

Food Safety and the EU

**The proposal for new hygiene rules
– a disaster in the making**

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Introduction

In July of this year, the EU Commission proposed a new package of food safety laws describing it as “the most radical shake up for 25 years of the Community’s food hygiene rules”. Commissioner David Byrne, in launching the proposal, claimed he was creating a new “single, transparent hygiene policy applicable to all foods and food operators”. “This package is of strategic importance in achieving my food safety objectives”, Byrne said¹.

At the heart of Byrne’s proposal is a move to simplify and improve food safety law and thus improve consumer protection. The Commission intends to dispense with prescriptive codes and replace them with measures where: “the focus is on setting objectives while leaving businesses flexibility in deciding the safety measures to take, rather than prescribing them in great detail”.

However, Byrne’s package is intellectually flawed, counter-productive and burdensome on business. Far from offering businesses flexibility, as the Commission claims, the implementation will occasion a significant increase in the complexity and cost of compliance without in any way improving food safety overall. It is a disaster in the making.

The disaster is given form by the Commission’s proposal to adopt a system of food safety management called “Hazard Analysis and Critical Control Points” (HACCP). Previously a voluntary system, this is to become compulsory in all food operations. In the words of a former senior government food safety official, “the compulsory imposition of this system will be a disaster, which will set back the cause of food safety by twenty years”.

In this paper, the application of the HACCP system in context of the Commission’s proposals is examined in detail, demonstrating why indeed its compulsory implementation will be a disaster, not only for the food industry but for public health in general.

¹ Press Release: Commission proposes new food safety hygiene rules. European Commission. 17 July 2000.

The HACCP system

Hazard Analysis and Critical Control Points (HACCP) is a management system applicable to food operations, devised to ensure the safe production of food. The system originated as a spin-off from the US manned space programme, triggered by the need to produce “zero-risk” foodstuffs for astronauts. It emerged from a tripartite co-operation between the food manufacturers, Pilsbury - one of the largest in the world - the US Army Natick laboratory and NASA.

At the heart of the system are seven elements which have been adopted by the Commission and which will form the basis of the compulsory scheme. These are:

1. identification of any hazards that must be prevented, eliminated or reduced to acceptable levels;
2. identification of the points in those operations where food hazards may occur;
3. establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;
4. establishing and implementing effective monitoring procedures at critical control points;
5. establishing corrective actions when monitoring indicates that a critical control point is not under control;
6. establishing procedures to verify whether the measures outlined above are working effectively – carried out regularly and whenever the food operation changes in a manner that could adversely affect food safety;
7. establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined above, and to facilitate official control.

For the system to work, food operators must assess each and every one of their food preparation procedures and accurately identify the “hazards” – those aspects of the procedures which have the potential to cause harm, i.e., food poisoning – to the consumer.

Having identified the hazards and the points at which they may occur in each procedure, the operators must identify each “critical point”. These can be defined as: “steps in the system at which a loss of control would lead to an unacceptable health risk and one which will not be remedied later in the system”².

At those critical points, the operators must establish procedures either to prevent hazards occurring (such as in preventing the contamination of food by bacteria); to eliminate them (as in cooking food to destroy bacteria); or to reduce them to acceptable levels (as in pasteurisation, which reduces bacteria to safe levels without necessarily destroying all of them).

Having established these procedures, operators must then establish monitoring procedures to identify whether the correct control procedures have been carried out and, in the event that they have not been, establish further procedures to be implemented in that eventuality. Each time a procedure is changed it must be reassessed, with new procedures devised as necessary.

² Emmett & Bowman. A dictionary of food hygiene. London: Chadwick House Group. 1998.

Each procedure must be documented and detailed records of checks carried out must be kept to demonstrate that the system is being properly implemented and thus to facilitate official controls.

Principled objections

In principle, there is nothing wrong with HACCP. Properly designed and implemented, it is an elegant and effective control system which can confer a high degree of safety in complex, high risk food processing operations. Its particular advantage is that it focuses controls on the “critical control points”, i.e., those points where, should procedures break down, there is a real risk of harm to the consumer. Thus, the key issues are addressed and management effort is concentrated where it is most needed.

If HACCP is an “elegant and effective control system”, however, it would seem perverse, at first sight, to object to its compulsory implementation by the EU Commission. But the objection is not to the system, *per se*. It is to its compulsory implementation and, therefore, its incorporation in the regulatory system. To this there are many objections.

The first is one of principle. In this context, the Commission in its discussion document³ advances the thesis that its “leitmotif” is that “food operators (should) bear full responsibility for the safety of the foods they produce”.

However, in proposing the compulsory application of HACCP, the Commission is going considerably further than creating – or restating - a simple obligation to produce safe food. It is specifying in absolute terms the management system to be used to achieve that end. This represents a considerable increase in the degree of intrusion of the regulatory system in that the law will not only require specific standards to be met - as is the traditional function of the law – it dictates the *means* by which those standards will be met.

The objection here should be self-evident. While it is an acknowledged and acceptable function of a legitimate legislative body to set standards for business operations for the protection of the public, it is considerably less acceptable to set the means by which those standards should be met.

When, as is the case, the Commission is interfering in the conduct of an operation, dictating the management system to be adopted, this is even less acceptable. When it is requiring the adoption of one specific system, which is not the only nor even the best system for all circumstances, this is completely unacceptable.

If this fundamental objection is not enough – and it should be – there are many other practical objections to the compulsory use of HACCP.

Of these, the first and most obvious stems from the objection in principle. This relates to the simple thesis that there is not necessarily a relationship between food safety and the operation of a HACCP system in a food operation. In essence, it is not possible to say that, simply by

³ COM(2000) 438 final. Proposal for a Regulation of the European Parliament and of the Council on the hygiene of foodstuffs, etc. Commission of the European Communities.

virtue of the system being implemented, any particular food operation is necessarily safe. No food safety expert would suggest otherwise⁴.

Equally, it is not possible to affirm that an operation in which the system has been implemented is necessarily as safe as, or safer than, an operation where HACCP is not in place. On the other hand, without HACCP, a commercial food operation can produce consistently safe food.

In other words, the Commission is proposing the compulsory adoption of one particular system of management which may or may not confer food safety in an operation, when there are other systems which may confer similar or even enhanced levels of safety.

Therefore, the Commission is requiring member states to create the new criminal offence of “not implementing HACCP”, giving rise to a situation where the management of an operation, which is in all respects safe, could be prosecuted under food safety legislation. This could happen even where the operation was safer than a similar unit which had implemented HACCP and was deemed compliant. Such a situation cannot be acceptable.

Another fundamental objection is that the Commission itself is requiring the implementation of HACCP as a “risk-based system” on the basis that a greater degree of consumer protection is achieved through such an approach, while minimising burdens on businesses. However, in deciding on legislation, the Commission itself should be risk-driven, requiring legislative measures only where there is good evidence that those measures address real risks in a proportionate manner.

In this the Commission is decidedly lacking. Neither the Commission nor any food poisoning surveillance authority can give any evidence that the absence of, or failures in implementing (properly or at all) HACCP systems, *per se*, are responsible for food poisoning in commercial food production environments. Neither can it affirm that operations which implement full-blown HACCP systems produce a lower level of food poisoning than operations which have not implemented the system. Without such evidence, there is no legitimacy in requiring the adoption of HACCP as specific system to the exclusion of all others.

The effect of compulsion

Developing the themes addressed in the previous sections, it must be emphasised that there are no principled objections to HACCP as a system. The flaw in the Commission’s proposal is to make the system *compulsory*.

HACCP has been at its most successful when it has been voluntarily implemented by a management committed to its principles who, with strong technical support and all the resources necessary, have designed their own systems and implemented them with the

⁴ Talking to a well known and respected food safety consultant, I once asked him what would happen if he inspected an operation and all the systems and procedures were found to be in order, with all the necessary checks made and recorded. Without hesitation, he replied: “It would pass the inspection”. “What would happen”, I asked, “if the operation went down with food poisoning three weeks later?”. “No system can be perfect”, was his response.

wholesale enthusiasm of their staff.

The system adopted by these highly motivated pioneers relies on the development of specific procedures which are rigorously implemented by committed staff. Here, it must be noted that it is the use of these procedures which confers the level of safety, not the documentation. The documentation, including the records kept of the performance of the systems, merely allows independent checking and validation of the system.

Under these precise circumstances, the documentation produced within the system will present an accurate record of its performance and can be used with confidence by monitors to check the adequacy of controls – in theory at least⁵.

However, where HACCP becomes a legislative requirement, the system is introduced in many operations only because becomes a criminal offence not to do so. Many managements, therefore, are not committed to the HACCP principles. They have little or no technical support and minimal resources will be allocated. Staff will be unenthusiastic and even completely ignorant of the rationale for the system, regarding the documentation requirements as an unnecessary burden.

Under these circumstances, the owners and operators of these food businesses – which will probably comprise the majority – will be “going through the motions” in their implementation of HACCP. Many will either copy “hazard analyses” from booklets, pamphlets or instruction leaflets, or employ consultants (the cheaper the better) to do the hazard analyses for them and prepare the accompanying documentation. The result is ritual and uncomprehending implementation, conferring little in the way of improved food safety.

That is the central flaw in the commission’s proposal – its failure to realise that, when adoption of the HACCP system becomes compulsory, the dynamics change completely. It fails to appreciate that, when the system is imposed, rather than adopted, self-enforcement can no longer be relied upon and the adequacy of the system must be assessed by enforcement officials rather than the food business operators. And, as the system relies on documentation, the basis of enforcement becomes the documentation review or “audit”.

In this scenario, the documentation, instead of being a by-product of the system, becomes the central part of it. And since deficiencies in recording – which will be monitored – rather than deficiencies in the actual conduct of proceedings – which will not be detected with the same facility, if at all – can form the basis of criminal charges, managements keen on avoiding prosecution will ensure, above all else, that records are maintained to the standards required by officials.

