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Review

Information systems in food safety management[☆]

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Abstract

Information systems are concerned with data capture, storage, analysis and retrieval. In the context of food safety management they are vital to assist decision making in a short time frame, potentially allowing decisions to be made and practices to be actioned in real time.

Databases with information on microorganisms pertinent to the identification of foodborne pathogens, response of microbial populations to the environment and characteristics of foods and processing conditions are the cornerstone of food safety management systems. Such databases find application in:

- Identifying pathogens in food at the genus or species level using applied systematics in automated ways.
- Identifying pathogens below the species level by molecular subtyping, an approach successfully applied in epidemiological investigations of foodborne disease and the basis for national surveillance programs.
- Predictive modelling software, such as the Pathogen Modeling Program and Growth Predictor (that took over the main functions of Food Micromodel) the raw data of which were combined as the genesis of an international web based searchable database (*ComBase*).
- Expert systems combining databases on microbial characteristics, food composition and processing information with the resulting “pattern match” indicating problems that may arise from changes in product formulation or processing conditions.
- Computer software packages to aid the practical application of HACCP and risk assessment and decision trees to bring logical sequences to establishing and modifying food safety management practices.

In addition there are many other uses of information systems that benefit food safety more globally, including:

- Rapid dissemination of information on foodborne disease outbreaks via websites or list servers carrying commentary from many sources, including the press and interest groups, on the reasons for and consequences of foodborne disease incidents.
- Active surveillance networks allowing rapid dissemination of molecular subtyping information between public health agencies to detect foodborne outbreaks and limit the spread of human disease.
- Traceability of individual animals or crops from (or before) conception or germination to the consumer as an integral part of food supply chain management.
- Provision of high quality, online educational packages to food industry personnel otherwise precluded from access to such courses.

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1. Introduction

In this contribution we will consider the role of information systems in developing effective food safety management protocols and, in particular, the role of databases in achieving this objective. Information systems are concerned with the capture, storage, analysis and retrieval of data providing the opportunity for the cumulative gathering of knowledge and the capability for more informed interpretation of the significance of new data collected to monitor or investigate natural phenomena.

In food safety management a well worn, but still highly illustrative, analogy introduced in 1994 is that of “Cole’s Cliff” (Zwietering, 2002) which holds that increasing knowledge of process/product/pathogen combinations and associated variability decreases uncertainty in achieving a positive food safety outcome. Thus, food safety management practices may be positioned closer to the cliff face without decreasing the probability of achieving the desired objective or increasing the probability of a fail-dangerous event.

2. Foodborne pathogens: enumeration and identification

Knowledge of microorganisms and the behaviour of microbial populations in foods for the purpose of developing effective food safety management strategies is required at the population level, the cellular level and the molecular level (McMeekin, 2003).

At the population level we are concerned principally with numbers of microorganisms which, depending on environmental conditions, will increase, decrease or remain static. The elements of the bacterial growth curve have been well characterised at the population level for more than half a century (Monod, 1949) and death kinetics have been described since the early 1900’s

(Bigelow, 1921; Chick, 1910; Esty and Meyer, 1922; Whiting, 1993). For a wide range of foodborne pathogens population response data has been synthesised into mathematical models that chart changes in pathogen density or describe environmental conditions precluding growth [see Ross and Dalgaard, 2004 for a comprehensive and definitive review of secondary models describing microbial population behaviour].

Whilst a numerical analysis of pathogen levels is the most useful type of information upon which to estimate the risk of foodborne illness, food safety management decisions are often based on “simply” recording the presence or absence of a pathogen in a food or the food processing environment. The decision not to quantify is, in the main, driven by pragmatic considerations of detecting a small number of pathogens with a low prevalence in a lot of food in which, if present, the microorganisms will be distributed heterogeneously or if the accept/reject criterion is based on the absence/presence of a pathogen.

The probability of detection of a particular pathogen is increased by resuscitation or non-selective enrichment of the sample during which damaged or dormant cells repair and start to divide. This is followed by manipulation of the diverse microbiota present in the enriched sample by selective enrichment during which more rapid development of a target organism is favoured. Selective enrichments are usually carried out in liquid media, the microbial components of which are further differentiated and physically separated by plating on solid selective and diagnostic media. Clones, derived from individual colonies, with the characteristics of the presumptive pathogen are subjected to taxonomic tests based on the composition of cellular components, physiological activity or analysis at the molecular level.

Clearly, databases containing information on microbial population behaviour or characteristics allowing the definitive

identification of a foodborne pathogen have a very significant role to play in food safety management.

3. The philosophy underlying databases

The food environment can be very complex and it may be difficult to quantify or even to categorise some of its features and their potential effects on microbial population dynamics or the ability to recover a target organism from a food sample. An example is the effect of food structure, reviewed by Brocklehurst (2003) which may affect environmental limits for growth (Koutsoumanis et al., 2004).

An additional difficulty is that, with the background information on the environment and with currently available techniques to measure microbial responses both variability and uncertainty may be large (Ratkowsky, 2004). Variability in microbial characteristics such as growth rate or lag phase duration is well characterised and increases markedly with increasing response times. Its effect is seen in the widening confidence limits of response time estimates (Ratkowsky et al., 1996; Ratkowsky, 2004) and may even lead to inability to recover a target organism under conditions where growth is possible (Graham and Lund, 1993).

Variability and uncertainty in microbial responses were also discussed by Bridson and Gould (2000) in their treatise on classical versus quantal microbiology. Uncertainty, of course, also arises when information is missing or conflicting, events that regularly cause consternation in the conduct of quantitative risk assessments (Nauta, 2002). In such situations, the accumulation of MANY pieces of information is essential. An analogy can be conceived as follows: if one can take a picture of only a small segment of the sky then it is impossible to see the trajectory of the Milky Way from a single picture. However, when the pieces are put together, a pattern may emerge showing the now well-known spiral of the Milky Way. We will call this pattern, showing the potential of databases to put pieces of information together, the “Milky-way effect”.

