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Driving predictive modelling on a risk assessment path for enhanced food safety¹

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Abstract

How do we best protect our citizens to allow the highest quality of life? Where do we put our food safety resources so that we gain the greatest positive impact? Risk assessment provides the critical scientific basis for these types of important risk management decisions. Increasingly, risk assessment is used to guide legislated and voluntary changes intended to improve safety, yet its formal application for enhanced food safety is in its infancy. Risk assessment includes disease characterization, dose–response assessment, exposure assessment, and risk characterization. Quantitative data is critical for risk assessment to realize its full value, yet much of our knowledge about the incidence of pathogens or toxins in foods, dose–response knowledge, incidence of acute food-borne illness, incidence of chronic sequelae, and cost of food-borne illness is qualitative or estimates are controversial. Predictive modelling should help to improve estimates and thereby allow quantitation of food safety risks. Predictive modelling will also find application for assessing prevention strategies in risk management. © 1997 Elsevier Science B.V.

Keywords: Risk assessment; Food safety; Predictive modelling; Risk management

1. Why risk assessment? The questions

Risk assessment is an analytical tool which is being used and proposed increasingly to help define priorities for establishing public policies. It is a logical approach which has been used successfully

for managing many types of risk including radiation control, chemical contamination of the environment and foods, and water quality. Application to microbiological food safety risks is a recent focus although the Food and Drug Administration, the primary regulatory authority for foods in the USA, has a long history of applying risk assessment to chemical components of foods. There are several recent reports applying quantitative risk assessment to specific food safety issues including the hazard of *Listeria monocytogenes* in milk, enterohemorrhagic *Escherichia coli* in ground beef, and *Salmonella* in egg (Peeler and Bunning, 1994; Todd and Harwig,

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1996; Buchanan and Whiting, 1996; Walls and Scott, 1996; Cassin et al., 1996). The strategy for using microbiological risk assessment to aid the development of the U.S. Environmental Protection Agency's National Primary Drinking Water Regulations was reviewed by Macler and Regli (1993). The desire in most instances is to be quantitative in assessing risk, yet often this is hindered by the available data relative to microbiological food safety risks. This chapter will define and illustrate applications of risk assessment, differentiate risk assessment and HACCP, illustrate points in risk assessment where data are lacking and therefore full effectiveness of the analytical process is compromised, and suggest applications of predictive microbiology to enhance risk assessment.

Risk assessment can be used to answer a variety of questions. The following are hypothetical questions for illustrative purposes. Where should we put our resources for food safety regulations, processing improvements, public education, and research? A regulatory official or food industry executive might consider the following. "If one intervenes by requiring some action (perhaps the inclusion of temperature recorders on each case of product) it is likely to cost \$1,000,000 and to save \$800,000 so that the real cost to the public or the company is likely to be \$200,000." A public health official might consider: "If we intervene in a certain way (for example an intensive food safety education program), it is likely to decrease the number of illnesses by 50% or 40,000 fewer individuals are expected to become ill and 50 fewer fatalities are expected to occur." An industrial food microbiologist might consider: "What tolerances (critical limits) of pathogens are appropriate in various foods?" An educated public might consider: "Recognizing that one cannot provide foods which are 100% safe, what is the real goal when we indicate that 'improved food safety' is desired?" Other questions might be: "How do we best protect the populace to allow the highest quality of life? Do we want to minimize illnesses, minimize the number of severe illnesses, minimize the number of deaths, or minimize the number of illnesses for selected populations?" or "Which management strategy would yield a product which is likely to be safer?" or "Which research knowledge is likely to be the most important for improved food safety?"

2. Definitions and history

As defined by the National Academy of Sciences (National Research Council, 1983), risk assessment is one step of risk analysis, which also includes management and communication of risk. Done properly, risk assessment puts the best objective, scientifically based, quantitative information to bear on the safety issue. Given a good scientific foundation, reasonable management approaches can be developed which will consider economics, ethics, science, public health, law, and politics. Success depends on valuable communication so that the needs and expectations of those affected by the risk can be considered and the public will have a true understanding of the risk.