One butcher – in an industry which is already being required to implement HACCP – described to this author his view of the system in the following terms: “You know as well as I do, you can’t f***ing do it... so you cheat”. He went on, “If anybody tells you they actually

⁵ Even that is debatable. This author visited a “state of the art” cooked meat production factory, which had implemented a full HACCP system, which had been “audited” many times. In one of the production halls, a serious equipment design fault was observed, which posed a significant risk of contamination to the food – a defect which had escaped the attention of a myriad of company and official inspectors.

do it properly, they're f***ing liars”.

On this basis, records can cease to be an accurate reflection of the performance of the system and, since enforcement officials have no means of knowing whether records are accurate or not, they will be presented with the task of first checking the records and then reconciling them with the procedures carried out, to ensure that the one is an accurate reflection of the other and that the procedures are safe.

Even where the managements are enthusiastically committed to the HACCP system, their technical ignorance may reduce the utility of documentation. A devastating example of this was seen in an edition of *Meat Trades Journal*, the weekly news magazine for butchers, in a feature on HACCP. Profiling a well-known butcher, it offered photographs of his HACCP system in operation, illustrating a cooked chicken being partially withdrawn from an oven for temperature checks, in order to determine whether cooking had been completed - the final temperatures being recorded in each case. Closer inspection of the photograph showed the chicken to be tightly trussed, with the probe of an electronic thermometer skewering the breast meat.

No doubt, this procedure met with the approval of the developers of the system - they made no subsequent complaint - and no doubt the butcher in question proudly assembled his worthless records as evidence of the effectiveness of his monitoring system. What, in fact, he was demonstrating was proof of the old adage: a little knowledge is a dangerous thing.

It is, of course, well known to any experienced food safety inspector that the zone of a chicken which responds slowest to the application of heat - given an unstuffed but trussed bird - is the inner thigh, shrouding an area of skin which is most likely to be contaminated. The breast meat, by contrast, responds rapidly to heating. Therefore, it is quite possible to record what appear to be safe temperatures by “probing” the breasts of a chicken, while leaving the inner thighs dangerously undercooked. The best way to check temperatures is to slide the probe between the thigh and the body, into the deepest part of the tissue.

Better still, however, is to roast the chicken untrussed, spreading its legs wide to maximise heat penetration to the inner thighs, commencing roasting with the carcass inverted for half an hour, before turning to complete the cooking. When the skin is uniformly brown and crisp, and the juices run clear, the bird will be well-cooked. There is no need whatsoever to confirm this with a thermometer. In fact, in a normal catering operation - if there is such a thing - what is the point of recording the fact that the chicken was cooked on a piece of paper, for some “auditor” subsequently to check and approve? Is any half-way intelligent chef going to take a chicken out of an oven and serve it, and then mark down on the records that it was undercooked?

Offered a choice between a bird cooked under the “fully documented” HACCP regime described in the *Meat Trades* article, and one cooked by an experienced chef who knows what he was doing - yet declined to record the fact on a scrap of paper - I suspect most people would opt for the latter. Yet the Commission scheme would not allow the latter.

However, if officials are charged with ensuring that the procedures are safe, which they can only do by observation and measurement, independently of the records kept, documentation becomes superfluous. If the management need to keep their own records, so be it. But enforcement officials cannot rely on them. Any enforcement regime which does rely on records generated in-house is fatally flawed. That is the measure of the Commission’s

proposals.

Simplifying the system

Inherent in the promulgation of a compulsory HACCP regime is the need to make the introduction of an inherently complex system as simple as possible. Recognising this need, particularly for SMEs where technical skills are often limited, the Commission is proposing to rely on “industry guides” and other aids in order to “simplify” the system. These are known as “generic guides”. But, far from representing a simplification, they actually complicate and confuse the issue.

The central flaw in “simplified” guides is that they promote the concept of generic “critical points”, ostensibly saving food business operators the task of carrying out their own risk assessments and identifying their own “critical points”. However, by their very nature, generic “critical points” have to cover all contingencies. Therefore, they cannot and do not reflect the actuality of risk within any specific operation. They are the very antithesis of HACCP, rendering the system largely meaningless.

Inevitably, the generic “critical points” will be accompanied by recommendations for controls which, in differing circumstances, may bear little relevance to food safety. Thus one finds, by way of example, an item such as “delivery” becoming a critical point. From experience with current industry guides and literature on HACCP, one then sees in this example a “generic” control which requires operators to ensure that goods come from a “reputable supplier”.

Already, this term “reputable supplier” is coming to mean a supplier who is able (and willing) to supply an increasing volume of paperwork on demand, purporting to testify that risk assessments have been carried out, often on the back of lengthy questionnaires which pose all manner of irrelevant and presumptuous questions. Supply of goods under the “simplified” regime becomes a test of clerical skills rather than a free arrangement between willing supplier and willing purchaser, based on the traditional criteria of quality of product and an acceptable price.

The problem which will be encountered if the Commission’s proposals are put into effect is that this phenomenon is an inevitable consequence of introducing a compulsory scheme. Unable or unwilling to determine, or argue for, realistic controls, small businesses will be prey to the misdirected enthusiasm of enforcement agencies. These will inevitably adopt risk avoidance strategies – not least because they may well be deemed to share the blame for any system inadequacies which give rise to food poisoning. Accordingly, they will seek to maximise rather than minimise the number (and extent) of controls required. To expect otherwise is to live in a fantasy world. The risk of “over-egging” is unavoidable.

Thus, in the context of the example given, while rigorous control of inputs (deliveries) might be highly significant in a cooked meat processing factory, handling hundreds of thousands of poultry carcasses to produce a standardised and safe manufactured product, they will be unnecessary in most (but not all) small operations.

For a small-time caterer buying one or two cases of poultry a week, the concern will probably be focused on the price and - none too infrequently - on the credit terms offered. But – on the basis of current experience – the small business will be required to adopt the same types of controls implemented in the larger operation.

To the purists – and the procedure-bound Commission - this may be seen as an improvement, the problem being that the procedures adopted in small operations might seem primitive. For instance, when cases of poultry arrive in a small restaurant, they might be scooped up by an indifferent kitchen porter, who dumps them unceremoniously on the floor of the cold store, hopefully in the right place. When he has time, a harassed chef will look them over - more to check that the right number has been sent, at something approaching the desired weight. If then, they look roughly like chickens, smell like chickens and are not covered in mould or even more objectionable matter, they will go “in the pot”.

This is the reality of the small catering operation, in which the concern of the food safety specialists will be that some of these birds will be contaminated by salmonella and or campylobacter bacteria.

In practice, the working chef has no means of telling which - if not all - birds are contaminated, and is best advised to work on the assumption that they all are. However, given that the birds are of marketable quality - which can be checked easily and quickly by sight (and a refund demanded if they are not) - it makes not one whit of difference whether they come from a “reputable source” or a local cash and carry. Even if there is any significant difference in salmonella loading between birds from different suppliers - which is unlikely - the actual impact on the safety of the operation would be minimal, assuming that cooking and other critical controls are maintained.

And, although the “generic controls” will be irrelevant, they will still be applied – leading to a greater danger. By insisting on, or accepting, an elaborate panoply of unnecessary checks - or checks with a marginal impact on the safety of an operation - the net effect can be a reduction in the degree of control, and safety.

Instead of focusing on the few things that matter, operators’ time is spread thinly over a wide range of controls, with no apparent prioritisation. The truly “critical” points are treated with the same emphasis as non-critical - and ultimately irrelevant - issues. Not only does this dilute the overall food safety message, it means that the system is either unlikely to be maintained, or will become a ritual. Once again, this is the very antithesis of HACCP.

False security

When first introduced by NASA, the HACCP system was applied to new, custom-built manufacturing premises. They were dedicated to single-line production runs, incorporating the best design and construction features which money could buy. Before production, preparation rooms were disinfected with formalin and sealed. All the equipment, from the knives to the pots, were sterilised, and all production staff wore surgical outfits, including rubber gloves and face masks. Not only the food, but the cost was astronomical.

The point here, is that the “space food” operation already incorporated the virtually every possible precaution, to ensure that the food was produced to the requisite standards. The HACCP system was then imposed as an overlay. In the system which thus emerged, there was no need to state that premises, layout and equipment standards should be maximised. This was assumed to be the case from the very start.

In a variety of existing premises to which systems are now being – or will be - applied, however, designs are often sub-standard or, at least, sub-optimal. All too often, they incorporate production flows where cross-contamination is an inherent feature and which can only be avoided by the application of constant, rigorous controls and continuous, high-level supervision.

In this situation, the application of HACCP can be fraught – and even inappropriate. If operations are taken on “as is”, an acceptable level of safety can only be achieved by applying increasingly complex and convoluted procedures, developing more and more “critical control points” and associated controls. But, as the number of controls increases, the complexity of the systems multiply. A once elegant and simple system becomes ever more fragile and prone to being discarded when an operation is under pressure.

This may be compensated for by devising still tighter supervision, more recording and more documentation - to say nothing of additional staff training - but the implementation of the HACCP system, *per se*, does not address the fundamental problems.

As it was originally devised, therefore, the HACCP system was fundamentally deficient in that it did not recognise this dynamic. It was never designed for that application. Neither does the Commission version of HACCP deal with this deficiency. And this focus on procedural controls *is* dangerous: it can (and does) obscure the need for the more rational approach of designing out problems, either by layout changes or the use of different equipment. The net effect is to impart a false sense of security. Operators (and enforcement officials) believe the processes to be safe, by virtue of the procedural controls implemented.

The myth of “flexibility”

Given the requirement for documentation inherent in the HACCP system, and the specific requirement to demonstrate to regulatory officials that the hazard analysis has been carried out, it will prove necessary to document all the production procedures, for each item produced. This, in itself, presents a considerable administrative burden but more so – proportionately and in absolute terms - for a small restaurant producing 100 or so menu items than for a large cooked meat manufacturer producing maybe a dozen food lines.

But the major handicap of the system – contrary to the Commission’s belief that it affords flexibility - is its inherent inflexibility. Once procedures have been documented, the hazards analysed and the “critical control points” established, these cannot be changed – or new procedures added – without the whole hazard analysis process being undertaken again, in respect of the changed or new item, with the production of a new set of documentation and controls.

