample came from a large frozen joint of raw meat. All samples contained VTEC O157 PT21/28 strains with PFGE profiles that were found in samples from people. The 'C' profile was present in five of the samples including raw and cooked meat, and the 'A' profile was found in one sample of cooked meat.
- 5.23 The five positive results found in unused cooked meat came from five different schools. The joint of raw meat was recovered from the premises of John Tudor & Son.

Further Testing

- 5.24 The Colindale Laboratory had undertaken extensive testing and typing as part of action to control the Outbreak, and had produced very detailed results using the PFGE method. However, given the unusually large number of profiles identified in the results, and in line with my commitment to a very thorough investigation, I wished to push the scientific boundaries of testing as far as possible. I therefore commissioned from Colindale some further tests using the VNTR method as a second independent methodology for assessing the original results.
- 5.25 The key elements of the VNTR approach are:
- (i) Bacteria such as *E.coli* O157 have in their DNA a number of short sequences that are repeated several times. The number of “repeats” of each sequence varies a good deal.
 - (ii) Amplifying these sequences and counting the number of repeats is a straightforward process in the laboratory.
 - (iii) VNTR profiles can change rapidly by mutation, even during an outbreak. However, the current consensus view of scientists is that *E.coli* O157 isolates that differ by no more than one “repeat” at one or two loci are very highly related and should be considered part of the same outbreak.
- 5.26 Colindale produced its report on 3 March 2008 [12]. It was exhibited to a statement by Dr Geraldine Smith dated 6 March 2008. Dr Smith is a senior scientist at the Laboratory. Colindale’s principal conclusion, as a result of the VNTR tests, was that strains from human cases were indistinguishable from each other and from those isolated from cooked meat supplied to schools and from raw meat recovered from John Tudor & Son’s premises.
- 5.27 Table 5.2 shows the pattern of repeat sequences from the strains of *E.coli* O157 tested.

Table 5.2: Comparison of VNTR Profiles of VTEC O157 PT21/28 from Human, Food and Environmental Samples, South Wales *E.coli* O157 Outbreak, September 2005

Source	Strains tested	'Repeats' at VNTR locus							
		3	34	9	19	36	25	17	37
Multiple Schools Outbreak	80	9	7	12	4	11	3	6	8
Multiple Schools Outbreak	1	8	7	12	4	11	3	6	8
Cooked Meat	10	9	7	12	4	11	3	6	8
Raw Meat	5	9	7	12	4	11	3	6	8
Raw Meat	20	8	7	12	4	11	3	6	8
Cattle Faeces	20	8	7	12	4	11	3	6	8
School Z1 Abercynon	2	11	7	16	6	10	3	6	8
Open Farm, England	1	8	7	15	6	7	2	6	7

Source: Produced from data in Report of The Health Protection Agency Centre For Infections, Laboratory Of Enteric Pathogens

- 5.28 The VNTR testing confirmed and simplified the previous PFGE fingerprinting. The table above shows very clearly the same sequence of repeats for all the strains with the exception of two, Abercynon Infants School, and that from a farm in England that also caused an Outbreak in 2005 and in which a 'C' PFGE profile has been identified (see paragraph 5.37). This means that all the different PFGE profiles in the main Outbreak are essentially the same organism. It also confirms that the Outbreak at Abercynon Infants School was caused by a different VTEC O157 PT21/28 strain, as had been concluded originally epidemiologically and by PFGE testing. The Abercynon outbreak is described in more detail later in this Chapter.

Path of Infection through the Food Chain

- 5.29 If possible, I wanted to try to identify the path that the contaminated meat that had caused the Outbreak had taken.
- 5.30 On 14 December 2005 an investigator from the Veterinary Laboratories Agency visited a farm ("The Farm") in the Vale of Glamorgan. Samples were taken of bovine faeces and bedding contaminated with bovine faeces. Analysis revealed that the strains of *E.coli* O157 found in stool samples taken from Mason Jones were indistinguishable from those strains found on unused cooked meats recovered from schools and the strains identified in cattle faeces on the Farm, as well as in a sample of raw meat recovered from John Tudor & Son's premises in Bridgend.
- 5.31 It is also known that John Tudor & Son was supplied with raw meat from J.E. Tudor & Sons Ltd's abattoir in Treorchy, which in turn slaughtered lambs and cattle from the Farm.

- 5.32 Evidence from British Cattle Movement Service records show the number of cattle from the Farm that were slaughtered at the abattoir in the month or so before the Outbreak:

Table 5.3: Cattle from The Farm, Slaughtered at J.E. Tudor & Sons Ltd. Treorchy

Date	Number of Cattle
2 August 2005	1
3 August 2005	1
10 August 2005	2
24 August 2005	3
31 August 2005	1
5 September 2005	2

Source: British Cattle Movement Records

- 5.33 As described above, the additional typing showed that a highly related VNTR profile was found in all human isolates except one. The same profile was also found in all the strains from raw and cooked meats.
- 5.34 The strains from cattle faeces had the same VNTR profile irrespective of their PFGE profile.
- 5.35 The additional typing simplified the previous PFGE fingerprinting data and supports the Outbreak Control Team's ("OCT") original conclusion, based on epidemiological evidence: that strains from people who were infected were indistinguishable from each other and from those isolated from cooked meat supplied to schools and raw meat at the butcher's premises. Contaminated cooked meat from John Tudor & Son was the source of the Outbreak.
- 5.36 On the balance of probability, I believe that the *E.coli* O157 organism that caused the Outbreak passed through the abattoir of J.E. Tudor & Sons Ltd. I base my conclusion on the following:
- (i) The Farm in question was confirmed as one of the main suppliers to the J.E. Tudor & Sons Ltd abattoir in Treorchy.
 - (ii) The abattoir supplied John Tudor & Son, Bridgend with raw meat.
 - (iii) Animal movements records indicate that cattle from the Farm were slaughtered at the abattoir in the weeks before the Outbreak, the last occasion being 5 September 2005 when two cattle were slaughtered.
 - (iv) The confirmation, microbiologically, of the link between the strains from samples of cattle faeces, those found on cooked meats supplied to schools, and those in people who were infected.

- 5.37 The additional typing I commissioned also confirmed another fact. The original PFGE profile analysis produced during the Outbreak had suggested a possible match between the 'C' profile isolates from the South Wales Outbreak and a strain that had caused an outbreak at an open farm in the East of England in 2005. The VNTR testing identified that the two were completely different. The South Wales strain of *E.coli* O157 is unique to this Outbreak.

The Colwinston Cases in the Vale of Glamorgan

- 5.38 The majority of the cases in the Outbreak were among school children in Bridgend, Caerphilly, Merthyr and Rhondda Cynon Taf. The OCT's investigations revealed that there were three cases, two adults and a child, in the village of Colwinston in the Vale of Glamorgan. They were of the same strain as the others i.e. phage type 21/28 and with the same unusual PFGE type. Accordingly, the Colwinston cases were deemed to be connected to the main Outbreak and managed as such.
- 5.39 The Inquiry wanted to ascertain whether there were links between those affected in Colwinston and the Outbreak. The people affected were Case 5 (which is the title given to the patient involved, the treatment of whom is examined in Chapter 15), Case 5's father, who tested positive for the strain but was asymptomatic, and another adult. Statements were taken from the parents of Case 5 and from the adult. Neither the statements nor information obtained by the OCT at the time of the Outbreak established any clear and positive epidemiological link between these cases and meats supplied by John Tudor & Son. However, as set out above, microbiologically, the *E.coli* O157 strain was the same as that involved in the main Outbreak. Based on the evidence available, it is not possible to explain how these three people became infected.

The Outbreak in Abercynon

- 5.40 In November 2005, more cases of *E.coli* O157 were found in Abercynon, a village in the same geographical area as the Outbreak.
- 5.41 On 5 November 2005, two families affected by *E.coli* O157 were linked to Abercynon Infants School, a small school with 64 pupils aged 3-7 years. Investigations by the OCT subsequently identified a total of 16 cases, all of whom either attended the school's nursery class or were related to affected children in the nursery class.
- 5.42 The OCT examined the Abercynon cases and epidemiological and microbiological analyses were undertaken.
- 5.43 Microbiological analysis identified a total of 16 confirmed cases, nine of which were symptomatic of *E.coli* O157. All cases were of phage type PT21/28 but the PFGE type was unique to the Abercynon outbreak.

- 5.44 The OCT report stated that despite exhaustive investigation, the source of the outbreak in Abercynon could not be identified. All the cases were of the same PFGE type, supporting a single source with subsequent person-to-person transmission. The vehicle and mode of spread was unknown.
- 5.45 The OCT report raised the question of how the Abercynon outbreak could have occurred, given that control measures flowing from the main Outbreak were in place at the time. The report then answered the question by stating that the control measures were designed to prevent spread from asymptomatic carriers after the implicated source for the main Outbreak and symptomatic children had been removed. All cold cooked meats implicated in the main Outbreak had been removed from the school at the time the original control measures were introduced. The OCT report points out that the source of the outbreak in this school was unknown so could not be removed to prevent transmission. This may explain why the outbreak occurred in Abercynon in spite of the measures already in place.
- 5.46 Microbiological experts at the Colindale Reference Laboratory concluded that the strain in the Abercynon outbreak was phage type 21/28. However, it was of a very different PFGE type to any of the main Outbreak strains.
- 5.47 Having considered the microbiological, chronological and epidemiological evidence, which included the fact that the Abercynon outbreak took place substantially after the main Outbreak had been controlled, the OCT concluded that Abercynon was a separate outbreak. The source could not be identified.
- 5.48 In the event, the Abercynon outbreak was curtailed promptly and was declared over, with control measures being lifted on 9 January 2006.
- 5.49 VNTR testing showed clearly that the Abercynon outbreak was caused by a different VTEC O157 PT21/28 strain, as had been concluded epidemiologically and by PFGE testing. I commissioned VNTR testing in the expectation that it would confirm the PFGE fingerprinting results, and that its totally sequence-based results might be simpler to interpret because the reading of PFGE has a subjective element. This expectation was realised. The two methods look for completely different kinds of variation in DNA. The agreement between the two methods shows that the conclusions drawn from them were correct beyond all reasonable doubt[13].

Introduction

- 6.1 An important part of the Inquiry's work was to look at the conditions that existed at the premises of John Tudor & Son ("Tudors"). Given the passage of time since the Outbreak, a physical inspection of the site was not possible. However, the Inquiry was given access to a mass of evidence that had been collated by South Wales Police as part of its investigation into the death of Mason Jones. Further evidence had been collated by the local authorities in respect of their prosecution of William Tudor, the proprietor, for food safety offences.
- 6.2 Importantly, the evidence collated included statements from employees at Tudors and reports prepared by Professor Chris Griffith, Head of Food Research and Consultancy at the University of Wales Institute Cardiff, and Mr Colin Houston, Deputy Head of Enforcement for the Food Standards Agency. They are experts in the field of food safety and regulation. Both gave oral evidence to the Inquiry.
- 6.3 The expert evidence provided by Professor Griffith and Mr Houston provided me with a clear picture of the principal aspects of Tudors:
- (i) The state of the premises.
 - (ii) The risks of cross-contamination, including the work practices relevant to those with risks, with particular focus on the weighing scales and vac packer.
 - (iii) Hygiene practices, including cleaning.
 - (iv) The Hazard Analysis Critical Control Point ("HACCP") plan. This is a system designed to enable businesses to identify, evaluate and control hazards affecting their business. A specific document is produced that should identify the particular hazards or risks and set out a plan for dealing with them. Its importance is obvious in a business such as a butcher, both in terms of the quality of the plan itself and its implementation. Tudors' HACCP plan is considered in detail in Chapter 7.
 - (v) Food safety culture.
 - (vi) Training of employees and the maintenance of food safety standards.
- 6.4 William Tudor was interviewed at length and on numerous different occasions by police officers, who were advised by Environmental Health Officers ("EHOs"). The transcripts of interviews, copies of which can be accessed via the Inquiry's web site, set out his answers to many issues regarding the business. However, as Counsel to the Inquiry pointed out in his opening address, there were two matters of note in this respect:
- (i) A part of what was said by Mr Tudor in interview might be thought to be significantly undermined by the picture that emerges from the statements of those that worked there.
 - (ii) Mr Tudor pleaded guilty to a series of offences with which he was charged and ultimately sentenced.

- 6.5 The Inquiry wished to know whether there was anything else that William Tudor wanted to say. On 13 November 2007, he was invited to provide a statement focussing in particular on the two expert reports. Repeated invitations were made to his solicitors. The invitations were met with silence.
- 6.6 On 13 February 2008, the Inquiry received a letter from Mr Tudor's solicitors. It was read into the record by Counsel to the Inquiry on 14 February 2008. It expressed Mr Tudor's regret at the events of autumn 2005 but stated that he did not wish to participate in the Inquiry by taking up the opportunity to provide a statement.
- 6.7 Under the powers conferred on me by the Inquiries Act 2005, I could have summonsed William Tudor to appear as a witness to the Inquiry. I decided not to do so. My reasoning was explained by Counsel to the Inquiry in his opening address. The rationale was three fold:
- (i) William Tudor's evidence was not necessary in order for me to make whatever findings I judged appropriate about the conditions and practices at Tudors. The evidence from employees, experts, and the transcripts of extensive police interviews of William Tudor himself were all available to the Inquiry.
 - (ii) By his guilty pleas, William Tudor accepted the essential thrust of the Local Authorities' case against him.
 - (iii) There would be nothing of substance to be gained by questioning him. The likely result would have been self-serving disagreement between William Tudor and the evidence of his employees and others, when the essence of the criminal proceedings had been made out against him.

The Business

History

- 6.8 John Tudor & Son was located at 15 Ogmore Crescent, Bridgend Industrial Estate, Bridgend, South Wales. The business had been operating on the estate since 1966 and at those premises since the early 1970s. The business was originally known as J.E. Tudor & Sons and was formed by Jack Ellis Tudor. It was then run by his sons, John Tudor and his brother William, who was known as Billy. John Tudor had a son named William. Billy Tudor had a son named Jonathan.
- 6.9 In the late 1980s, the original company was split. The established name of J.E. Tudor and Sons was retained by the new business run by Billy and Jonathan Tudor, which concentrated on the abattoir side of the industry and was based in Treorchy, Rhondda Cynon Taf. The inspection of the abattoir operated by J.E. Tudor & Sons Ltd is the subject of Chapter 9.

- 6.10 John and William Tudor maintained control of the factory on the Bridgend Industrial Estate. They operated under the name “John Tudor & Son”. At the time of the Outbreak, the business was a partnership between them. However, it seems John Tudor retired from the business approximately ten years prior to the Outbreak. Thereafter, William Tudor ran the business and was effectively solely in control.

Suppliers

- 6.11 Tudors used a number of different companies to supply the business with raw and cooked meats. The J.E. Tudor & Sons Ltd abattoir in Treorchy was one of its suppliers, providing mostly lamb and beef carcasses but occasionally pork.

Customers

- 6.12 Tudors sold raw meats such as chicken, turkey, beef, lamb, pork and gammon. It also sold cooked meats including ham, turkey, beef, chicken, lamb and pork. Faggots and burgers were also produced at the premises. Some meats arrived at the premises already cooked, either having been sliced and sealed in vacuum packets by the supplier and were then sold on to customers, or those processes would occur at Tudors. Meats were also cooked there. They might be sliced and packed or simply sold as whole joints.
- 6.13 Public sector organisations were major customers. Primary and secondary schools in the Rhondda Cynon Taf (“RCT”), Merthyr Tydfil and Bridgend areas were supplied by means of a joint contract that was co-ordinated by RCT. At the time of the Outbreak, schools in Caerphilly area were also being supplied by Tudors. The contracts to supply meats for school meals are dealt with in detail in Chapter 10.
- 6.14 Tudors’ other customers included:
- (i) Residential nursing and care homes.
 - (ii) Meals on Wheels services.
 - (iii) Catering facilities and canteens in local authority office buildings, in leisure centres, and in private companies.
 - (iv) Health authorities and hospitals.
 - (v) Day centres.
 - (vi) Public houses.
 - (vii) Restaurants.
 - (viii) Members of the public, who occasionally purchased direct from the premises in Bridgend.

6.15 It is evident that Tudors was “high-risk” in terms of food safety for two particular reasons:

- (i) The working environment involved dealing with raw and cooked meats with the risks of cross-contamination; and:
- (ii) The customers supplied by Tudors were, in large part, vulnerable groups.

The Premises

6.16 A plan of Tudors’ premises is provided in Appendix 5.

6.17 Professor Griffith emphasised that design, construction and maintenance of premises are fundamental to the prevention of cross-contamination. The exterior of the premises should be designed such that rodents and pests are not attracted to it. The interior of the premises should be designed, constructed and maintained to allow work to be completed, to facilitate cleaning and to facilitate correct work flow (which includes work, product and personnel flow), with separation of high and low-risk areas i.e. cooked meats from raw meat.

6.18 He identified a number of problems in this respect that were evident at the time of the Outbreak, including:

- (i) Poor finish to some internal walls, flooring, windows, toilets, drainage channels.
- (ii) Poor condition of fittings including sinks, rusty shelving.
- (iii) Poor siting and maintenance of some machinery, including storage of diesel next to raw meat and the siting of the fly killer over the packaging area.
- (iv) Rubbish accumulation to the exterior.

6.19 His view, with which I agree, was that cumulatively, the poor constructional aspects of the premises would make it difficult, even impossible, for the cleaning that did take place to be effective, even if an ideal cleaning protocol was being followed.

William Tudor

6.20 William Tudor was the Managing Director of the business and had worked there for many years. He was responsible for a wide range of activities: dealing with suppliers; dealing with customers; checking meat specifications; cooking meats; on occasions slicing meats; packing meats; loading delivery vans; checking orders; checking on cleanliness and indeed undertaking the cleaning himself; recording temperatures of meats, the oven, the fridges and freezer; and any other duties necessary. It was also his role to ensure that staff were trained and to arrange appropriate training.

- 6.21 William Tudor was described by his employees as a “workaholic”; the boss who did a bit of everything and who would work seven days a week if necessary, being always the first to arrive and the last to leave. He would be at the premises from as early as 05.30. He described himself as a “hands on Managing Director” who was actually on the factory floor from time to time working with everyone else, as well as on the office side of the business. He said he would cut meat or help to pack it, or produce orders.

Celyn Williams

- 6.22 Mr Celyn Williams was not interviewed by the police as a witness during the criminal proceedings. However, he provided a statement to the Inquiry. It was largely supportive of William Tudor and the practices that were employed at the premises. Mr Williams sought to justify many of the practices on the basis that the EHOs who inspected the premises did not pick up on them.
- 6.23 Mr Williams began working at Tudors in the mid 1990s, having completed a business studies course at the local college. Whilst Mr Williams told the Inquiry that he had no formal title, he was William Tudor’s second-in-command when it came to office and general administrative matters and would assume general management of the business in the absence of William Tudor. His job description, obtained from paperwork dated November 2003, only mentions his office role. He told the Inquiry that he would mainly deal with the paperwork associated with deliveries. However, he would also occasionally work on the shop floor if there was a lot of work or if someone was ill. He would prepare orders and bag meat. He stated that he received no formal training to complete such tasks. Records confirm this, indicating that until April 2005, Mr Williams had received no food hygiene training.

The Workforce

- 6.24 In September 2005, the following employees worked for Tudors. All gave statements to the police. None objected to their police statements being used by the Inquiry:
- (i) Mr Michael Perks – raw meat butcher at Tudors for over 30 years and was said to be in charge of meat operations in William Tudor’s absence.
 - (ii) Mr James Brown – raw meat butcher since 2001.
 - (iii) Mr Frederick Exton – cooked meats butcher. Had worked for William Tudor in the late 1980s and had returned in 2002;
 - (iv) Mr Jordan Thomas – van driver from 2001.
 - (v) Mr Christopher Sharkey – van driver from January 2005.
 - (vi) Mr David Tudor – part time van driver who had worked for William Tudor for more than 30 years.

(vii) Mr Glen Pridham – van driver. Started work for Tudors in September 2005.

(viii) Mr Neil Goss – part time cleaner who claimed he had worked at the premises from the early part of 2005.

6.25 Others that had worked at Tudors in the months and years leading to the Outbreak also gave statements to the police.

(i) Mr Gerald Carbis – worked at the factory for approximately ten years until October 2004. His responsibilities focused on cooking and slicing meat.

(ii) Mr Shaun McNamara – worked mainly on cooked meats section for several weeks in 2003 and then four to five months in the early part of 2005.

(iii) Mr Jason Chick – worked for William Tudor on three separate occasions between 1990 and 2002.

(iv) Mr Stuart Taylor – raw meat butcher on two separate occasions, 1988 -1991 and 2001- May 2002.

(v) Ms Eirlys Thomas – part time van driver who worked for Tudors between April and July 2005, although there is clear suggestion by others that she was working there in September 2005.

(vi) Mr Terry Goss – part time cleaner who retired in 2001 having worked at the premises since 1997.

General Workload

6.26 Employees stated that Tudors was always a busy working environment. William Tudor told police that he had sufficient staff to undertake all the work in the factory and to supply safe and high quality produce to his customers. However, Mr James Brown stated it was very understaffed. He said that there was always too much work and the solution was to work harder. He said that he had tried to leave on two occasions but he was persuaded to stay by William Tudor, who would promise more staff but would take the first person off the street, with no qualifications and no sense.

General Risks of Cross-Contamination

6.27 Preventing cross-contamination is critical in a business such as that operated by William Tudor. Raw beef and lamb can, and by businesses such as Tudors must be assumed to, carry the *E.coli* O157 organism. Raw beef and lamb will be cooked and the cooking process is likely, if conducted properly, to kill the organism. However, if the organism is allowed to transfer from raw meat to cooked meat, the organism will simply be ingested by those eating the cooked meat. It is for this reason that effective food handling practices to ensure that raw and cooked meats are kept separate, and good personal hygiene and cleaning practices, are essential.

- 6.28 William Tudor told police of the training he had undertaken and qualifications he had achieved, which included the Advanced Diploma in Food Hygiene. This meant that he knew about *E.coli* O157 and the devastating effects it could have. He told police that *E.coli* O157 was a “killer bug” and potentially dangerous, recognising that its consequences could be “fatal”. He stated that he knew that separation of raw and cooked meats would reduce the risks posed.
- 6.29 However, statements given to police by a number of employees highlighted working practices that indicate a serious risk of cross-contamination, which therefore compromised food safety. The main ones were:
- (i) Staff moving between the separate raw and cooked meat areas during the course of work.
 - (ii) The use of single machinery and equipment for both raw and cooked meats e.g. the vac packer and weighing scales.
 - (iii) A lack of adequate cleaning of the premises and machinery.
- 6.30 Specific examples, derived from the statements given to the police, include:
- (i) Cooked meat being brought into the raw meat section by any means possible e.g. box, crate, and placed on the metal table against the back wall. Bags would be open when brought into the section.
 - (ii) Cooked meat being placed in unsealed vac bags, put into two or three plastic trays and wheeled into the raw meat section where it would be vac packed, weighed and labelled. While this was being done, the raw meat staff would continue their work.
 - (iii) Mr Perks and Mr Brown preparing raw meat when cooked meat was being vacuum packed.
 - (iv) Persons entering the cooked meats area when the practice should not have occurred.
 - (v) Cooked joints of meat stored in cardboard boxes that had previously been used for storing raw meat.
 - (vi) William Tudor mixing with staff, as between areas, without changing.
 - (vii) Dirty clothing being worn between areas and the same clothing being worn between areas.
 - (viii) Cups of tea being brought into the raw section by Mr Exton, who was supposed to be confined to the cooked meats area.

- 6.31 Professor Griffith specifically considered the potential for cross-contamination at Tudors, based on statements made by employees and EHOs to the police, on video and photographic evidence, and on management documentation. His damning conclusion was that cross-contamination would “almost certainly” have occurred at Tudors. I share his opinion, which is based on the following principal matters:
- (i) Very poor maintenance and damaged construction including the cooked meat area would, cumulatively, make it very difficult, even impossible, for cleaning to be effective even if an “ideal” cleaning protocol was being used.
 - (ii) The wearing of clothes in raw and cooked areas and the fact that staff support for personal hygiene was not good.
 - (iii) The cleaning of plant and equipment, especially in relation to high-risk ready-to-eat meats and operational handling practices, was completely inadequate; some procedures described could actually increase rather than reduce the risk of cross-contamination.
 - (iv) The documented management system for food safety, including the HACCP plan, was very poor and inadequate for the type and size of operation and the need to avoid cross-contamination for high-risk products.
 - (v) The food safety culture for a business serving high-risk food was completely inadequate and would not have controlled the risk of cross-contamination.
 - (vi) Staff were poorly trained.
 - (vii) Evidence of practices that should not have been taking place and which would make the contamination of ready-to-eat meats highly probable, including those summarised above.

Bad Meat

- 6.32 Mr Brown said that during the Outbreak, a tub of pork legs was on the turn. William Tudor did not want the EHOs to see them. He wanted the pork legs boned and pumped with preservative, so it would not look as if the meat was going off. Mr Exton and Mr Brown began to follow the instructions. When it became known that EHOs were visiting, the pork legs were removed from sight. After the EHOs had left, William Tudor asked them to continue the task. The employees refused. Mr Brown said that he had been told to do the same thing about six times in four years.
- 6.33 Mr MacNamara told police of a similar incident. He said that some of the meat he dealt with didn't smell too nice. He said he had been told by William Tudor to bag it up and send it. Mr MacNamara ignored the instructions and threw the meat out.

- 6.34 Mr Carbis explained in his statement that if meat was placed immediately into a fridge without allowing it to cool on a trolley, the meat would “blow”. In other words, the bag would go hard and the juices inside the package would remain liquid. When the bag was opened there would be a dreadful smell. This would happen to approximately ten out of 120 bags. In terms of “bad” meat, William Tudor would often instruct staff to re-introduce it into the food chain, either by removing the “bad” parts of the joint or by simply placing the meat in with the faggot mix, which would hide the smell. Meat was only thrown away if the smell couldn’t be hidden by the spices. Mr Carbis states that if schools sent back sliced meats, the poor slices would be removed and replaced with new slices to make it look like it was a different joint. This suggestion is independently supported by a school cook who noted this practice and its unacceptability.
- 6.35 William Tudor denied these statements when they were put to him in police interview. However, it is significant that a number of different employees informed police of a number of different incidents each of a similar character. It seems highly unlikely that they would have conspired to lie to police in this way. Further, in respect of the allegation about the sliced joint replacement, there is independent confirmation. In the circumstances, I believe that the incidents did indeed occur. They provide a clear picture of William Tudor’s disregard for food safety and systems which are designed to ensure food safety and worse still, they illustrate conscious decisions to place unsafe meat into the food chain.

Storage of Stock

- 6.36 William Tudor accepted in interview with the police that raw and cooked meats had been stored together in the freezer. This had the potential to be a serious risk of cross-contamination. William Tudor claimed that siting and segregation was used to keep them apart. Mr Williams suggested that the practice was safe because the items remained in separate cradles. However, on 19 September 2005, EHOs discovered:
- (i) A large number of unwrapped meat carcasses; various cuts of unwrapped meat stored in boxes, bags and crates.
 - (ii) A large amount of raw and ready-to-eat items mixed together.
 - (iii) Some other foodstuffs including a packet of Yorkshire puddings, vegetable quiche; iced “tip-tops”, and ice cream, which were found amongst items of raw meat.
 - (iv) Numerous instances of cooked chicken portions found amongst raw chicken pieces.
- 6.37 Mr Williams claimed that there was a stock rotation policy in place, which all employees had a responsibility to follow. William Tudor also claimed that there was such a policy. He stated that when new stock was brought in, it would be stored in the freezer. Any pallets that were half-filled would be removed and new products put in. He considered this to be part of the job as the goods were perishable and had to be rotated on a regular basis.

6.38 The lack of any such system, or at least its ineffectiveness in practice, is clearly evidenced by:

- (i) The state of the stock recovered from the freezer on the inspection of 19 September 2005 after the Outbreak, including a large quantity of boxes marked as silverside and pork pieces, which had a date code of 11 September 1998, items with date codes of 2002, 2003 and 2004, which were all mixed up with more recent items; and a large quantity of meat in a large metal cage had gone green and was giving off a strong smell.
- (ii) The numerous references to the disorganised state of the freezer in EHOs' reports over the years.

6.39 The employees' statements to the police also support my conclusion that there was either no stock rotation policy or that the one that existed was ineffective. Mr Exton said that as far as he knew, no-one was in charge of monitoring stock but that when the raw meat butchers were running low, William Tudor and Mr Williams would obtain stock from the freezer. Mr Brown said that sorting out the freezer was the responsibility of Mr Williams. Mr Brown also said that there was no stock rotation for raw meat and that there were things in the freezer from long before he had started. Mr Macnamara said that some of the meat could have been in the freezer for ages; it was jammed packed full of boxes and as freshly frozen meat came in, it was stored in front and used first. As he put it, staff would take out whatever they could get to and last in was being taken straight back out.

6.40 Mr Houston commented in his report that cooked meats stored in the walk-in chill unit were not being protected against contamination. He pointed to the fact that cooked joints of meat were being stored in cardboard boxes that had previously been used for storing raw meat. He states that the claim in the HACCP plan that there was appropriate stock control was not supported by employees' statements and the findings made by EHOs.

6.41 I believe that there was a serious risk of cross-contamination as a result of the way in which meat was stored in the walk-in freezer and chiller.

6.42 There was also a clear risk of cross-contamination inside the vans given inadequate separation of raw and cooked meats.

Personal Hygiene, Clothing and Movement between Areas

Personal Hygiene

6.43 Employees' hands and clothing can be contaminated with bacteria after contact with raw meat and can therefore be potential vehicles for the transfer of harmful organisms between different parts of a food premises and between foods. Good personal hygiene and hygiene practices are therefore critical to food safety.

- 6.44 Tudors had personal hygiene rules for its employees. Signed copies of the document were available for some staff. These documents were signed in July 2003. However, despite this, the evidence indicates that the rules were not followed by staff nor were they being enforced by William Tudor.
- 6.45 There was no indication that any hand washing training took place. Fred Exton reported that hand wash was not always available, which was confirmed during the inspection in January 2005. Mr Brown said that more often than not there would be soap inside the dispensers but he had seen “fairy liquid” in them. If nothing was there they would just use water.
- 6.46 Professor Griffith formed the view, having seen the police video of Tudors’ premises, that the hand washing facilities were not good. The hand wash sink in the raw meat and preparation area was badly sited and finished and lever arm taps were incorrectly fitted. I agree with Professor Griffith’s assessment.

Clothing

- 6.47 Employees stated that clothing worn in the factory consisted of white steel toe-capped Wellington boots (“wellies”), white trousers, jacket/coat, apron and that laundry services for the clothing were provided by a company based in Swansea. They collected the dirty clothing and delivered clean clothing. Mr Williams stated that he was responsible for ensuring that all members of staff, including van drivers would be wearing the appropriate clothing at all times.
- 6.48 The evidence in relation to clothing practices was, in summary, as follows:
- (i) Mr Exton said that he would keep his own set of clothing, taking it home and washing it a couple of times a week because he might get something from the laundry service which was the wrong size or that there may not be sufficient items of clothing to wear. He would wear the same clothing when undertaking tasks in both the raw and cooked meat sections. He said that he would steam clean his wellies if they looked dirty. He knew that there was a wellie washer but he wasn’t sure if it worked. Other employees stated that the wellie washer did not work.
 - (ii) Mr Brown said that he did not wear the hats supplied and it was not enforced, although it was stated clearly to be part of the company’s Personal Hygiene Rules. He stated that Mr Exton was the only person to wear a hat at Tudors. He said that there were different colour-coded uniforms for raw and cooked meats and he did try to keep to it, but it was not always possible, so he would pick up whatever was there. He would normally put fresh on in the morning and keep them on until end of business but would change occasionally if there were blood spillages.
 - (iii) Mr MacNamara said that he was told by William Tudor that because he worked in the cooked meats area, if his clothes weren’t dirty, he wouldn’t need a clean set every day.

- 6.49 The cleaning company stated that, on the basis of their records of the number of items of laundry done for Tudors between 1 August 2005 and 16 September 2005, they would have expected a maximum of three people to be working in the premises. In fact a larger number of people were working at Tudors.
- 6.50 Video evidence shows the storage of clean and dirty clothing together. Wellington boots with blood on them were being stored. Also, Wellingtons were stored on top of clothing. Based on this and the above evidence, I agree with Professor Griffith, who noted that the lack of clean protective clothing and poor storage of the clothing that was available was likely to lead to cross-contamination.

Movement between Areas

- 6.51 William Tudor accepted that cooked meat slices were put into cryo (vacuum) bags in the cooked area and then taken unsealed into the raw meat area. In terms of the process of taking cooked meats into the raw meat preparation area for packing, he said that Mr Exton would move the cooked meats to the curtain separating the cooked meat area from the raw meat area and then he himself, or sometimes Mr Exton, would take them into the raw area for packing. He said that that was the procedure every time but that the raw meat operation stopped and the place was cleaned down. However, in this respect also, his evidence is contradicted by the statements of others. These describe raw meat preparation continuing when cooked meats were packed.
- 6.52 The following points led Professor Griffith to conclude that the evidence established clear risks of cross-contamination, a view with which I agree:
- (i) On Thursdays, Mr Exton would deal with cooked meats in the morning and then raw in the afternoon. He would wash his hands in between but would not change clothes.
 - (ii) Mr Thomas said that staff, including William Tudor and Mr Williams, would intermingle between raw and cooked sections without changing uniform or footwear.
- 6.53 Mr Exton also said that others, William Tudor, Mr Williams, Mr Perks or Mr Brown, might help him occasionally, but the latter two would wear the same clothes as they had been working in the raw area. If William Tudor or Mr Williams did a late or missing order, they would go from working in the raw meat room to the cooked meat area to do it.
- 6.54 Aside from movement of people between the raw and cooked meat areas, staff came together in the staff room for breaks. The staff had breaks between 10:00 and 10:15 to 10:30 and lunch between 12:30 and 13:30. In the same way that separate preparation areas for raw meat and cooked meats helps to prevent cross-contamination, measures are needed to reinforce this so that cross-contamination does not happen as a result of staff from the different areas coming together at break and lunch times.
- 6.55 Mr Brown said that some staff would not get changed for these breaks other than leaving their aprons hanging on their locker doors. Mr Brown also stated that Mr Exton (cooked meats) would normally leave his on. Mr Brown said that wellies would also stay on, and the wellie washer would not be used before going into the canteen.

- 6.56 Mr Macnamara said that he would take his wellies, trousers and jacket off, and sit there in a pair of shorts and T-shirt; some would go in for a break with their wellies on or with their over-trousers on, they may pull their over-trousers down to their knees and sit down to eat their food.

Cleaning

Cleaning Documentation

- 6.57 Tudors had a short written cleaning document for the plant and office areas, as well as the vans. This set out what was to be done:
- (i) Main cutting areas and chiller one: area to be thoroughly cleansed and sterilised after each shift or working day; machinery to be dismantled and cleaned separately; all cutting and sawing utensils to be placed in the steriliser; chiller to be emptied and cleaned at least once a week.
 - (ii) Main preparation area: area to be cleansed and sterilised after each shift or working day; all pallets and trolleys to be cleansed thoroughly.
 - (iii) Pumping and tumbling area: area to be cleansed and sterilised after each shift or working day; all machines to be stripped and cleansed separately; all plastic drums and tubs to be cleansed and set to dry.
 - (iv) Loading bay and outside chiller: area to be cleansed and sterilised after each shift or working day; the fly curtains to be taken down and manually cleansed once a week; outside chiller to be emptied and cleaned once a week or as necessary.
 - (v) Staff changing room and staff toilets: area to be cleansed daily, all rubbish and waste to be bagged and removed and toilets disinfected.
 - (vi) Offices: to be cleansed as frequently as required.
 - (vii) Vans to be cleaned and sterilised internally every day: all containers to be removed and cleaned thoroughly; twice a week, the exterior of the vans to be cleaned and the cabs once a week.
- 6.58 A further cleaning schedule is in existence. However, it was plainly out of date by the time of the Outbreak as it listed former employees as being responsible for certain aspects of cleaning at Tudors.
- 6.59 A "Cleaning Standards Recording Form" also existed. William Tudor said that whoever checked the cleaning standards would sign the column in the relevant form. The last entry in the "Cleaning Standards Recording Form" was 18 July 2005, which was the day before an announced (pre-arranged) inspection on 19 July 2005 to determine the award of the business's Butcher's Licence for another year. This is significant. It illustrates that the records were not maintained after the inspection had been completed and after a Butcher's Licence had been issued.

- 6.60 Professor Griffith was critical of the schedules that existed. In his report he describes the documents as being “confused” and “lacking in detail”. His overall conclusion was that the cleaning documentation was “completely inadequate”. In oral evidence he described the documentation as a “joke”.
- 6.61 The factual basis for Professor Griffith’s conclusion, with which I agree, was as follows:
- (i) A record of staff training in cleaning, most notably for the cleaners, was absent.
 - (ii) No protocol for cleaning in place.
 - (iii) The cleaning document did not include any reference to the cooked meat area.
 - (iv) Some items in the cleaning document specified cleaning on a daily basis, yet the cleaner was only present at most twice a week.
 - (v) There were no written details of a “clean as you go” policy.
 - (vi) There were no written details of how to clean machinery including the vac packer and precautions to prevent common use in high and low-risk areas.
 - (vii) It was not clear on the records the year to which they referred.
- 6.62 Professor Griffith was also critical of the use of a pressure washer for cleaning at Tudors. His conclusion was that the use of a pressure washer enhanced rather than reduced the spread of pathogens from raw to cooked food areas. Further, it was used outside and in both the raw and cooked areas. Professor Griffith concluded that the witness statements and video evidence pointed to the pressure washer head and hose being potential vehicles for the transmission of pathogens in their own right as they were often stored in the raw meat area.

Cleaning in Practice

- 6.63 William Tudor stated to police that it was his job to check cleanliness, and this is reflected in his job description. The checking could be done after working hours when he would walk around and have a look to make sure everything was right. He would also oversee others’ cleaning and he said that if he was there he would stand over whoever was doing it. He told police that all machines, floors, drains, indeed the premises as a whole, were cleaned on a regular basis and everything was sanitised during the working day.
- 6.64 Evidence from employees suggests that this was not the case, and that the cleaning schedule, poor as it was, was not followed. Some staff appeared not to know about the cleaning schedule. For example, Mr Brown said that there wasn’t one before the Outbreak but there was afterwards.

- 6.65 Few staff had been trained in cleaning techniques, including the part-time cleaner, Mr Neil Goss. Mr McNamara appears to have received some appropriate training in cleaning his work area, but the practice of using a dishcloth would have been a major contribution to cross-contamination if, as part of the procedure, the cloth was not sterilised before use.

Cleaning of Machinery and Equipment

- 6.66 Professor Griffith's opinion was that the cleaning of plant and equipment was completely inadequate. For the reasons he gave, and on the basis of the following evidence, I agree with his opinion.
- 6.67 In summary, the evidence in relation to this aspect was as follows:
- (i) William Tudor told police that he monitored how the machines were cleaned and he inspected the cleanliness of delivery vans every couple of days.
 - (ii) Mr Brown said that none of the machines were cleaned during the day although they may have been wiped down. He also said that the oven probe should be cleaned with a sanitiser but was wiped with a paper towel. The probe wipes recovered by Ms Jane Donagh, the Principal EHO at Bridgend when she inspected the premises during the Outbreak had an expiry date of 1991.
 - (iii) Mr Exton said that plastic or stainless steel tubs would be used to hold legs of pork after boning. The plastic tubs were obtained from the back of the premises where they would just stand outside. He said he would jet wash them first.
 - (iv) In relation to the slicing machine, Mr Exton said that he would strip down the slicing machine at the end of each day and would place the slider, guard and sharpener into the sink. He indicates the use of hot water and hand wash solution, which he thought was antibacterial. He would clean the body of machine with the hand wash and a cloth. The cloth was an ordinary household cloth and would be changed about every fortnight. It was kept in the sink and would be soaked in bleach overnight. He said that he did not remove the blade for cleaning as there was no spanner to do so. His last job of the day was to clean the cooked meat room.
 - (v) For half the week, Mr Exton said he would use a hose with no chemical and for the other half he would use the steam cleaner with truck wash in it. There were occasions when only cold water was used to hose down Tudors.
- 6.68 The cleaning of the vac packer is dealt with later in this Chapter. The evidence is of some considerable importance given the issues that arise about the vac packer in relation to the inspections that were carried out in 2005 by Mrs Angela Coles, an EHO in Bridgend County Borough Council. This is examined in detail in the next Chapter.

- 6.69 Mr Exton thought that Mr Brown cleaned the pumping machine. However, he would clean it using a paper towel or a piece of netting if there were any blood spillages. Mr Exton also said that Mr Brown would also be responsible for the cleaning of the mincing machine, which was situated next to the vac packer. Mr Brown said that he would be responsible for cleaning the raw meat area and the machinery within that area. He would steam clean the whole of the area at the end of the working day and would feed either bleach or truck wash through with the hot water. He would clean the mincer by hand. Mr Brown complained to William Tudor about the power points being on when he was cleaning with the steam cleaner. As a result, the cleaning in the vicinity of the band saw would be done by hand. The weighing scales were cleaned with a paper towel if there were any spillages of blood.
- 6.70 The evidence of employees was that the oven was rarely cleaned. The only time it was cleaned was when John Tudor attended at the premises and criticised William Tudor for it not being cleaned.
- 6.71 The freezer wasn't cleaned. William Tudor stated in interview that it had not been cleaned for 12 years. Mr Brown said that in his time at Tudors it was never emptied. In respect of the chillers, there was confusion amongst the staff as to who was responsible for cleaning them. According to Mr Exton, the chillers were cleaned by Mr Brown on a weekly basis, or more often if there was a spillage. James Brown said that he would clean them when he could but there doesn't appear to be any regularity involved. When he cleaned them he would use the steam cleaner and bleach. The photographs of the chiller that were provided to the Inquiry suggest that any cleaning that is said to have taken place would have been minimal given the volume and methods of storage used.
- 6.72 Mr Exton said that there was a sterilising machine for knives in the raw meat area, by the sink. It would sterilise the knives but not clean them. He said that he would not use it very often, perhaps once a month or maybe not even that often, and had not seen anyone else use it often either. This conforms with Mr Brown's account, who said he would use the steam cleaner to clean knives. He said that it was not his responsibility to clean them but he did it because he did not like working with dirty equipment. He would go around each knife in its scabbard with the steamer and while basic cleaning, "it was better than none".
- 6.73 The cleaning document mentions in four of its six parts the need for areas and equipment to be "sterilised". The following evidence leads me to conclude that effective cleaning was unlikely to be possible at the premises given the practices that were adopted. This is because:
- (i) The sanitiser was never available and only became available after the Outbreak: Mr Exton said that he had never seen any sanitising solution in the three years he was there, only hand wash.
 - (ii) Hand wash was often used for cleaning.
 - (iii) Bleach was occasionally used in the steam cleaner but "truck wash traffic film remover" appeared to be the product used most frequently in it.

- (iv) The steam cleaner was powered by diesel and on occasions when diesel ran out, cold unsanitised water would be used.
 - (v) Knives would be cleaned with the steam cleaner while in their scabbards, which were attached to the cutting tables.
 - (vi) Spillages such as blood or meat on the weighing scales or pumping machine would be cleaned up using a dry paper towel, or with a piece of wet netting before being dried with a paper towel.
 - (vii) Sterilising machine used to clean knives from cooked meat area once a month or not even than often.
 - (viii) For around half the week, just a hose with no chemical would be used to clean the cooked meats area.
- 6.74 Equipment used to carry out the cleaning was itself dirty or worn. The use of such equipment cannot allow effective cleaning to take place. For example, cloths were being changed every 14 days according to Mr Exton. Worn and dirty brushes were also used in the cleaning process.
- 6.75 There would be occasions when the drains would be blocked. Gunk and slime was noted and in one instance, maggots. These would be pressure washed.
- 6.76 There was inadequate cleaning of the vans.

The Vac Packer

Purchase and Service History

- 6.77 Tudors purchased a vacuum packing machine ("vac packer") on 12 September 1994 and another on 24 January 2002.
- 6.78 The records of Swissvac, a company that sells the machines and provides after-sales care and service and spare parts, show that it provided services and spare parts for the first machine, an Audion Vacuum Chamber Machine (Audionvac) Model VM201, between November 1995 and September 2001. The complete breakdown of this machine appears to be confirmed by the statements of the employees and of William Tudor himself.
- 6.79 The machine purchased on 24 January 2002 was an Audion Electro (Audionvac) Vacuum Chamber Packing Machine, Model VM213G, Serial Number 0121213297. This was the machine being used by Tudors at the time of the Outbreak and was the one taken away by the police for inspection. It was located in the raw meat area and plugged into the ceiling. It was being used for both raw and cooked meats.

- 6.80 Following the Outbreak, William Tudor ordered a new vac packing machine. The order was placed on the day that he was inspected on Monday, 19 September 2005 at the very start of the Outbreak. William Tudor contacted Quality Food Machinery to say that there was a fault with the seal bar of existing vac packer and that he wished to be supplied with a new machine. The new machine was delivered to Tudors on Wednesday, 21 September 2005.
- 6.81 The use of a single vac packer to pack both raw and cooked meats was noted for the first time only by Mrs Coles' on her inspection on 18 January 2005. Such use represented a major risk of cross-contamination, particularly if cleaning procedures weren't effective.
- 6.82 In my opinion, only one machine had been used for raw and cooked meats for a number of years. I base this on the points below and the paragraphs immediately after them:
- (i) Mr Thomas said that in four years employed there, he had only ever known one to be in use.
 - (ii) Mr Sharkey only ever saw one vac packer in use.
 - (iii) Mr Brown said that that the one machine was always on the raw section and in the four years he had been there he had only know there to be one.
 - (iv) Mr Goss, the part-time cleaner, said that there was an old vac packing machine in a small room at rear of factory but he had never seen it used.
 - (v) That was confirmed by Mr Exton who said that in the three years he had worked there, it was never used nor had it been moved.
 - (vi) William Tudor himself said in his statement to the police that his previous machine was defunct. It was defunct and being used for parts. He said he had had two machines working at the same time but that was about three, four or five years ago.
- 6.83 From January 2005 onwards, Mrs Coles was told first by Mr Williams and then by William Tudor that the other machine was away for repair and would be back shortly. It is clear that these statements were untrue. It appears that Mrs Coles did not probe the repeated explanations to this effect even when the repair period stretched from the original period of days into months.
- 6.84 Mrs Coles' recollection was that William Tudor had told her that the machine was physically moved from the raw to the cooked meat operations. William Tudor denied that; and indicated that the vac packer would have been very difficult to move. Accounts from the employees suggest that movement of the vac packer was rare and short lived.
- 6.85 Even after the Outbreak itself, William Tudor continued to lie to EHOs about the vac packer. During her inspection on 19 September 2005, William Tudor told Ms Jane Donagh, Principal EHO, that he only had one vac packer in operation at that time due to the electronic control being broken on the other. According to her note of the conversation, he also told her that the other one was away for repair. The truth was that there had only been one vac packer in use for at least three years.

- 6.86 In relation to the cleaning of the vac packer, William Tudor's version of events was as follows. He said that when the machine had finished on the raw sector, it was thoroughly cleaned and sterilised, then the cooked meat was brought through and the machine used. He claimed that he would do the cleaning or would oversee the process if another person was cleaning it. He said that if he was there, he would be standing over the person doing it. He said that there were no occasions when cooked meat was packed straight after raw meat without cleaning in between. Furthermore, there were no occasions when unsealed bags of cooked meat were in the raw meat area when raw meat production was happening at the same time. He said that [the packing of] unsealed cooked sliced or un-sliced meats when raw meat production was going on would not have happened. There would have been no occasions when unsealed bags of cooked meat were taken into the raw meat area when production was taking place. He said that a sterilising agent was used, "TR something". It would be cleaned manually and the chamber cleaned and parts removed, including the leaves and the sealing bars, and cleaned with hot water, the sterilising agent, a small nylon brush and disposable cloths. He said he had used the sanitiser for six or seven years.
- 6.87 Again, William Tudor's version is contradicted by other evidence:
- (i) The very practice he claimed would never happen; that is, unsealed bags of cooked meat in the raw meat area when production was taking place, was observed by Mrs Coles during her inspection in January 2005.
 - (ii) Mr MacNamara said that now and again there would be blood in the bottom of the vac packer where it had leaked from bags. He would wipe it up and said he had been told by William Tudor to wash it with hot water and rags and dry it with hand towels. He said that when he washed the shelves down he was told not to use any cleaning materials. However, if he couldn't see any blood or juices he would assume it was clean. He said that if he was doing cooked meat first, he would always wash the machine down before packing raw meat. However, the main risk is in the other direction; that is, from *E.coli* O157 being transferred from raw meat to cooked meat. He said he cleaned it in the way he had been shown by William Tudor, with a brush, a bucket of hot water and 1-2 spoonfuls of powder from a container, although he did not know what it was.
 - (iii) Mr Brown said that the machine would be used constantly because every piece of meat that went out from the factory was cryo (vacuum) packed. He also said that none of the machines were cleaned during the day although maybe wiped down. Mr Brown said that it was cleaned by hand and, as far as he knew, with a cloth and "fairy liquid", at most, twice a week and at the least, not at all. Brown said it was Mr Neil Goss's job and Mr Goss only worked two days per week, on Tuesdays and Thursdays.

- (iv) Mr Exton also said it was Mr Neil Goss's job. He stated that he had never known work to stop during the day for the vac packer to be cleaned. If it was cleaned, it was in the morning. Even when the single vac packer was being used in the raw meat area, Mr Perks and Mr Brown would be doing their normal work on raw meat. He also said that he knew that there should have been a sanitising solution available but there was never any available for the three years he was there, only hand wash.
- (v) Mr Neil Goss said that in addition to having no contract of employment, he had not been given any formal training or health and safety guidance. He had not been included in the Basic Food Hygiene training that was provided to seven employees in February 2005, the certificates for which were issued in April 2005. Mr Goss asserted in his police statement that the responsibility for the cleaning of the vac packer lay with Mr Brown.

6.88 If the vac packer was cleaned, the methods explained by William Tudor are highly questionable. Ms Alexa Pieris, an EHO from Rhondda Cynon Taf, was told by William Tudor when she accompanied Bridgend's officers on the inspection of Tudors on 19 September 2005 that the vac packer was cleaned with hot water, a brush and sanitiser. When it needed cleaning, someone would use a chemical in water in a bucket. She was shown the chemical by Mr Williams. It was identified as "TFR 1 Alpha Concentrated Traffic Film Remover" which the label described as a detergent. She also asked to see the brush used to clean the vac packer and was shown a small dirty brush.

6.89 In his evidence, Mr Brian Curtis, who provided expert witness evidence to the Inquiry, said that using a single vac packer for raw and cooked meats was "...a bit like playing Russian roulette". I agree.

6.90 The state of the vac packer when the EHOs made their unannounced inspection on 19 September 2005 provided a graphic illustration of the true and regular state of the vac packer during the working day.

- (i) In her statement to the police, Ms Pieris said that she saw the vac packer located next to the mincing machine. It was in a dirty condition with accumulations of food debris around the edges near the seal.
- (ii) When taking swab samples that same day, Miss Amy Lewis also noted that the vac packer was heavily dirty, with encrusted and congealed debris on its exterior and interior surfaces.

6.91 In addition to all this, it appears to me that the vac packer itself was in a state of disrepair:

- (i) Mr Exton said it would play up a bit. One sealing bar wouldn't work so it could only use one of the two bars. Mr Brown said that the pressure dial didn't work and one of the sealing arms. The lid was held together with "blu tac". He said that that both Mr Williams and William Tudor were aware of that.

- (ii) South Wales Police arranged for Dr John Holah of the Campden and Chorleywood Food Research Association Group to inspect the vac packer and to report on its hygienic design characteristics. His opinion was that the machine was in a poor state of repair. His examination of it also indicates that it was in a thoroughly unhygienic and, from a cross-contamination point of view, dangerous state. He identified that three of the machine's six gas injectors were fully clogged with meat residue and meat residue was present in the other three, confirming a complete inadequacy in the cleaning of the machine.

The Weighing Scales

- 6.92 The weighing scales sat on the table to the left of the vac packer machine. They had a stainless steel base and a tower with the weight display. The machine was stainless steel and could be pressure washed according to William Tudor. Only one set of scales was used in the factory as the old one had broken.
- 6.93 William Tudor confirms that the scales were used for raw meat and cooked meats. His claim was that unpacked raw meat would never have been put onto the scales because it had been cryo (vacuum) packed after being cut. I consider that claim to be untruthful.
- 6.94 The claim is again called into question by the employees' statements which indicate that the scales were another potential source of cross-contamination:
- (i) Mr Brown said that he would place a joint of meat onto a bag before putting on the scales. If twenty lamb chops were needed, he would put them in a bag and then weigh them.
 - (ii) Mr Exton said that if one person used the vac packer, another of them might weigh their orders first while waiting for the vac packer. This meant that bags weren't sealed so if they tipped over there could be some spillage of the contents, which could include juices or blood.
 - (iii) Mr Macnamara said that when cooked meat was weighed, it was already cryo (vacuum) packed. However, he also said that sometimes there would still be blood on the scales which would go on the outside of the bags (of cooked meat). He would wipe the bags down with warm water as he had been told to do by William Tudor. He would also wipe the scales down as well although he said he hadn't been told to do that.
 - (iv) Mr Exton said that if there was any spillage e.g. blood, meat, pumping machine salt or cure, he would clean it up using a dry paper towel from the sink area or a piece of netting from the nets in which joints were placed for cooking. He would wet the netting with water first. He would then dry the scales with a dry paper towel. He said that everyone would all clean the scales in the same way.

- 6.95 According to Professor Griffith, the use of one set of scales exacerbated the risk of cross-contamination. I agree. The practice of cleaning as described by Mr Exton would not, according to Mr Houston, remove any pathogenic bacteria such as *E.coli* O157 and any product or packaging being placed on the surface of the scales could be contaminated.
- 6.96 The fly-catcher was situated directly above the vac packer. This was not an ideal place to locate it. However, the risks are intermittent and depend on a fly falling into the machine at the precise moment a bag is being loaded into the machine. The risks are therefore very low and nowhere near the risk of *E.coli* O157 from cross-contamination.

Staff Training

- 6.97 William Tudor was, himself, trained to a high level. He obtained the Advanced Diploma in Food Hygiene qualification in November 2002, which is recognised on Bridgend's Butcher's Licensing Assessment Form. This makes the state of the premises and the practices evidently operated there all the more disturbing.
- 6.98 As Managing Director, it was William Tudor's responsibility to ensure that employees were trained and to arrange appropriate training. He failed to do so. Some members of staff worked for many years/months before attending a formal hygiene course:
- (i) Mr Exton said he had done various training courses years and years ago. He said that he had no real induction and that the one day course in February 2005 was the only training he had received in the three years since he started in Tudors. Further, he said that he was never given any specific instructions about cleaning the slicing machine nor any training on using the vac packer.
 - (ii) Mr Brown, who had been employed for four years after being taken on as a trainee butcher, was trained on the job or "shown the ropes" as he put it. Prior to the training in February 2005, no one had told him what should or should not be done about cross-contamination and cleaning procedures.
 - (iii) Mr MacNamara said that apart from being shown how to take apart the cooked meat slicer and how not to cut his fingers off in the band saw, there was no real training. William Tudor had told him to wash his hands after everything he did but he had had no health and safety or food hygiene training.
 - (iv) Mr Thomas said that the February 2005 course was the only course he had attended in four years.
 - (v) Mr Pridham, who started as a delivery driver at the beginning of September 2005, said that he had received no training at all from William Tudor or Mr Williams. He was not told how to clean the van and had learnt from what Mr Thomas and Mr Sharkey did.

- (vi) Mr Neil Goss, the part-time cleaner, had received no formal training or health and safety guidance. He had not attended the hygiene training in 2005.
- (vii) Mr Terry Goss was employed as a cleaner between 1997 and 2001. He had no experience in cleaning and received no training from Tudor or from external courses.

Health and Safety

- 6.99 There are some indications that health and safety practices were not maintained as rigorously as they should have been, as evidenced by Improvement Notices served on Tudors by Bridgend County Borough Council in October 2000 in respect of breaches of Health and Safety legislation. Mr Brown, who started in Tudors in 2001, said that he used to cut himself frequently when he started training and that before they were provided with blue latex gloves, no gloves had been used. He said that chain mail gloves should have been provided as protection, which is what William Tudor had been reminded to do in 1998 and 1999 by inspectors from the local authority. I believe that all this is symptomatic of William Tudor's widespread disregard for safety issues.

Sickness Policy

- 6.100 According to the Staff Hygiene and Work Rules kept by Tudors, employees were not allowed to blow their nose, sneeze or cough over food. The manager was to be informed if employees were suffering from vomiting, diarrhoea or stomach upsets. Employees that were suffering from food poisoning symptoms were not supposed to work.
- 6.101 It is questionable whether this policy was enforced. Mr Brown said that Tudors did not offer any sickness policy. There had been occasions when he was poorly, hot and shivery and he would be told to sit down for half hour then go back to work. He had never known William Tudor to send anyone home. He said he tended not to take sick days but when he did, William Tudor had not docked his pay and felt that this was because of the amount of work he took on. This position was supported by Mr Gerald Carbis, who stated that he and other staff were ill when working at Tudors and that he was required to work when suffering from illness.
- 6.102 As an employer, William Tudor was required to keep records of dates of sickness lasting at least four calendar days in a row reported by employees and records of payments of statutory sick pay. These records must be retained for three years. No such documents were recovered by police.

Food Safety Management

Hazard Analysis Critical Control Point Plan

- 6.103 Hazard Analysis Critical Control Point (“HACCP”) is a food safety management system designed to enable businesses to identify, evaluate and control hazards affecting their business. A specific document is produced that should identify the particular hazards or risks and set out a plan to address them.
- 6.104 Tudors had a HACCP plan, which was a requirement under the Butchers’ Licensing scheme. William Tudor was responsible for the plan and for implementing it. At the time of the Outbreak, the most recent HACCP plan was dated January 2005. The HACCP approach and Tudors’ HACCP plan is dealt with in the next Chapter.
- 6.105 The HACCP plan was kept in William Tudor’s office. William Tudor told police that he would have shown the HACCP plan to all staff, to make them aware of its contents, and that the process was actively, physically, showing them, looking through and reading it. However, on other occasions he appeared to indicate a less pro-active approach e.g. “it would have been available for anybody to read” and “they knew it was available”.
- 6.106 Again, William Tudor’s evidence is contradicted by the statements of his employees. Most of them stated to the police that they were unaware of a HACCP plan. Most did not even know what HACCP stood for. Mr Exton knew what HACCP was in the sense that documents had to be completed e.g. cleaning schedules, fridge and freezer readings. He did not see those records being completed at Tudors.

The Underlying HACCP Records

- 6.107 The authenticity of records kept by Tudors as part of their HACCP plan was investigated by the Forensic Science Service at the request of South Wales Police. The Service was asked to determine whether logs and cleaning standards forms from 6 December 2004 were completed on a daily/weekly basis or whether the entries were made in batches, and whether records of cooking and cooling times and temperatures and temperature records of work in progress, of the freezer, and for Chillers 1 and 2 were completed on a daily basis or in batches.
- 6.108 In her statement to the police, Dr Tina Reddick, Senior Forensic Scientist, said that there was conclusive evidence that logs and cleaning standards forms from 6 December 2004 and records of temperatures and times from 28 July 2004 onwards were not completed on a daily or weekly basis but that batches of entries were made at the same time. The forensic examination of Tudors’ records showed that the longest period written by one person in one ink was from 28 July 2004 to 2 February 2005. These dates are highly significant. There was a Butcher’s Licensing inspection on 28 July 2004. On 2 February 2005, there was a follow-up visit after an inspection on 18 January 2005. As evidence in Chapter 7 will show, the HACCP records weren’t available for inspection on 18 January 2005 as they had been “taken home for updating”. The analysis suggests that William Tudor did not maintain daily or weekly records during the period but made them up-to-date just in time for the EHO, Mrs Coles, to arrive on 2 February 2005 for her follow-up inspection.

- 6.109 William Tudor sought to explain the forensic report by saying that he would make notes of temperatures for the cooker, freezer, and chiller on pieces of paper and then transfer them later to the proper forms in the HACCP file. He said he would do this either on the day of taking the temperatures or within a day or so. He said that records of the fridges, freezer, cooking temperatures and work practice temperatures were in a record book/folder along with the cleaning schedule, staff records, and training records. Sometimes, records would be made on the sheets or they would be jotted down during the day and put in files at the end of the day. These statements were inconsistent with the Forensic Scientist's conclusions that much larger batches covering much longer periods were prepared by William Tudor.
- 6.110 He said that he never told EHOs about using scraps of paper. He said he had never been asked. He denied that he had tried to deceive any EHOs about the temperature records. When the police pursued questions about the notes on pieces of paper and commented that they had had not been able to find anything in any of documents recovered from the factory, William Tudor said that he could not answer that. I do not accept his "scraps of paper" explanation. I believe that William Tudors' account of updating the records from information on individual pieces of paper that he completed on contemporaneous basis was untruthful.

Food Safety Culture

- 6.111 Professor Griffith described food safety organisational culture as a manifestation of the values and beliefs and attitudes within a workforce. Its formation is dependent upon the knowledge, standards, motivation and leadership of the person in charge, how they communicate with, and are trusted by, the staff.
- 6.112 His conclusion on all the evidence was that Tudors' food safety culture was completely different to that which might be expected from a business managed by a person with an advanced food hygiene qualification. The culture that emerged was one of little regard for the importance of food safety but where making and saving money was the priority. This is typified by the approach of William Tudor in relation to the pork legs that were on the turn, namely to pump them with preservative when they should have been thrown out. A further example is passing off New Zealand Mutton as Welsh Lamb, thus increasing profit margins.
- 6.113 Professor Griffith formed the view that this culture is completely inappropriate for a business serving high-risk food for vulnerable customers and, rather than leading to "high quality safe food" being produced, would have increased the chances of food poisoning occurring. I agree.

Post-Outbreak Reaction at Tudors

- 6.114 On Monday 19 September 2005, Mr Thomas made his first drop of the day to Darren Las Primary School in Aberdare. He was told by the school that they had been told to accept the meat but not to use it. He received the same response from other schools on his delivery round. At around 12:30, William Tudor telephoned and told him not to make any more deliveries.
- 6.115 Mr Exton said that between 09:00 and 09:30 on 19 September 2005, Mr Williams entered the cooked meat room and said to expect a visit from EHOs. Members of staff were told to have a "tidy up".
- 6.116 Using a bucket, Mr Exton put hot water over the floor half a dozen times, rinsed it with the hose and squeegeed it dry, wiped the slicing machine, and removed to the bone bin some 3-4 kilo bags of mixed meat trim from the blast chiller. He also went around the factory collecting the red and green trays and put them outside at the rear of the factory. After EHOs had left, he said that William Tudor asked him to take the trays from outside and to place them on top of the main freezer. They were out of sight once they were there. Later that week, he said that William told him to take the trays down and to clean them with the steam cleaner and the new biochemical in it. He said he did not know why the trays were an issue to William Tudor but he wondered if it was because all trays looked exactly the same and whether the same trays had been used for raw and cooked meat.
- 6.117 Mr Brown said it was a case of "eyes down, start cleaning". He said that Mr Williams had told him that some schools had rung to say that there had been an outbreak and to expect a visit. He said that at the time nobody realised the seriousness of it.
- 6.118 Accordingly, it appears that a number of hours of cleaning at Tudors occurred prior to the EHOs arriving.
- 6.119 The next day, 20 September 2005, the vans and canteen were cleaned. William Tudor was said to be very busy and rushing around. Mr Pridham, had returned to work that day after a week's holiday to be told that the factory had been shut down. He said that "everyone was going mad cleaning". William Tudor told him to keep cleaning the vans. Mr Pridham stated that they cleaned the vans four times. After cleaning the vans, Mr Pridham then got involved in cleaning the factory, washing floors using a bucket with detergent. Intense cleaning occurred for a number of days. Following the Outbreak, William Tudor told Mr Exton to tell the Authorities that procedures were followed within the premises. Mr Exton changed his statement to the police, regarding the storing of cooked meats in raw meat boxes. Initially he told the police that this did not happen, out of loyalty to William Tudor.

Conclusions

- 6.120 William Tudor was well-qualified in food hygiene, knew about the risks of food poisoning, including *E.coli* O157, and had the ability to implement a food safety management system. The Outbreak happened despite all this. My overall conclusion is that William Tudor had a significant disregard for food safety and thus, for the health of people who consumed meats produced and distributed by his business. The basis for my conclusion is as follows:
- (i) There were serious, and repeated, breaches of Food Safety Regulations.
 - (ii) William Tudor did not ensure that critical procedures, such as cleaning and complete separation of raw and cooked meats, were being carried out effectively.
 - (iii) He falsified certain records that were an important part of food safety practice.
 - (iv) He misled, and lied to, Environmental Health Officers on some issues, such as the use of the vac packing machine and such a machine being away for repair.
 - (v) The views of the experts as summarised, notably those of Mr Curtis, Professor Griffith, and Mr Houston.
 - (vi) William Tudor's guilty pleas to a series of food hygiene offences.
- 6.121 The Outbreak need not have happened. The root cause of it, and thus the responsibility for it, falls squarely on the shoulders of William Tudor.

The Inspection of John Tudor & Son by Officers of Bridgend County Borough Council

- 7.1 Food businesses are subject to regulations designed to protect people's health. Environmental Health Officers ("EHOs") in the Public Protection Department of Bridgend County Borough Council, and those managing them, were responsible for carrying out inspections at the premises of John Tudor & Son ("Tudors").
- 7.2 The nature and scale of the problems at Tudors, and therefore the root cause of the Outbreak, were explained in Chapter 6. The problems gave rise to two principal issues:
- (i) Were Bridgend's systems and procedures appropriate and adequate to ensure an effective inspection and enforcement regime?
 - (ii) Were the actual inspections undertaken adequate and effective?

The Statutory Inspection Regimes

- 7.3 Two statutory inspection regimes applied to Tudors at the time of the Outbreak.
- 7.4 The first related to all food premises, which is defined in section 1(3) of the Food Safety Act 1990 ("the 1990 Act") as "any premises used for the purposes of a food business". Food authorities, of which Bridgend is one, are required to inspect food premises to ensure compliance with the provisions of the Food Safety (General Food Hygiene) Regulations 1995. It placed a duty on Bridgend when enforcing these Regulations to:
- (i) Ensure that food premises are inspected with a frequency which has regard to the risk associated with those premises and that inspections include a general assessment of the potential food safety hazards associated with the food business being inspected (Regulation 8(2)(a)).
 - (ii) Pay particular attention to the Critical Control Points identified by the food business operator to assess whether the necessary monitoring and verification controls are being operated (Regulation 8(2)(b)).
 - (iii) Give due consideration to whether the proprietor of a food business has acted in accordance with any relevant guide to good hygiene practice (Regulation 8(2)(c)).
- 7.5 Section 40 of the 1990 Act empowers the Secretary of State to issue Codes of Practice concerning the execution and enforcement of the 1990 Act and Regulations made under it. Section 40 also requires Food Authorities to have regard to the Codes when discharging their duties in enforcing the 1990 Act.
- 7.6 The second inspection regime was the Food Safety (General Food Hygiene) (Butchers' Shops) (Amendment) (Wales) Regulations 2000, which added to the 1995 Regulations. The 2000 Regulations were made after my review of the 1996 outbreak of *E.coli* O157 in Scotland. They came into force in Wales on 31 December 2000 and were in effect at the time of the Outbreak. They were subsequently replaced by new EU regulations, which came into effect on 1 January 2006.

- 7.7 The 1995 Regulations, as amended by the 2000 Regulations, required butchers' shops that carried out commercial operations for the supply and sales of ready-to-eat foods and raw meat to obtain a licence from the Food Authority. A licence was valid for one year. The conditions for granting licences were set out in paragraph 5 of Schedule 1A to the 1995 Regulations, as amended by the 2000 Regulations. These were:
- (i) The butcher's shop complies with the requirements of the 1995 Regulations, notably that working operations are carried out in a hygienic way.
 - (ii) The butcher's shop complies with the requirements of the Food Safety (Temperature Control) Regulations 1995.
 - (iii) All food handlers are trained in food hygiene to the standards required to enable them to perform their duties with a view to ensuring that all the food in the shop complies with those requirements.
 - (iv) At least one person is trained in food hygiene to enable him to supervise the activities of the food business with a view to ensuring that those requirements are met, and that the Hazard Analysis Critical Control Point ("HACCP") procedures which apply are followed.
 - (v) HACCP procedures are in place.
- 7.8 Regulation 8 of the 1995 Regulations, which imposes the inspection duties on Food Authorities as set out above, supported and enforced the butchers' shops requirements.
- 7.9 Guidance was also available. In 2001, the Food Standards Agency ("FSA") published a Licensing Supplement to the Industry Guide to Good Practice for Butchers' Shops. In addition, in October 2001 it published a second edition of guidance notes on the Licensing Regulations which replaced those issued in February 2001. The guidance notes were intended to provide informal, non-statutory, guidance on the legal requirements. They were designed to be read in conjunction with the Licensing Regulations. They complemented the specific guidance in the Supplement to the Industry Guide. The guidance:
- (i) Provided definitions of terms used in the Regulations.
 - (ii) Described the types of premises to which the Licensing Regulations did not apply.
 - (iii) Addressed administrative issues regarding the issue of licences.
 - (iv) Provided assistance in relation to specific licensing conditions, including HACCP procedures, HACCP records, and training records.
 - (v) Gave assistance on enforcement issues, including circumstances when a licence could be suspended or revoked.

The Codes of Practice

- 7.10 Prior to the 1990 Act, there was little guidance on the conduct of inspections. Codes of Practice were published after it was introduced including: Code of Practice No. 3: "Inspection Procedures - General"; Code of Practice No. 9: "Food Hygiene Inspections"; and Code of Practice No. 19 "Qualifications and Experience of Authorised Officers."
- 7.11 Code of Practice 3 dealt with inspections in general, visits to deal with complaints and for general advice and the co-ordination of inspection visits with other enforcement agencies. The requirement to write to businesses following inspections was highlighted.
- 7.12 Code of Practice 9 gave guidance on the frequency and nature of inspections. It included advice on assessing the potential risks of food businesses. Inspections would be prioritised based on those risks. The Food Authority was required to take into account management practices and past compliance when determining future risk. A risk rating scheme was set out. The greater the risk rating, the greater the frequency of inspections.
- 7.13 The purpose of an inspection was dealt with explicitly:
- (i) To establish whether food was being handled and produced hygienically.
 - (ii) To establish whether food was, or having regard to further processing would be, safe to eat.
 - (iii) To identify foreseeable incidences of food poisoning or injury as a consequence of consumption of food.
- 7.14 Code of Practice 9 set out the main objectives of a food hygiene inspection as:
- (i) Determination of the scope of the business activities and of the food legislation which applies to the business.
 - (ii) Thorough and systematic gathering and recording of information from observations and discussions with food handlers, managers and proprietors.
 - (iii) Identification of potential hazards and risks to public health.
 - (iv) Assessment of the effectiveness of process controls to achieve safe food.
 - (v) Assessment of the hazard analysis or HACCP-based food safety management system operated by the business.
 - (vi) Identification of specific breaches of food safety legislation.
 - (vii) Consideration of appropriate enforcement action to secure compliance with food safety legal requirements.
 - (viii) Provision of advice and information to proprietors and food handlers.

- (ix) Recommendation of practical, good food hygiene practices, in accordance with Industry Guides.
- (x) The promotion of continued improvements in food hygiene standards through the adoption of good practice.

7.15 It required a Food Authority to set up and maintain a database of food premises in its area and to have a documented procedure to ensure that the database was accurate and up to date. It also required the Authority to implement and maintain a documented programme for food hygiene inspections and, as far as practicable, ensure that inspection visits were carried out in accordance with that programme. Minimum inspection frequencies were to be observed. The Code stated that an effective inspection programme should recognise that the frequency of the inspection would vary according to the type of food business, the nature of the food, the degree of handling and the size of the business.

7.16 Code of Practice No. 9 also set out the minimum frequencies at which premises should be inspected:

Table 7.1: Risk Rating Categories and Corresponding Minimum Inspection Frequencies

Risk Rating Category	Scoring Band	Inspection Frequency
Category A	91-195	6 months
Category B	71-90	12 months
Category C	41-70	18 months
Category D	31-40	2 years
Category E	21-30	3 years
Category F	Less than 21	5 years

Source: Code of Practice No.9

7.17 Annex 1 to this Code set out in more detail the risk rating scheme, its scoring method and explanatory notes in relation to that assessment.

7.18 In relation to the conduct of inspections, Code of Practice 9 stated that the inspection should include:

- (i) A review of the information held on record by the Food Authority in relation to the food business.

- (ii) A preliminary discussion with the duty manager/proprietor, which should include:
 - (a) An explanation by the officer of the purpose of the inspection.
 - (b) Identification of all the food-related activities undertaken by the business e.g. the areas of the premises used for preparation, production, storage of foodstuffs, the processes used and the staff involved.
 - (c) Identification of the customer base of the business.
 - (d) Identification of any food safety management systems that may be in use.
 - (e) An assessment by the officer of the hazards posed by the business's activities.
 - (f) An assessment of the manager's/proprietor's understanding of the hazards posed by the business and the application of appropriate controls.
 - (g) An examination of any documented food safety management system/hazard analysis.
 - (h) An assessment of the provision of supervision and instruction and/or training of staff.
- (iii) A discussion with any staff responsible for monitoring and corrective action at critical control points to confirm that control is effective.
- (iv) A physical examination of the premises to assess: (a) if all the critical controls have been identified; (b) whether the controls are in place; (c) compliance with the relevant legislation. Chapter 2 of Code 9 provided specific guidance on the Food Safety (General food Hygiene) Regulations 1995.
- (v) An assessment whether to take microbiological or chemical samples.
- (vi) A closing meeting with the duty manager/proprietor, which should include:
 - (a) A discussion regarding any hazards that have been identified by the officer that have not been covered by the business's systems.
 - (b) A discussion regarding any failure to implement or monitor any critical controls that have been identified by the business.
 - (c) A discussion regarding any contravention of the relevant legislation.
 - (d) Any recommendation of best practice the business may wish to consider.
 - (e) A discussion regarding the timescale for any corrective actions needed and any follow-up action the officer intends to take.
- (vii) A written report prepared and sent to the business, confirming all matters discussed at the closing meeting and differentiating between work required to comply with legal requirements and recommendations of best practice.