It is important to consider the above capitalisation of the word MANY. This requirement means that the information must be put in a well-defined systematic format, following a strict database protocol, otherwise no computer program can be developed to retrieve the information. Database is not the same as “data-dump”! The fields of a database are created for a certain purpose (in the case of predictive models to represent Environment/Response mapping) and entering data in the field already requires categorisation, simplification i.e. food microbiology and modelling expertise. When, for example, the main environmental factors affecting microbial responses are identified, the same simplification is carried out as when a process is characterised by some mathematical variables. In other words, there is a parallel between mathematical abstraction and the creation of the database structure. The fields of the database correspond to mathematical variables; the relations between those fields correspond to mathematical equations and inequalities.

To introduce some philosophy, we will call the need for simplification, which is necessary to create a database, the “Platonian effect”, since it was Plato who emphasized first that the scientific thinking needs these simplifications (i.e. idealisations).

We will also speak about the “Gutenberg effect” of the databases. Namely, in the IT age, Internet databases have an effect analogous to that caused by the invention of printing. Before the 15th century, certain information, even if available, was not necessarily accessible, because hand-written books were too few to be available for everybody. Now, the amount of information (even if now in printed form) has become too large and a new technique, the FAST, ACCESSIBLE, RELATED database, has given new impetus to information processing. As the early creators of the first linked databases remarked, “Gutenberg could not make his books speak to each other”.

Such a database called *ComBase* (Combined, or Common i.e. joint, *dataBase* of microbial responses to food environments) was launched at the 4th International Conference on Predictive Modelling in Foods, Quimper, France, June 2003. Its technical details can be read in Baranyi and Tamplin (2004) and on the website, www.combase.cc. The *ComBase* idea came from two independent, but similar, initiatives on both sides of the Atlantic. The Ministry of Agriculture Fisheries and Food in the United Kingdom initiated, in 1988, a coordinated program to collect data on the growth and death of bacterial pathogens. Those data served as the base on which the first validated, commercialised predictive package, Food MicroModel was built. The task of supporting these developments was taken over, when established, by the UK Food Standards Agency (FSA). Parallel to these events in the UK, the US equivalent of Food MicroModel called PMP (Pathogen Modeling Program: www.arserrc.gov/mfs/pathogen.htm) was developed at the Eastern Regional Research Center of the USDA Agricultural Research Service.

In the meantime, a database (*ComBase*) was being developed in the Institute of Food Research, Norwich, UK to pool available predictive microbiology data. Soon the leaders of FSA and USDA-ARS agreed that incorporating all their data in this common database, named *ComBase*, would be mutually beneficial. The European Commission also embraced the idea, and now the original Food MicroModel and PMP datasets have been supplemented with additional data submitted by supporting institutes, universities and companies mainly from Europe. Besides, data have also been compiled from the scientific literature.

ComBase has its “Milky way”, “Platonian” and “Gutenberg” effect on predictive microbiology. Its “Milky-way effect” is obvious; the amount of data can compensate for the inaccuracy of the data. Le Marc et al. (2005) showed an example how to make use of the large amount of information provided by *ComBase* to define, at least approximately, the total growth region of *Listeria monocytogenes* in the space of the main environmental factors.

Numerically and computationally minded scientists are convinced that the “Platonian effect” of *ComBase* is very useful to bring more exact (mathematical and quantitative) elements in microbiology research. However, this is not necessarily popular among traditional microbiologists. Namely, many of them have a certain degree of aversion to the required simplifications, saying that the information in the database does not reflect the environment and/or microbial response with sufficient accuracy.

The fact is, however, that is not the function of the database. It is, rather, to make the most important aspects of the data available FAST, even if at the expense of omitting some details. It should be admitted, that this bears some danger of distortion and subjectivity, but this has always been hand in hand with the *Platonic* idea of idealisation and simplification. In fact, different disciplines omit different details from the same phenomena. The contributors to *ComBase* omit those details that, according to our food microbiology knowledge accumulated so far, do not significantly influence the Environment/Response mapping. This also shows that the “*Platonic* effect” can play a role in the development of a scientific discipline only after many observations and empirical descriptions have become accepted knowledge about the system to be characterised.

The “Gutenberg effect” of *ComBase* is probably the most popular at the moment. Thousands of researchers, risk assessors, legislative officers, food manufacturers and their laboratory managers can access published and unpublished data fast and at no expense. Publicly available databases like *ComBase* and, in fact, the whole Internet, are virtual forums of democracy. Besides, they can be major tools in the assessment of predictive microbiology results. Users can compare observations with independent predictions gained from other software packages, which contribute to the correct evaluation of the potential and limitation of the discipline. *ComBase* is a repository of predictive microbiology data that can be used by risk assessors of different countries; therefore, if *ComBase* is accepted internationally as the benchmark, the number of sources generating different views on risk can be decreased.

4. Information systems and microbial systematics

Microbiology today encompasses a wide range of techniques reflecting advances in cognate areas, such as molecular biology. Similarly, bacterial systematics utilizes traditional biochemical and microscopic procedures through the most advanced analytical and molecular based systems (reviewed from a food microbiology perspective by Uyttendaele and Debevere, 2003). Fundamentally, bacterial taxonomy and classification can be considered as a method of encoding information about data defining a single life form. The ultimate goal is to achieve the briefest and densest possible recording of this information in order to maximise its precision, accessibility and to lend it interoperability. Interoperable databases are standardised in some uniform fashion so that different types of data (e.g. protein electrophoretograms, gene sequences and food composition data) can be integrated (e.g. Ravichandran et al., 2004).

Applied systematics has undergone a revolution in the last 15 years. However, diagnostic laboratory needs are generally far behind the rapid scientific advances emanating, almost on a weekly basis, from pure research laboratories. Similarly, database development and integration, in other words “Knowledge Management”, lag behind technique development. Indeed, information systems have only recently become developed sufficiently to be able to handle the onslaught of information which is now a feature of the 21st century (reviewed by Liao, 2003). Online and offline databases continue to evolve and from this definitive microbial

identification. This carries with it an associated rich array of biochemical and genetic information which will benefit from the application of new and powerful biomathematical and computer programming techniques such as machine learning and neural networks (e.g. Gyllenberg et al., 2002).