This is no problem for the large manufacturer, where the introduction of a new product line might involve the investment of millions of pounds, years of research and development, laboratory testing and piloting, followed by staged introduction under the close supervision of technicians and managers. But it is a problem for the small food producer or a caterer. These are businesses which rely on selling a wide range of products produced in small quantities, with constant changes being made to accommodate consumer demands and preferences – to say nothing of the changes in price and availability of raw materials.

It is, in fact, from this sector that much of the innovation and variety in food production originates, and where flexibility is at a premium. Here, where the conflict will arise is in the

Commission's perception of "flexibility". It sees the shift from prescribed codes, to risk-based controls, as being more flexible, in allowing rules to be devised for each process, attuned to the specific needs of a process. For the small producer, however, having effectively to write a new rule book whenever a new product is to be produced, or a change made to a procedure, with production being prohibited until this process has been completed, is anything but "flexible".

In practical terms, implementation could also lead to manifest absurdities. A restaurant might, for instance, offer a cheese omelette on its menu but a customer might prefer a ham omelette, for which there was no recorded procedure. In theory – and in fact – for a chef then to produce a ham omelette, or any other type of omelette, would be a criminal offence if the Commission has its way.

Application to catering

Another major handicap becomes apparent when attempts are made to apply HACCP to catering. Here, the Commission proposes to transpose a system developed by highly structured, hierarchical organisations – which thrive on procedures and paperwork – to a completely different culture, where the traditional means of communication is oral. In most catering operation, when a chef instructs a junior, he does not issue a works order, or a written procedure. If his subordinate is unfamiliar with a process, the chef will show him how to do it, personally, without a slip of paper in sight.

But there is an even more fundamental handicap in that, in their own ways, the managements of commercial kitchens are also highly structured and hierarchical, but along completely different lines from the manufacturing and research organisations which developed HACCP.

Essentially, the basis of catering management is a well established organisational method known as the *partie* system. In a fully developed system, the kitchen head is the *chef de cuisine* and his deputy is the *sous chef*. Under these will be a number of departments or *parties*, each headed by their own departmental chefs, or *chefs de partie*, each, in turn assisted by their *commis chefs*, the whole making up the "brigade".

The most senior department is headed by the *chef saucier*, who produces all the meat dishes which are not roasted, grilled or deep fried, and all the sauces based on meat stock. Then there is the *chef rotisseur*, who produces the roasts and grilled dishes, the *chef poissonier*, who deals with the fish, and so on, down to the *chef garde manger*, who deals with all the cold foods, both foods which are served cold and those which are subsequently cooked by the other *parties*. Even when the full system is not adopted, the basics will usually be present.

The central feature of this system is that is *product* based, rather than process-orientated, each *partie* being responsible for different foods. Crucially, the structure cuts across any idea of risk-based production, with each chef or department handling both cooked and raw foods – especially the *garde manger* which handles both cooked and raw meats.

Imposition of the HACCP system in turn cuts across the traditional *partie* lines, which means that, if that system is implemented, the kitchen then has imposed on it two, conflicting management systems. This conflict is irreconcilable and, when the pressure is on production, as it always is, the HACCP regime will be suppressed. In short, HACCP cannot survive without fundamental changes in the management system of a kitchen. Furthermore, since most kitchens

are designed to accommodate the *partie* system, fundamental changes in design will also be needed.

This notwithstanding, it is possible to adapt the *partie* system to ensure safe operations, in which context it is a mistake to labour under the impression that the HACCP system can offer unequivocal benefits to a traditional catering businesses. To argue otherwise is to fail completely to understand the nature of the process and the limitations of superimposed, documented systems. More seriously, it demonstrates the fatuity of seeking to impose a management system devised for one industry sector – with its own distinctive culture – on another sector, where the culture is completely different.

Cost implications

What is poorly appreciated – not least by Commission officials - is that the cost of development and implementation of the first HACCP system was in excess of \$10 million. While current costs of implementation in particular operations will be less, the adoption of a full-blown HACCP system is nevertheless going to be expensive – and time consuming.

According to UK government sources⁶, there are 522,374 food business establishments in the UK. The indications are that most major retailers and most large food manufacturers “have generally satisfactory HACCP systems in place” but by far the greatest number of food businesses are SMEs. Most of these, according to the same sources, “will probably have little or no awareness of HACCP systems”. In fact, it is estimated that some 400,000 businesses “will have no documented HACCP system and very little knowledge of how HACCP operates”.

The government thereby estimates that short-term compliance costs for implementation of the Commission’s proposals could be “significant” for SMEs, although it falls short of providing an estimate.

Not least of the costs is in training management and key staff. From experience of current course costings, the charge for a suitable HACCP course will be unlikely to be less than about £300 per trainee, and it can be assumed that an average of two people per establishment will be required to attend. Add wage costs for, typically, an eight day course, and the basic training costs will be in the order of £2,000.

Estimates for the time taken to implement a HACCP system – complete with the documentation – vary widely, but the range may be anything from about 20 hours for a simple system in a retail premises with very little high-risk food, to 2-300 for a medium-sized manufacturing plant, or a restaurant. For those operators who lack the confidence – or the time – to devise their own systems, consultants may be employed. Either way, it is not unrealistic to assume that system implementation costs will average about £2,000.

Additional to that, operators find that they are often required to provide monitoring equipment, such as electronic thermometers, at up to £100 a time, and some are being required to provide data loggers with a desktop computer to process the data. To enable controls identified in the hazard analysis to be implemented, a wide range of work is often required, from provision of

⁶ Initial regulatory impact assessment (Draft). Food Standards Agency. Undated.

extra sinks, colour-coded knives and cutting boards, separate processing equipment, and even structural works. The costs involved here are impossible to determine with any precision, as they may range from £100s to tens of thousands. However, it is not at all unreasonable to estimate that operators will have to find on average at least £1000 for “incidentals” related to HACCP implementation.

On this basis, an average cost of HACCP implementation – and related works – will be £5,000. This amounts to £2 billion costs, for SMEs alone.

That, however, is only the start of a considerable commitment. In order to continue with the system, the documentation will have to be maintained, staff training will have to be updated, and the hazard analyses will have to be reviewed from time to time. Costs here will range from a few hundreds to £15-20,000 a year – the latter involving the employment of staff specifically to maintain the system. Even at a relatively modest average £500 per unit, this still amounts to £200 million per year.

To this must then be added enforcement costs, in which context there can be no doubt that additional costs here will also be “significant”. Even if the total cost per unit is a mere £100 per annum – and it is hard to see how it could be less - this still adds £40 million to the enforcement bill. Taking all these estimates together, the initial costs of implementation will be in the order of £2 billion, with an additional annual cost of £240 million.

Against this, the government has estimated possible savings, arising from the reduction in the burden of food poisoning. Taking illness arising from salmonella and campylobacter, and calculations as to the costs per case, it estimates that these illnesses cost the nation £77,320,000 in 1999. It acknowledges, however, that not all cases of salmonellosis and campylobacter enteritis are foodborne, but no estimate is offered as to the proportion which are actually related to food. In fact, this information is not known.

Nevertheless, it is argued that “the true figure for foodborne illness is higher as there are many other foodborne organisms that cause illness”, which have not been included in the government’s calculation, and there are also other hidden costs, such as the cost of outbreak investigations.

What is not calculated at all is the actual burden of foodborne disease directly attributable to failures in hygiene in SMEs, which would be amenable to prevention by the introduction of HACCP. Assessing this is difficult but it is generally estimated that some 80 percent of food poisoning occur in the home.

Then, much of the campylobacter enteritis is either not foodborne or arises from the sale of raw, contaminated food which will not be affected by the implementation of HACCP – as is the case with salmonellosis. A significant amount of illness attributed to *E. coli* O157 is now known to be transmitted by contact with animals or material soiled by animals – and is therefore not “food poisoning”. And, of course, an amount of food poisoning arises from large retail chains and large food manufacturers.

It is very hard to argue, therefore, that SMEs could be responsible for anything more than ten percent of recorded cases and it requires a leap of faith to believe that all these cases could be eliminated by the implementation of HACCP.

Even allowing for a hundred percent success rate, it would appear that the best the Commission's proposals could achieve would be a saving in the order of £8 million a year. Against that, HACCP implementation would cost SMEs £2 billion, with an ongoing cost to those businesses and the enforcement agencies of £240 million annually. This does not make financial sense.

Enforcement difficulties

Apart from the manifest problems already identified, the implementation of compulsory HACCP presents as many problems for enforcement officials as it does for food business operators. Theirs will be the task of assessing not only whether a HACCP regime is in place, but also whether it has been properly applied.

Officials, therefore, in addition to their traditional role of inspecting premises and observing operations, will be required to scrutinise HACCP documentation – the procedures and the operational records - and assess whether written procedures match the actual procedures adopted. Records will have to be examined for errors and even fraud⁷, whether the documents are in English or not.

These requirements will add considerable complexity to the inspection process, and substantially increase the time needed, to such an extent that it is questionable whether certain types of inadequate implementation of HACCP systems would be detectable in the time allowed for routine regulatory inspections. And even if the time was afforded – which itself would require a massive increase the food safety inspectorate - the level of skill required of inspectors successfully to complete this complex and demanding process far exceeds current levels. Implementation of HACCP, therefore, would impose a considerable training burden on enforcement authorities, for which no provision has yet been made.

According to the Chartered Institute of Environmental Health, environmental health departments – which enforce the bulk of food safety law – are already under-resourced. Even with current staffing levels, they are failing to meet inspection quotas set by the Food Standards Agency. Interestingly, amongst the explanations offered for failing to meet quotas is that EHOs are "...spending more time advising food outlets on HACCP"⁸.

Whatever resource might be allocated, it is readily acknowledged that the nature of HACCP enforcement is significantly different from the traditional inspection. The inspection actually becomes an "audit", requiring a considerable amount of documentation review, to say nothing of the time need to explain the system to managers.