- (viii) A record of the inspection findings and outcomes to be kept on file at the Food Authority. The file records should include:
 - (a) Information on the type of food business undertaken by the business including any special equipment, processes or features.
 - (b) Copies of correspondence.
 - (c) An assessment of the business's compliance with the appropriate hazard analysis requirement or HACCP requirement in product-specific food hygiene requirements.
 - (d) Information on the hygiene training undertaken by employees.
 - (e) For premises approved under product-specific hygiene legislation, details of any derogation in force, details of approved products and cleaning methods employed.
- 7.19 If contraventions and/or poor hygiene practices were found, a follow-up visit should have been undertaken. Where significant breaches had been observed, the revisit should have been carried out by the same officer who carried out the initial inspection. Code 9 and the other Codes of Practice provided officers with guidance on the range of options available when breaches of legislation were identified.
- 7.20 Code of Practice No. 9 also required Food Authorities to implement a system to monitor the quality and consistency of inspections. The management monitoring system should, as a minimum, have included measures to monitor the following:
 - (i) Adherence to the Authority's planned inspection programme.
 - (ii) Priority is given to inspecting the higher-risk premises (Categories "A" to "C").
 - (iii) Compliance with the Food Safety Act Codes of Practice and central government guidance.
 - (iv) That officers have due regard to published UK or EU Industry Guides to Good Hygiene Practice.
 - (v) Compliance with internal procedures, policies and the Authority's enforcement policy.
 - (vi) That the inspection ratings allocated are appropriate.
 - (vii) That the interpretation and action taken by officers following an inspection is consistent within that authority, and is consistent with central government/LACOTS (Local Authority co-ordinating Body on Trading Standards – now Local Authorities Coordinators of Regulatory Services (LACORS) guidance.

The Combined Code of Practice

- 7.21 In October 2004, the separate Codes of Practice were combined. The FSA issued a new Code of Practice ("the Combined Code") which replaced all codes previously made under the 1990 Act. It was this Combined Code that was in force at the time of the Outbreak. Although it was produced in October 2004, it came into effect in Wales from February 2005. Thus, until that date, the old Codes of Practice were in force. In terms of food hygiene inspections, the Combined Code of Practice provided EHOs with similar guidance to that in the previous, separate, Codes of Practice.

Qualifications, Knowledge and Training

- 7.22 Chapter 1.2 of the Combined Code states that Food Authorities must ensure that officers they authorise to carry out enforcement are suitably qualified, experienced and competent to carry out the range of tasks and duties they are required to perform. Food Authorities should not authorise new officers or extend the duties of currently employed officers unless they meet any relevant additional requirements relating to specific duties or enforcement responsibilities.
- 7.23 Officers appointed to undertake food hygiene and safety inspections should be suitably qualified, holding a Certificate of Registration of the Environmental Health Registration Board or the Diploma in Environmental Health.
- 7.24 Officers who are required to carry out inspections of businesses that have HACCP-based food safety management systems, such as Tudors, should also possess the evaluation competencies set out in Annex 2 of the Code. The officer has to be able to identify, through the conduct of an audit, the need for improved food safety control in food premises, to promote and support the implementation of HACCP-based management control systems in food businesses and to secure compliance with hazard analysis requirements in legislation.
- 7.25 Food Authorities should ensure that authorised officers receive relevant structured ongoing training, explaining new legislation and procedures and technological developments relevant to food businesses subject to their inspection. The minimum ongoing training should be ten hours per year based on the principles of continuing professional development.
- 7.26 New officers or officers returning to food law enforcement after an absence of more than three years should be monitored for at least three months and should receive, as a minimum, 15 hours revision training.
- 7.27 Records should be kept of certificates of registration, qualifications and documents relating to ongoing training undertaken by authorised officers.
- 7.28 The Combined Code requires officers to have a detailed knowledge of a listed series of matters including:
- (i) The nature and types of food businesses in their area and the technology utilised by the businesses that the officer is required to inspect.

- (ii) Relevant food hygiene and safety legislation.
- (iii) The Code of Practice.
- (iv) The Food Safety Act 1990 Practice Guidance.
- (v) The Food Authority's enforcement policy.
- (vi) UK and EU industry Guides to Good Hygiene Practice.
- (vii) Relevant guidance issued by the Food Standards Agency and the Local Authorities Coordinators of Regulatory Services (LACORS).
- (viii) Relevant industry codes of practice.

7.29 Very similar provisions were set out in Code No. 19 "Qualifications and Experience of Authorised Officers", which was the original Code of Practice on this topic.

Inspections

7.30 The Combined Code emphasises that food hygiene inspections are part of the system for ensuring that food meets the requirements of food hygiene and safety law, including microbiological quality; the absence of pathogenic micro-organisms; and the safety of food for consumption.

7.31 This Code sets out a system of assessing risks posed by particular businesses. Inspection "ratings" determine the interval that should elapse between one primary inspection of a food business and the next. Annex 5 sets out the minimum inspection frequency for different categories of food premises and the explanation/guidance as to the application of the scoring system in place to assess the appropriate category for a business. The precise scoring bands differ very slightly from those set out in Code of Practice No. 9 and there is no Category F. The inspection approach for the lowest scoring category refers to an "Alternative Enforcement Strategy" as opposed to the previous inspection frequency of 3 years.

Table 7.2: Risk Rating Categories and Scoring Bands and Corresponding Minimum Inspection Frequencies

Risk Rating Category	Scoring Band	Inspection Frequency
Category A	92-196	6 months
Category B	72-91	12 months
Category C	42-71	18 months
Category D	31-41	2 years
Category E	0-30	Alternative Enforcement Strategy

Source: Combined Code of Practice

- 7.32 The ratings also determine the priority of the next primary inspection of that business relative to the other businesses in the Food Authority's planned inspection programme. The ratings of a food business should be assessed or re-assessed at the conclusion of every primary inspection in accordance with Annex 5. The Food Authority should on request, advise and discuss with the proprietor the inspection frequency or rating applied to the business.
- 7.33 Each Food Authority should document, maintain and implement a food hygiene inspection programme that includes all the businesses in which the Food Authority has food hygiene law enforcement responsibility. The programme should be based on the food hygiene inspection ratings that have been determined in accordance with Annex 5.
- 7.34 Chapter 4 of the Combined Code sets out extensive guidance for EHOs on the conduct of inspections by local authorities such as Bridgend.
- 7.35 An inspection of a food business may be either a primary inspection or a secondary inspection.

Primary Inspection

- 7.36 A primary inspection is a structured inspection of a food business against a number of specified elements that are set out in a form developed for this purpose by a Food Authority. The inspection form is intended to assist EHOs and businesses by introducing a structured approach to the inspection process.
- 7.37 The Combined Code of Practice identifies a number of tasks to be undertaken by an officer carrying out a primary inspection:
- (i) Establish the scope of the business and the relevant food law that applies to the operations taking place.
 - (ii) Thoroughly and systematically gather and record information from the observation of practices, procedures and processes, and discussion with food handlers, contractors, proprietors and managers.
 - (iii) Determine whether it is necessary to collect samples for analysis and/or examination.
 - (iv) Identify any actual or potential breaches of food law and, if appropriate, gather and preserve evidence.
 - (v) Determine relevant enforcement action and communicate to business.
- 7.38 The inspection process should begin before the EHO even arrives at the business's premises with a review of the information held on record by the Food Authority in relation to that business.

- 7.39 At the beginning of the inspection, the EHO should discuss with the proprietor the purpose and scope of the inspection and what the officer intends to do. Staff who have been given specific responsibilities for ensuring compliance with relevant legal requirements may be questioned in order to verify that they understand their duties and are carrying them out effectively. EHOs should offer advice where it is appropriate or is requested and should encourage food businesses to adopt best/good practice.
- 7.40 The Combined Code then lists a number of things an officer should do depending on the type of primary inspection being undertaken.
- 7.41 If the inspection is a primary food hygiene inspection, the officer should:
- (i) Assess the risk of the business failing to meet food hygiene requirements.
 - (ii) Assess the hazards posed by the activities of the business, the manager's/proprietor's understanding of those hazards, and the application of the appropriate controls.
 - (iii) Assess and verify appropriate hazard analysis or HACCP food safety management systems, confirming that controls are in place and operating effectively and that the appropriate corrective action is taken when necessary.
 - (iv) Verify that any appropriate own-checks are being carried out effectively.
 - (v) Establish whether food is being handled and produced hygienically, it is safe to eat and that relevant temperature controls are being observed.
 - (vi) Recommend good food hygiene practice in accordance with EU and UK industry guides, relevant sector specific code, and other technical standards, and promote continued improvements in hygiene standards through the adoption of good practice.
- 7.42 In addition, a primary inspection should include:
- (i) A discussion with any staff responsible for monitoring and corrective action at critical control points to confirm that the control is effective. This is consistent with earlier guidance to the effect that staff of food businesses who have been given specific responsibilities for ensuring compliance with relevant legal requirements may be questioned in order to verify that they understand their duties and are carrying them out effectively.
 - (ii) A physical inspection to determine whether critical controls have been identified and whether the controls are in place and to assess compliance with relevant food law.
 - (iii) A discussion regarding any hazards that have been identified by the officer that have not been covered by the business's systems.
 - (iv) A discussion regarding any failure to implement or monitor any critical controls that have been identified by the business.

Secondary Inspection

- 7.43 A secondary inspection is defined by the Combined Code of Practice as any other visit to a food business that is not a primary inspection, for any purpose connected with the enforcement of food law. This includes:
- (i) Additional inspections of establishments that are subject to product-specific food hygiene regulations.
 - (ii) Visits to check on the progress of measures required after a previous inspection. A secondary inspection of this type should, whenever practical, be undertaken by the officer who undertook the original inspection.
 - (iii) Visits to investigate food and food premises complaints.
 - (iv) Visits to discuss the implementation of HACCP-based systems.
 - (v) Visits involving the training of food handlers.
 - (vi) Inspections of premises to assess a licensing application.
- 7.44 At the conclusion of every inspection, the officer should discuss any contravention of food law discovered, any corrective action necessary, the timescale for corrective action, any further action the officer intends to take and any recommendations of best/good practice that the officer considers appropriate. In closing the discussion and in subsequent reports or correspondence, officers should clearly differentiate between action required to comply with legal requirements and recommendations of good practice.

Report Writing and Record Keeping

- 7.45 The Combined Code of Practice reiterates the importance of report writing and record keeping. The outcome of a primary inspection should always be reported in writing to the proprietor either at the conclusion of the inspection or as soon as practicable thereafter, even if the outcome was satisfactory. Secondary inspections should be followed up in writing if the officer conducting the inspection: requires the proprietor to take action; needs to confirm something has been done; needs something to be noted.
- 7.46 The details to be included in reports are set out in Annex 6. The Authority's inspection record files should be updated after each inspection and should include:
- (i) Information on the size and scale of the business and its customer base.
 - (ii) Information on the type of food activity undertaken by the business, including any special equipment, processes or features.
 - (iii) Copies of correspondence with the business, including documentation associated with approvals or licensing.

- (iv) Copies of food sample analysis/exam results and in respect of premises inspected for food hygiene purposes.
- (v) An assessment of the business compliance with the appropriate HACCP requirements.
- (vi) Information on hygiene training undertaken by employees.
- (vii) For premises that are subject to product-specific food hygiene regulations, details of any derogations in force, details of approved products handled and cleaning methods employed.

7.47 Inspection records should be kept for at least six years, whereas Code of Practice 9 recommended two years. Bridgend's inspection records for Tudors went back much further than this, with a series of documents from as far back as 1991 and a small number from 1989. The additional records were helpful to the Inquiry.

Monitoring Inspections

7.48 Food Authorities are required to maintain documented procedures for monitoring progress of the planned inspection programme and the quality and consistency of inspections undertaken by their officers, to ensure that inspections are carried out competently.

7.49 The monitoring system should include measures to review:

- (i) Adherence to the Authority's planned inspection programme.
- (ii) The priority given to inspecting businesses according to inspection ratings.
- (iii) Compliance with the Code of Practice and FSA Guidance.
- (iv) The consistent assessment of inspection ratings.
- (v) Compliance with relevant inspection forms.
- (vi) Compliance with internal procedures, policies and the Authority's enforcement policy.
- (vii) That the interpretation and action taken by officers following an inspection is consistent within that food authority and is consistent with FSA and/or LACORS guidance.
- (viii) That officers are aware of, and have access to, other published industry codes of practice relevant to the businesses within the area of the Food Authority.

7.50 In relation to food hygiene inspections, the monitoring should also review:

- (i) The priority given to inspecting businesses that are subject to product-specific food hygiene Regulations.
- (ii) That officers have due regard to published UK or EU Industry Guides to Good Hygiene Practice.

The System Employed by Bridgend

The Food Law Service Plan

- 7.51 Bridgend's Public Protection Department publishes annual Food Law Service Plans, which set out the programme to ensure that relevant statutory requirements are met. The Food Law Service Plan current at September 2005 was the 2005-6 Plan ("the Plan"). The Plan gave an overview of the Department's work.
- 7.52 The Department's estimated budget for food hygiene and food standards was £324,246, of which £187,333 was staffing costs. This represented an increase of 3.5% over the 2004-05 budget. However, this was largely to take account of increased transport costs. It was stated that the staffing budget for 2005-06 was expected to be 2.2% lower than 2004-05.
- 7.53 There were 1156 food premises in the area, of which 1050 were registered food businesses. Bridgend's Plan identifies 157 as being in the "high-risk" categories of "A" (27) and "B" (130). The risk ratings determined the minimum frequency of inspection and the Plan shows Category "A" for inspection every 6 months and Category "B" every 12 months.
- 7.54 The Department envisaged 529 inspections in 2005-06, plus 14 overdue inspections from 2004-05. It was anticipated that inspections would generate 300 re-visits to ensure that corrective action identified by officers had been carried out. It was noted that the Department's ability to meet inspection targets in 2004-05 had been affected by staff movement within the section, which had resulted in consultants being engaged to cover vacant posts. The Plan specifically indicated that recruitment and retention needed to be addressed, and alternatives to the recruitment of qualified officers investigated.

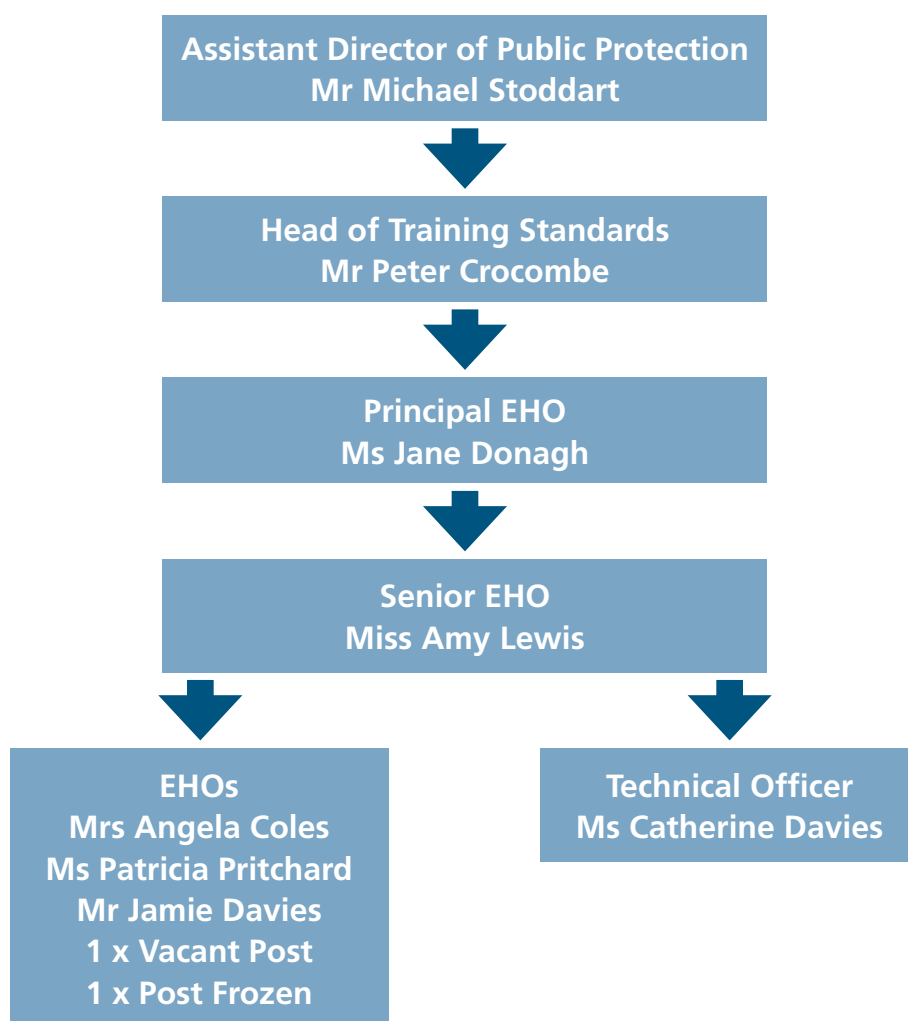
Organisational Structure

- 7.55 On the ground, Environmental Health Officers ("EHOs") are responsible for food hygiene inspections, investigating food complaints, food sampling for hygiene purposes, and food poisoning investigations.
- 7.56 The EHOs are managed by the Principal Environmental Health Officer ("Principal EHO"). The Food Law Service Plan includes the following as part of the Principal EHO's functions:
- (i) At the start of the year, preparing a work programme with monthly inspection targets, which are allocated to individual officers.
 - (ii) Responsibility for monitoring and assessing the quality of food hygiene inspections by reviewing all post-inspection paperwork.
 - (iii) Monthly reporting to the Head of Service.
 - (iv) Holding monthly section meetings.
 - (v) Holding regular meetings with line managers to give monitoring feedback, and annual staff appraisals.

(vi) Reporting performance to the Cabinet on a quarterly basis.

- 7.57 There was a change in the Principal and Senior EHOs during the period of inspections that was covered by the Inquiry. In the period leading up to September 2003, the Principal EHO was Mr Arthur Stuckey and the Senior EHO was Mr Graham Gubb.
- 7.58 Thereafter, the Principal EHO in the two-year period leading up to September 2005 was Ms Jane Donagh. At that time, she was assisted by Senior EHO Mr Peter Cole. Both were appointed to their posts on 1 September 2003. Mr Cole left Bridgend in August 2005.
- 7.59 The Team responsible for food hygiene enforcement was the Commercial Section of the Trading Standards Section, which was part of the Authority's Public Protection Department. The structure of Ms Donagh's team is shown in the diagram below.

Diagram 7.1: Structure of the Commercial Services Section, Food Safety Team, Public Protection Department, Bridgend County Borough Council, September 2005



Source: Bridgend County Borough Council
(extract from organisational charts)

- 7.60 Mr Cole was the Food Safety Officer from the date of his appointment as Senior EHO in September 2003. When he took up his post, he had food safety experience spanning four years at the beginning of his career between 1992 and 1996, at a time when HACCP was some years from being introduced. He took steps to go on a training course in October 2003. That was a two-day course, one day devoted to HACCP and the other to the meat products legislation which did not apply to Tudors. He also attended a three-day “HACCP for Enforcement Officers” course in March 2004. He did not receive a period of monitoring of the kind recommended by the Code of Practice for those who return to food law enforcement after an absence of more than three years. He assumed direct responsibility for overseeing the four EHOs who were dealing with food safety, although he worked closely with Ms Donagh.
- 7.61 Ms Donagh’s background from 1996 up to her appointment in September 2003 had been in the Pollution Control Section of Bridgend. She had never been a Food Hygiene Inspector and thus had no practical experience of food safety inspections. In October 2003, she attended the same course as Mr Cole, and also made further considerable efforts to gain the necessary knowledge on the ground. On appointment, she conducted a staff appraisal of all the EHOs. This indicated that a considerable number needed HACCP training, which she then arranged.
- 7.62 The Department was managed by Mr Chris Goacher who, in September 2005, was the Head of Environmental Health Services. Mr Goacher acted as Mr Stuckey’s line manager until 2001 when, after an internal reorganisation, Mr Peter Crocombe became the Head of Trading Standards Services. He became Ms Donagh’s line manager as she and her team were reallocated to the Trading Standards section. Mr Goacher was answerable to Mr Michael Stoddart, the then Assistant Director of Public Protection.
- 7.63 Mr Crocombe had no experience whatsoever of food safety regimes and food safety inspections. He stated in his evidence that his role in relation to managing food safety took approximately 20-25% of his time. He referred to having some discussions with Ms Donagh about the FSA’s audit, which is examined in detail in Chapter 8, and about the procedures that she and Mr Cole drafted. However, it was clear from his evidence that he did not proactively supervise or get himself involved in the detail of the work being done by the newly-structured team. He accepted that it could be argued, with hindsight, that, given the relative lack of experience of the new team, his management had been too reactive and not sufficiently proactive. In my opinion, his approach was not particularly helpful in a management sense. He had not considered there to be a need to understand and review the work of his team, which he should have seen as an important part of a manager’s function. It appears that Ms Donagh was provided with only limited support.
- 7.64 Mr Stoddart appears to have been rather more hands-on, at least immediately after the period of transition for the four months or so until the FSA’s audit of Bridgend. However, after that his role became a more distant and reactive one, despite Mr Crocombe, Ms Donagh’s line manager, having no practical experience of food hygiene matters. The positive feedback from the FSA’s audit was probably a factor that influenced this.

The Inspection Procedures Document

- 7.65 Bridgend produced internal inspection procedures (“the Procedures”). Work on this document commenced and was probably completed some considerable time before the date that appears on the version seen by the Inquiry, 18 June 2004, which Mr Cole thought was a print date. Its drafting was prompted by the arrival in post of Ms Donagh and Mr Cole, and the impending audit by the FSA. There was no equivalent document in place during the time of Mr Gubb and Mr Stuckey. Ms Donagh’s recollection, supported by minutes of a Team Meeting, is that members of the Food Safety Team had significant input into this document and the others that were developed at the time.
- 7.66 In preparation for an inspection, the Procedures states that the officer should remove the hard copy file relating to the relevant premises and check details of the previous visit/risk assessment. The use of the singular suggested that the practice should be to review the last visit. This appears to me to be a relatively narrow interpretation of Code of Practice 9. That Code says that there should be “a review of the information held on record” but does not appear to limit that review to only a review of the previous inspection.
- 7.67 There appears to have been a considerable divergence of approach between EHOs who inspected Tudors on how far to go back in files. Mr Cole stated that the document should not be treated as a straightjacket and that it was a matter for the judgement of each inspector how far back in the file to go in preparation for an inspection.
- 7.68 There was no system of “red-flagging” particular issues of concern from past inspections.
- 7.69 The principal working documents and forms used by Bridgend as part of inspections procedures were:
- (i) The Food Premises Inspection Report was used as an inspection guide on food hygiene inspections.
 - (ii) The Food Premises Inspection Report Summary, a copy of which was left at the premises when the inspection has been completed.
 - (iii) Food Hygiene Visit Progress Sheet, which provided a means of documenting a summary of progress arising from an inspection/visit.
 - (iv) Hazard Analysis Review of Progress form which was used as a check on the implementation of HACCP.
 - (v) An Application Form to Licence a Butcher’s Shop, which required the food business operator to state the number of persons working in the premises, the number with specific training on HACCP, and the number with Food Hygiene Certificates at Basic, Intermediate and Advanced levels.
 - (vi) Butchers’ Licensing Assessment Form which was completed at the annual licensing inspections and which included sections focusing particularly on HACCP.

- 7.70 The Procedures dealt with the practice to be adopted at the premises being inspected. This covered three-quarters of a page identifying some bullet points only. But as Mr Cole pointed out, the EHOs would be aware of other guidance on the practicalities of conducting an inspection, in particular, that contained in the Codes of Practice. The Procedures stated that the officer was required to:
- (i) Ask for the manager/proprietor; if unavailable, ensure there is someone present who can accompany the officer and “preferably” answer questions regarding practices and procedures. There was no reference at this point to the importance, accepted by Mr Cole, of EHOs talking to food handlers who were responsible on the ground for implementing food safety procedures. His answer was again that this would be known to EHOs through the Code of Practice. However, there appears to have been little or no such discussion with anyone other than Mr William Tudor, and in his absence, Mr Celyn Williams.
 - (ii) Check details on the premise’s Food Registration Form and Food Premises Inspection Report completed during the last inspection.
 - (iii) Adopt a formal system for recording the inspection.
 - (iv) Ask if hazard analysis had been carried out. If it had, documentation/control systems should be checked. If it hadn’t, an assessment should be carried out during the inspection and should be recorded on the Food Premises Inspection Report. Mr Cole explained that this was directed at hazard analysis and not specifically at HACCP. It follows that the Procedures contained no guidance whatever to EHOs inspecting businesses governed by the 2000 Regulations as to how best to go about ensuring that the HACCP requirements were being met. Ms Donagh pointed out however that the forms that inspectors were required to fill in themselves gave implicit guidance as to the areas to focus on.
 - (v) Discuss with staff the procedures involved.
 - (vi) Establish the type/quantity of food handled and the number and types of customers.
 - (vii) Discuss methods of processing/handling.
 - (viii) Establish that staff training should be commensurate with their duties – training/instruction and supervision.
- 7.71 The Procedures then dealt with inspection feedback, setting out the following steps to be taken by the officer concerned:
- (i) The Food Premises Inspection Report Summary to be completed.
 - (ii) The findings to be discussed with the manager/proprietor.
 - (iii) Explain what enforcement action is proposed; if any, distinguish between contravention/good practice.

- (iv) Advise the proprietor of appropriate guidance information, including drawing awareness to the appropriate industry guide to good hygiene practice.
- (v) Request proprietor/manager sign the Food Premises Inspection Summary and issue a copy to them.
- (vi) In addition to identifying risks and contraventions, take every opportunity to discuss where appropriate:
 - (a) The benefits of assessing and minimising risks, including information on HACCP.
 - (b) The benefits of exercising due diligence, in ensuring that customers and their businesses are protected.
 - (c) Any types of equipment or finishes, training course, leaflets etc which may be of use to them when assessing or minimising hazards.
 - (d) Forthcoming legislation and willingness for them to approach Bridgend for accurate information.

7.72 The Procedures then laid down the steps to be taken on return to the office:

- (i) Submit appropriate Food Hygiene Visit Progress Sheet to administration for update of the computer system operated by Bridgend for recording inspections information, which was the "FLARE" system.
- (ii) Complete a Food Premises Inspection Report and update the food business's file.

7.73 Enforcement options were dealt with in the Procedures:

- (i) In relation to warning letters, the Procedures required these to follow standard paragraph precedents and to be sent out within ten working days.
- (ii) If a conclusion had been reached that there was a breach of any legislation, the Procedures required that decisions about appropriate action should be based on the Food Enforcement Policy.

7.74 The Procedures also dealt with risk ratings. Any change of a premise from risk rating "A" or "B" needed to be approved by the Principal EHO. The risk rating was prepared in accordance with a scoring system and was in summary form the same system as that provided for in the Code of Practice.

7.75 Accordingly, while the Procedures document was better than the previous version (nothing), it was not adequate.

- 7.76 Mr Cole's evidence was that he did not provide any practical guidance to the EHOs going out to inspect butchers' premises. He explained that position on the basis that by the time he arrived in post, the EHOs were already familiar with such inspections. His role in this respect did not go beyond being available for discussion if EHOs chose to do so. He described in some detail in his evidence the sort of audit techniques he would have expected to be applied in the inspection of HACCP systems and the manner in which he would have gone about such an inspection. That description corresponded closely to the description given by Mr Brian Curtis, whose expert witness evidence to the Inquiry is examined later in this Chapter. Aside from a vague recollection of accompanying Mr Jamie Davies on an inspection in 2004, Mr Cole could not recall satisfying himself that his EHOs were conducting such inspections in the manner he considered to be appropriate.
- 7.77 In addition, around this time in late 2003, Ms Donagh and Mr Cole drafted a set of internal monitoring procedures. However, and despite recognising the importance of monitoring the quality of inspections, Mr Cole recognised that the newly drafted monitoring procedure was not followed "strictly to the letter of the procedure". For instance, apart from some accompanied visits, he was not able to identify any other step that he took to monitor and check the quality of the inspections being carried out. Ms Donagh explained that some of the monitoring procedures set out in this document had not been followed because of resource constraints. Specifically, it therefore appears that the only such procedure that was designed to monitor not merely the quantity but also the quality of inspections was not followed.

Enforcement Policy

- 7.78 Shortly after the production of the Procedures document, Bridgend also produced an Enforcement Policy, the purpose of which was to ensure consistent enforcement decisions were made. This was produced on 16 August 2004 and replaced the earlier policy of April 2001. It graded the severity of enforcement action and required considered judgements to be made as to the appropriate level of such action based on guidance set out in the policy.

Hazard Analysis Critical Control Point Approach

The Basic Theory

- 7.79 It is necessary to set out, in broad terms, how the Hazard Analysis Critical Control Point ("HACCP") approach works in a business such as Tudors.
- 7.80 The first stage in the development of a HACCP plan is to identify what operations the business undertakes. The intention is to split out those operations which carry different hazards so that effective plans can be developed for dealing with those hazards. So, for example, the operations at a butcher such as Tudors might have a basic split into dealing with raw meats, dealing with meats cooked on site, and dealing with processing ready cooked meats brought in.

- 7.81 The next stage would be to break down each type of operation into process steps. This would be done by creating a flow chart analysing each stage of the operation in question. So, for example, the 2005 HACCP plan for Tudors included a flow chart for the cooking on-site of hams. Ten process steps were set out from purchase and receipt through bagging and cooking to transport.
- 7.82 The third stage is then to use the analysis of the operations undertaken and the various process steps associated with each of them as the foundation for analysing what particular hazards are involved at each of the stages.
- 7.83 Once the hazards have all been identified it is then possible to work out what can be done to prevent or reduce the hazard. This stage therefore involves analysing the required controls. The 2005 HACCP plan set out to deal with this stage of controlling the hazards under four main headings:
- (i) The first was to assess the importance of controlling the particular hazard effectively in terms of food safety. A Critical Control Point indicates that it is critical to control the hazard at that point in the process because there is no subsequent part of the process that would reduce or eliminate the hazard to an acceptable level. If that was not the position, the control was merely characterised as good practice.
 - (ii) Next the steps necessary effectively to control the hazard were analysed. For example, if the hazard was survival of bacteria during cooking, the analysis at this stage would involve setting particular cooking temperatures for particular lengths of time. This identifies what is called the Critical Limit.
 - (iii) Then a plan would be needed to check or monitor that the necessary steps to control the hazard had in fact been taken.
 - (iv) Finally, a plan would also be needed for the action to be taken in the event that the necessary steps were not taken or did not work; that is, corrective action.
- 7.84 Two matters will be appreciated from this description of the basic analytical steps:
- (i) It is necessary for each food business to develop its own HACCP plan. Templates developed to assist in that process cannot simply be applied. That is because different butchers' businesses may well conduct different operations; and even where the operations are the same, may well apply different process steps.
 - (ii) There is no uniform way of setting out the HACCP plan. The basic analysis will need to be conducted. However, that having been done, it may be apparent that there is some or perhaps considerable overlap in terms of the hazards and controls applicable to various types of operation. The ultimate aim is to develop a tailored plan that is as simple and practical as possible as an effective working tool for controlling hazards in the particular business.

- 7.85 The discipline of proper record keeping is an essential part of the HACCP process. Record keeping would not merely assist the proper and systematic application of the HACCP plan. It would also enable checks to be made within the business, and by inspecting authorities, to ensure that that was being done.
- 7.86 Working in conjunction with HACCP and forming the foundation for it are “pre-requisite programmes”, which are universal, documented, hygiene practices that should be operational in any well-run food business[14]. Without such programmes, HACCP will not work effectively. Typical pre-requisite programmes include:
- (i) Personal hygiene and the health of employees.
 - (ii) Pest control.
 - (iii) Traceability and recall procedures.
 - (iv) Building design, construction and maintenance.
 - (v) Cleaning and sanitising.
 - (vi) Glass policy.
 - (vii) Training.
 - (viii) Waste management.
- 7.87 While there is some reference to these headline topics within Tudors’ HACCP documentation, and evidence of working forms under some of the subject headings, the evidence shows a lack of working programmes.

John Tudor & Son’s HACCP Plan 2005

- 7.88 The only HACCP plan the Inquiry has seen in relation to Tudors is the Plan dated January 2005. It is not possible to ascertain whether that version of the plan was the same as that developed after HACCP was introduced in 1997.
- 7.89 The evidence of the various EHOs who examined HACCP plans indicates that on some occasions at least, William Tudor told them that the plan had been reviewed. However, without the earlier versions of the HACCP plan it is not possible to ascertain how the HACCP plan developed or changed over time. What follows is accordingly a description of the 2005 HACCP plan. I have concluded that it is highly unlikely that any earlier version or versions of the HACCP plan were an improvement on the 2005 plan; or that omissions from that 2005 plan were present in earlier versions.

Company Background

- 7.90 The 2005 HACCP plan commenced with a section entitled “Company Background”. This was not an integral part of the HACCP analysis. However, it is of some interest because it contained a number of statements about Tudors that were, from the outset or at the least became, untrue. In some respects, the HACCP plan was inaccurate and misleading. As Mr Houston pointed out:
- (i) There was no evidence that Tudors was a member of the National Association of Catering Butchers (NACB), as was asserted in the Company Background section of the 2005 HACCP plan. William Tudor was not listed as a current member when Mr Colin Houston, Deputy Head of Enforcement at the Food Standards Agency checked the NACB’s web site when compiling his report for the police investigation.
 - (ii) There was no evidence that Tudors produced meat to the standards specified by the Meat and Livestock Commission (MLC) or followed the MLC’s guide in producing meat, as was also asserted in this section.
 - (iii) There was no evidence that Tudors had “a number of quality awards for excellent service and hygiene standards”.
- 7.91 No checks appear to have been made by any EHO on the accuracy of this section.

Flow Charts

- 7.92 The business operations of Tudors were analysed in three flow charts. There was one for raw meats, one for on-site cooking of hams, and another for on-site cooking of other meats (beef, pork and turkey). The difference between the latter two flow charts was solely that the flow chart for on-site cooking of hams included the step of “pumping and tumbling”.
- 7.93 Behind each of the flow charts was a further more detailed description of various parts of the process. Those descriptions went beyond simply identifying the steps involved and included a description of the nature of some of the hazards involved; for example, the times for which, and temperatures at which, meat was cooked, and to which it was then cooled.
- 7.94 The 2005 HACCP plan did not contain a flow chart for, and no HACCP analysis of, the hazards associated with the processing of ready-cooked meats bought in by Tudors.

Control Chart

- 7.95 This analysis then fed through into the control chart. The plan was in the form of a table. Down the left hand column were listed the steps undertaken. These were then analysed across the table under the headings
- Hazard – what could go wrong?
 - Control – what can be done to prevent or reduce the hazard?

- Critical Control Point - or good practice?
- Critical Limit – what is the standard?
- Monitoring procedure – what can be checked?
- Corrective action – what if things are not correct?
- Written records.

Problems with the 2005 HACCP Plan

- 7.96 The Inquiry concluded that it would be of assistance to instruct an expert to assist both in pulling together the relevant legislative provisions and Codes of Practice and other guidance relevant to inspections of businesses such as Tudors; and also to review and comment on the 2005 HACCP plan, the safety management systems and food safety policies and procedures operated by Bridgend, as they applied to their inspections of Tudors. To that end, Mr Brian Curtis was instructed to produce a report and invited to give oral evidence. He is a retired civil servant who has extensive experience of, and expertise in, HACCP and food safety issues in businesses. He has been a consultant to businesses and a trainer on matters relating to HACCP and food safety. He was an EHO before joining the Civil Service. I am grateful to Mr Curtis for the assistance he provided to the Inquiry.
- 7.97 He identified, as the first necessary stage, the validation of the HACCP plan. In other words, obtaining evidence that the elements of the HACCP plan are effective. This validation asked the question: will this plan result in the production of safe food; or, more simply, does it work as a plan? His description of the various stages of this validation process, from correctly identifying the processes undertaken by the business, has been dealt with above. He emphasised that in principle it might be possible to group similar activities together. However, if that was to be done considerable caution was needed to avoid, in doing so, missing a particular hazard or the need to address and control a similar hazard in a different way. He indicated that the nature and the rigour to be expected of a HACCP plan was influenced by considerations such as whether or not the food produced by the business was to be supplied to vulnerable groups. The aim was to produce an effective HACCP plan that was as simple and easy to follow in practice as possible.
- 7.98 There were a series of problems which prevented the HACCP plan being a validated plan; in other words a plan which, if implemented, would result in the production of safe food.
- 7.99 Firstly, it contained no analysis of the operation of processing ready-cooked meats. That was an operation conducted by Tudors since at least 1997. It required separate analysis of process steps, hazards, controls etc as part of the HACCP plan. The failure to include anything in that respect was an important failure and flaw in the 2005 HACCP plan.

- 7.100 Mr Ian Sullivan, a former EHO in Bridgend, recalled that the HACCP plan he assisted in the development of in 1997 had included such a section. In the absence of the relevant HACCP plan for 1997 it is not possible to conclude with any certainty whether that recollection is accurate or not. If not, the HACCP plan was seriously flawed in this respect from the outset. If so, the conclusion would be that it became flawed at some point between 1997 and January 2005.
- 7.101 On balance, I believe that Mr Sullivan's recollection is probably wrong. It would be surprising if the HACCP plan had been altered to remove an operation such as the processing of ready-cooked meats, which were part of the business. On balance, my conclusion is that the HACCP plan was flawed from the outset. I find it difficult to identify a reason why such a change would have been thought necessary or desirable.
- 7.102 Secondly, in relation to the "Cooking" step in the Plan, Mr Curtis noted that the Hazard, the Control and the Critical Control Point had been correctly identified. However,
- (i) The critical limit column simply referred the reader back to the flowchart. That rendered the plan unclear because it was not indicated with any clarity the part of the two pages to which reference was being made.
 - (ii) There should be no grey area or uncertainty about the steps that need to be taken to deal with the hazard and ensure the safety of food. That was not so in relation to the cooking step. There was a large oven capable of taking 120 joints of meat. It was not clear or specified how to be sure that all joints would be cooked to the requisite temperature identified in the flow chart (74 degrees internal temperature for two minutes). There could be hot or cool spots in the oven; joints would be of different sizes and so on. So something that provided clear indication to ensure that the meat was cooked for the right time to eliminate bacteria was needed.
 - (iii) Similar issues arose in relation to the monitoring procedure. This was described in the HACCP plan table as "temperature probe products". The flowchart, in a different part of the plan, stated "probe internal temperature of 74 degrees sustained for two minutes at the end of the cycle". However, if only a single piece of meat is taken that piece will not necessarily be representative of all the joints being cooked at that time. The question posed by Mr Curtis in this respect was: "Are we selecting the largest piece of meat in the coolest part of the oven?"
- 7.103 Thirdly, there were a series of flaws in relation to the step of "Chilling and Storage (cooked product)":
- (i) The chilling step was dealt with in the page behind the process steps. It recorded that hams were to be placed in the blast chiller and chilled immediately to an internal temperature of 8 degrees or below in approximately four to six hours. The time for cooling was unrealistic.

- (ii) The speed of cooling is critical, as the HACCP plan table identified. Yet the plan does not give one critical limit for the speed. Rather it gives a two-hour range; that is, between four and six hours.
- (iii) The "Monitoring procedure" in the HACCP plan table states simply "Visual inspection", which is understood to mean a temperature gauge. On this aspect the "corrective action" in the HACCP plan table states "Retrain staff". It is to be borne in mind that the corrective action stage arises when, in this case, the Critical Control Point has been breached, the controls have not worked and the identified hazard (in this case bacterium growth) is in play. Setting the corrective action as "Retrain staff" is patently inadequate, as is clear from the fact that lower down in the table under "Transportation", a similar hazard, is analysed, namely the growth of bacteria if food is kept at too high temperatures for too long during delivery. The corrective action is "Adjust chiller temperature, call engineer, reject food".
- (iv) The HACCP plan table merged together a number of the process steps that had been identified earlier. So, for example, in relation to the cooked hams table, there were ten process steps identified earlier, which were then further broken down in the following page containing the temperatures and so on. Yet in the HACCP plan table (Annex AAA, page 14, of the Plan) only three steps were listed: "cooking"; "chilling & storage (cooked product)"; and "transportation". That merger led to precisely the flaws identified above: a failure to correctly analyse the hazards and the requisite controls. In relation to cooked hams:
 - (a) There was inadequate analysis of the hazards and controls associated with the step of vac packing. That step should have been dealt with specifically. There are a number of risks identified with vac packing. Examples were identified including inadequate sealing resulting in organisms being allowed to grow in the inadequately sealed bag. There is also a particular risk associated with vac packing. A bacterium called *Clostridium botulinum* grows in the absence of air, and thus arises as a risk in vac packing. The standard control of this critical control point is by ensuring that the vac packed product is given, and labeled as having, a limited shelf life or use by date.
 - (b) There was inadequate analysis of the "Store in chiller" step that had been identified at the process step stage but was not specifically dealt with in the HACCP plan table. Inadequate control of the chiller temperature would lead to the growth of bacteria. The control mechanism would have been maintenance of appropriate temperature in the chiller room. The critical limit would have set the required temperature to be maintained. This did not feature in the HACCP plan table.
 - (c) There was nothing in the HACCP plan table dealing with the hazards associated with pumping and tumbling. No analysis whatever appears to have been carried out on this aspect.

- 7.104 Fourthly, there was no reference in the HACCP plan to shelf-life of products.
- 7.105 Professor Griffith's conclusion on the HACCP plan, with which I agree, was that:
- (i) The plan was very poor, inadequate for the type and size of operation and in relation to the need to manage cross-contamination for high-risk products.
 - (ii) The work flow chart in the plan lacked specific details of the type that would normally be expected.
 - (iii) Documentation was inadequate and incomplete and did not seem to form the basis of an "in use" system.
 - (iv) Examples of critical temperature limits that were exceeded but where no action was taken.
 - (v) There was some concern over the validity of some cooking records.
- 7.106 I have noted that Mr Houston was less critical than Professor Griffith of Tudors' HACCP plan but for the reasons set out above, I prefer the views of Mr Curtis and Professor Griffith. However, I agree with Mr Houston's assessment that despite being fully aware of his responsibilities as a food business operator, William Tudor did not put into practice safe methods for producing cooked meats nor did he control the Critical Points in his premises.
- 7.107 Bridgend County Borough Council accepts that particular elements of Tudors' initial HACCP plan could have been drafted better but points to the absence of risks associated with vacuum packing being an error on the part of Mr Sullivan, who no longer works for the Authority. Bridgend argues that were there to be a fundamental review of the plan again, this would be spotted. This seems to me to be an unfortunate, after-the-event, attempt on Bridgend's part to lay the blame for the failure on an ex-employee who no longer works for the Authority. The HACCP plan was, or should have been, subject to assessment on a number of inspections that took place between the time it was developed and the 2005 version seen by the Inquiry. If the omission was there from the start, it wasn't picked up on any of the inspections.
- 7.108 Mr Curtis identified verification as the second essential stage in ensuring that safe food was produced. This involved ensuring and checking that the HACCP plan was in fact implemented correctly in practice. His evidence on this aspect focused on how EHOs inspecting premises such as Tudors should go about doing that. This aspect is dealt with below after a description of the inspections in fact carried out by Bridgend of Tudors.

Inspections of John Tudor & Son

7.109 The various inspections carried out in the ten year period leading up the Outbreak in September 2005 and the identity of those carrying out the inspections are set out in the following Table. The risk rating and/or risk category is also included where available.

Table: 7.3: Inspections Chronology and Risk Rating Schedule, 1995-2005

Date of Inspection	Risk Score & Risk Rating	Inspecting Officer(s)
1 July 1995	50	Mr P Cole
23 September 1996	70 Risk noted as "Medium 04"	Mrs B. Price
11 August 1997	75	Miss J Reed
26 February 1998*	140 Risk Category 'A'	Miss J Reed
27 August 1998	125 Risk Category 'A'	Miss J Reed Mr P Cole
4 March 1999	95 Risk Category 'A'	Mr I Sullivan
6 September 1999	100 Risk Category 'A'	Mr I Sullivan
8 March 2000	100 Risk Category 'A'	Mr I Sullivan
9 October 2000	No Food Hygiene Risk Assessment Score Sheet on file.	Mr I Sullivan
23 April 2001	75 Risk Category 'B'	Mrs J Evans
17 July 2001	100 Risk Category 'A'	Mr J Davies
5 February 2002	120 Risk Category 'A'	Mr J Davies
29 July 2002	65 Risk Category 'C'	Mr G Gubb
31 January 2003	Food Hygiene Risk Assessment Sheet on file is blank	Mr G Gubb
17 July 2003	85 Risk Category 'B'	Miss A Lewis
Winter 2003/2004	No inspection	
28 July 2004	85 Risk Category 'B'	Miss A Lewis
18 January 2005	Risk Category 'A'	Mrs A Coles
19 July 2005	Risk Category 'B' (but revised to 'A'**)	Mrs A Coles

Source: Bridgend County Borough Council Inspection Records

Note: * New assessment category introduced "Significance of Risk"

** The original Category was recorded incorrectly due to an input error

1997-1998 and the Formulation of Tudors' Initial HACCP Plan

- 7.110 Mr Ian Sullivan was employed as an EHO in the Bridgend Food Safety Team from September 1996, shortly after qualifying as an EHO, until 2002.
- 7.111 In 1997, he was chosen to be the HACCP trainer/consultant in the Team. At that time, he had had a year's practical experience of inspections of butchers and other premises, although he had not inspected the larger scale factory type butchers such as Tudors. He had also had a two day HACCP training course at the Campden and Chorleywood Food Research Association. He was involved in the South East Wales Task Group. That group, working with Campden and Chorleywood Food Research Association, was responsible for the development of a "butcher's pack" designed to assist butchers such as Tudors to develop appropriate and effective HACCP plans for their businesses. The pack was in the form of a file. It contained explanations about what HACCP was and how it worked. It also contained templates of the various plans and flowcharts that would need to be developed and tailored to the particular processes in operation at individual butchers.
- 7.112 Bridgend's Food Safety Team also produced a guidance document entitled "A Practical Guide to HACCP in Butchery Retailing". It was provided to the Inquiry during the course of Miss Amy Lewis's oral evidence. The Guide was produced to assist butchers in the area to comply with food safety legislation. The Bridgend Guide contained explanations about HACCP and templates of various plans, flow charts and record forms. Miss Lewis told the Inquiry that it was compiled by Mr Sullivan and that businesses were provided with a copy. It was used as a working tool by the Department when dealing with HACCP. Miss Lewis herself had made reference to it.
- 7.113 In 1997, Mr Sullivan set up a number of public introductory sessions for butchers to explain to them what HACCP was and how it worked. He then went individually to butchers in the area in order to assist them to develop appropriate HACCP plans for their businesses. As part of that process, he visited Tudors on a number of occasions for a few hours at a time, left the butchers' pack with William Tudor and then finally worked through each of the operations undertaken by Tudors and helped William Tudor to design a HACCP plan. His impression was that William Tudor was co-operative, rather than obstructive, but less willing than some to embrace the cultural change that the introduction of HACCP represented.
- 7.114 It appeared from his oral evidence that his assistance in the design of the HACCP plan was purely advisory. He did not see it as part of his role at this initial stage to assess the validity of the HACCP plan that William Tudor then prepared. He would have advised William Tudor on what needed to be done and then left him, as the expert in terms of how his business operated, to prepare the plan. Accordingly, he did not sign off the HACCP plan. Nor did he review or validate the plan at that stage.

7.115 However, Mr Sullivan stated that he would have looked at the HACCP documentation when he did his inspections of Tudors later. It appears to me, however, that the limit of the review at this stage would have been to ascertain whether the plan was being used and what was in the plan was being implemented in practice. There was no validation of the HACCP plan but simply verification; that is, seeing if the plan was being followed, on the assumption that the plan was valid.

1997 and 1998 Inspections

7.116 In 1997 and 1998, the inspections of Tudors were conducted by Ms Joanne Reed, who later became Mrs Joanne Evans. Her first inspection was on 11 August 1997. Only the risk rating sheet remains on file in relation to that inspection. She did a two-day HACCP training course on 17-18 December 1997.

7.117 She inspected again on 26 February 1998. This and her other inspections were unannounced. She agreed with Mr Sullivan's views on the benefit of unannounced inspections. In her view, announced or warned visits were only useful when it was necessary to see a particular individual.

7.118 The Inspection Sheet she completed during the inspection recorded in relation to HACCP; "needs revising – lots of things in there that they don't do". Her follow-up letter dated 6 March 1998 noted that many of the control and monitoring procedures set out in the HACCP plan as it existed at that date were not being carried out by Tudors; for example automatic temperature recording print outs. The letter reminded William Tudor that "any information specified in this document must be not only applicable to your business but an accurate account of the system run by you to ensure the safety of your products". In her oral evidence, she stated that her recollection was that on this visit Tudors only had a "standard document" for HACCP not tailored to the business, and agreed that the HACCP problems identified were fairly fundamental.

7.119 The Inspection Sheet also records the following:

(i) Against "Numbers trained", Mrs Evans wrote "7" and then "Need to see certification on re-visit". She explained that she had done so in order to be sure that those working in a food business were actually properly trained, and without seeing the certification she could not be happy about that;

(ii) The risk rating was 140, resulting in an "A" rating and six-monthly inspections.

7.120 There appear from the follow-up letter dated 6 March 1998 to have been a series of hygiene problems identified during the inspection. These were listed in an extensive schedule to the letter, which constituted a "Minded To" Notice. This was the step before the service of an Improvement Notice and set out the legislative provision breached and the steps required to rectify the problem. The problems included failures in cleaning and sterilisation of equipment, storing product on the floor, dirty surfaces. Improvement Notices were then served.

- 7.121 It took the next few months, into July 1998, and a number of re-visits for the problems to be satisfactorily addressed, but there is no evidence that the training certification point was followed through.
- 7.122 Her next inspection was on 27 August 1998. It was again unannounced. Her risk rating was 125, still Category "A". The follow-up letter of 8 September 1998 identified some further, relatively minor, structural problems. In addition, the problems with the walk-in freezer were recorded for the first time. It appears from later reports that this was a recurrent problem. Mrs Evans noted that the walk-in freezer was in a poorly organised condition; that meat was stored uncovered and on the floor; that there was restricted access to the back of the freezer which restricted both stock rotation and cleaning. The freezer needed to be completely reorganised. This item in the 8 September 1998 letter is not ticked but ringed, signifying that it had not been sorted out by the time of the revisit on 13 October 1998.
- 7.123 In relation to HACCP, Mrs Evans noted in manuscript: "in the process of being formulated with Ian Sullivan". This note and the previous one indicate that William Tudor had done nothing to formulate his own tailored HACCP plan since his meetings with Mr Sullivan. Either he had not understood the need to tailor the plan to his business or he had decided that he would not bother to do so. Given Mr Sullivan's recollection of meetings and explanations in 1997, the latter seems the more probable.

1999-2000 Inspections

- 7.124 Mr Sullivan's first inspection was on 4 March 1999. Mr Sullivan emphasised in his statements to the Inquiry that both his primary inspections and his revisits were unannounced in the sense that the operator would not be given forewarning of the date or time of his inspection. In his oral evidence he set out what he perceived to be the advantages of unannounced inspections. The main benefit was that the operator would not be expecting the inspector's arrival with the result that the inspector was more likely to see the premises as they in fact operated on a daily basis. He did however see value in announced inspections in certain circumstances.
- 7.125 He recorded his findings on the inspection of 4 March 1999 on an Inspection Sheet.
- (i) In the "HACCP" box he wrote: "fully documented system". He explained that that meant that he was satisfied that a HACCP system was in place and that it was being followed. He did not validate the system.
 - (ii) He completed a food safety risk assessment. Tudors was rated "A", even though the score should, as Mr Sullivan accepted, have been even higher but for his error in not giving any score under "Significance of Risk", which was a category designed to assess the results if the risks in fact occurred. In the event, the error made no difference as "A" was the highest risk rating. This was an assessment done in accordance with the then Code of Practice which led to a score and a risk rating. That in turn determined the frequency of inspection. An "A" rated premises would be subject to inspection on a six-monthly basis.
 - (iii) He noted that in the freezer there was "very haphazard storage of stock".

- 7.126 Following the visit, and in accordance with usual practice, Mr Sullivan sent a letter to William Tudor dated 16 March 1999. This listed the problems found on the inspection that needed to be rectified. The letter was then used as the checklist for the revisit, which occurred on 20 April 1999, items dealt with being ticked during that revisit. The letter picked up the state of the freezer stating that it was in an extremely disorganised state; that meat was being stored uncovered and in some instances directly on the floor; and that there was no real stock rotation system. The letter required the freezer to be “completely reorganised”.
- 7.127 Following the revisit, a further letter dated 21 April 1999 was written. The freezer had not been dealt with. That was eventually done to Mr Sullivan’s satisfaction by 11 May 1999 when a further visit to deal with the remaining items occurred.
- 7.128 The next six-monthly inspection was carried out by Mr Sullivan on 6 September 1999. The Inspection Sheet again recorded that there was “very haphazard storage” in the walk-in freezer. This was described as a “reoccurring problem”. The point was picked up in the follow-up letter dated 15 September 1999. This, in effect, repeated what had been said in April 1999 noting the highly disorganised state. In addition, it noted two further problems with the walk-in freezer: a build up of dirty ice on the floor; and the fact that raw boxed goods were being stored adjacent to cooked produce. The letter advised in relation to the latter that “staff must be re-educated as to the importance of segregation of raw and cooked produce”.
- 7.129 There was a revisit on 25 October 1999 to pick up outstanding items. The ticks on the letter of 15 September 1999 suggest that, aside from the implementation of a freezer storage plan, the freezer issues had been dealt with.
- 7.130 The next six-monthly inspection occurred in 8 March 2000. It was undertaken by Mr Sullivan. The Inspection Sheet records that there had been a large improvement in the condition of the walk-in freezer and that generally the conditions were “good”. There was no need for a revisit.
- 7.131 On the file provided to the Inquiry, there was also a memo dated 28 September 2000. It records a complaint about Tudors from Mr David Dier of Merthyr Tydfil’s Environmental Health Department. Mr Dier had looked at a vehicle used by Tudors to deliver meat to a nursing home. He had done so because the nursing home had rejected meat because it had started to defrost. His examination of the vehicle revealed that the vehicle was not refrigerated, that frozen meat, fresh meat and cooked meat were stored on the floor of the vehicle and that meats were not in containers. This was plainly a matter of some concern given the unsatisfactory nature of the vehicle, the very poor hygiene practices and the obvious risk of cross-contamination. The complaint was investigated by a Miss White visiting Tudors and discussing matters with William Tudor. He showed her what the note records as being the vehicle in question, which was refrigerated. William Tudor informed her that he was changing the vehicle for one that had separation between raw and cooked meats. Miss White informed Mr Dier of the outcome of her investigation.

- 7.132 Shortly after this, on 9 October 2000, Mr Sullivan conducted the next six-monthly inspection. The Food Hygiene Risk Rating Sheet for this inspection is not on file, only a Health & Safety Risk Calculation Sheet. As the letter of 11 October 2000 sent after this inspection records indicates, the walk-in freezer had reverted to its previous state; that is highly disorganised, with dirty ice on the floor, meat being stored “uncovered and in some instances, directly upon the floor”. There was still no freezer storage plan. This problem was followed up at the revisit on 20 November 2000. There had been little improvement. Indeed, improvement only appears to have been achieved by 9 January 2001; but even then there was no freezer storage plan.
- 7.133 Mr Sullivan did not escalate the enforcement in relation to the walk-in freezer despite the recurring problems. No Improvement Notice was served, only warning letters. He stated that he did not do so because there was no way of knowing with any certainty that it would have precluded a subsequent problem of the same kind.

2001-2004 Inspections

- 7.134 Mrs Evans returned to Tudors for the next inspection on 23 April 2001. Her risk rating was 75. That resulted in a change in risk rating category from “A” to “B”. The consequence was that the next inspection would be 12 months rather than six months afterwards. The Inspection Sheet records that the change was approved by the then Principal EHO, Mr Stuckey. In fact, she had left the “Method of Processing” box blank rather than scoring it 20 as she should have done, and probably should have included a score in the “Vulnerable groups” that Tudors supplied. As she accepted in her evidence, these errors, made by her and not picked up by Mr Stuckey would, if corrected, have had the effect of leaving Tudors in the risk rating category “A”. In the event, the errors made no difference because the next inspection was in any event made in July 2001.
- 7.135 Mrs Evans completed a form entitled “Hazard Analysis Review”. This document indicated that Tudors had a “documented HACCP” held on site; that the date of its compilation was 8 January 2000, that it had been developed by William Tudor, and that it had not been reviewed. It noted that a variety of the HACCP records were in place on site. In relation to training records, it was stated that they existed “but need a copy of all hygiene certificates”. In relation to “Hazard Analysis”, it was stated that one existed “but needs extra steps added”. The form then went on to list the critical points identified by the proprietor as applicable to the business and to invite the inspector to list “additional critical points identified in this visit”. This is of some importance given that the structure of this part of the form specifically directed the inspector’s mind to the adequacy of the HACCP analysis in relation to the particular business being inspected. The critical points identified by William Tudor were noted as:
1. Purchase & receipt
 2. Storage
 3. Chilling
 4. Cooking
 5. Transportation

- 7.136 The additional critical points identified were noted as:
1. Purchase and delivery of cooked meats
 2. Further preparation and packaging of their own cooked meats
 3. Defrosting
- 7.137 Mrs Evans then noted under “Areas where improvements to the HACCP are needed”:
“Analyse hazards and carry out assessment for the CCPs and stages I’ve identified were missing”. The programme of action noted that this work was to be carried out in six weeks and “whole document to be reviewed”.
- 7.138 This document throws further doubt on Mr Sullivan’s recollection of the state of the HACCP plan he saw. His recollection was that it included a section analysing the hazards associated with the processing of meat already cooked when it arrived at Tudors. If that is so, any such analysis must have disappeared between the date he saw the plan and this date in April 2001. It is also of significance because it appears to identify as a missing step in the analysis, packaging, which will have included vac packing.
- 7.139 In relation to training, it is unclear whether training certificates were in fact seen by Mrs Evans on this visit. However, she recommended in her follow-up letter dated 30 April 2001, that a record and copy of all food hygiene certificates should be kept with Tudors’ HACCP plan.
- 7.140 As a result of this visit, Mrs Evans also made a note of considerable importance. She wrote under “Other Officer Comments”:
- “Records were being kept, systemic analysis but couldn’t help wondering whether some records were fixed as same style writing and colour pen on many of the records.”
- 7.141 This note was made, as she described it, as “food for thought...upon any future inspections”. It is a matter of real concern that an inspector should suspect that records might be being fabricated yet the information is not logged for future inspections. Steps should have been taken to ensure that it was not forgotten. It was a suspicion that would turn out to be well founded. As part of its investigation of Tudors, South Wales Police commissioned forensic analysis of the HACCP temperature records, probe/thermometer logs, and cleaning schedules and cleaning standards recording forms. As explained in the previous Chapter, there is conclusive evidence that records were not completed on a daily/weekly basis but in batches of entries made at one time.
- 7.142 Mr Jamie Davies inspected Tudors on 17 July 2001. He had qualified in 2000. He had done some agency work for Gloucester City Council and Rhondda Cynon Taf. He had joined Bridgend in June 2001, a month before this inspection. He undertook the two-day HACCP training course after this inspection in November 2001. However, he believed that HACCP had been dealt with as part of a course he had taken whilst doing agency work, and he had been to a butcher’s inspection before July 2001, accompanied by Mr Gubb.

- 7.143 Mr Davies stated that he would have gone back to the last inspection in preparation for his inspection, and possibly further. However, despite having a positive recollection of having done so on this occasion, he had no recollection of any particular concerns arising from the last inspection, specifically Mrs Evans' recorded suspicions that William Tudor might have been falsifying his HACCP records.
- 7.144 This was the first inspection for the purpose of assessing whether or not Tudors should be given a Butcher's Shop Licence under the 2000 Regulations that had been introduced following my report into the *E.coli* O157 outbreak in Scotland in 1996. As a result, the forms completed as part of the inspection process included a Butchers' Shop Licensing Assessment Form.
- 7.145 The inspection was unannounced, although William Tudor will have known that an inspection was likely within about a month of his application for a licence. The inspection gave Tudors a risk rating of 100, which was Category "A". The Food Safety Risk Score Sheet incorrectly recorded that the previous risk rating had also been "A". In fact, as appears above, it had been a "B".
- 7.146 Mr Davies described his practice in reviewing the HACCP plan. He stated that he would have looked at the plan, discussed it with the proprietor and seen if what he was saying about his operations married up with the plan. He had no written guidance as to the process of checking the HACCP plan. He did have the Butchers' Licensing Assessment Form which directed the inspector to various aspects of HACCP. He stated that he would have sought to check if the HACCP plan was in fact being followed. However, he would not have taken the plan around with him on his physical inspection; he did not take any particular aspect or aspects of the plan and work through the practical application of that aspect, the process being a more general or "overview" one.
- 7.147 The Butchers' Licensing Assessment Form included a box for recording whether the underlying HACCP records were available and properly maintained. Mr Davies' only record in this box related to temperature records ("cooking, cooling, cold storage"). No other record was even referred to. He could not recall if he looked at other records. He speculated that he might have done and then not recorded them in the box specifically designed for the purpose of enabling him to do so.
- 7.148 This form also dealt with training of staff. Mr Davies listed the fact that "9 out of 10 members of staff have Basic [food hygiene training]". He stated that he would have asked for certificates to support this; and that he would have expected the certificates to be kept on file. He had no recollection of Mrs Evans' note on the previous inspection that certificates should be kept on file. I consider that this part of the inspection was unsatisfactory:

- (i) The evidence before the Inquiry indicates that some employees did not in fact have such training. That is confirmed by the training records that were kept by Tudors and by employees' statements. These indicate that for some, even basic food hygiene training was not undertaken until February 2005. In the circumstances, I do not think Mr Davies did, in fact see certificates. If he did see the certificates, he did not check them against employees. He appears to have asked about training and then simply recorded the answer given to him by William Tudor without checking it.
- (ii) The relevant box on the Butchers' Licensing Assessment Form contained a number of segments: name, designation, training level, awarding body, record kept. Each segment should have been filled in. Instead, Mr Davies had simply written across each of the segments without filling in each one, and without recording the details that should have been recorded.

7.149 The follow-up letter was dated 17 July 2001. It raised a minor repair/maintenance problem, and a problem with uncovered bins. More significantly, Mr Davies concluded that William Tudor needed to be trained at least to intermediate level in food hygiene before being granted a Butcher's Licence. To avoid putting Tudors out of business, Bridgend arranged a specific test to bring the food hygiene training of William Tudor, and a number of other butchers in a similar situation, up to speed at the end of July 2001. The test was designed by Mr Sullivan and Mr Gubb. The pass mark was 50%.

7.150 The next inspection was also conducted by Mr Davies. It took place on 5 February 2002. It was solely a food hygiene, rather than a Licensing, inspection. A Food Premises Inspection Report was completed. The risk rating was again "A", based on a score of 120.

7.151 In relation to training, the Food Premises Inspection Report stated that there were approximately four to five staff and that they were trained to Basic Level in food hygiene. Mr Davies could not recall whether he asked to see certificates on this visit. I do not think he did.

7.152 On this occasion, and to his credit, he noted specifically that another member of staff needed to be trained to intermediate level "due to [William] Tudor's absence from the site on a regular basis". The follow-up letter noted that this was the second occasion on which Mr Davies had visited when William Tudor had been absent. This February 2002 inspection was unannounced and unexpected by William Tudor because the decision had recently been taken, after the introduction of the new Butchers' Licensing regime, that butchers would in any event be inspected every six months. No record of the additional training needed is made in a separate file note as a means of alerting another officer. Mr Davies' only action in relation to this problem was to state in the 11 February 2002 follow-up letter that the matter would be reviewed on the Licensing application in six months time. It appears that this did not occur because the next visit to Tudors was not allocated to Mr Davies. As the Food Premises Inspection Report of January 2005 indicates, even by that date almost three years later, there was no-one with the requisite level of training to manage in the absence from site of William Tudor.

- 7.153 Mr Davies said that he only stated this in the follow-up letter because he was satisfied that everything else with the premises was “okay”. However, there were other problems noted in the Food Premises Inspection Report and the follow-up letter. For example, the Food Premises Inspection Report also circled the answer “Yes” next to the box entitled “fitness of food at the premises, use-by dates, stock rotation, wrapping”. However, the comments column stated: “But difficult to tell due to over stocking of freezer”. It therefore appears that the problems with the freezer had recurred. That is confirmed by the follow-up letter dated 11 February 2002 which noted, in summary, precisely the same problems as had been previously been noted: dirty ice on the floor, stock being stored uncovered, stock being in a very disorganised state.
- 7.154 In addition to the Food Premises Inspection Report, another form entitled “Hazard Analysis: Review of Progress Form” was completed. This contained a sheet for checking that the necessary HACCP documentation was in place. Affirmative answers were given to most of the identified categories of documentation. However, the box next to “Cleaning Schedule” had not been filled out with either an affirmative or negative answer. Mr Davies stated that he may have just failed to fill out this part of the form. He gave the same explanation in relation to other boxes not filled out on this sheet relating to sketch plan and product recall.
- 7.155 Between the date of the inspection and the date of the follow-up letter, Mr David Dier, Principal EHO in Merthyr Tydfil, sent a letter to Mr Davies. He copied the letter to Mrs Sue Glendinning of the Procurement Department in Rhondda Cynon Taf. This features in Chapter 10, which examines the procurement of school meals. The letter raised a series of concerns about use-by dates and the traceability of the food supplied by Tudors. Significantly, Mr Dier expressed clear concern about William Tudor’s approach to enforcement officers saying “The fact that this supplier appears to be willing to tell untruths to enforcement officers..... gives me great concern”. Mr Davies did not make any connection between these concerns and the note recording Mrs Evans’ suspicions. Nor did alarm bells ring when this letter was put alongside the concerns that Mr Davies had about what William Tudor had said about always being in attendance on site.
- 7.156 Mr Graham Gubb was the Senior EHO at Bridgend until June 2003. He was also the Food Safety Officer whose responsibilities included ensuring that the relevant up to date guidance and Codes were available to the Food Safety Team. He was also responsible for ensuring, along with Mr Stuckey, the Principal EHO, that the necessary written guidance and enforcement procedures were in place. It became apparent following his departure from the Authority that much of that guidance and those procedures were inadequate, which meant that the new team of Ms Donagh and Mr Cole had to undertake an extensive drafting exercise in advance of the audit.
- 7.157 Mr Gubb prepared his statement to the Inquiry from memory and had not asked to refresh, or in fact refreshed, his memory from the contemporaneous documents in advance of doing so.

- 7.158 He inspected Tudors for the first time on 29 July 2002. His recollection, although it is not recorded anywhere, is that this would have been an announced inspection on the basis that he would have regarded it as important for William Tudor to be available. He stated that it was his policy on every Butcher's Licensing inspection to require the proprietor to be there and thus to have an announced inspection. This policy was in direct contradiction to the Code of Practice which recommended unannounced inspections. His inspection was a combined food safety and Butchers' Licensing inspection.
- 7.159 Mr Gubb would familiarise himself only with the inspection prior to the one he was completing. In consequence, he would not have seen Mrs Evans' suspicions about the Tudors' records. He had no recollection of Mr Dier's letter of 7 February 2002.
- 7.160 Prior to his inspection, he would have seen the application by Tudors for a Butcher's Licence. This stated that there were eight people working at the premises; that all eight of them had Basic Food Hygiene Certificate level training and that six of them had specific HACCP training. However, the Food Premises Inspection Report he completed stated that the number of staff was five. He recorded that all had basic training and William Tudor had intermediate training. The information that all had basic training is also recorded on the Butchers' Licensing Assessment Form. Mr Gubb failed to fill in the boxes marked "Awarding Body" and "Record Kept". He positively asserted that he would not have asked for the certificates. He accepted that that would be directly contrary to the guidance given in the form. There is no indication that he picked up the clear and significant discrepancy between the assertions made by William Tudor, untruthfully it would appear, in the licence application form and the facts as relayed to him on the inspection. He accepted that had he done so, he would have viewed the discrepancy as being both surprising and concerning.
- 7.161 In the Food Premises Inspection Report he noted that "lots of foods [were] not date coded". This appears from the follow-up letter dated 31 July 2002 to have been a problem with identifying on vac packed meat its shelf-life. His recollection is that William Tudor was unable to give him any explanation as to why the meats were there without any coding on them. He accepted that this was potentially a serious problem given the risks of *Clostridium botulinum* and the need to manage those risks by imposing a ten day shelf-life on vac packed meat.
- 7.162 He also filled out a form entitled "Hazard Analysis: Review of Progress" form.
- (i) The form recorded that a hazard analysis had been prepared in 2000; that the proprietor was unaware of his responsibility to review, and that there had been no review. The fact that William Tudor did not appreciate the need to review the HACCP plan was accepted by Mr Gubb as being of some concern, particularly given the assistance that William Tudor had been given about HACCP by Mr Sullivan.

- (ii) Mr Gubb ticked the box marked "Analysis and full controls" which he stated indicated that he had reviewed the HACCP plan. He then noted that the Critical Control Points applicable to the business that had been identified by William Tudor were: temperature control, condition of incoming goods, and cooking time/temperature. The heading marked "Additional critical points identified in this visit" was blank, indicating that none had been identified by Mr Gubb. It is not possible to know what was in the HACCP plan reviewed by Mr Gubb. However, it is possible for me to conclude that, based on the nature of the Tudors' business, the description of the Critical Control Points given in this form were plainly inadequate to deal with that business.
- (iii) The form went on to identify under "Areas where improvements in HACCP are needed" that control limits needed to be cross referenced to HACCP charts. Mr Gubb was unable to recollect what the problem there referred to had involved.

- 7.163 The Butchers' Licensing Assessment Form was filled out by Mr Gubb. He gave affirmative answers to all the relevant questions designed to probe the adequacy of the HACCP plan and its implementation. He stated that the last review of the HACCP plan had been in 2002, which was in contrast to the 2000 date given in other forms. The only records identified as required by HACCP, available and properly maintained were described as "Temperature control" and "Cooking time". Again, these were plainly not the only records required by HACCP as is indicated by later forms filled out by inspectors and indeed from the structure of the Hazard Analysis: Review of Progress Form which had a sheet listing further categories of record. Mr Gubb failed to have the Butchers' Licensing Assessment Form approved by his Principal EHO Mr Stuckey, as the form itself indicated was required. He was unable to explain why that had not happened.
- 7.164 Despite these matters, Mr Gubb's risk rating assessment gave Tudors a score of 65, Category "C". This contrasted sharply with the previous rating of 120, Category "A". It is not clear whether or not Mr Gubb was aware of that rating given that he failed to fill in the boxes in the Food Premises Inspection Report for the old and new risk ratings. His rating was heavily influenced by his conclusion that he could have moderate confidence in management. It is difficult to reconcile this conclusion with the results of his inspection.
- 7.165 A follow-up letter was sent to William Tudor on 31 July 2002 listing some of the problems identified in the forms, including the need to review HACCP at least annually. The outstanding items were addressed to Mr Gubb's satisfaction by the end of November as appears from a letter dated 28 November 2002, which recorded that fact following an inspection the day before.
- 7.166 Mr Gubb inspected again on 31 January 2003. The Inquiry was not provided with a copy of a Food Premises Inspection Report for this inspection. By implication therefore, it appears that Mr Gubb did not complete one and instead used the Food Hygiene Progress Sheet as an inadequate substitute on which he simply wrote that he had conducted an intermediate visit.

- 7.167 Mr Gubb's inspections fall some considerable way short of the standards to be expected of a Senior Environmental Health Officer to whom more junior officers would have looked for advice and experience. The completion of the inspection forms, which were designed to assist inspectors to focus on the relevant issues was inconsistent and slapdash; and sometimes not even filled in at all. Clear and important inconsistencies between different pieces of information provided by William Tudor were not identified. The indication from the forms that were completed, in relation to Critical Control Points for example, is that the underlying inspection and analysis, notably of HACCP, was inadequate.
- 7.168 Miss Amy Lewis inspected Tudors for the first time on 17 July 2003. She was at that time an EHO having graduated in 2000 and joined Bridgend as an EHO in June 2001. She had not had specific HACCP related training but had come across HACCP in her work and HACCP had featured as a part of another course she had undertaken in November 2001. In September 2005, she was made Senior EHO at Bridgend.
- 7.169 The inspection was unannounced. She also agreed with the views of Mr Sullivan and Mrs Evans about the benefits of an unannounced inspection.
- 7.170 Her risk assessment gave Tudors a score of 85 resulting in it being in risk category "B". That was an increase to the previous risk assessment carried out by Mr Gubb, which had placed Tudors in the "C" category. The result under the system, and in this instance in fact, was that the next inspection of Tudors took place 12 months later. I find this surprising for a butchery business such as Tudors.
- 7.171 The inspection was both an inspection for the purpose of the food safety regulations and also in order to determine the Butcher's Shop Licence application by Tudors. In relation to the former, she completed the "Food Premises Inspection Report". In relation to the latter, she completed the "Butchers' Shop Licensing Assessment Form". This form concentrated on HACCP and, as she accepted, required the inspecting officer to make a judgement about the efficacy and effectiveness of the HACCP plan in place. She stated that she would have looked at HACCP in detail. She described her process as commencing by looking at the HACCP plan and records. She then discussed the plan with William Tudor; and would have asked him to describe the processes. Then when she was doing the physical inspection she would recall what she had read in the HACCP plan.
- 7.172 In the Butchers' Licensing Assessment, Miss Lewis noted that the full HACCP plan was held on site and that the plan had last been reviewed in January 2003. It is not known whether this plan was the same as the 2005 HACCP plan. Under the title "HACCP audit" she answered "yes" to a series of questions focusing on whether or not food hazards had been correctly identified, whether effective controls had been implemented for critical steps, whether critical limits had been established, critical controls monitored, corrective procedures documented and corrective actions recorded. Her overall conclusion was that the HACCP requirements were met and that a Licence should be granted.