Risk assessment began in the field of radiation control and is now commonly used to estimate potential risk to individuals in the community and to identify opportunities for risk reduction relative to nuclear power plants. The history of its application as well as sources of dissatisfaction were reviewed recently by Graham (1995). Risk assessment is being applied increasingly to issues of public concern. In 1983, a seminal report on how federal programs in the USA should evaluate and control risk was published. This report by the National Research Council is entitled *Risk Assessment in the Federal Government: Managing the Process*. This became the guiding document for a series of studies and reports on the risk of food-borne illness. These included *Meat and Poultry Inspection: The Scientific Basis of the Nation's Program* (1985), and *Poultry Inspection: The Basis for a Risk-Assessment System* (1987). The report *Foodborne Pathogens: Risks and Consequences* (CAST, 1994) brought the potential for risk assessment to the attention of many individuals interested in food safety microbiology including food processors, academicians, and regulators. More recently, the Joint FAO/WHO expert consultation (1995) report called for the application of risk analysis to food standards and the General Agreements on Tariffs and Trade indicated risk assessment will be used to resolve trade issues.

Risk assessment includes the following four steps. (1) Disease characterization or hazard identification is the first step. Here it is qualitatively acknowledged that, for example, *Salmonella* may be present in raw

poultry and cause salmonellosis; *Vibrio parahaemolyticus* may be present in seafood and cause food-borne infection; or *Clostridium botulinum* may cause botulism if it is present and produces toxin in canned vegetables. (2) Dose–response assessment defines the relationship between the magnitude of exposure and the probability of occurrence of the spectrum of possible health effects. What is the likelihood of becoming ill if 10 *Salmonella* cells of a specific *Salmonella* serovar are consumed? How severe is the illness likely to be? This step needs to acknowledge differences in consumer susceptibility. (3) Exposure assessment is determining the extent of human exposure before or after application of regulatory or voluntary controls. What is the distribution of *V. parahaemolyticus* in seafood and how is the distribution affected by the type of seafood, the season, the harvesting location, and so on? Clearly, the permutations of this question which would be pertinent to accurate, quantitative risk assessments are endless. (4) The analysis culminates with risk characterization which is intended to integrate the above steps into a quantitative estimate (probability) of the adverse effects likely to occur in a given population. Additionally, it may identify economic and social impacts of human risk. This step clearly is vulnerable to the uncertainties and non-quantitative nature of much of the underlying data which is essential to predict health, economic and social impacts.

3. Risk assessment, risk analysis and HACCP

Through perusing the food safety literature, it is evident that risk assessment and hazard analysis–critical control point systems (HACCP) are often

included in the same discussions, yet may be confused and considered to be related in different ways by different people (for example, see Buchanan, 1995; Notermans and Jouve, 1995; Sperber, 1995; Buchanan and Deroever, 1993; Untermann, 1995; van Schothorst, 1994). Risk assessment is intended to provide the scientific basis for risk management and communication and was developed as an analytical tool for responsibly integrating science with public issues and public policy. HACCP is a systematic approach to the control of potential hazards in a food operation (Bauman, 1974; ICMSF, 1988; Mayes, 1992; CODEX, 1993). It aims to identify problems before they occur and establish measures for their control at the stages in production that are critical to ensuring the safety of the food. Thus, risk assessment concerns the overall product safety and is applied to analysis of the food product as presented to the consumer (analysis at the end point), while HACCP enhances overall product safety by assuring day-to-day process control and may be applied at any point in the processing/handling chain.

The steps in risk assessment and those in HACCP are summarized in Table 1. Confusion which may exist between risk assessment and HACCP is likely to occur because the first step of each is similar and involves recognizing microorganisms of concern. It has been suggested that the four steps of risk assessment are useful for specifying the criteria, or numbers of allowable organisms, in HACCP systems (Buchanan, 1995; Notermans and Jouve, 1995; Notermans et al., 1994, 1995); this concept is schematically illustrated in Fig. 1a. Although this approach is logical, to limit risk assessment to this one possible application does not take full advantage of the real power of the process. A broader view is illustrated in Fig. 1b, where it is acknowledged that

Table 1
Steps in risk assessment and HACCP

Risk Assessment	HACCP
1. Disease Characterization	1. Hazard Analysis
2. Dose–Response Assessment	2. Determine Critical Control Points
3. Exposure Assessment	3. Implement Control Measures and Specify Criteria
4. Risk Characterization	4. Monitor the Critical Control Points
	5. Apply Corrective Action
	6. Establish and Keep Records of the HACCP System
	7. Verify the HACCP System