However, for the most part, rapid identification in the majority of diagnostic laboratories relies on speed and simplicity and thus, use of streamlined semi- or fully-automated variations of traditional techniques (including serotyping and phenotypic testing) is still predominant (Uyttendaele and Debevere, 2003). Most species identification using such methods relies on databases of test results obtained for large numbers of strains for each species, usually species most commonly found in the diagnostic environment. For food microbiology this includes only about a dozen or so genera. As a result the data tends to be specifically very rich (several thousand strains analysed for each species are not uncommon) but often not integrated with other types of information. Typically, test results are converted to a numerical code format and require a dedicated computer program containing a proprietary database and are thus not available online. Examples of popular microbial identification tests systems include: API test strips (BioMérieux Corp.), Biolog carbon source utilization plates (Biolog, Inc.) and the BBL Crystal ID system (Becton-Dickinson, Corp.). Numerical taxonomic analyses of the test results provide a probabilistic determination of the species which are implemented as part of the heuristic database analysis. These methods are limited by the inherent variability (e.g. *Bacillus* spp.) or biochemical inertness (*Campylobacter* spp.) of various clinical species and can lead to misidentifications.

Various chemical based technologies also are used regularly in bacterial identification though rarely as a sole procedure. These include fatty acids analysis such as used in the Sherlock microbial identification system (previously called the Microbial ID or MIDI system) (MIDI, Inc.) which includes a large database of bacterial methyl ester-derivatized fatty acid profiles generated by gas chromatography, again of a proprietary nature. Though the Sherlock system is relatively inexpensive and simple to operate, fatty acid-based identification is usually only effective to genus level for many foodborne bacteria. Also several fatty acid components are only identified presumptively on the basis of retention time, while other components are not resolved fully. This can lead to difficulties in comparing MIDI data with other procedures.

Protein, and other chemical-based procedures, including gel electrophoresis, mass spectrometry and spectroscopy have important (potential) utility in bacterial systematics. SDS-PAGE in which crude protein extracts are denatured and separated by electric current in a polyacrylamide gel has had the most use in the comparison of multiple strains which are phenotypically hard to separate e.g. such as species of *Lactobacillus* (Venture et al., 2003). Electrophoretic methods separating specific enzymes (zymograms) may also be useful at the species or strain level (e.g. separating different enterolysins of enterococci) (Hickey et al., 2003). Few, if any, databases have been established for the purposes of taxonomy based on these types of data. Much more recently the application to bacterial systematics of sophisticated analytical instruments including Matrix assisted laser desorption/

ionization time-of-flight (MALDI-TOF) and quadruple ion trap mass spectrometry and Fourier transform infrared and Raman spectroscopy has been proposed (e.g. Lay, 2002; Jarvis and Goodacre, 2004). Though providing the exciting possibility of highly rapid (<1 min) real-time identifications, the methods still lack precision and reproducibility is affected by many experimental criteria (e.g. Williams et al., 2003). Refinements of these technologies with higher precision mass determinations of chemical components (such as protein and other chemical fragments) and technique standardization may lead to endpoint identifications of bacteria and development of integrable databases, especially with genome data (see below). The extremely high capital costs of the instruments (100–1000K\$ US) probably mean these will remain research tools only for the foreseeable future. Databases derived from such data may be also proprietary due to the significant investment of capital needed to develop them.

In bacterial taxonomy a taxonomic system is not fixed, once and for all, but is continuously updated as new data on existing taxa become available and new bacteria are discovered. This means that an unknown strain is either identified, that is, put into an already existing taxon, or, if it is sufficiently different (according to various criteria) from all established taxa, it forms a new taxon. This poses a problem for database management and information accessibility. Even keeping up with the expanding bacterial nomenclature can be daunting but, at least at the species level, it is possible with online resources such as the “List of Bacterial Names” database (Euzéby, 1997) or the online resources of various major culture collections e.g. CCUG, DSMZ, NCIMB and ATCC (see Euzéby, 1997 for contact information). Purely proprietary databases, which have to be updated continually, can represent a significant cost to the user. The internet, however, now provides cost effective, convenient and rapid access to huge volumes of integrated information and lends itself obviously to the large evolving and (potentially) interoperable databases. A good example particularly relevant to food microbiology is Pathogen Tracker v. 2.0 (developed through Cornell Univ., New York State) which includes extensive API and Biolog data (as well as various molecular data) for some food pathogens, which can be readily interrogated and has a provision for incorporating new data.

Increasingly, molecular techniques, gene sequencing (16S rRNA, gyrase large subunit, chaperonin 60) and fingerprinting methods (e.g. ribotyping, PCR of genomic repetitive elements and gene spacer regions, pulse field gel electrophoretic fingerprints) are finding widespread use for routine identification and epidemiology. Most unknown bacterial strains can be quickly identified by their 16S rRNA gene sequences by interrogating the GenBank nucleotide database as part of the National Collection of Biotechnology Information (National Library of Medicine, Bethesda, Maryland) which includes >80,000 16S rRNA gene sequences. Widely available and increasingly cheaper commercial nucleic acid kits, and high throughput DNA sequencing procedures have resulted in gene sequencing increasingly superseding the use of morphological and biochemical phenotypes in the initial identification of new bacteria, especially those from non-clinical sources. Indeed, a 16S rRNA gene sequence is

now a mandatory requirement for the description of new prokaryotic taxa. It is possible that gene- and genome-based technology may completely takeover from phenotypic analysis. Gene sequences can be used to identify directly bacterial strains *en masse* using a multiplicity of well-established and emerging nucleic acid amplification and probing technologies (some are reviewed by Sanderson and Nichols, 2003). From a diagnostic laboratory point of view such methods are not regularly used due to expense, required expertise and lack of validation (Uyttendaele and Debevere, 2003). Streamlined modifications of these procedures provide the possibility of such methods entering the diagnostic laboratory and provide a commercial impetus for larger more useful integrated databases. For example, loop mediated isothermal amplification (Nagamine et al., 2001) could allow single-tube detection of bacteria without use of thermocyclers or electrophoresis.

Finally, genomes are increasingly being used for bacterial systematics. For example genomic data reveals new insight into the relationship of virulence and taxonomic diversity in *L. monocytogenes* (Doumith et al., 2004). Comparative analysis of whole genomes also has revealed particular genes useful for the demarcation of new species (Zeigler, 2003) and could replace awkward procedures needed for definition of species at the genomic level. Genomic data when integrated with other information (as discussed above) will hopefully further the effectiveness and preciseness of taxonomy in general. At this stage whole genome data is difficult to manage though many databases have appeared in which this type of data can be mined (see <http://www.hgmp.mrc.ac.uk/GenomeWeb/prokaryote-gen-db.html> for a list of bacterial genome database resources). It is likely in the future that rapid whole genome sequencing will become possible and that this information will be integrated with much other phenotypic, chemical, proteomic and phylogenetic data. Further advances in information technology techniques and data management will also obviously be required before this information can be used effectively.