- 7.173 Miss Lewis listed on the form the various records required by HACCP indicating that they were available and with the exception of cleaning schedules properly maintained.
- (i) She said that she would have reviewed the file before making the inspection. This would have involved a review of "a few inspections". However, she had no recollection of Mrs Evans' note raising the suspicion that William Tudor had been falsifying records.
 - (ii) She was unable to recall what documentation she had seen in relation to cleaning, and assumed that her failure to tick the box "Properly maintained" had been an error. Miss Lewis was asked about the documents relating to guidance on cleaning that appear to have been in existence at Tudors. They comprised two pages of brief description which did not even cover all the physical areas to be cleaned. She did not agree with Professor Griffiths who, having reviewed the cleaning records, considered that they were a "joke".
 - (iii) Miss Lewis stated that she would also have reviewed the temperature records.
- 7.174 The Butcher's Shop Licence Assessment form also asked about staff training. The form invited responses for each employee as to "Training Level", "Awarding Body" and "Record Kept". William Tudor was described as having Advanced Level training and the "Record Kept" box was ticked. The "Awarding Body" box was not completed. Then Miss Lewis had written "all other staff members have BFH [Basic Food Hygiene] certificates". She stated in her evidence that it would have been general practice to request copies of certificates but that she could not recollect if she had done so. The Inquiry has seen a set of training records kept by Tudors. These are in the form of schedules, completed in manuscript recording by date "Course attended/on job training". It appears from these records that some employees did not have even basic food hygiene training until February 2005. That was confirmed, at least in the case of Mr James Brown, by his statements to the police. This suggests that Miss Lewis did not check any certificates and that her record that "all other staff members have BFH [Basic Food Hygiene] certificates" was based simply on what she was told by William Tudor. What he told her was untrue. Checks of the kind she described as general practice, but which evidently were not done, would have revealed the truth.
- 7.175 The concerns raised in the Inspection Report were picked up in the follow-up letter dated 24 July 2003. There were only three. One of them was again that state of the freezer room which was described as "not maintained in a clean condition".
- 7.176 Twelve months later, on 28 July 2004, Miss Lewis inspected again. This inspection was again for the dual purpose of the food safety regulations and in order to determine the Butcher's Licence application by Tudors. Two of the forms filled out by Miss Lewis were the Food Premises Inspections Report and the Butcher's Licensing Assessment Form.
- 7.177 The former scored Tudors at the same risk rating "B", which again I find surprising. However, on another form, the Food Hygiene Visit Progress Sheet, an inspection in six months was recommended by Miss Lewis.

- 7.178 In relation to staff training, the Inspection Form stated that there were nine staff and all had basic level training. Miss Lewis stated that she would have asked for certificates. However, the records maintained by Tudors indicate that some food handlers had not received certified training to that level at this date. Again, those records appear to be confirmed by statements made by employees to police. In the circumstances, I believe that that Miss Lewis' recollection that she would have asked for certificates is in error. The comments on the Inspection Form were simply based on what she had been told by William Tudor and were not checked.
- 7.179 The Butcher's Licensing Assessment Form was in the same form as on the previous inspection in July 2003. The HACCP plan is stated to have been reviewed. The questions asked on the form are all given an affirmative answer indicating no problems with the plan in the opinion of Miss Lewis. It was stated that the HACCP plan was last reviewed in January 2003 and that it required review.
- 7.180 The boxes relating to the existence and maintenance of the underlying HACCP records are also all ticked to indicate that in the opinion of Miss Lewis they were properly maintained. Miss Lewis stated that she would have been satisfied that those records complied with the HACCP plan. The temperature records, ticked by Miss Lewis as available and "Properly maintained" on the Butcher's Licensing Form, were examined in her evidence. She was asked about the records for March 2004, four months before her inspection date. The HACCP plan seen by the Inquiry stated that "when cooked the product is placed in the blast chiller and chilled immediately to an internal temperature of 8 degrees Celsius or below in approximately four to six hours". The temperature record however:
- (i) Contained no reference to the 4-6 hour cooling period, and no box for checking that this period had been complied with;
 - (ii) Contained instead two columns for recording the temperature after 2 and 10 hours;
 - (iii) Stated in the manuscript record of temperatures that even after 10 hours, the temperature varied between 8 and 10 degrees Celsius; only 6 of the recorded items out of 16 on this form were at 8 degrees, the remainder being 9 and 10 degrees after 10 hours.
- 7.181 It is open to serious question whether any checks were made beyond simply identifying that temperature records existed and were being filled in. My conclusion is that the temperature records at least, and probably the other HACCP records too, were not checked by Miss Lewis against the HACCP plan itself.
- 7.182 The follow-up letter was dated 30 July 2004. That raised a couple of minor repair items and stated that the HACCP documentation needed to be reviewed at least annually with any changes to operations being noted. The licence was granted for another year on 3 August 2004.

Inspections in 2005

- 7.183 Routine inspections occurred on 18 January 2005 and 19 July 2005, the latter being an inspection for Butchers Licencing purposes. Follow-up inspections occurred on 2 February 2005 and 2 August 2005 respectively.
- 7.184 On each of these occasions the inspection was conducted by Mrs Angela Coles, an EHO. She holds a BSc in Environmental Health and qualified as an Environmental Health Officer in 1994. She is a Chartered Member of the Chartered Institute of Environmental Health. At the time of the Outbreak she had been employed with Bridgend County Borough Council for 15 months, prior to which she was employed in a similar capacity with another local authority and in the private sector. Her training included a HACCP Principles course (Royal Society for Public Health and Hygiene) run by Campden and Chorleywood in December 1997. In her previous post with the other local authority, she had implemented the Butcher's Licensing Scheme in that area.

The Inspection on 18 January 2005

- 7.185 Mrs Coles' first inspection was on 18 January 2005. It was a food hygiene inspection and not a Butchers' Licensing inspection. Her recollection was that it was an unannounced inspection. William Tudor was not present. Mr Celyn Williams was.
- 7.186 Mrs Coles had no specific recollection of the preparation for this inspection. Her usual practice was to go back in the file only to the last visit, and specifically to the last follow-up letter to see if there were any un-ticked items outstanding, unless she felt that there were specific issues that needed to be looked at further. This was, in fact, in line with Bridgend's procedures. She accepted that she rarely came across un-ticked items still outstanding. She did not know that a previous inspector had raised concerns about the accuracy of the records maintained by William Tudor; nor did she know about the issues raised by Mr Dier in his letter to Mr Davies in February 2002.
- 7.187 Mrs Coles described her inspection routine. She would inspect and ask questions first and then compare what she had seen with the HACCP plan. She therefore did not use the HACCP plan to structure her inspection. On this occasion, in the absence of the HACCP plan, and as described below, she simply conducted a physical inspection of the premises.
- 7.188 A Food Premises Inspection Report was completed as a result of her inspection on 18 January 2005. This was based on manuscript notes she took at the time which were produced to the Inquiry. It appears that the risk rating category was increased at this time from "B" to the highest category "A". There is no Food Hygiene Risk Assessment Sheet on file for either January or July 2005 because this was not part of the system after Bridgend introduced its "FLARE" computer-based system. It is therefore unclear on what basis this upgrading of the risk rating occurred. However, this strikes me as an appropriate change.
- 7.189 A number of matters of concern were recorded in the Food Premises Inspection Report.

- 7.190 It was noted that there were “no records available at time of visit”; and later that she had been “informed by Mr Williams that Mr Tudor had taken them home that day for updating. Today’s records not available either!!! Will contact Mr Tudor”. In evidence, she stated that the HACCP plan itself was off site; and also every other document she asked for. She specifically asked about temperature records. She considered that the fact that all the records and the HACCP plan had been removed was “a bit strange or co-incidental”. The contemporaneous note in the Food Premises Inspection Report recorded that the records were being “updated”. She could not recall if that applied not merely to the HACCP plan itself but also to the other underlying HACCP documentation. She accepted that there should be no need to take home the latter documentation for “updating” because that documentation’s integrity depended on it being filled in contemporaneously rather than in batches after the event. Her evidence was that she did not suspect that William Tudor had taken them home “to fiddle them”. She also accepted that, as her exclamation marks indicated, it was of considerable concern that even that day’s documents were not present and were not therefore being filled out contemporaneously.
- 7.191 The fact that the HACCP records were not available should have given cause for serious concern. Mrs Coles accepted that the maintenance of records, both systematically and contemporaneously, was a critical indicator that the requisite food safety systems were in place. Moreover, on the basis of what Mrs Coles recorded what she was told, not merely was the HACCP plan being reviewed but other documentation had been taken home for “updating”, suggesting that some records were not being kept contemporaneously and were in fact being prepared in batches after the event. In short, the record keeping systems underpinning the effective application of the HACCP plan were not being operated. As it turned out, and with the obvious benefit of forensic science evidence obtained by the police specifically for their investigation, this is indeed what William Tudor appears to have done. As explained in the previous Chapter, there is conclusive evidence that logs and cleaning standards forms from December 2004, and records of HACCP temperatures and times records from 28 July 2004 were not completed on a daily/weekly basis but in batches of entries.
- 7.192 The Inspection Report dealt with training. My conclusions on this are as follows:
- (i) It stated that the number of staff was six and that four of them had Basic Food Hygiene Certificates. Mrs Coles did not ask to see the certificates. She took that from what she was told by Mr Williams, on the basis that he had identified the fact that neither he nor Mr James Brown had any training. She accepted that she could have asked for the certificates; and that if she had done so, and it had turned out that what she had been told was inaccurate, that might have raised additional and broader concerns that what she had been told was false.
 - (ii) To her credit, and in stark contrast to the lack of checking and enforcement action previously, Mrs Coles took robust action on the training issue. She served a formal Improvement Notice, which required William Tudor to ensure that all his staff were trained in food hygiene matters. That was done in April 2005, I am in no doubt only as a result of Mrs Coles’ action.

- 7.193 In addition, the Food Premises Inspection Report noted that the problems with the freezer had recurred with the freezer noted as being congested and there being no obvious system of stock rotation. Given the limited extent of her preparation for the inspection as described above, Mrs Coles was not aware that this was a recurrent problem and had been for years. This was not then picked up in the follow up letter of 19 January 2005. Moreover, similar problems with unhygienic storage of meat were noted in the chiller where raw meat was being stored on wooden pallets on the floor of the walk-in chiller.
- 7.194 The day after the visit a letter dated 19 January 2005 was sent by Mrs Coles to William Tudor. It referred to a telephone conversation with William Tudor after the visit, for which there is no note on file. Again, to her credit, she noted numerous breaches of Food Safety legislation that required immediate attention. The breaches were said to present a risk to food safety and to contravene the conditions of Tudors' Butcher's Licence. The letter listed numerous items that contravened the 1995 Regulations and one that contravened the 2000 Regulations. The contraventions listed in the letter included:
- (i) Soap dispenser in the wash hand basin in the cooked meat room was empty – must ensure soap is available at all times.
 - (ii) Wash hand basin in packing room not connected to the drainage system, resulting in waste water being collected in a bucket and discharging over the floor. Must be reconnected as a matter of urgency.
 - (iii) Drains underneath wash hand basin very dirty with meat debris – must be thoroughly cleaned and maintained in a clean condition.
 - (iv) Drains in main preparation area were dirty with food waste and debris – must be cleaned thoroughly and maintained in a clean condition. Weekly cleaning is unacceptable; drains must be cleaned on a daily basis.
 - (v) Wall in the vicinity of the wash hand basin in the cooked meat area was dirty – must be cleaned thoroughly and maintained in a clean condition.
 - (vi) Plastic clad coating to walls throughout premises damaged in parts – must be repaired.
 - (vii) Paint covering on floor had worn in parts throughout the premises; all affected areas must be repaired.
 - (viii) Damaged stock noted in the walk-in freezer in the main preparation area.
 - (ix) Raw meat on wooden pallets on the floor of the walk-in chiller in the main preparation area, some in open boxes and some lying on cardboard and the pallets themselves.
 - (x) The HACCP document and associated paperwork, including the records for the actual day of the visit, which were not available at the time of the visit.

- 7.195 The letter was also accompanied by two Improvement Notices served under the Food Safety Act and its Regulations. The Improvement Notices only dealt with some of the problems found on the visit. They required, both by 21 March 2005:
- (i) the provision of a facility for cleaning and disinfecting small pieces of equipment, and:
 - (ii) all food handlers to be trained in food hygiene matters.
- 7.196 Although these breaches of food safety legislation had been noted, Mrs Coles stated in her evidence that from a cleanliness point of view the premises “weren’t actually that bad”.
- 7.197 One matter arising out of this inspection needs to be specifically dealt with. That relates to the vacuum packing machines or vac packers, which was examined in the previous Chapter. Mrs Coles’ notes made during the inspection record read: “Vac pack machine used for cooked and raw meat at present. Ck’d [cooked] meat vac pack fixed this week”. Mrs Coles was told by Mr Williams that one of the two vac packing machines, or vac packers, had been sent away for repair. That is reflected in her manuscript comments on the Food Premises Inspection Report Summary in which she stated: “Vac pack machine repair and back in place as soon as possible”. The follow-up letter, dated 19 January 2005, noted these matters and went on
- “In order to minimise any food safety risk you must ensure that all cooked meat is protected against any risk of contamination. You must ensure that the vacuum packing machine is thoroughly cleaned and disinfected between the use of raw and cooked meat.”
- 7.198 Mrs Coles accepted that Tudors were supplying to vulnerable groups including school children. She was aware of the nature of the risks that might arise if cross contamination did occur, including infection of cooked meat with *E.coli* O157. She was aware of the potential consequences for children of being infected with *E.coli* O157. She accepted that the use of the single machine breached the central control mechanism of physical separation between cooked and raw meat areas – that control mechanism being set out in the HACCP plan (although for the reason set out above she had not seen the plan on this inspection). She also accepted that the risk of cross-contamination was higher if a single piece of equipment was used to pack both raw and cooked meat.
- 7.199 In her evidence she sought to defend her actions in relation to the use of the single machine to vac pack raw and cooked meats. That defence was that provided the machine was being used properly and was being thoroughly cleaned and disinfected between use for raw and cooked meats, the risk of cross-contamination was minimised and there was really nothing that could be done about it legally. She stated that all she could require by law was that there was no risk of contamination; and that there was no legal requirement for separate equipment for raw and cooked meats.

7.200 I do not consider her defence of her actions either acceptable or tenable for the following reasons:

- (i) Even if, in principle, using the same machine might be acceptable, the position depended upon her having the very highest degree of confidence that the cleaning was going to take place and would be adequate. The evidence simply did not support any such confidence.
- (ii) Mrs Coles' letter of 19 January 2005 and the Food Premises Inspection Report indicated a series of problems with food safety practices; and hardly inspired confidence that Tudors was a business that could confidently be left to implement the necessary rigorous cleaning of the vac packer.
- (iii) More specifically, Mrs Coles accepted that she did not check to see whether there were any sensible or appropriate procedures in place for cleaning. She saw no written cleaning processes or schedules. She first saw any such schedules on her follow-up inspection on 2 February 2005. She accepted that these schedules, described by Professor Griffith as "a joke", "did lack detail" and had "room for improvement". There was, in any event, nothing in the cleaning schedules relating to vac packers.
- (iv) Although Mrs Coles stated that she discussed the cleaning of the vac packer with Mr Williams, she did not ask any of the other employees about cleaning, in particular the person with the daily responsibility about how he did the cleaning. If she had done, it is likely that the truth about the manner of cleaning, and its unsatisfactory nature would have emerged.
- (v) There was nothing setting out who was responsible for cleaning or what disinfectant should be used. Mrs Coles stated that she thought that she had been told that Mr Williams would be doing the cleaning. However, she knew, because he had told her, that he did not even have basic level food hygiene training. She did not ask to see what sanitiser or disinfectant was in fact being used.
- (vi) She claimed that the difference between the position in January 2005 and the position on 19 September 2005 was that when she visited in January the vac packer was "clean". However, the cleanliness required to deal with cross-contamination cannot be assessed purely on visual aspects but should also consider microbiological safety.

7.201 In light of all these matters, I reject Mrs Coles' continued assertion that she was in effect powerless to act to stop the machine being used. The reality is that she did not adequately address or probe the relevant issues before making her decision. She was not in a position to make a proper judgement that the obvious cross-contamination risks had been properly or adequately dealt with. She could, and should, have concluded that the continued use of the vac packer did in the circumstances present an imminent risk to health.

The Follow-Up Action

- 7.202 There is no separate Inspection Report on file for the re-visit on 2 February 2005. There is reference to it on the letter of 19 January 2005, which was used as the checklist against which manuscript comments were written on 2 February 2005. There are also manuscript notes made at the time by Mrs Coles.
- 7.203 The revisit was announced. Its date had been set and referred to in the follow-up letter of 19 January 2005, which had stated that "all records will be examined at the time of the re-visit on 2 February 2005". Mrs Coles explained that this revisit was announced because she wanted to make sure that William Tudor was present. She accepted as "fair points" the possible advantages of not having alerted him to the date. This included whether the records absent on the first inspection had re-appeared, whether there had been improvement in relation to the items listed in the contraventions letter, and whether William Tudor himself, as the only person with the required level of training for a supervisory role, was in fact present.
- 7.204 On the copy of the original letter against the section relating to HACCP, which was unavailable at the time of inspection, is a note indicating that the HACCP plan was reviewed on 8 January 2005. A note on the last page of the letter states that HACCP documentation, temperature records of fridges, freezers and cooking/coding, cleaning records and the pest control contract were checked. She was told by William Tudor that he had reviewed the HACCP plan on 8 January 2005. Mrs Coles did not pick up or query this statement against the fact that 10 days later, on the date of her first inspection, she had been told that he was reviewing the plan on that date, 18 January 2005.
- 7.205 In her oral evidence, Mrs Coles described the process she followed. In relation to the HACCP plan she would have looked at the flow diagram and charts bearing in mind what she had seen on her visits. She would have examined the HACCP plan table. She would have looked at the titles and seen if anything stood out. She was looking to see if the basics were in place given that she believed that many butchers had difficulty following and applying HACCP. She claimed to recollect discussing the nature of Tudors' operations but had no specific recollection of asking about processing meats cooked off site.
- 7.206 As a plan, the business's HACCP plan was deeply flawed for all the reasons set out earlier. It is evident that most, if not all, of those problems were evident from the face of the plan itself. Some, such as the fact that it did not cover at all an entire process of dealing with meats cooked off site, should have been evident if there had been proper discussion or alertness to the nature of the processes in fact being undertaken by Tudors. The inevitable inference is that Mrs Coles did not carry out any adequate consideration of the adequacy of the HACCP plan. It is of some concern that, given her relatively senior position, training and experience, that she did not identify numerous flaws in the HACCP plan. She continued to maintain that the plan was "adequate" acknowledging only that there might be some areas for improvement.

- 7.207 The manuscript comments that Mrs Coles made on the copy of the 19 January 2005 letter also indicate that she checked some of the underlying HACCP records. However, she does not appear to have done so against the plan. If she had, it would have become quickly apparent that the format of the records, that is, the typed sections setting out what was to be recorded, frequently did not correspond to the details in the HACCP plan itself. For example, in relation to the record of cooling times and temperatures, the form had columns for the temperature after two hours and after ten hours. Yet the HACCP plan referred, as a Critical Control Point, to the cooling time needing to be between four and six hours. The temperature after the cooling time is stated in the HACCP plan to have to be eight degrees Celsius. That temperature was reached on only three out of the eight manuscript recorded temperatures in the form for January 2005.
- 7.208 In relation to the vac packer, nothing is marked next to the item in the follow up letter. Mrs Coles' handling of the vac packer issue on this occasion also gives cause for concern:
- (i) In her evidence, Mrs Coles stated that she recalled being told by William Tudor that the vac packer was still away for repair and that they continued to move the remaining vac packer between the raw and cooked meat areas. This was some considerable time after the week of 18 January 2005 by the end of which the vac packer was to have been fixed according to the notes she made on her previous inspection. She claimed that she would have asked him about the delay but could not remember what answer he gave. Given her concerns about possible cross-contamination from the use of a single machine, and given what she had been told before about the reasons of the absence of the other vac packer, Mrs Coles should not simply have let the matter rest.
 - (ii) She evidently made some check of the HACCP plan because that fact is recorded in the letter of 19 January 2005. However, she had no recollection of picking up the fact that the HACCP plan required as a Critical Control Point, strict physical separation between raw and cooked meat areas, a principle that had been breached by this point in February for a significant time and in a fundamental way by the continued use of a single vac packer for raw and cooked meats. This suggests that in fact William Tudor was not in reality using his HACCP plan as any real part of the food safety measures and that inadequate focus was put on the plan during the inspection.
 - (iii) Her response in oral evidence was to raise the hypothetical possibility that William Tudor could have changed his HACCP plan in this respect, although she did qualify this by saying that she would not have wanted him to go down that route as changing the words wouldn't have changed what was happening in practice.
 - (iv) Her recollection of discussions about the precise cleaning processes for the machine was limited. No record was made by her about those processes; and no record exists prepared by Tudors on this subject. Moreover, as a mechanism for checking the operation of the cleaning of the machine in practice, the revisit on 2 February 2005 suffered from the fundamental drawback of being an announced visit. As appears below, between January 2005 and the Outbreak the only unannounced visit was on 19 September 2005, at which point the vac packer was in a filthy condition.

- 7.209 After receiving copies of the training certificates on 2 June 2005, Mrs Coles wrote to William Tudor on 14 June 2005 confirming compliance with that Improvement Notice.
- 7.210 The other Improvement Notice issued on 19 January 2005 required Tudors to provide a facility for the cleaning and disinfection of small pieces of equipment. In the covering letter this is stated to be "sinks". A tick was placed against this item on the letter with a comment that a sink had been fitted to the raw meat preparation area but that a sink was still to be fitted in the cooked meat area. The file copy of the Improvement Notice carries a tick and note stating compliance with the Improvement Notice by way of a sink being fitted in the raw meat area. There is no record on file that written confirmation of compliance with this Notice was sent to Tudors.

The Inspection on 19 July 2005

- 7.211 The last inspection prior to the Outbreak was on 19 July 2005. It was a food hygiene inspection and a Butchers' Licencing inspection. Three forms were completed:
- (i) a Butcher's Shop Licensing Assessment Form (his licence was due to expire on 3 August 2005).
 - (ii) a Food Premises Inspection Report.
 - (iii) a Food Hygiene Award Assessment Sheet.
- 7.212 The latter indicates that the inspection visit had been pre-arranged. That was done, according to Mrs Coles, because William Tudor was going on holiday and asked for it. She did not consider the request unreasonable. I am well aware of the desirability of enforcement teams working with businesses wherever possible to facilitate the inspection process. However, in the light of the concerns raised in the earlier inspections, I consider that the decision to arrange an announced inspection was unwise.
- 7.213 According to the Butchers' Licensing Assessment Form, the business was judged to be compliant with the 1995 Regulations and the Food Safety (Temperature Control) Regulations 1995. Three contraventions were noted: damage to the wall of the walk-in freezer; the underside of the meat slicer was dirty; there were cobwebs in the cooked meat area.
- 7.214 This Assessment Form also records Mrs Coles' satisfaction that all aspects of HACCP had been met. Mrs Coles' evidence was that she spent possibly 20 minutes or so on this check. For the reasons given above, I consider that the check was inadequate.

- 7.215 I also have serious concerns about the checks made of the underlying HACCP records on this occasion. On the revisit in February 2005, Mrs Coles had specifically inspected the Record of Cooling Times and Temperatures recorded on the January 2005 sheet. That was therefore an obvious record that should have been rechecked in July. Had she done so, it would have been evident that there had been some surprising changes since January. The July records indicate that somehow, William Tudor was now managing to cool meat to temperatures of between 14 and 10 degrees after two hours, and between one and two degrees after ten hours. Mrs Coles was unable to explain how he was doing so; and accepted that she had probably only looked at the more recent record without appreciating the contrast. It also appeared from this record, if indeed it was accurate, that William Tudor was now doing things in a very different manner to that set out in the relevant part of the HACCP plan. I cannot see that this fact was appreciated by Mrs Coles.
- 7.216 Mrs Coles also indicated that on this inspection she had not discussed matters with employees as she went around the premises. She initially did not see any need to do so, and was happy with what she was told by William Tudor and Mr Williams. However, she later accepted both that the Codes of Practice refer to the need to talk to food handlers as part of the inspection process and that, with hindsight, she should perhaps have talked to employees as a means of checking that the HACCP plan was in fact being followed in practice.
- 7.217 The inspection record also notes that training requirements had been met. Information recorded on the form lists seven people working in the business, their job titles and the level to which they had been trained. It also confirms that a record of training for each person was kept. The evidence shows William Tudor as being trained to Advanced Level with a Diploma in Food Hygiene and all other employees including the manager, Mr Celyn Williams, at Foundation Level.
- 7.218 The Food Premises Inspection Report noted that the meat slicer was “not very clean” and “a couple of minor structural requirements”.
- 7.219 The Report indicates a downgrading of the risk rating of Tudors from “A”, the highest category, to “B”. According to a later file note made on 4 October 2005 during the Outbreak, this was an error. The note explains that a field was missed when data was input to the Department’s “FLARE” system, resulting in the lower risk rating.
- 7.220 On 27 July 2005, Mrs Coles faxed a letter to Mr Williams for the attention of William Tudor. Mr Tudor was asked to contact Mrs Coles once the matters set out in the letter had been attended to so that a Butcher’s Licence could be issued. The letter noted four minor contraventions. The cover sheet indicated the date and time of the re-inspection visit (2 August 2005 at 09:00).
- 7.221 It is necessary to focus again on the vac packer. As set out above, Mrs Coles had been told on 18 January 2005 that it would be back from repair by the end of the week. She had been told on 2 February 2005 that it was still being repaired but would be back shortly. As before, Mrs Coles made notes during her inspection. She noted: “Vac packer – used in high risk also”. She explained that she had been told by William Tudor that the vac packer was still being used in the high risk cooked meat area. No mention was made of the vac packer on either the form or in the follow up letter dated 27 July 2005.

- 7.222 Again, I must conclude that, for the following reasons, Mrs Coles' handling of this issue was seriously inadequate:
- (i) She stated that she would have discussed the continued absence of the second vac packer with William Tudor. However, she evidently did not probe or pursue the issue with any rigour. For example, she does not appear even to have asked about the cause of the asserted problem. That is particularly surprising given the explanations she had been given months earlier for the absence of the machine, and given the evident risks of cross-contamination that are associated with the dual use of a single machine. It is also unfortunate given that such probing might well have raised more serious general concerns about the truthfulness of the answers she had been given and was being given.
 - (ii) She did not raise this issue as an action item, still less as a state of affairs, carrying significant risk and in breach of the HACCP plan, that needed to be urgently sorted out.
 - (iii) She did not check the manner in which the cleaning was being done.
 - (iv) She did not make any checks to ascertain whether it was really the case that the vac packer was being physically moved. That is of some significance given that she was told that that was being done; yet Mr Houston indicated that the vac packer was plugged into the ceiling with semi-permanent fixings.
- 7.223 The fact that William Tudor concealed facts or did not tell the truth on occasions made the inspection task all the more difficult. Nevertheless, EHOs must be alert to the possibility that the inspected person might not tell the truth. That is where the EHOs' skills come into play, enabling them to probe and follow up signs that something does not tie up with their other observations or that something might be amiss.

The Follow-Up Inspection on 2 August 2005

- 7.224 As before, the letter of 27 July 2005 was used as the basis for the re-inspection on 2 August 2005, ticks being placed on that letter. This was also announced in the sense that William Tudor was told the date and time of the re-visit.
- 7.225 The single vac packer was still in place. Mrs Coles could not recall if she asked about the other vac packer on this occasion.
- 7.226 Following the re-inspection on 2 August 2005, a letter was sent to William Tudor on 3 August 2005 confirming that all matters had been addressed and a Butcher's Licence was issued.

The Inspections after the Outbreak on 19 and 20 September 2005

- 7.227 The next time the premises were inspected was about six weeks later on 19 September 2005, which was the first full working day after an Outbreak had been declared on the previous Friday. The inspection was conducted by Ms Donagh, Miss Lewis, Senior EHO and Mr Davies, EHO, all of Bridgend, and a Senior EHO from Rhondda Cynon Taf, Ms Alexa Pieris. A detailed report of this inspection, and the numerous problems and failings found, was made by Ms Donagh. Another report was prepared by Mr Davies of this inspection. This appears to have been based on his contemporaneous notes. It noted "It was evident whilst walking around the premises and taking the swabs that there were numerous contraventions of [the 1995 Regs] relating to cleaning and structural repair".
- 7.228 Ms Donagh stated in her evidence that she had specifically discussed the use of the single vac packer with William Tudor. She had asked him to demonstrate how he would clean the vac packer. She was not satisfied from what he told her that he could demonstrate that it had been cleaned effectively. William Tudor, in response to her request, took several minutes to come back with the equipment he claimed to use. It consisted of a worn plastic brush and a small plastic tub. The chemicals were stored out at the back. In these circumstances, it is difficult to see how Mrs Coles could have reached a different conclusion on the previous visits if she had asked the same questions as Ms Donagh.
- 7.229 The result was the issuing, on 19 September 2005 by Ms Donagh, of an Emergency Prohibition Notice. This had the effect of preventing the use of the vac packing process on the basis of "the serious risk of cross-contamination from the use of it for both raw and cooked foods". The Notice also referred to its situation beneath an electronic fly killer and its unclean condition. According to the note by Mr Jamie Davies, this was issued "due to Mr Tudor advising that it was being used for raw and ready-to-eat foods".
- 7.230 The next day, 20 September 2005, there was another inspection, this time by Ms Donagh and Mr Davies. Ms Donagh's detailed note also covered this inspection. Another Emergency Prohibition Notice was served, again signed by Ms Donagh. This one shut down the premises entirely, with the reason given as "unsanitary condition of premises due to inadequate disinfection procedures".
- 7.231 The Emergency Prohibition Notices were followed, on 21 September 2005, by an application to the magistrates court for an Emergency Prohibition Order to confirm the prohibitions set out in the Notices. The order was made on 22 September 2005.
- 7.232 Some days later, on 4 October 2005, three Improvement Notices were served, each signed by Miss Lewis. They specified different dates by which faults identified needed to be rectified: 18 October 2005, 25 October 2005, and 15 November 2005 respectively. They provided a long list of matters that did not comply with Food Safety Act 1990 Regulations:

Improvement Notice FI/138/05/AL

Raw meat cutting area

- Ceiling was dirty throughout the area.
- Ceiling mounted cooler units were dusty and dirty.
- Light units were dirty and dusty, with an accumulation of dead flies and insects.
- Walls were dirty and discoloured throughout the area, especially at high level.
- Band saw machine was heavily dirty with congealed debris.

Walk-in freezer off the raw meat cutting area

- Large accumulation of ice on the walls, floor and ceiling.
- Fan unit was iced-up and not maintained in a clean condition.

Ham pumping room

- Floor throughout area was dirty, with meat noted in the drain underneath the wash hand basin and insects/woodlice on floor behind the large stainless steel table.
- Walls not maintained in a clean condition.
- Two large pieces of equipment, namely the “Interjec” brand equipment and “Hollymatic” brand equipment, were dirty with congealed dirt and debris.
- Light covers not maintained in a clean condition, with an accumulation of files/insects and dirt.
- Large stainless steel table was dirty.

Cooked meat area

- Meat slicer was dirty with food debris.
- Tables to left and right hand side of the meat slicer were dirty with food debris.
- Walls throughout area were dirty, including underneath the wash hand basin, where the wall was discoloured yellow.
- Ceiling was discoloured and dirty throughout the area.

Walk-in chiller in the cooked meat area

- The walls were dirty and discoloured.

Improvement Notice FI/139/05/AL

Raw meat cutting area

- Numerous areas of chipped/missing/damaged paint to the walls in the raw meat cutting area.
- Three wall mounted power units were extensively rusty.
- Paint to the skirting areas (wall/floor junctions) throughout the area was chipped and worn.
- Paint to vertical pillars opposite the blue-coloured refuse bins was chipped and areas of rust noted.
- Gap noted under the rear external door in the corner, which was relevant to pest control.

Ham pumping room

- Cladding on door frame leading to this room was loose.
- Waste pipe from the wash hand basin not properly connected to the drain.

Cooked meat area

- Areas of chipped and missing paint noted to walls throughout the area.
- Paint was worn and missing to the skirting areas at the wall/floor junctions.

Walk-in chiller in cooked meat area

- Floor paint worn.

Improvement Notice FI/140/05/AL

Raw meat cutting area

- Damaged areas of floor throughout the area, exposing large areas of bare concrete.

Cooked meat area

- Damaged areas of floor throughout the area, with bare concrete in front of the walk-in chiller.

7.233 Accompanying the Improvement Notices was a letter from Miss Lewis dated 4 October 2005, which also brought the following matters to the attention of the business:

- (i) The electronic fly killer in the raw meat cutting area was inappropriately placed above the vacuum packing machine, posing a potential risk of contamination. The unit should be re-sited.
- (ii) Heavy pooling of water was noted on the floor throughout the area, the cause of which should be investigated and the matter remedied.
- (iii) The walk-in freezer in the raw meat cutting area was heavily overstocked, making it difficult to ascertain if there was an effective stock control system. Foods were also noted on the floor or the unit. The freezer must not be overstocked and foods should be rotated. Food must not be stored directly on the floor.
- (iv) Due to the amount of ice present there were also concerns over the effective operation of the freezer's condenser unit, which should be investigated and remedied.
- (v) There was a leak to the wash-hand basin in the cooked meat area, which should be investigated and remedied.
- (vi) Probe wipes were beyond their "Best Before" date and should not be used beyond their recommended shelf-life.
- (vii) The use of a degreaser and water pressure leaver operated at a hot temperature to clean the premises and degreaser and water in a container to clean the equipment was noted. The use of a sanitiser – a chemical incorporating both a detergent and a disinfectant – was recommended, with disinfection completed regularly.
- (viii) There was evidence of inadequate procedures to establish the traceability of food at all stages of production, processing and distribution, and a suitable system should be introduced to ensure adequate labelling.
- (ix) HACCP documentation and paperwork was not up to date. Records required in accordance with the business's HACCP including cleaning records and transportation monitoring had not been completed for August or September 2005, and the HACCP procedure had not been altered to take into consideration the breakdown of one of the meat vac packers.

7.234 Tudors applied to set aside the orders on the basis that the requisite one clear day's notice had not been given by Bridgend County Borough Council prior to the application being made to the magistrates court. That application was granted by the High Court on 27 October 2005. The High Court remitted the case for reconsideration by a different bench of magistrates in Bridgend.

7.235 In the event, this did not occur. There was some correspondence about compliance with the Improvement Notices. However, the criminal investigation and charges then intervened and William Tudor did not seek to recommence the business other than for a short period in December 2005. He is now subject to an Order under Section 11(4) of the Food Safety Act 1990 prohibiting him from participating in the management of any food business.

Expert Witness Evidence

7.236 In relation to the conduct of inspections generally, Mr Brian Curtis' evidence was as follows:

- (i) He did not consider that the Codes of Practice intended to set out a prescribed order in which inspections should be conducted. Specifically, his view was that professional practice varied and that some inspectors went first to the HACCP plan and then physically inspected and others did it the other way around. His view was that the test was ultimately whether, whatever order was adopted, the inspection as a whole was an effective assessment of the business activities, correctly identifying the hazards and the appropriate controls.
- (ii) He regarded the HACCP plan as the cornerstone of delivering safe food.
- (iii) To that end, his view was that inspectors should use an auditing approach. He emphasised in his evidence that this did not amount to a full blown audit. Nor did it require training or qualifications as an auditor. Rather it indicated a practical, common sense technique for ascertaining whether the HACCP plan was being implemented. This involved for example selecting one or more Critical Control Points and examining the implementation of those aspects of the plan in some detail, or "drilling down" – for example by examining the underlying HACCP records to make sure that they conformed to the plan and were being properly maintained, and by talking to employees responsible day to day for taking and perhaps recording the necessary control steps. It would be a question of time and judgement for the inspector how many aspects could be examined in this way. In relation to Tudors, he identified cooking, chilling and vac packing as the aspects he would have selected as the most important for detailed examination.
- (iv) The inspector, once satisfied as to the validity of the plan, should then focus on the monitoring procedure as the core element of ensuring that the plan was in fact being implemented. The four questions he identified in this exercise were the simple ones: Who does it? What do they do? When do they undertake the monitoring process? Have they recorded what they have done?

- (v) His view was that if a person was carrying out a key role in monitoring procedures at a Critical Control Point, it would be appropriate for an inspector to question them to ensure that they understand what they are doing and are following a documented procedure designed to control the hazard in question. The element of flexibility in the Code enabled inspectors to focus on particular Critical Control Points and closely analyse how they were being applied, including questioning employees. Talking to managers alone was a very unreliable way of establishing what was in fact going on. For that purpose it was essential to talk to the staff actually doing the checks.
- (vi) He identified advantages in both announced and unannounced inspections. The latter had the obvious advantage of giving the inspector a better opportunity of seeing how the business in fact operated. The former might be used if it was necessary for a particular individual to be present to explain systems or processes or documentation. A mix of the two was needed, but with unannounced being the norm. Judgements needed to be made against the backdrop of whether there had been unannounced inspection recently and of the nature of any live issues.

7.237 He indicated that if there was a properly validated plan in place, the next stage for an inspector was to ascertain that it was actually being followed in practice. This stage he described as the verification stage. In the light of his conclusions about the inadequacy of the 2005 HACCP plan as a valid plan, it follows that safe food could not in his view have been assured, even if that plan had been followed to the letter. In the circumstances, he examined the performance of the inspection functions by Bridgend inspectors more broadly.

7.238 His principal conclusions in the light of all the evidence, and leaving aside the vac packer issues, which are dealt with separately below, were as follows:

- (i) The inspections undertaken failed to identify the deficiencies and weaknesses in the HACCP plans as plans i.e. the validation exercise was not undertaken effectively.
- (ii) The inspections failed systematically to assess the accuracy and effectiveness of the underlying HACCP documentation. For example, the cleaning schedules were not very helpful, the temperature records and the chilling records had deficiencies and threw up the issues dealt with above.
- (iii) There was insufficient focus on identifying and assessing the working practices and procedures that were in fact being implemented for the purpose of ensuring that the HACCP plan was applied in practice. There was particular concern about the balance between announced and unannounced inspections; and about a failure to talk to employees to establish what really went on.
- (iv) There was inadequate reaction by inspectors when they did come across breaches of the HACCP plan: for example, when the records indicated that the cooling temperatures identified in the plan as critical limits were being regularly breached.

- (v) There was real concern as to whether the true importance of HACCP to ensuring food safety was in the minds of inspectors; and, following on from that, whether the inspections were in fact structured and approached effectively to test the HACCP plan and its implementation. That in turn raised concerns about the adequacy of the procedures and the internal guidance given to EHOs about these issues.
- (vi) There was no system within Bridgend for red flagging issues of particular concern identified on previous inspections, such as Mrs Evans' suspicions about the falsity of the documentation maintained by William Tudor.
- (vii) The result of these matters was a failure in the series of inspections to identify and deal with the poor hygiene and unsafe working practices in Tudors.

7.239 I agree with each of the above points.

7.240 I consider that it was essential, following the introduction of the HACCP approach, that the HACCP plan should lie at the very heart of the inspection process. Its prime purpose was to ensure that businesses such as Tudors adopted a proper and rigorous analysis of the particular hazards to food safety in business processes. The HACCP plan should have been used by the business to ensure that those hazards were dealt with in an effective manner; and that that fact could be demonstrated by proper records kept efficiently and contemporaneously. This was the key lesson and recommendation from my review of the *E.coli* O157 outbreak in Scotland in 1996.

7.241 The forms developed by Bridgend placed focus on HACCP. Evidence also indicates that each of the inspectors considered HACCP to some degree. However, my conclusion is that none of them did so in a sufficiently rigorous or systematic way. That is a failure on the part of individual inspectors and of management, part of whose functions was to ensure that at least adequate practices were, in fact, followed.

7.242 The inspectors' practices varied. The evidence on some, such as Mr Gubb, suggests at best a lackadaisical approach to this part of the inspection process. In relation to others, such as Mrs Coles, there appears to have been greater focus on HACCP and an approach that came at least closer to the sort of inspection approach and techniques identified by Mr Curtis. However, even in such a case there are a series of indications that the inspection was not done with the required understanding and rigour.

7.243 I agree with Mr Curtis that the 2005 HACCP plan was not a valid plan. It had a series of fundamental flaws that could, and should, have been picked up by an experienced EHO. An obvious example is the failure to follow through the process steps in the control chart itself. That should have raised issues, which would have indicated that the required hazard identification had not been done, for example in relation to vac packing. Another is the corrective action "retrain staff", which was specified as the action to deal with the hazard of bacteria growth in food.

- 7.244 The inference is that, whatever the form of any previous HACCP plans that existed at Tudors, they are unlikely to have been more detailed or more rigorous. So it is probable that the flaws, or the sorts of flaws, in the 2005 HACCP plan were replicated in earlier plans. Yet nearly all EHO's declared the HACCP plan to be valid.
- 7.245 I must also conclude that there were repeated failures to verify the HACCP plans to ensure that they were being followed in practice. If an inspection had HACCP at its heart, and had adopted the approach of selecting particular important aspects of the plan and then thoroughly testing how they were being implemented, the failures at Tudors would have been identified.
- (i) None of the inspectors talked to employees (other than Mr Celyn Williams in William Tudor's absence) to ascertain if Critical Control Points and monitoring procedures were being dealt with effectively.
 - (ii) None adopted with any degree of rigour or thoroughness the sort of audit-style approach that should have been followed.
 - (iii) The Hazard Analysis and the Butchers' Licensing Assessment Forms indicate that the checking of the underlying HACCP records was far from satisfactory, with examples of records not being checked, and other examples of relevant details e.g. in relation to training, not even being filled in as the form dictated.
 - (iv) Even when there is some indication that the underlying records were checked obvious inconsistencies and problems were not picked up. For example, the temperature and chilling records Mrs Coles examined indicated clear departures from the HACCP plan itself; and that was not picked up. To the extent that it was picked up, the reaction to clear breaches of the plan was insufficient.
- 7.246 EHOs are professionals who are trained in the basics of HACCP. It should not take an undue or impractical amount of time to check that the elements of a HACCP plan are effective. The verification process might take longer. But there is nothing to prevent an inspector exercising sensible judgements about which Critical Control Points to examine and the level of detail involved in that examination. Indeed, my view is that the operation and implementation of the HACCP plan should have been at the very heart of the inspection process rather than being viewed as something time consuming and impractical, or simply a "tick box" exercise to show that some sort of plan document existed.
- 7.247 I also conclude that the procedures in place and the management steps taken to support and monitor the EHOs' performance were not as effective as they should have been. In reaching this conclusion, I acknowledge that despite their limited experience in food safety, Ms Donagh and Mr Cole achieved significant improvements in, initially, difficult circumstances. They did this with only limited support from Mr Crocombe. My conclusion is based principally on two related matters:

- (i) The new management team developed a series of documents relating to inspections and monitoring where none, or insufficient written procedures or guidance, had existed before. However, those documents, notably the Procedures document, did not provide a useful practical guide for inspectors other than in a most general sense. In particular, it did not address at all the sort of inspection techniques that both Mr Cole, and Ms Donagh expected should have followed in checking HACCP.
- (ii) The monitoring of the quality and effectiveness of inspections by EHOs appears to have been inadequate. There does not appear to have been a plan implemented to ensure that inspections were being carried out in a thorough manner. It is very unfortunate in this respect that the only section in Bridgend's Procedures document that was aimed at monitoring quality of inspections was the victim of the decision, made on resource grounds, not to implement it.

7.248 As Head of the Team for a significant period before the Outbreak, Ms Donagh presided over, and therefore bears responsibility for ensuring that, the systems and practices were in place to ensure at least adequate inspections. It is evident for the reasons set out above that those systems and practices were flawed and that the inspection regime was accordingly not adequate. The same is true for Mr Cole, who perhaps bears some added responsibility as the Food Safety Officer.

7.249 My overall conclusion is that elements of Bridgend's inspection process for Tudors were not conducted adequately. It is reinforced by the evidence I have seen on events surrounding the use of the single vac packer from January 2005 onwards, which are dealt with below. Mr Stoddart's decision, reached with his Heads of Section, to fill both key posts with officers who lacked recent experience of food safety depended heavily on sufficient support being available to Ms Donagh by himself, as a person with some past experience of food safety, and by Mr Crocombe. Unfortunately, only a limited amount of support was provided. Mr Stoddart and Mr Crocombe accordingly bear some responsibility for the failures in process and guidance that have been identified.

The Use of a Single Vac Packer

7.250 The views of Mr Brian Curtis were as follows:

- (i) The use of a single vac packer to pack both raw and cooked meats carried with it a serious risk of cross-contamination.
- (ii) A judgement needed to be made at the first inspection in January 2005, in the light of the explanation given about the other vac packer being away for repair. The judgement was whether the use of the single vac packer presented an imminent risk to public health.
- (iii) However, he would have approached the matter by first asking what the HACCP plan provided for in such a situation; and then by discussing its use in detail with William Tudor. Given the seriousness of the risks involved, he would have discussed it with others back at the office who had experience of Tudors that, at that stage, Mrs Coles did not.

- (iv) At the January 2005 inspection, there was no HACCP plan available. However, by the February 2005 revisit, it would have been clear that the use of a single vac packer for raw and cooked meat was in clear breach of the HACCP plan. It had already been established that some staff had not been trained in food hygiene and that elements of routine cleaning had not been carried out. Those matters would have heightened the concerns surrounding cleaning the machine as an acceptable alternative.
- (v) In order for the vac packer to continue to be used, Mr Curtis said he would have needed to be satisfied that an effective cleaning process could be devised; and then to be satisfied that that process was clearly set out by way of amendments to the HACCP plan and written procedures. He considered that it would have been extremely difficult for him to be satisfied about “effective cleaning” as an alternative given the nature of the equipment and the difficulty of ensuring that the cleaning left the vac packer in a microbiologically safe condition on each occasion, and also given that, given its low dose infectivity, *E.coli* O157 risks needed to be met by ensuring that all the bacteria were eradicated.
- (vi) He was reluctant to state that it would never be possible to achieve safety by cleaning a single vac packer. However, it was also evident that his view was that, for a machine of this complexity and in the light of the *E.coli* O157 risks, it would not be practically possible to ensure such safety. That view was reinforced by the features of Tudors, such as its relatively small size as a business, the lack of training and the history of concerns over food hygiene issues.
- (vii) The additional element in the analysis was described by Mr Curtis as “a bit like playing Russian roulette”. The cleaning, with all its difficulties and risks, needed to be completely effective each time it was done. Prolonged use increased the chances of that not occurring.
- (viii) He would have been concerned the explanation being given, namely repair, did not then lead to a swift conclusion.

7.251 Again, and as set out below, I agree with the views of Mr Curtis. If anything, my conclusions are firmer on this issue than his:

- (i) I have set out my principal conclusions in analysing the actions and inspections of Mrs Coles in 2005. My principal conclusion is that Mrs Coles failed to deal adequately with the issue of the vac packer. Given the risks involved, and given the concerns about hygiene that she had herself identified and in particular the absence of any clear and documented procedures designed to achieve effective cleaning, there was plainly an imminent risk to health in the use of the single vac packer to pack raw and cooked meats. She could, and should, properly have told William Tudor, even at the January inspection, that such use could not be allowed to continue.

- (ii) As events progressed, that course of action should have become all the clearer. The reasons given for the absence of the machine, notably away for repair and due back shortly, should have become increasingly unacceptable. Indeed, as the months passed, those explanations should have raised serious and broader concerns about whether the explanations being given were even truthful.
- (iii) I do not accept that Mrs Coles had no real legal option. Nor do I accept that the absence of an insistence in legislation or the Codes on separate equipment indicates that Mrs Coles was powerless to act in an appropriate way. It may in some situations be possible to clean machinery to a safe standard. Situations can be envisaged in which it might be appropriate to accept that cleaning of particular equipment could be a satisfactory alternative to separate equipment. That would explain why there is no legislative or Code insistence on separate machinery. However, each situation would need to be assessed individually. The situation at Tudors should, in my view, have led an experienced EHO to conclude that cleaning was simply not a viable and safe alternative.
- (iv) The consequence needs also to be borne in mind. On the one hand, there were serious risks of cross-contamination of a serious kind in a business supplying vulnerable groups. On the other hand, there was at worst a need, as a precondition to continuing this part of the Tudors operation, to buy a new vac packer.

Developments since the Outbreak

7.252 The most significant changes made by Bridgend to its policies and procedures are:

- (i) Paperwork from the previous two inspections/risk assessments must be checked prior to inspection, and registration details.
- (ii) System for flagging issues has been introduced and the flagging sheet is reviewed before an inspection takes place.
- (iii) Additional paragraphs from the Codes of Practice pertaining in food hygiene inspections in the Inspections and Revisits Procedure.
- (iv) Inspection form updated to record evidence of training for individual food handlers and answers on Critical Control Points. Details of cleaning and disinfection practices also now documented even if the business is doing things correctly.
- (v) Inspectors talk to staff as well as management and information is recorded along with answers received, and advice given and decisions made on enforcement action where significant food safety issues arise.
- (vi) Files now record whether previous inspection was unannounced or announced to check if a pattern is forming.
- (vii) Policies and procedures reviewed annually or when legislation changes.

- 7.253 With specific reference to butcher's shops, HACCP documents are now copied for detailed consideration and audit in the office with feedback to proprietors. A record is kept on file. The Authority continues to ensure that at least two inspections per year are undertaken in butchers that handle unwrapped raw and ready-to-eat products due to the level of risk involved. Joint inspections of butchers' shops have been undertaken
- 7.254 Most inspections of butchers' shops by Caerphilly are done by officers working in pairs. Caerphilly have also introduced a flagging system to highlight issues of ongoing significance. The Authority has also undertaken work to improve the consistency of risk ratings and shared this with the South East Wales Food Safety Task Group.
- 7.255 Changes introduced by Rhondda Cynon Taf as a direct result of the Outbreak include the review of Inspection Protocols. The completion of inspection forms and reports is monitored and officers are required to have sight of original training certificate as evidence of food hygiene training. The practice of sending pre-inspection warning letters to premises due for inspection has ceased.
- 7.256 Rhondda Cynon Taf also took the step of requiring food businesses operators to sign voluntary agreements prohibiting the use of vac packers or slicers for both raw and cooked meats in situations where concerns over cleaning arose during inspections. That decision has been reviewed and "total separation" is now required, irrespective of the legislative requirements.

The Audit of Bridgend's Food Law Enforcement Service by the Food Standards Agency

- 8.1 This Chapter focuses on the role of the Food Standards Agency ("FSA") and issues related to it. The Agency's involvement as a provider of Codes of Practice and guidance on inspections of butchers' premises by local authorities such as Bridgend was dealt with in the previous Chapter. Its role in respect of the Meat Hygiene Service and the inspection of abattoirs is examined in detail in the next Chapter. The Agency's role in the control of the Outbreak is examined in Chapter 11. This Chapter focuses on two main topics:
- (i) The FSA's 2004 audit of Bridgend, which was the food law enforcement service responsible for inspecting the premises of John Tudor & Son ("Tudors"); and:
 - (ii) The broader issues surrounding the funding of FSA Wales by the Welsh Assembly Government, and the view expressed by the Director of FSA Wales that it was under-funded.

The FSA and its Functions

- 8.2 The FSA is a non ministerial government department, established in 2000 by the Food Standards Act 1999 ("the 1999 Act"). The FSA exercises functions under the 1999 Act, the Food Safety Act 1990 and other enactments.
- 8.3 The main objective of the FSA is:
- "...to protect public health from risks which may arise in connection with the consumption of food (including risks caused by the way in which it is produced or supplied) and otherwise to protect the interests of consumers in relation to food."
- 8.4 Food safety is central to this objective.

Structure

- 8.5 The FSA is a UK-wide body with devolved executives in Scotland, Wales and Northern Ireland. It has an Executive Management Board, the membership of which includes Directors from FSA Headquarters in London, the Directors of the FSA in Scotland, Wales and Northern Ireland, and the Chief Executive of the Meat Hygiene Service.
- 8.6 The FSA Directors for the Devolved Administrations are responsible for the smooth operation of the FSA in their respective countries, within the resource constraints imposed locally. In practice, their level of autonomy varies between policy areas. For example, Directors of the devolved arms have taken the lead on areas such as local authority enforcement policy but have relied on FSA Headquarters far more in respect of highly specialised areas such as toxicology.
- 8.7 The Directors report directly to the FSA Chief Executive. There is no separate line of accountability from the FSA in Wales to Welsh Ministers, although Mrs Joy Whinney, Director, FSA Wales, told the Inquiry that there is close liaison on a day-to-day basis with officials in the Welsh Assembly Government. The FSA is accountable to the National Assembly for Wales through Welsh Ministers for the FSA's activities in Wales in the same way that it is accountable through the Secretary of State for Health to the UK Parliament.

FSA Wales

- 8.8 FSA Wales was established in April 2000. At that time there were nine members of staff. Mrs Joy Whinney was appointed as its Director. She came from a post within the Welsh Office's Public Health Division, in which she had led on the Welsh aspects of the Food Standards Bill and the establishment of the FSA. At the time of the Outbreak, the FSA had the equivalent of 21 full-time staff and an annual budget of £2.352 million.
- 8.9 At the time of the Outbreak, the Enforcement Division of FSA Wales comprised six staff, including two Environmental Health Officers. The Division's remit included all local authority enforcement issues, and microbiological food safety, with key responsibilities for:
- (i) Training, general liaison and support to enforcement officers.
 - (ii) Performance monitoring, surveillance and audit.
 - (iii) Managing the response to incidents, including considering the control powers available.
- 8.10 The Enforcement Division is headed by Mrs Jane Davies who has held that position since January 2001. She is one of two Assistant Directors in FSA Wales and deputises for the Director in her absence. Mrs Davies provided written and oral evidence to the Inquiry.

Functions

- 8.11 The FSA was established as the primary source of policy advice on food safety for the Government as a whole and for the devolved governments. Section 6 of the 1999 Act gives the FSA the functions of:
- (i) Developing policies, or assisting in the development by public authorities of policies, relating to matters connected with food safety or other interests of consumers in relation to food; and
 - (ii) Providing advice, information and assistance to public authorities in respect of matters connected with food safety or other interests of consumers in relation to food.
- 8.12 Examples of the way in which the functions have been exercised in Wales include advice to Welsh Ministers on the EU Food Hygiene Regulations and the Butchers' Licensing Scheme. The Agency's food safety input is also evident from its involvement in multi-agency projects such as the "Food for Thought" guidance on public sector food procurement. The latter features in Chapter 10, which examines the procurement arrangements for school meals.
- 8.13 The FSA's statutory functions on food safety also include proposing and drafting secondary legislation in order to improve food safety and standards. Schedule 3 to the 1999 Act gives the FSA power to undertake consultations on draft legislation on behalf of the Secretary of State in England or Welsh Ministers. The FSA also represents the UK's interests on food safety at official level in Europe and internationally.

- 8.14 Section 12 of the 1999 Act gives the FSA the specific function of monitoring the performance of local authorities in enforcing relevant legislation. To enable it to carry out this function, the FSA has statutory powers, amongst others, to:
- (i) Set standards of performance in relation to the enforcement of food law.
 - (ii) Monitor the performance of enforcement authorities.
 - (iii) Require information from local authorities relating to food law enforcement and inspect any records.
 - (iv) Publish information obtained through monitoring the performance of local authorities in enforcing food legislation.
 - (v) Make reports to individual authorities, including guidance on improving performance.
 - (vi) Require local authorities to publish these reports and state what action they propose in response.
- 8.15 The FSA is empowered by Section 19 of the 1999 Act to publish the advice it provides to public authorities and others, including Ministers. Before doing so, the FSA must consider whether the public interest in disclosure is outweighed by confidentiality considerations.
- 8.16 Section 20 of the Act gives the FSA the specific function of providing guidance to local authorities, including health authorities, on the management and control of outbreaks of foodborne illness.
- 8.17 The FSA also has a role in providing guidance and advice to businesses to assist them in meeting legislative requirements. Direction and guidance is provided in Codes of Practice to which local authorities must have regard in exercising their enforcement functions, and other, less formal, advisory documentation.
- 8.18 A wide range of literature, advice and guidance in relation to Butchers' Licensing, food safety management and avoidance of cross-contamination has been issued or endorsed by the FSA over the years. For example, it has:
- (i) Published guidance on general food law (December 2004).
 - (ii) Published the Food Safety Act 1990 Code of Practice and Practice Guidance (February, 2005).
 - (iii) Endorsed the Industry Guide to Good Hygiene Practice: Butchers Shop Licensing Supplement to the Retail Guide (2001), which included guidance on putting Hazard Analysis Critical Control Point (HACCP) procedures in place.
- 8.19 Since the Outbreak, there have been changes to the guidance issued by the FSA. These are summarised at the end of this chapter.

Monitoring Enforcement

- 8.20 The majority of food law is set at the European level. The General Food Regulations 2004, which came into force on 1 January 2005, provide for the enforcement of EU Regulation 178/2002 in Great Britain. As stated earlier, there are a series of Codes of Practice issued by the FSA which provide guidance and a set of practical and detailed standards against which local authorities can enforce.
- 8.21 The responsibility for monitoring and verifying compliance with, and enforcement of, the main body of food law specific to the Inquiry's terms of reference rests with local authorities. The FSA has a responsibility to monitor the way that local authorities discharge their enforcement functions.
- 8.22 The FSA monitors by reference to a Framework Agreement, developed in conjunction with the Local Authorities Coordinators of Regulatory Services ("LACORS") and local authorities across the UK. It was first introduced in 2000 and became fully operational in April 2001. The Framework Agreement contains:
- (i) A requirement for local authorities to produce a service plan for food law enforcement.
 - (ii) A Standard for food law enforcement which local authorities are expected to meet. This sets out the minimum levels of performance expected in relation to all aspects of local authority food law enforcement activity including food hygiene, food safety, food standards, feeding stuffs and imported food. The Standard consolidates the obligations on local authority food enforcement services arising from legislation, guidance and Codes of Practice. This includes local authority performance in relation to inspections, sampling, formal enforcement, promotion and advice to business.
 - (iii) Details of the system by which the FSA monitors local authorities' performance, including details of the Agency's audit scheme of local authorities' enforcement activities.

The FSA Audit Scheme

- 8.23 The Enforcement Division of FSA Wales has the responsibility for monitoring and overseeing the food law enforcement activities of all Welsh local authorities. It also provides training, advice and support to enforcement officers in the authorities. An important part of this function is the formal auditing of enforcement activities. Each audit is led by Environmental Health and Food Standards Officers with lead auditor qualifications.
- 8.24 Bridgend County Borough Council's Public Protection Department was audited by the FSA in 2004, some 18 months prior to the Outbreak. This occurred as part of a planned programme by FSA Wales to undertake full audits of all 22 local authorities between July 2001 and February 2005. Given the problems that were identified with the inspections of John Tudor & Son by Bridgend, this audit and its findings are relevant.

The Audit Process

- 8.25 The audit procedures are set out in a series of Audit Protocols and Checklists. There are protocols for full audits and for audits that focus only on specific elements of food law enforcement services.
- 8.26 Prior to an audit, the Chief Executive of the relevant authority is notified and provided with background information on the nature of, and arrangements for, the audit. Approximately three months notice of the on-site audit visit is provided.
- 8.27 The Local Authority is asked to complete a standard Pre-Visit Questionnaire. The Questionnaire requires an Audit Liaison Officer to be nominated.
- 8.28 In relation to food hygiene, the Questionnaire requires information on staffing, procedures, and enforcement activity. The documents required include:
- (i) The Authority's inspection procedure, including a list of all premises inspected for hygiene over the previous four months.
 - (ii) The Authority's enforcement policy and procedures including lists of premises in respect of which different types of enforcement activity had been undertaken.
 - (iii) A list of licensed butchers' premises.
 - (iv) The Authority's outbreak control plan and a list of any food poisoning outbreaks in the previous two years.
- 8.29 Once received, auditors at FSA Wales review the material to assess whether or not the documentation complies with the Standard. This initial analysis would take in the region of five days.
- 8.30 Before the audit visit, auditors select a minimum sample of ten premises from the lists provided by the Local Authority. Premises are selected to obtain a representative cross-section of the Authority's activities in different types of business. Prior to the visit, the Local Authority is asked to ensure that files and records relating to those premises are available during the visit.
- 8.31 Annexed to the Pre-Visit Questionnaire would be a full list of staff, their positions and their experience. From staffing information provided by the Local Authority, the auditors select staff members to be interviewed. Typically, five officers are selected for interview but this depends on the size of the Local Authority's team. The Local Authority is informed of staff to be interviewed prior to the audit visit.

The Audit Visit

- 8.32 During the course of an audit, the auditors hold discussions with senior managers and interview selected staff. The sample files identified prior to the audit are examined thoroughly and the Local Authority's actions assessed against the Standard. Findings are discussed with the Audit Liaison Officer. This process takes up a substantial part of the auditors' time during the audit.
- 8.33 Formal feedback sessions with the Audit Liaison Officer and others are also incorporated into the audit timetable. These sessions are seen as an important opportunity to communicate key messages to the Local Authority in an informal but direct way.
- 8.34 The on-site audit visit lasts approximately four days. On the final day, a closing meeting takes place at which the Audit Team discuss present their findings and recommendations.
- 8.35 The general intention is that a draft written audit report is produced within 20 working days of the audit on-site visit. The Local Authority then has 20 days to identify factual corrections and to provide comments on the draft. The Authority is also required, within that same timeframe, to provide a draft action plan to address any matters identified within the audit and its recommendations; and to set out a timetable for implementation. A final report is then published along with any finalised action plan. As will be seen below, this aim was not met in the case of Bridgend's audit.

The FSA's Audit of Bridgend

Initial Stages

- 8.36 The FSA contacted Bridgend County Borough Council during the summer of 2003 to inform them that they were to be audited. The Council requested that the audit be delayed as it was experiencing ongoing staffing problems within the Department. That request was agreed and the planned audit timeframe was deferred by a few months.
- 8.37 Another letter was sent to Bridgend's Chief Executive on 22 October 2003 informing him of the FSA's intention to undertake an audit.
- 8.38 The audit team was led by Mrs Davies and included four of her colleagues. Three of the five members of the team were qualified Environmental Health Officers and members of the Chartered Institute of Environmental Health; one held a Certificate of Competence in Food and Agricultural Standards and the other an Advanced Certificate in Food Safety. All had undertaken and completed a training course on the assessment of quality systems.
- 8.39 The letter of 22 October 2003 was accompanied by a Pre Visit Questionnaire. Bridgend were asked to complete and return it by 3 December 2003. The on-site audit visit was scheduled for week commencing 16 February 2004.

- 8.40 However, Bridgend identified logistical problems in complying with the deadline to complete the Questionnaire and so an extended deadline of 16 January 2004 was set. The Questionnaire was returned to the FSA under cover of a letter dated 20 January 2004. That letter, written by Mr Peter Crocombe, Head of Trading Standards, pointed to the fact that the Bridgend's Food Law Enforcement Service had experienced a difficult two year period. He explained that senior members of staff within the Department had left and that a major review of both how the service was operating, and its policies and procedures had taken place. The end result was that many of the documents forwarded with the Questionnaire had been recently re-drafted. The letter stated that Bridgend was looking to the FSA for assistance in improving the service provided within the Borough.
- 8.41 A letter was sent to Bridgend on 11 February 2004 stating that the on-site visit would take place between 17 and 20 February. The letter informed Bridgend of the files the Audit Team wished to inspect during the visit and the staff that were to be interviewed by the auditors. Mr Peter Cole was officially designated as the Liaison Officer who would deal with further requests for information from the auditors, although in oral evidence the Inquiry was told that in reality, Ms Jane Donagh shared this role with him.
- 8.42 The documents provided by Bridgend with the Pre-Visit Questionnaire included:
- (i) Public Protection Overarching Enforcement Policy (September 2002).
 - (ii) Draft version of the Food Safety Enforcement Policy (January 2004).
 - (iii) Inspections and Re-Visits Procedure: Food Safety (date unknown).
 - (iv) A document entitled "Procedures for the Control of Communicable Disease" (September 2000).
 - (v) A list of 28 butchers licensed by the Authority.
 - (vi) Lists of enforcement activities undertaken in the previous two years, including prosecutions; formal cautions; emergency prohibition orders; voluntary closures of food premises; improvement notices; seizures of food and voluntary surrenders of food.
 - (vii) Draft documents entitled "Procedure for Investigating Outbreaks of Communicable Disease" and "Procedure for Investigating Communicable Disease Notifications".
- 8.43 Mrs Davies explained that there was a concern that some of the documents presented were either in draft form or had been recently drafted. Previous versions of the documents were not available for inspection.
- 8.44 The files of 13 licensed butchers' premises were selected at random for review during the audit. However, the aim was to include a mix of premises e.g. a supermarket, a large retailer, as well as high street butchers.

- 8.45 John Tudor & Son was not among the 13 files selected. Therefore, I cannot determine what the FSA would have found or concluded if they had reviewed Bridgend's inspections of Tudors. The FSA's conclusions which, as appears below, were broadly satisfactory, were based on a review of the files of other businesses.

Audit Visit

- 8.46 The process of interviewing staff and reviewing sample files began after the opening meeting.
- 8.47 Mrs Davies described the main components of this exercise as follows:
- (i) The auditor would take a file and would then analyse its contents against a series of published checklists and protocols.
 - (ii) The auditor would tend to look at the three most recent inspections, but would go back further into the file if necessary.
 - (iii) In looking at the files, the object of the exercise was to consider whether it indicated that the correct processes had been followed and that consideration had been given to the appropriate legislation.
 - (iv) The process would also include an assessment of whether:
 - (a) The relevant documentation relating to an inspection was present.
 - (b) The relevant matters had been considered.
 - (c) The appropriate boxes had been ticked.
 - (d) The appropriate options been circled.
 - (v) Correspondence generated by and relating to the inspection would also be viewed as important in assessing whether or not the action taken by the inspector was in fact the correct action and consistent with the corresponding inspection report.
- 8.48 In summary therefore, the audit was "systems" based. It focussed on whether processes were in place rather than on the merits of individual decisions and on individual decision making techniques. Mrs Davies accepted in her evidence that the nature of the process did not necessarily allow the auditor to form a conclusion as to the processes that were undertaken by the local authority officers in order to enable them to fill in the forms. The audit process was principally directed at ensuring that on the face of it, the documents had been filled in correctly i.e. that the right boxes had been ticked.

8.49 So, for example,

- (i) In relation to staff training certificates at a premises such as John Tudor & Son, the audit would only assess whether the EHO had asked the question on staff qualifications. It would not go behind the detail written on the form to identify how EHOs had satisfied themselves that the information given by the food business operator was in fact correct.
- (ii) Similarly, the processes were not designed to test how EHOs went about checking the effectiveness of the HACCP procedures in respect of an individual premises, either from a validation point of view, obtaining evidence that the elements of the HACCP plan are effective, or a verification point of view; that is, ways of determining compliance with the plan.

8.50 Mrs Davies noted that it was possible that some impression in relation to these matters might emerge by reference to any file notes or notebooks that were being reviewed or to questions asked in interview. But this was not the focus of the systems-based audit.

8.51 Mrs Davies acknowledged in her oral evidence that the FSA audit system that operated prior to the Outbreak was not set up to identify the sorts of problems identified by Mr Brian Curtis, Mr Houston and Professor Griffith when they considered the Tudors case. The audit system did not allow for access to the underlying HACCP documentation or its review, and auditors did not accompany EHOs on inspections.

8.52 Counsel to the Inquiry took Mrs Davies through interviews that had taken place with EHOs during the audit. The records of the interviews gave me cause for concern:

- (i) In one of the interviews that Mrs Davies had undertaken, a blank space had been left on the topic of "Knowledge of inspection procedure". How would you undertake an inspection?" Mrs Davies accepted that she had not asked the question of the EHO and could not say why that was the case.
- (ii) A similar position existed in relation to a later question on the interview proforma relating to "Records and inspection reports".
- (iii) It was also evident that although structured forms had been developed by the audit team, only two of the five interviews that took place at Bridgend were conducted by reference to those forms. It was unclear what, if any, structure was followed in the other three interviews or by reference to what criteria or objectives these had been conducted. For example, whilst the pro forma had room to make notes on the topic of inspections, one auditor who had not followed the pro forma had simply written the word "inspections" and placed a tick after it – providing no information on what, if anything beyond the fact of inspections having taken place, had been discussed with the EHO.

- 8.53 The limitations of the FSA's systems-based approach are evident from the notes of interviews with EHOs. Specifically, there was no focus on the approaches that officers took when reviewing HACCP and the effectiveness of HACCP in the butchers' premises that the officer was examining. Nor do those notes indicate any real "drilling down" into what the EHO was, in fact, doing in order to generate not merely an answer, but the right answer, placed on the inspection form.

The Closing Meeting

- 8.54 Although a meeting would take place at the end of each day of the audit to reflect and to provide feedback to the Liaison Officer, the auditors held a formal closing meeting at the end of the audit. It was attended by members of the Public Protection Team and the relevant Council Cabinet Member.
- 8.55 At the meeting, Mrs Davies made it clear that no major concerns had surfaced during the audit. She said there was general satisfaction with Bridgend's food hygiene performance and the Department was particularly strong in formal food hygiene enforcement. The audit findings were summarised and key areas for improvement set out. Mr Crocombe and Ms Donagh acknowledged the weaknesses and issues that had been identified during the audit and said that these would be addressed.

The Results of the Audit

- 8.56 The audit revealed some weaknesses and an instance when the Local Authority inappropriately issued a Butcher's Licence at the same time as an Improvement Notice relating to the breach of Food Safety Regulations remained outstanding. This was contrary to Regulations extant at the time. The audit also identified that records of food hygiene complaints were less comprehensive. In three cases, records were insufficient to determine whether an appropriate investigation had been carried out.
- 8.57 However, in the main, the findings of the Audit Team were favourable. In particular:
- (i) The files reviewed during the audit indicated that the records kept by Bridgend were generally comprehensive and well maintained.
 - (ii) Subject to the instance referred to above, the FSA concluded that Butchers' Licensing had been undertaken by the Authority in accordance with the required criteria and the Standard.

- 8.58 The draft audit report concluded, at paragraph 5.10, that lead officers had the knowledge, training and qualifications required for appointment. However, none of the senior management in the Food Hygiene Team at Bridgend had any significant experience in food hygiene inspections. Mrs Davies stated that the circumstances in Bridgend were unusual, but that Mr Cole and Ms Donagh demonstrated a realisation of their shortcomings and had arranged for extensive training in those areas. Moreover, Mr Cole had demonstrated his knowledge through lengthy discussions with the audit team. While acknowledging the steps taken by Ms Donagh and Mr Cole to seek to ensure that they had additional training, I feel that the audit report should have highlighted the importance of support for them from their line managers.
- 8.59 The draft audit report concluded, at paragraph 7.3, that the Authority had a draft documented procedure for food hygiene inspections and revisits that established a uniform approach to food safety inspections; and that the procedure indicated that inspections would be carried out at the frequency determined by the risk rating scheme set out in Code of Practice No. 9.
- 8.60 However, that document was not as helpful or as comprehensive as it could have been. Mr Cole, accepted in evidence to the Inquiry that the document could have been fuller and more instructive. His evidence in this respect does not sit easily with the FSA's conclusion. It may indicate, in line with its general approach, that the FSA's audit was not focussed on whether the documentation and systems operated were as effective as they could be; for example:
- (i) Paragraph 4.2 of the document gave little guidance to officers who were undertaking inspections on behalf of the Department.
 - (ii) There was no reference to "red flagging" persistent problems to alert the inspector who carried out the next inspection to the problems.
 - (iii) The document did not have any guidance on announced and unannounced inspections/visits, although there is reference to Code of Practice 3, which dealt with announced/unannounced inspections.
 - (iv) As was accepted by Mr Cole, there was no reference to HACCP within it.
- 8.61 Paragraphs 16.4 -16.6 of the draft audit report concluded that the records, including risk rating information, and inspection reports and associated correspondence, were well maintained and comprehensive. Because of the different ratings given by the EHOs in relation to Tudors, Mrs Davies was asked if the audit evaluated the way in which the risk rating for a premises was established. She said that unless a particular issue was identified, there wouldn't have been any direct questions on it. This appears to be another example of the limitations of the systems-based approach. Mrs Davies could not recall being told that the policy within Bridgend was to inspect butchers' premises on a six-monthly basis irrespective of their risk rating, a policy which was a mistake with a positive dimension in that checks were more frequent.

- 8.62 The draft audit report also concluded that “Bridgend were strong in the field of food hygiene enforcement”. Mrs Davies explained that the paper records showed that Bridgend had demonstrated a wide range of enforcement activities. They had used prosecutions, cautions, emergency prohibition action, improvement notices. Mrs Davies explained that the auditor would look at the type of offence and consider whether the path followed by the inspection team was the correct one in the circumstances. There would be an evaluation of whether the local authority chose the best enforcement method on that particular occasion, for example, an Improvement Notice over immediate prosecution.
- 8.63 Paragraph 19.1 of the draft audit report concluded that Bridgend had set up a comprehensive draft documented internal monitoring procedure for food hygiene in accordance with Food Safety Act Code of Practice No. 9 and centrally issued guidance. Mrs Davies confirmed that prior to the draft document created just before the audit, there had been no similar document in place. It also appeared from Ms Donagh’s evidence that for resource reasons, this new document was not being followed shortly after its implementation.

Conclusions on the Audit

- 8.64 It is clear that the FSA’s audit of Bridgend’s Food Safety Team in February 2004 found little systemically wrong with Bridgend’s team and methods of working. However, the conclusions stemmed from an audit that was systems-based and was principally directed at ensuring that on the face of it, the documents had been filled in correctly i.e. that the right boxes had been ticked. The system was not designed to probe how an officer arrived at the decision to tick one box or another, or to examine the techniques of an effective inspection.
- 8.65 Prime responsibility for the quality of inspections rests with individual EHOs and their managers. The FSA audit scheme is atop this, providing the FSA with a means of overseeing local food law enforcement activities and informing practice. It also provides independent assessment and feedback to local enforcement teams for performance and development purposes. The problems that existed at Tudors, the problems with the Bridgend inspections of the business, and the audit of Bridgend in February 2004 leads me to question the effectiveness of some aspects of the audit scheme and the manner in which it was conducted. My concerns, which focus on the inspections dimension, are two-fold:
- (i) The way that some of the audit interviews were carried out in terms of structure and coverage. As Lead Auditor, this was down to Mrs Davies, who herself omitted to ask a key question about how an inspection is undertaken.
 - (ii) The ability of the scheme to cover not only issues such as record keeping, systems and processes, which are important, but also the thoroughness of inspections, particularly in relation to the assessment of HACCP in food businesses as a core component of food hygiene and food safety.

The Production of the Audit Report

- 8.66 The FSA audit of Bridgend took place in February 2004. A draft report should have been produced and sent to Bridgend in March 2004. It was not until over a year later, on 17 June 2005, that a draft report was finally sent to Bridgend.
- 8.67 That draft report was sent to Mr Michael Stoddart, Assistant Director of Public Protection at Bridgend, under cover of a letter dated 17 June 2005. The letter requested Bridgend to consider the report and return it with details of any factual corrections or omissions. Also requested, by 29 July 2005, was a draft Action Plan in response to the audit findings.
- 8.68 Bridgend responded under cover of a letter dated 21 July 2005. Mr Stoddart signed the letter, which pointed out the delay in the production of the report. Mr Stoddart stated that the improvement of service was impaired by the prolonged delay. He stated that the content of the report was now “out of date” and did not reflect the food law enforcement services that were being offered by the Authority at that time. Mr Stoddart felt it appropriate that when the report was published, a note to that effect should be included. A number of points of clarification and comments were raised. Mr Stoddart requested a reply to his letter prior to the Authority submitting a draft action plan.
- 8.69 It seems that no response was made to Mr Stoddart’s letter and consequently no draft action plan was prepared. Mrs Davies states at paragraph 41 of her statement to the Inquiry that the only point raised on food hygiene inspections was in relation para 7.2 of the report and this was amended in the final report, in line with the Bridgend suggestion.
- 8.70 On 16 September 2005, the Outbreak was declared.
- 8.71 The final report was sent to Bridgend County Borough Council on 7 October 2005. At that date, there was no agreed action plan. Correspondence seen by the Inquiry shows that the FSA recognised that the delay in publishing the report put it in a difficult situation. Options for publication were discussed and it was published on the FSA’s web site during the Outbreak, on 13 October 2005. No doubt the decision was influenced by the level of media interest in the audit and two requests under the Freedom of Information Act for a copy of the report.
- 8.72 The delays in the production of the draft and final reports were unfortunate. The timely production and publication of such reports can only be of assistance in securing improvement in the standards of enforcement of food safety. Most, if not all, such audits will include valuable lessons that other local authorities can learn from.