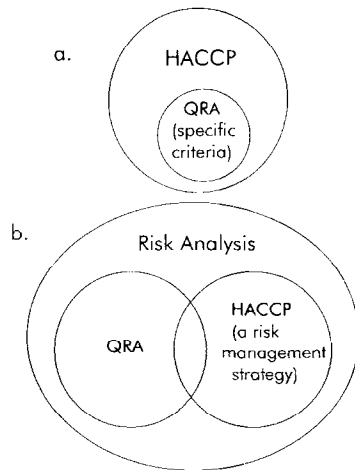


Fig. 1. Schematic diagram illustrating perspectives on the relationship of HACCP and quantitative risk assessment (QRA). (a) View which considers QRA a tool for establishing HACCP systems; this use of risk assessment is valuable yet limiting. (b) Perspective which considers QRA and HACCP interrelated yet different approaches to understanding and enhancing food safety. In this view, each approach may impact the other, reflecting the iterative nature of risk analysis, for which HACCP is a risk management strategy.

risk assessment and HACCP have some overlapping components (CAST, 1994; Sperber, 1995; Untermann, 1995). Both HACCP and risk assessment are encompassed in risk analysis, where HACCP represents one management strategy. Where a HACCP

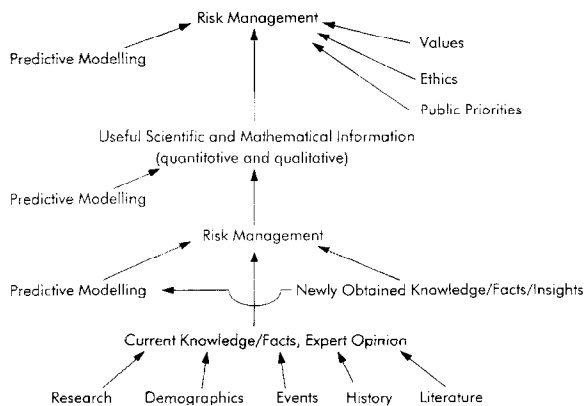


Fig. 2. Schematic indicating the chronology where HACCP systems are used as a risk management strategy (Pearce, 1996).

system is implemented, risk assessment would be applied to the product with this management strategy in place, as this is the product to which the consumer is exposed (Fig. 2).

4. Looking beyond food safety

It is useful not to be too myopic in one's view. Risk analysis, including risk assessment, is a process which is used outside the food industry. Although HACCP is related to approaches used in other industrial sectors, the term itself is familiar principally to the food manufacturing industry. This is illustrated by Morgan (1993), who writes (concerning airline manufacturing) about enumerating failure modes, constructing fault trees, and determining the probability that individual elements will fail. Note how his description includes modified approaches which sound like HACCP (emphases added):

“on the basis of their findings,” Boeing “revised its safety standards to mandate the use of programmable logic controllers for safety-critical controls.” He goes on to write they “instituted rigorous testing of automatic shut-off valves for leaks and added alarms that warn operators to close manual isolation valves during shutdown periods. This reduced the likelihood of explosions by a factor of 20.” “When risk specialists must estimate the likelihood that a part will fail or assign a range of uncertainty to an essential value”... “sometimes workers can build predictive models to estimate probabilities based on what is known about roughly similar systems, but often they must rely on expert subjective judgement.”

Expert subjective judgement could be elicited in a quantitative manner and therefore applied in modelling scenarios. This was illustrated by Martin et al. (1995) who used expert elicitation to quantify probabilities of mild, moderate, and severe outcomes relative to consumption of selected food-borne pathogens.

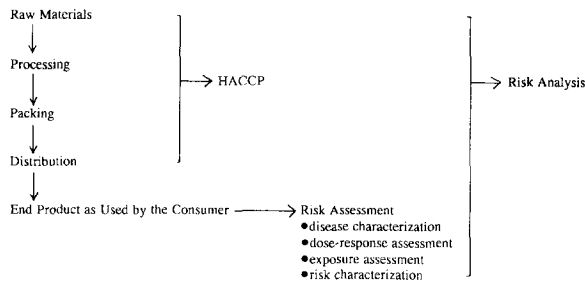


Fig. 3. Flow diagram illustrating the steps in risk assessment and risk management including points where predictive microbiology is likely to have an impact.