This requirement will inevitably reduce the amount of time which can be spent reviewing the physical standards of premises and the conduct of operations. Yet it has by no means been demonstrated that time spent on auditing documentation will provide a better safeguard than routine "eyeball" inspections. Nor – as previous illustrations have indicated - can it be shown

⁷ A standing joke offered by inspectors reviewing HACCP systems relates to an inspector finding impressively documented procedures, with immaculate process records: last weeks, this weeks.... and next weeks, all written in the same hand, with the same biro.

⁸ CIEH calls for more food staff. Environmental Health News. 21 July 2000.

that a documentation-orientated review, as opposed to the traditional “eyeball” inspection, will necessarily detect more potential (or actual) food safety problems.

Furthermore, as food business operators become aware that inspectors have less time to spend in operational areas, they may allow overall standards to decline. Operators have even been known to increase the amount and complexity of documentation, to increase the amount of time needed to be spent by inspectors on documentation audits, in the certain knowledge that the effect is to reduce the time spent by inspectors watching procedures. These factors could again lead to a reduction in overall food safety.

By way of compensation, it might be argued that the very implementation of HACCP would confer such an increase in the level of safety that a decline in standards, which might otherwise be detected, becomes irrelevant. There may be some merit in this argument, for many of the items normally detected by inspectors relate only to “floors, walls and ceilings” defects, which have very little impact on food safety.

However, any “HACCP effect”, in improving food safety, will only be realised if arrangements are made for effective systems. But the indications are that the resources – and skills – to ensure proper supervision by the regulatory officials will not be in place, and monitoring will be ineffective. In fact, the argument has already been put that monitoring by external assessors cannot be effective.

In any event, it is more than likely that the bulk of HACCP schemes adopted by food operators will simply be “window dressing”, designed to satisfy notional regulatory requirements. Managements will adopt documents and procedures which are deemed to satisfy the regulatory officials, who will be limited by the time they have available to check them. We are in danger of suffering the worst of all possible worlds, where adherence to the bureaucracy becomes more important than the reality of food safety.

Furthermore, the burden of bureaucracy, and its impact, should not be under-rated. Imagine a not-unrealistic situation in a butcher’s shop, where small amounts of meat are cooked. The butcher is a practical man, with a dislike for paperwork not uncommon in the trade. The enforcing officer might notice that his cooking controls are not entirely adequate and there is some risk of cross-contamination. He might instruct him to take more care over the cooking, and to make a few checks. He might also advise him on specific controls to avoid the risk of cross-contamination. Once implemented, the man will have conducted his “risk assessment” and be operating a safe system – without a barrage of paperwork.

Now imagine what will happen if the same man is told he must do a “hazard analysis”, for which purpose he must be sent on an impenetrable course. There, the lecturer - barely familiar with the principles of food safety - tells him he must implement this “HACCP system” and gives him a four-volume manual which purports to tell him what he must do. Back in the unit a few months later, the manuals will be found, unused, on the shelf. If one were to ask the butcher about his HACCP system, he might well tell you that this is far too complicated for him or, with less honesty, he may simply say that he has been too busy to implement such a complicated system. He has not, in fact, been defeated by the system, but by the bureaucracy.

One chief environmental health officer in Scotland estimated that the push for “hazard analysis” – which is HACCP without the documentation - in the bulk of his food premises (mostly SMEs) had set back the cause of hygiene by years. Food traders were struggling

with the concept and inspectors were spending hours trying - and failing - to explain it to them. A fraction of the time, spent on addressing real problems, in simple language, he maintained, would have been much more effective.

Ethnic operations and literacy skills

This situation in SMEs will be further complicated by the presence in the market of a substantial number of “ethnic” operators whose English language skills are poor. Given the current preoccupation of legislators with “equal opportunities” and the avoidance of racial discrimination, it is hard to see how the authorities can avoid permitting HACCP documentation to be produced in languages other than English.

This has significant additional resource implications for enforcement authorities. While English-speaking inspectors can inspect ethnic operations with no familiarity of the languages used in the operations, the same inspectors would not be able to audit documentation produced in those languages. Equally, those inspectors would have considerable difficulty in discussing the arcane technicalities of HACCP with some ethnic operators.

In the real world, away from the political correctness of the race relations industry, ethnic operators have been known to retreat behind “language difficulties” in order to frustrate the attempts by enforcement officials to impose their requirements.

In order to make HACCP work, therefore, enforcement authorities would have to expend considerable resources on recruiting inspectors with the necessary language skills, the training of whom would take several years – assuming they could be prevailed upon to take the courses.

Additionally, if more prosaically, a large number of indigenous food operators have limited English literary skills. In fact, the food trades – being essentially practically orientated - have become a repository for workers of low educational attainment, many of whom perform perfectly adequately even in junior management roles. The implementation of HACCP systems, and the maintenance of the associated documentation, would be entirely beyond the capability of many of these workers⁹. Those unable to cope would either have to be excluded from these trades, or be excluded from management roles which required the higher levels of literacy needed to implement HACCP. Many, in fact, would be dissuaded from working in the food trades altogether, restricting their employment opportunities.

A license for over-zealousness

Central to what passes for thinking in the Commission is the belief that, in some ways, HACCP represents a deregulatory measure. By applying HACCP, the legislative code apparently moves away from prescriptive measures, to risk-based requirements determined on the basis of hazard

⁹ It is doubtful, in fact, whether many of these workers could successfully complete the technical courses required by the enforcement authorities. In Scotland, 70 percent of butchers taking the Intermediate Food Hygiene course – required in the legislation – failed the examination.

analysis. Regulations cease to demand slavish adherence to a fixed code and, in theory, become more flexible as they are geared to avoiding real problems.

That is the theory. In practice, an entirely different dynamic takes over. Where “critical points” are defined, the controls to be applied will be determined by the perception of the hazard and the opinion of the operator as to what is necessary to ensure food safety. The controls which need to be introduced, therefore, become a matter of opinion rather than one of conforming with a specific code.

However, in practice, the controls to be applied will have to be agreed with the enforcement officers who visit the premises, who will have their own opinions. Many will (as experience has shown) seek to impose their opinions, with the apparent force of law, praying in aid the requirement to implement an effective HACCP system. Controls which previously were not mandatory can be imposed by this means.

With a prescriptive code, operators at least have defences against over-zealousness. They can refer to the code and check whether the measures being demanded by enforcement officers are mandatory. If they are not, the operator can refuse to adopt them.

This safeguard ceases to have force once the HACCP system becomes compulsory. A failure (or refusal) to adopt specific controls demanded by an enforcement officer – whether they are included in a code or not – can be deemed to be evidence of failure properly to implement HACCP. Legal sanctions can then be applied in respect of that failure of implementation, notwithstanding that there is no specific (or any) statutory requirement in respect of the particular measure required.

HACCP, therefore, releases enforcement officers from the obligation to restrict their requirements to items specified in a statutory code and allows opinion-led requirements to be enforced. In effect, compulsory HACCP becomes a license for over-zealousness.

Judicial implications

At the heart of the HACCP system is an unavoidable degree of subjectivity. The nature and importance of various hazards, the number of “critical control points”, the types and number of controls required, and the extent and format of documentation, all require judgement.

Where judgement is required, it is inevitable that even (or especially) experts will have differing views of what, in any particular situation, constitutes an adequate HACCP system. Equally, different enforcement officials may – and almost certainly will - have different views. Therefore, it is also highly likely that, on occasions, food business operators will have disagreements with their enforcement officials.

Since the Commission is proposing that the HACCP system becomes a legal requirement, failure to implement what, in the opinion of the enforcement official, is an adequate system, constitutes grounds for criminal charges. If proved, these could lead to a conviction for a criminal offence.

In the UK, the arbiter of whether a difference of opinion between a food business operator and an enforcement official constitutes a criminal offence will, in the first instance, be the Magistrates. Whether a lay panel, or stipendiaries, the question must be raised as to whether

either are capable of the highly technical function of assessing the adequacy of HACCP systems. It must be questionable, to say the very least, whether a non-technical judiciary can deal satisfactorily with what can be arcane arguments about a very technical system.

However, that could be the least of the problems. Bearing in mind that, in criminal proceedings, the burden of proof rests with the prosecution, and a defended case may involve arguments between experts, the dictum of “beyond reasonable doubt” will apply in favour of the defence. As a result, it will almost certainly be the case that the criteria adopted by the judiciary for judging the acceptance of a HACCP system will differ from – and be less rigorous than – the strict technical criteria required to ensure that the system works effectively.

In the nature of things, therefore, there is a very real danger that compliance with HACCP requirements will end up being geared to legally enforceable standards and not to the necessary technical standards which will ensure that the HACCP system actually confers a reasonable standard of safety. If that becomes the case, the value of mandatory HACCP implementation will be highly questionable.

Due diligence

Also in the judicial context, the implementation of HACCP systems will provide *de facto* evidence of any food business operation’s “due diligence” measures. This will create problems for enforcement officers, in that their auditing of any particular system – and subsequent absence of adverse comment – will be taken as their approval of that system, even where formal approval mechanisms are not in place. This “approval” will effectively validate the system, making it very difficult for prosecutions to succeed against operations in which subsequently food poisoning outbreaks arise.

Major operations, and consultants, will undoubtedly be aware of the possibilities which HACCP affords in this respect, and will tend to devise systems which maximise the success of a “due diligence” defence. Since the proof tends to rely on the documentary trail, emphasis will inevitably be on continuity of paperwork and recording, rather than on ensuring that systems are fully functional.

Already it is very difficult for enforcement authorities to mount successful prosecutions against food business operators, in the event of a food poisoning outbreak¹⁰. In that deterrence is an important mechanism in the maintenance of standards, any measure which makes it even more difficult to succeed will have an effect on overall food safety standards. Operators will quickly learn – if they have not already – that, as long as their paperwork is maintained, their chances of being convicted for food hygiene offences is considerably reduced. The actual standard of safety will be of less importance.

In actuality, therefore, with greater involvement by the regulatory authorities in vetting systems, the food business operator actually takes *less* responsibility. If an approved system fails, the enforcement officials take part of the blame.

¹⁰ This author has recent personal experience of four food businesses operators charged with offences relating to food poisoning outbreaks, all of whom have mounted successful defences and have been either acquitted or the trials have been abandoned.