- 8.73 I accept that the weight of concern at these delays is lessened by two facts. First, the FSA communicated its key conclusions to Bridgend at the closing meeting. The draft and final reports were likely therefore to cover ground that had already been discussed at the end of the audit. Second, if a matter of general importance is discovered during an audit, the FSA can publish and circulate guidance covering that issue. That said, these facts do not justify the delay. The FSA failed to adhere to its own timetable for the audit process, which included the timescale for the production of the draft report and action plan. In addition to identifying under-performance, the audit scheme aims to identify and disseminate good practice and to encourage continuous performance. Prompt preparation and publication of the audit reports and action plans is therefore essential to meeting these aims, both for the local authority that is the subject of the audit and other local authorities in Wales.
- 8.74 It appeared from the evidence of Mrs Joy Whinney, Director of FSA Wales at the time of the Outbreak, that the delays in publishing audit reports were caused by resource issues, volume of work and consequent decisions by the FSA to prioritise what were perceived to be more pressing issues. She said that FSA Wales did not originally have a dedicated Audit Team. The audits were undertaken by enforcement officers in FSA Wales as part of their overall responsibilities. When urgent and unexpected situations arose on food safety, the ongoing work of drafting audit reports could not be given priority.
- 8.75 The delay in the production of written audit reports was not confined to Bridgend. It had been a problem for some time before the Bridgend audit. By November 2003, 11 local authorities in Wales had been audited. Final written reports, with agreed action plans, had been published for only three of them. Draft written reports had been produced in respect of another three.
- 8.76 A meeting took place with the authorities affected. The authorities had a particular reason for being concerned at the delays. The FSA's reports could be used when departments applied for annual funding to carry out their food safety enforcement activities. The proposal they made was that the outstanding reports should be published before the audit programme continued. This was discussed internally at FSA Wales and the decision taken was to continue with the programme of on-site audits rather than completing the reports for the authorities that had already been audited. Mrs Whinney explained that FSA Wales had insufficient resource to complete both the on-site audits and the report writing for all 22 authorities in Wales, given the increased demands on the enforcement team. It was not possible to resolve the problem by re-assigning other FSA Wales staff to audit work because of the need for professionally qualified staff to undertake it.
- 8.77 In the event, the FSA was able, by 7 December 2005, to publish audit reports on all 22 authorities that had been audited.

Funding of FSA Wales

- 8.78 The explanation for the delays in the preparation and publication of the audit reports by FSA Wales, and the evidence of Mrs Whinney, led to evidence being received on the broader issue as to whether FSA Wales was adequately funded to carry out its functions.
- 8.79 Written evidence was received from Mrs Ann Lloyd, the Head of the Welsh Assembly Government's Department for Health and Social Services and Chief Executive of the NHS in Wales, and the sub-accounting officer for the Health and Social Services Budget; also from Mr Peter Farley, Acting Head of the Health Protection Division. Oral and written evidence was received from Mrs Whinney, the Director of FSA Wales.

The Budget Process

- 8.80 The FSA's Headquarters and staff, and its activities in England are funded directly from HM Treasury. The FSA's arms in the Devolved Administrations are funded by those Administrations, pursuant to section 39 of the Food Standards Act 1999. Therefore, FSA Wales is principally funded by Welsh Ministers. It submits bids for funding to the Welsh Assembly Government and presents the case for the amounts sought in bids.
- 8.81 Mrs Lloyd explained that the process of Departments submitting bids for funding normally starts in the spring with the Finance Minister inviting Departments to identify their funding requirements for the following three financial years, on a rolling basis. Initial submissions are then made to the Finance Minister in early summer. These are considered through meetings between the Finance Minister and the Ministers submitting the bids. Detailed draft budgets are then prepared and published in early autumn. The final budget is subject to debate and a vote by the National Assembly for Wales to approve it.
- 8.82 FSA Wales' bids are made as part of the larger bid submitted by the Department for Health and Social Care. That Department covers the broad range of health and social care programmes including the provision of NHS services in Wales. Mrs Whinney explained that in Scotland and Northern Ireland, the mechanisms for submitting bids for funding and for negotiating bids are different. They involve FSA Executives negotiating directly with HM Treasury equivalents in those administrations, whereas in Wales the bids are made to the Finance Division of the Assembly's Health and Social Care Department.
- 8.83 FSA Wales saw this as a significant disadvantage and repeatedly lobbied the Welsh Assembly Government on the issue. FSA Wales' perception was that this mechanism placed it at a disadvantage principally because:
- (i) Bids were submitted through the Health and Social Care Department.
 - (ii) Negotiations that occurred were conducted principally by those with responsibility for the entirety of that budget, in which the FSA was a relatively small line item.
 - (iii) FSA Wales' bids in effect competed directly with NHS priorities.

- 8.84 Mrs Whinney produced correspondence which showed that the issue of funding had been raised. For example, the letter of 21 February 2005 to the Head of the Public Health Division, which specifically pointed out the link between the under-resourced FSA and delays in the production of Local Authority audits. The Welsh Assembly Government also produced copies of the minutes of quarterly liaison meetings with the FSA at which the issue of under funding is clearly raised.
- 8.85 The Assembly Government pointed to discussions in April 2004, when the then Acting Director of FSA Wales, Mr Steve Wearne, indicated that there were no strategic unfunded pressures. The FSA countered this by explaining that he was seeking to work within the funding allocated by the Assembly Government and to prioritise expenditure, and that under funding was raised again in September 2004.
- 8.86 Both the Welsh Assembly Government and FSA agree that prioritisation on the use of funding is a matter for the FSA. The Assembly Government states that the FSA's core role is food safety and points out that discussions on unfunded pressures was not only about food safety and enforcement but about other work such as dietary health and nutrition. The FSA argues that such work is not a discretionary supplement to its main activities and is part and parcel of its central function.

Funding of FSA Wales before the Outbreak

- 8.87 The monies allocated to FSA Wales by the Welsh Assembly Government in the period leading to the Outbreak were as follows:
- (i) In 2001/02, the allocated budget was £2.230 million. During the 2001 bidding round, the FSA's bids for increased core budget, including for FSA expansion, were rejected.
 - (ii) In 2002/03 the budget was established as a baseline at £2.351 million.
 - (iii) A three year bid was submitted in the 2002 budget planning round for 2003/04, 2004/05 and 2005/06. The bid included an item in respect of the increase to the funding baseline that was presented by FSA Wales as necessary for the implementation of food safety management systems for food businesses, based on HACCP, which mirrored bids in other parts of the UK. The bid failed and a reduction of £0.074 million was imposed in 2003/04. As a result, the FSA pursued the possibility of funding a scaled down Food Fraud Investigation Unit. This renewed bid for £0.075 million led to a £0.075 million increase to the FSA's baseline funding in 2004-05.
 - (iv) In 2005, the FSA produced a business plan/case for increased funding. That was completed in draft form on 27 April 2005 and sent to the NHS Finance Department. It included a comparative table with funding in other devolved administrations. A finalised bid was sent on 12 May 2005. The updated bid sought £1,041,000 in addition to the baseline budget of £2.352 million. This increased amount covered a wide range of Agency work, including a specific bid for funding to promote food safety management systems. On 26 July 2005, the Welsh Assembly Government wrote to FSA notifying them that funding for 2005-06 was £2.352 million. The additional bid had effectively failed.

Funding of FSA Wales after the Outbreak

- 8.88 The Outbreak occurred in September 2005. As a result, there were urgent discussions on the budget between Dr Jon Bell, the FSA Chief Executive, and Sir Jon Shortridge, Permanent Secretary to the Welsh Assembly Government. FSA Wales was invited to submit a supplementary bid for 2005/06, which was done on 3 November 2005. The headline figure in the bid showed that £1.5 million was sought. The bid was accompanied by a business case. Subsequently, Dame Deidre Hutton, Chair of the FSA Board met Dr Brian Gibbons, Minister for Health and Social Services. The divergence in funding between FSA Wales and FSA Executives in the rest of the UK was raised.
- 8.89 In a meeting between Welsh Assembly Government officials and FSA Wales, the FSA was advised that an additional £121,000 was being made available for 2005/06. Dame Deidre Hutton wrote to Dr Gibbons expressing her disappointment that only part of the bid had been met by the Assembly Government and stating that it was inadequate to address the cumulative under-funding position which existed at FSA Wales. Comparisons with the other administrations were again raised. The FSA explained that the under-resourcing of the Agency by the Assembly Government carried real risks in terms of the Agency's ability to operate effectively in the interests of consumers in Wales. The Welsh Assembly Government maintained the increase of £121,000 for 2005/06 in a letter to the FSA on 26 January 2006.
- 8.90 The FSA's budget for 2006/07 was increased to £2.852 million, an increase of £379,000 on that for 2005/06. Mrs Whinney again complained to the Health Finance Division that this was not sufficient and did not meet the FSA's needs.
- 8.91 In June 2006, the Assembly Government's Health Protection Division was asked by the Permanent Secretary to undertake a detailed review of FSA accountability and funding in light of the FSA's bids. The review included information on funding and comparative information from other parts of the UK. It recommended the following:
- (i) FSA Wales enter into a broad service delivery agreement with the Welsh Assembly Government.
 - (ii) FSA Wales deliver presentations on their work and achievements on an annual basis to the Health and Social Services Committee and the Environment, Planning and Countryside Committee.
 - (iii) Annual meetings to be organised between the Minister for Health and Social Services and the Chair of the FSA.
 - (iv) FSA Wales to attend an annual strategic review meeting with Assembly officials, details and representation to be agreed.

- 8.92 In August 2006, correspondence between Dr Gibbons and Dame Deidre Hutton confirmed that a review of the working relationship and areas of responsibility of the FSA and the Welsh Assembly Government had taken place. A Concordat, or agreement, was to be drafted. There was acceptance on the Assembly Government's part that FSA Wales appeared under-funded compared with other administrations. The Minister took the view, in light of the relatively small size of the FSA budget, that it could not be funded outside the Health and Social Services Main Expenditure Group. The Minister invited the FSA to bid for additional resources for 2007-08 and 2008-09.
- 8.93 In July 2007 and following further negotiation and bids, the FSA were informed that their baseline budget had been increased to £3.502 million for 2007/2008.
- 8.94 In March 2008, FSA Wales received confirmation that budget provision for 2008/09 remains at £3.502 million.

The Issue of Under-funding

- 8.95 Mrs Whinney's view, given in evidence to the Inquiry, was that FSA Wales was under-funded compared to other arms of the FSA in the UK, and that this had a significant impact on the effective performance of the Enforcement Division's functions, including the audit programme. She produced tables making that comparison. The Welsh Assembly Government also produced, in a paper prepared for Ministers and senior officials, a comparison of FSA funding throughout the UK.

Table 8.1: Comparison of FSA Funding in Scotland, Wales and Northern Ireland, 2000/01 to 2006/07

Financial Year	Scotland	N Ireland	Wales
2000/01	£5.154	£1.110	£1.457
2001/02	£5.805	£1.200	£2.230
2002/03	£5.498	£1.461	£2.351
2003/04	£6.372	£2.864	£2.277
2004/05	£8.345	£2.820	£2.352
2005/06	£9.771	£3.825	£2.473
2006/07	£10.271	£3.831	£2.852

Source: Welsh Assembly Government

- 8.96 The Assembly Government's paper explained that over the period since 2002/3, FSA Scotland's budget had increased by 87%, Northern Ireland's by 162%, and Wales's by 21%. It said that in per capita terms, in 2006/7, Scotland's budget equated to £2.02 per head of population, Northern Ireland's to £2.24, and Wales's to £0.97.

- 8.97 I am well aware that the public purse is not unlimited. Within the finite resources available, difficult decisions have to be made by the Welsh Assembly Government on competing demands for those resources. It is often the case that public bodies performing important public functions do not receive the budget they would wish. Ultimately, it is for each public body to work within the budget allocated to it; and to prioritise its work accordingly. It is inevitable that in those circumstances, some parts of the performance of the public body's functions may suffer in order to enable other parts, considered to be of greater priority, to be performed the more effectively. Mr Farley pointed out that FSA Wales' budget was available to it to be spent and prioritised as FSA Wales saw fit.
- 8.98 I note that the funding issue arose principally in the context of the delay in production of the draft and final audit reports. However unfortunate that delay, there is nothing to suggest to me that that delay contributed to, or exacerbated, the Outbreak. Moreover, the FSA does not suggest that the budgetary constraints under which they were operating had a material impact on the manner in which they conducted the audit of Bridgend in 2004.
- 8.99 In these circumstances, I do not consider it necessary to resolve the question as to whether Mrs Whinney's view that FSA Wales was under-funded compared to other arms of the FSA was well founded. Nor am I in a position to make any judgements as to whether the delays in production of audit reports could, or could not, have been avoided. I have no reason to believe that those responsible for FSA Wales were making prioritisation decisions on anything other than a proper and efficient basis. I simply note the following matters without, I must emphasise, making any judgement on the issue of funding:
- (i) Ms Whinney produced figures comparing the funding of FSA's arms in England, Scotland, Northern Ireland and Wales. It is of, course, a crude comparison based on total funding. While there are common strands, different countries have different priorities and starting points. A full comparison would require considerably more detail than was available to the Inquiry including, for example, the extent to which the regional arm relied on FSA Headquarters in London. Nevertheless, at the time of the Outbreak, there was a striking difference in the overall funding levels, notably between Scotland and Wales, with FSA Scotland receiving around four times the funding of FSA Wales.
 - (ii) FSA Wales raised what it perceived to be under-funding and the problems caused by it on a number of occasions. The matter was the subject of discussion with the Welsh Assembly Government over several years.
 - (iii) The apparent under-funding of FSA Wales appears, ultimately, to have been accepted by the Welsh Assembly Government. After the Outbreak, its funding including in particular the baseline funding was increased significantly.

Developments since the Outbreak

- 8.100 The FSA has reviewed its audit scheme and consulted with local authorities in Wales as part of the process. I note that the intention is for audits to remain systems-based, but with a focus on outcomes and the use of “reality checks”, which would involve auditors attending and observing inspections. The proposed changes will be reflected in the audit programme on a pilot basis.
- 8.101 FSA Wales is planning to develop its audit programme around a series of “Focused Audits”, which are considered to be increasingly risk and outcome based. Each audit will incorporate some reality checks. Full audits will be used in exceptional circumstances where there is a need for a comprehensive assessment of an authority’s entire food law enforcement service.
- 8.102 The staffing of FSA Wales’ Enforcement Division has been strengthened and now includes four Senior Environmental Health Officers. In early 2006, guidance was published on new food hygiene legislation and the application of HACCP principles. Guidance on General Food Law was re-issued in July 2007 while revised Codes of Practice for England and Wales were published on 17 June 2008 and 18 September 2008 respectively.

The Inspection of J.E. Tudor & Sons Ltd by the Meat Hygiene Service

- 9.1 While the Outbreak itself was dominated by the focus on the butcher's premises of John Tudor & Son, I wanted to check if there was anything further down the food chain that could have contributed to it. What I found led to an abattoir and the inspections of it by the Meat Hygiene Service ("MHS") becoming a significant strand of the Inquiry's work.
- 9.2 This chapter considers in detail the Abattoir operated by J.E. Tudor & Sons Ltd at Treorchy (the "Abattoir"), and the role of the MHS in enforcing food safety legislation in relation to it. The word "slaughterhouse" may on occasions be used instead of "abattoir", which reflects the wording in legislation and in evidence submitted to the Inquiry.
- 9.3 The significance of the Abattoir is explained in Chapter 5. The results of microbiological testing and typing confirmed the same strain of *E.coli* O157 in cattle faeces, on raw meat recovered from John Tudor & Son's premises, on cooked meats recovered from schools, and in people who were infected. Given that cattle from the Farm (Chapter 5 refers) were slaughtered at the Abattoir in the days and weeks before the Outbreak, and that it supplied John Tudor & Son with raw meat, it can therefore be inferred that the organism passed through the Abattoir to John Tudor & Son and then on to individuals.
- 9.4 The Abattoir owned by J.E. Tudor & Sons Ltd was located in a very old building. First constructed around 1860, it was located near the centre of Treorchy, which is a small town in the Rhondda Valley. The Abattoir was owned and operated initially by William (Billy) Tudor. From approximately 2001 onwards, its operation was taken over by his son, Jonathan. Jonathan Tudor is a cousin of William Tudor who, as explained in Chapter 6, operated John Tudor & Son as a catering butcher in Bridgend.
- 9.5 As explained in my introduction, I did not designate J.E. Tudor & Sons Ltd as a core participant because the focus of my investigation was the inspection of the Abattoir by the Meat Hygiene Service. However, in advance of the oral hearings, Jonathan Tudor, the manager of the Abattoir at the time of the Outbreak, received a copy of all the relevant material provided to the Inquiry by the MHS and was given an opportunity to respond. He chose not to.
- 9.6 Butchers have to design and operate their processes on the assumption that the meat they receive from abattoirs and other sources may contain *E.coli* O157. However, an abattoir's processes also need to minimise the chances of meat infected with *E.coli* O157 being supplied up the food chain. Two steps are particularly important:
- (i) The hide must be removed carefully to prevent the outside of it coming into contact with the animal's raw flesh.
 - (ii) The gastro-intestinal tract, which hosts the *E.coli* O157 organism, must also be removed carefully to prevent its contents contaminating the surface of the carcass.
- 9.7 The Inquiry called for, and received, a considerable quantity of material about the operation of the Abattoir over a long period and the enforcement steps taken by MHS. The MHS was responsible for enforcing the food hygiene regime set out in legislation.

- 9.8 The central purpose of food hygiene legislation is to minimise the risks of unsafe meat progressing up the food chain. At the risk of stating the obvious, legislative requirements are not optional. They need to be complied with by those, such as J.E. Tudor & Sons Ltd. Bodies, such as the MHS, which are responsible for enforcing such requirements, also need to carry out the functions ascribed to them. This Chapter examines the methods of enforcement used by the MHS in the case of the Abattoir.

Prior to the Establishment of the Meat Hygiene Service

- 9.9 In 1991, an EU Directive had the effect of making a common market for meat. The Fresh Meat (Hygiene and Inspection) Regulations 1992 ("the 1992 Regulations"), implemented that Directive into UK law. At that stage, the competent authority for implementation of the legislation was the Ministry of Agriculture, Fisheries and Food ("MAFF"). The responsibility for licensing decisions in Wales rested with the Secretary of State for Wales.
- 9.10 It was recognised in the 1992 Regulations that it might take some time for businesses to make the changes required to satisfy the new legislative requirements. To that end, the Regulations included transitional provisions. The effect was to exempt certain types of business from the full rigour of the new requirements for a period of time. That applied to the requirements relating to the structure of the building. It did not apply to the new requirements governing hygiene practices, which had to be complied with by all businesses from the date the 1992 Regulations came into force.
- 9.11 Pursuant to the 1992 Regulations, decisions made at Ministerial level in respect of licensing were subject to appeal to a specialist Tribunal. At that stage, the daily responsibility for official control remained with local authorities. They operated through a combination of Official Veterinary Surgeons ("OVSs") and Meat Hygiene Inspectors ("MHIs"). The OVS was responsible for all of the official controls in a slaughterhouse and was assisted by the MHIs. MHIs were permitted to assist the OVS with all tasks except ante-mortem inspection. Further, if anything unusual was found by a MHI at the post-mortem stage, a referral had to be made to the OVS.

The Establishment of the Meat Hygiene Service

- 9.12 The MHS is now an Executive Agency of the Food Standards Agency ("FSA"). It had operated as an Executive Agency of the Ministry of Agriculture, Fisheries and Food, the predecessor to what is now the Department for Environment, Food and Rural Affairs. The MHS describes itself as "...first and foremost an enforcement body and its primary function is the full and proper enforcement of hygiene rules...in licensed meat premises."
- 9.13 On 1 April 1995, the MHS took over meat inspection duties at abattoirs from local authorities. From its inception, the MHS was staffed by MHIs who came from local authorities and OVSs, the majority of whom were employed on contract from local veterinary practices.

The Fresh Meat (Hygiene and Inspection) Regulations 1995 (“the 1995 Regulations”)

- 9.14 The 1995 Regulations came into force on 1 April 1995 and gave effect to Council Directive 91/497/EEC. It amended and updated a previous Directive relating to health problems affecting intra-Community trade in fresh meat to extend it to the production and marketing of fresh meat. Concerns had been identified by the European Commission’s auditors. The European Commission took formal infraction proceedings against the UK for failure to implement Community Law correctly. In addition, two specific outbreaks had given greater impetus to the need to change and drive up standards. The outbreak of *E.coli* O157 in Scotland had occurred, as had BSE, or as it is more commonly known, “mad cow disease”.
- 9.15 The basic requirement was for slaughterhouses to be licensed by the relevant Minister. Unlike Butchers’ Licensing, that did not involve periodic re-applications by slaughterhouses. A licence, once issued, was permanent, but could be subject to revocation. If an application for a licence was refused, there was the possibility of an appeal to a specialist Tribunal set up under the 1995 Regulations. The Tribunal’s jurisdiction was not simply one of review. It could substitute its view for the appropriate decision in the event that it disagreed with the Minister’s decision.
- 9.16 For a business such as the Abattoir in question, three requirements needed to be met:
- (i) The construction, layout and equipment used at the premises had to meet the detailed requirements set out in the Regulations.
 - (ii) The method of operation had to meet specified requirements.
 - (iii) The meat processed had to be inspected post-mortem, and if rejected, should not be used.
- 9.17 The method of operation requirements were contained in Schedule 7 of the 1995 Regulations.
- 9.18 In relation to construction, layout and equipment, the details of the requirements that needed to be met were dealt with in Schedule 5 of the 1995 Regulations. Schedule 5 applied to low-throughput, that is, handling relatively small numbers of animals, slaughterhouses such as that in Treorchy. However, the possibility of obtaining exemptions from some of the stricter requirements relating to construction, layout and equipment continued from the 1992 Regulations. That transitional position was initially until 1 January 1996, but was then extended by subsequent Regulations to a later date at the discretion of the Minister. This applied in the cases of slaughterhouses where the operator had begun to bring the premises into compliance with the requirements and had demonstrated to the satisfaction of the Minister that, for reasons not attributable to him, the requirements could not be met by 1 January 1996.

- 9.19 Regulation 11 related to inspection and a system of Health Marking. The purpose of the Health Marking system was set out in Regulation 11(2) which provided that where fresh meat was intended for sale for human consumption, it must have been passed fit for human consumption following ante and post-mortem health inspections, and complied with the requirements of the Regulations, and been Health Marked. Regulation 11(5) provided that the Health Mark should be applied by persons acting under the responsibility of an OVS, and that no other person should apply the Health Mark or possess or use the equipment for applying the Health Mark.
- 9.20 Accordingly, the 1995 Regulations made provisions which required focus on both the premises and the practices operated at slaughterhouses. Because the microbiological cleanliness or safety of the meat produced by a slaughterhouse could not be determined as a result of the visual inspection, food safety could not be guaranteed. The Regulations were designed rather to ensure that the premises and practices minimised the risks of unsafe food being produced.

Duties and Enforcement

- 9.21 Regulation 8 of the 1995 Regulations provided detail of the functions of the OVS and MHI.
- 9.22 The OVS was responsible for:
- (i) The ante-mortem health inspection of animals in accordance with Schedule 8 of the Regulations.
 - (ii) The post-mortem health inspection of slaughtered animals in accordance with Schedule 10.
 - (iii) The Health Marking of fresh meat.
 - (iv) Securing the observance of the requirements relating to the premises and the practices as set out in the Schedules, including Schedules 5 and 7.
- 9.23 The MHIs acted under the supervision and responsibility of the OVS. Regulation 8(4) made it clear that they should only make initial checks on animals and assist with purely practical tasks.
- 9.24 Regulation 20 was specifically entitled "Duties of the occupier". It set out a variety of precise and express duties, including duties on the occupier/operator to:
- (i) Keep an adequate record of the number of animals received into the premises, and the amounts of fresh meat despatched from the premises during each week.
 - (ii) Take all practicable steps to secure compliance by any person employed by him or by any person invited onto the premises with the provisions of the Regulations.

- (iii) Ensure that an OVS, Inspector or Veterinary Officer is provided with adequate facilities so as to enable him to carry out his duties under the Regulations and that he is given such reasonable assistance and access to records as he may from time to time require for that purpose.
- (iv) Take all necessary measures to ensure that, at all stages of production, the requirements of the Regulations are complied with and carry out checks (including any microbiological checks the Minister may require) on the general hygiene of conditions of production in his establishment to ensure that equipment and, if necessary, fresh meat, comply with the requirements of the Regulations.

- 9.25 Mr Peter Hewson, Acting Veterinary Director of the FSA, suggested in his statement to the Inquiry that the 1995 Regulations were less than satisfactory. The implication appeared to be that this made the task of the MHS more difficult. The particular issue he identified was what he characterised as a blurring of the lines of responsibility for the production of safe food as between the operator and the OVS.
- 9.26 I do not consider that to be an accurate or relevant characterisation of the 1995 Regulations or their effect. It is not accurate because the duties and functions on those involved are clearly and expressly set out in the 1995 Regulations. As appears from the terms of the 1995 Regulations, the operator has to comply with the requirements in relation to the premises and the practices operated at the slaughterhouse. It is the OVS's job to take whatever steps are appropriate and necessary to ensure that the operator does so. I have seen no evidence to suggest that there was any real confusion in the case of the Abattoir.
- 9.27 In fairness to him, in his oral evidence, Mr Hewson accepted that, if there was any doubt about roles and responsibilities, Regulation 20 put the matter beyond any conceivable doubt; and that that Regulation provided a clear and express duty or responsibility on the operator. It is also to be noted that Mrs Jane Downes, the Veterinary and Technical Director of the MHS, accepted in oral evidence that the 1995 Regulations, and subsequent Regulations that refined and added to them, were a perfectly workable scheme for seeking to minimise the risk of unsafe food entering the food chain.
- 9.28 The ultimate sanction for failure to comply with the requirements in the 1995 Regulations was revocation of the operator's licence. This was dealt with in Regulation 5. It conferred a discretion on the relevant Minister to revoke in two relevant circumstances:
- (i) "the conditions of hygiene at those premises are inadequate and the occupier has failed to take the necessary measures to make good the shortcomings within such period as the Minister may specify" ; or
 - (ii) "any requirements of these Regulations as to hygiene has not been complied with and inadequate or no action has been taken to ensure that a similar breach does not occur in future."

- 9.29 It is to be noted that in relation to the second of these grounds the Minister could properly have taken into account persistent past breaches; particularly if those breaches were of a similar or identical nature.
- 9.30 One of Mr Hewson's principal concerns about the regime was that the Tribunal to which revocations of licences could be appealed by an operator was readily satisfied once the operator had rectified specific identified problems. At paragraph 9 of his statement Mr Hewson stated that the Tribunal tended to favour the operator, where it was shown that the specific problems identified at the refusal visit had been addressed. Mr Hewson further stated in oral evidence that the plants would change their company name, re-apply for a licence, and on the day of re-applying, do just enough to comply.
- 9.31 I am unconvinced by Mr Hewson's argument. It is clear that the second of the legislative grounds for revocation would have enabled those considering it to rely on persistent, similar breaches on compliance. The solution to whatever perceived difficulties there might have been with the Tribunal's decisions was to operate an effective enforcement policy. If that had been done in a way that moved from initial light-touch enforcement to increasingly serious measures, an operator would either have dealt with the source of the repeated non-compliance, or a clear picture would have emerged of a refusal or failure to take the necessary steps. That picture could then have been used as the foundation for an application for revocation that could properly have been defended before a Tribunal. It should have been possible to ensure that devices, such as changes of name, were not used abusively to circumvent the system.
- 9.32 It is also to be noted that in 2001, the enforcement regime was given new and additional tools. The Meat (Enhanced Enforcement Powers) (Wales) Regulations 2001 provided an additional power, short of revocation, to suspend an operator's licence. They also provided a new power for the OVS, short of suspension, to give notice to the operator when it appeared that:
- (i) Any of the requirements of the Regulations as to hygiene were being breached, or:
 - (ii) Adequate health inspection in accordance with the Regulations was being hampered.

The Meat (Hazard Analysis and Critical Control Point (Wales) Regulations 2002 ("the HACCP Regulations"))

- 9.33 The HACCP Regulations gave effect in Wales to European Commission Decision 2001/471/EC, by amending the 1995 Regulations. The purpose and effect was to introduce a requirement for HACCP principles to be applied in slaughterhouses, as an additional means of minimising the risks of unsafe food being produced by slaughterhouses.

- 9.34 Regulation 3(7) imposed a number of additional duties on the operator, which were additional to those in Regulation 20 of the 1995 Regulations. The operator of any licensed slaughterhouse was required to conduct regular checks on the general hygiene of conditions of production in their premises by implementing and maintaining a permanent procedure developed in accordance with a number of principles. These principles were to:
- (i) Identify any hazards that must be prevented, eliminated or reduced to acceptable levels.
 - (ii) Identify the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or reduce it to acceptable levels.
 - (iii) Establish critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards.
 - (iv) Establish and implement effective monitoring procedures at critical control points.
 - (v) Establish corrective actions when monitoring indicates that a critical control point is not under control.
 - (vi) Establish regular procedures to verify whether the measures outlined above are working effectively.
 - (vii) Establish documents and records commensurate to the nature and size of the business to demonstrate the effective application of these measures and to facilitate official controls.
- 9.35 The HACCP Regulations came into force for “small meat establishments” such as the Abattoir on 7 June 2003. They required operators to apply the HACCP principles set out in Regulation 3(7). Thus, from that date in June 2003, Parliament had decided that operators needed to comply with the HACCP Regulations. This process was not introduced overnight. There had been substantial warning that the HACCP Regulations would be introduced as a legislative requirement in relation to small slaughterhouses such as the Abattoir, given that the Commission Decision was dated 8 June 2001, and larger establishments had been subject to the Regulations since June 2002.
- 9.36 Mr Hewson again suggested in his statement and in his oral evidence that the HACCP Regulations were not easy to implement or enforce.
- 9.37 His first point was that a difficulty arose because the HACCP Regulations were being introduced in a legislative environment where operators did not have, what he described as “full and unambiguous responsibility for the production of safe food”. I do not consider that this is any more accurate or relevant than his suggestion that the perceived blurring of roles hampered effective implementation of the legislation. The principles set out in the HACCP Regulations were well-established HACCP principles. There should have been no insurmountable difficulty in taking all necessary steps to enable the industry, with such assistance as was necessary from, for example, the MHS/FSA, to comply with them in an effective manner and on time.

- 9.38 Mr Hewson's second suggestion, made in oral evidence, was that, to have enforced the law as enacted by Parliament would have had the effect of shutting down the meat processing industry. As he put it in answer to questions, "it depends whether you want an industry or not. We could have just implemented it to the letter of the law, as you suggest, and import our meat". I do not support that expression. I do not accept that this would have been the position and it is of concern to me that that should have been the position of someone as senior as Mr Hewson. Mr Hewson himself has explained that the answer was given in the heat of the moment and that it was ill-judged and inappropriate.
- 9.39 My conclusion is that it was for the FSA, as the policy makers, and the MHS as its enforcement arm, to take whatever steps were necessary to educate and train, and then enforce the requirements that Parliament had decided should be in place. That could, and should, have occurred in advance of the date on which the requirement came into force to a level that operators were in a position to comply with the legislation either on, or shortly after, the date set by Parliament.
- 9.40 Having said this, it is evident that some steps were taken to this effect. Mrs Downes stated that the MHS did ensure that their staff were properly trained, explaining that MHS OVSs were given an hour a month with small premises to discuss HACCP with the operator and give advice and some training. Training courses were run in the period up to July 2003. Mrs Downes stated that she personally wrote to all premises in July 2003 informing them that the time had come for HACCP to be implemented. However, it is evident from the difficulties of enforcement and the scale of non-compliance in the months and indeed years after the date the requirements came into force that the preparatory work had been inadequate.
- 9.41 However, in relation to the Abattoir, the documents indicate that some guidance and explanations were, in fact, given to Jonathan Tudor in advance of the 1 June 2003 implementation date applicable to him. Such guidance included the following:
- (i) 10 April 2002: Guidelines on HACCP by the OVS, Mr David Phillips.
 - (ii) March 2003: HACCP implementation discussed.
 - (iii) May 2003: a meeting with Jonathan Tudor to go through the HACCP legislation.
 - (iv) May 2003: Jonathan Tudor states that he does not need help with the implementation of HACCP.
- 9.42 Despite the assistance provided, nothing came of it. As explained later in this Chapter, it did not lead to the development of an effective HACCP plan by the required date or indeed, within a reasonable timescale thereafter.

“Light touch” or Non-enforcement of HACCP

- 9.43 Mr Hewson stated that there was a deliberate FSA policy to allow operators longer than the legislation allowed on its June 2002/2003 dates to comply with the legislative requirements. He confirmed that in practice, some operators were allowed until 2006 when the 2006 EU Regulations came into force to apply HACCP properly. The other MHS witnesses also referred to a policy of “light” or non-enforcement of the HACCP Regulations.
- 9.44 The documents produced by the MHS after the oral hearings confirmed the existence of such a policy. This policy was the FSA’s. It was reflected in instructions to the MHS. In the initial period, the policy was that the MHS were to encourage and advise small establishments on HACCP but not take any formal enforcement action. This period lasted until the end of February 2004. On 27 February 2004, the policy changed. In relation to small establishments, formal enforcement action was to be taken but only in relation to establishments which had made no effort to implement HACCP requirements. For those which were assessed to have made such an effort, encouragement and cajoling should continue with informal enforcement action, verbal or by letter, being the limit of the enforcement action. The policy was reflected in a new Chapter 5 of the MHS Manual, introduced in February 2004. This was then amended in May 2004. At this stage, Chapter 5 continued to suggest a light touch approach where in summary, genuine efforts at compliance were being made. However, it also made clear that for others the enforcement hierarchy should be followed. In fact, it appears from the MHS Annual Report for 2004/2005 that that hierarchy was not followed to a point beyond Improvement Notices in any case in that period.
- 9.45 Mr Hewson sought vigorously to defend this policy.
- 9.46 His first reason was that the HACCP Regulations did not add much, or were not perceived as adding much to the current legislation. He stated that in regulatory terms, the prescriptive nature of the 1995 Regulations provided for production of meat as safe as possible and, for slaughterhouses, HACCP did not really add a great deal, except to transfer the responsibility for the production of safe meat to the operator away from the OVS. Mr Hewson stated that if the introduction of HACCP was not critical to the industry, then it should be given time to do it properly.
- 9.47 This seems to me a surprising and unfortunate position. It appears to suggest a deliberate choice by the MHS not to press ahead as quickly as possible with measures that Parliament had decided were necessary for the purpose of enhancing the prospects of safe food being produced by slaughterhouses. The necessity of the HACCP Regulations was a matter for Parliament, whose decision should have been respected and implemented, and not for the MHS whose sole function was to organise and put in place an effective enforcement regime. Further, and in any event, I do not agree with the suggestion that the requirements of the HACCP Regulations did not add materially to the existing regime. On the contrary, those Regulations should have been, and were intended by Parliament to be, an important, indeed a central, part of a new enhanced regime.

- 9.48 Mr Hewson's second reason was that the operators needed to be allowed a period of understanding how to comply because the legislation came in very quickly. However, it is evident from the dates given above that, by the time the HACCP Regulations became applicable to slaughterhouses such as the Abattoir, over two years had elapsed since the relevant Commission Decision to which they gave effect, and over a year had elapsed since they had been brought into effect for larger establishments.
- 9.49 Mrs Downes' recollections as to what occurred, and her position in relation to the legislation, were different from those of Mr Hewson. She accepted that there could be no sensible excuse after June 2003 for low-throughput slaughterhouses not to comply with the additional requirement that Parliament had chosen to be in place to minimise the risk to food safety. However, her recollection, which documentation subsequently indicated to be broadly accurate on this point, was that the guidance at that point from the policy division at the FSA was to start to encourage the first step of the hierarchy of enforcement and to take a light touch with enforcement.
- 9.50 After Mrs Downes had given her oral evidence, the Inquiry received from a source other than the MHS, a copy of an internal MHS audit report relating to the implementation of HACCP principles. It is both unfortunate and very disappointing that this report was not provided to my Inquiry by the MHS in the first place. That is particularly so as Mrs Downes was the sponsoring director of the report. The revelation of the document and the references to a policy of only the lightest touch of any real enforcement, prompted further requests for information from the Inquiry to the MHS. This resulted in Mrs Downes providing a further statement, which was accompanied by 84 exhibits. Mrs Downes apologised for the omission, which I note and accept.
- 9.51 One of these internal audit reports was an audit report conducted at the end of 2003 and the beginning of 2004 by the MHS's Verification and Audit Unit entitled "A comparison of HACCP based controls in plants and the levels of implementation reported by the OVS".
- 9.52 The 2003/2004 MHS internal audit had been undertaken to establish levels of operator compliance with the requirement of HACCP based controls (introduced by the HACCP Regulations) and to compare them with levels of implementation reported by OVSs. It presented a concerning picture in relation to small plants (such as the Abattoir):
- (i) Only 52% of the small plants were even reported by OVSs as having HACCP-based controls fully in place.
 - (ii) Of this 52% figure, the auditors concluded that 64% of OVSs in small plants had declared that HACCP-based controls were fully in place when in fact they were not.
 - (iii) There was no assurance that OVSs had sufficiently advanced knowledge of HACCP to make the required judgements.

- (iv) Instructions to OVSs on the use of formal enforcement to achieve adequate HACCP-based requirements had not been clear. That had caused some OVSs to hold back from initiating formal enforcement action; and had created an impression with some operators that the MHS/FSA would not formally enforce the requirements of the HACCP Regulations.

9.53 A series of recommendations were made. These included the following:

- (i) MHS Area Managers should take action to ensure that OVS assessments of HACCP-based controls are consistent and, in summary, well founded.
- (ii) Where HACCP-based controls are assessed as not in place, as was the position in the Abattoir, MHS Area Managers should determine the reasons. Regional Veterinary Advisors should provide support in initiating an appropriate programme of enforcement.
- (iii) This recommendation was stated to rely on “prior clarification of the enforcement policy for the... HACCP Regulations”. Once that policy had been agreed between FSA and MHS a detailed, clear statement of the MHS’s position on enforcing operator compliance should be included in the general MHS Enforcement policy. In addition, clear in-depth procedural guidance for the OVS should be given on formal enforcement for the most likely situations where an operator’s HACCP-based controls could be judged non-compliant.
- (iv) Additional training should be given if necessary to MHS staff involved in providing support to OVSs in the enforcement of HACCP-based controls. The MHS needed to establish whether OVSs had sufficient capabilities to deal with HACCP and, if not, to deal with that.
- (v) A co-ordinated MHS action plan needed to be formulated to address the findings and recommendations of the report.

9.54 Over the following months, an action plan was developed and steps were taken to follow these recommendations.

9.55 A second internal audit carried out at eight premises, seven of which were large and only one small, by teams of FSA Veterinary Meat Hygiene Advisers auditors in December 2003 and January 2004 also revealed results of concern. The findings, summarised in a table at section 5 of the report, indicated that at no plant was the HACCP plan satisfactory and that at no plant was the operator implementation satisfactory.

9.56 This report contained similar recommendations to the first, including that:

- (i) The MHS consider how the knowledge and understanding of HACCP by OVSs could be improved.
- (ii) The FSA provide to MHS and its staff clarification of its policy on enforcement of HACCP.

- 9.57 Concerns as to the lack of effective implementation of the HACCP Regulations was also raised in the FSA's annual 2003-2004 audit of the MHS. That audit had expressed concern at the "MHS's lack of effective action and, more fundamentally, the underlying failure of many operators to take responsibility for their own operations". The MHS's response to this finding was to point out that the FSA had acknowledged that this was a difficult area; and to state that achieving full operator compliance required "a joint approach to improve education and understanding by the operator".
- 9.58 I do not underestimate the challenge of securing and enforcing compliance with the HACCP Regulations. It is also right to record that the MHS did take a number of steps in an effort to prepare both the industry and the enforcers, notably the OVSs, for the introduction of the HACCP Regulations. However, this aspect of the MHS's work, in conjunction with the FSA, is of considerable concern.
- 9.59 First, I do not consider enough was done to ensure that the HACCP Regulations could be implemented and enforced in a timely manner. As indicated above, some steps were taken. The FSA has acknowledged that the scale of the challenge involved in the implementing and enforcing the HACCP Regulations was underestimated. Most, if not all, of the reasons relied on by the MHS as illustrative of the difficulties of making progress with enforcement after introduction should have been evident before introduction. In particular, more than the usual preparation and training would be needed; and a clear approach to what was required in practice would also need to be developed. It should also be noted that, in relation to small abattoirs, the MHS and FSA had an additional year in which to prepare and to benefit from the first year's implementation in large slaughterhouses.
- 9.60 In all the circumstances, as events clearly demonstrated after introduction, the preparations for introduction were inadequate. They were inadequate in relation to levels of understanding, training and preparation at small slaughterhouses such as the Abattoir. They were also inadequate in relation to the understanding, training and preparation of the OVSs who were to be the front line enforcers of the new regime.
- 9.61 Second, the failure to prepare adequately, placed the FSA and the MHS in a very difficult position. The result was a deliberate decision by the FSA, giving effect by instructions it issued to the MHS, to ignore the dates by which Parliament had decided the new requirements in the HACCP Regulations should be implemented.
- 9.62 Despite the evident difficulty of the position, it then took far too long for the combination of the FSA and the MHS to manage the problem. Again, I note that some steps were taken but they were inadequate to provide a solution within an acceptable timeframe. Compliance was not secured in practice, it appears, for a significant section of the industry, for a period not of weeks or even months, but of years, indicated by the history of HACCP implementation, or more accurately non-implementation, at the Abattoir. The failure is made all the more serious by the fact that the MHS's own internal audits and the FSA's audits of the MHS in 2003/2004, clearly identified the scale of non-compliance and the nature of the difficulties.

2006 Onwards

- 9.63 In January 2006, this sector became subject to new legislative requirements, the Food Hygiene (Wales) Regulations 2006 ("The 2006 Regulations"), after new EU Regulations (Regulation (EC) No 852/2004) were introduced. These required the operator to demonstrate that the establishment was complying with all the requirements of food law.
- 9.64 Pursuant to the 2006 Regulations, all previously licensed premises were subject to a review in order to ascertain whether they were suitable for compliance with the Regulations. Although the MHS concluded that the Abattoir was not in a position to make a successful application under the new Regulations, in the event no application was made. The Abattoir surrendered its licence with effect from 1 February 2006.
- 9.65 Mr Hewson stated that of the premises visited; only approximately 70% were approvable at the first visit. He stated that the premises were afforded three months to carry out improvements with an extension of three months, but that if they did not achieve compliance after six months, they were refused a licence.
- 9.66 Mr Hewson attached considerable weight to the 2006 Regulations. The suggestion was that, before their introduction, the MHS was seriously hampered in effectively conducting its enforcement duties; and that the 2006 Regulations made all the difference. I do not accept the argument that there was a sea change. The fact that the 2006 Regulations were on the horizon could not, and should not, have provided a legitimate basis for non-implementation of the then current regime. I consider that Mr Hewson overstated the true significance and impact of the 2006 Regulations; and that there was a great deal that the MHS could, and should, have done to ensure that the Abattoir complied with the relevant food safety requirements extant prior to the 2006 Regulations.

Enforcement in Practice at J. E. Tudor & Sons Ltd

The 1990s

- 9.67 During the 1990s, the licensing decisions were taken by the relevant Minister, advised by officials. Those who provided the advice or had input into it included Regional Meat Hygiene Advisors ("RMHA") and Veterinary Officers ("VO"). Mr David Thomas was a RMHA and gave evidence to the Inquiry about the licensing of the Abattoir at that time.
- 9.68 His evidence was that RMHAs were told that provided at the final inspection a slaughterhouse met minimum structural conditions and hygienic slaughter could be observed at that time, then a licence was to be recommended. He stated that if the appraisal of the premises showed that any necessary structural works could be undertaken to allow it to be licensed as fully compliant with the legislative requirements, then the operator could be licensed and given a temporary derogation from those structural requirements. In that way, the slaughterhouse could continue to operate while the work was being undertaken.

- 9.69 His view was that the legislation was interpreted in a way that would allow establishments to be approved. He agreed that it was a worrying state of affairs. He stated that he thought he would have passed on his concerns to his senior colleagues, but that he was not aware of any feedback as inspectors were essentially told to get on and do their job as per the policy at the time.
- 9.70 Mr Thomas's evidence as to the approach in place at that time appears to be borne out by the history of the licensing of the Abattoir.
- 9.71 In March 1992, J.E. Tudor & Sons Ltd was operating the Abattoir as a full-throughput slaughterhouse. In relation to slaughtering, Billy Tudor had a stated annual throughput of 700 cattle, 7000 sheep and 1500 pigs. Billy Tudor applied for the temporary exemption (derogation) from the detailed structural requirements on 23 March 1992. He expressly stated in his application that it was not his plan to update his existing premises. He explained in his application that he was searching for a suitable site on which to build a new slaughterhouse.
- 9.72 Mr Thomas stated in oral evidence that at that time, Billy Tudor was adamant that he wanted to continue with his current throughput. In terms of licensing it as a full-throughput slaughterhouse, however, Mr Thomas explained that "it didn't have any chance at all" of meeting the structural requirements. The situation was such that Billy Tudor could only comply if he moved to totally different premises, as yet un-located, and obtained planning permission for those premises. Mr Thomas stated in evidence however, that, in the application of the policy referred to above, it was judged to be sufficient that Billy Tudor had simply said that he intended to move to such premises.
- 9.73 On 7 August 1992, the VO and an Environmental Health Officer ("EHO") from Rhondda Borough Council made an exploratory visit to the premises and listed a series of hygiene deficiencies which they identified as requiring rectification prior to a permanent licence being recommended. Approximately four months later, on 11 December 1992, the VO and the EHO made a further visit to the premises. As a result of that visit, the VO was unable to recommend a permanent licence because the slaughterhouse was not operating to the hygienic standards required. A list of the deficiencies were again included in a letter to Billy Tudor and the following were identified as the more serious of the deficiencies:
- (i) The roof was leaking and water was dripping close to exposed carcasses.
 - (ii) Several parts of the plant and equipment were not clean.
 - (iii) Unhygienic practices were being performed by the operatives, including infrequent personal washing and sterilisation of implements. Carcasses were being wiped down with dirty cloths. Contamination of carcasses was taking place from various sources.
 - (iv) The amenities were unhygienic.
 - (v) There was inadequate fly/vermin proofing. Flies were present in the slaughterhouse.

(vi) In several places, metal surfaces were corroded with rust and presented a potential food hazard.

- 9.74 The VO stated to Billy Tudor that the majority of the points had been discussed at the earlier meeting on 7 August 1992 and nothing had been done since that visit; indeed, conditions had in fact deteriorated. Mr Thomas stated in oral evidence that the letter would have been copied to Rhondda Borough Council, which was at the time responsible for enforcement. Despite this, as Mr Thomas confirmed, the Abattoir continued to operate as a full-throughput slaughterhouse.
- 9.75 On 23 December 1992, a meeting took place between the Chief EHO at Rhondda Borough Council and the VO at which there appears to have been some disagreement as to whether or not the Abattoir should stay open. The Local Authority produced a copy of a letter dated 16 December 1992 which they had sent to Billy Tudor, in which they stated that they would be refusing his licence under the Slaughterhouses Act 1984 and that the slaughterhouse should close on 31 December 1992. The VO pointed out to officials, however, that a temporary licence could be issued to Billy Tudor under the Fresh Meat (Hygiene and Inspection) Regulations 1992 ("the 1992 Regulations"), provided that he met the minimum hygiene requirements and that he had a forward plan.
- 9.76 On 22 January 1993, a three-month temporary licence was issued on behalf of the Secretary of State for Wales to expire on 18 April 1993. Mr Thomas's view in his evidence was that this was a rather surprising decision given the nature and extent of the apparently unrectified problems with hygienic operation that had been clearly identified.
- 9.77 On 11 March 1993, the VO and the EHO visited the Abattoir again. They reported that no progress had been made by Billy Tudor in rectifying the contraventions that had been found on 11 December 1992.
- 9.78 Another visit took place on 7 April 1993. Cattle and pig slaughter were considered to meet the minimum hygiene standard required for a permanent licence. However, sheep slaughter was considered to be unhygienic. In addition, many of the points raised in correspondence following previous visits had still not been corrected. In relation to the forward plan, Billy Tudor stated that he still intended to move ahead with a new slaughterhouse with a revised layout at his farm. He stated that planning permission had been refused but indicated that he would be appealing against the decision. The Secretary of State nevertheless extended his temporary licence. Billy Tudor was given until 20 May 1993 to carry out the requirements.
- 9.79 On 19 May 1993, inspectors again visited the Abattoir. Sheep dressing was demonstrated. The beginning of the demonstration was noted to be unhygienic as faecal contamination of the carcasses was visible. However, with the advice of the VO, techniques were improved and a hygienically-acceptable dressed carcass was produced.
- 9.80 On 7 July 1993, Billy Tudor signed the necessary form enabling him to have a temporary derogation from some of the structural elements required by the 1992 Regulations and the forward plan agreed was to up-grade to another slaughterhouse. Mr Thomas stated in oral evidence that there would have been a detailed plan to renovate the new premises.

- 9.81 On 20 July 1993, the Abattoir was granted a licence as a full-throughput premises with a temporary derogation. Again, Mr Thomas's view given in evidence was that the decision might be considered surprising given the history of the premises; however, he stated that the officials were under pressure to try and help the industry as much as possible and not to close establishments down. He stated that there was also pressure from local MPs for slaughterhouses to remain open in their area, and from the farming unions. His evidence is supported by a Welsh Office document dated 9 June 1993. The document sought the agreement of the Secretary of State for Wales, which was subsequently given, to recommendations on licensing decisions for slaughterhouses. This included the issue of a further temporary licence for the J.E. Tudor & Sons Ltd abattoir. The briefing papers said that if it were not for Ministers' stated preference to close only those plants where meat was actually being contaminated, these [plants with borderline hygiene standards] would also have been recommended for closure.
- 9.82 On 7 October 1993, the VO carried out a routine visit to the Abattoir. On this occasion Billy Tudor informed him that he no longer intended to purchase alternative premises nor had he any intention of building a new abattoir at his own premises near to where he lived. As such, it was the opinion of the VO that Billy Tudor had broken the conditions of the agreed derogation. It was the VO's opinion that the existing slaughterhouse could never be upgraded to an acceptable full-throughput layout; but that it was licensable as a low-throughput slaughterhouse. However, even for that to occur, structural upgrading would be required which would have to be the subject of a forward work plan within a new agreed derogation. Billy Tudor declined to sign the application to be licensed as a low-throughput slaughterhouse. Despite all of this, he continued to operate as a full-throughput slaughterhouse.
- 9.83 In December 1993, the RMHA emphasised to Billy Tudor that he would have to either re-negotiate his conditional licence with an acceptable alternative to the current forward plan, or apply to become low-throughput premises and agree a new forward plan. Neither appears to have occurred, yet no action was taken and the Abattoir continued to operate.
- 9.84 On 3 February 1994, the VO visited the Abattoir and observed cattle being slaughtered. He concluded that Billy Tudor had failed to maintain the standards of hygiene and working practices that were necessary. Cattle were not being dressed hygienically, and in particular:
- (i) There was faecal contamination of the brisket, hocks and knees.
 - (ii) The washing of cattle carcasses took place before de-hiding resulting in dirty water entering the body cavities.
 - (iii) Slaughtermen used the steriliser and drop hoses for personal hygiene. Neither washing booth was operational as the valves were broken.
 - (iv) Sterilisation of contaminated knives was not taking place.
 - (v) In the amenity block, lockers were not being used as intended and were storing filthy equipment.
 - (vi) The filing cabinet in the office was used to contain protective clothing.

- 9.85 Still no action was taken to revoke the licence.
- 9.86 On 3 March 1994, the newly introduced system for scoring and assessing hygiene at abattoirs was applied to the Abattoir for the first time. This was the Hygiene Assessment System ("HAS"). The assessment gave a score in various categories: ante-mortem, slaughter and dressing, personnel and practices, maintenance and hygiene of the premises and general conditions and management. The total marks were given out of 100. Scores below 66 were deemed to be unacceptably low. The Abattoir scored only 15 out of a possible 100. The clear conclusion was that there were the most serious problems with the hygienic production of fresh meat at the Abattoir.
- 9.87 During this visit Billy Tudor finally applied in writing to become a low-throughput slaughterhouse. However, no agreement about an acceptable forward plan was reached.
- 9.88 On 6 May 1994, there was another inspection. It was noted that little progress had been made with Billy Tudor's forward plan.
- 9.89 The VO completed a second HAS score-sheet on 27 June 1994. This time the Abattoir scored 31 out of a possible 100. Although this was an improvement on the previous score, the score was still half the score that would have been acceptable. At this visit, no agreement could be reached about an acceptable forward plan.
- 9.90 As a result of this visit, in a letter dated 15 July 1994, the VO finally recommended to Mr Thomas, the RMHA, that Billy Tudor's licence to operate as a slaughterhouse be revoked.
- 9.91 On 21 July 1994, the RMHA and the VO jointly visited the Abattoir. The HAS score-sheet was again completed. The score was 35. Billy Tudor demonstrated the slaughter of four lambs. A series of concerns and breaches of the legislative requirements were noted:
- (i) There was infolding of fleece and transference of faecal material and wool on to the carcasses.
 - (ii) The oesophagus, which contains ruminal contents, was not being removed from the red offal.
 - (iii) Green offal was being discarded and not made available for inspection.
 - (iv) Operatives were allowed to come into the slaughter hall from the lairage in the same clothes which were used in the lairage and there was no wash point.
 - (v) There was inadequate disposal of waste and by-products.
 - (vi) Washing of carcasses was taking place before final inspection. This resulted in the splashing of other carcasses and offal.
 - (vii) Carcasses in the chillers showed evidence of contamination and poor dressing.

- 9.92 The RMHA wrote to Billy Tudor to explain the reasons for awarding such a low HAS score. Because Billy Tudor was still not able to agree a forward plan, Mr Thomas informed him that he had no alternative other than to recommend to the Secretary of State for Wales that his licence to operate as a slaughterhouse under the 1992 Regulations be revoked. Mr Thomas stated in oral evidence that he also wrote to the OVS responsible for the plant in relation to his duties and listed what he thought he should be doing. This system was provided for under the 1992 Regulations but was very rarely used.
- 9.93 On 18 August 1994, at the request of the RMHA, the VO made an unannounced visit of the premises. The VO discovered and listed numerous contraventions of the 1992 Regulations, and also contraventions under the Slaughter of Animals (Humane Conditions) Regulations 1990. A HAS assessment was also undertaken. The score was 11 out of 100. Mr Thomas stated in oral evidence that this was the lowest score, and thus the worst hygiene record, ever recorded in Great Britain. After the visit, Mr Thomas wrote to Billy Tudor. He said that the HAS score was unacceptable, indicating that there were serious problems in the hygienic production of fresh meat.
- 9.94 Mr Thomas put up a recommendation to his superiors that the Secretary of State for Wales should revoke the licence. Officials went as far as preparing a submission. Three drafts of the submission are on file, the last of which is dated 22 August 1994. The drafts set out the background and key issues.
- 9.95 In the event, the licence was not revoked. I have been unable to determine the precise reason why that did not occur. The additional documentation provided to the Inquiry after the hearings was in the form of Welsh Office papers as it was responsible for the relevant statutory functions at that time. The papers do not include a copy of a final version of the submission to the Secretary of State for Wales. Neither do the papers include any record of a decision not to put up a submission. It appears that there was a prolonged debate by officials within the Welsh Office and also discussions with MAFF about whether the correct procedures had been followed in order for the licence to be revoked. That debate appears to have carried on throughout the remainder of 1994 and into 1995. It is not clear whether it was resolved before September 1995. The available records are less than complete, which is disappointing. It means that I am unable to resolve the issue.
- 9.96 On 21 September 1995, by which stage the 1995 Regulations had come into force, Billy Tudor agreed to the plant becoming a low-throughput slaughterhouse. A schedule of works to bring the premises into compliance with the 1995 Regulations was verbally agreed between Mr Thomas and Billy Tudor at the time. It related mainly to the by-products yard, the lairage, the slaughter hall, the chiller, although general points about the structure were also raised. In terms of hygiene practices, whilst there was nothing on Mr Thomas's file to show what the position was, he stated that the VO would have drawn up a list which would thereafter have been monitored.

- 9.97 On 3 March 1996, Mr Thomas, having inspected the Abattoir on 16 February 1996, made a recommendation that Billy Tudor be given a low-throughput licence without any derogations. By this date, it appears therefore that some work had been carried out to bring up the standards at the Abattoir. However, Mr Thomas stated that under the policy in place at the time, all that had to be demonstrated was hygienic slaughter. This policy went as far as allowing people to slow down production lines in order to achieve this. He referred to it as "the Hollywood effect", in that everything was done in slow motion when officials were visiting the premises. He further stated that the visits were announced and that operators would have been aware that the inspectors would attend, having been given two to three weeks notice. Consequently, the operators would put on a show for the inspectors and the policy was that if they slaughtered hygienically on the day of the inspection and the minimum structural requirements were met then the officials were to licence.
- 9.98 My conclusions in relation to the period up to March 1996 are as follows:
- (i) There was flagrant disregard for the requirements of the legislation by the Abattoir.
 - (ii) Those responsible for enforcing the requirements appear to have operated a policy which cannot sensibly be squared with their obligation to enforce the legislation.
 - (iii) It must have become apparent to those operating the Abattoir that the enforcement was utterly ineffective. The result was the absence of any real improvement in the hygiene conditions and of any real attempt to achieve such an improvement.
 - (iv) The licence to operate as a full-throughput slaughterhouse should never have been granted.
 - (v) The decision to recommend revocation of the licence should have been taken years earlier than it was.
 - (vi) If a Ministerial decision not to revoke was in fact taken, it would seem to have been unjustifiable on the basis of the evidence I have seen. However, it may be that officials did not actually put a submission to the Secretary of State for Wales and therefore that no such decision was taken. If that is so, it is also very unfortunate because it would mean that it took over a year for those responsible to make a decision on whether or not correct procedures had been followed. In the meantime, a slaughterhouse that had been recommended for revocation of licence on hygiene grounds continued to operate on a basis that was in clear and persistent breach of the relevant legislation to the knowledge of the enforcement authorities.

2000 Onwards

- 9.99 The principal significance of the inspection history in the early 1990s is the light it sheds on lessons being learned, or not learned, and the recurrence of problems that appear to have persisted for many years.

Roles and Responsibilities

- 9.100 The following is a brief description of roles and responsibilities of those involved in the enforcement of the regime as it applied to the Abattoir.
- 9.101 The OVS would, and was required to, attend the Abattoir during operations. The OVS performed the functions set out in the Regulations, notably the 1995 Regulations. Those functions, included Health Marking and securing the observance of the legislative requirements relating to the premises and the practices in operation. There is little doubt that OVSs were in considerable demand and they had only limited time to devote to each of the slaughterhouses for which they were responsible.
- 9.102 The OVS inspected every animal ante-mortem, but did not inspect every carcass post-mortem. All carcasses post-mortem would be inspected by the MHI. Mr Jesus Alvaro Pastoriza, an OVS employed by the MHS, stated that it would depend on the severity of the case as to whether the OVS would get involved in the post-mortem inspection.
- 9.103 There were two types of inspectors, working to the OVS. The MHI carried out inspection of the carcasses while they were being produced at the Abattoir. A Meat Technician was principally responsible for inspection work related to a particular type of material produced during the slaughter: the Specified Risk Material, which is material suspected to have any infectivity for BSE, or “mad cow disease”.
- 9.104 From 3 August 2004, the decision was taken that it was no longer necessary for the Meat Technician to be in attendance at the Abattoir. This was a controversial decision and opposed by the MHIs who attended the Abattoir as, in their view, it potentially compromised both hygiene and animal welfare. Some two months later, in October 2004, an entry in the J.E. Tudor & Sons Ltd’s Staff Day Book by a different inspector stated that there was no Meat Technician at the plant, that 100% line supervision was unattainable and that in that person’s opinion the health and safety of the MHI was compromised.

- 9.105 Mr Phillip Stallard, Area Manager for South East Wales employed by the MHS, did not agree with the view expressed by the MHI. He stated in his evidence that he had discussed the issue of the continued presence of the Meat Technician with the OVS. They did not agree with the view of Mr Mark Mumford, Senior MHI. Mr Stallard went on to say that the Regional Meat Veterinary Advisor ("RMVA") was also of the view that the MHI and the OVS at the plant together could more than cope with what was required bearing in mind the line speeds at the plant. Mr Stallard stated that in his view, the duties of the Meat Technician were specific and not onerous. Further, he stated that the Meat Technician was not authorised under the Regulations to act in any hygiene or inspection capacity whatsoever and that he would purely carry out checks in relation to Specified Risk Material and dentition.
- 9.106 Ostensibly, cutting the number of people responsible for monitoring and assisting with compliance with the relevant legislation, particularly at a time when a series of concerns had recently been identified and raised, might not appear to be a sensible management decision. However, I note Mr Stallard's evidence on this issue that the matter was given full consideration and was discussed with those involved. I conclude that the problems at the abattoir could, and should, have been dealt with without a Meat Technician and that the decision, which was following MHS policy, did not contribute materially to addressing the ongoing problems at the abattoir.
- 9.107 The regional management of the MHS was in a position to oversee, and was responsible for overseeing, the work of the OVS and MHIs in the region. Mr Phillip Stallard was the Area Manager for the South East Wales region of the MHS. He occupied that post from 18 May 2003. Before that date, he had been an Area Resource Manager for that region for eight-and-a-half years.
- 9.108 As Area Manager, Mr Stallard received from each OVS every month a copy of all the monthly reports that originated from each premises for which they were responsible. Mr Pastoriza stated in oral evidence that this would have meant that Mr Stallard was sent the monthly HAS score, the enforcement action form, a HAS schedule to explain any variation of the HAS score between the present and the previous month, and the OVS monthly report. He did not think that Mr Stallard would have been provided with a copy of the daily Animal Welfare Reports or the daily Hygiene Reports. Mr Stallard stated in oral evidence that he would review the enforcement action at all plants within his area. He would go through the various reports with the RMVA every month and discuss with him whether or not the enforcement action taken was reasonable and proportionate.
- 9.109 One of Mr Stallard's functions as Area Manager was to monitor the performance of those OVSs who were employed by the MHS. This was done in part by him completing the Performance Monitoring Forms. These forms employed a traffic light system for judging Key Performance Indicators, which are particular indicators designed to show how well an OVS was performing. In summary, an amber light highlighted an area of concern and a red light indicated the need to take action to deal with a serious issue.

- 9.110 Mr Stallard stated in oral evidence that he was very much aware that the requirements should have come in by June 2003 but that no progress had been made. Mr Stallard stated that he had written to OVSs on that basis but was advised by the RMVA's that they should not be following the regime of enforcement in respect of HACCP, and should instead be advising rather than enforcing. On the basis that enforcement was a current requirement of the legislation, Mr Stallard agreed that this stance struck him as rather odd as it went against what the MHS were trying to achieve in relation to improving standards at plants.
- 9.111 I conclude that, as the Area Manager, Mr Stallard should, and could, have taken further steps to address what were obvious problems. Moreover, there is no contemporaneous evidence in respect of the advice said to have been given by the RMVA, and I do not consider that, even if such advice was given, that alters the conclusion Mr Stallard could, and should, have taken further steps.

Hygiene Reports and Other Forms

- 9.112 One of the functions of the OVS was to secure observance with the hygiene and other standards set out in the Regulations. To that end the MHS had designed a series of forms to be completed by the OVS and/or the MHI. They included an Ante-Mortem Report which assessed the physical condition and cleanliness of the animals before slaughter and a daily Animal Welfare Report.
- 9.113 The Red Meat Slaughterhouse Operational Hygiene Reports ("the Hygiene Reports") were the most important. Mr Pastoriza agreed in his oral evidence that the Hygiene Reports were a critical, if not the central element, in monitoring and securing compliance with the legislative requirements. They were completed on each day of operation and were signed by the on duty OVS. The Hygiene Reports were broken down into three main sections:
- (i) The first listed a series of around 35-40 categories that were used in generating the HAS score. They covered everything from the maintenance of the structure to pest and vermin control to the various processes and practices operated during slaughter. Each category was scored with a letter from "A" to "D". The letter scoring was described in the MHS Operations Manual ("the MHS Manual"). That indicated that even a "B" score did not necessarily indicate compliance with the legislation. However, "C" or "D" scores indicated that the particular category was in breach of the legislative requirements designed to secure the production of safe food. They also indicated that the breach was such as to create a risk to public health. The MHS Manual stated:

"...awarding a "C" and "D" score indicates that you have identified a risk to public health as a result of a regular or frequent failure to implement the requirements of the Regulations and you must take appropriate enforcement action..."

- (ii) In practice, "D" scores were rarely given (none were given in relation to the Abattoir). Both Mr Pastoriza and Mrs Downes indicated that the approach was only to award a "D" score where there was an imminent risk to public health requiring the plant to be closed. So, for example, even in relation to HACCP, after the HACCP Regulations came into force in June 2003, the complete absence even of a HACCP plan would still lead only to a "C" and not a "D" score.
- (iii) The second section enabled a record to be made of the corrective action agreed with management in relation to any problem categories recorded in the first section. An additional column was set aside for recording the date at which the corrective action was completed to the satisfaction of the OVS.
- (iv) The third section was designed to record the state of the operator's own hygiene checking system through HACCP and microbiological testing. As appears above, for small slaughterhouses such as the Abattoir, the HACCP requirements became law in June 2003.

- 9.114 The scores recorded in the Hygiene Reports then formed the basis of the monthly or quarterly HAS scoring. Monthly HAS scores were generated for slaughterhouses causing concern, such as the Abattoir. The HAS used the same categories as those contained in the Hygiene Reports. It then converted the letters scored in the Hygiene Reports into numbers. The system was weighted. Some of the categories carried more points than others based on judgement as to the relative importance of the category in hygiene terms. An "A" score led to a higher number than a "B" score, down to a zero number for a "D" score.
- 9.115 There is one important and fundamental point in relation to how the system was used. In considering the HAS scores, one should note that, as set out above, "D" scores were virtually never used save in the most extreme situations requiring the immediate cessation of production. That is of some significance because in most cases even a persistent and clear breach of the legislation would lead only to a "C" score, carrying with it at least some scoring points under the HAS and thus contributing to a higher overall score.
- 9.116 If the "D" score had been used more frequently, the HAS scores for a slaughterhouse such as the Abattoir would have been considerably lower and thus more obviously below the level deemed acceptable, which is less than 66 of 100. My conclusion is that the HAS scores need to be viewed with some caution, and are not to be taken as a measure of legislative compliance. This was accepted by Mrs Downes .
- 9.117 Detailed guidance on the completion of these forms and the manner in which the HAS scores were to be calculated was provided in the MHS Operational Handbook and on the HAS forms themselves.

The Abattoir as a Failing Slaughterhouse in 2000

- 9.118 A note of a meeting on 18 January 2000 relating to the Abattoir identified that Mr Phillips was the OVS responsible for the plant and that Mr Stallard was responsible for providing resource to such licensed premises. The note of the meeting indicated that, as at that date, the Principal Official Veterinarian Surgeon ("Principal OVS") had serious concerns in relation to the way in which the Abattoir was operating. It records that it was consistently scoring below the acceptable HAS level of 65. The purpose of the meeting was to make sure that focus was placed on the problem and an attempt was made to drive up standards at the plant. The note identified the effective use of formal enforcement as one of the means to be used to correct serious deficiencies and breaches of the Regulations.
- 9.119 Mr Stallard was involved as a resource manager at this stage. He recalled that in early 2000, the MHS and the OVS teams had focused on the Abattoir as one that was difficult or failing. His evidence was that, whilst he was not aware of the scale of the problems at the plant in 1994, he was at least aware of them generally. He stated that he had attended the premises in 1995 when he first became an area resource manager and he was surprised, having had a background in export-approved premises, that the Abattoir was still operating. His recollection was that at this time there were problems with the operator, namely Mr Billy Tudor, who he described as very aggressive and confrontational. Mr Stallard confirmed that the Principal OVS at the time, Mr Phillips, required special support due to intimidation by Billy Tudor; and how at one stage, the MHS had to increase their level of attendance at the plant as Billy Tudor had attempted to assault a MHS member of staff by, reportedly, throwing an object at them across the slaughterhouse.
- 9.120 Mr Stallard provided the Inquiry with a table setting out the HAS scores achieved at the Abattoir. The table identifies that in 2000, the premises were subjected to monthly HAS scoring as opposed to the typical quarterly assessment for low-throughput premises. Mr Stallard was unable to clarify in oral evidence the basis for the monthly assessments.
- 9.121 The HAS scores for the period 2000-2003 indicate a slaughterhouse at or just below the level of acceptable hygiene performance. Some problems were identified in the monthly reports; for example, Mr Phillips reported the chronic problem of having to constantly advise people to do their jobs properly.

2002 and 2003

- 9.122 In 2002, the forms would appear to indicate some improvement. Mr Phillips, the OVS, was responsible for filling out the inspection forms, in particular the Hygiene Reports. Whilst there was the odd "C" score, the majority were "A" or "B" scores.
- 9.123 Mr Pastoriza is a Veterinary Surgeon who qualified in Spain. He was the OVS who most frequently visited the Abattoir from the beginning of 2003 until August 2004. It is to be noted, however, that, as the records indicate, there were a number of different OVSs who did so during the period. Ms Ainhoa Astorquiza succeeded him at that time. However, Mr Pastoriza returned to become its OVS again from August 2005. He continued in that role until the plant ceased operation at the end of January 2006.

- 9.124 When he first went to the Abattoir, Mr Pastoriza had had sight of the folders from the previous OVS with the paperwork which was physically on site. He had been unaware however, of the history going back to the early 1990s and would have focussed on the past 12 months.
- 9.125 Mr Pastoriza stated that when he first arrived at the Abattoir, he was overwhelmed by its condition. The premises were very old and in a very poor condition. He considered the enforcement issues to be a priority.
- 9.126 The first Hygiene Report Mr Pastoriza prepared, dated 15 December 2002, reflected the Abattoir's poor condition. It was in marked contrast to the previous series of Hygiene Reports produced by Mr Phillips. In contrast to the "A" and "B" scores that Mr Phillips had been scoring for most of 2002, Mr Pastoriza began scoring whole sequences of "C" scores. "C" scores indicated both a breach of the legislative requirements and a risk to public health. They included "C" scores for dressing, skinning and depilation practices, cross-contamination controls, handling control staining/sterilisation of by-products, rooms and facilities available, maintenance of the slaughterhouse structure and operational cleaning.
- 9.127 My conclusion is that the scores of Mr Phillips and Mr Pastoriza cannot be reconciled. Given the descriptions of the state of the Abattoir over the period before and after 2002, and the clear and long running problems of the same nature. The clear inference is that the scores of Mr Pastoriza are to be preferred. I note that in his 2004 audit, Mr Thomas concluded that Mr Phillips may have been inflating the scores recorded in the Hygiene Reports. I do not feel able to provide any firm view on that, and do not consider I need to do so given the clear picture that emerges from the Hygiene Reports from 2003 onwards.
- 9.128 In January and February 2003, Mr Pastoriza and other visiting OVSs continued to record a large number of breaches or borderline breaches of the Regulations and gave "C" scores to items including, but not limited to, the handling control and sterilising of by-products, contamination incidents and control and correction, gut room practices, maintenance of slaughter house structure, fly and vermin control, slaughter practices, skinning and depilation practices, dressing practices, cross-contamination, and staff hygiene practice.
- 9.129 The picture that emerged in the first weeks of Mr Pastoriza's involvement was a clear one. The Abattoir had fundamental problems. The problems extended from the structure to the controls and practices operated (or not operated) at the Abattoir. In view of the serious hygiene problems evident from the scores recorded in the Hygiene Reports, decisions needed to be taken as to the appropriate action to be taken to move the Abattoir from a position of serial non-compliance with the legislation to a position of compliance. Given the number and nature of the breaches identified, this was a matter that needed to be addressed both urgently and seriously.
- 9.130 Instead, successive Hygiene Reports record that the action taken was simply to make management "aware" of the problems by reporting them to management. That continued to be the course taken even in the face of weeks and then months of the same problems recurring time and time again, and little or nothing being done by management to deal with them.

- 9.131 Mr Pastoriza's arrival, and his correct identification of the fundamental problems at the Abattoir, provided a good opportunity for him and the MHS management to confront and deal with those problems. That opportunity was not taken. The result was that the problems persisted.
- 9.132 The fact that, substantially, the same problems persisted is evident from the Hygiene Reports prepared by Mr Pastoriza and other OVSs in 2003. On occasion, some categories would move from "C" to "B" only to move back to "C" in later reports. However, no real impact was made on the fundamental and persistent nature of the problems. Throughout 2003, there continued to be a large number of "C" scores, mostly in the same categories.
- 9.133 Mr Pastoriza did seek to take enforcement action in relation to some problems. For example, isolated Improvement Notices were served in relation to the chiller door and to the condition of the ceiling in the mess room. However:
- (i) Enforcement action was sporadic and evidently inadequate to deal with the problems and to compel the Abattoir to take the necessary steps to comply with the legislation.
 - (ii) Far too often and for far too long, as the Hygiene Reports indicate, the preferred solution was simply to report to management. As the months passed without any significant improvement, it must have been or become apparent both to the OVS and to those within the MHS who oversaw the reports coming out of the Abattoir, that management were either unwilling or unable to deal with the problems and to comply with the legislation. Yet the level of enforcement action was not escalated and the Abattoir continued to operate at hygiene levels below those required by the legislation.
- 9.134 The HACCP Regulations came into force in relation to the Abattoir in June 2003. My conclusion is that the enforcement of these requirements by Mr Pastoriza, other OVSs and the MHS generally was wholly inadequate for the following reasons:
- (i) Despite the guidance that was given, there is nothing in the Hygiene Reports to indicate that steps were taken in advance of June 2003 to ensure that a developed plan was in place for the June 2003 date. That is because of the policy decisions dealt with above in relation to the enforcement of the HACCP Regulations.
 - (ii) However, in the Hygiene Report dated 11 June 2003, the "HACCP monitoring" category on the Hygiene Report was scored for the first time. Mr Pastoriza gave it a "B"/"C" score. That indicates borderline compliance. Yet, at this date, as Mr Pastoriza accepted, the Abattoir did not even have a HACCP plan. He gave the score because Jonathan Tudor had listened to some advice about HACCP that Mr Pastoriza had given and had indicated that he would try to implement a plan, which was at that time unformulated.
 - (iii) The next series of forms in June and July 2003 either do not score "HACCP monitoring" at all or indicate "Not Observed" in relation to it or, in one case described by Mr Pastoriza as "a mystery", indicate "Not Applicable".