4.1. Sources of further information

Many of the microbial identification systems outlined above are proprietary and further details are available from the manufacturers. Detailed information on microbial taxa and the availability of strains may be obtained from the databases and culture collections listed in Table 1.

5. Information systems and investigation of foodborne diseases

Above, the value of databases in microbial systematics to identify microorganisms at various taxonomic levels was discussed. Thus, characteristics constituting recognition of the presence of an organism in a sample as a member of the family Enterobacteriaceae, the genus *Escherichia* or the species *E. coli* provide useful information on the hygienic status of a product or a processing line. Further differentiation of the species *E. coli* into serovars may identify strains such as *E. coli* 0157:H7 or *E. coli* 0111 which are well recognised causes of foodborne illness.

Table 1

A list of commercial and non-profit organizations and internet resources useful for bacterial taxonomy and identification

Company	Product/function	Website
<i>Commercial bacterial identification systems:</i>		
Becton-Dickinson, Corp., Franklin Lakes, New Jersey, USA	BBL Crystal ID system for microbial identification.	http://www.bd.com
Biolog Inc, Hayward, California, USA.	Biolog microbial ID/characterization test trays.	http://www.biolog.com
BioMérieux Corp., Marcy l'Etoile, France	API microbial identification test panels	http://www.bioMerieux.com
MIDI Inc., Newark, Delaware, USA	Sherlock Bacterial Identification System and Fatty Acid MIDI System	http://www.midi-inc.com/
<i>Culture collection service providers:</i>		
ATCC: American Type Culture Collection, Manassas, Virginia, USA.	Bacterial strain supplier; genomic analysis	http://www.atcc.org/
LMG/BCCM, University of Gent, Gent, Belgium	Bacterial strain supplier; identification service	http://www.belspo.be/bccm/
CCUG: Culture Collection, University of Göteborg, Sweden.	Bacterial strain supplier; identification service	http://www.ccug.gu.se/
German Collection of Microorganisms, Braunschweig, Germany	Bacterial strain supplier; identification service	http://www.dsmz.de
NCIMB, Ltd.: National Collection of Marine and Industrial Bacteria, Aberdeen, Scotland, UK	Bacterial strain supplier; identification service	www.ncimb.co.uk
<i>Other useful web-based resources and databases:</i>		
List of Bacterial Names with standing in Nomenclature	Continually updated taxonomy database	http://www.bacterio.cict.fr (J. Euzéby)
National Collection of Biotechnology Information.	GenBank nucleotide and protein database	www.ncbi.nlm.nih.gov
Pathogen Tracker (v. 2.0)	Expanding food pathogen database for epidemiological applications	http://cbsusrv01.tc.cornell.edu/users/PathogenTracker/pt2/login/intro.aspx
Prokaryotic Genome Database	Cross-referenced database of bacterial genomic information	http://www.hgmp.mrc.ac.uk/GenomeWeb/prokaryote-gen-db.html

Below we consider “finer” differentiation of pathogens for use in epidemiological surveillance, outbreak investigation and response.

5.1. Epidemiological surveillance of foodborne diseases

Public health surveillance is defined as the ‘ongoing, systematic collection, analysis, interpretation, and dissemination of data regarding a health-related event for use in public health action to reduce morbidity and mortality and to improve health’ (Centers for Disease Control and Prevention, 2001). One of the main aims of surveillance of foodborne diseases is to detect outbreaks. This allows public health investigators to identify the food responsible and prevent further cases. Surveillance of these diseases often relies on doctors and pathology laboratories reporting to health departments about patients infected with microorganisms, such as *Salmonella*, *Campylobacter* and *Listeria*. The proportion of these infections that are transmitted by food varies by pathogen, and can only be verified by investigation of multiple related human cases (Mead et al., 1999).

The nature of foodborne disease epidemiology has changed significantly in the last ten years, mainly due to more centralised production of large volumes of food and a wider array of choices available to consumers. There has also been significant improvement in laboratory diagnosis of many foodborne infections, such as those due to norovirus. These changes have led to better recognition of large outbreaks that are distributed over a wide geographical area. Consequently, this has led to a change in the way that investigators approach foodborne outbreaks, which is more dependant on information technology (Hedberg et al., 2003).

In the past ten years, information technology has revolutionised the conduct of surveillance for foodborne diseases. This has

ranged from widespread use of free software for collection of epidemiological data, such as Epi Info (<http://www.cdc.gov/epiinfo/>) and Epidata (<http://www.epidata.dk/>), to web-based databases for surveillance of infections and outbreaks. Many countries, such as the United Kingdom (<http://www.hpa.org.uk/infections/default.htm>) and Australia (<http://www.cda.gov.au/index.htm>), make surveillance data, for infections that may be due to food, available on websites, either as static reports or dynamic datasets. For examples of countries reporting surveillance data on foodborne outbreaks, see the United States (http://www.cdc.gov/ncidod/dbmd/outbreak/us_outb.htm) and New Zealand (http://www.surv.esr.cri.nz/surveillance/annual_outbreak.php).

There have been moves in many countries to collect infectious disease surveillance data from doctors and laboratories electronically using standardised reporting formats (Effler et al., 1999). These systems are highly effective and provide better information than paper-based reporting (Effler et al., 1999; Backer et al., 2001). In practice, there are issues that are difficult to resolve for many health departments to receive data over the internet. These include privacy concerns, standard terminology and technological difficulties (Bean and Martin, 2001; Panackal et al., 2002). The more widespread introduction of electronic transfer will have many benefits for foodborne disease surveillance, which relies on timely information to properly interview infected patients (Widdowson et al., 2003).