Furthermore, this dynamic has profound implications on the investigation of food poisoning, a task which is also undertaken by enforcement officials. In determining causation, there will be a natural – and virtually unavoidable – bias, whereby investigators will seek explanations which do not incriminate themselves or their colleagues, where they may have inadvertently approved unsound procedures.

Alternative strategies

The difficulty for any critic evaluating the Commission's proposal for compulsory HACCP is the concept of carrying out a risk assessment – on which the HACCP system is based - is ultimately sound. Furthermore, in many instances, when products and processes are changed, risk assessment is a very necessary safeguard, the lack of which has been demonstrated to have been a significant causal factor in a large number of food poisoning outbreaks.

The utility of risk assessment is clearly evident from the 1989 botulism outbreak in the UK, where the implicated product was identified as hazelnut yoghurt. Some 16 people were affected, and the contamination was traced to canned hazelnut purée produced by Youngs Foods, a manufacturer in Folkestone.

Effectively, the problem had been that the manufacturer, more used to producing high acid fruit purées, had employed the same process to make hazelnut purée, a low-acid product presenting a completely different order of risk. Had a full risk assessment been carried out before the product had been made commercially, and appropriate steps been taken to modify the processing regime, the outbreak could have been avoided.

This notwithstanding, risk assessment is not necessarily effective in identifying less obvious risks and, in some cases, can produce a contrary effect, where the analysis is flawed.

For instance, there was a salmonellosis outbreak reported in February 1988, involving “Pepperami” salami sticks imported by Matteson Walls from Germany. The product was contaminated by *S. typhimurium* DT 124 and eventually affected 101 people. Investigators subsequently acknowledged that an important contributory factor in the outbreak was, perversely, the *refrigeration* of the product by UK retailers. Being an uncooked, fermented product, the salami-making process relied for its safety on the fermentation process at ambient temperatures. Refrigeration arrested the process and actually preserved entrained pathogens¹¹.

Salami-making is of course a traditional method of preserving meat without refrigeration. As such, it is highly successful. The product is rarely associated with food poisoning. But, on the basis of a flawed risk assessment, the product had been refrigerated in the mistaken belief that this would improve its safety. After the event, the German exporters took to keeping the product for a further six weeks at ambient, before it was considered safe to export to the UK where it would be refrigerated (unpublished data).

¹¹ Cowden JM, O'Mahony M, Bartlett CLR, *et al* (1989) A national outbreak of *Salmonella typhimurium* DT 124 caused by contaminated salami sticks. *Epidemiology and Infection*; 103: 219-225.

Even if “risk assessment” is a generally sound and necessary stratagem in most circumstances, however – and especially in “high risk” operations where there are known problems and the consequences of failure are potentially extreme (such as in canning) – this does not mean that it is necessary in all circumstances, in all operations in respect of every single food and procedure – much less that every risk assessment should be documented.

Furthermore, any comprehensive review of food poisoning outbreak reports will readily indicate that the majority of outbreaks are caused by a limited number of problems, which constantly recur. Arguably, focusing on these specific problems will have the greatest effect in reducing food poisoning, while imposing the minimum of burdens on food businesses. Certainly, this has been the general tenor of traditional – and current – control strategies, and there is no evidence to indicate that the principle is flawed.

Nevertheless, the history of food poisoning is punctuated with the accounts of the emergence of novel phenomena, where risks have had to be reassessed. The emergence of *Listeria monocytogenes* in cheese and patés is but one example, another being the emergence of *E. coli* O157 in beefburgers and cooked meats.

Another of these phenomena occurred in the late 1980s and subsequently, when the bulk of the food poisoning outbreak investigation reports published in the UK involved egg-based foods and allegations of the use of contaminated materials (i.e., “infected” eggs). Catering premises, small bakeries and retail sandwich shops were the locations most often implicated.

Although the primary “cause” was often attributed to the prevalence of eggs infected with *Salmonella enteritidis* in the supply chain, by no means all of the “egg associated” outbreaks involved this causal organism¹². But what was common to the larger number of these reports was the involvement of a single product, or its derivatives - home-made mayonnaise produced from fresh shell-eggs¹³.

In this context, while it has long been recognised that home-made mayonnaise is a problematical food, mayonnaise-associated outbreaks in this country, and in the United States, remained rare until the mid-1980s, despite the cyclical appearance of so-called “invasive” salmonellas which had the capability to infect eggs. Only one such outbreak has been identified between 1945 and 1985, from a review of literature describing over 2,000 outbreaks.

An explanation for the paucity of these outbreaks (in the UK, at least) came from Betty Hobbs, then Director of the Food Hygiene Laboratory, Colindale, who wrote in 1974 that:

¹² Many, for instances involved phage variants of *Salmonella typhimurium*.

¹³ Agriculture Committee (1989b), Session 1988-89, First Report, Salmonella in Eggs, Vol II, Minutes of evidence and appendices. London: HMSO.

“Some countries like a bland mayonnaise with a pH of 5 to 7; others, such as the UK, prefer a sharp flavour and add vinegar or lemon juice until the pH is approximately 3 to 4.5 and the growth of pathogens repressed...”¹⁴.

However, towards the mid-1980s there is some evidence that home-made product began to be produced to high pH recipes. One factor may have been the dominance of the prestige *novelle cuisine* movement which swept the restaurants of the nation during that period, fostering the use of a blander product to avoid swamping the subtle flavours produced in this style of cooking. The trend having been set by the prestige sector of the market, bland mayonnaise seemed to have become fashionable in most of its applications. Extension of the transatlantic habit of serving side-salads with restaurant meals, and the growth of sandwich bars and fast-food operations, with their extensive use of mayonnaise, may have contributed to this trend¹⁵.

The epidemiological consequences of these changes were demonstrable in England in 1985 when, during July/August in the City of London, 141 people were affected by *S. enteritidis* PT8 food-poisoning after consumption of egg mayonnaise sandwiches (unpublished data). Investigators remarked that a batch of mayonnaise produced after the incident was:

“...found to be rather less acid than is desirable to suppress bacterial growth”.

Then, by the end of 1988, home-made mayonnaise had been implicated in 16 food-poisoning outbreaks, accounting for 593 reported cases, and more continued to be reported. Significantly, of the 1988 outbreaks, three phage types of Typhimurium were reported and two of the outbreaks involved *Staphylococcus aureus*, indicating that the problem was of much wider significance than “infected eggs”.

While specific inferences drawn as to causation centred mainly on the emergence of invasive salmonellas in raw shell-eggs - the true significance of the events was that a common recipe had been changed, turning a low-risk product into one of exceptionally high-risk. To accommodate a low-acid product which may well contain small numbers of salmonellas, or which is prone to contamination during making, exceptional environmental hygiene is required, together with rigorous batch segregation and good temperature control. This contrasts with the high acid product which can be kept safely at ambient, and which has an active biocidal capability at room temperature, given sufficient length of storage.

In this context, any change of recipe should have been preceded by a comprehensive risk assessment, with substantive improvements in procedures where necessary. In many cases, it is clear that this was not done, but it was not done on a national – and even international - scale.

Thus, the point to emerge in the context of the Commission’s proposals is that, had an accurate and timely “risk assessment” been undertaken by the surveillance authorities, on the basis of epidemiological data, and promulgated nationally, the effect of such intervention

¹⁴ Hobbs B C (1974), *Food Poisoning and Food Hygiene* (3rd edn). Edward Arnold: London, pp 63.

¹⁵ North R A E (1995) *The quality of public sector food poisoning surveillance in England & Wales* (PhD thesis). Leeds Metropolitan University.

could have been significant. It could easily have been as effective, if not more so, than will probably be the wholesale introduction of HACCP.

But the more telling point is that, without surveillance-led intervention, new threats will not necessarily be recognised and the risk-assessments carried out in the context of HACCP will be to little avail. The question to be addressed, therefore, is whether the adoption of a surveillance-led strategy could or should be seen as an alternative (or a supplement) to the Commission's proposals.

But what seems to be the case is that the Commission – far from considering the relative merits of alternative strategies – has not even considered any alternatives.

Inspection-based controls

Another valid alternative to the Commission's proposals is the use of expert inspection as part of the control regime, employing either or both public sector or private inspectors. Traditionally, local authority inspectors have routinely inspected food premises to determine food poisoning risks, and many companies – including most of the major retailers – have employed their own inspectors for like purposes, with considerable success.

In reviewing this option, it nevertheless has been frequently acknowledged – mainly as a result of the activities of inspectors prior to the John Barr *E. coli* O157 outbreak - that food hygiene inspections (particularly those carried out by public-sector inspectors) are often deficient. Visiting inspectors have failed to identify obvious dangers in operations which, had they been remedied in good time, would have prevented a food poisoning outbreak. It is certainly the case that, had the inspections of John Barr's premises been more effective, the outbreak would have been prevented.

To that extent, while the compulsory implementation of HACCP is seen as a means of improving food safety, the Barr outbreak provides evidence that properly conducted inspections have the potential to achieve a result – specifically in terms of preventing food poisoning from commercial premises – without compulsory HACCP being adopted¹⁶.

However, while at this stage there is no conclusive evidence to suggest that a more focused and effective inspection regime would have the same or better effect than widespread application of HACCP, there is some evidence to support a thesis that – even if HACCP was implemented universally – the application of HACCP principles to the inspection regime would not prevent all outbreaks.

Illustrating this thesis, one can refer to a salmonella outbreak in July 1990, in a South Wales hospital. It affected 101 patients - of whom one died - and nine members of staff. The food vehicle identified was beef rissoles which had been deep-fried in a bratt pan. The subsequent (unpublished) report revealed that the local EHO had taken an active part in the management of the catering operation. He had assisted in setting up hygiene systems and had trained all the

¹⁶ Arguably, had effective inspection been guided by good surveillance data, the emergence of *E. coli* O157 in cooked meats would have come as no surprise. In that context, the Barr outbreak was as much a failure of the surveillance system as it was the inspection process. For an exploration of this issue, see Appendix 1.

staff. However, what he did not appear to understand, when he investigated the outbreak, was that the use of a bratt pan for deep frying is unsafe.