- (iv) The Hygiene Report dated 30 July 2003, which was after the June 2003 deadline and which was completed by Mr Pastoriza, indicated that there was “no procedure based on HACCP principles”; and that “management [had been] informed of their responsibility of implementing that procedure”.
- (v) The August and September 2003 reports were similar, recording the continued absence of any HACCP procedure and that further discussions with management about that were carried out. Eventually on 14 September 2003, the Hygiene Report records that a warning letter was issued in relation to the fact that there was “no HACCP in place at the premises”.
- (vi) That letter evidently had no effect. The 26 October 2003 report again indicates “no effective HACCP plan in place”, and awards a “C” score accordingly. The Report also records, again, that management had been made aware of the HACCP and the other issues.
- (vii) That remained the position until December 2003 when a Hygiene Report of 21 December 2003 records “HACCP implemented but not working well”. Mr Pastoriza explained this in his evidence, describing multiple deficiencies in the operation of HACCP and his “constant feeling that they were all just a ticking exercise”.

2004

The Hygiene Reports and HACCP

- 9.135 The Hygiene Reports for 2004 indicate that the position at the Abattoir remained unimproved to any significant degree throughout 2004. Small pockets or periods of apparent improvement quickly relapsed into persistent non-compliance.
- 9.136 It is not necessary to set out in detail the content of all the Hygiene Reports. They continued to record a series of categories as non-compliant with the legislation, the same fundamental problems with structure and practices leading to a failure by a considerable margin to meet the hygiene requirements. The same categories were persistently non-compliant. Some attempts were made to enforce the legislation. Those attempts were demonstrably unsuccessful because they did not achieve or lead to any real improvement.
- 9.137 HACCP monitoring was consistently scored as non-compliant “C”. Despite some apparent progress on HACCP, whatever had been put into place continued not to work. The Hygiene Report for 11 July 2004 for example recorded “HACCP still not done...monitoring control procedures not working effectively”. The Report for 21 November 2004 stated: “HACCP system not applied in these premises as it fails from prerequisites...as clean and hygienically safe environment”.
- 9.138 The approach to enforcement of the HACCP Regulations has been dealt with above. There appears to have been some disagreement as to that approach, as appeared from emails sent in 2004 and the evidence of Mr Stallard.

- (i) On 5 April 2004, Mr Stallard sent an email to Mr Pastoriza focusing on the implementation of HACCP at the plant. HACCP-based principles had been a statutory requirement at low-throughput premises since June 2003. The e-mail was sent approximately ten months after the legislative requirement had come into force and stated that it was essential that Mr Pastoriza and his team (or other OVSs) follow the correct procedures in respect of the enforcement of HACCP, to include verbal and written Improvement Notices. The email further stated that any action should be accurately recorded in the appropriate MHS form (MHS56).
- (ii) When asked what led to the need for him to send that email, Mr Stallard stated that he was very much aware that the HACCP requirements should have applied since June 2003 but there had been no progress on them. However, he went on to say that, although he had written to the OVSs on the basis set out in the email, the RMVA's advice was that they should be advising rather than enforcing in respect of HACCP. Mr Stallard stated that he had received this advice via the FSA shortly after he sent the email to Mr Pastoriza. He acknowledged in his evidence that this went against what the MHS were trying to achieve in relation to improving standards at plants.

The Need for Enforcement Action in early 2004

9.139 On 8 March 2004, by which time he had been the Area Manager for ten months, Mr Stallard sent an email to Mr Pastoriza. It read as follows:

"I refer to our meeting of 18 February 2004 during which we discussed the need to escalate enforcement action at 7042 [the reference number given to the Abattoir]. Since our meeting it has come to my attention that this plant has now fallen into the category of one of the seven worst performing plants in the Wales region and as such an immediate escalation in enforcement action at the premises is required. To facilitate monitoring of progress I would request that a HAS and a MHS56 (Enforcement Form) are completed on a monthly basis for this plant until such time that the required standards compliance are consistently achieved".

9.140 In oral evidence, Mr Pastoriza originally agreed that he had not acted upon Mr Stallard's request. He explained that he was responsible for nine different plants, two of which were performing very poorly, and that he had no time available to complete reports which would basically illustrate that nothing had changed. He said that he certainly made Mr Stallard aware that the request could not be met and also of his concerns in relation to his lack of time to complete the reports which were taking him away from carrying out his enforcement duties at the plants for which he was responsible. As it turned out, contemporaneous records indicated that reports had been completed monthly from March 2004 to October 2004 before reverting back to quarterly reporting at the end of 2004 and into 2005. Mr Pastoriza explained that they [the OVSs] were struggling to keep up in 2004 and that in 2005, it was not possible to manage monthly reporting.

The MHS Audit in April 2004

- 9.141 Ms Maria Sebastia and Mr Steve Lodge of the MHS Validation and Audit Unit drafted an Internal Audit dated 20 April 2004. Mr Stallard explained in oral evidence that the purpose of the audit was to check that the OVS and staff at the plant were working in compliance with the MHS Operations Manual. In fact, the purpose of such a report was described in the report itself as follows:

“... [in relation to the areas of enforcement work examined by the auditors] to drive improvement in consistency and quality of enforcement by the MHS. Auditors seek to gather evidence to demonstrate that MHS enforcement activity at the licensed premises is effective and as a minimum conforms to the requirements of the MHS Operations Manual, legislation and operating instructions.”

- 9.142 The Executive Summary noted a series of non-compliances including inconsistency in completion of HAS, enforcement of hygiene conditions (detailed in part 14 of the report), completion of monitoring records and application of enforcement action (part 12 of the report). The conclusion was that Mr Pastoriza was “proactive in his approach and doing a good job at what is a difficult plant because of its age”. The Executive Summary noted that many of the deficiencies at the Abattoir were long-standing and were inherited by Mr Pastoriza with no enforcement in place; and stated that the OVS needed to ensure that all enforcement issues were dealt with in a timely and appropriate manner, ensuring that the hierarchy of enforcement is followed. In total, seven minor non-compliances and five areas for improvement were identified.

The Thomas Audit in May 2004

- 9.143 Mr Thomas had few if any dealings with the Abattoir in the period after his recommendation in 1996 that a low-throughput licence be granted. However, on 27 May 2004, a month after the internal MHS audit referred to earlier, he also conducted an audit of the performance of the MHS in performing their enforcement functions at the Abattoir. The aim was to see whether the MHS was doing so properly in accordance with the MHS Manual.
- 9.144 In the Executive Summary of his report, Mr Thomas stated that the fabric of the building was deteriorating rapidly and that, realistically, the premises were coming to the end of their working life. He further stated that the HAS scores assessed before the arrival of the current OVS, Mr Pastoriza, who had been in post since September 2003, were inflated and did not accurately reflect the operation or condition of the premises. Mr Thomas accepted in his oral evidence that this was an inference as opposed to there being any direct evidence; he said that he had formed that view by comparing the plant scores awarded prior to the current OVS taking over (which were in the upper 60s to 70s) with those awarded thereafter (in the low 60s to high 50s). Mr Thomas was of the opinion that the current OVS was, in general, taking the appropriate measures to rectify the situation and was putting into place enforcement action. Mr Thomas stated however that the OVS had a difficult task ahead of him, for although Jonathan Tudor was co-operative, he objected to spending money on a building which had only a very short life left.

- 9.145 The audit report noted the following deficiencies at the Abattoir:
- (i) It recorded that the OVS had correctly identified hygiene deficiencies.
 - (ii) It concluded in relation to the structure and maintenance that the time was approaching when the decision must be made to move to a new establishment because in parts the structure of the building was deteriorating rapidly.
 - (iii) It noted that the staff had basic hygiene induction training only, that there was no training programme and there were no training records. The report concluded that the MHS staff had failed to take action in relation to these failings.
 - (iv) In relation to operator checks on cleaning, the report noted that, on some occasions if slaughter went on late in the day, cleaning only took place on the next day of slaughter. That might not be until the following week and this happened on more than one occasion. Another problem identified was that effective cleaning was becoming extremely difficult because of the pitted surfaces in the plant.
- 9.146 In relation to enforcement procedures taken by the MHS, the report stated that the first steps in the enforcement hierarchy were being started. In oral evidence (but not in the report), Mr Thomas stated that it was concerning that only the first steps of enforcement were apparently being implemented. He stated that it had been his intention to encourage OVSs to start taking more rigorous enforcement action. He stated that, in order that a strong case for revocation could be presented, evidence of both structural problems and hygiene problems would be required and the appropriate hierarchy of enforcement would need to be demonstrated.
- 9.147 He returned to this theme at the end of his report. Singling out the fact that cleaning was on occasion left until the next slaughter day he concluded that the OVS should have served enforcement notices on the operator to deal with the issue. More generally, he commented that:
- “...unless there is a dramatic change in the condition of the structure and maintenance of the building, including cleaning, then there is going to be a recommendation for the revocation of the operational licence. In this situation the application of the appropriate enforcement action is essential.”
- 9.148 HACCP does not feature in the report. Mr Thomas stated in oral evidence that he was told not to audit the performance of the MHS in enforcing HACCP.
- 9.149 The report was then commented upon by the OVS responsible for corrective action to be taken to remedy the specific deficiencies identified. He confirmed in November 2004 that the corrective action described in the Corrective Action Report had been taken. Specifically,
- (i) In relation to training of staff, the corrective action involved Jonathan Tudor being “reminded” of the need to implement further training.
 - (ii) In relation to enforcement action, the corrective action was described as follows:

"Enforcement escalated at the premises, there has been multiple notices served to the plant operator and though the general condition of the building has not improved dramatically, action has been taken to ensure that the hygiene of production improves and there is an ongoing process and the disposition of the plant operator look good to get the situation improved." (sic)

- 9.150 On 5 January 2005, Mr Stallard signed off the Corrective Action Report confirming that the corrective action had been completed to his satisfaction.

Conclusions on Audit Reports and Corrective Action Report

- 9.151 Judged in the context of the Hygiene Reports, my conclusions in relation to the Audit Reports and the Corrective Action Report are as follows:
- (i) The reports prepared by the Internal Audit Team and by Mr Thomas and particularly the Corrective Action Report were inadequate in the light of the clear picture that emerged from the Hygiene Reports. Even a cursory examination of the Hygiene Reports in the period leading up to the audit report must have shown a long history of persistent non-compliance with a number of fundamental hygiene requirements laid down in the legislation. Such an examination would also have revealed, even since the new OVS took over at the end of 2002, that the enforcement action taken had been patently inadequate to cause any real improvement in the situation. The so-called "first steps" of enforcement action at that date in reality comprised little more than alerting the management of the Abattoir to problems which were then ignored and not dealt with.
 - (ii) Rigorous and properly escalated enforcement action was plainly needed. It should have been identified as set out in clear terms in the audit report and then taken until it had the effect of moving the Abattoir to compliance with the legislation.
 - (iii) It is difficult to detect more than a marginal improvement from the scores recorded in the Hygiene Report in the period leading to the OVS signing off the Corrective Action Report in November 2004. The "multiple notices" do not appear to have had a significant impact, and on no view secured a state of legislative compliance by that time.
 - (iv) Even if there was some temporary improvement, it appears to have dissipated by the time Mr Stallard signed the Corrective Action Report off indicating his satisfaction with the corrective action taken. For example, the latest Hygiene Report before he signed off indicated that there was legislative non-compliance and thus a "C" score in seven categories on one inspection (4 January 2005) and six, with one borderline at "B/C", on the next (5 January 2005).
- 9.152 I note the stark contrast between the tone and conclusions of the reports prepared by the Internal Audit team and that of the report prepared by Mr Thomas. This is surprising on the basis that the same underlying documentation would have been used as a baseline for drafting the reports, and the purpose of the reports was also the same.

- 9.153 It is also to be noted that in early to mid 2004, Mr Stallard identified a number of concerns about the performance of the OVSs at the Abattoir.
- 9.154 In an email dated 20 April 2004, Mr Stallard noted his concerns about one of the OVSs responsible for the Abattoir, namely Ms Astorquiza. He said in oral evidence that his concern arose as a result of some feedback he had received from the RMVA and an unannounced visit that he undertook at the premises on 16 March 2004. During his visit, he had noted that in the hanging hall there were kit bags with outdoor clothing and shoes, cups of tea and empty milk bottles on the table and some old rusty saw blades had not been disposed of properly but just left on the floor. In addition to the poor state of the premises, Mr Stallard stated that he was also not impressed with the standard of supervision that was being operated at the plant by the OVS. What he saw was not reflected in the report for that time.
- 9.155 On 7 July 2004, Mr Stallard sent Mr Pastoriza an email attaching an Employed OVS Performance Monitoring Form dated 6 July 2004 noting the Key Performance Indicators against which “amber lights” had been awarded. These included one instance when no completion date had been agreed for the Abattoir to comply with requirements, and two completion dates had expired with no evidence of the Abattoir’s compliance provided.
- 9.156 Mr Pastoriza received a further warning, this time in the form of a “red light” on 16 August 2004. Mr Stallard confirmed in oral evidence that the red light meant that Mr Pastoriza needed to “pick his game up” and that the warning related to his supervision of the Abattoir. Enforcement action at the plant had been seriously/unacceptably delayed in the opinion of the RMVA. Mr Stallard stated that there was nothing more serious than a red light in this scheme and that, as a result of a red light being given, both himself and the RMVA would usually visit the OVS concerned to at least provide some indication in terms of direction about the improvement needed. It is not clear whether this in fact occurred or what the result was.
- 9.157 These documents and others referred to above are of particular significance as they indicate that Mr Stallard, as the MHS Area Manager, either was, or should have been, well aware that:
- (i) the Abattoir was a serious problem which was non-compliant with the legislation in a number of respects.
 - (ii) those responsible for its day-to-day monitoring were encountering serious difficulties effecting improvements, and did not appear to be using the enforcement tools at their disposal to good, or indeed any real, effect.
- 9.158 The result should have been the active involvement of MHS senior management, in particular Mr Stallard, in monitoring the performance of the Abattoir and of those responsible for enforcing the Regulations (the employed OVSs). That involvement should have continued until standards were driven up or a position was reached where it became clear, if it was not already, that the Abattoir should not be operating because it could not do so in compliance with the legislation.

2005

The Thomas Appraisal Report in April 2005

- 9.159 Some months before the Outbreak, on 5 April 2005, Mr Thomas produced an Appraisal Report following a visit to the Abattoir. The purpose of the visit was to assess the prospects of the premises being able to comply with the 2006 EU Regulations that were due to be introduced in 2006.
- 9.160 Mr Thomas stated that some of the problems contained within the Appraisal Report looked “remarkably similar” to the problems identified in 1994.
- 9.161 The core of the report was contained in the schedule of deficiencies produced by Mr Thomas:
- (i) Mr Thomas accepted that the schedule provided a damning summary of the structure and layout of the premises; and that the deterioration of the structure carried with it a serious risk of contamination of food.
 - (ii) He concluded that the hygiene operations were seriously flawed, with “clean” operations taking place next to “dirty” operations. The hygiene facilities were also not adequate.
 - (iii) Under “HACCP-based controls” he concluded that the pre-requisites were not being fully implemented. Cleaning procedures were not being implemented. The maintenance log did not reflect the true condition of the premises. Mr Thomas stated in oral evidence that the maintenance log should, for example, identify matters such as cracks in the floor and flaking paint and that a corrective action programme should be drawn up by the operator on a risk basis to address them. A generic FSA HACCP plan had been used as a template and had been directly transposed to the Abattoir. That rendered it ineffective even as a plan because it had not been customised to take account of the process steps in the establishment. The plan had not been validated. There was no evidence of a hazard analysis having been undertaken. Very little monitoring had been done. Mr Thomas accepted that the situation at the Abattoir was almost the definition of a fundamental failure to have a decent HACCP system in place.
 - (iv) In relation to history of past compliance, Mr Thomas stated that there was evidence to show that most deficiencies had been identified in the past but that the hierarchy of enforcement action had not been enforced to its logical conclusion. The reason given was that the operator was looking for a site to build a new facility but that he had so far been unsuccessful. Mr Thomas confirmed in oral evidence that this was what he had first been told some 11 years earlier in 1994.
- 9.162 The report concluded that the establishment did not comply with the current legislation and that the amount of work required in order to do so was probably not a financially-viable prospect at the current location.

- 9.163 Given the contents of the report, I find it extremely surprising that the Abattoir was allowed to remain in operation for a further six months. More pertinently, despite the report, it was still in operation at the time of the Outbreak in September 2005 and continued to operate until January 2006.

The Hygiene Reports

- 9.164 The picture as it appears from the Hygiene Reports in 2005 is the same as that which emerges from the Appraisal Report, and indeed as appears from the Hygiene Reports for earlier years. The persistent and serious problems continued. Such enforcement action as was taken did not have any real impact on the state of legislative non-compliance.
- 9.165 In relation to HACCP, there was no significant improvement in 2005. HACCP monitoring continued to score "C" or (after the change in scoring systems) to be marked non-compliant. Mr Pastoriza stated that the change in scoring systems in May 2005 was because there was a different emphasis by this time moving closer to verifying and audit rather than more active supervision of the operator. That was because, as he put it, "by this time all plants will have HACCP systems in place". In fact, as he acknowledged, at this time the Abattoir was still a long way from compliance: "they have a [HACCP] plan but it was not credible".
- 9.166 I have examined with particular care the Hygiene Report for Monday, 5 September 2005 and Tuesday, 6 September 2005. According to records, 5 September 2005 was the last occasion before the Outbreak on which cattle from the Farm were slaughtered at the Abattoir. Microbiological testing and typing confirmed the outbreak strain of *E.coli* O157 on the Farm was the same as that in people who were infected. The report is fairly illustrative of the sort of problems that persisted. On those dates, the same problems that had been in place since 2003, and indeed in some categories for years earlier stretching back to 1994, were identified and recorded. The Report recorded the following specific aspects as being non-compliant with the legislation:
- (i) Slaughter practices; the problem being described in the second section of the report as poor knife hygiene.
 - (ii) Cross-contamination controls including operation cleaning.
 - (iii) Staff hygiene practices.
 - (iv) Other practices.
 - (v) Rooms, equipment and facilities – the second section indicating that rooms and facilities "fall short from legislative requirements".
 - (vi) Operator maintenance programme – the second section indicating "no appropriate maintenance carried out".
 - (vii) Layout – the second section indicating "layout compromising hygiene of practices".
 - (viii) Separation of clean and dirty areas.

9.167 HACCP was also marked as non-compliant. The Hygiene Report indicates that even then, over two years since the HACCP Regulations came into force in relation to the Abattoir, and despite the repeated identification of the problem and repeated discussions, HACCP had still not been implemented at the Abattoir. The Report indicates that even then (and even after the Appraisal Report some months earlier), the HACCP plan remained incomplete and unfinished.

Conclusions

9.168 My principal conclusions are as follows:

- (i) Over a prolonged period, the MHS repeatedly failed to perform effectively its overall enforcement function in relation to the Abattoir. The longstanding, repetitive, failures were made much worse by the fact that there was an abundant knowledge amongst the staff that it was a failing abattoir. Despite this knowledge, the Abattoir was allowed to continue to function in breach of the legislative requirements
- (ii) It is not in dispute that the Abattoir was in serial breach of the legislative requirements. The nature of those breaches remained substantially the same throughout the period. The breaches did not simply relate to peripheral or technical matters. They went to the heart of the ability of the Abattoir to produce safe food; to the structure and its maintenance, to its layout, to the slaughtering and hygiene practices, and from June 2003 to the very existence of an effective and operating HACCP plan.
- (iii) The breaches were not the result of some recent downturn. The documentation that exists in relation to the early to mid 1990s indicates that substantially the same problems had existed un-rectified and unaddressed since that time.
- (iv) It appears from the contemporaneous documentation that those responsible for enforcement of the legislative requirements were well aware of these serial and persistent breaches. The MHS had designed a series of forms for recording relevant details. Those forms were well-designed and tailored to the legislative requirements. They achieved their purpose, focussing the minds of those responsible on whether the Abattoir complied with those requirements. The Hygiene Reports from 2003 onwards provide a clear picture of the true state of the Abattoir and its operations and practices. The monthly HAS reports also indicated a failing slaughterhouse, at least sufficiently to the point where they should have caused those in management who saw them to examine more closely the true extent of non-compliance at the Abattoir.
- (v) The OVSs knew the true position because they completed the relevant forms, including the Hygiene Reports. However, it is also clear that area management became aware of the state of non-compliance at the Abattoir. Mr Stallard's correspondence in 2004, dealt with above, establishes that at the latest by that time he was well aware of the problems.
- (vi) Despite all this, the position did not improve. The same breaches recurred; the same problems remained embedded. The MHS utterly failed to take the necessary, or any effective steps to secure legislative compliance.

- (vii) The responsibility for that failure lies in the first instance with the OVSs but equally, however, with area management. Area management could, and should, have realised that, for whatever reason, the enforcement steps being taken by the OVS were not effective to achieve a state of, or even approaching a state of, legislative compliance. Area management needed to become actively involved in ensuring that the requisite enforcement, and if necessary advisory, action was taken. It is, and should be, a basic function of managerial oversight to identify situations such as this, as they in fact did, and then to ensure that they are properly addressed. Area management should have ensured that the staff were equipped with the support and training necessary.
- (viii) There appears to have been a variety of reasons for the failures.
- (ix) In relation to HACCP, the evidence of Mr Hewson and others indicates that a deliberate decision was taken by the FSA not to enforce the legislative requirements. That decision was, and is, unacceptable. The function of the MHS and the FSA was to apply the legislative requirements that Parliament saw fit to impose in order to minimise the risk of unsafe food being produced. It was not for the MHS or the FSA to choose not to enforce that legislation. Moreover, the concerns expressed about the timing of the legislation appear to me to be without real foundation in a case such as this. There appears to have been plenty of warning that compliance with HACCP principles was to be introduced as a requirement, more than sufficient for any preparatory training or advisory work to be undertaken to enable the industry to be ready on the date the requirement came into force. In any event, by the time of most interest, that is, September 2005 when the Outbreak occurred, the HACCP requirement had been in force so far as the Abattoir was concerned for over two years. Yet there was still not even a credible or effective HACCP plan in place, as indicated both by the Hygiene Reports and from the damning Appraisal Report prepared by Mr Thomas in April 2005.
- (x) In relation to the other failures, the reason consistently advanced by the MHS and OVS witnesses was that they were seeking to work with Jonathan Tudor, they sought deliberately to adopt a co-operative approach to enforcement, and that some warning letters and Improvement Notices were served. On this aspect, my conclusions are:
- (a) There is, of course, benefit in seeking, in the first instance, to achieve the resolution of problems and compliance with legislative requirements by discussion and agreement with the management of a slaughterhouse. However, as the MHS Manual itself recognised, sometimes that approach would not be sufficient. It was for precisely that reason that the MHS Manual (Chapter 18) set out and gave detailed guidance about the hierarchy of enforcement taking progressively more serious enforcement steps in order to ensure compliance with legislative requirements.

- (b) As the legislation and the MHS Manual indicates, all the necessary enforcement tools were available, from advice and recommendation to the service of formal notices to suspension of the licence and, ultimately, to revocation of the licence. Chapter 18 of the MHS Manual noted specifically, but tellingly, given the length of time over which the persistent breaches recurred, that prior to a recommendation by the MHS to revoke a licence “a good trail of enforcement action in relation to the premises exists over a period of time, normally six months... a shorter period may be appropriate depending on the condition and/or history of the premises”. As Area Management was aware of what was happening at this Abattoir, the necessary technical and enforcement support should have been provided to secure compliance.
- (c) The Hygiene Reports clearly indicate that the limited enforcement action that was taken was demonstrably ineffective to achieve compliance with the legislative requirements. Months and then years passed without significant improvement, still less achieving the required compliance.
- (d) What was needed, but never put into place, was a rigorous enforcement programme designed to compel compliance, if necessary put in place and overseen by more senior MHS management. If J.E. Tudor & Sons Ltd was unable, or for economic reasons unwilling, to achieve compliance, steps should have been taken, after working up the hierarchy of enforcement in order to demonstrate such inability or unwillingness, to suspend or revoke the licence.
- (e) No doubt time and resource would have been necessary in order to pursue this. However, the outcome was that, in effect, the body responsible for enforcement of legislation designed to secure food safety permitted a slaughterhouse to produce food that risked being unsafe because of a failure to comply with the legislation.
- (xi) The result of that failure was that an abattoir that should either have become compliant or have been shut down continued to operate whilst failing in serious respects to comply with food safety legislation. By reason of the MHS not effectively controlling compliance with food safety legislation within the Abattoir, there would have been a substantial increase in the risk of *E.coli* O157 on meat coming out of the Abattoir. As a result, the risks of unsafe food being produced and supplied into the food chain were considerably higher than they should have been.

Development since the Outbreak

- 9.169 Under the EU Food Hygiene Regulations, which came into force on 1 January 2006, the MHS carries out some professional inspection duties, but there is a greater emphasis on auditing the efficiency and effectiveness of operator controls for hygiene, animal welfare and animal health as opposed to directly supervising business activities. Some premises such as catering butchers, which were previously under Local Authority control, now require veterinary controls and fall under the responsibility of the MHS.

- 9.170 The MHS Operations Manual has been replaced with the MHS Manual for Official Controls. It includes a new audit and risk assessment scheme which includes the element “confidence in [food safety] management”.
- 9.171 MHS systems and controls in abattoirs have been subject to a variety of reviews in the period since the Outbreak, including internal and external audits, and independent reports. The European Commission’s Food and Veterinary Office also reported on the application of HACCP-based procedures.
- 9.172 The MHS points to changes in its management structure, saying that it has seen the opportunity to centralise and strengthen decision-making, particularly on enforcement. It is said that the new management structure, to be fully operational in April 2009, will support the escalation of enforcement action.
- 9.173 Consistently non-compliant operators will be brought to the attention of MHS Headquarters and a case conference system will consider such cases for immediate suspension or withdrawal of approval. Alternatively, an operator may be allowed to agree to an action plan to correct deficiencies. If the action plan is not adhered to, procedures to withdraw approval will be initiated automatically.
- 9.174 I am disappointed to note that the changes to the management structure will only become fully operational more than three years after the Outbreak. I am simply not in a position to judge whether the changes made will lead in practice to more effective enforcement of the legislative requirements.

Introduction

- 10.1 The source of the Outbreak was contaminated cooked meats supplied to schools by John Tudor & Son ("Tudors"). That supply was made under a contract with Rhondda Cynon Taf ("RCT"), Bridgend, Caerphilly and Merthyr Tydfil County Borough Councils. The contracts were awarded following competitive tendering processes.
- 10.2 The last full tendering process before the Outbreak was undertaken in 2002. RCT, Bridgend and Merthyr Tydfil contracted with Tudors for a term of three years to 31 May 2005, with an option to extend for a further period of up to two years. These authorities had previously contracted with Tudors for the supply of meat into schools in 1998, although Tudors had in fact been a supplier to Mid Glamorgan County Council prior to local government reorganisation in 1996.
- 10.3 In 1998, Caerphilly decided to contract with another meat supplier and in the 2002 tendering exercise, decided to stay with that supplier.
- 10.4 In early 2005, a decision was taken by RCT, Bridgend and Merthyr Tydfil to extend the Tudors contract by a year. In May 2005, Caerphilly also contracted with Tudors because their supplier was unwilling to extend the term of its contract.
- 10.5 So, at the date of the Outbreak in September 2005, all four authorities were using Tudors to supply meat into their schools.
- 10.6 In those circumstances, questions were raised about the procurement processes that led to the award of those contracts. They were the subject of extensive evidence to the Inquiry from each of the four authorities, both written and oral. They are the subject of this Chapter.

Procurement by Local Authorities

- 10.7 Contracts are tendered in accordance with an authority's Standing Orders, which take account of EC Procurement Directives. A local authority may from time to time produce its own guidance on good purchasing practice. From 1 April 2000, and as indicated in the tender documentation, local authorities in England and Wales had a statutory duty to provide Best Value in terms of functions being delivered. This required certain criteria to be monitored, including product quality, customer satisfaction, and the number of complaints made against the contractor/supplier.

National Guidance

- 10.8 In July 2004, the Welsh Assembly Government published "Food for Thought". This document provided guidance on good procurement practice. It formed part of a broader initiative called the "Welsh Procurement Initiative". The guidance was endorsed by the Welsh Local Government Association, and was distributed to Chief Executives of all Local Authorities in Wales.

- 10.9 It was not binding. It was guidance. But considerable work had obviously gone into it, and it was endorsed by the Minister for Environment, Planning and Countryside. Moreover, as Ms Alison Standfast (who works for a section of the Welsh Assembly Government's Department for Public Service and Performance called "Value Wales") stated in her evidence, her view was that it was reflective of current best practice at the time.
- 10.10 "Food for Thought" was aimed at procurement professionals and catering managers. It contained a section on public health and safety, which stated that public sector procurement must ensure that it minimises any safety risks to its recipients. Under this section, it stated:
- "....public sector organisations supplying food have an obligation to complete effective due diligence to ensure the quality and compliance of their suppliers. Suppliers are expected to have an adequate Hazard Analysis and Critical Control Point system ("HACCP"). This affects the supply, preparation, packaging, storage and distribution of food..."
- 10.11 It also contained a section on due diligence. This stated:
- "Public sector organisations have a responsibility to carry out due diligence which requires that they have taken reasonable steps to inspect physically the supplier's operation and food samples to check compliance with their requirements for health and safety systems (and HACCP systems), food quality and nutritional content and consistency...Periodic reviews of existing suppliers are also required...."
- 10.12 It also stressed the importance of regular communication with existing suppliers and pointed out that contract compliance may reduce over time if effective compliance and performance monitoring is not in place.
- 10.13 In April 2005, as a follow-up to its guidance, the Welsh Assembly Government published, as part of its Procurement Initiative, a series of case studies showcasing organisations that were leading the search for better quality food. John Tudor & Son was one of two suppliers featured in the "Lamb for Lunch" school meals pilot project, which was led by RCT .

Procurement Systems at the Local Level

RCT becomes the Lead Authority

- 10.14 In 1996, local government in Wales was re-organised. That led to a re-organisation of the way in which local authorities' food procurement arrangements were implemented. Initially, the procurement re-organisation involved RCT, Merthyr Tydfil, Bridgend and part of Caerphilly. After a short period, it involved Caerphilly as a whole.
- 10.15 The new arrangement was a collaborative one. It involved the four authorities working together on food procurement rather than individually. The intention behind it was that the authorities would benefit from economies of scale and pooled expertise.

- 10.16 From the outset of the new arrangements, Mr David Evans was the leading individual. He is now Senior Project Manager in "Value Wales", part of the Welsh Assembly Government, reporting ultimately to Ms Standfast. He had been involved in food procurement for the old Mid Glamorgan County Council. He then moved, on the local government re-organisation in 1996 to Bridgend. As a result, Bridgend initially took the lead in the new arrangement.
- 10.17 From early 1997, Mr Evans worked two days a week for RCT's Procurement Department. The remainder of his week was spent with County Borough Supplies working out of Bridgend County Borough Council. The Head of RCT procurement, and Mr Evans' manager, was initially Mr Derek Stacey. From 2002, it was Mr Andrew Maisey. Then, following an internal re-organisation from 2004, Mr Vince Hanly. Mr Evans' assistant was Mrs Sue Glendinning.
- 10.18 From 1997 onwards, RCT became the lead authority in the food procurement arrangements. It was accepted by all concerned that this was the position. There was, however, some difference between the four authorities as to what this role of lead authority entailed.
- 10.19 As Mr Evans was aware, others regarded him as having the requisite experience and expertise to take the lead role. In that position, as he accepted, the system of procurement was effectively his to design and operate. He also accepted, in my opinion fairly and correctly, that:
- (i) The lines of responsibility and roles each authority was expecting the other to play needed to be clear in order to ensure good and effective decision making.
 - (ii) It was his responsibility to ensure that that was so.
 - (iii) A written document clearly setting out those lines of responsibility and roles (of the kind put in place after the Outbreak) should have been, but was not, in place at any time before it.
 - (iv) That lack of clarity represented a serious failure in the system as it operated under him as Contract Manager.
- 10.20 Two other structural matters need to be mentioned at this point:
- (i) A Catering Managers' Group ("CMG") was set up to deal with food procurement issues and collaboration between catering departments. It had representatives from each of the four authorities. Its Chair was Mr Evans. Its proceedings were described as "informal". No minutes or notes were taken of its meetings for the first few years. The relatively few minutes that were produced to the Inquiry are very brief. They contain only the bare minimum of information about discussions and decisions.
 - (ii) Each authority had its own catering department. For example, in RCT, this was Catering Direct. Catering Direct was not part of RCT's Procurement Department. The catering departments acted as the day-to-day links between Tudors as the supplier, and schools.

Tender and Contract

- 10.21 In both 1998 and 2002, RCT as the lead authority produced the tender documentation that was used to assess and decide which supplier should be awarded the contract for the supply of meat to the schools; and produced the terms of the contracts then entered into. That documentation was produced by Mr Evans after some consultation and discussion with the Trading Standards Department in RCT, principally to ensure that the correct legislation was being referred to in it. The tender documentation was not discussed or checked with RCT's Environmental Health Department (which was in the same office as Trading Standards).
- 10.22 Although the other authorities were provided with this documentation, and could have commented on it if they wished to do so, they did not in fact do so. Evidence from Mrs Norma Griffiths, Group Manager Schools Services, Bridgend, Ms Marcia Lewis, Catering Contracts Manager, Caerphilly, and Mrs Margaret Gibbons, Business Unit Manager, Merthyr Tydfil, is that they relied on Mr Evans and RCT as the lead authority to deal with this aspect. My view is that they were justified in taking that approach given Mr Evans' experience and expertise and RCT's status as lead authority. The limit of their input into the tender documentation was in the provision of information about their individual meat requirements.
- 10.23 Mr Evans also took the lead in organising and managing the tendering process. RCT issued the tender documents and received and then distributed the responses to the other authorities. RCT also organised sample tastings of meats at which all four authorities attended.
- 10.24 However, although RCT took the lead in organising the process, each authority contracted on its own behalf. As Caerphilly's decisions in 1998 and 2002 indicate, it was for each authority to make its own mind up about whether to contract with Tudors for the supply of meat.
- 10.25 The principal difference between Caerphilly on the one hand and Bridgend and Merthyr Tydfil on the other is that Caerphilly adopted a proactive approach to this decision making, making their own checks about a potential supplier. They had their own Supplier Review Group. They were clear that the decisions about who to contract with were theirs to make.
- 10.26 Bridgend and Merthyr Tydfil by contrast adopted a far more passive role. They treated the arrangement as amounting to what, in effect, was a complete delegation of the decision-making to RCT.

Contract Monitoring

- 10.27 Mr Evans accepted the need for proactive contract monitoring by RCT. In this respect also, RCT acted as the lead authority. Again, Merthyr Tydfil and Bridgend treated the contract monitoring function as being one to be carried out by RCT and not proactively by them.
- 10.28 The handling and processing of complaints necessarily involved each of the authorities to a much greater degree. This aspect is dealt with in detail later in this Chapter.

What Happened

The 1998 Tender and Award

- 10.29 Tudors had supplied meat to schools in Mid-Glamorgan before local government reorganisation took place in 1996.
- 10.30 From 1996 to 1998, Tudors supplied all four local authorities with meats for their schools.
- 10.31 In April 1998, the meat supply contract for a significant part of the local authorities' needs, including the supply of meat to schools in the area, was put out to tender. The period of the proposed contract was three years. RCT took the lead in the sense described above.
- 10.32 Tudors tendered on 4 May 1998.
- 10.33 It is evident that there were some concerns about Tudors' performance of the contract even at this stage.
- (i) A letter dated 30 July 1998 referred to concerns expressed by RCT's Catering Direct "regarding delivery and quality...backed up by a number of complaints received from cooks during the past few months". These complaints related to the quality of turkey, the undercooking (on numerous occasions) of pork, the high fat content of the pork, the use-by dates on sliced meats and the storage together in the delivery vans of raw and cooked meats (with several incidents of blood found on the outer packaging of cooked meats).
 - (ii) In addition, Caerphilly had had a number of complaints over the preceding two years about Tudors' supplies. Between September 1996 and October 1998, Caerphilly recorded 40 complaints including: undercooked meats; bad taste and/or smell; blood on the outside of bags; foreign bodies in meat (e.g. a bug; pieces of plastic); products past their use-by dates; lack of delivery; underweight deliveries; excessive fat in products; excessive temperatures on delivery. There was also concern at Caerphilly about the way that complaints were handled by Tudors and the action undertaken to redress them. Ms Marcia Lewis, Caerphilly's Catering Contracts Manager, drew these to the attention of Mr Evans and, through Mr Andrew Maisey, who at that time was working for Caerphilly, and who then transferred to RCT in 2002 shortly before the contract with Tudors was entered into. She specifically asked that complaints be taken into account in deciding whether or not to continue the contract with Tudors.

- 10.34 Mr Evans' evidence is that he did take them into account, and that Ms Lewis had made a verbal report to the CMG, with the result that representatives of the other authorities were also aware of them before making their own decisions on the choice of supplier.
- 10.35 As part of the process of deciding who to contract with, officers from Caerphilly had themselves visited the factory of another butcher (which was referred to in the Inquiry's hearings and which will be referred to in this report as "ABC Butchers") on 8 July 1998. They did so because ABC Butchers was a new supplier. They reported that aspects of ABC Butchers' premises were checked, including quality systems, HACCP and traceability.
- 10.36 Tudors was not inspected by Mr Evans in this way. The closest he came to doing so was in visiting Tudors' offices on a number of occasions. Nor did he visit ABC Butchers at any stage.
- 10.37 Ms Lewis told Mr Evans that this inspection had been undertaken. She also made a report to the CMG explaining in "firm" terms why Caerphilly had decided to contract not with Tudors but with ABC Butchers. That decision was based on quality, cost and organisational capability.
- 10.38 Caerphilly decided that they did not wish to contract with Tudors. Instead, they decided to contract with ABC Butchers. Ms Lewis did not consider that the call between Tudors and ABC was a close one; she accepted that there was, in her view and in the context of the three factors above, "clear blue water" between them. Caerphilly notified RCT of their decision on 14 July 1998.
- 10.39 Notwithstanding Caerphilly's concerns, the other three authorities remained with Tudors. Inadequate attention was paid to the evident problems with Tudors. On 7 September 1998, the contract was awarded to Tudors for schools in RCT, Merthyr Tydfil and Bridgend.

The 2002 Tender and Contract Award

- 10.40 The contract was due to be re-tendered in 2001 but because of the foot and mouth outbreak, it was extended for a year to allow the market to stabilise. It was then extended for a further three months to 31 August 2002.
- 10.41 The new contract was for a three year period, with an option to extend for up to another two years.
- 10.42 The tendering process was again organised and led by Mr Evans on behalf of RCT.
- 10.43 Seventeen invitations to tender were issued. The invitation to tender stated the value of the contract to supply the four authorities as approximately £500,000. So, it was a substantial contract.

The Questionnaire

- 10.44 William Tudor submitted the required tender documentation on 27 May 2002.
- 10.45 A 'General Information Questionnaire' was used to assess the suitability of potential suppliers in the tender exercise.
- 10.46 Tudors' completed questionnaire stated that:
- (i) William Tudor could supply copies of inspection reports of visits by Environmental Health Officers, of visits as a result of accreditation to a Society or Trade Organisation, and of visits by Health Authority personnel and other local authorities (Question 3a-e).
 - (ii) Tudors operated a quality assurance scheme which monitored products from the time of delivery to the time of orders being dispatched (Question 5).
 - (iii) Tudors had been previously assessed in relation to quality assurance by way of the "factory visits and audit reports shown" (Question 7).
- 10.47 In response to information requested on the HACCP requirement of maintenance of the cold chain during distribution/storage, William Tudor said that all stages of the cold chain were recorded and set down in their HACCP document. The quality of Tudors' HACCP document was examined in detail in Chapter 7. The names of three other customers were provided for reference purposes: Neath Port Talbot County Borough Council; Pontypridd & Rhondda NHS Trust; Swansea City Council. I saw no evidence that the references were taken up as part of the contract award process.
- 10.48 My view is that, for the following reasons, there were serious flaws in both the design and use of the Questionnaire:
- (i) Question 3 asked if the tenderer could supply copies of inspection reports of Environmental Health Officer visits, with a simple "Yes/No" answer. There was no requirement for copies of the documents to be provided. Copies were not requested from, or provided by, Tudors. Mr Evans was unable to explain why he did not do so, and accepted that he had made an error in not doing so.
 - (ii) Question 2 asked whether Tudors were seeking accreditation to ISO9002, or BS5750 (standards relating to quality assurance in production). However, by 2002, BS5750 was out of date. Mr Evans accepted that its continued inclusion in the form was another error. Not merely that, but precisely the same question had been asked in 1998. At that time, William Tudor had stated that he was "working towards" accreditation. Four years later he gave essentially the same answer, stating that, despite the four year gap, he was still working towards accreditation. Mr Evans accepted that he had been in error in not checking back to the previous form either in relation to this answer or more generally.

- (iii) Question 5 asked about Tudors' internal quality assurance scheme. Mr Evans accepted that no checks had been made of Tudors' positive answer to that question.
- (iv) Mr Evans then accepted that the reality was that no checks whatever had been made in relation to the answers that had been given on the Questionnaire by Tudors.
- (v) Butchers' Shops Licensing Regulations had been introduced after my report into the 1996 outbreak in Scotland. However, the Questionnaire did not ask whether the tenderer was in possession of a Butcher's Licence.

Other Checks

- 10.49 In 2002, as in 1998, there was no inspection of Tudors by RCT as part of the contract award process.
- 10.50 Mr Evans did not at any stage make contact with Bridgend's Environmental Health Department, which was responsible for inspecting Tudors. Contact with the relevant Environmental Health Department, the "Home Authority", for a business in another area was done for the first time when Mr Hanly of RCT did so immediately following the Outbreak when consideration was being given to which supplier would replace Tudors
- 10.51 Nor, as Mr Evans accepted, was any risk assessment undertaken in relation to Tudors. Such an assessment would have involved, according to him, a food quality expert visiting Tudors and reviewing the Hazard Analysis Critical Control Point ("HACCP") records and the facilities.
- 10.52 Mr Evans did not do so because in his judgement Tudors were "low risk". That judgement was based on the fact that Tudors was trading under an inspection and licensing regime operated by Bridgend, was the current supplier under the previous contract and to other public authorities, and that significant complaints about their performance of the 1998 contract had not been raised at CMG.
- 10.53 The fact that the checks referred to above were not carried out is of concern not least because all the other authorities were either operating on the assumption that the checks on health, safety, quality and/or accreditation issues had been conducted by RCT as part of the process of evaluating the tenders received. .
- 10.54 The tender documentation was not circulated to procurement officers in Merthyr Tydfil and Bridgend prior to the contract being accepted. Rather, it was only provided to Catering Managers. This was accepted in oral and written evidence by Bridgend and Merthyr Tydfil's Procurement Officers, Mr Paul Davies and Mr James Ferris, as being a flaw in their respective systems. The Inquiry was told that their Procurement Departments had little, if anything, to do with the food contract. Developments since the Outbreak, indicate that Procurement Officers are now involved in such decisions.

Tender Evaluation

- 10.55 Mr Evans co-ordinated the analysis and evaluation of tenders, although (as noted above) it was for each authority to make its own mind up as to the supplier with which it contracted.
- 10.56 Three tenders were received: from Tudors, ABC Butchers and another company. Copies of the tenders were sent to Catering Managers in the four authorities along with a tabulation of the prices of the products required. Members of the CMG were asked to consider the tenders and agree recommendations.
- 10.57 The CMG met on 10 June 2002. CMG asked Mr Evans to check and confirm the origins of cooked meats and to clarify certain prices.
- 10.58 The CMG met again on 27 June 2002. At this meeting, Mr Les Shawcroft (of Catering Direct) reported that between January 2001 and May 2002, 56 complaints were logged about Tudors and 27 letters were issued to Tudors. The meeting note records that Mr Evans had spoken to William Tudor about the complaints; and that William Tudor believed that the complaints had been resolved.
- 10.59 There is no reference in the minutes to a complaint that had been received some months earlier in February 2002. On 7 February 2002, and as described in Chapter 7, Mr David Dier, Principal Environmental Health Officer in Merthyr Tydfil, had registered with Bridgend Environmental Health Department a complaint about the wrapping of meats and meat products by Tudors. As a result of what he had been told and what he had found himself in foodstuffs supplied to their schools meals service, he had concerns about a supplier that appeared to be willing to tell untruths to enforcement officers and to actively avoid traceability issues and correct labelling of high-risk foods. He copied his letter to Mrs Glendinning at RCT. Mr Evans believes that, because of its seriousness, she would have rung him. Mrs Glendinning believes that she did so. But he has no positive recollection of ever having seen the letter or considering the complaint.
- 10.60 It remains unclear whether and if so, to what extent, Mr Dier's concerns fed into the discussions about renewing the Tudors' contract in 2002. Mr Evans does not recall mentioning it; and Mrs Glendinning was not present. The Merthyr Tydfil Catering Managers Team of Mrs Gibbons and Mrs Marjorie Hope were aware of the gist of the complaint made by Mr Dier although they hadn't seen the letter itself. Mrs Gibbons said in oral evidence that she could not remember Mr Dier's letter being discussed at the CMG. This is important because it shows that she was aware of the issue at least.
- 10.61 At the meeting on 11 July 2002, the only issue identified for Tudors was the complaints procedure. It was agreed that arrangements would be made to meet William Tudor to explain the deficiencies in this procedure.
- 10.62 In those circumstances, RCT, Merthyr Tydfil and Bridgend decided to stay with Tudors.

- 10.63 Caerphilly also decided to stay with ABC Butchers. Their reasons for doing so were recorded in the 11 July 2002 meeting note as being “because of cost differential not economical to change supplier”. However, an internal email from Ms Lewis to Mrs Elizabeth Lucas, Head of Procurement, a month earlier, on 10 June 2002, said “...we had to rule out ... Tudor on quality issues (apparently he is still delivering inferior products to the other areas)...” In her evidence, she accepted that quality was a major factor in Caerphilly’s decision not to contract with Tudors.
- 10.64 It is to be noted that Caerphilly produced a schedule of complaints relating to the service provided by ABC Butchers. Ms Lewis indicated however, that the main difference between Tudors and ABC Butchers in that respect was that ABC Butchers had a very comprehensive complaints procedure in place and did deal with complaints in a satisfactory way. That was in her view in stark contrast to the position at Tudors.
- 10.65 At RCT, Mr Evans prepared the contract report and submitted it to Mr Andrew Maisey, Head of Procurement at RCT, for approval. Mr Maisey had been with Caerphilly in 1998 when the decision not to proceed with Tudors had been taken. He approved the recommendation on 7 August 2002.
- 10.66 The award letter was sent on 9 August 2002. The estimated annual value of the contract for the three local authority areas at the time of award was £340,000 (Bridgend £110,000, Merthyr £40,000 and RCT £190,000). The new contract, which was allocated reference number R053/02, covered the period 1 September 2002 to 31 May 2005. It included an option to extend the contract for up to two years. The contract was in the form of a “Framework Arrangement”. Under this form of contract, a supplier offers the goods at agreed prices with individual orders placed by the catering arms of the local authorities concerned.

The Extension to the Contract in 2005

- 10.67 The Tudors contract had been due to expire on 31 May 2005. The decision was taken that it should be extended for a further year.
- 10.68 That decision was made at the Catering Managers Meeting on 13 January 2005 following discussions at the end of 2004.
- 10.69 Mr Evans confirmed that, although “Food for Thought” had been published in July 2004, it did not have any impact on the contract extension process.
- 10.70 Caerphilly, which was the only authority not using Tudors, offered ABC Butchers a 12 month extension commencing 1 June 2005. The offer was declined in April 2005 because a pilot project in Caerphilly to source meat from local farms had resulted in fewer orders for the company.

- 10.71 Faced with having to find a new supplier, officers from Caerphilly considered their options. They, through Mr Derek Morris, Senior Buyer in the Council, made enquiries of Mrs Glendinning about whether there continued to be concerns or complaints about Tudors. They said (and I accept) that they were told that there had not been any and that the other three authorities were happy with Tudors. In addition, there was concern that, by this stage, Caerphilly's only option to contracting with Tudors would have been to re-tender. There were three problems with that. First, there was very little time in which to conduct such a process. Second, to have done so and contracted with another supplier would have put Caerphilly out of synchronisation with the others in the collaborative arrangement effectively putting them out on their own for the future, and thirdly, there was a lack of obvious alternative suppliers.
- 10.72 Discussion took place with Tudors. Ms Lewis and Mr Morris met William Tudor on 12 May 2005. Mr Morris recommended acceptance of Tudors as the supplier for twelve months from 1 June 2005.
- 10.73 In those circumstances, Caerphilly concluded that they should change suppliers to Tudors. The arrangement allowed Caerphilly to participate in the Tudors' contract under existing terms. This was confirmed in writing to William Tudor on 20 May 2005; and the new Caerphilly contract started on 1 June 2005.

Contract Monitoring and Review

The Importance of Monitoring

- 10.74 Contract monitoring is vital for all contracts but particularly for the contracts in question as they involved supplying food for consumption by vulnerable groups, including young children and older persons.
- 10.75 It is therefore obvious that monitoring the performance of a contractor such as Tudors was a matter of importance. Effective monitoring ensures that the contract is being followed, and that the supplier is performing to the requisite standard(s). It also ensures that when decisions about renewals or extensions of a contract are made, full information about past contract performance is available to inform the decision-making process.
- 10.76 In a joint contract involving a number of local authorities, it was necessary for clear structures to be in place to ensure that relevant information was fed into the monitoring process. Complaints were made at the school level and thus within individual local authority areas. Systems were needed to ensure that those complaints were properly recorded and considered by those responsible for monitoring the contract in individual Catering Departments and, ultimately, by RCT's Procurement Department.
- 10.77 Mr Evans accepted that it was his responsibility to ensure that such systems were in place. His evidence was that he expected others on the CMG to participate in the process and to feed matters of significance into it.

- 10.78 From 1 April 2000, local authorities had a statutory duty to provide “Best Value”. This made it clear that the following were to be monitored as part of contract management: the number of complaints made against the contractor/supplier; customer satisfaction; product quality. To similar effect were RCT’s Contract Procedure Rules. These included provisions requiring the Contract Manager to establish and maintain a programme of contract monitoring against agreed performance indicators, including complaints.
- 10.79 The Conditions of Contract contained a series of provisions designed to ensure that only safe food was supplied, and that good hygiene practices were followed by Tudors. Significantly, in the present context, the Conditions also included (at Condition 12(e)) a provision specifically entitling the purchaser to inspect consignments in transit or at Tudors’ premises and conditions at the premises themselves.

Monitoring

- 10.80 Mr Evans accepted that the responsibility for operating this provision was his; and that it had never been operated. The only form of monitoring was reactive; that is, in response to complaints. No proactive steps of the kind envisaged by the above were ever taken.

Complaints

The System for Recording and Considering Complaints

- 10.81 Given that monitoring of complaints appears to have been the sole method of monitoring the contractual performance of Tudors, the system for doing so assumed particular importance. Mrs Glendinning accepted that complaints were the cornerstone of the contract monitoring carried out by RCT.
- 10.82 The starting point is that there was a Condition of Contract obliging Tudors themselves to keep records of complaints (Condition 32). William Tudor had stated in the 2002 Questionnaire (Question 8) that each complaint was monitored, logged and addressed individually.
- 10.83 Mr Evans accepted that this Condition would have been particularly useful in the context of multiple local authorities. It would, if properly operated, have removed the potential for confusion about what should or should not have been fed into the monitoring process. The facts are:
- (i) Tudors did not have anything that could properly be described as a system for recording complaints.
 - (ii) Mr Evans did discuss with William Tudor whether he had such a system in place and whether he was maintaining it, but only on one occasion. This was a matter that he was specifically tasked to deal with by the CMG on 11 July 2002 as part of the acceptance of their tender.

- 10.84 There are three levels at which the systems for recording, processing and escalating complaints needed to be considered. The first level involved the cook or school which had direct contact with the supplier (Tudors) and had a complaint. The second level involved the catering departments of each authority (such as Catering Direct in the case of RCT). The third level involved the Procurement Departments of the authorities. It is evident that, in order for the number and nature of complaints to feed into decision making about, for example, contract award, there needed to be appropriate and effective systems for the recording and escalation of complaints so that those involved in the decisions had a full and accurate picture of the complaints made. Full records and proper calling for, and use of, those records should also have been an integral part of proactive contract monitoring and management.
- 10.85 The evidence indicated that, with the exception of Caerphilly, where there needed to be clarity of systems and a clear understanding amongst those involved about their responsibilities at each level, there was a marked lack of clarity and uncertainty about roles and responsibilities.
- 10.86 At RCT:
- (i) Mr Evans stated that, as he understood it, the system that operated was that complaints would be dealt with on the ground i.e. at school level direct with Tudors. Catering Managers would co-ordinate complaints for their respective organisations. Issues that could not be resolved would be escalated to the Contract Manager/ Officer to act directly with the supplier. Mrs Glendinning confirmed that the Contract Manager/Officer was Mr Evans acting with her assistance. Only the escalated complaints would be recorded by RCT's Procurement Department and would be fed into the monitoring process. However, Mr Evans also stated that he believed that every authority recorded every complaint.
 - (ii) Mrs Glendinning also stated that the only complaints recorded by RCT's Procurement Department were those escalated to the Contract Manager. She agreed with the statement from Ms Anne Bull of Catering Direct that Catering Direct operated a policy of only escalating complaints to the Contract Manager in RCT Procurement if there was an evident trend developing, involving more than five complaints in a week. She then suggested that in addition, there may have been a policy of escalating complaints (in the judgement of whom it was not clear) that raised health and safety issues.
 - (iii) Ms Bull stated that if a cook had any concerns relating to the goods, a complaint form would be completed and sent to the Quality Assurance team at Catering Direct. Mrs Glendinning stated that there was such a system in place. However, Mr Shawcroft stated that while cooks were encouraged to complain to Catering Direct if they felt they ought to, he believed that there was element of discretion as to whether a particular complaint did or did not get passed up the line.

- 10.87 The other authorities described similar systems for schools to record and report complaints to Catering Managers. Cooks were expected to deal with any problem in the first instance, escalating it to their Catering Manager for action if it could not be resolved. Mrs Gibbons accepted that although they were encouraged to do so, cooks in Merthyr Tydfil had some discretion and did not always send in complaint forms. Mrs Griffiths of Bridgend also accepted that not all complaints were forwarded by cooks, although she said that all problems would be recorded in a kitchen diary. During the Inquiry, Bridgend discovered a further 21 complaints which had been recorded in kitchens but which had not been passed on to her at the time.
- 10.88 In addition to these systemic problems, the Catering Managers encountered specific problems with Tudors in following complaints through to their conclusion. For example, Mrs Gibbons in Merthyr Tydfil told the Inquiry that the main problem she had with William Tudor was him not responding to her investigation of complaints after she had notified him. He would be contacted but would not respond. Mrs Gibbons was unable to say how many of the problems were resolved. The complaints forms did not assist, save to say that the "situation would be monitored". Mrs Griffiths of Bridgend pointed to similar problems with Tudors in the summer of 2005. She stated that William Tudor was not answering any of their complaints. They had faxed the complaints to him; they had telephoned him and had contacted him, and the service was not improving. She stated it was getting poorer.
- 10.89 The systems in place and operated by Caerphilly in relation to complaints were clearer and more effective. Caerphilly recorded complaints made about their suppliers (Tudors and then, after 1998, ABC Butchers, and then from June 2005, Tudors again) pursuant to a documented system which provided guidance on handling a complaint and ensuring that it was properly recorded. In relation to the latter, Ms Lewis explained why that was considered important: without such a system they would not be able to identify trends or to know what was happening on the ground; with it they were able to keep abreast of problems and to manage the situation accordingly.
- 10.90 My conclusion on the basis of all the evidence is that the complaints system for the contract with Tudors lacked the necessary clarity and robustness. The operation of such systems as were in place at RCT, Merthyr Tydfil and Bridgend was inadequate.
- 10.91 First, it is unlikely to have been possible under those systems to provide a complete picture of complaints made about Tudors' supply under the contract. I accept that complaints about Tudors were recorded by cooks in RCT, Bridgend and Merthyr Tydfil and reported to their respective Catering Departments, and that the pattern of complaints may have varied over time. However, given the evidence above, it is clear that there was confusion and uncertainty about the roles and responsibilities and about the systems in place. I am not convinced that the systems in fact led to all complaints being recorded at the first level (in the schools).

- 10.92 Secondly, it is evident in any event that not all complaints were in fact escalated to Catering Managers. Systems with varying and no clearly defined tests for escalation to the second level (Catering Managers) were in place and some complaints were escalated. However, given the nature of those tests, it is clear that not all complaints were so escalated. Thus, if Catering Managers wanted a complete picture of all complaints recorded at the first level they would have needed to ask the schools to produce those. That was not done routinely as part of contract monitoring; and was not done across the three authorities for the purpose of generating a clear and full picture as part of the contract award process.
- 10.93 Thirdly, it is clear that the complaints information called for and received at the third level by those involved in the procurement decision making process was inadequate. There was no system in place for collating and presenting that information. Mr Evans' recollection was that in the lead up to the 2002 contract award, complaints about Tudors were only reported once to the CMG. That was a reference to a schedule of complaints prepared by Mr Les Shawcroft, Commercial Manager, Catering Direct. It covered only a limited period of time running up to the consideration of the contract award and only one of the three authorities. The complaints were both serious and varied.
- 10.94 The need for systems that captured and collated this information is obvious. Without them, procurement decisions and contract monitoring would be dealt with on the basis of an incomplete picture of Tudors' performance. Even a small number of complaints within one authority could become significant when put alongside similar complaints in another or other authorities. This point is brought into sharp focus by the policy at RCT's Catering Direct of only escalating if a trend of five or more complaints in a week became evident. The policy rightly recognised the potential significance of such a trend; but given the involvement of more than one authority, and the possibility of complaints to those other authorities, this significantly reduced the chances of a trend being spotted.

The Evidence of Complaints

- 10.95 Evidence from Merthyr Tydfil initially included details of only two recorded complaints between 2002 and 2005. Both were in June 2005 about the temperature of meat being too high on delivery. That figure increased in subsequent statements. By that stage, a further 12 complaints had been identified. Mrs Gibbons stated in her evidence that none of the complaints were fed into the CMG.
- 10.96 Evidence from Caerphilly indicated that in the first two months after they switched to Tudors from ABC Butchers, namely June and July 2005, 27 complaints were made by schools in Caerphilly. Most were about deliveries e.g. no delivery, late delivery, or delivery incorrect. However, some were about quality and temperatures of delivered meat.

- 10.97 In Bridgend, there are records of a series of complaints about Tudors in the period leading up to June 2005. Mr Evans met with Mrs Linda Harris, Procurement Manager, and Mrs Norma Griffiths, Group Manager School Services, around this time and assured them that he was going to sort out the problems. He then had a meeting with William Tudor at which assurances that the problems would be dealt with were again given. The complaints were clearly of concern to Mrs Griffiths, who stated that she put forward to the CMG that Bridgend was having problems with Tudors and that an alternative supplier should be sought. She even went as far as to investigate contracting with an alternative supplier. She said she also informed her own Procurement Department.
- 10.98 In RCT, Mr Shawcroft produced the schedule of 56 complaints in the run up to the contract award in 2002. However, during the hearings, a file of further complaints was produced. The complaints covered the period 5 January 2005 to 14 September 2005. It listed 32 about Tudors evidently made to Catering Direct but not, it would appear, passed to those who made the decisions about contracting with Tudors. While some complaints were made because of the late delivery of orders, several related to meats that were reported to be smelling.
- 10.99 In relation to the schedule of complaints he compiled, Mr Shawcroft's evidence established the following:
- (i) He had prepared the schedule "because [he] did not feel at the time that Tudors should be considered as a tenderer".
 - (ii) The nature of the complaints recorded included some concerning serious problems with the quality of the meat being provided by Tudors; and that was a matter of serious concern.
 - (iii) The complaints recorded were unlikely to be the true number of complaints in fact made; the true number would be higher. That was because cooks had an element of discretion about what they reported up to Mr Shawcroft.

End of Contract

- 10.100 The contract with Tudors was formally terminated under Clause 5 of the conditions of contract, by letter from RCT dated 9 December 2005.

Conclusions

- 10.101 My principal conclusions are as follows.
- 10.102 The process by which the meat contracts were awarded in 1998 and 2002 was seriously flawed in relation to food safety. The Questionnaire was poorly designed and out of date, and the process was not properly followed through. Important information that could have been required from Tudors was not sought. No checks of any kind were done in relation to the answers provided. There was no liaison with Bridgend as the authority with inspection and licensing functions in relation to Tudors. Evidence about contract performance and complaints was not properly marshalled and considered.

- 10.103 The system for contract monitoring was not operated properly. There was contractual provision entitling RCT to inspect Tudors and to take proactive steps to monitor Tudors' contract performance and to inspect premises. It did not. That was important both in its own right in order to ensure that the contract was being followed; and in order to inform decisions about contract renewal and extension.
- 10.104 The system for recording complaints and ensuring that a full picture of complaints was available was seriously flawed. The policies operated by the authorities appear to have varied. There was confusion about what information should be available for feeding into the monitoring process. This failure had practical significance because there were a series of complaints about Tudors from 1998 onwards, and continuing up to the Outbreak in 2005. Only some of them, and it appears a small proportion, were considered by members of the CMG when making contract decisions.
- 10.105 The arrangements for the joint contract were inadequate, with a particular lack of clear and agreed roles and responsibilities between the organisations and key individuals. While the principal responsibility for the failures in the system and operation of procurement from Tudors lies with RCT, some responsibility lies also with Bridgend and Merthyr Tydfil County Borough Councils.
- 10.106 Finally, there appears to have been a failure to adopt some elements of best practice guidance ("Food for Thought") after it was published in July 2004. The guidance included clear steps that might have helped avoid food safety problems. I recognise that it was, of course, only guidance and organisations were not bound to follow it. However, considerable effort went into producing it. Some members of the Catering Managers Group were involved in the Group that developed it. It seems to me that the intention of the Welsh Assembly Government must have been that best practice would be adopted, including that relating to food safety.

Developments since the Outbreak

- 10.107 Immediately after the Outbreak, RCT commissioned premises inspections before any purchase order was placed to supply schools and other premises. I note Mr Hanly's evidence that the reaction to the Outbreak has been the most significant driver of change in food procurement. I also note that the four local authorities involved in the Outbreak have made substantial changes to procurement practice and to systems and arrangements for joint working. The changes cover both contract award and contract management and include:
- (i) Tender processes and documentation are now agreed by the authorities before any new or repeat tender. Trading Standards and Public Health Protection Departments are consulted.
 - (ii) References are taken up and there is a review of complaints prior to the tender before contract award.

- (iii) Copies of inspection reports are provided by suppliers, where EHO reports have been received, or by the independent contractors used by the Authorities. These reports are reviewed by the lead authority and Catering Managers Group.
- (iv) Clarification of responsibilities for cooks, catering managers, procurement officers and Environmental Health Departments in dealing with complaints and contract management.
- (v) The development of model forms and templates for logging complaints, and all complaints or issues are logged.
- (vi) All complaints forms are forwarded to Catering Managers for monitoring even if the issue is resolved, and are then collated by the lead authority for comparative and trend analysis. This is reported to the Catering Manager Group and a monthly summary is forwarded to the Procurement Department.
- (vii) Suppliers record complaints and provide them to the lead authority each month. This information is compared to that collated by local authorities and analysed for any trends or issues.
- (viii) A Memorandum of Understanding for contract management signed by the four authorities.

10.108 The authorities say that any immediate concerns are taken up immediately and if necessary, Environmental Health Officers are involved. Food safety issues arising from complaints or other means are now fully investigated, with samples taken for testing if thought appropriate. Unannounced visits to suppliers may be undertaken and corrective action agreed. A contract will be terminated where there are consistent problems and to support this statement, local authorities gave a recent example.

10.109 The authorities say that their procurement strategies will encompass a high emphasis on food safety. "Value Wales" and associated developments, such as the Welsh Purchasing Consortium Food Forum, should help by improving the emphasis on food safety.

10.110 I am encouraged that action has been taken to learn lessons. As the evidence of change relates only to those authorities involved in the Outbreak, I sincerely hope that other public sector organisations in Wales, and indeed businesses, will also learn lessons. Food safety is a fundamental requirement and cannot, and must not, be taken for granted. It must be a pre-requisite at all points in the food chain and procurement process, whether a public sector organisation or business. People's health depends on it.

- 11.1 In the event of an outbreak of *E.coli* O157 or indeed any form of food poisoning, prompt and effective action is required to control it in order to reduce its spread and impact.
- 11.2 The very nature of outbreak control means that a number of different organisations are involved. In the case of this outbreak in South Wales, the key ones were:

Table 11.1: Key Organisations in the Control of the Outbreak of *E.coli* O157 in South Wales, September 2005

Organisation	Main Role(s) and/or Function(s)
Local Authorities	Responsible for the control of food poisoning and notifiable infectious diseases in their areas.
Local Health Boards ("LHBs")	Responsible for the health of people in their areas and for commissioning health services.
The National Public Health Service for Wales ("NPHS")	Provides wide range of services, support and expertise, including microbiological testing, to help local authorities and LHBs to fulfil their statutory duties.
The Food Standards Agency ("FSA")	Responsible for protecting the public from risks to food safety. Advises and assists local authorities and others on food safety matters.
The Health Protection Agency	Provides specialist and reference microbiology services through its Centre for Infections at Colindale, London.
Healthcare Providers	Provide care and treatment. Includes primary healthcare providers such as General Practitioners ("GPs"), hospitals, and out-of-hours services.

The Beginning of the Outbreak

- 11.3 Those affected by the infection began experiencing symptoms from as early as 10 September 2005. However, it took some days for the first cases to be reported as the seriousness of the symptoms became apparent and children began to be admitted to hospital.
- 11.4 A child (Case 4, one of the serious cases examined in detail in Chapter 15) was admitted to hospital on 13 September 2005. On 14 September 2005 three children were admitted to Prince Charles Hospital, Merthyr Tydfil, with watery blood-stained diarrhoea. On 15 September 2005, two other children were admitted to that hospital. Three other children with bloody diarrhoea had been seen in the assessment unit and discharged home.

- 11.5 On 16 September 2005, information was provided to the NPHS's local Health Protection Team by the Paediatric Senior House Officer at Prince Charles Hospital, Merthyr Tydfil. She informed the Team of cases that has been admitted to, and seen by, Prince Charles Hospital in the previous couple of days.
- 11.6 A microbiologist from the Hospital also reported that two stool specimens had tested positive for *E.coli* O157. One had been taken from a child seen in the Assessment Unit of Prince Charles Hospital; the other was a specimen from a GP's surgery.

The National Public Health Service for Wales

- 11.7 The NPHS was established by the Welsh Assembly Government in 2003, when LHBs were first established. It was established as part of Velindre NHS Trust through an agreement between the Assembly Government and the Trust. The NPHS provides services and support to, amongst others, the Assembly Government itself, LHBs, local authorities, and NHS Trusts. It provides the resources and expertise to enable these organisations to discharge their public health responsibilities, including statutory functions.
- 11.8 Dr Gwen Lowe is a Consultant in Communicable Disease Control ("CCDC") in the NPHS. Two CCDCs cover the areas of Cardiff, the Vale of Glamorgan, Rhondda Cynon Taf ("RCT"), and Merthyr Tydfil: Dr Lowe and Dr Marion Lyons.
- 11.9 Each CCDC is primarily responsible for the designated geographical area for which he or she is appointed. Together, they provide an "All Wales" service including an out-of-hours on-call service. Within the NPHS's Cardiff base, individual team members work collaboratively as a Health Protection Team.
- 11.10 Dr Lowe explained to the Inquiry that she also performs the statutory duties of Proper Officer for the local authorities in the same area. When undertaking that role, she does so as an officer of the Local Authority. The role of the Proper Officer is explained below.

The System and Plans for Handling Outbreaks

- 11.11 The legislation relevant to the handling of outbreaks is the Public Health (Control of Disease) Act 1984 and the Regulations made under it: the Public Health (Infectious Diseases) Regulations 1988.
- 11.12 Under that regime, statutory responsibility for the control of an outbreak of food poisoning is placed on local authorities. In summary, the system is as follows:
- (i) Local authorities appoint Proper Officers to assist them to comply with their responsibilities. They are experts such as Dr Lowe and Dr Lyons. As stated above, CCDCs usually hold the appointment of the Proper Officer for infectious disease control for local authorities in their area.
 - (ii) Legislation requires doctors to notify to Proper Officers of certain types of infectious disease. *E.coli* O157 is a notifiable disease if it is suspected that the cause is food or water borne.

- (iii) Once a notification has been made, a variety of experts and authorities are involved in deciding how best to deal with and manage the matter.
- 11.13 The NPHS itself has no statutory functions or responsibilities but in practice and unsurprisingly, it is heavily involved in the co-ordination and management of an outbreak.
- 11.14 For the purpose of controlling an outbreak, there are a number of plans designed to ensure that everything that needs to be done is done. At the time of this Outbreak, there were two national plans of particular importance:
- (i) Model Plan for the Management of Communicable Disease Outbreaks in Wales.
 - (ii) Plan for Handling Major Outbreaks of Food Poisoning.
- 11.15 The Model Plan for the Management of Communicable Disease Outbreaks in Wales was dated March 1995. In the early part of 2005, the South Wales Communicable Disease Liaison Group, which comprise Environmental Health Officers (“EHOs”) from local authorities, microbiologists from hospitals, and staff of the NPHS and its Communicable Disease Surveillance Centre Wales, undertook work to update the plan. Dr Lowe was installed as Chair of the Group, taking over from Dr Marion Lyons as the plan was being signed off. It led to a revised draft of 15 April 2005, which was submitted as such to the Welsh Assembly Government at that time. The reason for the update was to reflect the fact that in 2003, the structure of health services in Wales altered. However, the principles of the 1995 plan did not change.
- 11.16 The objectives of the Plan are intended to ensure prompt action to:
- (i) Recognise and investigate an outbreak of communicable disease.
 - (ii) Identify and where possible, eliminate the source.
 - (iii) Stop or limit further spread.
 - (iv) Prevent recurrence.
 - (v) Ensure satisfactory communication between all concerned.
 - (vi) Disseminate lessons learnt.

- 11.17 The first stage of the plan involves assessing whether there is an outbreak. An Outbreak Control Team ("OCT") would be formed if an outbreak is declared. An outbreak is characterised by one or more of the following:
- (i) Immediate and/or continuing health hazard to the local population.
 - (ii) One or more cases of serious disease.
 - (iii) Large numbers of cases.
 - (iv) The involvement of more than one local authority.
- 11.18 The OCT is usually established with the CCDC as the Chair; in this case Dr Lowe. Its core members would include the CCDC/Proper Officer, Director of Public Protection, Local Consultant Microbiologist, LHB Chief Executive or Public Health/Medical Director. Cross-boundary outbreaks would include Directors of Public Protection from other local authorities affected by the outbreak, the Regional Epidemiologist, and Chief Executives of the LHBs in other areas that are affected. Other individuals and bodies would be co-opted as necessary.
- 11.19 The terms of reference for an OCT include:
- (i) Developing a strategy to deal with the Outbreak and allocating individual responsibilities for implementing action.
 - (ii) Investigating the Outbreak, implementing control measures and monitoring their effectiveness.
 - (iii) Ensuring adequate manpower and resources are available for the management of the Outbreak.
 - (iv) Keeping relevant agencies, the general public and the media informed.
 - (v) Declaring the conclusion of the Outbreak.
 - (vi) Preparing a final report and evaluating lessons learnt.
- 11.20 The 2005 version of the Plan refers to the Food Standards Agency. The FSA, when notified of an outbreak of foodborne disease which has wider implications, offers support to local authorities during their investigations. The Agency will, where necessary, issue food hazard warnings by means of a "Food Alert".
- 11.21 In addition to the Model Plan for the Management of Communicable Disease Outbreaks, there was another national plan entitled "Plan for Handling Major Outbreaks of Food Poisoning". This provided a detailed plan for dealing with such outbreaks. The Second Edition was produced in January 2004. It was designed as a template document, which each local authority could use to produce its local plan.

- 11.22 Local authorities were invited to, and did, adopt the template filling in local details; for example, who had responsibility for what on the ground. The Inquiry was sent copies of local plans.
- 11.23 Two particular guidance documents are mentioned at this stage because they were relied on by the OCT:
- (i) "Preventing person to person spread following gastrointestinal infections"[15]. This was produced by a committee in which Dr Roland Salmon, Consultant Epidemiologist and Director of the NPHS Communicable Disease Surveillance Centre, played a significant part. It was directed to health physicians and EHOs. It is an important source for professionals in deciding what advice should be given on this subject. It highlights as the most important factor in preventing the spread of such diseases the thorough washing of hands with soap in warm water. It also deals in general terms with the issue of exclusions from work, school and other institutional settings;
 - (ii) "Guidelines for the control of infection with Vero cytotoxin producing *E.coli*" (March 2000)[16]. These were principally directed at CCDC's and EHOs but were more broadly relevant as setting out good practice in the light of current knowledge at that time. This document included recommendations for preventing the spread of the microbe, including in schools.

The Core Events early in the Outbreak

- 11.24 Dr Lowe considered that two presumptive *E.coli* O157 cases in the same area, on the same morning in unrelated children, coupled with an unusual number of children presenting with bloody diarrhoea was highly unusual and very serious. She immediately contacted various colleagues, including Dr Salmon, the Regional Epidemiologist, the Microbiologist and clinicians from Prince Charles Hospital, and EHOs from Merthyr and Rhondda Cynon Taf ("RCT") County Borough Councils. A meeting was set up for 15:30 on 16 September 2005. The Welsh Assembly Government was informed as Dr Salmon happened to be at their offices.
- 11.25 At that meeting, the Outbreak was declared. The first steps to setting up the OCT, with Dr Lowe as the Chair, were then taken. It included a variety of specialists from the NPHS, EHOs and others from the local authorities affected, from the RCT and Merthyr Tydfil Local Health Boards and from the Food Standards Agency ("FSA"). A full list of the members of the OCT and those who assisted it in its work is provided in Appendix A of the OCT's Report.