5.2. Outbreak detection

Information technology advances have specifically allowed the development of surveillance tools that have assisted with the detection of outbreaks of foodborne disease. These include databases for the routine collection of reported infections to

algorithms used to detect if counts of cases have increased above historical baselines (Stern and Lightfoot, 1999). Geographic information systems have also improved the ability of epidemiologists to detect spatial clustering (Hightower and Klein, 1995). However, probably one of the greatest changes in foodborne disease surveillance and control has been the use of molecular techniques in clinical laboratories combined with databases of genetic information.

A good example of a database of genomic information for foodborne pathogens is the PulseNet system established by the Centers for Disease Control and Prevention (Swaminathan et al., 2001). The PulseNet system types human isolates of *Salmonella*, *Listeria*, and *E. coli* O157:H7 using Pulsed Field Gel Electrophoresis (PFGE) and relies on harmonised laboratory protocols for subtyping (Swaminathan et al., 2001). The resulting patterns are entered into a Bionumerics database, which is shared amongst participating laboratories. The system has assisted in identifying large complicated foodborne outbreaks and provides a library of DNA patterns for future reference during investigations (Centers for Disease Control and Prevention, 2000).

There are other databases available on the web, which allow genetic comparison of foodborne pathogens. One example is the norovirus sequence database in the United Kingdom that records strains causing infections over a ten-year period (<http://www.hpa.org.uk/srmd/bioinformatics/norwalk/norovirus.htm>). These databases are powerful tools for determining the source of foodborne infections and emerging trends of infections (Lopman et al., 2004).

Infectious diseases epidemiologists are also exploring more novel approaches to predict the occurrence of outbreaks using sophisticated modelling and neural networks (Black, 2002). However, these tools have not yet developed to the stage where they are more useful than traditional surveillance techniques for identifying epidemics.

5.3. Response to outbreaks

In responding to outbreaks, public health agencies rely heavily on communication networks. This is particularly important as foodborne outbreaks are more commonly spread over wide geographical areas, even internationally. The benefits of rapid communication using email have improved investigation of widely dispersed outbreaks (Sobel et al., 2002; Lindsay et al., 2002). Communication via email list servers allows people to discuss the changing nature of an investigation, as well as a novel means of contacting people affected by foodborne disease (Raupach and Hundy, 2003). Once a food is identified as the cause of an outbreak the internet is a useful vehicle for disseminating information globally. Two such public mailing lists that commonly disseminate information about foodborne and emerging infectious diseases are FSNET (<http://www.foodsafetynetwork.ca/>) and Promed (<http://www.promed-mail.org>). Posting information on these list servers about food responsible for foodborne outbreaks has resulted in the detection of international outbreaks (Kirk et al. 2004). The World Health Organization has established a Global Outbreak and Alert Response Network, which conducts surveillance of outbreak rumours posted on the internet through media outlets

and other sites (Heymann and Rodier, 2004). The primary aim of this type of surveillance is to detect and respond to outbreaks of international significance, which could encompass those caused by contaminated food.

6. Predictive microbiology application software

Development of models to predict growth, survival or inactivation of microorganisms in foods has been a most active area of food microbiology within the last 20 years and a considerable number of models to predict responses or growth limits in foods are available. Description of the types of model developed and a summary of currently available models in the public domain were presented by Ross and Dalgaard (2004).

Predictive microbiology involves the development of mathematical models of microbial population changes in food. It is based on the premise that the responses of populations of microorganisms to environmental factors are reproducible and that, by characterizing environments in terms of those factors that most affect microbial growth and survival, it is possible from past observations to predict the responses of those microorganisms in other, similar environments. To model microbial responses in foods a two step approach has been used widely: (i) “Primary” models are used to express changes in concentration of organisms over time using a limited number of kinetic parameters e.g. lag time, rates of growth or inactivation, maximum population reached, that together describe the change in the population size and (ii) “Secondary” models that express the effect of environmental parameters (e.g. temperature, NaCl, pH, etc.) on the kinetic parameters (Ross et al., 2000).

Predictive microbiology models are important tools for food safety management as they provide a scientific basis to underpin key aspects of HACCP and quantitative microbial risk assessment. Growth limit models in particular help identify potential microbial hazards in specific foods. Growth and inactivation models provide a quantitative link between measurements used to monitor processes (e.g. time, temperature, pH, and salt) and potential responses of specific pathogens. This information is useful when limits for critical control points need to be specified or corrective actions determined to achieve compliance with performance criteria (see e.g. Ross and McMeekin, 1995). Growth or inactivation of pathogens in foods along the farm-to-fork chain is fundamental to microbial risk assessment and predictive models, therefore, are key components in estimating consumer exposure to pathogens in foods at the time of consumption. Furthermore, predictive microbiology models are valuable for teaching and consulting (McMeekin and Ross, 2002). However, wider use of predictive models in industry, research and teaching depends on availability of application software that allows different users to obtain information from models in a rapid and convenient way. Available predictive microbiology application software packages are described below whereas more complex expert systems are discussed in Section 8.

Pathogen Modeling Program (PMP) is available free of charge (<http://www.arserrc.gov/mfs/PATHOGEN.HTM>) and,

with more than 5000 downloads per year, is the most widely used predictive microbiology application software. PMP has been available for about 15 years and is continually being updated and expanded. The present version includes more than 35 models for 11 bacterial pathogens (Tamplin et al., 2004). The software allows growth or inactivation of pathogens to be predicted for different combinations of constant temperature, pH, NaCl/ a_w and, in some cases, other conditions such as organic acid type and concentration, atmosphere, or nitrate. In addition, PMP includes models that predict the effect of cooling temperature profiles on growth of *Clostridium botulinum* and *C. perfringens* after cooking. Predictions can be exported and the software contains references to studies from which the models were developed. Lacking in PMP is information from validation studies showing the performance of models in specific foods as well as more general facilities to predict the effect of fluctuating temperature conditions on growth and inactivation.

The commercial software, “Food MicroModel”, was in several ways similar to PMP but it is no longer available. However, data from Food MicroModel has been integrated in the Growth Predictor software available free of charge since 2003 (<http://www.ifr.ac.uk/Safety/GrowthPredictor/>). Growth Predictor v. 1.01 includes 18 models and allows predictions to be obtained at constant conditions of temperature, pH, NaCl/ a_w and, in some models, an additional fourth parameter. Predictions can be exported but the Growth Predictor software is simple and includes little information on model development and on the performance of models in different foods. Note that the reason for this simple functionality is that Growth Predictor is just a stop-gap solution before the new integrated ComBase–PMP (Combined Database and Predictive Microbiology Program) system is launched. It will combine the best features of the already mentioned ComBase database introduced in Section 4 (www.combase.cc) and the PMP predictive program supplied with new, improved models that would also be available via the internet.