This equipment, then relatively new to catering premises - and still to be found only in the larger units - is a tiltable, shallow pan, with typical dimensions of 3 x 3.5 ft. The pan is constructed with a heavy, cast-iron base, usually rectangular, the whole assembly mounted on pivots supported by a sturdy frame. Pans can be gas or (more usually) electrically heated. They are designed for shallow frying, braising or boiling, but are not intended for deep frying. Thermostat controls are not sufficiently accurate, the heating elements are not correctly positioned for heating large masses of oil and temperature recovery is too slow and erratic. When thus used for deep frying, considerable variations in oil temperatures can be experienced, leaving both hot and cool spots. Uniform cooking is impossible.

Analysis of the South Wales outbreak report indicated that the most significant causal factor in the outbreak was the use of this equipment, resulting in too high an oil temperature in certain parts of the equipment. The result was that surface cooking occurred without the body of the rissoles being fully heated¹⁷.

Amongst other things, this aspect underscores the need for inspectors to be knowledgeable about the role - and limitations - of certain equipment, and highlights the dangers which can arise if the technical knowledge of inspectors is deficient. But more importantly, the whole incident underlines the limitations of the HACCP approach.

Take a hypothetical scenario where rissoles are not infrequently on the menu of an institution. Such products would tend to be cooked in a deep fryer and, in a HACCP regime, a procedure would be written for the use of this equipment with this product. No procedure would be written for cooking the product in a bratt pan, as this equipment would not be authorised for such use.

Developing this scenario, it is then possible to postulate a situation in which the deep fryer was either out of action or unavailable at the time when rissoles required to be cooked. An enterprising but ill-informed member of staff - with management assent - might then decide to use the bratt pan. Unaware of the dangers, the process goes ahead and a food poisoning outbreak arises.

In a properly devised and monitored HACCP regime, the use of the alternative equipment would not be permitted unless a procedure had been written, which - in the hypothetical scenario - it would not have been. But, in the real world, where equipment does break down and all manner of things go wrong, the production imperative is dominant. Pressures are such that improvisation is an essential part of any operation. Can it be imagined that the hospital management would be satisfied the “excuse” of equipment breakdown, as an explanation for several hundred patients not being fed? The temptation to use alternative equipment would be very strong indeed¹⁸.

¹⁷ North, R A E. *op cit*.

¹⁸ HACCP is very often extended in food manufacturing to cover foreign object control. In one plant, observed by this author – where a highly sophisticated HACCP regime was in place – glass was totally prohibited from the lines where plastic bottles were being filled. Then a major supermarket customer demanded a change from plastic to glass bottles on one of the lines. This breached the “no-glass” policy in the area so the machine in question was

Prior to the outbreak, however, an inspector might have been satisfied that the HACCP system was entirely adequate, and procedures were in place. A documentation check might have revealed that all menu items - even those not seen in the course of preparation - had procedures written for them. Under the HACCP doctrine proposed by the Commission, the operation would pass the inspection and be deemed satisfactory.

Under this regime, when an inspector visited the kitchen and saw a bratt pan, his checks would be limited to the procedures for the items known to be cooked in the equipment. However, with a knowledge of its potential for misuse, he might additionally, question the staff to ascertain whether they understand the limitations of the equipment. He could also check with the management, as to whether they understand the dangers of misuse and, if he found that the understanding was not good, he could remind (or inform) them of the potential dangers. But a HACCP-based inspection would not involve any of this. Furthermore, after auditing the HACCP documentation, it is unlikely that an inspector would have the time to explore hypothetical risks.

However, the fundamental truism of food poisoning causation is that it may not be the procedure which is seen - or authorised - which causes the damage. The danger will be caused by the procedure which should not be used. An inspection regime which relies solely on HACCP principles would not pick this up. An inspection based on the use of traditional skills rather than documentation – and which sought to predict possible system failures - might have a better chance of so doing (given that training can be improved).

Above all else, therefore, this example identifies the utility of carrying out inspections on the basis of a knowledge of food poisoning causation, whereby the inspector should seek to identify those aspects of an operation where failures might give rise to an outbreak.

Food poisoning causation

In this context, it may well be that the explanations offered by various workers as to the causes of food poisoning, such as failures in temperature control and cross-contamination, do not adequately represent the true causes, thus leading inspectors to focus on the wrong things or to take a superficial view of the effectiveness of control systems. A more profound understanding of causation indicates that these biological or “mechanistic” explanations are the symptoms of failure, the real problems (or underlying causes) being the failures of managements to maintain safe systems. Thus, the specific faults identified by most workers are only the last in chains of events (or omissions) which led to the outbreaks - the “proximate” causes.

Thus, if effective control of food poisoning in commercial environments is to rely (to an extent) on an appreciation of causal factors, then the determination of the factors in terms of

encased in plastic screens by way of containment. However, the new glass containers did not behave the same way as their plastic predecessors so the line kept jamming. To maintain production, management had the screens thrown open and positioned staff along the line to clear jams as they occurred – in clear breach of their own HACCP policy. Anyone who believes a conflict between production and a HACCP policy is always going to be resolved in support of the policy is exhibiting a child-like naivete.

the last or “proximate” causes provides little information on which managements can rely to develop preventative models. Rather than being expressed in terms of essentially biological or mechanistic causation, the actual causes need to be expressed in management terms, identifying the specific (and general) management failures responsible.

This thesis can be well demonstrated by reference to an actual outbreak investigated by this author. It involved cold roast beef prepared for a luncheon party at a medium-sized hotel. Investigation of the circumstances revealed that the beef had been cooked the night before and, according to the chef, there had been nothing particularly untoward about the preparation. As is so often the case, there seemed no good reason why the outbreak should have happened.

However, on further investigation, it transpired that the chef had left work earlier than he had claimed. During a prolonged and tense interview, he finally admitted that, on the night in question, the oven he had intended to use to roast the beef had broken down. Being a keen and dedicated servant of the company, he had been determined not to disappoint his customers – or the hotel management – and had packed the raw joint in a cardboard box, taken it home and cooked it in his own, domestic oven. He had then repackaged the cooked joint in the same box and returned it to the hotel, whence it was finally refrigerated – for a short time – prior to it being sliced and served.

The proximate causes of the outbreak thus became clear: cross-contamination of the cooked meat followed by inadequate cooling and its retention for some time at temperatures at which bacteria could multiply. It could also have been maintained that the chef had shown lamentable ignorance of basic hygiene principles and, therefore, that inadequate training had been a contributory factor. Had the outbreak been officially reported, the causal factors would undoubtedly have been expressed in mechanistic terms, identifying cross-contamination and temperature control failure. A view might also have been expressed that hygiene training was desirable. But readers would have been little the wiser as to the true cause(s) of the outbreak.

For instance, a view that the chef might have been inadequately trained, while attractive, would have been difficult to sustain. He was by no means untutored in hygiene theory and practice, and was clearly aware of what he had done. He knew it to be wrong. But there was a more pressing imperative – the urgent need to deliver the goods, a driving force which has spawned many an outbreak.

Looking beyond the simple explanations, therefore, more profound issues become evident. The crucial factor in the outbreak was the breakdown of the oven. But, in the nature of any process which relies on equipment for its completion, it is a matter of inevitability that, sooner or later, there is going to be an equipment failure¹⁹.

In any sound operation, that fact is recognised. Built into the system is an element of redundancy, so that the failure of any single unit is not critical. Therefore, it is germane to ask whether the operation itself was sound in that the failure of a single piece of equipment

¹⁹ This is often cited as “sod’s law”, or “Murphy’s law” – anything that can go wrong, will go wrong, with the rider that, when it does go wrong, it will do so at the least convenient time.

degraded the capacity of the unit to such an extent that the chef was driven to seeking such a catastrophic alternative. Should there not have been a back-up oven, to provide for the eventuality of a failure? Alternatively, should there not have been a maintenance contract, with an emergency, 24 hour call-out option?

Lacking these, there were other possibilities. In the area, there were other hotels and, in the industry, it is common practice to have reciprocal arrangements, even with competitors, to deal with overbooking, so that late-arriving guests can be redirected to alternative accommodation when their rooms have been sold. In the event of equipment failure, it is by no means fanciful to suggest that similar reciprocal arrangements should exist, so that a chef in difficulty could use the equipment in a neighbouring hotel. Alternatively, there was the possibility of buying-in pre-cooked meat the next day, or even substituting another meat.

What all this demonstrates is that, at the hotel in question, there was lacking either equipment redundancy or a coherent contingency plan, either of which provision could have prevented the outbreak. There was possibly another failure in that the system was either so inflexible – or so judgmental – that the chef felt he could not call on the unit management to assist him in resolving a problem.

The point here, of course, is that a HACCP regime would not have prevented the outbreak in that, confronted with the production imperative, the chef would wilfully have ignored the written protocols. It is extremely doubtful, however, whether the lack of a contingency arrangements would have invalidated any HACCP plan offered to the enforcement authorities, yet the provision of back-up equipment would have prevented this outbreak – with or without a HACCP system being in place.

In this general context, this author's own research has shown that the primary causes of food poisoning can be expressed in terms of a number of distinct management failures. After an evaluation of the records of some 2,000 outbreak reports, the ten most frequent failures detected were as follows:

1. Failure to establish safe procedures for all high risk operations and failures in checking whether they were carried out consistently.
2. Failure to carry out risk assessments before making changes to any ingredients, processes or recipes, and implement any new safety requirements identified.
3. Failure to make alternative arrangements (contingency planning) for the production, storage and/or delivery of high risk foods, in the event of breakdowns, crises or unexpected changes
4. The use of management systems or structures which penalised staff (financially or operationally) for maintaining good hygiene standards.
5. Failure to convey information on practices and hazards people who had the authority to deal with these problems, and failure to pass back information on hazards down the chain.
6. Failure to ensure that systems and processes were regularly reviewed by persons who were fully competent to recognise hazards and report on them.