- 11.26 The first meeting agreed on a range of immediate steps to be taken. At this stage, and on the basis of the available information, the source could not be identified. The immediate concern was to gather as much information as possible and as quickly as possible. To that end, EHOs in RCT and Merthyr Tydfil were asked to contact probable and confirmed cases that evening to begin the information gathering process. A standard process and set questions were used, utilising the South East Wales *E.coli* O157 protocol questionnaire. The OCT also set in train processes designed to alert GP's, out-of-hours centres, and local hospitals to the Outbreak and to find other cases. For that purpose, case definitions were agreed.
- 11.27 This produced a working definition for identifying cases within the Outbreak. The definitions were explained in paragraph 5.8.
- 11.28 Mrs Lynda Williams, Executive Nurse Director in RCT LHB queried why Dr Lowe had not informed the RCT and Merthyr LHBs at the time of the first meeting. Dr Lowe explained that the meeting ended at 17:30, i.e. out-of-hours, and that the people she needed at the meeting in order to decide whether to declare an outbreak on 16 September 2005 were present. This point is considered in more detail in the next Chapter.
- 11.29 Dr Lowe contacted Dr Sally Venn, a Specialist Registrar in Public Health. That weekend, Dr Venn was the NPHS's "First Responder" on call. The First Responder receives lists from all areas regarding reported cases of diseases such as *E.coli* O157. The on-call CCDC, Dr Sara Hayes was alerted. Dr Lowe realised that the regular GP services had closed. In the circumstances, a fax was sent to the central number for the out-of-hours services in the affected areas with a telephone request that it be distributed to out-of-hours services in RCT and Merthyr. The fax was not sent to GP surgeries as they would not receive it until Monday, by which time it was expected that the picture would have altered. Dr Lowe stated that the contact fax numbers for the out-of-hours services were not immediately to hand but were obtained quickly by Dr Venn. The Out-of-Hours Service in Gwent was not contacted on the Friday night because the cases were confined to the RCT and Merthyr areas.
- 11.30 That evening, Dr Lowe contacted the on-call Paediatric Registrars at Royal Glamorgan Hospital in RCT and the University Hospital for Wales in Cardiff.
- 11.31 On the morning of 17 September 2005, Dr Lowe contacted senior managers of the NPHS and briefed Mr Christopher Lines, the Communications Director for the NPHS.
- 11.32 Dr Venn and Dr Ciaran Humphreys were tasked with contacting out-of-hours services and hospitals in Merthyr Tydfil, RCT and Gwent in order to appraise them of the situation and to locate cases.

- 11.33 Dr Lowe encountered difficulties in contacting the LHBs' officer on-call. Dr Lowe explained that her understanding was that the method by which the LHBs were to be contacted out-of-hours was via the Welsh Ambulance Service. She contacted the Service but the Service wasn't sure how to contact the LHBs. This begs the question what would have happened in the case of a major incident as defined in statute, as raised by Counsel to the Inquiry with Dr Lowe. The task was taken on by Dr Jane Layzell of the NPHS, who managed to contact Mrs Lynda Williams from RCT LHB. The communications with LHBs during the Outbreak is the subject of more detailed examination in the next Chapter.
- 11.34 By the afternoon of Saturday 17 September 2005, when the OCT met again and had the results of initial interviews with those affected, it had become apparent that the one thing all the cases had in common was that they had eaten school meals. However, the research to that date had not identified the precise source. The OCT considered control measures at its meeting on 17 September 2005. These were put in place at hospitals that had treated the cases to date. More generally, it was decided that schools that had cases should be thoroughly cleaned before 19 September 2005 and that symptomatic children should be excluded from school. It was also decided that letters should be sent both to parents in affected schools and to GPs in South East Wales on 19 September 2005, raising awareness and reminding GPs that antibiotics are contraindicated i.e. they should not be prescribed in cases, or suspected cases, of *E.coli* O157 infection.
- 11.35 The OCT met again on the morning of Sunday, 18 September 2005.
- (i) It was noted that a cascade fax had been sent to all on-call services and Accident & Emergency Departments for transmission to paediatric and medical on-call teams informing them that there were confirmed cases of *E.coli* O157 infection;
 - (ii) The source of the Outbreak was discussed, with attention focussing on school meals. It was decided to investigate further the chains of distribution and supply common to the schools with *E.coli* O157 cases, and to investigate school menus for the relevant period.
- 11.36 Dr Salmon prepared a draft questionnaire designed to take forward the epidemiological investigation, known as a Rapid Case Control Study. This was designed to compare people with an illness to an otherwise similar group of people who were free from that illness. It examines whether the cases of illness were exposed to a common factor that might explain it: it was looking for a common link or links between the cases.

- 11.37 Another meeting took place at 17:00. Dr Salmon reported that the likely cause was an element of school dinners but that on the basis of information available at that time, the source could not be confirmed. A long and detailed risk assessment process of potential sources took place during the meeting. A number of potential sources; for example, school milk, school water and school fruit, were excluded. However, the information did raise serious concern that the source might be cold cooked and sliced meat supplied to schools, which was not re-heated before being served. The decision was therefore taken on a precautionary basis and, as it turned out, very wisely, that all such meat should be withdrawn from school kitchens in RCT and Merthyr pending further tests and analysis. The meats were supplied by John Tudor & Son ("Tudors"), a catering butcher business based in Bridgend. Also at this meeting the OCT:
- (i) Concluded that the Outbreak could not be due to failures in standards in school kitchens because of the pattern of cases covering so many different schools.
 - (ii) Agreed that schools could remain open.
 - (iii) Decided to implement control measures beyond the enhanced cleaning that EHOs had already discussed with schools; these included withdrawing cooking activities, and plasticine, sand and water play.
 - (iv) Drafted letters to parents of children in affected and unaffected schools about the importance of hygiene and hand washing, and to head teachers, and agreed a series of further measures to ensure that those who needed to know about the Outbreak and receive advice were informed.
 - (v) Decided that the NPHS would set up a helpline from 07:00 on 19 September 2005. In the event, over 800 calls were received during the Outbreak.
 - (vi) Asked Mrs Lynda Williams to brief the Chief Executives of NHS Trusts and LHBs across South East Wales on the situation. She was to cascade the GP information to the other LHBs for e-mail transmission to GPs' practices in their areas.
 - (vii) Started a series of press releases commencing on Sunday, 18 September 2005, urging those with severe or bloody diarrhoea to seek medical attention.
- 11.38 By the time of the meeting on Sunday afternoon, no cases had been reported in Bridgend or Caerphilly and no cases had been reported by other outlets of meat supplied by Tudors.
- 11.39 The first case outside RCT and Merthyr was reported on 18 September 2005 following the OCT meeting. Some other cases of bloody diarrhoea and even *E.coli* O157 were identified but were considered to be unrelated to the main Outbreak. Dr Lowe impressed upon the Inquiry the difficulty in initially identifying the exact scope and extent of an outbreak.

Monday, 19 September 2005, Onwards

- 11.40 The identification of cold cooked and sliced meats supplied to schools as the likely source of the Outbreak led to a series of steps being taken to control it.
- 11.41 On 19 September 2005, all remaining cold cooked and sliced meats were withdrawn from school kitchens in RCT and Merthyr Tydfil. The meat was isolated and stored for testing. On 20 September 2005, the same steps were taken by Caerphilly and Bridgend to withdraw from the schools food chain, meats that had been supplied by Tudors.
- 11.42 When the OCT met at 16:00 on 20 September 2005, there were 48 cases fitting the case definition.
- 11.43 Officers from Bridgend reported that they had contacted all relevant local authorities with a view to them identifying and notifying customers of Tudors about the suspected contamination. Details of those customers had been obtained from a customer list provided at Tudors' premises. An examination of Tudors' premises had taken place. Serious risks of cross-contamination had been identified. A decision was therefore taken by the local authorities and the FSA to withdraw from the food chain cooked meat products that had been vacuum-packed at Tudors. A Food Alert for Action was issued by the FSA on 21 September, with an update on 22 September. An update was given in relation to the Helpline, which was operating well, and communication to health professionals on the ground was taking place. It was agreed that general guidance on hygiene would be given to all schools and not just those affected to date.
- 11.44 By the time of the OCT's meeting on 23 September 2005, 75 cases compatible with *E.coli* O157 had been identified. There was detailed discussion in relation to specific cases.
- 11.45 Local Authority representatives reported that they had been reinforcing the "hand washing message". However, the Helpline had received complaints about the lack of hand washing facilities in schools.
- 11.46 Dr Salmon reported on the progress of his epidemiological investigation. It was decided that the Helpline would remain open that weekend.
- 11.47 The next meeting took place on 27 September 2005. The number of cases meeting the case definition had increased to 118. This figure excluded certain cases which, if included, brought the total to 125. Discussion took place on the inclusion and exclusion of specific cases, and, after some cases had been removed the agreed total was 122. The FSA reported that the Outbreak was confined to Wales and that products had not been distributed to Scotland, England or Northern Ireland. A debate took place as to whether to close swimming pools in the areas affected. The result was that, provided the OCT could be satisfied that pools were properly maintained and chlorinated, they could remain open.

- 11.48 It appeared that by this time, the cases that were arising were secondary in nature. A secondary case is defined in paragraph 5.8. There was a decision to maintain the Helpline until 29 September 2005. Media queries were decreasing. Following discussion, there was agreement that a single letter be sent to schools giving advice on swimming pools and on taking food into schools.
- 11.49 By 29 September 2005, there were 155 cases of which 81 had been confirmed and three were presumptive. The importance of completing the questionnaire and obtaining a full and detailed history from cases was emphasised. It was decided that every case identified would be treated as a new case rather than as a case in the Outbreak, and investigated as such, rather than trying to specifically link each to a school. A food chain list with all suppliers and customers of Tudors was being drafted. The number of calls to the Helpline had decreased dramatically. Dr Lyons proposed that the lines be closed down on 30 September 2005. An answering machine would direct general queries to NHS Direct and health queries to the patient's GP. More specific queries would be directed to the Health Protection Team in the NPHS. There was discussion on the release or otherwise of microbiological data into the public arena, which would be reviewed at the next meeting.
- 11.50 The OCT's meeting on 3 October 2005 considered that the message concerning hand washing in the home had drifted. It was agreed that those homes where there were cases would be visited by a Health Visitor to re-emphasise the point. Microbiological and epidemiological studies and investigations were continuing. There was further discussion as to whether microbiological results should be disclosed within a press statement.
- 11.51 In the early hours of 4 October 2005, Mason Jones died.
- 11.52 At the OCT's meeting on 7 October 2005, it was noted that a teacher at Glenboi Primary School in Mountain Ash had reported finding bloody diarrhoea in the boys' toilets. The School's pupils were spoken to as a group and each boy was interviewed individually. Had the source been identified, it would have been a case of removing him from the School and thoroughly cleaning the School. However, the source was not identified. If the affected pupil returned to school the next day, there was an ongoing risk. The decision was taken by the Local Education Authority in conjunction with the NPHS to close the school. A letter was drafted for parents of children at the School. A request was made for members of the OCT to meet parents at the School, as an opportunity to provide testing kits for their children, offer advice and discuss the process by which the school would be re-opened. The OCT agreed that if the child's identity could not be identified then the strategy would be to "pot"; that is, obtain a stool sample, from each of the 97 pupils. The children would then be screened once and as they tested negative would be allowed to return to the school. If a high carriage rate was identified, staff would also be screened.

- 11.53 As a result of events at Glenboi Primary School, it was agreed that control measures already in place in all schools would remain. It was reported that the Helpline had re-opened and that parents were asking “very medical questions”. Dr Lowe re-assured the OCT that there would always be a health professional manning the Helpline and that it was perfectly acceptable for others manning the Helpline to put concerned parents in touch with the Health Protection Team at the NPHS.
- 11.54 At the meeting on 11 October 2005, it was reported that health professionals from the NPHS had met with parents at Glenboi School on 7 and 8 October 2005. Sixty-one negative results had been received and the remainder were due on 12 October 2005. The families of nine children were unable to attend either meeting held at the School and so were yet to be tested. The microbiological results confirmed compatibility with one source. The Helpline was still receiving calls, approximately six to eight each day. There was also discussion at the meeting on the OCT’s response to the Chief Medical Officer’s Review, which had by that time been initiated. The Review is examined in Chapter 16.
- 11.55 The OCT continued to meet during October, and less frequently in November and December 2005. In this period, Dr Lowe and Dr Salmon began work on the OCT’s report.
- 11.56 The Outbreak was declared over on 20 December 2005.
- 11.57 The first draft of the OCT report was prepared in December 2005. The final version was agreed at the beginning of June 2006. The report was not published until 11 September 2007 because of the ongoing police investigation into the death of Mason Jones and, subsequently, criminal proceedings brought by the local authorities in relation to food safety offences.
- 11.58 During the Outbreak, the OCT was confident that the risk was contained to the maximum practical extent by the control measures introduced.

Control Measures

Schools and School Closure

- 11.59 Dr Lowe explained that the control of the spread of *E.coli* O157 relies on two main principles:
- (i) Removal of any suspected source e.g. cooked sliced meat or anyone symptomatic with diarrhoea until 48 hours after symptoms ceased.
 - (ii) Exclusion from work or school/child care settings of those infected individuals, and close contacts at increased risk of spreading the disease, until microbiological clearance is obtained.

- 11.60 A key element of the control measures was targeted at schools. The OCT's strategy was as follows:
- (i) Sources of possible infection, food, were removed as soon as identified as cooked sliced meats.
 - (ii) All symptomatic children were excluded until they had been asymptomatic for 48 hours as these could also be considered sources for infection.
 - (iii) Those cases and close contacts in high-risk groups, such as food handlers, carers and young children, were not permitted to return until microbiological clearance had been obtained.
 - (iv) Control measures were put into schools to minimise the risk of spread through the school environment.
 - (v) Awareness of parents and staff was raised to ensure symptomatic children were not sent to school and excluded promptly if any became symptomatic.
 - (vi) In most cases, schools with symptomatic cases underwent extra cleaning. Advice was given on hygiene and cleaning issues.
 - (vii) The situation was closely monitored in collaboration with local authority staff and school staff.
- 11.61 The control measures were in line with National Guidelines.
- 11.62 During the Outbreak, symptomatic school children with diarrhoea were immediately excluded from school and stool samples sent for testing.
- 11.63 Dr Lowe explained that except in exceptional circumstances, schools in general are only closed if there is evidence of secondary spread within the school environment, not because of the presence of a child recently identified as having *E.coli* O157. In the majority of cases where a school child is identified with *E.coli* O157, the child is excluded until 48 hours after being symptoms free. Children past their fifth birthday return to school even if the stool sample is positive, provided personal hygiene is deemed to be satisfactory.
- 11.64 Dr Lowe explained that it is a matter of judgment by the EHO and CCDC in individual cases why some children return to school before they had obtained a negative result. Dr Lowe stated that provided the individual child was capable of good personal hygiene, the spread of *E.coli* O157 was very unusual. This combined with the fact that to keep children away from school for months and months, when the risk could be managed, was unnecessary. If there had been doubts about that risk, then the individual child would not have been allowed back to school.

- 11.65 Before a school is closed for an infectious disease, there is usually a clear reason for why the school has been closed, and:
- (i) A decision on what action needs to be taken to remedy the situation.
 - (ii) A strategy for when the school should be re-opened.
- 11.66 In the Outbreak, the OCT concluded that there was no reason to close schools generally at the outset because the source had been identified and removed, and primary cases had been excluded whilst symptomatic. However, the OCT was prepared to close schools promptly should secondary spread occur, or in special cases such as the case of Glenboi Primary School, which was mentioned earlier.
- 11.67 Dr Marion Lyons, the lead Consultant in Communicable Disease for the Health Protection Team, analysed the primary and secondary cases in considerable detail in her evidence in order to explain how the OCT had come to the conclusion in its report that there had been no secondary transmissions in schools. In summary, that analysis showed the following:
- (i) There were 48 cases that were identified as secondary as opposed to primary cases (primary cases being those believed to have eaten the infected meat source).
 - (ii) Of those 48 cases, 29 had no contact with schools whatever. So the transmission to those cases had nothing to do with schools.
 - (iii) The other 19 cases did have contact with schools being schoolchildren between the ages of three and eleven.
 - (iv) In relation to eight of the schools involved in this group of 19, the cases were the first cases in those schools. That indicates that the source of the transmission was not the schools but much more likely the home environment where other siblings were infected.
 - (v) That left 11 cases in which the children became infected as secondary cases and attended a school at which there were one or more primary cases. However, in relation to these 11 cases, there were no secondary cases in the schools concerned that did not have a sibling or relative in the home environment as a primary case; and in relation to the schools concerned, no other secondary cases. This leads strongly to the inference that the secondary cases in this group were infected not at school but in the home environment.
- 11.68 I accept this analysis. As far as can be determined, there were no cases of secondary transmission within schools.

- 11.69 Dr Lowe explained that, had the OCT closed all the schools when the Outbreak was declared, there would have been only two possible strategies for re-opening them. All children and staff would have had to be microbiologically screened before being allowed to return, or the schools would have to remain closed until the Outbreak was declared over. There was a problem with mass screening and it would have taken weeks or months to screen all children. Dr Lowe states that the population aged 5 to 14 in the four local authority areas is around 75,000 and the Cardiff Laboratory processes around 17,000 faecal samples per year. During the Outbreak, 2094 faecal samples were analysed.
- 11.70 In addition, there was the difficulty in terms of controlling the risk of the consequences of closing schools from the outset. Had schools been shut they would have remained so for several weeks, if not months. During that time, many asymptomatic positive and initially well children were likely to be cared for by relatives and friends outside their immediate household, which represented a risk for the spread of *E.coli* O157 that may be higher than that in the relatively controlled school environment.
- 11.71 As described above, the issue of school closure was considered and discussed extensively by the OCT throughout the Outbreak. There was always agreement that schools should not closed except in exceptional circumstances, such as the case of Glenboi Primary School.
- 11.72 My conclusion is that, in light of all these reasons, the decision not to close schools was not merely a reasonable decision but was the correct one.

Communications from the OCT

The Evidence of Mr Christopher Lines

- 11.73 Evidence was given to the Inquiry by Mr Christopher Lines, Communications Director for the NPHS. His role involves aiding and improving communications with staff within the NPHS, with other organisations and the public. He explains that communications played an important part in the management of the Outbreak and the OCT was pro-active in informing people as to what was occurring and in making advice available.
- 11.74 Mr Lines attended the OCT's meeting on 17 September 2005 at the request of Dr Lowe. Initially, the lead on communications was taken on by RCT. The lead then moved to Mr Lines.
- 11.75 Mr Lines explained that letters to head teachers and to parents were important ways of putting in place the control measures agreed by the OCT and ensuring an awareness of them and their importance. It was important to ensure consistency in tone and language, so all letters were filtered through Mr Lines before being sent. Letters were drafted by members of the OCT.
- 11.76 The *E.coli* Helpline was described earlier. It was promoted through letters to schools and parents and in press releases to the media. Dr Lyons explained that throughout the Outbreak, the NPHS had five lines available. Only on one occasion, on 19 September 2005, were all five lines actively engaged.

- 11.77 Holding public meetings was an issue that was discussed although in the main, the decision was that letters to parents together with the Helpline was more constructive and productive. Meetings were, however, held at Glenboi Primary School, Abercynon Infants and at Deri School.
- 11.78 Some local authorities used their web sites to post regular press releases from the OCT. Mr. Lines stated that the NPHS web site was not used as a means of communications because a process to improve the site with the recruitment of a Scientific Web Editor was interrupted by the Outbreak. This doesn't strike me as a particularly good reason for not using the NPHS web site as a means of communication. The expertise within the NPHS was utilised to produce a wide range of essential information and advice, including letters and information sheets. The NPHS already operated a web site. I am sure that in the circumstances, far more use could have been made of the NPHS web site during the Outbreak.
- 11.79 Mr Lines dealt with the media throughout the Outbreak. Press statements were issued at regular intervals. Dr Salmon gave interviews in the broadcast media on behalf of the OCT. Mr Lines justified the fact that no press conference was held during the course of the initial weekend of the Outbreak on the grounds that a clear enough picture had not yet formed to allow a properly formulated message to be given to the public and secondly because weekly newspaper journalists are unlikely to attend a weekend conference. Newsrooms are not well resourced on weekends. The briefings on an individual basis, which is the method preferred by Mr Lines, began on 18 September 2005.
- 11.80 The area where there appear to have been problems was the initial communications with, and outwards from, the LHBs. This is dealt with in detail below and in the next Chapter.

The Evidence of Dr Gwen Lowe

- 11.81 Dr Lowe explained that rapid communication is often required during the acute stages of any outbreak. The communication is often out-of-hours when the routine mechanisms are not available. During a localised outbreak, this does not present too much of a problem because direct individual contact can be made. Dr Lowe took the view that the process needed streamlining as the Outbreak covered a large geographical area, impacting on numerous organisations. Given the problems with communications to, and by, the LHBs, which are dealt with in the next Chapter, I agree.
- 11.82 Dr Lowe explained that the NPHS had the facility to disseminate information urgently with fax cascade. For out-of-hours services, they speak either to the GP on duty directly or speak to the administrative staff and ask them to disseminate. In addition, there is facility for LHBs to disseminate information to their local practices.

- 11.83 Dr Lowe explained that the process of communicating with hospitals was time-consuming for the NPHS. The only way that Dr Lowe could be confident that all acute admission areas/teams will get the information and feedback is to ring around all the relevant individuals. Dr Lowe explained that this was extremely resource-intensive and there is no guarantee that the information will be passed over to the next individual on-call. During the Outbreak, Dr Lowe targeted Accident & Emergency Departments and Paediatric Registrars on-call.
- 11.84 Decisions on the content and issue of letters to parents and schools took place throughout the Outbreak. Standard letters were drafted by individuals or sub groups within the OCT, usually headed by Dr Lyons and Mr Lines of the NPHS. These letters could then be adapted to suit local circumstances. Local Authorities were welcome to send extra communications if there were specific local issues.
- 11.85 Vulnerable groups were identified who would benefit from early advice and information e.g. independent care homes, registered child minders and independent nurseries. Registers of these groups exist as they are regulated centrally but the use of these lists for this purpose was not agreed. For example, Caerphilly's EHOs encountered difficulties in obtaining the database of child minders registered with Care Standards Inspectorate Wales.

The Involvement of The Food Standards Agency

- 11.86 Food Alerts are the FSA's formal means of communicating with local authorities during an incident. Where the FSA's risk assessment has identified urgent action for local authorities such as the removal of products for sale, the FSA issues a Food Alert for Action. If the company in question has already withdrawn and/or recalled products or is in the process of doing so to the satisfaction of the FSA, then a Food Alert for Information may be circulated to all local authorities.
- 11.87 The FSA is not routinely part of an OCT but in light of the apparent seriousness of the Outbreak, the decision was taken to participate. This decision was endorsed at the time by Dr Michael Simmons, Acting Deputy Chief Medical Officer, Welsh Assembly Government. The FSA were informed that Tudors had undertaken to withdraw from the food chain all cooked meats which it had supplied to customers. There was concern that William Tudor would not undertake this task effectively. The FSA telephoned him to say that they intended to issue a Food Alert for Action and a press release linking the Outbreak with cooked meats supplied by his business.
- 11.88 It was decided that the FSA should issue a Food Alert to all local authorities, enclosing a list of Tudors' customers, and requiring those authorities to make contact with customers in their area to ensure that any cooked meats supplied by Tudors were removed from the food chain. The OCT meeting on 20 September 2005 decided that the best course of action was for the FSA to issue the Food Alert the following day.

- 11.89 Tudors' customer lists were spread over hundreds of pieces of paper. Mr William Tudor was reported to have been asked to provide a full list but expressed concerns regarding how long this would take and the volume of paperwork. The FSA had to analyse the documents to ensure that as clear and comprehensive a list of customers was produced to accompany the Food Alert. The documents provided by Tudors suggested that it only supplied catering outlets. However, shortly before the Food Alert was due for release the FSA were contacted by an EHO at Vale of Glamorgan who informed them that Tudors supplied at least one retailer in their area. The Food Alert was consequently changed to include reference to retail premises.
- 11.90 A note warning local authorities that a Food Alert for Action was imminent was issued at 16:35 on 20 September 2005. The Food Alert itself was sent at 16:47. It stated that there remained a danger that some of Tudors' products would be found in catering and retail premises. Local authorities were asked to make contact with the premises listed in the annex to the Food Alert to ensure that items delivered on or before 20 September 2005 were removed from the food chain. Local authorities were also asked to consider providing local publicity on the issue. The accompanying press release on the issue was sent out at 16:52.
- 11.91 By the morning of 22 September 2005, it became clear that the annex containing customers of Tudors was not comprehensive. Local authority officers were contacting the FSA to say that premises in their areas, including public houses and a canteen, were absent from the list. Therefore, at 09:05 an update to the Food Alert was sent to all local authorities informing them that the list of customers was incomplete.
- 11.92 On 23 September 2005, a further update was sent out alerting local authorities to the possibility of more widespread distribution of cooked meats from Tudors. The update asked for urgent feedback on contacts already made with retail and catering premises. It became apparent that morning that William Tudor had initially submitted an incomplete list of customers. Some 10,000 invoices were being sorted to try and provide a clearer picture.
- 11.93 At this stage, it was still a possibility that the contaminated meat had in fact been supplied to Tudors, who had innocently passed it on, and so that possibility had to be investigated thoroughly. That task fell to the FSA. In order to do so, the Agency decided that it would analyse the 10,000 invoices mentioned above. In the meantime, all local authorities would be asked to contact small and medium-sized businesses likely to sell or use cooked meats within their areas and to remove from the food chain any cooked meats supplied by Tudors.
- 11.94 A further update to the Food Alert reflecting this was issued at 15:06. Local authorities were asked to contact all premises likely to sell or use cooked meats, particularly small and medium-sized caterers and local shops, delicatessens or pubs. It required any products supplied by Tudors be removed from the food chain and for local authorities to report back to the FSA on actions taken by 10:00 on 26 September 2005. A press release was also issued.

- 11.95 The task of contacting Tudors' suppliers was an onerous and time-consuming one. Once a full list of Tudors' suppliers had been established, the relevant local authorities or the Meat Hygiene Service were contacted, depending on which were responsible for regulating the suppliers involved. Information was sought on complaints about those suppliers. Where companies had a wide distribution and no cases of *E.coli* O157 had arisen, the decision was taken that those companies could be discounted from the enquiries. Of particular concern to the OCT were companies that supplied turkey to Tudors. The three companies that did so were based in separate parts of the UK. The local authorities and Meat Hygiene Service in the respective areas were contacted. All were reported to have had good compliance records and excellent standards.
- 11.96 On the afternoon of 23 September 2005, a disk containing details of Tudors' customers was secured by EHOs in Bridgend. It was passed to the FSA. Unfortunately, the information on the disk was difficult to access and was organised in a poor fashion. FSA staff spent that weekend going through the database in order to identify customers. During the course of the weekend, another 28 customers were identified. These were in addition to the 582 listed in Annex A to the original Food Alert. The information indicated that these customers were purchasers of raw meat only and most were in the Bridgend and RCT areas. Those authorities were contacted that weekend to identify these specific premises. Other local authorities affected were contacted on the morning of 26 September 2005.
- 11.97 On 26 September 2005, responses were due from local authorities on the efforts that had been made to contact potential customers of Tudors. All authorities in Wales eventually responded, the vast majority that day. Many local authorities had telephoned businesses concerned, often running into the hundreds. Others were continuing to do so. Some authorities had written to businesses asking them to contact their local Environmental Health Department in the event that they had been supplied with meats by Tudors. Some authorities had done both. Many authorities stated that premises within their area were not supplied by Tudors, mainly those geographically distant from the South Wales valleys.
- 11.98 At the OCT's meeting on 27 September 2005, Mrs Jane Davies of the FSA informed those present of the analytical work that had taken place over the weekend and the responses that had been received from local authorities regarding customers of Tudors. No additional premises had been identified as customers of Tudors since the weekend.
- 11.99 On 28 September 2005, a full list of all known Tudors customers was sent to the NPHS. This included the 582 premises identified in the annex to the Food Alert, the 28 premises that had been identified through information provided by Bridgend and a further nine premises identified by the Vale of Glamorgan Council.

- 11.100 Supplier investigations had continued during this time and by the afternoon of 28 September 2005, the FSA were reasonably satisfied that the source of the Outbreak was not as a result of infected meat that had been supplied to Tudors in the first place. On 29 September 2005, Mr Robert Wilkins of the FSA reported to the OCT that a supplier list and a list of what each supplier had supplied and when they had supplied it was in the process of being compiled, and would be made available as soon as possible. That, in fact, occurred on 30 September 2005.
- 11.101 During the weekend of 1-2 October 2005, Mr Wilkins worked with five colleagues collating and organising information that had been obtained from those supplying Tudors and those being supplied by Tudors. Deliveries received and made by Tudors were logged. The full detailed list of suppliers to and customers of Tudors was thereafter provided to FSA headquarters.

The OCT's Recommendations

- 11.102 In line with the requirements of the Model Plan for the Management of Communicable Disease Outbreaks, the OCT produced a report on the Outbreak.
- 11.103 Dr Lowe was asked to expand on the recommendations set out in the report. She explained that the recommendations represented what the OCT thought would protect public health in this situation either by preventing future outbreaks or by making the control of a similarly large and complex outbreak easier. Dr Lowe stated that at the time of the Outbreak, the OCT had implemented any action identified as necessary to protect public health.
- 11.104 Dr Lowe also explained that the OCT originally discussed the actions which would form the basis of the recommendations at its meeting on 11 October 2005. This was in response to a request from the Welsh Assembly Government in the form of the Chief Medical Officer's Review Team to let them know of any urgent action necessary to protect public health. These recommended actions were formally set down in a letter dated 13 October 2005 and the rationale behind them explained in a letter of 13 December 2005. Six out of the nine actions recommended said "urgent". Dr Lowe was asked by the Assembly Government to define the term "urgent" in the context of the OCT's recommendations. Dr Lowe confirmed that none needed action prior to publication of the Chief Medical Officer's Review which was expected to, and ultimately did, take eight weeks. When the Outbreak report was being prepared, the recommendations were reviewed. The OCT felt all were important and should constitute recommendations in the final report.
- 11.105 The principal recommendations were as follows:
- (i) The OCT felt that it would be prudent to review procurement policies generally and the quality checks in place when food is obtained. No specific issue was raised at the time about procurement. Procurement is the subject of Chapter 10.
 - (ii) The OCT felt that despite regulation to prevent cross-contamination, the Outbreak still occurred, which presented an opportunity for those regulations to be revisited.

- (iii) Dr Lowe explained that it is standard practice to review outbreak plans after any major outbreak. No significant issue arose during the Outbreak with regard to these plans, but a review was thought to be of value, particularly as the Outbreak covered multiple local authority areas.
- (iv) The OCT's view is that legislation does not adequately cover the exclusion of close contacts from work or group childcare settings where they could potentially put others at risk. Local Authority members of the OCT complained that the current powers under communicable disease legislation do not allow the exclusion from school or pre-school childcare cases or contacts of *E.coli* O157. During the Outbreak, only requests were made. It is Dr Lowe's understanding that these requests were universally complied with. However, towards the end of the Outbreak, families of children who were excreting the organism over a prolonged period were expressing their frustrations. Had they become uncooperative there would have been no statutory powers to act as a safety net. As regards work situations, the legislation allows for the compulsory exclusion of food handlers suffering from *E.coli* O157. Contacts or cases in other professions can only be requested to stop work. Whilst full co-operation was given, assisted by the power to pay compensation for loss of earnings, had there been a refusal to stop work the absence of legal powers may have caused difficulty.
- (v) National minimum standards should be developed to ensure good hygiene within the school environment. School toilets and handwashing facilities is the subject of Chapter 13.
- (vi) An enforceable Code of Practice should be developed to ensure that all health professionals have a responsibility to ensure that families of individuals with infectious disease receive appropriate infection control advice. Problems of this nature were experienced during the Outbreak. Local authority officers had difficulty contacting hospitalised cases, particularly those transferred out of the area. There was concern that they were not receiving appropriate infection control advice. This may be because health professionals may not realise that the families had not been advised on the issue, may not see it as their role or may be in doubt as to the correct type of advice. A Code of Practice, containing the standard advice to give for gastrointestinal infections making it clear would be helpful. It may also be a useful tool for GPs.

Conclusions

11.106 My overall conclusion is that the Outbreak was handled well. Importantly, the Outbreak Control Team identified a common link between the cases at a very early stage. They reacted with speed and applied a precautionary approach that led to the early removal of Tudors' cooked meats from the food chain. The prompt action resulted in some unused cooked meats infected with *E.coli* O157 being recovered from schools. I am in no doubt that, but for the quality of the analysis and the control measures taken, the Outbreak would have been considerably more severe and prolonged.

- 11.107 The Outbreak Control Team comprised staff from the NPHS, the FSA, from LHBs and from other parts of the Health Service. They were joined by EHOs from the different local authorities, who did a huge amount of work in tracking down, interviewing and advising people who were caught up in the Outbreak. Other local authority personnel, including education and catering staff, were also involved.
- 11.108 The families have told me that the tracing of the Outbreak was quick, efficient and praiseworthy. I fully endorse those comments. I know that those involved in the Outbreak Control Team and the many others who were also involved in action to control the Outbreak put in considerable time and effort to tackle the Outbreak, including extra hours and out-of-hours working. I am aware of the difficulties that were experienced in the early stages of the Outbreak. I am also aware of some people who said that information did not reach them or reached them later than they would have liked. I fully appreciate their concerns but within the context of such a large Outbreak, the number of such cases is very small. I also know that despite a job well done, those involved in managing the Outbreak have reflected on their work with a view to improving, where possible, the plans and arrangements for handling any future outbreaks.

Developments since the Outbreak

- 11.109 No changes to the basic principles in outbreak plans or the composition and working of the OCT have been considered necessary. A Task & Finish Group is bringing together the three existing outbreak plans into a single plan. It covers the work of an Outbreak Control Team and roles and responsibilities specific to outbreaks in hospitals. The Group has identified the need for some changes in the detail of the plan.
- 11.110 The Outbreak has confirmed the importance of communicating directly with members of the public and has informed thinking on the use of different methods. The NPHS has worked to improve helpline services and now promotes its web site as standard practice in outbreaks, updating it with the latest information and advice. In addition to the public, the NPHS now considers community leaders and organisations to ensure they are well informed as they could comment on an outbreak and lead public opinion.
- 11.111 The system of communication with hospitals, which is usually an initial phone call to specific departments and then written follow-up, remains unchanged. The NPHS state that one of the advantages of direct contact between the Consultant in Communicable Disease Control and hospital staff is that it enables dialogue to explore what is happening, undertake initial case finding, and if necessary to seek a specialist clinical opinion on symptoms seen. I agree with this approach.
- 11.112 Communicating with health professionals in the community is, as the Inquiry identified, a complex issue. Changes have been made. In a large outbreak, the NPHS will now co-ordinate its actions through a Senior Response Team, which would retain an oversight of all NPHS activity, including communications, to ensure it is approached in a structured way. The precise mechanism used may vary depending on the outbreak, the areas and agencies involved, and decisions on communications made by an OCT.

11.113 Consultants in Communicable Disease Control can e-mail multiple contacts in GP surgeries, which can be used both in and out of office hours. E-mail is now considered a reliable means of communication although a cascade e-mail or fax may be sent in localised outbreaks. This reflects local arrangements, which will be considered when communicating across boundaries in widespread outbreaks. Initial contact with out-of-hours centres is still by telephone initially to brief the service before e-mailing or faxing information. This is manageable because there are relatively few centres.

11.114 The Welsh Assembly Government states that an e-mail alert system is being developed to cascade messages to all parties. It states that the system, which will also be available to Assembly Government officials, should be more robust, easier to administer and more effective at reaching recipients. As seen in the Outbreak, the initial cascade of information is vitally important. But equally important are the processes in the recipient organisation to note, act upon, and, where necessary, to disseminate it internally.

11.115 The Assembly Government also explained that:

- (i) Issues about the formal exclusion from school of children who are contacts of cases should be addressed by the Health and Social Care Act 2008. Part 3 (Public Health Protection) of the Act revokes Part 2 of the Public Health (Control of Disease) Act 1984 and replaces it with more up-to-date provisions.
- (ii) A best practice guide is being developed to support the Assembly Government's strategy for reducing healthcare associated infection. This will include guidance on the need for clinicians to give patients, relatives and visitors verbal and written information as appropriate. Professional codes of conduct should also address the need for patient information.

11.116 I make no judgement on the adequacy of the above developments and note that in some cases, no changes are considered necessary. Although the Outbreak was handled well, I am encouraged that action has still been taken to learn from it to make further improvements to systems and procedures where necessary.

- 12.1 Local Health Boards (“LHBs”) were established in Wales in April 2003 under the Local Health Boards (Establishment) (Wales) Order 2003 No. 148. At the time of the Outbreak, there were 22 Local Health Boards. Each LHB works in partnership with the Local Authority for the same geographical area and with other local organisations such as the NHS Trusts.
- 12.2 LHBs are responsible for determining the health and well-being needs of their local population, and for commissioning services for disease prevention and healthcare from NHS Trusts and others to meet these needs. They also work in partnership with the National Public Health Service for Wales (“NPHS”). The Public Health Director of each LHB is an employee of the NPHS.
- 12.3 Healthcare services are provided by primary care contractors, GPs, dentists, pharmacists and optometrists and hospitals.
- 12.4 This Chapter considers the role of LHBs during the initial stages of the Outbreak. It examines the system of communication that existed to allow those at the LHBs to be made aware of the Outbreak when it was declared, and the way in which the LHBs disseminated that information to others with frontline responsibility for providing advice and care to those affected by the Outbreak, notably hospitals, GP surgeries and Out-of-Hours Services.
- 12.5 Mrs Lynda Williams, Nursing Director for Rhondda Cynon Taf LHB, explained that there are 43 GP practices and 66 pharmacists in the Rhondda Cynon Taf area. There are eight hospitals in the two NHS Trusts that serve the area. Much of Mrs Williams’ written evidence was adopted by representatives of the other LHBs.
- 12.6 She explained the structure for treating people those who become ill:
 - (i) “In hours”, a sick person would either go, or be taken to, their GP or, in more serious cases, to the local Accident and Emergency Department in a local hospital;
 - (ii) During “out of hours”, a person who is ill could either go, or be taken to, an Accident & Emergency Department. A telephone call to the GP’s surgery would lead to the caller being provided with the telephone number for the local Out-of-Hours Service. Rhondda Cynon Taf LHB contracted with a private sector provider for its Out-of-Hours Service. The Company maintains a pool of GPs and nurses to provide advice over the telephone and at out of hours centres, which are usually co-located with hospitals.
- 12.7 In order for that system to work effectively during, and in particular in the initial stages of, an outbreak, it was necessary for information about an outbreak and any relevant guidance to be disseminated to those in the frontline of care provision. The LHBs were an integral part of that dissemination process.

Stage 1: Contacting Local Health Boards Out-of-Hours

- 12.8 The first stage in the dissemination chain involved the provision of the relevant information to the LHBs.
- 12.9 Each LHB has the services of a Consultant in Communicable Disease (“CCDC”) from the NPHS, who is responsible for the surveillance, prevention and control of communicable disease in that area. Mrs Williams explained that it was her understanding that the CCDC would be informed about an outbreak and would then pass the information on to the LHB via telephone. The person taking the initial call at the LHB would take ownership of the issue and responsibility for communication to relevant individuals within the LHB. She stated that in her LHB, there were a number of people that could be contacted in the event of an outbreak, starting with the Local Public Health Director, then either the Medical or Nursing Director (her) and then other Directors if those before them were not available. Her written statement suggested that there was in place a system for LHBs to be contacted out-of-hours.
- 12.10 The evidence I have seen indicated a position of considerable and unsatisfactory confusion about this initial stage of communication.
- 12.11 The Outbreak was declared “out-of-hours”, leading to a need to communicate in particular on the weekend of 16-18 September 2005. I note that the LHBs have raised the issue about whether the initial communication to the LHBs should have occurred in normal working hours on Friday, 16 September 2005, and that if that had occurred there would have been no difficulty. I do not consider that to be any real answer to the concerns: first, because the relevant meeting of the Outbreak Control Team (“OCT”) did not end until 17:30 that day and there would, and should, have been no need to communicate in advance of that meeting ending. Second, because there should in any event, have been a robust process in place for out-of-hours communication with LHBs.
- 12.12 Mrs Williams’ oral evidence clarified that, at the time of the Outbreak, a system enabling the CCDC to communicate with those within the RCT LHB who needed to be contacted out-of-hours (e.g. on weekends) only existed in the case of a “major incident”. That was a defined term (in the Civil Contingencies Act 2004) and did not cover an outbreak such as the *E.coli* O157 Outbreak. There was, therefore, no formal process or system in place for communications to LHBs out-of-hours in relation to such an outbreak.
- 12.13 The absence of such a system led to problems at this stage of initial communication to LHBs. Dr Gwen Lowe was unable to contact someone from RCT LHB on the morning of Saturday, 17 September 2005. She attempted to do so because RCT was the area from which the majority of cases at that time had come.

- 12.14 The task was taken on by Dr Jane Layzell of the NPHS. A file note made by Dr Layzell sets out the considerable difficulties she encountered when attempting to contact RCT LHB. Those difficulties included having to contact a variety of different people; contacting the Ambulance Service in the belief that they were the initial point of contact only to be informed that this was not a major incident and so that was not the correct process; and attempting to find numbers for, and then make contact with, people who evidently were not contactable.
- 12.15 In the event, Dr Layzell was able to make contact with Mrs Williams at around 12:15 on Saturday, 17 September 2005. Mrs Williams then assumed responsibility on behalf of RCT LHB.
- 12.16 Mrs Williams accepted that the process of contacting personnel within her LHB by those people at the OCT had not worked well that weekend. She told the Inquiry that this was the first occasion when a CCDC had had to utilise the process.
- 12.17 She explained that following the Outbreak, a review was undertaken by Mr Roy Simmons, Emergency Planning Co-ordinator for South Wales and Gwent Local Health Boards. As a result of the review, a written contact system has been introduced whereby organisations such as the Welsh Assembly Government, Welsh Ambulance Service, NPHS, Care Standards Inspectorate for Wales, Pontypridd and Rhondda NHS Trust, North Glamorgan Trust and the Out-of-Hours Service for the area, are given contact details for all LHBs. The type of incident which would trigger the employment of this system would include, for example, an *E.coli* O157 outbreak or the need for the immediate closure of a nursing home because of winter/bed pressures.
- 12.18 That written system or process as produced to the Inquiry by RCT was headed "RCT" procedure. However, Mr Ted Wilson, former Chief Executive of Merthyr LHB, indicated that he knew of the review and understood that the RCT document was also designed to set out the process for contacting other LHBs. By contrast, Mrs Abigail Harries, Chief Executive of Vale of Glamorgan LHB, was not aware of any equivalent document in her LHB. It appears that the document is not being universally applied.
- 12.19 My conclusion is that there was not a robust system for contacting LHBs out-of-hours. I am also concerned that, even after Mrs Williams' evidence, the LHBs continued to assert, in their jointly-signed response (August 2008) to my Note of Emerging Issues paper, that there was, and is, in place a robust system for contacting LHBs out-of-hours in the case of emergency, namely through the Welsh Ambulance Service, which "operated well" on the date when the Outbreak was first identified:
- (i) This is directly contrary to the evidence, that (a) such a system was available only in the case of a "major incident" and (b) the system of communication out-of-hours with the LHBs operated only inefficiently, requiring Dr Layzell to make multiple attempts before being able to make contact.

- (ii) The LHBs' assertion is further weakened by information provided by the National Public Health Service for Wales in its response to my Note of Emerging Issues. In June 2008, the NPHS wrote to all LHB Chief Executives asking about arrangements for contact out-of-hours for "major incidents" and for events that are not, or not at the time that contact is needed, categorised as a "major incident". While all LHBs use Ambulance Control for "major incidents, a variety of means is used for out-of-hours contacts in the case of other serious health issues. The NPHS reports the response from seven LHBs, including The Vale of Glamorgan and Caerphilly, as "No formal system at present – awaiting the publication of the interim report of the *E.coli* Inquiry in order to develop a system that will be fully commensurate with its recommendations". I find this response both surprising and disappointing. Given the difficulties that arose during the early stage of this Outbreak, I expected that action would have been taken earlier to put in place some formal arrangements even if, after the publication of my report, those arrangements were reviewed and adjusted. Instead of this, and contrary to the evidence received by the Inquiry, the LHBs appear still to be in denial as to even the existence of a problem.

Stage 2: Dissemination of Information by Local Health Boards

- 12.20 The second stage in the chain of communication involves dissemination of information from the LHBs to front line care providers. The effective and efficient notification of those who are in the front line with the public in cases of this kind is essential. The obvious reasons for alerting those providers to an outbreak is so that they can identify other cases coming into the surgeries and hospitals, and can advise and treat them appropriately. In addition, communication enables the message to be reinforced or provided to those professionals on the front line as to recommended treatment. In the case of *E.coli* O157, the communications sent to GPs and others included reminders that antibiotics and anti-diarrhoea medicines are contraindicated i.e. positively not recommended for the condition.
- 12.21 In her statement to the Inquiry, Mrs Williams stated that there was a process in place to disseminate information to providers. This form of words was also used by other LHBs in their statements. In her oral evidence, it became clearer what that process involved so far as the LHBs were concerned:
 - (i) The process was not set down in writing.
 - (ii) It involved information being faxed via a so called "safe haven" fax; that is, a fax in a designated area within, for example, a surgery, that can be locked to protect confidential information. The faxing was not done or requested by LHBs according to Mrs Williams' oral evidence. It was done by the NHS Business Services Centre. It was requested by the OCT and not the LHBs. Mrs Williams' oral evidence was initially to the effect that LHBs had no responsibility for the faxing because they had been assured that the OCT had done it. The limit of the LHBs' responsibility was to assure themselves that the faxing was happening. However, she later recollected that the LHBs had had a role in faxing some of the information provided by the OCT for dissemination to the front line professionals.

- (iii) It involved some telephoning of GPs and hospitals. Mrs Williams' oral evidence was that contact lists were available.
 - (iv) It also involved some e-mail communication with GPs and Chief Executives of NHS Trusts.
 - (v) Pharmacies were only contacted later by ordinary post and following a specific recommendation to do so by the OCT.
- 12.22 Mrs Williams' statement also indicated that a "matrix" was kept by RCT LHB at the time in order to keep a record of who had received what and when. It would plainly have been sensible for a comprehensive record to have been kept. In the event, as Mrs Williams accepted in her evidence, the matrix did not encapsulate all of the information that went out.
- 12.23 Nor was there any system for ensuring that the sender of the communication received confirmation, by email, fax or post, that it had in fact been received. Mrs Williams accepted that it could have been a good idea for such a system to have been in place. The LHB did telephone a number of GP practices to check that communications had been received. However, no record of that was kept and Mrs Williams was unable to say how many had been contacted.
- 12.24 Mr Wilson of Merthyr LHB suggested in his written statement that "a system was in place for the dissemination of information by the Local Health Board to its providers". He then indicated in his oral evidence that, whilst such system was in place generally, the dissemination of information during the Outbreak was the responsibility of the OCT and not the LHBs. He also indicated in his oral evidence, but not in his statement, that he had asked for, and received confirmation from, the OCT about this. Despite that, the LHB did become involved in faxing and e-mailing GPs following a request to do so from the NPHS and then from the OCT. They did so as a result of what Mr Wilson described as "communication ambiguities".
- 12.25 Mr Wilson took the view that pharmacists should be made immediately aware of the Outbreak and so, on its own initiative, Merthyr Tydfil LHB arranged for the information that had been received from the OCT to be faxed to pharmacists on the morning of 19 September 2005. This seems to me to have been a sensible step to take given that pharmacists could be the first port of call for some people who are experiencing a bout of diarrhoea.
- 12.26 Mrs Colleen Bright, Director of Planning and Primary Care for Caerphilly LHB, was clear that information received by the LHB about the Outbreak needed to be disseminated by the LHB. I note that no record was made of communications issued by Caerphilly although I accept that certain fax sheets were retained, particularly for the initial information disseminated on the afternoon of 19 September 2005. This includes information faxed at that time to the GP surgery that was dealing with Case 6, which is examined in detail in Chapter 15.

- 12.27 Mrs Harris of the Vale of Glamorgan LHB confirmed that it did not retain records of any contact made with front-line professionals in their area. In light of this, the unsatisfactory position is that no-one knew if all of those who should have been contacted were in fact contacted.
- 12.28 Mr Matthew Bunce, Deputy Chief Executive and Director of Finance and Commissioning at Bridgend LHB, told the Inquiry that he had been informed by Mr Mel Evans, Chief Executive of RCT LHB, that it was the LHB's responsibility to disseminate information. There was a delay in the information being received by Mr Bunce because of errors by others in respect of his e-mail address. It was ultimately received by him on 19 September 2005 at 16:55. The information was not distributed to GPs (via the Business Services Centre) until 13:30 on 20 September 2005. Mr Bunce could not provide a reasonable explanation for the delay when he gave his evidence but in a follow-up letter to the Inquiry he said that an explanation could be the fact that he was in a meeting in Carmarthen on the morning of 20 September 2005 and did not return to his Bridgend office until the afternoon.
- 12.29 Mr Bunce stated that Bridgend LHB had not maintained a record of the communications that were disseminated to primary care providers. However, following his oral evidence, Mr Bunce produced documentation confirming distribution of the initial letter of 19 September 2005 to GPs.
- 12.30 Dr Lowe appeared to lose faith in the LHBs disseminating information effectively, leading to her deciding that the task should be undertaken by the NPHS.
- 12.31 From the evidence of Mrs Williams and other witnesses from Local Health Boards and the NPHS, my conclusions in respect of Stage 2, namely communications by LHBs to front-line health care providers, are as follows:
- (i) There was confusion about roles and responsibilities.
 - (ii) The system for disseminating information was not set down in writing.
 - (iii) There were differences between LHBs in understanding how the system was meant to work.
 - (iv) No adequate record of communications was retained by any of the LHBs.
 - (v) No system was in place for recipients of communications to confirm receipt.
 - (vi) The unrecorded "audit" carried out by RCT LHB by telephoning a number of GP surgeries was not satisfactory.
- 12.32 The system for communications to front-line care professionals was not a robust and effective one.

- 12.33 I also note with disappointment that their response to my Emerging Issues paper, the LHBs appear to deny the existence of any real problem. They assert, in the face of evidence received by the Inquiry and contrary to that of Mrs Williams, that there was in place at the time of the Outbreak, a system of logging responses to communications issued.

Overall Conclusion

- 12.34 The evidence received by the Inquiry does not indicate that the communications difficulties highlighted led to any specific adverse consequences. However, the Outbreak was a very real test of communications on a serious public health issue. It exposed some weaknesses and potential weaknesses in systems, which are likely to be relevant in most health incidents and/or outbreaks of a communicable disease, not just *E.coli* O157.

Introduction

- 13.1 Given that *E.coli* O157 causes diarrhoea and can be spread person-to-person by faecal/oral contact, the importance of schools having in place adequate toilet and hand washing facilities and hygiene practices for pupils and staff is obvious. That importance applies generally but it is brought into particular focus in the context of *E.coli* O157. That is because, as explained earlier, *E.coli* O157 is a particularly unpleasant bacterium which is easily spread; it has low dose infectivity. It also has an incubation period of up to around 12 days. That means that the presence of *E.coli* O157, at least in the early stages of an outbreak, may not be known. The requisite facilities and practices therefore need to be in place before an outbreak is known, in addition to the need for particular vigilance once an outbreak is known about or suspected.
- 13.2 Against this background, the Inquiry considered the facilities and practices in the schools affected in order to form a view on the ability of schools to prevent and control the spread of *E.coli* O157 in an outbreak such as this one.
- 13.3 One matter is emphasised at the outset. The conclusion of the OCT was that there was no demonstrable evidence of secondary transmission within the school environment.
- 13.4 I accept this conclusion for the reasons given in evidence by Dr Marion Lyons. This matter is emphasised because it suggests that the dissemination by the OCT of information required precautionary measures and the precautionary measures that were taken in schools appear to have been effective in preventing secondary transmission.

The Evidence

- 13.5 The Inquiry wrote to schools affected by the Outbreak focussing on the hygiene policies, practices and facilities that were in place; the schools' responses to the Outbreak, and communications to schools from local authorities. The Inquiry received responses from all of the schools concerned. The Inquiry also received statements from representatives of the Local Education Authorities.
- 13.6 The Welsh Assembly Government was asked to provide evidence in relation to school toilets generally and more particularly, about a report published in May 2004 by the Children's Commissioner for Wales entitled "Lifting the Lid – A Report into the State of the Nation's School Toilets".

The Systems in Place

- 13.7 Section 542 of the Education Act 1996 allows Welsh Ministers to prescribe by way of secondary legislation, the standards for school premises, including school toilet facilities. The standards are currently contained in the Education (School Premises) Regulations 1999 which apply in both Wales and England. Local Authorities must ensure there are such number of washrooms, which is defined to include one washbasin and a water closet or urinal, as are adequate having regard to the ages, sex and numbers of pupils and any relevant special requirements they may have.

- 13.8 The Regulations have been supplemented by “Welsh Office Circular 15/99: The 1999 School Premises Regulations”. The Guidance is aimed at Local Education Authorities and sets out matters such as the number of toilets required in a school dependent on the age and number of pupils; the separation and location of facilities depending on age and sex of pupils and; the dimensions of facilities within school toilets.
- 13.9 Regulation 17(3) of the 1999 Regulations requires local authorities to ensure the health, safety and welfare of the occupants of a school building. Toilets form part of a school building. When new school buildings are being designed or existing buildings are being refurbished, authorities must have regard to various Building Bulletins, which are produced by the Department for Children, Schools and Families and apply to England and Wales. The Bulletins cover toilet facilities. They assist in the development of design briefs for those carrying out work at schools.
- 13.10 Mrs Elizabeth Taylor, Director of the Children, Education, Lifelong Learning and Schools Department in the Welsh Assembly Government, stated that the 1999 Regulations were, at the time of the oral hearings, being reviewed by the Welsh Assembly Government, including the requirements for school toilet provision.
- 13.11 Responsibility for compliance with the standards set nationally rests on a combination of Local Education Authorities and the governing bodies of schools. Mrs Taylor explained that responsibility for investing in school buildings and compliance with the building regulations that apply to schools is vested in different bodies depending on the type of school. That responsibility falls to a local authority in the case of community, voluntary controlled, maintained nursery schools and community special and foundation schools, pupil referral units. It is the responsibility of the governing bodies in the case of voluntary aided schools.
- 13.12 School Councils also play an important part in delivering satisfactory facilities. The National Assembly for Wales School Councils (Wales) Regulations 2005 passed under the Education Act 2002 require all maintained primary, secondary and special schools to establish a School Council. The regulations state that both the governing body and the head teacher of a school must consider any matter communicated to them by the School Council and respond. Mrs Taylor states that Statutory guidance on School Councils includes amongst the list of issues which it would be appropriate for a School Council to consider: “improvements to the school environment such as toilets”.
- 13.13 In addition to the setting and implementation of these standards, the general health and safety legislation, notably the Health and Safety Act 1974, applies.
- 13.14 Funding for school buildings is available to local authorities through school building improvement grants provided by the Welsh Assembly Government; general capital funding allocations to authorities; and use of receipts or prudential borrowing. Funding is also provided to voluntarily aided schools.

- 13.15 It is evident that considerable resources have been devoted to supporting and maintaining the infrastructure of schools, including their toilet facilities. Between 1997-98 and 2007-08, the Welsh Assembly Government made available funding of £1.234 billion (excluding support for schools constructed under PFI arrangements). In that period, a total of £1.335 billion was invested in school buildings when one adds in Local authority investment. Some 107 projects providing new school buildings or significant extensions/ refurbishments have been supported; as have 125 (stand alone) school toilet projects in 18 local authorities. Mrs Taylor stated that in the period 2002-03 to 2007-08, 1817 schools benefited from Assembly Government grants.
- 13.16 It is also evident that considerable work remains to be done. The Welsh Assembly Government's stated objective is that all schools should be fit for purpose and properly maintained. Originally, a target of 2010 was set. However, because of the extent of work required, extended targets have been negotiated with local authorities.

The Children's Commissioner's Report

- 13.17 The Children's Commissioner was established in Wales in 2001 following a recommendation by Sir Ronald Waterhouse and his "Lost in Care" report on child abuse in North Wales care homes. The Commissioner heads an office, independent of the Welsh Assembly Government, which represents the rights of children in Wales.
- 13.18 In 2002, the then Children's Commissioner, the late Mr Peter Clarke, decided to carry out an investigation into the state of school toilets in Wales, having received recurring complaints from children across Wales. On its completion, in May 2004, he published the report "Lifting the Lid".
- 13.19 Information gathered by the Commissioner, which is summarised in Appendix 2 to the Commissioner's report, revealed that children were having to use substandard toilet facilities during their school day. The Commissioner looked at the legislation in place, relevant guidance and various research studies. Correspondence was also received from individuals and organisations. Discussions took place with children, staff, governors, policy makers and campaigners.
- 13.20 The Children's Commissioner found, having carried out a survey of 708 school children of mixed age and sex that 61% were unhappy in some way about the state of the toilets in their schools. For at least 20% of respondents, the inadequate provision of, or access to, toilet paper, soap, towels or other drying facilities prevented many from using the toilets. The standard of cleanliness was found to be unsatisfactory in many cases. Only 20% of respondents said that their school toilets were clean. However, there were some positive accounts given about schools where the toilet environment was being managed effectively. The Commissioner made plain in his introduction to the report that "the state of the Nation's toilets is not all bad".

- 13.21 The Commissioner also found that there may be potentially serious short and long-term health effects for children using sub-standard toilet facilities and that there appeared to be no strategic approach to improving the standards of school toilets involving the pupils, the school, the governors, Local Education Authorities, ESTYN (the Schools Inspectorate for Wales), the Health & Safety Executive, the Assembly Government and the UK Government.
- 13.22 The Commissioner made a series of recommendations including the following:
- (i) The Welsh Assembly Government should assist all schools and their associated governing bodies, to conduct an audit of the current condition of school toilets within the next 12 months.
 - (ii) The Welsh Assembly Government should consult with relevant bodies and children, in order to devise an auditing process at is based on Health and Safety regulations, health research and all relevant legislation. The structure and content of the audit must be child centred.
 - (iii) Children were to be involved in the audit process.
 - (iv) Following the audit, schools and their governing bodies, with involvement from pupils, should develop an action plan to improve the conditions of their school toilets. The plan would need to identify any resource implications.
 - (v) Each school should work with the Local Education Authority to carry out the work identified in the plan linking it to their longer term capital expenditure programme to transform the conditions of their school.
 - (vi) The role of ESTYN in respect of school toilets needed review in light of the report.
- 13.23 The Commissioner also recommended that the Welsh Assembly Government reflected on the issues covered in the report and ensured that future guidance and standards for design and location of toilet facilities was given prominence.
- 13.24 The report was published by the Commissioner. It remains unclear to what extent or how, if at all, it was sent to local authorities by the Children's Commissioner's office. It was not made available formally to the Welsh Assembly Government. However, the Assembly Government requested a copy, later in May 2004, and considered it. There was some debate at the Inquiry's hearings as to the status of the report and its recommendations. In the event, I do not consider that anything of significance turns on that issue. Mrs Taylor acknowledged that the report and its recommendations had been considered with care by the Welsh Assembly Government and had been regarded as important.

- 13.25 The report was considered by Ministers in January 2005, along with other reports produced by the Commissioner in 2004. A briefing dated 18 January 2005, from Mrs Taylor's office to Ministers, was produced to the Inquiry. The recommendation, which was agreed by Ministers, was that the recommendations of the Commissioner should not be followed, at least to the extent of conducting an audit and consulting local authorities as to the state of school toilets.
- 13.26 There was no discussion with local authorities prior to that decision having been made; for example, to ascertain whether they had in fact put specific focus on the issue of hygiene in school toilets. Mrs Taylor, in her oral evidence, accepted that that might have been instructive, but indicated that no consideration was given at the time to doing so.
- 13.27 After the hearings, the Welsh Assembly Government produced some further documentation. It appears to indicate that some consideration was in fact given to taking forward the recommendation and to seeking local authority views. In June 2004, Mrs Taylor sent a colleague an e-mail referring to the Commissioner's report on school toilets stating:
- "I think we need to address this as a health and safety issue – since a lot of it is to do with the way toilets are maintained, cleaned and supervised – for the new branch to handle. However I think we need to put this on the agenda of an appropriate ADEW Group [the Association of Directors of Education in Wales]. In particular I would like views from authorities on how to handle the issue of auditing the state of school toilets as proposed... let me know what you think might be an appropriate route into ADEW".
- 13.28 There is no further documentary evidence to indicate what led to the submission and decision in January 2005 not to proceed with the recommendations.
- 13.29 The basis for the decision by the Welsh Assembly Government not to conduct the audit and engage in the local authority consultation as recommended in the report, was explained by Mrs Taylor in her oral evidence to the Inquiry. She stated that at the time, the Assembly Government was engaged with local authorities in seeking to ensure that they had in place asset management plans and investment programmes, based on building condition surveys for schools within their areas; and regarding ongoing maintenance and cleaning to be the responsibilities of schools and local authorities. In addition, it was considered that such an audit and consultation process would be a big piece of work imposing a significant burden in terms of resource on local authorities and schools. The overall judgement was that it was not worth expending that resource, or even seeking the views of local authorities as to whether they had specifically focussed on the issues highlighted by the Commissioner, given the other processes that were in train which it was anticipated might lead to the desired outcome in a quicker timeframe.

- 13.30 I accept that difficult cost/benefit and resource judgements need to be made by the Welsh Assembly Government. Nevertheless, I have some concerns about the decisions taken in January 2005 that the Children's Commissioner's recommendations in "Lifting the Lid" should not be followed, at least to the extent of consulting local authorities as to the state of school toilets:
- (i) The Commissioner's report appeared to indicate that, despite the ongoing work relating to general maintenance of school buildings and facilities, there was a specific problem relating to school toilets. It was therefore open to serious question whether simply relying on current work and projects would give the requisite degree of focus to the problems identified by the Commissioner.
 - (ii) It would not have been unduly onerous for the Welsh Assembly Government to have consulted or communicated with local authorities at least to the extent of (a) ensuring that they were aware of the Commissioner's report and concerns and (b) had focussed, or were focussing, on the specific issues raised in the report. Such limited communication or consultation would have informed the consideration of the whether the Commissioner's recommendation should have been taken forward.
 - (iii) In fact, as the local authorities' evidence to the Inquiry made clear, few of the local authorities were even aware of the Commissioner's report. The communication or consultation would therefore also have dealt with that fact.
 - (iv) Given what occurred when local authorities did in fact focus on school toilets some years later as a result of the Outbreak, it is likely that even some form of preliminary or limited consultation led by Welsh Assembly Government would have indicated that appropriate attention had not been given to this issue and that there were significant problems on this subject as indeed the Commissioner's report appeared to indicate.

Local Authorities

Rhondda Cynon Taf

- 13.31 Mr Mike Keating Director of Education and Lifelong Learning, confirmed that schools in Rhondda Cynon Taf ("RCT") could choose to have their buildings, including toilets, cleaned either by a local authority-appointed contractor or by a contractor of their own choice. He explained that the schools that contracted with the former would be assured that the cleaning company would have been issued with comprehensive guidance through the contractor's quality and safety site folder, which would include guidance on materials to be used, storage of materials, training of cleaners and expectations of general standards. Schools that did not contract with the local authority appointed cleaning company would receive some general guidance but it would not be as detailed. At the time of giving oral evidence, Mr Keating stated that a proposal for the same comprehensive guidance to be provided to all schools, and their contractors, irrespective of contract funding was under review.

- 13.32 Mr Keating explained in his statement that of the 29 schools in RCT that were affected by the Outbreak, three of them had raised issues regarding the standard of toilets prior to the Outbreak. Two were primary schools. In relation to the first, complete toilet refurbishment was carried out in 2003 and 2004 following complaints in 2001 about the continued use of toilet facilities built in 1875. In relation to the second, there was a problem with the boiler and valve system which led to a lack of hot water. This was rectified in November 2005. The third, a secondary school, had problems with a lack of soap in the toilets. This was brought up by the School Council and addressed.
- 13.33 Mr Keating stated that he and colleagues in RCT were unaware of the existence of the Commissioner's report until after the Outbreak. Mr Keating confirmed that neither the Commissioner's Office nor the Welsh Assembly Government had made the Council aware of it or its recommendations.
- 13.34 Mr Keating pointed out that RCT worked with schools on a general rolling programme of refurbishment. However, it was the *E.coli* O157 Outbreak that led to precisely the sort of inspection and audit of school toilets that had been recommended over 18 months earlier by the Commissioner.
- 13.35 That inspection and audit was carried out by RCT in October 2005. Schools in RCT were informed by e-mail on 14 October 2005 that inspections would be carried out to investigate the general provision and condition of all toilet facilities. The availability of soap, paper towels and toilet tissue as well as the general standards of hygiene and cleaning practices were to be assessed. A gap analysis was to be prepared. Guidance notes for inspection were drawn up for Technical Officers to ensure that all Surveyors were undertaking a generic approach and to ensure consistency of approach.
- 13.36 RCT's audit revealed that:
- (i) A significant number of schools did not have hot water.
 - (ii) There was a widespread need to improve and provide the basic requirements such as soap, paper towels, hot water, adequate numbers of toilets, basic refurbishment. There were examples of no soap, no toilet roll holders, no toilet paper, no locks on cubicles, broken taps, no paper towels, missing toilet seats, toilet pans, broken cisterns, no paper bins, lack of ventilation, poor decoration, vandalism.
 - (iii) There was a worrying picture forming in the secondary school sector. Some toilets were locked during the day. Pupils had to ask the School Secretary for the key and for toilet paper. Some toilet areas had been converted into teaching areas without permission of the Authority.
 - (iv) Inspections of toilets of secondary schools that did not contract with the authority-appointed contractor revealed "extremely poor practices that needed to be challenged". For example, there was no colour coding of buckets, cloths and cleaning equipment to differentiate uses such as toilets, sinks, floors.

- 13.37 Work to address the problems was then undertaken. The significant funding that was needed was sought and provided.

Caerphilly

- 13.38 Ms Donna Jones, Principal Health and Safety Officer in the Directorate of Education and Leisure explained in her statement that Caerphilly delegated budgets to head teachers and governing bodies, and placed responsibility on them to put in place and monitor effective hygiene standards within their schools.
- 13.39 Ms Jones stated that there was no policy in place at the time of the Outbreak concerning the cleaning of schools and, more specifically, school toilets. She considered that uniform guidance for all schools within the Borough was a desirable aim.
- 13.40 Ms Jones stated that the Authority's Property Services Department had "happened upon" the Commissioner's report in 2004 having seen it on a website. Ms Jones, then a Senior Health and Safety Officer, had first seen the report in 2005. It does not appear that the report led to any particular action by Caerphilly at the time.
- 13.41 In common with other local authorities, the focus on school toilets was triggered by the Outbreak. Following the Outbreak, inspections of all school toilets in Caerphilly took place. These were carried out by Environmental Health and Health and Safety Officers. Pro-forma inspection sheets were used to guide the inspecting officer through the inspection.
- 13.42 A series of problems were identified, mainly concerning heating and plumbing at 51 schools. The investigation highlighted that measures taken by some schools to conserve water, on the advice of the Authority, namely the installation of push-taps had resulted in young children being unable to wash their hands. Some schools had not been spending their delegated funds allocated for maintenance on maintenance. In addition, it was discovered that 103 caretakers within Caerphilly were not adequately trained.
- 13.43 Action was taken to address the problems:
- (i) Works were carried out and follow up inspection visits were arranged to monitor progress in respect of hygiene standards. Further hygiene standards inspections took place at those schools which did not meet the initial standards. Follow-up visits were then arranged and undertaken between March and April 2006. The follow up visits were aimed at monitoring progress since the initial inspections. All schools received written feedback which indicated a marked improvement in the standard of hygiene. In November 2006, schools that arranged their own cleaning contracts and schools that had not achieved a satisfactory rating in the follow-up inspections were re-visited. There were 12 in total. Again, written feedback reports were provided to Head Teachers, the Chairs of Governors and the Director for Education and Leisure at the Council. The schools that were rated as poor during this inspection rectified the problems identified within the timescales stipulated.

- (ii) Hygiene inspections have been incorporated into future work programmes of the health and safety section, to ensure the maintenance of standards. These are done on an annual basis.
- (iii) Caerphilly introduced a system whereby if a school failed to spend their allocation over a four year period, a weighting would be applied to their budget. In effect, a failure to spend the allocated budget would lead to future funding being reduced and re-circulated amongst other schools.
- (iv) In December 2005, guidance was provided to all head teachers in the Area. Further training in a follow up session has taken place with caretaking staff. This applied to caretaking staff irrespective of how they were funded.

Bridgend

- 13.44 Mr Mark Beauchamp, Group Manager, Education Leisure and Community Services, explained that schools in the area could either enter a service level agreement with the Authority's corporate cleaning service on an annual contract or could make their own arrangements and employ their own cleaning staff, working under the supervision of the caretaker/site manager and ultimately the head teacher.
- 13.45 He explained that all schools in the area were provided with a "Model Health and Safety Policy" document issued by Health and Safety Officers. The document was provided irrespective of how the individual school was funded. He also stated that documents appended to his first statement to the Inquiry, such as the advisory and procedural documents for caretakers and senior cleaners on cleaning and cleaning products, and the procedural document for cleaning areas and advisory documents for specific cleaning tasks, were also developed and distributed on an Authority-wide basis not dependent on how the cleaners were funded.
- 13.46 Bridgend did not carry out school toilet audits in the Autumn of 2005. Mr Beauchamp first became aware of the Commissioner's report after the Outbreak. The trigger for the audit of the school toilets in Bridgend was the publication of the Chief Medical Officer's report into the Outbreak in January 2006. Indeed, it appeared from a note of a meeting which took place in July 2006, that Bridgend were not aware of the Children's Commissioner's report even at that time.
- 13.47 When the Chief Medical Officer's report was received, all schools were asked for information on the state of their toilets, including a review of the cleaning regime and pupil access to toilet paper, soap and hot water. No inspections by Local Authority officials took place, although the action required by the Chief Medical Officer's report did not specify this as a requirement. The responses revealed a series of problems concerning the supply of hot water to schools. Of the 72 schools in the area, 14 had no, or only partial, hot water supply in all toilets. It became apparent that in some instances, boilers had been disconnected and not replaced.

- 13.48 A group was set up within Bridgend to consider two main issues: the supply of hot water and general cleaning standards in school toilets. The Group met on three occasions between July and October 2006. The result of the Group's work was:
- (i) To issue revised guidance to schools in relation to cleaning standards and cleaning materials.
 - (ii) To ask the Authority's Technical Officers to undertake an audit of all schools to assess the hot water supply in school toilets.
- 13.49 As a result of this notification, a database was drawn up setting out the works that needed to be done at various schools. The programme of works was being implemented at the time of the Inquiry's hearings.

Merthyr Tydfil

- 13.50 Ms Edwina Pickering, Contract/Health & Safety Advisor to the Integrated Children's Services Directorate, explained that Merthyr Tydfil County Borough Council gave schools a choice. Either they contracted with the authority-appointed cleaning company or they organised their own cleaning services. Eighteen of the schools contracted with the Local Authority and 16 schools contracted with their own supplier of services.
- 13.51 There was a system of monitoring and quality control in place. Monitoring of the authority appointed contractor was undertaken by Ms Pickering. She described a system whereby she would work through a checklist pro forma, which is set out in the contract with the cleaning firm. Inspections she carried out would either be unannounced or in response to a complaint from the head teacher. Ms Pickering visited schools regularly and would complete checks on the cleaning that had been carried out.
- 13.52 Prior to the Outbreak, the specifications followed by the 16 schools that arranged their own cleaning contract were not the same as that of the authority-contracted firm. Assessing the standards being followed in the schools that were not part of the authority contract would be left to the Head Teacher and Caretaker on the individual sites, unless specific advice or assistance was requested. There was some general authority-wide guidance issued in 1988 and given to the non-contracting schools on hygiene and cleaning standards.
- 13.53 Ms Pickering explained that since the Outbreak, all schools follow the same specification, namely that which existed for the contracting schools prior to the Outbreak. From January 2008, school toilets were to be inspected by Environmental Health Officers from Merthyr Tydfil.
- 13.54 Extensive enquires within Merthyr Tydfil County Borough Council had revealed that no-one had heard about the Commissioner's report.
- 13.55 Ms Pickering explained that in any event, Merthyr Tydfil had conducted a considerable upgrading of toilet blocks between 2002 and 2007. She stated that the process was ongoing.

- 13.56 Following the Outbreak, Environmental Health Officers in Merthyr Tydfil carried out inspections of school toilets in order to assess their cleanliness.
- 13.57 Ms Pickering had also taken the initiative. On 18 September 2005, she arranged for schools in the Borough identified as being involved in the outbreak to be “deep cleaned”. The three schools involved were visited by her on 19 September 2005 to ensure that that was done satisfactorily. Letters were also written to all nursery, primary and comprehensive schools by Ms Pickering to warn them to be vigilant and to carry out measures to prevent cross contamination e.g. the disposal of sand, plasticine. Arrangements were then made for all schools to be inspected by Ms Pickering and her assistants Mr Phil Fryzer, Supervisor of Caretakers, and Mr Mark Goode, Permanent Relief Caretaker. Mr Fryzer explained in his statement that he carried out demonstrations to show caretakers exactly how to clean effectively in critical areas such as toilets.
- 13.58 Following the Outbreak, Ms Pickering explained that all comprehensive schools in Merthyr Tydfil now employ their own hygienists who clean the toilets regularly throughout the school day. Non-contracting schools are provided with checklists devised by Ms Pickering to ensure maintenance of high hygiene standards. Ms Pickering has devised a quality assurance monitoring report document to be completed at the start of each term by a member of her team, with the aim of ensuring that school toilets are clean and remain clean.

Other Developments since the Outbreak

- 13.59 After the Outbreak, The Welsh Assembly Government produced two hygiene booklets. “Mind the Germs” was distributed to nurseries, playgroups and other childcare providers in June 2006. “Teach Germs a Lesson” was distributed to primary and secondary schools. It has also worked with the Welsh Local Government Association and the Association of Directors of Education to ensure the availability of appropriate toilet facilities. A protocol has been established to clarify the handling of reports prepared by the Children’s Commissioner for Wales.
- 13.60 There has been progress on refurbishing school toilets in schools in all four local authority areas. The levels of activity reflect the number of schools in each area and refurbishment needs, which have been informed by the audits. A lack of hot running water in school toilets has been a problem across the four areas, although the number without it varied considerably. All four authorities have taken action to address this. Audits of school toilet facilities appear to be continuing in all four areas, which is encouraging. The means of audit, frequency and timing vary slightly between the authorities but, most importantly, the standard of facilities are being monitored.
- 13.61 Action has also taken place on training cleaning staff, and the provision of more guidance on cleaning procedures. There is evidence that schools that employ their own cleaners have been covered as well as those that are covered by a contract with the Local Education Authority. This is important to consistency in standards in all schools.

