Part 1

General issues

1

Introduction

T. H. Pennington, University of Aberdeen

Even in a new millennium we can be certain that myths will continue to play an important role in people's lives. A longstanding and pervasive one is that the only general spin-off from space travel and rocket science has been the non-stick frying pan. Far more important, of course, was the development of HACCP by NASA, Pillsbury and others. What a debt we owe to those who addressed the need to protect space missions from food poisoning and the appalling prospect of diarrhoea in zero gravity!

As a medical microbiologist specialising in the molecular typing of human pathogens my involvement with HACCP was, until recently, remote and indirect. This changed suddenly and dramatically at the end of 1996, when Central Scotland suffered one of the largest outbreaks of *E.coli* O157 food poisoning ever recorded with more than 500 cases and 21 associated deaths. It centred on a butchery business.[1] Like the 1993 Jack-in-the-Box hamburger chain outbreak in the United States,[2] it had a profound impact on politicians as well as public opinion. While it gave red meat – yet again – a negative role as a vector of disease, it also created a window of opportunity for driving forwards improvements in food safety. Early in the outbreak I was asked by the Secretary of State for Scotland to chair an Expert group 'to report on the circumstances leading to the outbreak, the implications for food safety, and the lessons to be learned.'

In the deliberations which led to our final report[3] we tried to identify measures which would help to reduce the incidence of future infections with *E.coli* O157 and, in particular, outbreaks of the scale involved in Central Scotland. We were also determined, in considering food safety legislation, guidance and practices that, in coming to our views, public health considerations should be regarded as paramount in the handling of potential and actual

outbreaks of food poisoning. We were persuaded of the overriding need to tackle the dangers which *E.coli* O157 presents and to reinforce public health considerations in the area of food safety. This overarching principle guided our work. Moreover, while we believed that the measures proposed were justified with reference to the circumstances of the outbreaks examined, we also acknowledged the influence of more general concerns about the growing incidence of food poisoning cases, and their economic and social costs, in supporting the precautionary and preventive approach adopted.

A 'public health' approach concerns itself primarily with prevention. So does HACCP, with both its philosophy and its practice centring on critical control points. This is why the principles of HACCP were central to our deliberations. We sought to identify the critical points in the process of food production 'from farm to fork' at which, based on our examination of the circumstances of recent outbreaks, there seems to be most risk of contamination.

It was brought home to us early in our investigation of the Central Scotland outbreak that the successful introduction and implementation of HACCP is not a trivial undertaking. A prerequisite for these is an understanding by management and workforce of the hazards and risks that underpin Good Hygiene practice, and the effective operation of the latter. All these things were lacking in John Barr's, the butchery business that was the source of the outbreak. Thus at the time of the outbreak there was no training programme for its staff, no cleaning schedule for its equipment or premises, no temperature monitoring of cookers or refrigerators, and neither soap nor drying facilities at the inadequate number of wash hand basins. There were, on the other hand, more than 30 points at which there was a high risk of cross-contamination. The sheriff principal who conducted the Fatal Accident Inquiry into the 21 deaths associated with the outbreak summarised the problem succinctly: 'I have no doubt Mr John Barr liked a clean shop and maintained a clean shop. What he failed to do was to maintain a safe shop and the main ingredient of his failure was ignorance of the requirements which would produce that result.'

1.1 *E.coli* O157

As a test for food safety systems *E.coli* O157 is unparalleled. This is because of its propensity to be transmitted to people at any point in the food chain, because of other properties like its ability to survive well in hostile environments and its low infectious dose, and because of its nastiness as a pathogen. These things make it an important public health problem and a serious challenge to the meat industry. It cannot be bettered as a focal point on which to centre considerations of HACCP. So it is worth considering the biology and natural history of the organism in some detail.