7. Failure to investigate, rapidly and fully, food safety incidents (food poisoning, etc.), the failure properly to evaluate the findings and ensure that any changes needed were fully implemented.
8. Failure to eliminate conflicts between “best practice” and actual working practices, whether arising from unit design or management/commercial requirements.
9. Deliberate or commercially-driven misuse of equipment or premises, and/or allowing (or requiring) production levels over and above the safe capacity of the operation.
10. Requiring staff to conduct operations without the means, knowledge and/or the resources to carry out instructions on good practice.

Analysing these failures in the HACCP context, it is true to say that a number of them would be identified and mitigated if HACCP systems were properly implemented in all premises. Needless to say, those failures would not be addressed if the HACCP implementation was in some way defective, while they would equally have been mitigated by an effective “risk assessment” without resort to full-blow HACCP.

However, it is also true to say that the majority of failures would not be addressed by the HACCP system, or represent management faults which could only be detected by the skilled application of conventional inspection techniques, unrelated to HACCP auditing procedures. On this basis, risk-driven inspection might well be better focused on detecting and dealing with the issues most likely to cause food poisoning, rather than simply verifying that HACCP systems are in-place.

Here there is an important distinction in the relative utility of inspection regimes. A unit management can very easily “put on a show” to demonstrate that a HACCP system has been implemented. However, that very demonstration can serve conceal underlying management weaknesses which can only be detected by more careful probing of the management ethos.

Furthermore, management awareness of “critical points” will lead them to ensure that specific defects which may give rise to food poisoning outbreaks as “proximate” causes, are not present when “auditors” are on-site. But these, by their very nature, are by their nature transitory and are difficult to detect during routine inspections²⁰. By contrast, underlying management deficiencies are often of a long-standing nature and can be detected (and addressed) prior to the event.

In any event, official control systems would not be adequate if they were confined solely to auditing HACCP. However, given the resources which would be consumed by this task (and

²⁰ Such defects can even be difficult to identify when they are present. In 1981, an outbreak of salmonellosis occurred during the European Summit conference at Maastricht in late March. About 700 of 1200 people exposed fell ill, with the food vehicle being attributed to a “salad base” used for snacks and cold buffets. The same firm was to cater for a family dinner and cold buffet shortly afterwards so, as a precaution, the preparations were supervised by an inspector from the Food Inspection Service yet, despite this, 31 people fell ill with the same type of salmonella.

the resources required to carry out a more probing inspection), it is hard to see how inspectors would find the time to do anything else.

Hygiene by design

Another option which the Commission could consider as alternative to – or improvement on – HACCP is the intelligent use of design and engineering controls, within the context of existing (i.e., conventional) management structures.

Within the framework of sound management – especially in catering – it is eminently possible (and desirable) to design and equip an operation with hygiene in mind, to such an extent that it is possible to operate with a minimum of formal procedures (and minimal record-keeping) while imparting a high level of safety. There is no compelling need to resort to the HACCP system.

A good example - which typifies the role of design in ensuring food safety - comes from a hotel chain where it was the practice throughout the group to produce in the kitchens (organised and managed on modified *partie* lines) extensive midday buffets comprising a large range of cooked, sliced meats.

Every morning, each chef responsible for buffet preparation would draw from the main (and only) cold store a number of uncut meat joints, to take to his work station at the other end of the kitchen. There, he would slice the meats and present them on platters. This involved several hours of work, during which the meats were exposed to ambient temperatures, presenting an unacceptable risk of bacterial multiplication.

To minimise the risk, one option would have been to require each of the workers to take the joints out one at a time, to deal with each and to return the sliced and the unused meat to the main cold store, before taking out another joint. Under a rigid HACCP system, that would have been the essence of the written procedure, possibly also incorporating formal checks - with records kept of the temperatures of meats in and out of the cold stores.

Such a regime, however, would have involved a considerable amount of extra walking and would be thus have been enforceable only with difficulty - not least because the extra time taken would have delayed the completion of the buffet. In fact, it would not have been enforceable. In the time available, the operation could not have been completed.

The answer was to provide in each hotel kitchen a cabinet refrigerator at the workstation - although the final solution was more imaginative. The amount of workspace was halved, so that each worker had room only to deal with one joint at a time. Since the most convenient option (in fact, the only option) was then to store the other joints - and completed work - in the cabinet refrigerator, temperature control was maintained by design - rather than by management intervention. As to a written procedure, this was superfluous. There was only one way the job, physically, could be done. And that was the right way.

Illustrating the fragility of the Commission's proposals, enforcement agencies would be required to accept a HACCP-based regime which involved the multiple journeys to the cold store, as long as it was accompanied by a written procedure. In the manner of things, there would undoubtedly be assiduous compliance when it was known that an "auditor" was on the premises.

Yet the regime would be inherently unsafe. Should the alternative regime adopted - but without formal monitoring and documentation - it would not conform with the Commission's idea of safe operation. Indeed, such an alternative approach to food safety, the Commission plans to make a criminal offence. This cannot be right.

Discussion and conclusions

Central to the Commission's proposals for the compulsory introduction of HACCP is a major intellectual flaw, which is easy to identify. Essentially, the Commission has looked at a food safety control system, enthusiastically pioneered by leading firms and institutions which have been dedicated to the production of safe food, and sought to adopt it. In so doing, it has failed completely to understand that the dynamics of a voluntary system are wholly different from those of a system which is compulsorily introduced.

Even if the compulsory system was workable, however – and a number of good reasons have been given as to why it cannot be – the Commission's proposal would still be misplaced. Simply put, there are a number of management systems and control strategies available, most of which, most of the time, are implemented to such good effect that food safety is maintained. To impose a single system, without recognising the validity of alternatives – without any evidence that its effects would necessarily be beneficial – cannot be justified.

Furthermore, it should be constantly borne in mind that the Commission is not dealing in abstracts. The effect of its compulsion will be to make the failure to introduce what – in many operations – is an alien system of management a criminal offence, punishable by fines and possible imprisonment. The Commission should be very sure of its ground before embarking on such a course of action and, not least in the interest of “transparency”, it should have made its grounds – i.e., the evidence of need and the evidence of utility – very clear indeed. It has not.

In fact, all the Commission can offer by way of justification for its proposal is that it will “...bring Community legislation into line with the principles of food hygiene laid down by the Codex Alimentarius”. For such a profound – and expensive change - this simply is not good enough. Nor is the bland – yet unsupported - assertion that “the correct application of the system will increase consumer protection”²¹.

Nevertheless, it is entirely predictable that a bureaucratic organisation such as the Commission – which lives and dies by its paperwork – should seek a bureaucratic solution to an intensely practical problem like enhancing food safety. It likes paper-based controls because these are amenable to “official control”.

Dealt with as a practical problem, however, the approach might be entirely different. To assess the level of food safety in a business requires a great deal of skill, gathering evidence from very often subtle clues as to the nature and performance of the operation. Two very similar operations, with apparently identical procedures and standards of record-keeping, can present very different orders of risk. Furthermore, an operation with immaculate paperwork can present a considerably greater risk than one which fails to keep records of routine operational details.

²¹ COM(2000) 438 final. *op cit*.

Inevitably, assessing the safety of an operation – rather than the clerical skills of its management - relies on the skill and integrity of the inspector. It defies standardisation. Essentially, the food safety monitoring system will rely on trusting the judgement of the officials employed in it, on their professionalism and competence.

Immediately, it can be seen that such a reliance would be an anathema to the Commission. That would require it to take into account intangibles, which could not easily be measured. How much more simple it is – and how much more secure – for it to lay down bureaucratic procedures and a form of recording which it can then physically measure. But for that to work, the Commission has to believe that its procedures are a measure of safety – and the records are an accurate reflection of it. That they are not is something which the Commission evidently cannot countenance.

Interestingly, the one thing that the Commission does not address is the competence or training of enforcement officials, other than veterinary auxiliaries employed in slaughterhouses. It lays down no standards for inspection procedures, for the monitoring of inspections, or the methodology to be adopted. Instead, it relies on its own inspectors of the Food and Veterinary Office (FVO), the majority of whom have no formal training in inspection techniques and little enforcement experience. And, in the context of slaughterhouse and meat cutting plants, it insists on the “competent authority” in the UK employing veterinary officials who have no formal qualifications in food law enforcement, inspection techniques or food safety monitoring - many of whom are demonstrably incompetent.

If the Commission was really serious about improving food safety, it should address these central problems, although it is hard to see how an EU-wide protocol could be useful. Effective inspection (and enforcement) techniques rely greatly on the understanding of the psychology of those inspected, which is heavily influenced by cultural aspects. What would be effective in one culture, would not necessarily apply elsewhere.

More importantly, the Commission should encourage the identification (and better understanding) of causes of food poisoning in commercial premises and design the regulatory and supervisory systems accordingly. Instead, it is proposing to make mandatory a management system which may or may not have an effect in improving food safety, the precise effect of which is entirely unproven and which, in many operations, is unlikely to work.

Furthermore, it was only in 1993 that the Commission promulgated, then, a new directive on food safety which, in some member states, has yet to be adopted and, in all member states, has yet to be fully implemented. During the subsequent period, food poisoning throughout Europe – with some exceptions – has declined dramatically, to the extent that food safety is by no means the crisis issue that it once was.

Also it was during that period that it emerged, certainly in the UK, that inspection procedures by enforcement officials have been flawed, and in many instances are inadequate. It also emerged that competence is a major issue, and that training in inspection techniques is deficient.

Given just these factors, it seems hardly appropriate for the Commission to be introducing

new requirements, the effects of which are unproven, on the back of law which has yet fully to take effect and which may prove entirely adequate, providing enforcement systems can be improved.

As to the costs, it is questionable as to whether the Commission should be allowed to ignore the broader question of whether any such increased expenditure is justified, in comparison with the expected result²² and the effects that similar expenditure might have elsewhere (say, in reducing the 5,000 or so deaths per annum arising from hospital infection). Questions such as these should also be addressed in the context of assessing the merits of the Commission's proposals. The Commission should be required to ascertain whether similar or greater improvements in food safety could be achieved with less expenditure.