Sym’previus (<http://www.symprevius.net/>) is a decision support system in French that includes (i) a database with growth responses of microorganisms in foods and (ii) predictive models for growth and inactivation of six pathogenic bacteria (Leporq et al., 2003). Information from Sym’previus is available on a commercial basis through contact centres as indicated on the homepage cited above.

The Food Spoilage Predictor (“FSP”, Neumeier et al., 1997), the Seafood Spoilage and Safety Predictor (SSSP, www.dfu.min.dk/micro/sssp/) (Dalgaard et al., 2003) and the Safety Monitoring and Assurance System (SMAS, Koutsoumanis et al., 2003) are examples of more specific predictive microbiology application software. These software include facilities to read product temperature profiles, as recorded by data loggers, and thus predict the effect of fluctuating temperatures on growth of microorganisms. Software analogous to FSP, but based on the *E. coli* growth rate model of Ross et al. (2003), is also under development. In addition to models for different seafood spoilage bacteria, SSSP includes a model to predict the simultaneous growth of *L. monocytogenes* and spoilage

microorganisms in sliced and vacuum packed cold-smoked salmon (Giménez and Dalgaard, 2004).

7. Quantitative microbial risk assessment software

Currently, there are no software packages specifically available for the application of predictive microbiology models within quantitative risk assessments. Simulation modelling software packages (e.g. @Risk, Analytica, Crystal Ball) are often used for quantitative, stochastic, risk assessment and predictive microbiology models are embedded within them (e.g. Cassin et al., 1998; Fazil et al., 2002; Ross and McMeekin, 2003; Oscar, 2004). The application of predictive microbiology within quantitative microbial food safety risk assessment was discussed by Ross and McMeekin (2003).

Specific software tools to aid in microbial food safety risk assessment are, however, being developed. A food safety risk ranking decision aid in spreadsheet format was presented by Ross and Sumner (2002) and is available free of charge (<http://www.foodsafetycentre.com.au/riskranger.htm>). The tool requires the user to select from qualitative statements and/or to provide data concerning factors that will affect the food safety risk arising from a specific food product and hazard, during the steps from harvest to consumption. The spreadsheet converts the qualitative inputs into numerical values and combines them with the quantitative inputs in a series of mathematical and logical steps using standard spreadsheet functions. Those calculations are used to generate indices of the public health risk. While there are many caveats surrounding its application, the tool offers a simple means of comparing foodborne risks from diverse products and serves as an aid to structured problem solving, helping to focus attention on those factors in food production, processing, distribution and meal preparation that most affect food safety risk.

FareMicrobial (<http://www.foodriskclearinghouse.umd.edu/faremicrobial.htm>) is a more sophisticated software program for conducting probabilistic microbial risk assessment. The program was developed by a private company, Exponent (formerly Novigen Sciences, Inc.) at the request of and in conjunction with the United States’ Food and Drug Administration. The software is an extension of the Novigen Foods Analysis and Residue Evaluation program, a multi-objective research program for mining patterns from food consumption databases and computing exposure distributions. While it incorporates algorithms developed for *L. monocytogenes* the system is said to be capable of performing risk assessment for a variety of foodborne pathogens (Exponent, 2004). Data from the U.S. Department of Agriculture’s continuing food intakes survey are included in the program. Other systems are also under development in the USA (Don Schaffner, Rutgers University, New Jersey, *pers. comm.*, 2004).

Various programming tools have been used for development of predictive microbiology application software and this is unlikely to change in the future. However, consensus-based specifications/standards are lacking for input (temperature profiles, product characteristics) and output (kinetic parameters and predicted changers in concentration with time). These aspects need further study as this will increase the possibility of integrating predictive

microbiology application software with other information systems e.g. traceability or expert systems and HACCP software.

8. The use of decision support systems in food safety management

8.1. Decision support systems and expert systems

Expert systems are systems imitating the performance of a human expert and can simulate human expert-like reasoning and decision making within a special domain of expertise (Linko, 1998). They can also be called knowledge based systems or decision support systems. The term decision support system can be considered more general, since those systems can also be very quantitatively oriented, using quantitative methods to support the making of decisions. The most promising is a merger of qualitative, knowledge based information, and quantitative information.

8.2. Food safety control

For control of food safety, HACCP is the most generally used system. It has changed food safety control from end-product testing to more effective control at those places in the process where the risk can be controlled to an acceptable level. This system can only be used effectively, if beforehand general hygiene is under control, by the use of, for example, good manufacturing processes (GMP). For even more elaborate general food safety control measures, for instance on a national or international scale, quantitative risk assessments (QRA) are increasingly carried out. For these analyses, quantitative methods as well as databases with quantitative data concerning microorganisms and food products and processes can be coupled. A problem, both for setting up HACCP plans and for carrying out QRAs, is often that quantitative data in some parts are missing or, in certain cases, not relevant for a specific application. On the other hand, expert knowledge exists, both in the form of real knowledge in experts' minds as well as knowledge existing in the scientific literature. Therefore, it is useful to combine quantitative parts of the analyses with qualitative knowledge. In parts where both qualitative and quantitative data exist, the former can be used in a confirmatory role and to provide more confidence in the quantitative determination. It may even show contradiction, necessitating more attention to a certain aspect. It is the combination of expertise, experiments, literature and quantitative microbiology that will be fruitful and not specifically a focus on one of these areas.