E.coli O157 exists in a wide range of animals (wild, farmyard and domestic) and even birds. It is generally accepted that its main reservoir is in the rumens and intestines of cattle and, possibly, sheep. The organism can be excreted and

may therefore exist in animal manure or slurry, which could be a source of environmental or water contamination, or direct contamination of food such as vegetables. (Most of the evidence for this is, however, circumstantial.) It seems likely that there can be animal to animal infection/reinfection. There is good evidence that it is transferred to animal carcasses through contamination from faecal matter during the slaughter process. Many early outbreaks were associated with the consumption of hamburgers. There have also been documented cases attributed to meat, meat products and other foods such as milk, cheese and apple juice. In the very large Japanese outbreak, radishes were identified as a possible source of the infection. The vehicle for most cases of infection, however, remains unknown. The organism survives well in frozen storage and freezing cannot be relied upon to kill it. It is killed by heating but can survive if food is not properly cooked. If appropriate hygiene measures are not taken, there can also be cross-contamination between raw meat carrying the organism and cooked or ready to eat foods. *E.coli* O157 appears to be relatively tolerant to acidic conditions (compared, for example, to *Salmonella*).

Human infection may occur as a result of direct contact with animals carrying the organism, from contamination from their faeces, or through consumption of contaminated food or water. It may also spread directly from person to person as a result of poor hygiene practices which allow faecal–oral spread. The latter is, obviously, a particular potential problem in institutions such as nursing homes, day-care centres or hospitals and in places where pre-school children meet, and underlines the need for good personal hygiene and meticulous attention to procedures designed to prevent cross-infection. Cases may be related to outbreaks or may be sporadic (i.e. isolated and apparently unrelated to other cases). The role of asymptomatic food handlers in outbreaks is unclear but may be important in light of the low infectious dose.

Infection with *E.coli* O157 is potentially very serious for vulnerable groups, particularly the elderly and the very young. There is no specific treatment available for infection or to prevent complications. These include haemorrhagic colitis (bloody diarrhoea), the haemolytic uraemic syndrome (HUS) and thrombotic thrombocytopaenic purpura (TTP). The latter two complications are much less common but can be very serious, causing kidney and other problems and, in the most severe cases, even death. Infection with *E.coli* O157 and associated HUS is the most common cause of acute renal failure in children in the UK. Morbidity for the vulnerable groups is particularly high compared to other forms of foodborne illness.

Despite improvements in surveillance and testing techniques, the organism remains more difficult to detect and identify accurately than most other important foodborne bacterial pathogens. *E.coli* O157 does not generally cause illness in animals other than, at worst, transient diarrhoea in very young animals. There is, therefore, no reason for farmers to seek to identify the presence of the organism in their animals.

The very few organisms that are required to cause harm in humans can, under present rules and practices, easily escape detection and pass along the food

chain, whether from animal faeces, carcasses, meat, equipment or humans. *E.coli* O157 has been difficult to identify in foods and, although techniques have improved over the years, rates of detection are still unsatisfactory. This is due in part to the low levels of the organism which appear to occur in food. The most sensitive techniques for identifying the organism (particularly, but not only, in food) are complex and sophisticated, requiring specialised equipment and expertise that is not generally available.

1.2 HACCP and food safety

Clearly, all these things make *E.coli* O157 a formidable challenge. No single immediately and universally applicable technical fix is available to eliminate it from the food chain. Eradication from its ruminant hosts is not a practical proposition at the present time. This is why my expert group spent a lot of time considering the HACCP system. This was not just because it is the overarching system which governs the UK's (and indeed the emerging global) approach to tackling food safety issues, but because of its applicability at many parts of the food chain. This derives from its nature – a structured approach to analysing the potential hazards in an operation; identifying the points in the operation where the hazards may occur; and deciding which points are critical to control to ensure consumer safety. These critical control points are then monitored and remedial action, specified in advance, is taken if conditions at any point are not within safe limits. Thus HACCP is both a philosophy and a practical approach to food safety.