In this context, the Commission itself maintains that "the general implementation of the hazards analysis critical control points system which, *together with the application of good hygiene practice* (this author's italics), should reinforce the responsibility of food operators"²³. What is has evidently not countenanced is the possibility that, in many operations, the application of good hygiene practice alone could achieve the necessary result.

Arguably, only if it can be demonstrated that the compulsory introduction of HACCP would yield unequivocal benefits – which could not be achieved by other means - would the Commission's proposals be at justified. In particular, if it was acknowledged that the "official control" encompassed in conventional inspections (perhaps more skilfully executed than is currently the case) of food businesses was an effective mechanism for reducing food poisoning, then the extra effort expended in policing the compulsory introduction of HACCP would have to be weighed against the effects which could be achieved by those other means.

On this basis alone, the Commission's proposals are flawed. For the other reasons specified above, they are unworkable. Rarely has there been such a situation, where a legislature is proposing a such a "radical shake up" of an important tranche of law, which is so misguided, illogical to the point of being irrational, and plainly wrong.

Certainly, the new law will not address the real risks, nor improve food safety, which is what the Commission presumes to require of food producers. In the interests of public health alone, these proposals cannot be allowed to pass into law.

ends.

23 August 2000

²² Any cost-benefit is assumed on the basis that the compulsory introduction of HACCP will reduce food poisoning, and its attendant costs, an effect which remains an assumption without any evidence to support it.

²³ COM(2000) 438 final. *op cit.* p 19.

Appendix 1

The John Barr (Lanarkshire) *E. coli* O157 outbreak

When the John Barr outbreak occurred in November 1996, the occurrence of a major *E. coli* O157 outbreak associated with cooked meats was regarded as something new and different in terms of the threat posed to food safety. Hitherto, *E. coli* O157 infection had been associated with undercooked beefburgers and the consumption of raw or inadequately pasteurised milk. The events prior to the outbreak, however, indicate that the outbreak should have come as no surprise.

The chronology of a threat

The first “high profile” outbreak involving *E. coli* O157 occurred in Oregon and Michigan, USA, during 1979, when it was associated with beefburgers supplied by McDonalds. Over 50 people were affected.

In 1985, another 73 people were affected - 19 pensioners died. But, this time, the food vehicle was cold meat sandwiches prepared in a Canadian nursing home. Over ten years before the Barr outbreak, therefore, there had been linkage between the consumption of cooked meats and *E. coli* O157. In the UK, however, no warnings were passed to foodsafety enforcement authorities.

Then, two years later, in 1987, a “mystery disease” was reported as having killed two children and a woman. The causal organism was later identified as *E. coli* O157. As is so often the case with food poisoning organisms, it had crossed the Atlantic to strike in the UK. Again, cooked meats were involved, this time turkey roll sandwiches.

A year later, back across the Atlantic, in a school in Wisconsin, it was roast beef which struck another 54 people. But the organism took only a few months to make headlines in the UK, in February 1989 with an outbreak “associated” with a McDonald’s “burger bar” in Preston, affecting about 20 people. Months later the organism was making an appearance in West Germany, when it was found in a male patient after he had eaten an undercooked beef burger.

By this time, the “new” organism had acquired public notoriety but, both in the United States and the UK, it was dubbed the “burger bug” from its association with the well-known burger chain.

Nevertheless, in the year 1989, in North Wales, a large outbreak of *Salmonella typhimurium* outbreak occurred, affecting over 600 people and causing three deaths – the largest outbreak of its kind for over five years. The vehicle of infection had been cooked, stuffed pork, supplied by a butcher in Delwyn, North Wales. On the other side of the country, there was another salmonella outbreak, also from cooked butcher’s meat, this one involving *S. kedougou*. Both outbreaks – although caused by salmonellas – had considerable similarities with the John Barr outbreak.

The outbreaks reinforced that which was already well known – that manufacturing butchers presented a considerable risk of food poisoning.

By 1991, the *E. coli* O157 had become well entrenched in Scotland, with two outbreaks being reported - one in Aberdeen, from a restaurant, where six people were affected. The other was in the Lothian region, affecting five people who had consumed foods from a local delicatessen. Both outbreaks involve cooked meats. The next year, it was in Northern England, affecting four people. Again cold, cooked meat was implicated.

A year later, however, the focus was back in the United States. In January 1993 there was the “Jack in the Box” burger outbreak, centred in the Pacific Northwest. A 2-year-old boy died and more than 200 people were stricken. By July, two women in their early 20s were being treated a Sheffield hospital for *E. coli* O157 poisoning. The previous month, eight people - including three children - had fallen ill with the disease. The cases were associated with a farm producing green top milk. In August, the *Lancet* reported that six people had suffered *E. coli* poisoning in Maine, USA, and a child had died - after eating vegetables from a garden which had been fertilised with cattle manure.

And it was not over for the year. In November, *The Times* newspaper reported that a girl aged five had died in a Birmingham hospital “after contracting a rare form of gastroenteritis possibly caused by eating poorly cooked beef”. *E. coli* O157 had claimed another victim.

In May 1994, there was another milk outbreak in the UK, this time in West Lothian, Scotland. A two-year-old girl died and over 100 were affected. This was widely reported, but there was also a smaller outbreak, this one in the Fife region, affecting 19 people. “Butcher’s meat” was described as the vehicle of infection. Then, in December 1994, stretching into early 1995, there was a serious *E. coli* outbreak in Adelaide, Australia. One girl died and 22 children become very ill. But, crucially important from the surveillance point of view was the food vehicle – it was *mettwurst*, a form of cooked sausage. The outbreak was never reported in the UK.

However, there was professional concern about *E. coli* O157, so much so that in April 1995, *The Sunday Times* reported: “Killer in beef spreads alarm”. This heralded the Advisory Committee on the Micro-biological Safety of Food report on *E. coli* O157. Commenting on it, Robert Tauxe, a senior government official at the US government’s Centres for Disease Control, was cited, saying: “It is a tough problem, and I predict it will be of growing concern in the future”.

The following month (May) BBC Scotland’s “Frontline” programme ran a short documentary about *E. coli*. Professor Lacey, from Leeds University, was commissioned to test samples of mince from five supermarkets and five butchers’ shops in the Glasgow area. He was “dismayed, upset, concerned and angry” that all ten samples taken were found to have had thousands of *E. coli* bacteria per gram.

In June 1995, *The Sunday Telegraph* picked up the *E. coli* story, to report, “Dozens of people in Britain, mainly children, have been killed since 1990 by the bacterium, known in the US as the ‘burger bug’”. Cases of *E. coli* O157 infection were “soaring” from a “handful” ten years earlier, to 656 the previous year.

Again in 1995, this time in August, another twelve people were affected by *E. coli* O157. Once again, they had eaten cooked meats purchased from a butcher, this one in Sunderland. Cross-contamination was evident in the shop. Then, in October, a three-year-old Aberdeen toddler was infected by the organism after contracting it from her father's cattle.

At the end of October, in North Warwickshire, there had been eleven possibly linked cases of *E. coli* poisoning. Attention focused on a local butcher but investigating officials – undoubtedly influenced by the association between the organism and burgers - initially sampled only minced meat and beef burgers.

At the conclusion of the investigation, cooked ham was implicated. The investigators reported that there had been plenty of opportunities for cross-contamination, but the premises had been inspected previously by EHOs when they had assessed the risk of the operation, and had allocated a “C” on risk assessment. Crucially, the details of the outbreak were not published until May 1997, well after the Barr outbreak.

In January 1986, John Barr's shop was inspected by a North Lanarkshire District Council EHO. The operation's risk status was reduced from “A” to “B”. The effect of this was to change the inspection interval from 6-monthly to once a year. The result was that, between January and November, when the outbreak occurred, Mr Barr's establishment received no formal inspections.

By June, *E. Coli* O157 was on the rampage through the southern states of Bavaria, with “at least seven deaths” having been caused. Cooked meats were implicated and the origin was thought to be cattle. Dr Jochen Bockeinuhl of Hamburg University's Hygiene Institute estimated that there had been 1000 cases.

A month later, 6,000 Japanese children were hit by poisoned meals in a number of schools. This was a major *E. coli* O157 outbreak; over 9,000 people were eventually affected, 11 died and over 500 were hospitalised.

Then, in November 1996, “*E. coli*” erupted in the UK media. This was the John Barr outbreak, which was to become the largest fatal *E. coli* outbreak in the world. Already that year, there had been 13 outbreaks in England and Wales, including two butcher's shop outbreaks in Nottinghamshire, and an outbreak in a canteen in the Northern home counties, all involving cooked meats.

Discussion

If it is accepted that one of the functions of the surveillance authorities is to gather information on disease trends and to disseminate information to those who need it - what is manifestly evident from this chronology is that there was a major surveillance failure.

Had the information on the growing burden of *E. coli* food poisoning – and the vulnerability of cooked meats to cross-contamination had been noted and translated into coherent action - history might have been very different.

For instance, had the local authority inspector who visited J M Barr in January 1996 been alerted to the *E. coli* problem, it is entirely reasonable to assert that he would not have reduced the shop's risk rating. At least one more inspection would have been carried out

before the outbreak, with a focus on the *E. coli* threat. As it was, prior to the outbreak, inspectors never discussed *E. coli* with Mr Barr.

After the outbreak, and as a direct result of the Barr incident, compulsory HACCP was introduced into butchers' shops, in an attempt to ensure that a similar outbreak did not occur. However, had the inspection and surveillance authorities been performing adequately, the outbreak might have been avoided – whether HACCP had been implemented or not.

On the other hand, if inspection standards in relation to HACCP are to the same poor standard as they were prior to the Barr outbreak, then little confidence can be expressed in the ability of inspectors to determine whether HACCP implementation is adequate, or not.

Given the vital role of inspection in any food safety programme, therefore, it is vital that measures are taken to ensure that standards are maintained. And, on the basis of the Barr analysis, if inspection standards are adequate, the universal implementation of HACCP is not needed.

For inspections to be adequate, they need to be properly focused, and inspectors need to be aware of emerging threats. Clearly, therefore, adequate surveillance is also vital to any food safety control programme. Without it, again it is difficult to see how any HACCP programme, compulsory or otherwise, can be entirely successful.

ends