8.3. Hazard identification

One relevant part of both HACCP and QRA is the identification of hazards. This is often based on experience and qualitative reasoning. This experience can be very well structured in expert systems and even be improved by combining it with quantitative measures. The advantages of structured systems are the following:

- systematic, structured and transparent procedure: giving the same response if the same question is asked (not depending on place, time, person)

- speed of answer and continuous availability
- can be updated if new information becomes available

Examples of such systems for the identification of hazard were described by Zwietering et al. (1992), van Gerwen et al. (1997), and Wijtzes et al. (1998). These systems are based on a coupling of quantitative databases containing parameters of organisms and food products (pattern matching), in combination with well-defined qualitative knowledge rules. The strength of such systems can be explained with the following example, in which a group of eight students carried out a hazard identification for a vegetable product during a week based on a literature survey. This resulted in a list of potential hazards for the product. After this analysis the program was used and in 15 min almost the same list resulted. On first sight, the students did not see the advantage of using the system since it did not result in additional hazards. However, there were two important factors, the first being the time: the system resulted in almost the same result in 15 min, compared to 320 h of work. Secondly, the ability to compare the two results increases confidence that one approach does not overlook hazards. Therefore, both time investments were useful.

8.4. Critical control points and chain analysis

If within HACCP hazards are identified, one has to determine where these hazards can be controlled (CCPs) and to set critical limits. Carrying out these processes can be very well automated, having again the advantage of a structured, transparent automated system, in which quantitative aspects as well as qualitative knowledge can be combined. For example, the selection of CCPs following the HACCP approach (with a decision tree) can be automated and support in the selection of the answers can be given. All selections can be stored (with date/time/user) and all information, including potential changes in the information, can be traced back. Also, one can automatically check for completeness (are all hazards controlled, do all critical limits contain their target value and limits, etc.?) and measured values at CCPs can be entered (and automated) to enable automatic analyses, giving alerts if values are off limits or if trend analyses show structured deviations, although still within limits.

For process line analyses, combinations of quantitative and qualitative information are also of great utility. Examples of computer systems developed for line analysis to be used, for example, in HACCP or for quantitative risk assessment, are given in Table 2. In all these systems quantitative modelling techniques, product and organism data and qualitative knowledge are combined with a user-friendly user-interface, using various approaches.

8.5. Quantitative risk assessment

More and more extended quantitative risk analyses are being carried out. However, the outputs represent only those hazards and product groups for which they were designed. For other cases, and even for specific processing lines, reduced analyses can be very useful. A good example of a system that can help to carry out a specific analysis was developed by Ross and Sumner (2002).

Just as with the hazard identification system, this system should not be viewed as giving definitive answers, but rather as giving a first analysis of the magnitude of the risk and also especially as a risk ranking tool. Although extended analyses can never be carried out for all product groups/process lines these extended QRAs (for example, HHS/USDA, 2003) contain a wealth of information that can be relevant for other analyses such as storage time and temperature distributions, serving sizes, general approaches and scenario analyses.

An important point mentioned by Ross and McMeekin (2003) is that systems are developed in which users are notified of model limits and warned against modelling unrealistic scenarios. Such extensions in tertiary type models are useful in order to make IT-tools flexible and, on the other hand, to warn the user if potentially dangerous conclusions are likely to be drawn.

All these quantitative and computational techniques can be very helpful in the management of food safety, but it is necessary to realize that every procedure, tool and approach has its strong points and weak points and that, overall, generally large uncertainties remain. It is important to use various information sources and not rely solely on one, noting the opinion first attributed to G.E.P. Box, that “all models are wrong, but some are useful”. We would prefer to state that “many models are correct, but they are not perfect”.

9. HACCP software and traceability systems

HACCP is the international reference system for food safety management and this system, relying on seven basic principles, is used extensively worldwide (NACMCF, 1997; CAC, 2001). As mentioned above information systems, including ComBase, predictive microbiology application software, risk assessment software and decision support systems, can be most useful when hazards, critical control points or critical limits are identified in the development of HACCP plans. HACCP is a structured approach that involves careful recording of all details and actions in order to provide documentation that a safety management system is in operation and in full control of all hazards in food processing. Clearly, information systems can facilitate the use of such a structured approach and several dedicated HACCP software have been developed. The number of available software is too large for individual programs to be discussed here but information about several HACCP software can be obtained from the following references (Mermelstein, 2000; <http://peaches.nal.usda.gov/food-borne/fbindex/-HACCP.asp?subtopic=general>; <http://www.food-safetycentre.com.au/fstoolkit/>). HACCP software typically provides step-by-step instructions for development and documentation of HACCP plans e.g. with reference to specific regulatory requirements. In addition, these software substantially facilitate record keeping and thereby also internal and external auditing of HACCP plans and of the associated prerequisite programs. To identify hazards and critical control points decision trees consisting of a structured series of questions have been suggested (ILSI, 1997) and software makes it easy to use such trees.

Traceability or product tracing has been a hot topic within the food sector during the last several years. The European Food Law (EEC, 2002), which applies from January 2005, demands that

each business operator shall be able to identify their supplier and customer and on demand provide this information to the competent authorities. Interest in traceability is primarily stimulated by the need to withdraw from the market, as specifically as possible, a product, a production lot, or products originating from particular animals or crops, when these are suspected of being hazardous to human health. It remains uncertain how the requirements of the so-called ‘one up, one down’ traceability model demanded by EU will be enforced, but it seems most likely that paper-based record keeping, e.g. in relation to existing HACCP systems, will be sufficient.

Nevertheless, it has stimulated interest in electronic systems for chain traceability e.g. systems that communicate with finance software, business systems and work as an integrated part of production management. In this way, traceability systems can contribute to brand protection by making available information on e.g. origin of raw materials, processing history or other information of interest. With electronic chain traceability systems information only needs to be entered once rather than written down each time a raw material or product is processed, packed or repacked. This may reduce errors and results in savings, in some steps of a supply chain (Frederiksen et al., 2002; Denton, 2003; Furness and Osman, 2003; Larsen, 2003).