Conclusion

- 13.62 I note that past investment in infrastructure projects have resulted in improved toilet facilities in some schools. I have also noted that action has been taken since the Outbreak to address problems that have been identified, which has been accompanied by the provision of more training and guidance on cleaning and cleaning procedures. The Outbreak, as opposed to the recommendation of the Children's Commissioner to the Welsh Assembly Government, was the trigger for audits of toilet facilities. While there were problems with the toilet and hand washing facilities during the Outbreak, they did not appear to cause or contribute to its spread. However, the provision of adequate toilet and hand washing facilities in schools is a basic requirement and it takes on a particular importance in terms of preventing the spread of an infection.

- 14.1 The Outbreak affected many people but in different ways. Some of those infected showed no symptoms at all. Some had mild to serious effects in terms of diarrhoea and bloody diarrhoea while, as this chapter and the following chapter will describe, others suffered complications and very serious illnesses.
- 14.2 The greatest impact of all was the tragic death of young Mason Jones, with which his family have lived with since the Outbreak and continue to live with today. His death illustrates well the danger of *E.coli* O157 and the importance of prevention. The infection is relatively rare but there is no room for complacency. The Outbreak shows that without continual vigilance and commitment to preventing it entering the food chain, it will occur, and with devastating results.
- 14.3 Deri is a small mining village in the Rhymney Valley in the area covered by Caerphilly County Borough Council. The Inquiry was told that it has a keen sense of community spirit. Sharon Mills and her partner, Nathan Jones, have lived together there since 1996. They had three sons. Chandler was born on 1 July 1997. Mason was born on 24 December 1999. Cavan was born on 11 November 2004. Sharon is a housewife and Nathan works for Caerphilly County Borough Council.
- 14.4 Chandler and Mason attended Deri Primary, a small school with approximately 100 pupils. Sharon told the Inquiry that it is a very friendly school where parental complaints and concerns are answered and where, in her opinion, the hygiene standards were very high. Sharon and Nathan had nothing but praise for the way in which the school was, and is, run.
- 14.5 On 13 September 2005 Sharon received a telephone call from Deri Primary School, not long after she had dropped Mason and Chandler off for the day, to say that Chandler was feeling unwell and that he should be collected. When Sharon arrived, Chandler wanted to stay at school because the feeling of illness had worn off. That evening Chandler was complaining of a painful stomach ache. Sharon took the view that it was a twenty-four or forty-eight hour bug. He started to suffer from diarrhoea.
- 14.6 The diarrhoea and abdominal pain continued into 14 and 15 September 2005. On the afternoon of 15 September 2005, it became worse. Sharon noticed that Chandler had blood in his motions.
- 14.7 She rang the local Out-of-Hours Service. She explained the symptoms to a Doctor who thought that a blood vessel may have been broken as a result of Chandler's frequent visits to the toilet. The advice was to monitor the situation overnight but to ring back if further assistance was needed. That evening, the blood loss stopped although the diarrhoea did not.
- 14.8 An appointment was made with the family's General Practitioner ("GP") on Friday 16 September 2005. The GP advised Sharon to monitor Chandler over the weekend. A sample pot was also provided to be returned to the Surgery on Monday, 19 September 2005.
- 14.9 Chandler's diarrhoea and stomach pain subsided and had disappeared by the afternoon of 17 September 2005.

- 14.10 On 19 September 2005, Chandler returned to school. He was a little bit pale but Sharon saw no reason why he should remain away from school.
- 14.11 On 19 September 2005 Sharon became aware of the Outbreak, having been informed by a relative about reports on the news.
- 14.12 She rang the *E.coli* Helpline. Those manning the Helpline arranged for an Environmental Health Officer ("EHO") to attend the home with advice sheets and a food history questionnaire. Sharon told the Inquiry that the advice she received from an EHO was to sanitise everything in order to avoid cross-contamination. The Officer also brought sample pots with him.
- 14.13 Two days later, on 21 September 2005, the school telephoned Nathan to say that Mason had fallen ill. Nathan picked Mason up from school and put him to bed. Mason was complaining of a headache and Nathan noted that he was running a high temperature. Mason did not appear to his parents at that stage to be exhibiting the same symptoms as Chandler.
- 14.14 Sharon returned home. Mason was taken to Nathan's parents' home to be looked after as Sharon had an appointment that afternoon. The Environmental Health Department managed to ascertain that Mason was staying with his grandmother. A sample pot was dropped off for him. The EHO said the Department would collect both Mason's and Chandler's sample pots the next day; and advised that Chandler should remain away from school notwithstanding the lack of symptoms at that stage.
- 14.15 Chandler went to stay with Nathan's aunt, who lived a few doors away from Sharon and Nathan. Mason returned home. Cavan was also at the family home.
- 14.16 Later that day, whilst visiting his great aunt's home, Mason began vomiting. Nathan collected him and brought him home. He had to be carried. He was hot. Sharon put a fan by his bed, placed a flannel on his forehead and left a bottle of weak squash by his bedside.
- 14.17 At this point, in light of the media coverage about the Outbreak, Sharon thought that Mason may well have *E.coli* O157 infection. She gave Mason "Calpol" to try and bring his temperature down. He seemed slightly better overnight and into the next day, 22 September 2005. However, that afternoon the diarrhoea started.
- 14.18 An EHO from Caerphilly County Borough Council collected the sample pots on 22 September 2005.
- 14.19 On 22 September 2005, Sharon telephoned her GP, as the contemporaneous notes record. She wanted to know whether Mason should take a second dose of a medicine called "Pripzen", which he had been taking since early September for threadworm. The GP confirmed that he was able to take the dose.
- 14.20 On 23 September 2005, Mason seemed just as poorly as the day before. He started to pass blood that afternoon.

- 14.21 Sharon told the Inquiry that she then telephoned the *E.coli* Helpline but that no-one answered. The Inquiry asked for evidence on this issue from the National Public Health Service for Wales. It was given by Dr Marion Lyons, the Lead Consultant in Communicable Disease Control, in her third statement and orally. This evidence indicates that the helpline was operating normally and well within its five-line capacity at this time. On the basis of the evidence before me, I conclude that Sharon was mistaken in her recollection of this and that she may have confused the call to the Helpline with the one she made to the GP on 22 September 2005.
- 14.22 There is a contemporaneous record of her having contacted her GP on this date. However, the record is untimed and refers only to diarrhoea and not to blood in the diarrhoea.
- 14.23 Sharon then rang the Environmental Health Department to see whether the test results had come through. She spoke with an EHO. He said he would check with the office in Cardiff before it closed for the evening and would get back to Sharon. Sharon said that he did not.
- 14.24 Sharon told the Inquiry her recollection is that evening she telephoned Hospital 1; and was put through to a nurse on the Paediatric Ward. The nurse advised Sharon that she should ensure Mason was taking plenty of fluids, to monitor his blood loss and to make sure he was passing urine. The nurse also said to look out for cold hands and cold feet as they are a sign of potential renal failure. There is no contemporaneous record of this call.
- 14.25 On 24 September 2005, Mason continued to pass blood in his diarrhoea, although it was not as noticeable as before. He was drinking water and he was passing urine.
- 14.26 In her statement to the Inquiry, Sharon's recollection was that she had then made a single call: she had rung Hospital 1 for re-assurance. Again, there is no contemporaneous record of this call. However, there are transcripts of conversations Sharon had with nurses at the local Out-of-Hours Service at this time. Sharon stated in her oral evidence that she then recalled that her call to the Hospital was in addition to this call.
- 14.27 The transcripts referred to above record that at 16:52 on 24 September 2005, Sharon spoke with Nurse B at the Out-of-Hours Service. The consultation appears full and detailed. Sharon explained that Mason was passing blood and that the results of the test samples were due on 26 September 2005. A series of relevant questions were asked by Nurse B and clear explanations were given by her concerning the symptoms presented by Mason. Sharon confirmed that Mason was passing urine and drinking water. Advice was given on kidney failure in this respect. Advice was given about cross-contamination, including practical advice such as changing towels and washing bedding regularly. Sharon was re-assured that if she had any further concerns over the weekend that she should contact the Out-of-Hours Service.
- 14.28 That evening, Mason's condition became worse. The amount of blood being passed increased. Sharon had to put a nappy on him. He continued to vomit and eventually he and Sharon spent the remainder of the night downstairs. Sharon particularly recalled that the smell from the nappy was awful.

- 14.29 On 25 September 2005, Mason was poorly and was agitated. He was still passing blood. At about 11:45, Sharon received a phone call from the Public Protection Department in Caerphilly County Borough Council. The person Sharon spoke to informed her that both Chandler and Mason had tested positive for *E.coli* O157. The lady enquired as to how they both were. Sharon explained that Chandler's condition had improved and that he was much better. Mason on the other hand was poorly. The lady advised that Sharon seek immediate medical assistance.
- 14.30 Sharon telephoned the Out-of-Hours Service at 12:12. She again spoke with Nurse B who was on duty. There is also a transcript of this conversation. Sharon explained to Nurse B that she had received confirmation that both Mason and Chandler had tested positive for *E.coli* O157; Mason was passing less urine than the day before and the smell from the diarrhoea was dreadful. Nurse B arranged an appointment for 12:50, as the car journey to the Medical Centre would take 20 minutes.
- 14.31 Sharon and Nathan wrapped Mason in a blanket and drove to the Centre. On arrival they were seen quickly by Dr C. There are contemporaneous notes of this consultation. It lasted 16 minutes between 12:51 and 13:07.
- (i) Dr C was aware that Mason had tested positive for *E.coli* O157;
 - (ii) He noted that Mason had bloody diarrhoea;
 - (iii) He noted that Mason was very lethargic and poorly, although he appeared alert and co-operative;
 - (iv) He noted that Mason was passing reduced amounts of urine. However, as the notes record, he was drinking and appeared "well hydrated". The notes also record that there was a "long chat re hydration/urine output", no doubt, stressing the need to keep an eye on this;
 - (v) Mason's pulse and temperature were said to be satisfactory;
 - (vi) Mason's capillary refill time was two seconds;
 - (vii) Dr C prescribed paracetamol and Ibuprofen. Dr C stated (in his police statement) that he informed Sharon that if Mason's temperature increased uncontrollably, if he began drinking less fluid or if the diarrhoea and vomiting became worse, to re-contact the Out-of-Hours Service.
- 14.32 Sharon's recollection was that at this time that the corners of Mason's lips were blue; but she cannot recall whether she drew the doctor's attention to this. Dr G, the Clinical Director at the Out-of-Hours Service, who gave live evidence and commented on Dr C's notes, accepted that if Mason's lips had been blue at the edges this would have been significant to record. There is, however, no record to this effect in what appear to be full notes of a lengthy examination undertaken in the knowledge that Mason was infected with *E.coli* O157. It is also to be noted that there is a reference to blue lips in the transcript of the telephone conversation Sharon had later that day, at 19:49, with Nurse D of the Out-of-Hours Service. By this time it is evident that Mason's condition had taken a serious turn for the worse.

- 14.33 After the Inquiry's hearings and in response to an opportunity to make representations to me, Sharon submitted two new statements about the corners of Mason's lips being blue. I have given these careful consideration but, with particular reference to the contemporaneous records, it remains my view that Sharon might be right in her memory of Mason's lips beginning to turn blue at about 13:00 but it was not evident enough to Dr C to comment on it.
- 14.34 Dr G, who had consulted colleagues on the issue, told the Inquiry that it was his view that the decision not to admit Mason into hospital at the stage at which Dr C examined him was an acceptable clinical judgment, in particular, given the absence of dehydration and peripheral shutdown. He explained, in terms, that GPs in Dr C's position have "very difficult calls to make". He accepted, however, that there was an argument for admission on what was described as humanitarian grounds, in other words removing the burden of assessing deterioration away from the parents.
- 14.35 Mason was taken home by his parents. They gave him a spoonful of Ibuprofen and a spoonful of "Calpol". His condition did not improve. It deteriorated. Sharon's recollection is that: his feet and hands started to go cold; he was becoming very pale in the face; he began hallucinating; and his lips were blue.
- 14.36 This deterioration led Sharon to telephone the Out-of-Hours Service again at 19:49. She spoke with Nurse D who went through the symptoms Mason was presenting, including a high temperature and cold hands and feet. As set out above, there is reference in the transcript of that conversation to Mason's lips being blue. Sharon also said that Mason was delirious. The nurse arranged for a consultation at 20:40 at the Out-of-Hours Centre.
- 14.37 Dr G was asked at the Inquiry's hearing whether at that time it would have been more appropriate for Mason to be transferred to hospital by ambulance. He answered that the internal inquiry subsequently carried out by the NHS Trust into the handling of Mason's case had considered the point. The view was that that was a difficult issue to assess because of unknown factors, such as ambulance waiting times, that would have had to be taken into account.
- 14.38 Sharon telephoned the Out-of-Hours Service again at 20:10. She suggested to the operator that Mason was not fit enough to be transported to the Out-of-Hours Centre. The operator, who was not a trained health care professional, told Sharon that there was a four to five-hour wait for a home visit. In those circumstances, Sharon agreed to take him to the Centre to be seen by a doctor. Dr G confirmed that Mason would have been seen quicker at the Out-of-Hours Centre than he would have been had a Doctor called at the home.
- 14.39 I note that in addition to giving evidence on the review of Mason's case, Dr G described changes that have since been made, particularly in relation to home visits.
- (i) The original standard required a home visit to be made within four hours of the initial call to the Out-of-Hours Service. Within the Trust this has been reduced to one hour as a maximum;

- (ii) Further, the NHS Trust has been in the process of simplifying the unscheduled care system which, in Dr G's words, "from the point of view of a patient... really is a mess". Dr G explained that GP Out-of-Hours Service Centres will be situated next to hospitals within the Trust so that the GP seeing patients would have access to hospital expert opinion.
 - (iii) The Out-of-Hours Service has formalised its procedure for disseminating public health notifications. It sets out what staff in the Service must do when they receive public health alerts. An internal audit trail for the receipt and dissemination alerts is also being implemented.
- 14.40 Mason was taken back to the Out-of-Hours Centre. He was seen by Dr F at 20:47. Dr F noted that his feet and hands were cold, his temperature was 34.9 degrees. He was lethargic. His pulse was very feeble. He contacted the Paediatric Department at Hospital 1 and arranged for Mason to be admitted. The consultation ended at 20:57.
- 14.41 Mason was taken to Hospital 1 in his parents' car. They carried Mason into the Accident & Emergency Department. They were told that they were in the wrong part of the Hospital. They had to put Mason back into the car and drive to the other side of the hospital site where the Paediatric Department was situated. Mason eventually arrived at the Paediatric Department at 22:00.
- 14.42 Consultant W dealt in his evidence with the care and treatment provided to Mason thereafter. On arrival at the Department, a detailed history was taken. Mason was very lethargic and very pale. He was not speaking but was able to perform simple commands. His hands and feet were cold and difficulty was experienced in measuring the capillary refill time. His heart rate was raised and the blood pressure a little low. He had sunken eyes but a moist tongue. An intravenous cannula was inserted and Mason was given a rapid infusion of normal saline to improve his circulation. This led to a clinical improvement. He was more alert and had a slightly better colour.
- 14.43 Blood results available at 23:10 showed a low platelet count, the white cell count was markedly raised indicating inflammation. The biochemistry results were also abnormal showing a raised urea, a raised creatinine level and a markedly reduced sodium level, which was indicative of concerns about his kidneys and the onset of Haemolytic Uraemic Syndrome ("HUS").
- 14.44 The renal unit at Hospital 2 was contacted for advice. A re-hydration regime was advised and commenced at 23:30. Repeat blood tests were undertaken. Mason's heart rate remained raised. His respiratory rate was raised, although his blood pressure remained normal. A decision was taken that, in light of his serious condition, Mason should be transferred to that hospital.

- 14.45 At 03:00 on 26 September 2005, Mason was transferred by ambulance with a nurse escort to Hospital 2. Sharon accompanied Mason in the ambulance. Nathan followed in the car. They arrived at Hospital 2 at approximately 04:15. He was initially taken to the Accident & Emergency Department and was then transferred to the Renal Ward.
- 14.46 Mason was under the care of the Paediatric Nephrology Team at Hospital 2. When he was seen at 06:00 on 26 September 2005, he was in acute renal failure. He was admitted to surgery and had a peritoneal dialysis catheter inserted. He was given fluids to expand the amount of fluid in his circulation. Initially Mason rallied a little and seemed more like his normal self. However, his condition deteriorated further.
- 14.47 The Paediatric Intensive Care Unit was alerted to Mason's condition. His neurological state worsened. It was apparent that he was becoming confused. It was also discovered that the peritoneal catheter was not functioning properly.
- 14.48 On 27 September 2005, there were a number of concerns that faced the consultants treating Mason: his high pulse rate, indicating possible involvement of the heart in the HUS; his reduced level of consciousness and the neurological effects of HUS; and concerns about his abdomen, which was distended. A surgical opinion was sought. As a result, a haemodialysis catheter was inserted.
- 14.49 At approximately 17:00 that day, Mason started fitting. Action was taken and the fitting stopped. Later that evening, Mason was admitted to the Intensive Care Unit. Mason required a ventilator and heart stimulant drugs to maintain his blood pressure. At that stage Mason was under the primary care of the Consultant Intensivist, with regular reviews carried out by the Consultant Paediatric Nephrologists.
- 14.50 On 28 September 2005 Mason's condition appeared to have stabilised. His blood pressure was being maintained without stimulation. Plasma exchange and magnetic resonance imaging scans ("MRI") of the brain were part of the plan. The MRI scan was normal.
- 14.51 On 29 and 30 September 2005, Mason again appeared to be comparatively stable. He was maintained on ventilation. Plasma exchange and haemodialysis were required. Fluid removal, subject to cardiovascular status, was completed. The diarrhoea continued. In view of his ongoing bowel distension he was given antibiotics.
- 14.52 On 1 October 2005, Mason's condition was unchanged. Clinical observations indicated no evidence of fluid overload and his blood chemistry was satisfactory so haemodialysis was not required. All other care continued.
- 14.53 On 2 October 2005, Mason developed a blanching rash on his trunk.
- 14.54 On 3 October 2005, plasma exchange continued. The blanching rash had spread to his face. His parents felt his abdominal distension was decreasing. Mason continued to pass watery stools. His blood pressure was maintained with the support of drugs. Further dialysis was required with an aim of removing more fluid. Haemofiltration was advised for 4 October 2005.

- 14.55 At 17:00 on 3 October 2005 Mason's blood pressure began to drop. The Intensivist was concerned about Mason developing an infection and blood cultures were performed. It was anticipated that he could be started on further antibiotics. However, his blood pressure dropped suddenly at 23:00. This was resistant to any of the medication introduced by the medical team. The team began external cardiac massage. Resuscitation procedures were carried out for 30 minutes. During this time, the Consultant Intensivist explained the precariousness of Mason's situation to Sharon and Nathan. They were allowed into the room for what the consultant felt would be Mason's final moments.
- 14.56 Some cardiac function returned and further measures were implemented. However, at midnight there was a precipitous fall in his blood pressure associated with a gradual drop in his heart rate. His circulation was totally unresponsive to conventional cardio-pulmonary resuscitative measures.
- 14.57 With Mason's parents' consent and with full agreement of the Medical and Nursing Team, resuscitation attempts were ceased at 00:30 on 4 October 2005.
- 14.58 A post mortem took place on 6 October 2005. The cause of death is recorded as, first, Haemolytic Uraemic Syndrome and, secondly, *E.coli* O157 infection.
- 14.59 Sharon and Nathan were in a state of disbelief after Mason died. They returned to Deri to give Chandler the dreadful news. He was devastated. Sharon told the Inquiry that Chandler has not really recovered from the death of his brother. He stayed with his great aunt for a considerable time. Chandler and Mason shared a bedroom in the family home and he could not face returning to it.
- 14.60 Chandler has been under the care of a Nurse and Clinical Psychologist provided by the local Children and Adolescent Mental Health Services. Sharon explained to the Inquiry that Chandler built up a good relationship with the Psychologist. Sharon explained that the family GP had been supportive and helpful. Sharon also told the Inquiry that Chandler and indeed the family had received great support from Deri Primary School. There was a sense of grief within the school as Mason was a big character within it.
- 14.61 Finally, I note that Sharon was particularly complimentary about the care that Mason received and the way in which she and Nathan were treated by Hospital 2. She said that they had done all that could have been done and that she could not have wished for Mason to spend his last few days with better people.

The Inquiry's Approach

- 15.1 The Inquiry received more than 50 statements from persons and families affected by the Outbreak. They were all considered with care. The Inquiry also received a statement from Mr Stephen Webber, a partner at Hugh James Solicitors, who act for a substantial number of the families affected by the Outbreak. His statement summarised the concerns of those families about the Outbreak, including specifically concerns about various aspects of the healthcare provided to those affected.
- 15.2 The Inquiry decided that it would be impracticable to seek to chase down every individual concern raised. The Inquiry considered that the benefit of doing so would not have been likely to warrant that time, effort and resource. That was particularly so given that it was not part of the Inquiry's function to determine individual complaints or allegations about healthcare matters.
- 15.3 In these circumstances, the Inquiry decided that the appropriate and efficient course was to select a small number of cases, and examine the healthcare issues and concerns expressed by the families involved using those selected cases as representative examples.
- 15.4 There was, and is, a need to preserve confidentiality in relation to these cases. That need extends to the identity of the families involved in the selected cases. In two cases, the families indicated that they were content for their names and experiences to be made public. One was the family of Mason Jones, whose case is the subject of the previous chapter. The other is the Bray family. In the other cases, the families' names were protected at the hearings and in evidence published on the Inquiry's web site, with numbers and letters used to do so. The same numbers and letters are used in this and other Chapters.
- 15.5 The anonymity also extends to those healthcare professionals and bodies who were involved in the handling of the selected cases. Their identities were protected because the selected cases were precisely that. It would be unfair to single out particular healthcare professionals and bodies given that the selected cases have been examined as a representative sample only and as a convenient way of exploring common themes of concern.

Lisa Bray

- 15.6 Before turning to the other selected cases, I deal with the case of the Bray family. The Inquiry received a statement from Mrs Lisa Bray. The Inquiry asked her to give live evidence, not as a representative sample case of the kind referred to above, but simply in order to get an impression of the serious and traumatic effects of *E.coli* O157 infection affecting a family. Mrs Bray's evidence provided a further powerful reminder of just how important it is to seek to minimise the chances of such an outbreak in the future.

- 15.7 She lives in the Rhondda Cynon Taf area with her husband and two children. At the time of the Outbreak, she was 34 years old. Her daughter, Caitlin, was aged three (nearly four), and her son Thomas was aged four (nearly five). They attended Penygraig Infants School in Rhondda Cynon Taf.
- 15.8 On 13 September 2005, Caitlin fell ill with diarrhoea and stomach pains. On 14 September 2005, she started to show blood in her diarrhoea. She was examined at a local Out-of-Hours surgery that morning. By the evening, her condition had become worse. The stomach cramps were severe.
- 15.9 On 15 September 2005, the Brays were visited by Ms Heather Lewis, Food and Health and Safety Manager for Rhondda Cynon Taf County Borough Council, who was investigating a potential food poisoning outbreak involving children that attended Penygraig Infants School. In reality, that was part of the Outbreak, although it was not known at that time.
- 15.10 Caitlin's condition deteriorated. She was extremely pale and the blood in her diarrhoea was more obvious. She became unable to bear her own weight and was unable to walk to the toilet.
- 15.11 At that point, she was admitted to hospital. She was put on an intravenous drip. Mrs Bray was able to stay with Caitlin overnight. A number of blood tests were carried out. Caitlin found this process traumatic. Her parents had to physically restrain her for the blood to be taken.
- 15.12 By 16 September 2005, Caitlin had become very pale and lethargic. She was in severe pain and was unresponsive. She was not speaking. She was not crying.
- 15.13 That evening, the Registrar informed the Brays that Caitlin had developed Haemolytic Uraemic Syndrome ("HUS") and would have to be transferred to a specialist hospital for dialysis treatment. The same evening Caitlin underwent a procedure to insert a catheter. This procedure failed, so a tube had to be inserted through her nose.
- 15.14 By 17 September 2005, Caitlin was suffering from acute renal failure. She was extremely poorly. Her heart rate was fast and her blood pressure raised. She was transferred to a tertiary hospital (Hospital 2) that day. She had a peritoneal catheter inserted to allow dialysis. She also received a blood transfusion. Initially, the dialysis was not successful and she had the added complication of a blockage in the bowel. Caitlin remained uraemic for more than two weeks before being discharged on 6 October 2005.
- 15.15 On 18 September 2005, Mrs Bray herself became ill and was ultimately admitted to hospital on 20 September 2005. Her husband, who had been looking after Thomas at home, went to the hospital to be with Caitlin. Thomas stayed with his grandparents.

- 15.16 Mrs Bray was able to give a first hand account of how it feels to have *E.coli* O157. Her symptoms consisted of diarrhoea which was watery and bloody. She had severe stomach cramps. She told the Inquiry that the pain was difficult to describe, but she knew what real pain was from having given birth. On top of her own symptoms, Mrs Bray had to cope with the knowledge that her children were also extremely unwell, and she was not well enough to help with them.
- 15.17 Mrs Bray was ultimately transferred to a specialist renal unit on 23 September 2005, having also been diagnosed with HUS. She was suffering from acute renal failure, thrombocytopenic anaemia and liver derangement. The diarrhoea and vomiting continued. She was being given fluids via an intravenous drip. She was continually having blood tests, including the taking of arterial blood from the wrist. She underwent five blood transfusions. She was discharged on 30 September 2005.
- 15.18 On 19 September 2005, the day after Mrs Bray became ill, Thomas became unwell. He had bloody diarrhoea, abdominal cramps and vomiting. On 23 September 2005, he was confirmed as being infected with *E.coli* O157. He was hospitalised and monitored closely. He did not develop HUS nor did he suffer renal failure.
- 15.19 For a number of days, Thomas was in one hospital, his sister and father in a second and his mother in a third. He was then transferred to the same hospital as his mother.
- 15.20 The effects on the family have lasted beyond the initial infection:
- (i) Mrs Bray told the Inquiry that Thomas developed psychological problems as a result of suffering from the infection. Initially, he did not want to go to school. He had to be forced to attend. He would spend the whole day crying. The weekends would be spent worrying about what the next school week would bring. He would not want to go to birthday parties. He would not stay at his grandparents' home. Thomas was on the point of being referred to a psychologist when he gradually started coming back to his old self.
 - (ii) Mrs Bray has been told by those treating her there is a possibility that there will be a relapse with her kidney problems. Her reviews at the Nephrology Clinic continue. She has been taking iron tablets and folic acid. There may be problems with any future pregnancies. She has suffered with numbness and weakness in her lower limbs as well as hair loss as a result of low haemoglobin levels. She has been diagnosed with suffering from Irritable Bowel Syndrome. She had no problems of this sort prior to the Outbreak.
 - (iii) Caitlin was placed on a restrictive diet following her discharge from hospital. Her potassium and phosphate levels were monitored. She had to take folic acid supplements. She remained lethargic and weak following the Outbreak. She remained absent from school for three months. She then returned on a part-time basis. She has become clingy to her mother and remains under the care of the local hospital. The Brays have been told that there is a possibility of long-term damage caused to her kidneys and that damage has been caused to the bowel.

Case 4

- 15.21 Case 4 lives in the Rhondda Cynon Taf area. She attended a local primary school. At the time of the Outbreak, she was nine years old.
- 15.22 The Inquiry received the following evidence in relation to this case:
- (i) A statement from Case 4's mother setting out her recollection of what had occurred, along with her statement to the police.
 - (ii) A statement from Consultant S, a Consultant Paediatrician and a lead clinician at Hospital 5, along with statements she made to the police, concerning the care of Case 4 at the hospital.
 - (iii) A statement from Consultant X, a Consultant and Medical Director of the NHS Trust that operates Hospital 5, about the results of the Trust's investigation into the receipt and dissemination of information in Hospital 5 about the Outbreak.
- 15.23 The Inquiry heard live evidence from the two Consultants, but not from Case 4's mother.
- 15.24 On 11 September 2005, Case 4 started showing signs of what her mother thought was a stomach bug. She had diarrhoea and was refusing food. She then started vomiting. She was up all that night with diarrhoea and vomiting. This was some days before the Outbreak was declared.
- 15.25 On 12 September 2005, Case 4's mother noticed that there was blood in her daughter's diarrhoea.
- 15.26 On 13 September 2005, Case 4 was taken to her GP's surgery. The medical notes indicate that the GP was told that some watery blood was being passed and that there was some abdominal pain. Case 4's mother was warned that if her daughter did not keep fluids down she may need to be admitted to hospital.
- 15.27 The symptoms did persist and when the evening surgery opened at 16:30, Case 4's mother rang the Practice. She spoke to a GP. There had been more vomiting and more blood. The GP arranged over the telephone for Case 4 to be admitted to hospital. She was taken to hospital in her mother's car.
- 15.28 On arrival, she was taken into the hospital building in a wheelchair because she was too weak to stand. She was placed in an isolation room and then taken to the Paediatric Ward.
- 15.29 The history provided by Case 4's mother to a doctor on the Paediatric Ward who admitted her daughter was that there had been 20 episodes of diarrhoea in the previous 24 hours. The doctor's conclusion was that Case 4 was suffering from acute gastroenteritis and was mildly dehydrated. The treatment plan was to prevent further vomiting and reduce the diarrhoea by giving intravenous fluids, then establishing if Case 4 had any haematological or biochemical abnormalities that needed treating, as well as investigating the cause of the gastroenteritis.

- 15.30 Blood tests were taken. They revealed that Case 4 had slightly elevated urea, consistent with mild dehydration. Consultant S told the Inquiry that renal function at this stage was normal, indicated by normal sodium, potassium and creatinine levels.
- 15.31 Two stool samples were sent to the Microbiology Department. The *E.coli* O157 organism did not show up on the first sample sent, according to enquiries Consultant S had since made with the Laboratory at the Hospital.
- 15.32 Consultant S saw Case 4 on 14 September 2005 on her ward round. This was the only time that she saw her, although Case 4 was seen daily by other consultants. At the time of the ward round undertaken by Consultant S, the results of the samples were not known. Consultant S noted in her evidence to the Inquiry that when Case 4 was admitted, the Outbreak had not been declared and that Case 4 was being dealt with as a case of gastroenteritis of unknown cause.
- 15.33 Consultant S was specifically asked whether Case 4's blood pressure during her initial admission caused concern. Consultant S explained that high blood pressure can be caused by hundreds of factors, one of which was renal difficulty. The main reason is often anxiety as a result of being in hospital. Consultant S pointed to the fact that when she completed her ward round, she specifically asked the nurses to carry out blood pressures on all four limbs to see whether the child had a condition called coarctation of the aorta. Consultant S explained that if there was a renal problem one would expect to see raised blood pressure all of the time. However, at different times of the day, for example, when the child was asleep, the pressure came right down, which re-assured the doctors.
- 15.34 On 14 September 2005, a doctor questioned whether the cause of the abdominal pain was in fact gastroenteritis. He called the surgeons to assess whether there was a surgical problem as bloody diarrhoea often indicates such a problem. X-rays were taken. Consultant S emphasised in her oral evidence that it is necessary for a doctor to constantly question a diagnosis in light of the changing clinical picture.
- 15.35 Further blood tests were carried out that day to check Case 4's renal function and to ensure that the intravenous fluids that were being given to her were of the correct type.
- 15.36 Following the advice of the surgical team, Case 4 was placed on two types of antibiotic. They were given against the risk that Case 4 was in fact suffering from appendicitis, peritonitis, or some other surgical problem. The antibiotics were stopped on 15 September 2005. The Consultant at that stage would have had the results of the X-rays and, as Consultant S put it, the benefit of time. She noted that as the spectre of surgical intervention receded there was less justification for the antibiotics.

- 15.37 Whether to prescribe antibiotics in such a case is a clinical judgement made on the evidence available at the time. Their prescription always carries the risk of side effects. One of them is the possibility that they increase the risk of developing HUS in patients with *E.coli* O157 gastroenteritis. The evidence supporting this view is not overwhelming but is strong enough for their precautionary avoidance in *E.coli* O157 infections to be the consensus view in Europe and North America. The decision to prescribe antibiotics on 14 September 2005 was reasonable in light of a) the Outbreak not yet being declared, b) the rarity in "normal" times of *E.coli* O157 infections in Wales, and c) an "acute abdomen" with unknown cause.
- 15.38 On 16 September 2005, Case 4 appeared to be getting better. She was managing to drink and was keeping fluids down. The consultant that carried out the ward round on that day examined her. Her abdomen was soft and tender and he wanted her observed for a further 24 hours, whilst taking oral fluids. She was no longer taking intravenous fluids.
- 15.39 Later that day, the stool culture from the day of admission came back from the laboratory with a negative result for amongst other things, *E.coli* O157.
- 15.40 There were at least two, and possibly four, contacts about the Outbreak prior to the discharge of Case 4 on 17 September 2005:
- 15.41 The first such contact was from a nurse working for the NPHS. It was to the Microbiology Department between 17:30 and 18:40 on 16 September 2005. Consultant X said that it could not have been contact with the Consultant Microbiologist, who took a series of actions the next day when she became aware of it, including ensuring that the relevant clinical areas knew about it. The evidence confirms this. An NPHS diary note indicates that at 12:26 on 17 September 2005, the Consultant Microbiologist rang Dr Sally Venn of the NPHS to raise questions about the Outbreak, and stated that she had been unaware of it and indicated that she would gather information about cases in Hospital 5 and transmit it to the OCT.
- 15.42 I conclude that the information provided to the Microbiology Department at Hospital 5 between 17:30 and 18:40 on 16 September had not reached the Consultant Microbiologist by 12:26 on 17 September 2008.
- 15.43 At 20:45 on 16 September 2005, Dr Lowe of the OCT spoke with the Registrar on-call at the Paediatrics Department. The suggestion from Dr Lowe's manuscript note is that the Paediatric Registrar informed her that there was a patient on the ward who had developed renal failure and HUS as a result of *E.coli* O157. Consultant S was unable to recall this patient; and did not know whether the doctors treating Case 4 were aware of this other patient or the fact that Dr Lowe had contacted the ward on the Friday evening.
- 15.44 The information given by Dr Lowe to the on-call Paediatric Registrar on 16 September 2005 at 20:45 does not appear to have been disseminated within the Department.

- 15.45 On 17 September 2005, the NPHS made contact with Hospital 5 again, through Dr Ciaran Humphries, who was acting on instructions from Dr Lowe. The evidence suggests that contact was by telephone to (a) the Medical Registrar and (b) the Accident & Emergency Registrar on the morning of the 17 September 2005. Dr Humphries was tasked to ring Hospital 5 and three other hospitals at around 10:00 on 17 September 2005.
- 15.46 Shortly after midday, at 12:05 on 17 September 2005, Case 4 was discharged from the Hospital by the Consultant who was treating her (not Consultant S).
- 15.47 Case 4 was discharged by the Consultant, who was unaware of an ongoing *E.coli* O157 Outbreak.
- 15.48 In the light of this, the Inquiry sought evidence as to the policies and procedures for dissemination of important information, such as the existence of an *E.coli* O157 Outbreak, within Hospital 5. That evidence was provided by Consultant X who was not in post at the time of the Outbreak. She carried out an investigation into the dissemination of information in the Hospital on the morning of 17 September 2005. Her evidence was to the following effect:
- (i) She explained that the processes and procedures in place at the time of the Outbreak were very similar to the systems that were in place at the time of the Inquiry's hearings.
 - (ii) The Hospital would be alerted to outbreaks like the *E.coli* O157 Outbreak by the NPHS, the Local Health Boards or through the Welsh Ambulance Service. If the Hospital was notified during "in hours" then dissemination within the NHS Trust was said to be relatively straight forward. It would be sent from the Chief Executive to the Clinical Director, the Director of Nursing and the Consultant Microbiologist/ Infection Control Consultant. Normally a matter like the Outbreak would be dealt with by the Consultant Microbiologist, who would be the key individual, co-ordinating the dissemination of information in conjunction with the Infection Control Team.
 - (iii) The relevant clinical areas within the hospital would be contacted, namely Clinical Directors, Directorate Managers and Lead Nurses to ensure dissemination within their teams. This would be done by telephone and pagers. Within individual departments, communication boards are used to ensure staff, are kept up to date with information, as well as verbally during staff changeovers.
 - (iv) Consultant X estimated that it would take half a day to ensure that every key individual within the hospital hierarchy would be informed of an event, such as an outbreak of *E.coli* O157. In terms of whole teams, that could be several days to account for changes in shifts.

- 15.49 However, whilst she was able to help the Inquiry in relation to the procedures, Consultant X could not, on the basis of the investigation that had been undertaken, assist as to whether the information had in fact been widely disseminated during the morning of 17 September 2005. She stated however, and understandably, that it would be of concern if the Consultant who discharged Case 4 on 17 September 2005 was not aware of the existence of the Outbreak. The fact that she was unable to assist the Inquiry in relation to the question whether, and if so to what extent, the information received by the Hospital about the Outbreak had, in fact, been disseminated prior to the discharge of Case 4 raises questions about the records kept by the hospital on the dissemination of important information.
- 15.50 Consultant S also did not know whether the Consultant who made the discharge decision was aware of the Outbreak. Consultant S was asked whether she would have allowed Case 4 home had she known that there was an *E.coli* O157 outbreak and a patient on the ward with similar symptoms and had developed renal failure/HUS. Her view, based on the notes, was that that decision would have involved consideration of a number of factors, including:
- (i) the reduction in vomiting and diarrhoea and the increase in oral fluids during the stay in hospital;
 - (ii) the fact that Case 4 had tested negative for *E.coli* O157;
 - (iii) the fact that only 5% to 10% of patients go on to develop HUS, usually the very old and the very young, whereas Case 4 was 9 years old and did not fall within the highest-risk age groups;
 - (iv) that Case 4's temperature had remained afebrile i.e. with a normal temperature, throughout her stay;
 - (v) that Case 4's blood counts had been shown to be normal.
- 15.51 Her view was that, even if she knew the child had contracted *E.coli* O157, given the factors described above, there would have been good grounds to allow her home on the provisos that (a) the parents brought her back if there was deterioration in condition, and (b) she return for blood tests the next day. She would also have given detailed advice in relation to avoiding the risk of cross-contamination.
- 15.52 The day after Case 4's discharge, on 18 September 2005, Environmental Health Officers ("EHO") attended Case 4's home to discuss the symptoms. Her mother recalls that by this stage her daughter had begun hallucinating and talking about "a man in black".
- 15.53 On 19 September 2005, an EHO returned with sample pots for the family. Her mother recalls that by this stage Case 4 had begun vomiting again. Her diarrhoea was bloody. She was unable to urinate. She was lethargic and was unable to sit up on the toilet. She appeared to her mother to be in a trance and on the edge of consciousness. So her mother called the Emergency Services on 999 and an ambulance took her back to Hospital 5.

- 15.54 She was readmitted that day. Urea & electrolytes ("U&E") tests were completed. The medical notes at this stage do refer to the *E.coli* O157 Outbreak. The full blood count showed that Case 4 was quite anaemic and the white cell count was quite high. There were fragmented and nucleated red cells, which Consultant S told the Inquiry are classic signs of HUS. These were all absent on the blood counts completed a few days earlier. It was clear to Consultant S that at this stage, Case 4 was in renal failure.
- 15.55 Case 4 was airlifted to Hospital 6. Whilst in the helicopter, she began hallucinating and again referred to "a man in black".
- 15.56 She was confirmed to be *E.coli* O157 positive on 30 September 2005.
- 15.57 She required peritoneal dialysis for 23 days. She started to pass urine on 27 September 2005. She received six blood transfusions and one platelet transfusion in total. The last transfusion was received on 17 October 2005. She was discharged on 19 October 2005. She returned to school in mid-November 2005.
- 15.58 The NHS Trust that runs Hospital 5 has since taken steps to improve arrangements for disseminating important information.

Case 5

- 15.59 Case 5 lives with her parents and younger brother in the Vale of Glamorgan. At the time of the Outbreak, she was six years of age.
- 15.60 In relation to Case 5, the Inquiry received the following evidence:
- (i) A statement from Case 5's parents setting out their recollection of what had occurred, along with the mother's statement to the police.
 - (ii) A statement from Consultant Z, a Consultant Anaesthetist and Medical Director at Hospital 4, who gave evidence about the receipt and distribution of information about the Outbreak within Hospital 4.
 - (iii) A statement from Consultant AA, a Consultant Paediatrician at Hospital 4 who had care of Case 5.
 - (iv) The contemporaneous hospital notes.
- 15.61 The Inquiry asked the local Out-of-Hours Service to obtain a statement from the doctor who examined Case 5. He was absent from work and on long-term sick leave. He did not respond. The Inquiry then corresponded directly with the doctor concerned but received no response. Given that I had access to the doctor's notes, I did not consider it necessary for me to order him to appear at the Inquiry.

- 15.62 The two consultants gave live evidence. I did not consider there was a need for the parents to do so. However, at the conclusion of Consultant AA's evidence, they specifically indicated to me that they wished publicly to thank both Hospital 4 and Hospital 3, to which Case 5 was transferred, for the care that she received.
- 15.63 On 8 November 2005, Case 5 came home from school complaining of stomach pains. Her parents gave her "Calpol" to ease them. She attended school on 9 November 2005.
- 15.64 The sickness became worse in the early hours of 10 November 2005 and Case 5 remained away from school that day. Case 5 started to suffer from diarrhoea. That evening, blood started to appear in the diarrhoea and her parents became more concerned.
- 15.65 In the early hours of 11 November 2005, they telephoned their local Out-of-Hours Service. They were directed to a local treatment centre run by the Service. By this date, the Outbreak had been widely publicised for a considerable period of time.
- 15.66 The contemporaneous medical note completed by the GP reads "o/e t.35.9 abdo.soft ent chest cvs fine mild d/hydration passing urine fine p/n gastroenteritis – advice given". There is no reference to *E.coli* O157. On another document, there is specific mention by the doctor of blood in the diarrhoea. The notes completed over the telephone make reference to "lots of blood evident in the stool".
- 15.67 The parents of Case 5 state that their recollection is that the doctor gave them the impression that there was nothing seriously wrong; that he explained to them that it was not uncommon to see blood in the stools when the patient was frequently going to the toilet; and that he diagnosed gastroenteritis.
- 15.68 Case 5 continued to remain unwell. Her parents were concerned to the extent that they sought a second opinion at their GP's Surgery (not the Out-of-Hours Treatment Centre they had earlier attended) when it opened on the morning of 11 November 2005. They took with them a towel which held a sample of the diarrhoea that Case 5 had been passing. On seeing the towel and examining Case 5, the GP, who was not the same doctor who had examined Case 5 previously, immediately referred her to Hospital 4 as a suspected case of *E.coli* O157. According to the parents, he also expressed surprise that the doctor at the Out-of-Hours Centre who had seen her in the middle of the night had sent her home, given that the Outbreak had been declared.
- 15.69 Consultant AA is a Consultant Paediatrician at Hospital 4. She was on call during the Hospital's weekend rota for 11, 12 and 13 November, when Case 5 was admitted to her department by her GP.

- 15.70 The contemporaneous hospital notes indicate that Case 5 was admitted to the Paediatric Department with a history of 20 episodes of diarrhoea since the day before, with blood being reported in the stools and 3-4 episodes of vomiting. The observation figures/levels were normal save for a slightly raised pulse rate. The impression was that the child was suffering from some sort of infective dysentery with mild dehydration. The treatment plan was for further observations, blood tests, a full blood count, U&E tests, a C reactive protein test (a marker of infection), liver function test and blood cultures to be taken. A review of Case 5's fluid intake was also part of the plan.
- 15.71 These tests were undertaken that day. The results revealed a normally functioning liver, the protein marker indicated infection or inflammation, the white cell count was above the normal range. The U&E test results were also within normal limits.
- 15.72 At 16:05 on 11 November 2005, there was a review of Case 5's condition and her treatment. It was noted that she had taken small sips of water since her admission but was not tolerating the fluids. She had passed a bloody stool since her admission and looked tired. She had therefore been placed on intravenous fluids. At the review, the decision was made that the intravenous fluids instruction was to remain in place.
- 15.73 On 12 November 2005, the patient was reviewed just after 09:00. The revised plan was to continue intravenous maintenance, to encourage oral intake, both water and "Calpol" for pain relief. Repeat U&E tests were to be completed later in the day.
- 15.74 At 10:50 that morning, the Microbiological Department contacted the Paediatric Department with the results of Case 5's stool culture sent to them the previous day. The result identified was highly suggestive of *E.coli* O157. The notes at this stage state that no anti-motility agents and no antibiotics were to be prescribed.
- 15.75 At 18:00, the U&E results came back. They were normal and causing no particular concern.
- 15.76 On 13 November 2005, it was noted that the child had slept overnight. Fluid input and output levels had been monitored. In other words, fluids taken orally or intravenously as against the urine, stools and vomiting were observed. Consultant AA explained that carrying out such an analysis would indicate the patient's hydration status and allow doctors to decide how to respond to the situation.
- 15.77 The Microbiology Department became less certain about the cause of the infection and contacted the Paediatric Department to say that they were unable to exclude or confirm *E.coli* O157, and requested that a further stool sample be forwarded to them.

- 15.78 Case 5's treatment plan was revised to include reducing the intravenous fluids, repeating the full blood count and U&E results and to continue with the rest of the management. The U&E results that were obtained revealed a change in her condition. Sodium was higher than the normal range, potassium was within the normal range, creatinine was up but still within normal range and urea was within the normal range. A blood count had also been done. Haemoglobin levels were normal, the white cell count remained elevated and neutrophils were raised. The platelet count was lower than it should have been (the platelet count is a sensitive indicator of the onset of HUS). Further blood tests were completed. The platelet count was confirmed as falling and HUS became the firm diagnosis.
- 15.79 The treatment plan was reviewed. There was to be close monitoring of urine output, blood film tests to identify specific signs of damage to red blood cells, which is typical of HUS, and renal function tests. That this occurred is confirmed by a tabulated blood test chart which had been maintained within the Department during Case 5's stay. The chart was used to monitor changes in condition.
- 15.80 The blood test results were explained to Case 5's mother, including specific reference to the reduction in platelet levels. At that stage the Paediatric Department was still awaiting confirmation from the laboratory that it was *E.coli* O157 that Case 5 had contracted.
- 15.81 At 18:00 on 14 November 2005, the urea and creatinine figures were rising. In the light of this, the Paediatrics Department considered transferring Case 5 to a specialist Renal Department. Consultant AA explained that the decision was taken at that time because definite indicators of the condition and the threshold point had been reached for transfer to a tertiary centre. On 13 November 2005, the indicators had not been firm enough and so close monitoring had been agreed as the best way forward at that time.
- 15.82 The mother of Case 5 was informed about the plan to transfer at 18:30. The transfer to Hospital 3 took place at 20:00.
- 15.83 Whilst at Hospital 3, the blood tests and stool sampling carried out at Hospital 4 were repeated. Her neurological condition was also monitored.
- 15.84 On 15 November 2005, kidney function was stable. She was allowed fluids equivalent to her urine output. She was given a calorie supplement to maintain her energy levels.
- 15.85 On 16 and 17 November 2005, blood and urine tests continued to ensure the correct amount of fluids were being administered. Case 5 was encouraged to drink and was given intravenous fluids.
- 15.86 On 18 November 2005, she was given a blood transfusion. She began complaining of headaches. A CT scan was carried out.

- 15.87 On 19 November 2005, there had been a distinct improvement in Case 5's condition. Folate was prescribed to build new red blood cells. On 20 November 2005, she began eating as well as drinking. On 21 November 2005, further blood tests showed that her kidney function was improving as expected. She was started on some iron syrup. She was discharged that day.
- 15.88 In relation to Case 5, the Inquiry also received evidence from Consultant Z about the initial communication of information about the Outbreak and the procedures in place for disseminating such information at Hospital 4. Consultant Z is a Consultant Anaesthetist and Medical Director of Hospital 4. The initial information was received on 19 September 2005, and there are no indications on the basis of the evidence examined by the Inquiry that there were any problems with its dissemination within the Hospital.
- 15.89 Consultant Z described the process:
- (i) The Hospital first knew about the Outbreak on 19 September 2005, when a Consultant Microbiologist within the Hospital received an e-mail from Dr Roland Salmon at the NPHS's Communicable Disease Surveillance Centre, requesting that they report any cases of bloody diarrhoea.
 - (ii) That e-mail was forwarded by the Microbiologist to the Paediatric Consultants and the Clinical Director for integrated medical specialties, including Accident & Emergency.
 - (iii) It was also sent to other microbiologists and the Infection Control Nurse for the Hospital.
 - (iv) Signs were put up in the Accident & Emergency Department by the Lead Consultant.
 - (v) Also on 19 September 2005, the Local Health Board sent the Chief Executive of the Hospital the information pack that was being distributed amongst GPs. That was forwarded to Consultant Z, who read the information on 21 September 2005. He distributed the pack to all consultants within the Hospital on the same date.

Case 6

- 15.91 Case 6 lives with his mother, his brother and his mother's partner in the Caerphilly area. At the time of the Outbreak, he was seven years old and attended a local primary school.
- 15.92 In relation to Case 6, the Inquiry received the following evidence:
- (i) The police statement given by Case 6's mother.
 - (ii) A statement from Dr V with various attachments including transcripts of telephone calls. Dr V is a GP at the Health Centre that dealt with Case 6 on 19 September 2005 and spoke to his mother's partner on that day.
 - (iii) The medical records of Case 6.

- 15.93 Case 6's mother was asked if she wanted to produce a further statement or give evidence in light of Dr V's written statement but declined. The Inquiry heard live evidence from Dr V.
- 15.94 At approximately 17:00 on 18 September 2005, Case 6 began to feel unwell. He complained of stomach cramps. Later that evening he started to experience diarrhoea. This continued throughout the night. At approximately 08:00 on 19 September 2005, he began vomiting. At 15:00 that afternoon, Case 6's mother saw the news on the television about the Outbreak in the South Wales Valleys, and decided to contact the family's GP practice. She did so and spoke to a receptionist.
- 15.95 Case 6's mother stated in her police statement that her recollection of the events that ensued was as follows:
- (i) She explained the symptoms to the receptionist. She asked for a doctor to make a house call. The receptionist said that a doctor would not be calling at the house.
 - (ii) At approximately 16:00, her partner received a phone call from the Health Centre stating that a prescription for "Disprol" was waiting at the Surgery for Case 6. The mother took the view that as Case 6 had not been examined, the Doctor could not prescribe medication and so she did not collect the prescription.
- 15.96 I conclude that that recollection of events involving Dr V and staff at his Surgery is incorrect. Having regard to the contemporaneous records, including in particular the transcripts of the telephone calls that took place, I therefore accept the accuracy of Dr V's evidence. Those documents, and the statement of Dr V which is consistent with them, show that what in fact occurred was as follows:
- (i) On 19 September 2005, Dr V was the "on-call" doctor for the Practice, which meant that he would deal with telephone calls and requests for home visits from patients.
 - (ii) At 16:15, a phone call was made to the practice by Case 6's mother. She explained the symptoms. She stated that she was not prepared to bring her son to the surgery or to move him given his condition. She said that she would like the Doctor to come and see him. The receptionist took the child's details and said that a doctor would call her back shortly. The receptionist did not tell the mother that a doctor would not attend at the home. Dr V explained to the Inquiry that the decision to make a house call or to provide advice over the telephone having spoken with the patient is one that the "on-call" doctor makes.
 - (iii) Following the phone call, the receptionist made an entry in the Health Centre's day book requesting that the Doctor telephone Case 6.

(iv) Dr V called the mother at 16:30. Prior to making the call, Dr V told the Inquiry that he would have called up and read the computerised medical records of the patient. In fact, Dr V spoke to the mother's partner. Dr V took a full history of the symptoms. Dr V explained that Case 6 had probably picked up a tummy bug or eaten something which had caused the diarrhoea and stomach cramps. Dr V explained that it was best to let the bug run its course. He told the mother's partner not to give the child anti-diarrhoeal medication that had been collected from the local pharmacy that morning. He recommended that Case 6 take some paracetamol or "Calpol". He asked whether someone could go to the Surgery to pick up a prescription. However, the partner explained that he was looking after the child and the mother had gone shopping. The partner said he would ring the mother and get her to pick up the prescription. There was further advice to keep Case 6 hydrated and not to give him much food. Dr V stated that if Case 6's condition deteriorated then he would be seen. There was no discussion within that conversation about a home visit.

(v) There was no mention of blood in Case 6's diarrhoea at any stage during either of the conversations.

15.97 Dr V explained to the Inquiry that complaints of a child suffering with diarrhoea are common in general practice. As a result of the information provided over the telephone, he felt it appropriate to prescribe paracetamol to relieve the pain and "Buscopan" which is an antispasmodic. Dr V told the Inquiry that at that stage there had been no mention by the partner of blood being present in Case 6's diarrhoea.

15.98 The prescription prepared after this call by Dr V was not in fact picked up for reasons that are not known to the Inquiry.

15.99 It appears from the mother's statement that during 19 September 2005, Case 6's condition deteriorated further.

15.100 In the early hours of 20 September 2005, his mother was sufficiently concerned to ring the Casualty Department at Hospital 1. She explained the symptoms and was told to bring Case 6 to hospital straight away. It is not clear whether by this stage Case 6 had blood in his diarrhoea. She and her partner took him to the Hospital and he was admitted to the Children's Ward.

15.101 Dr V was contacted by an EHO from Caerphilly County Borough Council on 20 September 2005 at 12:50. There is also a transcript of that conversation. The EHO was trying to obtain details of Case 6's GP. She informed Dr V that Case 6 had been admitted to the Children's ward at Hospital 1 and that traces of blood had appeared in his diarrhoea overnight, and that his was being treated as a presumptive case of *E.coli* O157.

15.102 Dr V then rang Hospital 1 to enquire about Case 6's condition. This conversation indicates that Case 6 only developed blood in the diarrhoea overnight or during the day of 20 September 2005.

- 15.103 At the time of his telephone call on 19 September 2005, Dr V was not aware that an Outbreak had been declared. Dr V told the Inquiry that had he been aware of the Outbreak he might have focussed his mind more on the fact that the child may have the infection. He pointed out that the child was not presenting with bloody stools at the time the mother's partner spoke with him. However, he agreed that had the information been to hand, he might have specifically told the parents to look out for the development of that particular symptom as time progressed.
- 15.104 Dr V said that he first became aware of the Outbreak on the Tuesday morning, 20 September 2005, when speaking to the EHO and when looking at documents that had been received by his practice from the NPHS. He explained that there was no dedicated "safe haven" fax in their surgery and that all faxes would be placed in the post tray which is seen by the "on-call" doctor on duty for the day in question. Dr V explained that the Duty "on-call" Doctor would look at the contents of the tray several times a day.
- 15.105 On the basis of all the evidence, I conclude that it is likely the fax was delivered to Dr V's Health Centre at 14:40 on 19 September 2005. What happened to that information within the Surgery is unclear. It did not, however, reach Dr V, raising questions about the adequacy of procedures for the swift dissemination of this sort of urgent information.
- 15.106 Case 6 was ultimately transferred from Hospital 1 suffering from renal failure. Initially he was taken to Hospital 3 and was further transferred to Hospital 2. He was taken to surgery for a haemodialysis catheter to be inserted. He underwent daily dialysis. He responded well to the treatment. His renal function improved. He did not require platelets or blood transfusions. Haemodialysis was stopped on 30 September 2005.
- 15.107 On 5 October 2005, he tested negative for *E.coli* O157 and was discharged.
- 15.108 He remained off school until December 2005. He required folic acid. He has required regular checks at the local hospital under the care of paediatric nephrologists.

Case 8

- 15.109 At the time of the Outbreak, Case 8 was two years old. She lived in the Rhondda Cynon Taf area with her parents and sisters.
- 15.110 In relation to Case 8, the Inquiry received the following evidence:
- (i) A statement from Case 8's mother setting out her recollection of what occurred, and a further statement providing further details in relation to some aspects of her first statement.
 - (ii) Witness statements from Mrs AC, the current Head of Clinical Governance at an Out-of-Hours Service provider, and Mr AD, an Operations Manager also employed by the Service.

- (iii) A statement from Dr AB, a GP who worked for the Out-of-Hours Centre that saw Case 8.
 - (iv) A statement from Consultant W, a Consultant Paediatrician, who oversaw the care of Case 8 when she was admitted to Hospital 1.
 - (v) A statement from Consultant Y, a Consultant Physician and the current Medical Director at Hospital 1.
 - (vi) A copy of medical records.
- 15.111 Live evidence was received from Mrs AC and Mr AD, from Dr AB and from Consultant W. Case 8's mother did not give live evidence.
- 15.112 The Inquiry also had the contemporaneous medical records made by Dr AB and the various healthcare professionals, including Consultant W, who were responsible for Case 8's care whilst in Hospital 1. However, she provided a further statement seeking to clarify her experiences whilst her daughter was an in-patient in that hospital.
- 15.113 At the end of September 2005, the family were on holiday in Minehead, Somerset. On 21 September 2005, Case 8 looked very pale and had flu-like symptoms. She was no better by the next day and on the 23 September 2005 Friday started to suffer from diarrhoea. The journey back to South Wales was uncomfortable. She was lethargic. She complained of pains in her stomach and she did not want anything to drink or eat.
- 15.114 On Saturday 24 September 2005, her mother noticed that there was blood in Case 8's stools. She phoned the local Out-of-Hours Service, and was told to take Case 8 to the local Centre.
- 15.115 She did so and Case 8 was seen by Dr AB at that Surgery at 09:45. Dr AB is an experienced GP having been qualified for over 15 years. The consultation lasted until 09:50. Dr AB made notes in manuscript of the consultation. His evidence, both in his statement and orally, was consistent with those notes.
- 15.116 Case 8's mother's recollection of events on 24 September 2005 was that Doctor AB at the Out-of-Hours Service had told her that an *E.coli* bug was "going around" but that he did not think her daughter had it and that the symptoms would pass. The mother's recollection was also that Doctor AB gave her "no further explanation".
- 15.117 I believe that Dr AB's account was correct and that what, in fact, occurred was as follows:
- (i) Case 8 presented at the consultation with no history of vomiting, no high temperature and no dehydration. Her pulse was normal. Her tongue was moist and there were no signs of pallor. Her abdomen was soft but not tender. She was said to be well in herself and was up and about, smiling and running around the corridor.

- (ii) She had had blood-stained diarrhoea. Dr AB's recollection was that there was a single episode complained of, although he told the Inquiry that the annotation "++" in his notes could signify that there were more frequent episodes.
- (iii) Dr AB was aware of the Outbreak at the time of the consultation and had received information from the NPHS through his own surgery as well as from the Out-of-Hours Service. He wrote in the notes that Case 8 was a "suspected case of *E.coli*".
- (iv) He provided a sample pot to Case 8's mother and told her to obtain a stool and take it to her GP.
- (v) He advised Case 8's mother about cross-contamination, and the need to take careful steps to prevent it.
- (vi) He took the view at that stage that Case 8 was not suitable for admission to hospital but that the position should be reviewed in the next 12-24 hours, if there was deterioration in her condition.
- (vii) His notes also record: "see if any concerns at [Hospital 1]". His recollection based on this note is that he had a long discussion with the Paediatric Senior House Officer at Hospital 1 about the necessity and appropriateness of admitting Case 8 given her symptoms.
- (viii) Dr AB agreed with Counsel to the Inquiry who referred to contemporaneous notes which stated that a detailed explanation was given to the mother about the risks of cross-contamination, cross-infection and about *E.coli* O157 being a possible cause for her symptoms.

15.118 During the day of 24 September 2005, and overnight, Case 8's condition deteriorated. Her mother spent the night with her because she was so concerned. Case 8 had more bloody diarrhoea episodes during the night. In the morning of 25 September 2005, the mother found her daughter collapsed on the bathroom floor. So the mother rang the Out-of-Hours Surgery again and told them that Case 8 had got much worse. She then took Case 8 back to the Surgery, arriving at 08:50.

15.119 Dr AB was working that morning also. The contemporaneous notes made by Dr AB indicate that the following occurred at this consultation which started at 08:57:

- (i) Dr AB was told that there had been further episodes of bloody diarrhoea and that Case 8 had been found collapsed on the bathroom floor that morning. He continued to treat it, accurately as it turned out, as a suspected case of *E.coli* O157.
- (ii) Dr AB's notes indicate that by this time Case 8 was pale and dehydrated and not well.
- (iii) Dr AB took immediate steps to admit her to hospital.

- 15.120 Case 8 was taken to Hospital 1 and admitted to the Children's Ward at 10:25 on 25 September 2005. Her care whilst there was dealt with by Consultant W in evidence, again on the basis of the contemporaneous notes made by him and others at Hospital 1.
- 15.121 From this time until 27 September 2005, when the father took over, Case 8's mother was in residence and looking after her.
- 15.122 A nurse took Case 8's initial details. The nurse noted the following:
- (i) Case 8 had had frequent bloody diarrhoea for two days.
 - (ii) She had also vomited five times since the night before.
 - (iii) She was alert and responsive but appeared listless and pale, with dry lips and sunken eyes. She had mild tenderness on the right side of her lower abdomen.
 - (iv) She was moderately dehydrated.
 - (v) Her temperature was a little low. Her blood pressure and breathing rate were a little raised.
- 15.123 Case 8 was seen by a doctor on admission to the Paediatric Unit. A treatment plan was drawn up which included giving intravenous fluids via a cannula, a blood test, a full blood count and a U&E blood test. Stool samples were also to be taken. Discussion with the middle grade doctor was included in the plan.
- 15.124 At 12:35 on 25 September 2005, the Microbiology Department isolated a toxin of probable *E.coli* O157. A definite diagnosis was not expected until 26 September 2005 when the culture became available. At 15:30 there was a discussion about the microbiology findings. A decision was taken that, as there were no definite findings, it would not be appropriate to disclose the "probable" findings until the culture results were returned the next day .
- 15.125 Blood tests were carried out on 25 September 2005. The results, recorded in the notes at 13:10 of that day, apart from indicating some infection, were normal. U&E tests were also carried out around the same time. In the context of *E.coli* O157, the potassium levels were of particular significance as an indicator of possible renal failure. These were also normal.
- 15.126 It appears from the notes that, although the findings were not discussed at this time, at about 15:30 there was a "long chat" with Case 8's mother about *E.coli* O157. The notes record in some detail the content of that conversation. It included an explanation that there is no treatment for *E.coli* O157, but that Case 8 would be monitored in the Hospital, kept on intravenous (IV) fluids and given daily blood tests. Case 8's mother was told that the Hospital did not as yet know for sure if Case 8 had *E.coli* O157 infection. In this conversation, the mother was also told that the blood results were normal. The mother was spoken to again about *E.coli* O157, and according to the notes was reassured, at 18:40.

15.127 On 26 September 2005:

- (i) A nursing entry was completed at 10:00. Case 8 had slept for most the night, had been passing urine and had not vomited again;
- (ii) There was a ward round at 11:00. Case 8 appeared pale, had dry lips but was “otherwise well hydrated”. The plan remained to encourage her to drink, to maintain her on IV fluids and to repeat the blood and U&E tests;
- (iii) The blood and U&E tests results came back at 14:00. They were normal;
- (iv) Another nursing evaluation took place at 18:30.

15.128 On 27 September 2005, the probable *E.coli* O157 diagnosis was confirmed by microbiologists. The notes record that the findings were explained to Case 8’s mother. The plan was to complete a full blood count test and the U&E tests and to continue with IV fluids.

15.129 The afternoon of the 27 September 2005 was a quiet one. Case 8’s father had taken over from her mother and was resident at this point. The child was passing urine, had slept for a long period and had taken a small amount of fluid when awake.

15.130 Blood and U&E tests were again made. The results were stable and normal.

15.131 At 09:20 on 28 September 2005, a ward round took place in the Paediatric Department. Case 8 was drinking some water and orange juice. The plan was to encourage oral fluids, continue with intravenous maintenance and to repeat U&E tests, the latter entry being reiterated by a nursing entry later in the morning.

15.132 At 13:30, Case 8 vomited twice and had mild abdominal pain.

15.133 A nursing evaluation that afternoon stated that all observations were stable. Her temperature was normal. She had passed a small amount of urine on two occasions. IV fluids had been discontinued. She had had no further abdominal cramps.

15.134 However, later that afternoon her temperature rose and she had high pulse and respiratory rates. She is recorded as having been pale and miserable. “Calpol” was given to reduce the temperature.

15.135 It is clear that the blood and U&E tests for this day did not occur until late in the evening. It is not clear why that was so. It is evident, however, that as suggested by Consultant W, “it was a plan that wasn’t fulfilled”.

- 15.136 Case 8's parents recollect becoming upset about the fact that the tests had not been done and themselves demanding that they be done. The notes do not indicate when that occurred for the first time or when this concern was passed on to the healthcare team responsible for Case 8's care. They do record that after the tests had been done, Case 8's father was upset "regarding the delay of medical care". This note follows the diagnosis of HUS and unsuccessful attempts to insert a drip. A second note immediately following the first records that the father became verbally abusive towards the nursing staff and doctors.
- 15.137 The results of the tests came in at 23:30. They brought bad news. The creatinine, the urea and the potassium were up, the creatinine markedly so, indicating that waste product was not being excreted by the kidneys. The platelet blood count was down dramatically. The diagnosis was HUS, with its associated risk of kidney failure. The decision was quickly taken that Case 8 should be urgently transferred to Hospital 2, which was better equipped to deal with serious cases of this kind.
- 15.138 Consultant W accepted that it was reasonable to state that things might have been caught earlier if the tests had been carried out sooner. The tests should have been done routinely on the morning of 28 September 2005 and I note that Consultant W accepted that it was a pity that they weren't done. He pointed out, however, that the results had been normal for four days beforehand and that action had been taken when the child became clinically worse, indicated by the rise in temperature. It is also to be noted that, in cases of HUS onset, the deterioration can occur very quickly. It therefore cannot be assumed that the tests would have given rise to serious concern if they had been taken routinely in the morning.
- 15.139 Case 8 was transferred from Hospital 1 to Hospital 2 on the morning of 29 September 2005. There are no parental criticisms of the care received by Case 8 at Hospital 2. At this time Case 8's mother began feeling ill and so the father looked after his daughter at Hospital 2.
- 15.140 Case 8 received nine days of peritoneal dialysis, and had one blood transfusion. She was discharged on 15 October 2005.
- 15.141 Aside from the blood tests issues dealt with above, two particular complaints were made in the first statement of Case 8's mother. I have considered both of them carefully but have come to the view that, on the basis of the evidence before me, it is not possible for me to reach any firm conclusions on the correctness or otherwise of these complaints.
- 15.142 The first complaint was that there had not been sufficient explanations to, or communication with, her or Case 8's father during their time at Hospital 1. I am unable, on the basis of the contemporaneous notes, to come to any firm conclusion as to precisely what degree of explanation and/or other communication was provided. However, the notes do at least appear to indicate that a series of explanations were given to Case 8's mother about *E.coli* O157 and about the tests that were undertaken. There also appears to have been a lengthy explanation given to Case 8's father on the night of 28 September 2005.

15.143 The second complaint, which is linked to the first, was that the levels of cleanliness on the Paediatric Ward at Hospital 1 were unsatisfactory and that Case 8's mother was not given sufficient assistance or explanation about caring for a child with suspected, and then confirmed, *E.coli* O157. As to that:

- (i) Consultant W stated in relation to allegations of poor cleanliness that the ward had never been criticised by the inspectors who checked that process;
- (ii) He also pointed to the "barrier nursing" records in the medical notes. He considered it highly likely that barrier nursing would have been explained to the parent staying in hospital with the child. There are also references in the medical notes to barrier nursing being enforced throughout the child's stay at Hospital 1. He explained that having the parents in residence at the Hospital with the child assisted because the nurses were less likely to spread the infection. He also pointed to standard leaflets that would be handed out to parents on the procedures involving diarrhoea and vomiting. Finally, he explained in his statement to the Inquiry that patients suspected of having *E.coli* O157 were kept in isolation.

15.144 One thing is clear. The effects of *E.coli* O157 are very serious. I have no reason to doubt the description of those effects in the statement of Case 8's mother. The effects she describes are consistent with the descriptions given by others (notably Lisa Bray). Case 8's mother described that the Outbreak was an awful time for her and her family. She and her husband felt totally helpless. Case 8's sister also contracted the infection and required inpatient treatment at Hospital 1. Case 8's mother also contracted the infection while Case 8 was in hospital. She was admitted to hospital as well for a number of days. There were terrible strains on the family in terms of child care. Case 8's father was clearly under considerable stress as a result of events. He was unable to attend work and went unpaid.

Cases 2 and 3

15.145 Two cases were considered by the Inquiry on the contemporaneous documents alone.

Case 2

15.146 Oral evidence was not necessary in Case 2 because the treatment and care afforded to the family appears to have been exemplary and no significant complaint is made about it.

15.147 Case 2, who was three years old at the time of the Outbreak, lives in the Merthyr Tydfil area with her parents and her older brother and sister. The children all attend a local primary school. Case 2's mother provided a statement to the Inquiry.

- 15.148 On 14 September 2005 Case 2's brother developed symptoms of bloody diarrhoea. He was complaining of stomach pains. He had no vomiting. On 15 September 2005, he attended at the local hospital where he was seen and discharged, with advice to keep him hydrated and for his parents to "keep an eye on him". The diarrhoea stopped on 16 September 2005. By 18 September 2005, he was said to be back to his normal self. He returned to school on 20 September 2005. Case 2's mother telephoned Merthyr Tydfil's Public Protection Department having heard about the Outbreak in the media. They provided the family with advice and stool sample pots.
- 15.149 On 1 October 2005, Case 2 woke with a nappy full of diarrhoea. She continued to suffer from diarrhoea on an intermittent basis that day and the next.
- 15.150 On the morning of 3 October 2005, Case 2's mother had to wake her as she was very drowsy. There was blood in the nappy as well as diarrhoea. Case 2 was taken straight to her GP. The GP is said by the mother of Case 2 to have acted promptly and admitted her to the local hospital, Hospital 1.
- 15.151 Case 2 was monitored on the children's ward for three days. She was tired and slept for much of that time. She was on an intravenous drip and was given medication for stomach cramps. When she was awake she remained lethargic. Blood tests were taken.
- 15.152 On 6 October 2005, Case 2 was diagnosed with HUS. She was transferred to a specialist children's hospital on 7 October 2005. She underwent surgery in order to insert tubes to allow dialysis to take place. She received blood transfusions and underwent dialysis for 12 days. On 18 October 2005, the tubes were withdrawn under anaesthetic.
- 15.153 She was discharged on 20 October 2005. Her recovery has been slow. Her mother says that she appears to be tired a lot of the time. She was anaemic and was given folic acid for a number of months. She eventually returned to school in January 2006.
- 15.154 Her mother says that her daughter has become a different child as a result of having contracted the infection. Her appetite has reduced. She is prone to pick up infections. She is clingier than she used to be and suffers pains in her side. On occasions she cries herself to sleep thinking about what happened to her. Her mother describes the experience, in terms I have no reason to doubt, as a "nightmare from start to finish".

Case 3

- 15.155 Case 3 lives with his parents in Rhondda Cynon Taf. At the time of the Outbreak he attended a local primary school and was nine years old.
- 15.156 The Inquiry had a statement by his mother and his medical records were obtained with the consent of his mother.

15.157 According to his mother's recollection:

- (i) On 13 September 2005 Case 3 complained of stomach cramps and diarrhoea, whilst on holiday in Spain.
- (ii) At 18:30 on 14 September 2005, the pain was such that he collapsed and was screaming on the floor. A doctor was called.
- (iii) He was prescribed re-hydration sachets and paracetamol.
- (iv) On 15 September 2005, he started to pass blood in his stools.
- (v) On 17 September 2005, he started to vomit regularly.

15.158 Case 3 returned to the UK on 18 September 2005. Case 3's mother's recollection is then that:

- (i) She telephoned the local Out-of-Hours Service that day for advice; and informed them of his vomiting and diarrhoea and the fact that there was blood present in the stools.
- (ii) She was advised that it was likely that Case 3 had picked up a bug in Spain and that if he was still feeling ill in seven days time to contact his GP.

15.159 Case 3's condition deteriorated. At 04:00 on 19 September 2005, he was taken to Hospital 1 by his parents. He was suffering from acute renal failure. He was diagnosed with HUS. He was airlifted to Hospital 6 on 19 September 2005.

15.160 On arrival at Hospital 6 he was started on fluids. On 20 September 2005, peritoneal dialysis commenced and continued until 25 September 2005. Case 3 also underwent a blood transfusion.

15.161 Case 3 was discharged and returned home on 30 September 2005. He returned to school on 1 November 2005.

15.162 Case 3's mother's principal complaint was that the advice she received from the Out-of-Hours Service was not appropriate, particularly as the Service had been made aware of the Outbreak at the stage she telephoned them.

15.163 The evidence of Dr Lowe and Mr AD, the Team Manager responsible for dissemination of the Outbreak information within Out-of-Hours Service, is that Out-of-Hours Services were provided with the necessary information during the weekend of 17 and 18 September 2005. Therefore, the letters to health professionals authored by Dr Lowe, dated 16 and 17 September 2005, would have been in the possession of the local Out-of-Hours Service at the time at which Case 3's mother telephoned. These letters highlight the need for health professionals to be alert to patients presenting with community-acquired bloody diarrhoea and to contact the NPHS with any such cases.

- 15.164 The Inquiry obtained the contemporaneous note recorded by the Out-of-Hours of service. The note recorded by the nurse working for Out-of-Hours Service read “p/h of strokes, diarrhoea and vomiting, no temp, no rash, no blood in stool, gen adv oral fluid any worries call us back, see own gp tomorrow sos”.
- 15.165 Accordingly, it appears that the issue of blood being present in the stool was discussed on the telephone with Case 3’s mother and that she told the nurse that it was not present in the stool. It appears that Case 3’s mother was told to call back if there were any problems and she indicated to the Out-of-Hours Service that Case 3 would be taken to his own GP the following day.
- 15.166 The nurse’s contemporaneous note in relation to the issue of blood being in the stool is further supported by the notes completed by health professionals when Case 3 was admitted to the local hospital and on being transferred to the tertiary hospital. They suggest that the history given by the parents was that there was no blood loss in the stools.
- 15.167 In these circumstances, there is no basis for the complaint that the telephone advice that Case 3’s mother received from the Out-of-Hours Service was inappropriate. The evidence indicates that her recollections that she told the health professional on the telephone about the presence of blood in her child’s stools was mistaken, given that the nurse’s contemporaneous note states “no blood in stool”.