European Union (EU) food law places the responsibility for ensuring the safety and protection of the consumer very firmly with individual food businesses. HACCP-based principles, some of which are enshrined in much of this law, provide the tool for food businesses to address this responsibility, and these principles are backed up in law by prescriptive requirements and provisions requiring enforcement. The advantages of the HACCP approach are now internationally recognised, through the Codex Alimentarius Commission, where it is agreed that HACCP is based on seven principles:

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 preventive measures necessary for their control.
2. Determine the critical control points (CCP). Identify the procedures and operational steps that can be controlled to eliminate the hazards or minimise the likelihood of their occurrence.
3. Establish critical limit(s). Set target levels and tolerances which must be met to ensure the CCP is under control.
4. Establish a system to monitor control of the CCPs.
5. Establish the corrective actions to be taken when monitoring indicates that a particular CCP is not under control.

6. Establish procedures for verification to confirm that the HACCP system is working effectively.
7. Establish documentation concerning all procedures and records appropriate to these principles and their application.

How did my group apply these principles to *E.coli* O157?

After the farm, slaughterhouses represent the second critical point in the food production process. My expert group believed that HACCP should apply to the slaughter process. In this context, we took cognisance of the Australian approach where slaughterhouses have adopted HACCP in full and accept their responsibility for food safety. These measures appear to have largely eliminated the problem of faecal contamination of carcasses. However, even starting from the base of high standards necessitated by the demands of export markets, it took at least five years for Australia to reach this position. My group identified a range of issues relating to slaughterhouses and the potential for cross-contamination at various key stages in the slaughter process. These included:

- the presentation of animals in a clean and dry condition suitable for slaughter;
- processes relating to removal of the hide and the intestines of the animal;
- the need to consider and evaluate end-of-process treatments;
- issues related to the transportation of carcasses and meat; and
- more general issues related to the achievement and enforcement of good hygiene standards within abattoirs.

My group also concluded that HACCP principles and the need for the highest hygiene standards should apply to the transportation of carcasses and meat. We felt it to be pointless promoting hygiene within abattoirs and butchers if meat was permitted to become cross-contaminated during transportation to or from cutting plants or butchers. We indicated that vital importance of preventing, for example, unwrapped meat from touching the sides of transport vehicles during loading, carriage and unloading and that HACCP principles needed to be understood by transport interests and reflected in regulations and subsequent enforcement in this area.

The potential for cross-contamination of foods points to the critical nature of meat production and butchers' premises in the food chain. Even with measures taken earlier in the chain to help prevent contamination, it is inevitable that from time to time meat will enter the premises contaminated with *E.coli* O157. All raw meat, therefore, needs to be treated as though it is potentially contaminated and appropriate handling and hygiene standards adopted with HACCP as the universal approach. Clearly, if an effective HACCP had been in place at the butchery business responsible for the Central Scotland outbreak, the large amount of raw and ready-to-eat meats being handled there daily – with a very high cross-contamination potential – would have figured high in the list of critical control points and for action. Many lives would have been saved.

1.3 The successful implementation of HACCP

The successful application of HACCP requires the full commitment of management and the workforce. It also requires a multi-disciplinary approach. A prerequisite to implementation is knowledge, understanding and expertise in identifying the hazards and assessing the risk involved in an operation. Introduction of a new system requires structured implementation. From information and evidence that my expert group collected during the course of its work, we identified a number of concerns about the current position of HACCP in the UK.

- The scheme relies primarily on businesses themselves, albeit with external expert advice and assistance as appropriate, to identify potential hazards and critical control points within their own operations.
- Businesses require expertise and training for successful implementation.
- Many businesses have yet to discover HACCP, or to put it into practice. The concept is sound, but it is relatively new and as yet insufficiently well known or understood – across the spectrum of issues involved or of business.
- The period over which HACCP principles can effectively be introduced is lengthy (in the UK senior environmental health officers with first-hand knowledge and experience of food premises, and individuals involved in education and training in food safety, suggest that this will take up to five years or even longer, regardless of the risks inherent in a particular business). As recent events have shown, there is the potential for many serious outbreaks of food poisoning over that period.