A number of companies that provide e-business solutions also provide traceability systems (Rowan, 2002). However, development of inexpensive and flexible systems that are suitable for small food businesses remains a challenge (Frederiksen et al., 2002). Another challenge includes exchange of data between chains and this problem is related to lacking specifications for electronic

Table 2
Examples of computer systems for use in HACCP or quantitative risk assessment

Reference	Subject
Zwietering et al. (1992), Wijtzes et al. (1998), van Gerwen et al. (2000)	Pattern matching, data and knowledge base, quantitative microbiology
Voyer and McKellar (1993)	Quantitative microbiology, expert system, flow chart
Adair and Briggs (1993)	Quantitative microbiology, data and knowledge base
Schellekens et al. (1994)	Quantitative microbiology, data and knowledge base, physical modelling
Zwietering and Hasting (1997a,b)	Quantitative microbiology, data base, physical modelling
van Gerwen et al. (1997)	Hazard identification, pattern matching, data and knowledge base
Brown et al. (1998)	Quantitative microbiology, physical modelling, stochastic modelling
Linko (1998)	Expert systems in food industry
Barker et al. (2002)	Bayesian belief network
Buche et al. (2002)	Fuzzy logic, data and knowledge base
Ross and Sumner (2002)	Risk ranking tool
Tuominen et al. (2003)	HACCP tool
HHS/USDA (2003)	QRA: scenario tools
Australian Food Safety Centre (2004)	Risk ranger (see Ross and Sumner, 2002)
	Food Safety Toolkit™ for development, implementation and maintenance of food safety strategy

traceability systems (Furness and Osman, 2003). As discussed below European projects have recently focused on these aspects.

The project Info-Fisk (Frederiksen et al., 2002) studied a fresh fish chain and demonstrated that an internet-based open system with full traceability from catch over collector, auction, wholesaler and final sale in a supermarket could be developed using ‘off the shelf’ hardware. The system relied on bar codes to identify for traceable units and XML for internet-based transfer of data between operators. The Info-Fisk system not only locates a product but also allows temperature measurements, or any other information, to be transmitted along the whole chain in real time and thus fish of known and documented time/temperature history to be marked.

The EU-funded project Tracefish has established specifications for holding and encoding of information for electronic traceability systems concerning seafood. The specifications are available on the projects homepage <http://www.tracefish.org/>. FoodTrace (<http://www.eufoodtrace.org/>) has focused on other food sectors and their suggested specification most likely become available during 2004.

10. RFID technology, standards and traceability

In recent years, Radio Frequency Identification (RFID) has received significant coverage by many interested parties. Much of the impetus for the use of this technology has come from the enormous drive that companies such as Wal-Mart (USA), Tesco (UK), Department of Defence (US) and Food and Drug Administration (FDA) in the US have provided in the area of commercialising what has been available for some 50-plus years as a new means of efficiently managing the supply chain.

The use of RFID tags and readers will revolutionise the way supply chain data is captured and communicated. In addition to the increased benefits perceived by the drivers, it will facilitate the link between the various parties touching the supply chain that traditionally viewed their role as neither relevant nor applicable to traditional supply chain practices. The supply chain is often treated separately to the traceability chain, but, in fact, co-exist together and all parties must consider that, whilst their roles and responsibilities may lie independently of each other, their impact on each other is not mutually exclusive.

How does the supply chain have an impact on or complement traceability and testing procedures within the food industry? For some 30 years, manufacturers of food and grocery items have been asked by their customers to apply bar codes to their products to enable the more efficient capture of data initially at the point of sale but, more so, within the entire supply chain. The use of such technology enabled increased accuracy, speed and sourcing of information that, in traditional retail environments, was labour intensive and not cost efficient. In the last five to ten years, a shift in understanding of the use of this technology has changed. More and more companies are realising the benefits of using this specific technology, global standards and emerging technologies not only to ensure their supply chains become more efficient but, more importantly, to leverage the technology to improve traceability requirements. However, to be able to gain leverage from existing and newer

technologies within the supply chain and move forward to the full use of technologies such as RFID, it is critical for all parties to understand the role of standards within this context.

To underpin the use of RFID tag technology, and for the more traditionally perceived bar code, common standards are required and this is where the EAN•UCC system comes into play. Regarded as the true global standard for product identification, attribute information, location numbering, asset tracking and logistic unit tracking, the EAN•UCC system is a global standard administered by over 100 similar, not for profit organisations throughout the world (see <http://www.ean.com.au/>). The system offers a standard to support supply chain best practice and is endorsed by, not only, the Fast Moving Consumer Goods industry but by over 24 industry sectors worldwide, including Health, Foodservice, Meat and Transport.

The fundamental principles of the EAN•UCC standards are based on the need for a common identifier, traditionally represented within a bar code. This common identifier, referred to as a Global Trade Item Number (GTIN), is the number that most people associate with the grocery trade experiencing it when they hear the common “beeps” from the scanners at their local supermarket.

Complementing the technology of bar codes is the emerging drive to utilise RFID within industries required to have full traceability. Be it food, transport units and assets to name a few, this technology can provide opportunity to capture data efficiently across trading partners within a supply chain and amongst participants not commonly linked within a traditional supply chain. However, a critical path to the successful adoption of this technology lies in standards. Hence, EAN•UCC have established EPCglobal Inc., a subsidiary of the EAN International and Uniform Code Council organisations to develop, administer and maintain the EPCglobal network, the standards and network for the application of RFID within the supply chain (see <http://www.epcglobalinc.org/>).

The EPCglobal network has a vision to be a network of databases around the world. Using the Internet, these databases are identified through a discovery service [the Object Naming Service (ONS)]. These track and trace product movement using a standard for communicating data between interested parties called the Physical Mark Up Language (PML). The Electronic Product Code (EPC) is the serialised identification of these items and, combined with the EPCglobal network, will provide for increased visibility and, thus, greater traceability.

The development of standards within this technology opens the world to potential opportunities to further connect trading partners, clinicians, scientists etc. to the world of information already available, but not necessarily accessible, due to proprietary systems.

11. Conclusions

The ability to manage microbial food safety risks has clearly benefited greatly from ready access to the wealth of knowledge

pertaining to the types of pathogens found in foods and the effect of environmental conditions on the behaviour of those organisms at the population level.

Respectively, these uses demonstrate how databases are empowered:

- to match the compiled characteristics of a microorganism with those of a newly isolated strain for the purposes of identification and/or epidemiological investigation, and
- when combined with information on the environmental conditions pertaining during the processing, distribution and storage of food, to provide probabilistic or quantitative kinetic estimates of changes in microbial population densities.

In the latter application, the microbial food safety status of a food is predicted on the basis of prior knowledge by monitoring the food environment rather than by *de novo* microbiological studies.

As information systems become more sophisticated (e.g. RFID technology) and are combined with increasingly extensive microbial databases (e.g. *ComBase*), prospects for continual, real-time monitoring will take food safety management to new levels of precision and flexibility.

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