- 16.1 The announcement of a review by the Chief Medical Officer for Wales was made on 4 October 2005. The Review's terms of reference were:
- "To review the arrangements in place for the protection of public health and food safety immediately before and during the Outbreak of *E.coli* infection in South Wales commencing September 2005 and to advise the Welsh Assembly Government immediately, as the review progresses, on any changes it recommends".
- 16.2 Dr Michael Simmons, who was Acting Deputy Chief Medical Officer at the time, was asked to chair the Review. The Project Manager was Mr David Worthington, the Assembly Government's Deputy Chief Environmental Health Adviser. A Review Team was formed. The aim was to complete the review by Christmas 2005, providing the Minister with recommendations for any urgent action that should be taken while a Public Inquiry was being established.
- 16.3 The Review's report was published on 6 January 2006, after which arrangements were made to take forward its recommendations.

The Review

- 16.4 The Review Team met for the first time on 17 October 2005 and on two subsequent occasions, the last meeting being on 30 November 2005. It was anticipated that the police investigation could have the greatest potential impact on the Review. This subsequently proved to be the case.
- 16.5 The Review sought to answer three particular questions:
- (i) Was the legislation sufficient (if implemented correctly) to prevent a further outbreak?
 - (ii) If it was sufficient, did the Outbreak occur as a result of a failure to implement the legislation or follow the guidelines?
 - (iii) Was everything done to minimise the effect of the Outbreak?
- 16.6 Background information was obtained from the Chartered Institute of Environmental Health and Cardiff City Council. Discussion with the latter covered enforcement and procedures on food hygiene. A meeting was also held with the Welsh Local Government Association to discuss procurement procedures and practice.
- 16.7 Information was requested from organisations involved in the Outbreak, namely the local authorities, the National Public Health Service for Wales ("NPHS"), and the Food Standards Agency ("FSA"). They were asked to provide a chronological log of action taken.

- 16.8 The Review had no powers to compel third parties to attend, to give, or to produce evidence. Parties involved in the Outbreak had signed confidentiality agreements with South Wales Police to avoid potentially prejudicing proceedings brought against William Tudor. The Review therefore relied entirely on voluntary co-operation. That co-operation was forthcoming insofar as organisations involved in the Outbreak provided background information and timelines of action taken to control it. However, a series of structured interviews to gather more information had to be cancelled and the Outbreak Control Team (“OCT”) felt unable to provide the Review Team with a copy of its report.
- 16.9 The Minister for Health and Social Services was informed of the difficulties. Dr Simmons said that despite the difficulties, they had sufficient information for the report.

Concerns raised by the Review Team

- 16.10 The Review Team noted the introduction of new EU legislation, which would replace the Butchers’ Licensing Scheme. Dr Simmons raised it with the Chief Medical Officer as a matter of immediate concern. The Minister was advised to seek assurance from the FSA and did so. The FSA responded, saying:
- (i) Butchers’ licensing had been recommended as a temporary measure until EU legislation required all business to operate HACCP, and had served its purpose.
 - (ii) The hygiene requirements of the new EU rules were substantially equivalent to Butchers’ Shops Licensing. Public health will remain protected provided the new requirements are properly applied and enforced.
 - (iii) The Agency did not believe the *E.coli* O157 Outbreak gave cause for a change of decision on Butchers’ Shops Licensing.
 - (iv) John Tudor & Son was licensed at time of Outbreak which suggests that licensing in itself is not the complete answer.
 - (v) The 30% compliance figure referred to all food businesses, which is similar to rest of UK. Within that, 100% of butchers handling raw/cooked meat were expected to operate HACCP.
- 16.11 The Review Team also wrote to Local Health Boards after a request from the Health Minister. The Boards were asked to review issues such as capacity, communications, out-of-hours arrangements and public health support. They were slow in responding. A report summarising the feedback included the following recommendations:
- (i) A review to examine in depth the experiences of the Outbreak Control Team generally and Caerphilly and Rhondda Cynon Taff Boards in particular to see what lessons can be learned.
 - (ii) Current outbreak plans should be reviewed to ascertain if they have been produced using a realistic assessment of the potential impact on service provision of a major outbreak.

- (iii) Outbreak control arrangements in South East Wales should be reviewed to ensure that those for Blaenau Gwent, Monmouth and Torfaen satisfy Welsh Assembly Government guidelines.
- (iv) Additional analysis by someone with GP experience.

Publication of the Report

- 16.12 The report was published on 6 January 2006. It made 22 recommendations, which were targeted at specific organisations. By its own admission, several of the Review Team's recommendations were based on anecdotal evidence. Dr Simmons stated that the report was based on professional evaluation of available information and that which was in the public domain. He stated that because of the inability to interview people involved, the recommendations were drafted in such a way to incorporate the need to reassure or clarify areas that they had been unable to determine. However, he believed that the primary aim was met; that is, advising whether the extant legislative base and guidance would, if properly implemented, be sufficient to safeguard public health.

Response to the Report

- 16.13 Comments on the Review's findings and its recommendations were invited. Several organisations responded.
- 16.14 The FSA provided a detailed response to each of the recommendations directed at it. It noted that the Review Team had been unable to engage with the Agency because of confidentiality issues. It said it wasn't clear why certain subjects couldn't have been discussed when the report was being prepared and said it was disappointing the Review Team had to rely on anecdotal evidence when the Agency might have been able to make a useful contribution.
- 16.15 The Chartered Institute of Environmental Health recognised the constraints on the Review but expressed concerns about the report. It was critical of the lack of consultation on the recommendations. It did not accept that all were necessary or, in some cases, appropriate.
- 16.16 Bridgend County Council criticised the assumption that the OCT relied on press releases as the major means of disseminating information. It also warned that any wording that suggested that the Emergency Prohibition Notices were served because John Tudor & Son was the source of the Outbreak could be detrimental to the investigation and any legal proceedings that may result.
- 16.17 The Outbreak Control Team appreciated that information for the Review had been constrained. However, it had major concerns about the format and relevance of many of the recommendations and the understanding behind them. It also thought it important to consider the appropriateness of the recommendations in the light of further information that might emerge. Dr Simmons said that he hoped to review all recommendations in light of responses received.

- 16.18 Caerphilly County Borough Council queried whether all recommendations were valid. It made detailed comments on recommendations, some of which were critical. The lack of consultation was a common theme. It said that some of the issues covered were not legally sensitive and would have benefited from direct contact with the relevant authorities.
- 16.19 Rhondda Cynon Taf County Borough Council said it did not believe the Review intended to imply any criticism of how the Outbreak was controlled. There was disappointment that the report was published without being subject to any consultation or challenge. It was felt it would have been possible to have explored many of the subjects around which recommendations were based as they were generic and would not have prejudiced the police investigation.

Implementing the Review

- 16.20 A Steering Group was established to take forward the Review's recommendations. Dr Simmons was asked to chair it. The Group comprised core members of the Review Team and representatives of the NPHS, FSA, Chartered Institute of Environmental Health, Directors of Public Protection Wales and the Welsh Local Government Association.
- 16.21 The Group's first meeting was on 11 May 2006. All recommendations were discussed. The remainder of this Chapter examines the recommendations and action taken.

Food Standards Agency

- 16.22 Eight recommendations were targeted at the FSA. Two related to the introduction of the new EU Regulations, which ended the Butchers' Licensing Scheme. The response to these is reflected in information set out in paragraph 16.10. Another related to the application of food hygiene legislation in the specific case of John Tudor & Son. The FSA had prepared an initial report during the Outbreak and would produce a report later, taking into account the police investigation that was ongoing at the time.
- 16.23 The Review sought assurance that guidance for butchers reflected the importance of a fully implemented HACCP system as an integral part of good food safety management, not as an end in itself. The Group agreed that the FSA would continue to work with local authorities. It heard about the joint FSA/local authority Food Safety Management (HACCP) Strategy Group and training being provided to all local authorities in Wales. Mrs Joy Whinney, Director FSA Wales, highlighted the issue of funding and the lack of it for the FSA in Wales to carry out such work. The FSA's funding issue was dealt with in Chapter 8.

- 16.24 On other recommendations, the FSA said it would continue to reinforce food safety to businesses handling raw and cooked meats. It would continue to work with local authorities on issues such as the frequency of performance indicators and the frequency of inspections. The frequency of inspections was discussed at length. Mrs Whinney reported that the revised Code of Practice that was due to be published did not contain any changes to inspection frequencies but that the FSA had announced its intention to produce an interventions strategy, which would include interventions other than inspection. The revised Code of Practice was published in England on 17 June 2008 and in Wales on 18 September 2008. The FSA said it would review its audit scheme which, as described in Chapter 8, it has done.
- 16.25 The Review asked for clarification of the FSA's own role in outbreak control, which had been raised during the Outbreak. The FSA said it would also review its guidance on the management of outbreaks, which was a Department of Health document that had been produced in 1994, long before the Agency had been set up. The revised guidance was published on 11 February 2008. The FSA also undertook its own internal review of the Outbreak and a series of recommendations were made, including some that addressed the interaction between FSA Wales and FSA Head Office during the Outbreak.

Local Authorities

- 16.26 Two recommendations for local authorities overlapped with recommendations targeted at the FSA. One stated that local authorities should work closely with the FSA in the introduction of the new EU Regulations as they relate to butchers' premises. In particular, they should assess the need to ensure their attendance at training sessions and contribute appropriately to the development of enforcement guidelines. The recommendation was signed off.
- 16.27 Local authorities were also asked to have proper regard to the standards and procedures of "Value Wales" when securing food contracts. This was examined in Chapter 10. They were also asked to review hygiene in schools, including access to toilet paper, soap and hot water. The action taken by the four authorities affected by the Outbreak is described in Chapter 13.
- 16.28 The other recommendations required local authorities to consider their resources to manage outbreaks and to keep outbreak plans up-to-date. The FSA said that out-of-hours contingencies would be included in its focused audits and all local authorities had been asked to consider the action. The FSA undertook a review of local outbreak plans.

Other Organisations

- 16.29 The NPHS and members of the OCT were asked to review action taken during the Outbreak and hygiene in schools, local outbreak control plans, and advice for public. The Group agreed that it would await publication of the OCT's report but as the report had not been published by the time of the Review Team's third meeting in January 2007, it was agreed that it would be looked at after publication. The OCT's report was eventually published on 11 September 2007 after criminal proceedings against William Tudor had ended. The NPHS undertook its own internal review and made available to the Inquiry the relevant papers. Evidence received by the Inquiry indicates that training events were held in July and September 2007 to address communications issues that were raised.

Welsh Assembly Government

- 16.30 There were three recommendations for the Welsh Assembly Government, the first of which related to the establishment of the Steering Group itself. Action was taken to encourage all organisations actively involved in outbreak control to participate in the sponsored Lead Officer for Communicable Disease training scheme. It is noted that six training events took place between September 2006 and December 2007.
- 16.31 The Review's final recommendations related to the difficulties of trying to run an Assembly Government review or investigation alongside a police investigation.
- 16.32 Dr Simmons said in his evidence that by the end of the Steering Group's third meeting he was satisfied that all recommendations had been addressed or any remaining actions were clearly identified to a lead organisation.

Conclusions

- 16.33 The Minister for Health and Social Services was right to order an early review in the circumstances around the Outbreak. In this case, no immediate gaps or weaknesses were identified. However, every outbreak has its own set of circumstances and features and therefore prompt action to review the situation is important in case there is need for specific and urgent action.
- 16.34 I recognise the difficulties encountered by the Review Team and the constraints placed on it by the police investigation. The police investigation and criminal proceedings also had an impact on the Inquiry's progress. Ultimately, the Review's planned information gathering exercise was cancelled. The Review Team appeared to rely on anecdotal information on some issues. As described earlier in this Chapter, the Review was criticised by some organisations that were directly involved in the Outbreak.

- 16.35 Perhaps more could have been done to clarify precisely what could and what couldn't be discussed with the organisations that formed the Outbreak Control Team. I recognise that sorting that out would not have been easy given that sensitivities were clearly heightened because of the police investigation. However, it seems to me that public organisations should be able, on a case by case basis, to find a way of sharing important information in a way that doesn't risk prejudicing any criminal investigations or proceedings, with whatever arrangements are required to ensure confidentiality.
- 16.36 I note that after the Outbreak Control Team published its report in September 2007, the Welsh Assembly Government established a Task & Finish Group to consider the report and to explore further work that could be undertaken. The Group's work is reflected in developments set out in Chapter 11, which examined the way in which the Outbreak was handled.

- 17.1 The previous Chapters have set out in detail the key facts relating to the Outbreak, the circumstances around it, and issues I considered necessary for a thorough investigation. In this Chapter, I summarise my overall conclusions and thoughts before setting out my recommendations in Chapter 18.

The Outbreak

- 17.2 The Outbreak was caused by food that had been contaminated with *E.coli* O157. This happened because of food hygiene failures at the premises of John Tudor and Son, Bridgend ("Tudors"). Genetic fingerprinting was undertaken on *E.coli* O157 bacteria isolated from cooked meat recovered from schools, from raw meat recovered from the premises, and from faecal samples from people who were infected. This, together with information on the foods people ate and when they were eaten, and information from inspection records and reports about Tudors, gives overwhelmingly strong evidence to support this conclusion.
- 17.3 A fundamental principle underlying the prevention of food poisoning by *E.coli* O157 is the establishment and implementation of defences in depth. The essential issue is how to stop the bacteria from cattle and sheep getting onto food and surviving in infectious form. Preventive action is required at slaughterhouses, at premises that prepare food – including butchers – and by those who buy the food.
- 17.4 Preventive measures at slaughterhouses and butchers are underpinned by legislation, delivered by proprietors, and enforced by inspectorates. The regulatory systems in operation at the time of the Outbreak had been reformed throughout the UK with the aim of improvement in the years immediately before it happened.
- 17.5 The Food Safety Act dates from 1990. The Meat Hygiene Service started work on 1 April 1995. The Food Standards Agency was established in 2000, the year in which Butchers' Licensing had been introduced as a consequence of the 1996 *E.coli* O157 outbreak in Scotland. In my opinion, the consensus view in 2005 was that all these changes were leading to improvements in food safety. They had been in place long enough before the Outbreak for them to have bedded down and become effective. So the defences that were in place in 2005 were modern. One of them had even been specifically introduced to prevent *E.coli* O157 infections. All this makes the failures that led to the Outbreak particularly shocking.
- 17.6 Effective defences in depth are essential if the foodborne spread of *E.coli* O157 is to be prevented. Ingesting a very small number of organisms can initiate a fatal infection. The presence of millions of *E.coli* O157 on a piece of meat can escape detection by visual inspection. The nature of work in slaughterhouses means that the delivery of meat uncontaminated by *E.coli* O157 cannot be guaranteed. The risk of contamination can be reduced by sound practice. Nevertheless, all raw meat must be regarded as potentially contaminated.

- 17.7 The risks from *E.coli* O157 mean that butchers who prepare ready-to-eat foods must prevent cross-contamination from occurring in their premises. In this sense they are high-risk businesses. It explains why they must receive special attention from Environmental Health Officers (“EHOs”).

The Inspections of John Tudor & Son by Officers from Bridgend County Borough Council

- 17.8 The practices at John Tudor and Son at the time of the Outbreak were such that Professor Griffith’s conclusion was that cross-contamination would “almost certainly occur”. He said that the cleaning documentation was “completely inadequate”. It was “a joke”. Mr Curtis said that using a single vac packer for raw and cooked meat was “a bit like playing Russian roulette.”
- 17.9 Psychologists have shown experimentally that hindsight biases judgement [17]. Knowledge of an outcome can increase the perceived relevance of events in a judge’s mind without him or her being aware of it. But I do not consider that hindsight biased the opinion of the Inquiry’s expert witnesses, Professor Griffith, Mr Curtis or Mr Houston.
- 17.10 Their opinions were based on evidence about the practices at Tudors at the time leading up to the Outbreak. There is no evidence that there was a sudden decline in food safety practice just before the Outbreak. Deficiencies had been there for a long time before. I note the additional contract taken on in summer 2005 to supply schools in the Caerphilly area but the nature of the business, its staffing and its premises had not changed significantly since the introduction of Butchers’ Licensing in 2000. Vac packing started in 1994 with a single machine. When it broke down at the end of 2001, it was replaced with the one in use at the time of the Outbreak. The single vac packer had always been situated in the raw meat section and probably had been used there for cooked meats since 1997. Walk-in freezer problems were recorded in 1998 and in subsequent years. They were still there in 2005.
- 17.11 The long-standing issues of the use of a single vac packer for raw and cooked meat and the failure of William Tudor to give some of his staff the food hygiene training they needed did not result in action by Bridgend’s EHOs until Mrs Coles’ inspection in January 2005. Before the Outbreak, EHOs did not detect the “completely inadequate” cleaning regime. Nearly all failed to notice that William Tudor’s HACCP plan was not valid. The plan states that things were being done that were physically impossible. It was also incomplete. It did not cover, for example, a vital hazard, namely the processing of cooked meats.
- 17.12 The events that preceded the Outbreak constituted an “incubation network”[18]. This is not incubation in the sense of the time a disease takes to make someone ill, but is a description of chain of events that are discrepant but not perceived, or are misperceived. The significance of this incubation period in Tudors is that it was long.
- 17.13 William Tudor was dishonest. He misled EHOs about the training of his staff and about the vac packer. In February 2005, just in time for a repeat inspection, he filled in the forms about cooking and cooling times and the temperature of the freezer and the chillers

covering the previous six months work. His 2005 HACCP plan said that he was a member of the National Association of Catering Butchers when he was not.

- 17.14 Questions about William Tudor's honesty had been raised in April 2001 when Mrs Joanne Evans noted after an inspection "couldn't help wondering whether some records were fixed as same style writing and colour pen on many of the records". In February 2002, Mr David Dier wrote to Bridgend's Environmental Health Department raising concerns about William Tudor being willing to tell untruths to EHOs. It is a great pity that these opinions were not logged and transmitted to the other EHOs who inspected Tudors.
- 17.15 EHOs' reliance on William Tudor's word was misplaced. Detecting deliberate deceit is much harder than inspecting walls and ceilings. I recognise the difficulty. But EHOs have to be alert to the possibility. If Tudors' inspection records had been reviewed properly prior to inspections and if issues or concerns had been logged for that purpose, the suspicions of any experienced EHO would have been aroused. A check of Tudors' 2005 HACCP plan, which claimed membership of the National Association of Catering Butchers, would have aroused suspicions further.
- 17.16 Deceit is relatively uncommon but has been identified as one of the factors behind previous outbreaks. It was a very important causal factor in the enormous Walkerton *E.coli* O157 outbreak in Canada in 2000 (paragraph 4.7 refers). The operators of the town water system made false entries in the records, failed to measure residual chlorine in the water, misled health staff about what they had done and submitted false annual reports. Similarly, the butcher at the centre of the 1996 Central Scotland *E.coli* O157 outbreak concealed the full extent of his business from EHOs. The fact that there was dishonesty in these two very well-publicised *E.coli* O157 outbreaks does not appear to have registered in the minds of the EHOs who inspected Tudors.

The Procurement of School Meals

- 17.17 The very real threat posed by *E.coli* O157 means that those who buy food from such businesses on behalf of individuals who are particularly susceptible to the serious complications that follow *E.coli* O157 infection – the young and the old – must ensure that their suppliers are delivering safe food.
- 17.18 The process by which the contracts were awarded in 1998 and 2002 was seriously flawed in relation to food safety. The arrangements for the joint contract were inadequate with a particular lack of clear roles and responsibilities between the organisations and key individuals. Better arrangements might have thrown more light on the weaknesses in John Tudor & Son's approach to hygiene and more questions about his practices. If anything was likely to have encouraged William Tudor to get his act together on food hygiene, it would have been the direct threat of failing to secure, or losing, what was a very significant contract.

J.E. Tudor and Sons Ltd Abattoir and the Meat Hygiene Service

- 17.19 I have concluded that, on the balance of probability, the *E.coli* O157 that caused the Outbreak entered William Tudor's premises on meat that had come from the J.E. Tudor and Sons Ltd Abattoir in Treorchy.
- 17.20 The likelihood of meat becoming contaminated with *E.coli* O157 at the slaughterhouse would have been significantly reduced if the Meat Hygiene Regulations in force in 2005 had been followed and enforced. There were big shortcomings in relation to both. The report of the BSE Inquiry[19] gives a concise history of the establishment of the Meat Hygiene Service. It says:
- "In an era of deregulation, a convincing case had to be made out for the introduction of the centralised MHS. Standards of hygiene in British slaughterhouses provided that case".
- 17.21 Mr John Gummer, Secretary of State for Agriculture, in making this case, gave this vignette to the House of Commons Agriculture Committee in October 1992:
- "Slaughter hall heavily soiled with blood, gut contents and other debris – no attempt to clean up between carcasses. Car cleaning brush heavily contaminated with blood and fat being used to wash carcasses. Knives and utensils not being sterilised. Offal rack and carcass rails encrusted with dirt. Missing window panes in roof – birds, flies and vermin entering".
- 17.22 The December 1992 inspection of the slaughterhouse in Treorchy revealed a similar set of totally unacceptable hygiene failures.
- 17.23 The Inquiry was provided with a copy of a letter sent by Rhondda Borough Council Environmental Health Office to J.E. Tudor & Sons Ltd after the December 1992 inspection. It informed the business that a slaughterhouse licence would be refused. But a temporary one was issued in January 1993. An inspection in August 1994 resulted in a hygiene assessment score of 11 out of 100, the lowest and worst hygiene score ever recorded in Britain. Mr David Thomas recommended that the Secretary of State should be asked to revoke the licence. But it was not revoked. I have been unable to determine precisely why it was not.
- 17.24 The Meat Hygiene Service ("MHS") began operating in 1995. But it did not rectify the problems at Treorchy. Hygiene assessment scores rose. I conclude, however, that this had more to do with the way the scores were arrived at than being the result of real hygiene improvements. The scores were over-optimistic. There was a reluctance to give scores that could result in closure. There was a regulatory "light touch". This also applied to the introduction of HACCP, which should have been operational from 7th June 2003. But the Abattoir never developed, far less implemented, an effective plan. Mr Thomas inspected the premises in April 2005. He concluded that some of the problems he found were remarkably similar to those detected in 1994.

- 17.25 The hygiene problems at the Abattoir had not been missed. The signals that the premises and the practices in it were unsafe were strong. They passed up lines of management in the MHS. But it was allowed to continue in business in the way it always had, without significant improvement. I conclude that although the safety rules were being broken, those who had the power to act must have accepted that the breaches could be lived with. There was, in effect, a “normalization of deviance”.
- 17.26 The normalization of deviance is how, in her influential analyses of the Space Shuttle disasters[20], Diane Vaughan describes the acceptance by NASA as tolerable risks, the long-standing and frequent solid rocket booster O-ring erosion events that led to the destruction of Challenger (an acceptance described by Richard Feynman as “playing Russian roulette”) and the foam debris strikes that led to the destruction of Columbia. The statement by a senior executive at the discussion about whether it was safe to fly just before the fatal launch of Challenger that the managers should “Take off your engineering hat and put on your management hat” has, as its MHS equivalent, Mr Hewson’s point in his oral evidence that the enforcement of HACCP in 2003 would have shut down the meat processing industry: “It depends on whether you want an industry or not. We could have just implemented it to the letter of the law, as you suggest, and import our meat”.
- 17.27 But HACCP in slaughterhouses was far from new in 2003. It had become mandatory for slaughterhouses in Australia in 1996. My 1997 report on the Central Scotland *E.coli* O157 outbreak recommended that HACCP should be enshrined in the legislation governing slaughterhouses and that until this could be achieved, enforcers and the industry should ensure that HACCP principles were observed. In the USA, its implementation was required in large plants in 1998, in small plants in 1999, and in very small plants in 2000. The most important factor leading to its introduction into US slaughterhouses was the Jack-in-the-Box *E.coli* O157 outbreak (paragraph 4.5 refers).
- 17.28 *E.coli* O157 is the most important human pathogen that can contaminate red meat in UK slaughterhouses. There is a consensus view that HACCP is a more effective way of preventing this contamination than the traditional prescriptive measures. Constructing a HACCP plan is a big challenge for the operator of a small business. But I consider that with appropriate advice and help, which is available in abundance, its formation is far from rocket science. The “light touch” policy around this process has a long history in relation to the introduction of HACCP in the UK, as described in paragraph 4.9 of my 1997 report. I consider that the “light touch” policy in the case of the Treorchy Abattoir was wrong.

The Past Revisited

17.29 In 1998, the House of Commons Agriculture Committee inquired into food safety. I gave evidence about my 1997 report[21]. The early dialogue was as follows:

(Chairman) “We have had evidence from the Royal College of Veterinary Surgeons and they said that your inquiry had not actually addressed our knowledge in any way over what we already knew and that was that they knew were the critical control points for meat hygiene were. Do you think that is fair observation?

(Professor Pennington) In broad principle I would agree with that. The overwhelming majority of our recommendations were recommendations which had been made by others before us. Basically we are saying, get on with it now rather than have delays here or leave this until later and so on. We were basing our recommendations on sound principles which had already been enunciated by other people, yes.

(Chairman) And ignored.

(Professor Pennington) And to a degree ignored or were being implemented more slowly than we thought it wise.

(Chairman) It was a great shame that it was necessary to have this outbreak and your report at all.

(Professor Pennington) Indeed, yes”.

17.30 I had hoped that the lessons from the shocking events in 1996 would stay in people’s minds. But comparison of the failures that led to the this Outbreak in South Wales with the conclusions of the Sheriff in his determination of the Fatal Accident Inquiry that investigated the Central Scotland outbreak shows that this has not been the case.

17.31 The Sheriff said that contributory defects were among others: “The failure to devise or enforce..... cleaning schedules and equipment..... which would have reduced the risk of surfaces being contaminated and to ensure that all staff were given adequate hygiene training, the failure to separate completely within the premises the processes relating to (a) raw meat and (b) cooked meat and in particular to have provided separate..... scales and a vacuum packer for each of these separate processes, and the failure on the part of the EHOs prior to the outbreak to identify the food safety hazards inherent in the practices carried out within (the) premises and in particular in relation to the failures identified..... above”.

17.32 Nearly ten years later and in relation to a separate outbreak, the above description is, disappointingly, highly relevant.

- 17.33 Large, intensively investigated, and well-publicised outbreaks like that in Central Scotland are pedagogically powerful. But their rarity, unique features, and the passage of time reduces this power. It is the job of the policy makers and educators to draw and promulgate the lessons from them. That job hasn't been done as well as it should have been done, particularly regarding issues around cross-contamination. Its catastrophic consequences and the virulence of *E.coli* O157 were the two main lessons of the Central Scotland outbreak. But the first of these was an old lesson. Cross-contamination, for example, caused more than half of the 507 cases in the 1964 Aberdeen typhoid outbreak, and without it the 1989 Clwyd/Cheshire *Salmonella typhimurium* outbreak (640 cases with three deaths) would not have happened.
- 17.34 One of the recommendations of the Report of the Departmental Committee of Enquiry into the Aberdeen Typhoid outbreak[22] was that "Only detergents and sterilisers whose bactericidal properties have been proved should be used in food premises: the responsibility for approving such materials should rest with the central health departments". The second part of this recommendation has never been implemented.
- 17.35 A misplaced reliance on cleaning with chemicals to sanitise surfaces in contact with raw and cooked meats was a very important issue in the Central Scotland outbreak. Aside from additional failures in the actual cleaning procedures, it was in William Tudor's premises as well. I do not consider that this recurrent problem has yet been satisfactorily resolved, particularly in the light of the virulence of *E.coli* O157, its low infectious dose, and its ability to survive in biofilms on metal surfaces.
- 17.36 Fading memories of 1996 is not the only reason that the lessons from it have not remained strong. An actual experience of an event is the best away of learning from it, but most Environmental Health Departments and EHOs have not met *E.coli* O157. For them, history has not been generous with experience, a paucity that conspires against effective learning[23]. It could be said that the introduction of butchers' licensing and a subsequent reduction in the number of *E.coli* O157 outbreaks linked to butchers may have lessened the attention paid to it as foodborne pathogen. The 2001 Task Force on *E.coli* O157, which was sponsored by the Food Standards Agency (Scotland) and the Scottish Executive Health Department, said in its opening chapter (paragraph 1.6) "Past reported outbreaks of *E.coli* O157 infection were associated mainly with food sources. The food chain remained at risk from the organism, but much had been done post-Pennington Report to improve knowledge, training practices and controls. Hence the Task Force was formed in response to evidence that showed that the majority of sporadic cases were associated with contact with animals or from the environment". The ending of Butcher's Licensing may have also contributed to an impression that big *E.coli* O157 problems were a thing of the past.

- 17.37 It is paradoxical that the specific attention paid to *E.coli* O157 in slaughterhouses is dwarfed by that paid to BSE, when the human health impact is within the same order of magnitude (164 vCJD deaths since 1995) and that the only specific guidance from the FSA regarding the use of vac packers relates to the prevention of botulism (68 food-borne cases with 20 deaths in the UK since 1922, none from food vac packed in the UK). It is right that the specific controls for BSE and botulism receive special attention. They have worked and continue to work so well that the risk to human health from them in the UK is negligible. That is not the case for *E.coli* O157, for which there are no specific controls. HACCP should therefore receive the same attention as that given to the controls for other pathogens.
- 17.38 A central recommendation of my 1997 Report was the implementation of HACCP in food businesses and slaughterhouses. I have concluded that the lack of progress in this regard in John Tudor & Son and in J.E. Tudor & Sons Ltd were particularly relevant to the circumstances that led to the Outbreak.

Hazard Analysis Critical Control Point (HACCP)

- 17.39 HACCP has essential prerequisites. Both Tudor businesses failed regarding them as well. The slaughterhouse building was not fit for purpose. William Tudor's cleaning plan was "a joke". The use of biocides falls into the prerequisite category. Their effective application is not a control measure applied at a critical control point "that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level" (Codex Alimentarius)[24], because for *E.coli* O157, their routine use cannot be relied on to deliver this; there is no "acceptable level" for *E.coli* O157 in ready-to-eat foods. In the case of Tudors, a reliance on biocides to reduce the risk from cross-contamination could, and should, have been made unnecessary by the use of separate equipment for raw and cooked meats. My conclusion applies with particular force to complex equipment such as vac packers but in the case of the descriptions of cleaning practices in Tudors, this could also apply to equipment such as the weighing scales.
- 17.40 The principles that underpin HACCP have been in effective use for three-quarters of a century; milk pasteurisation as introduced in the 1930s follows the seven Codex Alimentarius principles exactly[25]. Direct measures of its success are not available because it is not possible to identify and enumerate the cases of milk-borne infection that have not occurred because of its application. Nevertheless, it is beyond reasonable doubt that the number is enormous. Pasteurisation failures or post-pasteurisation contaminations are rare. They have been responsible, however, for the North Cumbria (1999; 117 cases) and West Lothian (1994; more than 100 cases) outbreaks, which are respectively the third and fourth largest *E.coli* O157 outbreaks in Britain. Both outbreaks centred on small dairies whose products were consumed locally. William Tudor's business was also small. Barr's butchery department in Wishaw in 1996 was not much bigger. It is small food producers/processors in Britain that have the greatest difficulty in achieving and maintaining the safety standards that are required to prevent the contamination of ready-to-eat products with *E.coli* O157. There should be no relaxation of regulation for them. The opposite should be the case.

Controlling the Outbreak

- 17.41 Population-based surveillance for *E.coli* O157 started in Wales in February 1990, since when all first-time acute-phase faecal specimens sent to laboratories have been tested for the organism. Wales was the first country in the world to do this. Introduced by Dr Salmon, the system exemplifies the excellent public health work done on the organism in Wales, which was reflected in the timeous and effective work of the Outbreak Control Team led by Dr Lowe.
- 17.42 Had it not been for prompt action by the Outbreak Control Team, the Outbreak would have been even bigger. The recovery from schools of meat samples that were contaminated with *E.coli* O157 prevented more children, and possibly adults, from becoming ill.

Schools and Hygiene

- 17.43 Well before the Outbreak, the Children's Commissioner for Wales highlighted a problem with toilet facilities and recommended that the Welsh Assembly Government should assist schools and governing bodies to undertake audits. Few of the schools and governing bodies appear to have been aware of the Commissioner's report, which was unfortunate to say the least. The Assembly Government was aware of the report but did not bring it to the attention of local authorities. As a result, and notwithstanding ongoing programmes of school improvements, the sort of action envisaged by the Children's Commissioner was triggered by the Outbreak itself. Fortunately in this case, the problems with hand washing facilities do not appear to have caused, or contributed to, the spread of infection.

Treatment and Care

- 17.44 In-patient hospital care was as effective as it could be in the face of an infection that produces severe complications for which there are no specific preventive measures. The specialist nature of the treatments needed to manage these complications meant that some patients were cared for in hospitals outside Wales. This was inevitable, and appropriate, considering the rarity of such cases.
- 17.45 Some communications difficulties were experienced in the very early stages of the Outbreak in contacting health service personnel out-of-hours. These did not have any adverse effects as far as outbreak control is concerned.

E.coli O157

- 17.46 *E.coli* O157 occurs silently in a significant minority of British cattle and sheep. The poor hygiene practices in the Treorchy Abattoir and in William Tudor's business were long standing. Why, therefore, didn't an outbreak happen before 2005? The same conditions - long standing hygiene failures in a catering butcher's premises - preceded the 1996 central Scotland outbreak. I think it probable that, similar to 1996, the "trigger" for the 2005 Outbreak was the entry into the Tudors' premises of heavily contaminated raw meat. Cross-contamination did the rest.
- 17.47 In 2000, I wrote[26]: "That Barr's had escaped so long and that *E.coli* O157 outbreaks centring on other poorly run butchers were not frequent and regular was explained by postulating that the heavy contamination of a carcass is itself a relatively rare event.... linked to the pattern of carriage of *E.coli* O157 in cattle.... with most positive individuals carrying few organisms and only a few harbouring the majority".
- 17.48 The existence of "supershedder" cattle was first demonstrated in 2002. A total of 589 cattle entering a Scottish slaughterhouse were tested. Of these, 44 were positive for *E.coli* O157 but four were supershedders. Each of them had more than 10,000 *E.coli* O157 per gram of faeces. These four animals alone carried more than 96% of the *E.coli* O157 found in all the animals[27]. This finding has been confirmed. The proportion of phage-type 21/28 supershedders, which was the type identified in the Outbreak, is significantly greater than for other types. It is a reasonable hypothesis that a supershedder played a role in the events that led up to the Outbreak. I note that modelling shows that control measures targeted at supershedding could be very effective control strategies for reducing the prevalence of *E.coli* O157[28].

Learning Lessons

- 17.49 My Inquiry has spent much time finding out what went wrong. This has been harsh for some individuals. Their shortcomings have been put under the spotlight. It is inevitable that the inspections immediately prior to an outbreak receive particularly close scrutiny and Mrs Angela Coles' inspections fall into this category. However, the evidence shows serious problems in some of Bridgend's previous inspections of Tudors. I make no excuses for William Tudor. However, for the others I have criticised in this report, it must not rest on their shoulders alone. "Changing personnel is a typical response after an organisation has some kind of harmful outcome. It has great symbolic value. A change in personnel points to individuals as the cause and removing them gives the false impression that the problems have been solved, leaving unresolved organisational system problems[29]." I agree. Indeed, some of those I have criticised could be particularly well-placed to drive improvements in food safety regulation because of their personal experience of how readily *E.coli* O157 can slip through defective defences.
- 17.50 The only systems that worked well were outbreak control and clinical care. There were system failures everywhere else. Issues around HACCP were the most important. Wherever it should have been applied, there was insufficient appreciation of its power to deliver safe food. Understanding of it was imperfect, raising questions about the emphasis given to it in the training and professional development of inspectors. Organisational commitment to it was lacking.
- 17.51 In 1999, I wrote a paper entitled "VTEC: Lessons Learned from British Outbreaks"[26]. I opened it by saying that the absence of a question mark in the title pointed to a less pessimistic view than that of Hegel, who said: "What experience and history teach is this – that people and governments never have learned anything from history, or acted upon principles deduced from it". I ended it by saying that when *E.coli* O157 is controlled "we may safely judge Hegel to have been wrong". We owe it to the memory of Mason Jones to learn the lessons from this Outbreak and to remember them, so that we can all make this judgement.

- 18.1 In addition to investigating the Outbreak and the way it was handled, I was also asked to consider what action might be needed to prevent a similar outbreak. This Chapter sets out my recommendations, together with a brief commentary on each.
- 18.2 I have already said that the food hygiene requirements in place at the time of the Outbreak, particularly the application of the HACCP approach, should have been sufficient to prevent the Outbreak. My recommendations therefore reflect what I believe needs to be improved, tightened up or reinforced.
- 18.3 The Inquiry was called by the National Assembly for Wales and established under its powers. My recommendations are therefore targeted at organisations that serve people in Wales, which includes organisations based in Wales and others that operate, or oversee action, in Wales. I am, of course, well aware of wider interest in the Inquiry and its relevance to practice elsewhere in the UK, a fact that is acknowledged by the Welsh Assembly Government. *E.coli* O157 has no boundaries.

Food Safety Practice

- 18.4 All food business operators should take note of this report, which should serve as a reminder that *E.coli* O157 is a real threat. It can, and will, exploit weaknesses and failures in hygiene practices, be they down to a lack of knowledge, to sloppiness, or even downright indifference to risk.

Recommendation 1: All food businesses must ensure that their systems and procedures are capable of preventing the contamination or cross-contamination of food with *E.coli* O157.

- 18.5 Current food hygiene regulations, which have evolved over the years, should be fit for purpose. Much depends on whether food business operators fully discharge their responsibilities. By far the majority do. People's health depends on it. I am concerned that some operators are unaware of bacteria such as *E.coli* O157 and even if they are, do not necessarily appreciate the risk. Some may believe they can cut corners. Anyone who does so puts at risk the health of their customers.
- 18.6 *E.coli* O157 should be at the top of an operator's agenda as far as risks are concerned. If procedures can prevent it from causing infection, then they can be expected to prevent most other forms of food poisoning as well. The risks from *E.coli* O157 are unpredictable and intermittent, which unfortunately can lead to complacency in food businesses. That must not be allowed to happen. As the Outbreak has shown, when *E.coli* O157 does occur, the infection can have very severe consequences for individuals and a profound impact on public services.

Recommendation 2: Food businesses must get to grips with food safety management based very clearly on the seven key HACCP principles, ensuring it is a core part of the way they run their business.

- 18.7 The seven HACCP principles are listed in Appendix 6. I believe that HACCP is the heart of effective food safety management. I recognise that some businesses, notably the smaller ones, do not necessarily have the resources to get it up and running. Some may not understand HACCP or may misinterpret it as bureaucracy and red tape instead of it being a fundamental tool for running their business safely. But it isn't rocket science. The current situation, with problems with the take-up and implementation of HACCP, is unacceptable. Developments such as the EU's proposal to exempt some smaller businesses from HACCP threaten food safety. According to The Food Standards Agency, that proposal is unlikely to go further. However, the proposal itself has not helped because some business operators may have taken from it that HACCP is unnecessary bureaucracy and not, as it is, an important means of achieving food safety.
- 18.8 Food businesses must get to grips with HACCP. Regulatory and enforcement bodies, and others, need to help them to do it. There should be a balance between self-development, using consultants, and templates and other tools that can be tailored to individual businesses. But all can help to encourage the use of the HACCP approach.

Recommendation 3: Additional resources should be made available to ensure that all food businesses in Wales understand and use the HACCP approach and have in place an effective, documented, food safety management system which is embedded in working culture and practice.

- 18.9 Since 2006, food businesses have been required to have a (written) food safety management system based on HACCP principles. The Food Law Code of Practice (Wales) 2006 requires enforcement officers to assess and verify business procedures based on HACCP principles, establish that effective controls are in place and that corrective action is taken when necessary. Where a written plan doesn't exist and procedures and actions are not based on HACCP principles and are inadequate, formal action can be taken.
- 18.10 The Food Standards Agency's target^[30] is that by the end of December 2010, at least 75% of food businesses will be fully compliant with food safety management requirements; that is, will have written systems in place; and all will be actively working towards it. The Agency states^[31] that delivery of the target is on course and that it is "...a challenging target due to a range of factors", which no doubt it is.
- 18.11 I know the FSA is working hard to make progress. Its "Safer Food Better Business" initiative is one example. I do not know what is being done by all local authorities in Wales but from evidence presented to me, I know that some are making strong efforts. But more needs to be done.
- 18.12 I will leave it to the Welsh Assembly Government to determine, in conjunction with others, what is reasonable by way of additional resources and how resources are best deployed in order to achieve the desired outcome. For the same reasons, I do not define "resources", which will allow consideration to be given to the most appropriate form(s) for the assistance to take, its cost-effectiveness, and how it will be evaluated.

- 18.13 I am well aware that resources are limited. Prioritisation will be necessary and resources should be targeted at smaller businesses and higher-risk premises. I define neither. Local authorities will know their local food businesses and therefore are best placed to target assistance so that it produces the best return on investment in terms of compliance levels and reduced risks to food safety.
- 18.14 The aim must be to remove any misunderstanding about the requirement for, and benefits of, HACCP and the difference between simply having a HACCP plan and actually using it as a fundamental way of running a food business. HACCP need not be complex, and there are risks from oversimplifying or diluting the approach to the extent that it becomes less effective, but greater efforts are required.
- 18.15 Additional resources will supplement and reinforce, but not replace, the advice that Environmental Health Officers (“EHOs”) deliver during inspection visits. All forms of assistance are important as they provide the basis for robust enforcement of food hygiene regulations.

Recommendation 4: The principles underpinning the Butchers’ Licensing Scheme, which was introduced in response to the 1996 *E.coli* O157 outbreak, should guide food hygiene measures in businesses processing raw meat and unwrapped ready-to-eat foods.

- 18.16 HACCP is not yet universal in all food businesses. It is clear that even in high-risk premises, confidence in its effective implementation might, from time-to-time, be misplaced. The use of the same equipment for both raw and ready-to-eat meats and its effective decontamination is the central issue. The Scottish licensing rules allowed a butcher that handled both products to continue working without a HACCP provided there was physical separation between them, in particular, the use of separate refrigerators, production equipment, and utensils for raw and cooked meats. We expect that today, all butchers in Wales are implementing an effective HACCP plan. Physical separation may well be a part of the plan. But where it isn’t and where there is doubt in the mind of an EHO about the efficacy of such a plan in practice, physical separation is the safest approach. The difficulties of making complex equipment microbiologically safe, bearing in mind the very low infective dose of *E.coli* O157, and the need for a business to be able to demonstrate that such safety can be, and is, delivered routinely, are important issues. For a vac packer, I do not think that such a demonstration is possible to allow its use for ready to eat foods and raw meat.

Recommendation 5: The Food Standards Agency should review its current guidance and should be proactive in generating new guidance where needs are identified.

- 18.17 Views expressed to me suggest that some current guidance may be too limited or far from clear and that some gaps may exist. For example, in July 2008, the Agency published guidance on vac-packed and modified-atmosphere packed chilled foods for the control of *Clostridium botulinum*. This is all very well but after many years of concern about botulism and vac packers, the risk remains theoretical: the risk from *E.coli* O157 is not.

- 18.18 The need for better and/or more guidance for enforcement officers and businesses, particularly high-risk businesses, should be considered. The FSA will no doubt wish to consult interested parties to determine all that needs to be done. Any guidance deemed necessary should be produced without delay.
- 18.19 However, a note of caution. Guidance is just that, and will rarely cover every situation. There will be situations where the professional skills of EHOs and others will need to come into play; where judgements will need to be taken on the basis of the evidence and observations. A lack of guidance is no reason for not taking action to address identified or potential food safety issues.

Recommendation 6: The Food Standards Agency should remove the confusion that exists among food business operators about what solution(s) should be used to prevent cross-contamination from surfaces and equipment.

- 18.20 Businesses must prevent cross-contamination. Effective cleaning requires robust procedures and the use of appropriate solutions. In the case of the Outbreak, the former was lacking and there was confusion about the latter. The terms “steriliser”, “sanitiser” and “disinfectant” were used in evidence, sometimes interchangeably, which indicates the need for greater understanding.
- 18.21 Whether this is achieved by way of an “approved” or “recommended” list of products and solutions or achieved by way of better information and guidance to industry, is a decision I leave to the FSA, which will no doubt consult local authorities and industry representatives. The objective must be to remove any confusion that exists about what is and isn’t suitable for preventing cross-contamination from surfaces and equipment. It would not remove the need for thorough cleaning processes that are carried out diligently, but it would make it easier for food businesses operators to identify and use appropriate solutions and easier for EHOs to assess that element of cleaning procedures.

Food Hygiene Inspections

Recommendation 7: Regulatory and enforcement bodies should keep the choice of “light touch” enforcement for individual food businesses under constant review.

- 18.22 Businesses are responsible for producing safe food. The majority do what is required. Advice, education and training for managers and employees is essential to achieving and maintaining compliance, and is an important consideration in enforcement. A failure to acquire and/or apply knowledge is not an acceptable excuse for poor hygiene practices.

- 18.23 A “light touch” or “softly softly” enforcement regime, which includes advice and education, has its place. However, enforcement bodies should recognise its limitations and the need for an alternative approach where persistent breaches of food safety are observed over time or where serious risks or potential risks are identified. A “light touch” approach simply cannot be allowed to roll on without a suitable point being reached at which more formal and robust action is taken. Authorities must come down hard on businesses that present serious risks to health and those that persistently fail to comply with food hygiene requirements.
- 18.24 The new Regulatory Enforcement & Sanctions Act 2008, which came into force on 1 October 2008, implements some of the recommendations in the Hampton Report[32]. It establishes the Local Better Regulation Office, which has a responsibility to advise and consult Welsh Ministers. It also puts in place a framework of administrative (to supplement criminal) regulatory sanctions to tackle non-compliance, and requires regulators not to impose or maintain unnecessary burdens on businesses. Another part of the Act, which deals with co-ordination of enforcement, comes into force on 6 April 2009.
- 18.25 The Act focuses on a risk-based system. I have no difficulty with that but will highlight some pertinent points[33]. Risk-based approaches have a greater emphasis on a food business managing its own risks. That can help enforcement agencies focus resources on the worst offenders for non-compliance and, given that most businesses take action to comply with food safety requirements, is perfectly sensible. However, it makes assumptions about businesses’ capacity to appreciate and manage risks, which can be lacking in some smaller ones. It also places greater reliance on risk-rating schemes and components such as confidence in a business’s management, each of which require subjective assessment. Risk-based approaches typically rate small businesses as a low risk compared to large businesses. However, this may hide some real difficulties in some cases which, as the outbreaks in Wales and Scotland testify, pose a serious risk.
- 18.26 I make no judgement on the 2008 Act, which would be inappropriate at this early stage. However, as a general point, and recognising the pressure on resources, I must emphasise that risk-based approaches and reducing the burden of inspections do not equate to an opportunity to reduce the resources for food law enforcement and food safety. They do not lessen the demands on inspection resources but merely help in prioritising their deployment. Inspections should not be regarded as a burden. They are often the main ways of helping smaller businesses to achieve compliance. Elected members of local authorities have an important part to play in supporting, and scrutinising, such services, which protect the health of the people they serve.

Recommendation 8: The inspection of HACCP plans must be audit-based.

- 18.27 There is confusion about the word “audit” and the term “audit-style” approach. In using the word, I am talking about a review, check or assessment that a HACCP plan or, as currently may be the case, another form of written food safety management system, addresses all the relevant hazards in a business. An audit-style approach does not mean simply running through a pre-determined list of questions. It means having a sound understanding of HACCP and a structured approach that enables EHOs to use their professional judgement. An experienced EHO should be able to spot gaps in, or queries about, elements of the plan, which can be explored. When set against the results of other checks and observations made during a visit, such action will help to ensure that a robust assessment of risks and compliance can be made.
- 18.28 There are advantages for both food business operators and EHOs in having an audit-based approach for HACCP. It can, among other things, help avoid the risk of a “walls and ceilings” inspection approach where the visual inspection of the premises, albeit important, takes up a disproportionate amount of a visit. Observation is important but the heart of producing safe food is a comprehensive HACCP approach that is operated in day-to-day practice. It is not the only part of an inspection but it is, or should be the fundamental part.

Recommendation 9: Training provision should be developed to ensure that all officers in Wales who check HACCP and HACCP-based plans, including those responsible for overseeing the work of those officers, have the necessary knowledge and skills.

- 18.29 A variety of training courses on HACCP exist at different levels. I believe there is a need for additional provision based on an agreed content appropriate to legislative requirements and to issues arising from this Inquiry. This should help ensure consistently good practice.
- 18.30 The new provision should be accredited and should include a means of assessing and recognising competence. An appropriate transitional period will be required but the goal must be to ensure that, at some point in the future, without demonstrating the required level of competence an officer would not be allowed to check a HACCP or HACCP-based plan without supervision. It is for the relevant bodies to determine the precise scope and level of training required, and a reasonable timescale for its implementation. As part of developing the provision, the relevant bodies should consider the need for future revalidation of competence.
- 18.31 I make one other point in relation to training, not only for EHOs but for others as well. This is not a specific recommendation but nonetheless is as important. I made comments along rather similar lines in my Group’s report into the 1997 outbreak in Scotland. I sincerely hope that lessons are learnt as a result of the 2005 Outbreak. Given that it spanned organisational, functional and geographical boundaries, and the fact that it is one of the most thoroughly investigated outbreaks caused by *E.coli* O157, it will be a particularly valuable case study for both academic and professional learning.

Recommendation 10: Environmental Health Officers should obtain a copy of a business's HACCP/food safety management plan at each inspection, which should be held on the business's inspection file.

- 18.32 Obtaining a copy of a business's HACCP plan will enable a more detailed assessment to be undertaken if that is deemed necessary. It also offers the opportunity to compare different versions of the plan over time and should place the importance of the plan higher in the mind of the food business operator.

Recommendation 11: A system of logging issues, concerns or potential problems, whether by "red flagging" specific documents or by file notes, should be standard practice.

- 18.33 This will, if combined with a sound review of a business's records before a visit, provide better intelligence about a business's operations and its track record on compliance. It will contribute to a more accurate assessment of food hygiene compliance and risks, and should help to achieve greater consistency in inspections. Perhaps most importantly, it will ensure that concerns or "clues" as to potential risks in a business are not lost, as was the case in the inspection history of John Tudor & Son.

Recommendation 12: Decisions about confidence in a business's management of food safety should be evidence-based.

- 18.34 It is reasonable to expect that the word of a business manager or proprietor can be relied upon. But the events described in this report have shown that this is not always the case. The following quote sums up the issue very neatly: "We place and refuse trust not because we have torrents of information (more is not always better), but because we can trace specific bits of information and specific undertakings to particular sources on whose veracity and reliability we can run some checks. Well-placed trust grows out of active inquiry rather than blind acceptance" [34]. The results of questioning proprietors and employees during an inspection, combined with checks of documentation and observations, provide the basis for such judgements to be made.

Recommendation 13: All inspections, primary and secondary, must be unannounced unless, exceptionally, there are specific and justifiable circumstances or reasons why a pre-arranged visit is necessary.

- 18.35 This is self-explanatory and indeed is already covered by requirements. But it needs to be reinforced. Where there are specific concerns about a food business operator, particularly if the operator is in a high-risk category, EHOs should consider additional, unannounced, spot-check visits, to assess practice on specific issues of concern. The Food Law Practice Guidance (Wales) issued in 2006 states that official controls, which includes inspections, may be carried out on an ad-hoc basis.
- 18.36 Unannounced inspections and selective spot-check visits should increase the uncertainty among food business operators as to when precisely an inspection will take place. This might help avoid specific action by an operator to improve the cleanliness of a premises purely for an inspection. While it might be argued that the latter may actually improve conditions at one point in time, it is unlikely to make any difference in the medium to long-term, or change hygiene practices for the better, thus it won't reduce risks to food safety.

Recommendation 14: Discussion with employees must be a standard part of food hygiene inspection visits.

- 18.37 This is not new but there is a need to emphasise it. I recognise the difficulties that may exist in some businesses but assessing the training people have received, their knowledge, and what they do is vital to building an accurate picture of food hygiene knowledge and practice. This should be achieved by way of some simple and informal questions around, for example, the way they clean surfaces and equipment.
- 18.38 Difficulties may also occur in some businesses when English is not the first language of employees. Environmental Health Officers will need to use their professional judgement in such circumstances as to the risks posed and any action that is necessary to minimise or to negate those risks.

Recommendation 15: The Food Standards Agency should develop, as part of its Audit Scheme or as an adjunct to it, a means of assessing how food hygiene inspections are undertaken by local authorities, including assessment of HACCP and HACCP-based plans.

- 18.39 The FSA's Audit Scheme covers important ground. However, its focus on systems and procedures must be accompanied by a much better assessment of how inspections are conducted. I am content to leave the detail to the FSA. I am aware of plans to develop such assessments or "reality checks" as they have been called, and of plans to pilot the new approach, in which I hope Wales will be included.
- 18.40 Whether the objective is achieved by accompanying local EHOs on an inspection or by undertaking a separate inspection of a premises and then comparing it with the results of the local authority inspection are matters for the FSA to weigh up. So too is the focus; for example, selecting high-risk premises for the reality checks.

- 18.41 I make no recommendation on the timescale for the outputs of the FSA's audits, namely the draft and final reports and action plans. The FSA's original timetable seems reasonable. But I will say that if a timetable is set for the process, all parties, and particularly the FSA itself, should stick to it.

Procurement

Recommendation 16: Businesses contracting for the supply of high-risk foods, such as raw and cooked meats, to public sector organisations must be subject to independent food hygiene audits.

- 18.42 Food safety must be a fundamental criterion in the evaluation of tenders for food contracts. There is no reason why the checks on suppliers to the public sector should be any less rigorous than those used by catering and retail businesses. Independent audits are not a substitute for inspections undertaken as part of local food law enforcement but can supplement and reinforce them. This is particularly important where vulnerable people are the consumers.
- 18.43 Accredited audit schemes already exist and should be considered. "Value Wales" has developed a means by which audit expertise can be utilised. It is being taken up by public sector organisations and also addresses the issue of sharing information between organisations.
- 18.44 I make no specific recommendations on monitoring complaints. If contracts incorporate the requirement for a robust system for recording and acting upon complaints, which most should, it should happen without fail regardless of whether the contract is for one authority or a joint contract involving several.

Health and Care Services

Recommendation 17: All health and care organisations should have an effective means of contacting key personnel during and outside normal working hours and for disseminating important information.

- 18.45 Simulation exercises play an important part in ensuring that organisations can respond effectively in the case of a real incident. However, there is no substitute for the latter as far as learning is concerned. The Outbreak was a test of the system. Overall, the system worked and contributed to outbreak control. Some weaknesses were identified but fortunately in this case, did not bring with them any adverse consequences.

- 18.46 The NHS in Wales is undergoing a re-organisation. There are opportunities to review systems and build better ones into the new organisations systems from the start. Care will be need to ensure that this is not overlooked or lost in the complexity of organisational change. Arrangements for out-of-hours contact and for disseminating, and being able to track the dissemination of, important information must be in place as the new organisations come into being.
- 18.47 Future action on handling outbreaks and methods of communicating with the public, with NHS staff and with others, has been informed by the experience of the Outbreak and by subsequent action to review arrangements. I have no doubt that the Welsh Assembly Government will continue to work with all relevant organisations to monitor and, where necessary, to co-ordinate developments and improvements.

School and Hygiene

Recommendation 18: Every local authority should have a programme of audits to ensure that all schools have adequate toilet and hand washing facilities.

- 18.48 The maintenance and improvement of school toilets has been the subject of investment programmes in past years. Audits have been undertaken since the Outbreak, which stimulated more action to address problems that existed. It is important that the momentum does not fall away in future. In the case of the Outbreak, the lack of such facilities did not appear to have had any adverse consequences. However, the provision of adequate toilet and hand washing facilities in schools is a basic requirement and it takes on a particular importance in outbreak control given that good personal hygiene and hand washing is vital to preventing the person-to-person spread of, among other things, *E.coli* O157. I leave it to local authorities to determine an appropriate frequency for audits.

Learning Lessons

Recommendation 19: All local authorities in Wales should review their policies, procedures and systems against issues raised by this report.

- 18.49 I make this recommendation for two reasons. First, I want to prevent another major outbreak of *E.coli* O157 anywhere in Wales, not just in areas affected by this Outbreak. Second, the need is reinforced by some evidence I received in relation to inspections. In a statement to the Inquiry, Mr Christopher Goacher, Acting Assistant Director of Public Protection at Bridgend County Borough Council says ".....since the Inquiry, I have spoken to a number of officers from different Local Authorities who have taken an interest in the Inquiry and in the role played by this Department within it. In all such discussions I have been told that the approaches adopted by our officers and the standards of our systems and procedures are no different from those adopted by others."

- 18.50 My Inquiry only needed to consider Bridgend's inspection practices. I cannot therefore make a judgement on inspection practice elsewhere. The Outbreak and the Inquiry itself have triggered some reviews and developments but all local authorities need to consider the lessons can be learned from the Outbreak. I want to ensure that lessons are learned across Wales and therefore wish to see structured and systematic reviews take place for that purpose. The reviews should consider the weaknesses and failures that have been identified but also, instances where arrangements have worked satisfactorily or well so that they too may be adopted. This should help to ensure consistently good practice across Wales by addressing any weaknesses or areas needing improvement, by identifying and sharing good practice that exists, and by identifying areas of confusion or uncertainty where greater clarification and understanding is needed.
- 18.51 It is for each authority to undertake a review or reviews, making public their findings and any developments that will occur as a result. Local authorities should discuss the reviews with the Welsh Assembly Government, given its responsibility for protecting people's health, and with the Food Standards Agency given its responsibility for food safety. Discussion with other relevant bodies may also be useful. This will help ensure that the reviews cover the necessary ground and a consistent approach across Wales.

Recommendation 20: The National Assembly for Wales should consider my recommendations and monitor and report progress on implementation.

- 18.52 I want to ensure that action is taken as a result of my report and that it happens at an appropriate pace. I have no doubt that the Welsh Assembly Government will respond formally to my recommendations, as indeed may other bodies. I am also in no doubt about the commitment of the First Minister and his Cabinet colleagues to ensure that lessons are learned across policy areas and that action is taken wherever necessary. I am content to leave it to the Members of the National Assembly for Wales to determine, in conjunction with others that have an interest in matters raised in this report, the most appropriate means of, and timescale for, monitoring and reporting progress.

Recommendation 21: A substantial review of food hygiene enforcement in Wales should take place approximately five years after the publication of this report.

- 18.53 Approximately ten years after reviewing the outbreak in Scotland in 1996, I have found myself considering another major outbreak, the circumstances of which are remarkably similar. I do not hide my disappointment. Some of the lessons from Scotland appear to have been forgotten. I hope that this report will help to ensure that it doesn't happen again.

- 18.54 Therefore, in addition to the previous recommendation on monitoring and reporting progress. I would like to see a substantial review of food hygiene enforcement take place in Wales approximately five years after the publication of this report. I will leave it to the National Assembly for Wales, the Welsh Assembly Government, and other relevant bodies to agree the precise timing, terms of reference, how it will be done, and by whom. I do not see the need for a public inquiry but consideration will no doubt be given to the benefits of an independent review and to the need for transparency in terms of the information gathered and reported.
- 18.55 A review will enable the relevant bodies to take stock of, among other things, the incidence of food poisoning, compliance with food hygiene requirements, the take up and use of the HACCP approach, and food law enforcement matters. Services and practice across Wales should be compared in the interests of achieving consistently high standards in the delivery of what is an important public service for protecting people's health. I anticipate that such a review could assess, or would take into account the results of any earlier assessment of, the Enforcement and Sanctions Act 2008. The results of other reviews, such as those from the Food Standards Agency's Audit Scheme, will also be relevant.

Recommendation 22: Good practice advice and guidance issued by public bodies should be subject to follow-up and/or more detailed evaluation.

- 18.56 Two specific examples of good practice guidance have featured in this report. First, that produced by the South East Wales Task Force after my report in Scotland, which was a good example of trying to learn from a serious incident elsewhere. Second, "Food for Thought" to develop public sector procurement practice. Both are good examples of organisations working proactively to bring about improvement. Both are highly relevant to issues investigated by the Inquiry. Unfortunately, some elements were not put into practice and therefore the benefits were lost.
- 18.57 Much time and effort is invested in developing best practice guidance in, no doubt, the clear hope that it will be taken up. Unfortunately, it doesn't necessarily happen. The downside of that is at best, a waste of resources, but at worst, weaknesses in practice. If some aspects of best practice guidance had been followed, the chances of spotting the risks from John Tudor & Son might have been greater.
- 18.58 It stands to reason that if it is considered necessary to develop best practice guidance, follow-up and evaluation should be undertaken to determine its impact and the need for any further action.

Learning More

Recommendation 23: Variable Number Tandem Repeat (VNTR) should be validated as a standard method for the typing of *E.coli* O157.

- 18.59 The VNTR typing of *E.coli* O157 worked well when applied to strains isolated in the Outbreak. I agree with the opinion of the Health Protection Agency's experts at Colindale. While the current consensus view is that it will complement Pulsed Field Gel Electrophoresis (PFGE), more data are required on epidemiological relevance, reproducibility and technical aspects before it can be seen as a replacement. The advantages of VNTR over PFGE are significant. Being sequence-based it is not subjective, can be automated, and its results are simple to transfer electronically. It is also faster and less labour intensive. A fundamental advantage is that it has a genetic basis that is much more secure[35].

Recommendation 24: The feasibility of identifying "supershedder" cattle on farms should be explored as a potential means of reducing the likelihood of spreading *E.coli* O157 to other cattle.

- 18.60 Cattle that shed large amounts of *E.coli* O157 bacteria present a major challenge to food safety and can exploit gaps or weaknesses in hygiene practices and procedures in the food chain. Given that modelling has shown that control measures designed to tackle supershedding could be very effective control strategies for reducing the prevalence of *E.coli* O157, it would be sensible to take the idea to the next stage and explore options in more depth.

APPENDIX 1

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List of Abbreviations

ADEW	Association of Directors of Education in Wales	LHB	Local Health Board
BSE	Bovine Spongiform Encephalopathy	MAFF	Ministry of Agriculture, Fisheries and Food
CCDC	Consultant in Communicable Disease Control	MHI	Meat Hygiene Inspector
CIEH	Chartered Institute of Environmental Health	MHS	Meat Hygiene Service
CMG	Catering Managers Group	MLC	Meat & Livestock Commission
CPS	Crown Prosecution Service	MRI	Magnetic resonance imaging
DEFRA	Department for Environment, Food and Rural Affairs	NACB	National Association of Catering Butchers
DNA	DeoxyriboNucleic Acid	NHS	National Health Service
<i>E.coli</i>	<i>Escherichia coli</i>	NPHS	National Public Health Service for Wales
EHEC	Enterohaemorrhagic <i>Escherichia coli</i>	OCT	Outbreak Control Team
EHO	Environmental Health Officer	OVS	Official Veterinary Surgeon
EU	European Union	PFGE	Pulse Field Gel Electrophoresis
FAFA	Food Alert for Action	RCT	Rhondda Cynon Taf
FSA	Food Standards Agency	RMHA	Regional Meat Hygiene Advisor
GP	General Practitioner	RMVA	Regional Meat Veterinary Advisor
HACCP	Hazard Analysis Critical Control Point	TTP	Thrombotic Thrombocytopenic Purpura
HAS	Hygiene Assessment System	U & E	Urea & Electrolyte
HUS	Haemolytic Uraemic Syndrome	VNTR	Variable Number Tandem Repeat
IV	Intravenous	VO	Veterinary Officer
LACORS	Local Authorities Co-ordinators of Regulatory Services	VTEC	Verocytotoxin producing <i>Escherichia coli</i>

APPENDIX 3

Glossary of Terms

Asymptomatic: Person who carries a disease or infection, becoming potentially infectious to others, but shows none of the symptoms it can cause.

Anti Motility Agent: Reduces the symptoms of diarrhoea by slowing down bowel activity and by promoting fluid absorption.

Bacterium: A minute single-celled organism, which may be harmless or capable of causing a disease e.g. *E.coli* O157.

Bovine: An animal of the family Bovidae, refers generally to cattle.

Butchers' Licensing: Introduced after 1996 *E.coli* O157 outbreak in Scotland. Set out requirements for butchers handling raw and ready-to-eat products.

Case: A person who has a particular disease.

Case Definition: Criteria that must be met in order to identify a person as a case of a particular disease. Criteria can include symptoms of the illness, laboratory test results and the time and location of the outbreak.

Catheter: Flexible tube inserted into the body to permit introduction or withdrawal of fluids or to keep a passageway open.

Codes of Practice: Published by the Food Standards Agency and must be adhered to by Food Authorities. Covers food safety practice and the conduct of food safety inspections.

Codex Alimentarius: Series of food standards and related texts that aim to provide consumer protection and fair practice in the international trade of food and agricultural products. Developed by the Codex Alimentarius Commission, an intergovernmental body jointly sponsored by the Food and Agriculture Organisation and the World Health Organization.

Core Participant: Individuals and/or organisations considered closest to issues investigated by an inquiry. Actively involved in the Inquiry process.

Communicable Disease: Any disease that can be passed from one person to another.

Consultant in Communicable Disease Control: Doctor with specific responsibility for the prevention and control of communicable disease.

Cross-contamination: The transfer of organisms from one surface to another. Can occur directly, or indirectly from contact with hands or machinery, work surfaces or tools.

Detergent: A chemical used to remove grease, dirt and food. Used for general cleaning.

Dialysis: Medical procedure to remove waste products from the blood with special equipment after the kidneys have stopped functioning.

Disinfectant: A chemical used for disinfecting, which kills bacteria.

DNA Sub-typing: Analysis of sections of DNA sequence variations for purposes of identification. Commonly referred to as “DNA fingerprinting”.

Environmental Health Officer (EHO): An individual trained in environmental health issues such as housing, sanitation, food, clean air, noise and water supplies. Responsibilities include inspecting restaurants and other food premises and investigating cases of food poisoning.

Epidemiology: Study of factors affecting health and disease in populations and the application of the knowledge to the control and prevention of disease.

***Escherichia coli* O157:** A particularly virulent type of *Escherichia coli* bacteria that can cause severe illness.

Faggots: A kind of sausage made from pork offal, fat, breadcrumbs, onions and seasoning wrapped in pig caul and baked.

Fatal Accident Inquiry: Statutory public inquiry under Scottish law into the circumstances of a death.

Food Authority: Authority, such as a local authority for example, that has a statutory duty to enforce the Food Safety Act 1990 Act and Regulations made under it. Must have regard to Code(s) of Practice when discharging its duties.

Food Hygiene: The measures and conditions necessary to control hazards and to ensure fitness for human consumption of a foodstuff, taking into account its intended use.

Food safety: The assurance that food will not cause adverse health effects to the final consumer when it is prepared and eaten.

Haemodialysis: Used in the case of kidney failure. The patient’s blood is pumped through a machine, which filters waste products from the blood before returning it to the patient.

Haemolytic anaemia: Anaemia due to the abnormal breakdown of red blood cells either in the blood vessels or elsewhere in the body. It has numerous possible causes, ranging from relatively harmless to life-threatening. The general classification of haemolytic anaemia is either acquired or inherited. Treatment depends on the cause and nature of the breakdown.

Haemorrhagic Colitis: Symptoms of inflammation and bleeding from the large intestine, which can result in bloody diarrhoea.

Haemolytic Uraemia Syndrome (HUS): A condition characterised by acute kidney failure, anaemia due to increased destruction of red blood cells and thrombocytopenia (a lowered body level of platelets, which are needed for normal blood clotting).

Hazard Analysis Critical Control Point (HACCP): A food safety management method designed to enable businesses to identify, evaluate and control hazards.

Improvement Notice: Can be served if a food business proprietor is failing to comply with food hygiene regulations. Failure to comply with the terms of an Improvement Notice is an offence.

Incubation Period: Time between becoming infected with a micro-organism and the symptoms appearing.

Isolate: Substances that have been separated, or isolated, from their original source. A pure specimen obtained by microbial culture.

Local Authorities Coordinators of Regulatory Services (LACORS): Local government body that supports and coordinates activities across the UK relating to trading standards, including food law enforcement.

Microbiology: The study of microbes and micro-organisms and, in the context of a food poisoning outbreak, identifies the pathogen(s) causing it.

Outbreak Control Team: A team formed to control the spread of disease during an outbreak. Assesses the outbreak; tries to identify its source, and implements prevention and control measures.

Outbreak: An increase in the number of people with an illness or disease above that normally expected to be seen in the population at a particular time, or two or more linked cases with the same illness.

Outbreak Plan: A national or local plan for controlling an outbreak.

Out-of-Hours Service: Non-emergency health services provided when GP surgeries are closed in the evening, at night and on weekends.

Pathogen: An infectious microorganism, bacteria, virus or other agent that can cause disease by infection.

Pathogenic: Causing disease or capable of doing it.

Pennington Report: The report produced by the Pennington Group into the outbreak of *E.coli* O157 in Lanarkshire, Scotland in 1996.

Peritoneal Dialysis Catheter: Soft tube inserted into the abdomen. Used to remove from the blood waste products normally removed by the kidneys.

Phage Type: A system of sub-classifying certain species of bacteria according to whether they are susceptible to infection by panels of different viruses that infect bacteria ("bacteriophages", which literally means "bacteria-eaters").

Primary Case: The first individual within a group or family to get a disease. There may be several primary cases in a group if they are exposed to the same source around the same time.

Proper Officer: Appointed by local authorities to assist them to comply with their responsibilities. A Consultant in Communicable Disease Control usually holds the appointment of the Proper Officer for infectious disease control for local authorities in their area; Legislation requires doctors to notify to Proper Officers of certain types of infectious disease.

Pulse Field Gel Electrophoresis (PFGE): A scientific process based on chopping up with enzymes

the DNA material of bacteria such as *E.coli*. It enables scientists to determine whether *E.coli* strains taken from different people and from the environment are related to each other.

Salmonella: A group of bacteria that cause typhoid fever and other illnesses, including food poisoning, gastroenteritis and enteric fever from contaminated food products.

Sanitiser: A two-in-one product that acts as a detergent and a disinfectant.

Secondary Case: A person that catches a disease from a primary case.

Serogroups: Groups of micro-organisms that differ by their composition in terms of antigens (substance that stimulates production of an antibody).

Serotypes: A group of microorganisms or viruses based on the cell surface antigens. Allows organisms to be classified at the sub-species level, which is important in epidemiology.

Strain: Population within a species or sub-species distinguished by sub-typing.

Supershedders: Animals, usually cattle, that excrete relatively large amounts of *E.coli* O157 bacteria in their faeces.

Tertiary Hospital: Hospital providing specialised services, beyond the normal scope of most hospitals. Patients usually referred there from another hospital.

Toxin: A poison, often a protein produced by some plants, certain animals and pathogenic bacteria, which is highly toxic for other living organisms.

Typing: Method used to distinguish between closely related micro-organisms.

Vacuum packing: The removal of all or most of the air within a package of, for example, food, preventing its return by an airtight seal.

Variable Number Tandem Repeat: A robust typing method of typing the specific strains of bacteria such as *E.coli* O157.

Verocytotoxin: Potent toxins that can cause disease. Verocytotoxin producing *E.coli* (VTEC) are responsible for a range of illnesses which may be severe and sometimes fatal, particularly in infants, young children and the elderly.

VTEC: Verocytotoxin producing *Escherichia coli* that characteristically produce powerful toxins that kill a variety of cell types, including Vero cells on which their effects were first demonstrated.

Bridgend County Borough Council

Instructing Solicitor: Kelly Watson and then Patricia Gavigan

Counsel: Anthony Vines

Caerphilly County Borough Council

Instructing Solicitor: Gareth Richards

Counsel: Jonathan Walters

Food Standards Agency

Instructing Solicitor: Peter Whitehead and then Louise Timmons, Treasury Solicitors

Counsel: Alan Maclean

Individuals Affected by the Outbreak

Instructing Solicitor: Stephen Webber, Hugh James Solicitors

Counsel: Mark Powell QC

Merthyr Tydfil County Borough Council

Instructing Solicitor: Lai-Sheung Yeung and then Simon Jones

Counsel: Alexander Greenwood

National Public Health Service for Wales

Instructing Solicitor: Tessa Shellens, Morgan Cole Solicitors

Counsel: Clive Lewis QC

Rhondda Cynon Taf County Borough Council

Instructing Solicitor: Paul Nicholls

Counsel: Graham Walters

Welsh Assembly Government

Instructing Solicitor: Mark Partridge

Counsel: Rhodri Williams

Local Health Boards and NHS Trusts

Instructing Solicitor: Mark Harris, Welsh Health Legal Services

Counsel: Huw Lloyd

Floor Plan of Premises of John Tudor and Son, Bridgend

The image displays a detailed architectural floor plan of the ground floor of a building. The plan is oriented with a north arrow pointing towards the top right. A scale bar at the bottom left indicates distances from 0 to 10 meters. The plan is divided into several functional areas:

- Offices:** Located on the left side, including a large office (2832) and a smaller one (2941).
- Reception & Loading Area:** A central area with a reception desk and loading dock.
- Staff Room:** A room for staff, located near the reception area.
- Locker Room:** A room for staff lockers, located near the staff room.
- Toilets:** Multiple toilet facilities, including a female WC and a male WC.
- Shower:** A shower facility located near the locker room.
- Store:** Several storage rooms throughout the plan.
- Pumping Room:** A room for mechanical equipment, located near the staff room.
- Cooked Meat Preparation Area:** A large area for preparing cooked meat, including a sink, hopper, and various equipment.
- Freezer Room:** A room for storing frozen goods.
- Cold Room:** A room for storing chilled goods.
- Raw Meat Preparation Area:** A large area for preparing raw meat, including a sink, hopper, and various equipment.
- Corridor:** A central corridor connecting the various rooms.
- Stairs:** Stairs leading to the ground floor and stairs to the ground floor.

The plan includes numerous dimensions and labels for various features, such as doors, windows, and equipment. The overall layout is designed for efficient workflow and storage.

Principles of the Hazard Analysis Critical Control Point (HACCP) System

- Principle 1: Conduct a hazard analysis. Identify the potential hazards associated with food production at all stages up to the point of consumption; assess the likelihood of occurrence of the hazards and identify the measures necessary for their control.
- Principle 2: Determine the Critical Control Points. Identify the procedures and operational steps that can be controlled to eliminate the hazards or minimise the likelihood of their occurrence.
- Principle 3: Establish critical limit(s). Set target levels and tolerances which must be met to ensure that the Critical Control Point is under control.
- Principle 4: Establish a system to monitor control of the Critical Control Point.
- Principle 5: Establish the corrective action to be taken when monitoring indicates that a particular Critical Control Point is not under control.
- Principle 6: Establish procedures for verification to confirm that the HACCP system is working effectively.
- Principle 7: Establish documentation concerning all procedures and records appropriate to these principles and their application.

Source:

CAC/RCP 1-1969, Rev. 4-2003 - Annex Page 23

The Pennington Group (1997) 'Report on the Circumstances Leading to the 1996 Outbreak of Infection with E.coli 0157 in Central Scotland: The Implications for Food Safety and the Lessons to be Learned' Edinburgh: The Stationery Office