E.coli O157 is of course not the only hazard that challenges the meat industry. Other *E.coli* serogroups like O111 and O26 behave in a similar way, and *Salmonella* is still with us. However, I have focused on it in this introduction for four main reasons. First, its versatility and nastiness as a food poisoning organism makes it an unremitting and particularly severe – and therefore good – test for food safety systems. Second, its propensity to cause dramatic and severe outbreaks means that in addition to its direct effects on those who suffer disease – devastating as these often are – it also has a broad range of negative impacts of a general kind. Thus in addition to ruining businesses, its impact diminishes public confidence in food safety. Third, its public impact can drive public policy. Thus on both sides of the Atlantic major outbreaks have led to an acceleration and an increase in rigour in the development of HACCP programmes.[4,5,6]

Finally, and important for HACCP, as a new and emerging pathogen with distinct properties *E.coli* O157 has reminded us that even the best HACCP relies on past information in its identification and management of critical control points. Continued programmes of research are needed to keep up with the evolution of pathogens as well as the lessons from outbreaks, which are still occurring and still giving new insights into pathogen behaviour.

The prevention of food poisoning by HACCP is not, of course, an issue restricted to the meat industry. The Central Scotland outbreak highlighted the importance of food hygiene at the point of consumption – eight of those who

died were infected by food served in a church hall – and one of the recommendations of my Expert Group was 'that steps should be taken by local authorities to encourage the adoption of HACCP principles in non-registered premises where there is catering for functions for groups of people involving the serving of more than just tea, coffee and confectionery goods.'

Fortunately, *E.coli* O157 infections are still relatively rare. It is an unfortunate and depressing fact, however, that when outbreaks are studied in detail it turns out that for many of them their root cause was ignorance or disregard of well-understood safety principles, with failure at management levels being key. Even though *E.coli* O157 is a relatively new organism, having emerged as a problem only in the last 20 years, its critical control points are in principle the same as for other meat-borne pathogens.

For all these reasons, it is abundantly clear that the solution to these problems lies in the effective implementation of HACCP. The authoritative chapters which follow show how this can be done.

1.4 References

1. AHMED S and DONAGHY M, 'An outbreak of *Escherichia coli* O157:H7 and other shiga toxin-producing *E.coli* strains', in *Escherichia coli O157:H7 and other Shiga Toxin-producing E.coli Strains*, ed KAPER J B and O'BRIEN, A D, pp 59–65, Washington DC, ASM Press, 1998.
2. TUTTLE J, GOMEZ T, DOYLE M P, WELLS J G, ZHAO T, TAUXE R V and GRIFFIN P M, 'Lessons from a large outbreak of *E.coli* O157:H7 infections: insight into the infectious dose and method of widespread contamination of hamburger patties', *Epidemiol Infect*, 1999 **122** 185–92.
3. PENNINGTON T H, 'The Pennington Group. Report on the circumstances leading to the 1996 outbreak of infection with *E.coli* O157 in Central Scotland, the implications for food safety and the lessons to be learned'. Edinburgh, The Stationery Office, 1997.
4. PENNINGTON T H, 'Factors involved in recent outbreaks of *E.coli* O157:H7 in Scotland and recommendations for its control', in *Food Safety: the Implications of Change from Producerism to Consumerism*, ed SHERIDAN J J, O'KEEFE M and ROGERS M, pp 127–35, Food and Nutrition Press, Trumbull, CT, 1998.
5. The UK government has accepted the recommendations of the Pennington Report, including those which said 'HACCP (i.e. the Codex Alimentarius approach and the seven principles) should be adopted by all food businesses to ensure food safety' and 'The Government should give a clear policy lead on the need for the enforcement of food safety measures and the accelerated implementation of HACCP.'
6. USDA Food Safety and Inspection Service, 'Pathogen reduction; hazard analysis and critical control systems (HACCP); final rule', Federal Register **144** July 25 1996.