5. Where might predictive microbiology fit in?

Fig. 3 begins to show where predictive microbiology might be applied in the risk assessment and management processes. Current and newly obtained knowledge, facts, and expert opinion are used to build predictive models related to food safety issues and each of these provide information which is useful in the process of quantitative risk assessment. The outcome of risk assessment is useful quantitative information which, along with modelled predictions and knowledge of public priorities and values are important in risk management decisions. Given that in the food industry, one management strategy would be application of HACCP, then the consequence of proper implementation of HACCP may lead to a revision of the risk assessment and this would impact subsequent decisions. The process is iterative and thus is responsive to current issues, situations, management strategies, and shifting public opinion.

6. Missing data

The challenge is to provide objective, prospective and predictive information for application in risk assessment and ultimately for risk management. What we know is based upon the past and there are many gaps in our knowledge due to gaps in our data. Using the four-step quantitative risk assessment framework as an outline, gaps in our knowledge which are believed either to limit our ability to implement quantitative risk assessment, to increase the uncertainty associated with the outcome, or to be

likely sources of criticism of the analytical tool are discussed below. It is hoped that this list will not be seen as a damnation of the process, but rather as a means to focus research in order to fill these gaps.

6.1. Disease characterization

The first step of risk assessment is the area where we have the most comprehensive knowledge. Generally we have good information of which microorganisms may be food-borne and may cause disease, as well as the disease consequences. Two areas where information is lacking are the viral pathogens and possible long-term consequences (chronic sequelae) which may result from some infections. Furthermore, it is certain that there are as yet unknown food-borne pathogens and toxins; predictive microbiology could be applied to understanding newly recognized pathogens, food handling circumstances of concern, and the disease state.

6.2. Dose-response assessment

There is a paucity of quantitative information regarding the likely outcome of ingestion of a food contaminated with varying levels of pathogenic microorganisms or toxins. Such questions as “What is the likelihood that infection and illness will occur and for what proportion of the population?” and “Will the disease outcome be mild or severe?” beg to be answered. Given that further studies of this type with human subjects are unlikely, we will have to rely upon animal models or on outbreak data to construct appropriate dose-response models. Mathematical approaches will be essential to success. Predictive microbiology could be very useful in identifying or developing appropriate dose-response models; in predicting the probability of infection, illness, and death; in extrapolating from animal studies or human feeding studies to other populations; and in predicting from vector-to-vector, for example from water-to-food or from one food to another. Are the consequences the same when the medium is water versus chicken or when consuming the pathogen as part of a snack versus a large, high-fat meal? Certainly not! What is the effect of the food matrix on likelihood of illness? Predictive

modelling could help us to anticipate the different consequences which are likely.

There are a few illustrations in the literature of probability models relative to food-borne or water-borne pathogens (Haas, 1983; Regli et al., 1991; Rose et al., 1991; Rose and Sobsey, 1993; Rose et al., 1995). Haas (1983) evaluated three dose–response models for estimation of risk due to low doses of microorganisms using pathogens of water-borne significance (*Shigella dysenteriae*, *S. typhosa*, *S. flexneri*, poliovirus, echovirus, and *Entamoeba coli*). He indicated a beta-distributed model appeared to be the most widely applicable. Regli et al. (1991) modelled the risk from *Giardia* and viruses in drinking water and Rose et al. (1991) modelled the probability of illness from *Giardia* cysts. Rose and Sobsey (1993) used dose–response models developed from human feeding studies to estimate the risk of infection due to rotavirus and hepatitis A virus from contaminated shellfish. Rose et al. (1995) used models in evaluating risks of disease from food-borne *Salmonella* and *Escherichia coli*.

Models to predict infection or illness for more of the common food-borne pathogens which could be applied to various food consumption scenarios would be very useful because they are quantitative; it is important that they acknowledge the inherent uncertainty of the numbers by reporting probabilities. Clearly, development of such dose–response models is difficult. The complexity of the food system, nature of the organism (for example, the relative virulence and impact of injury on virulence), individual consumer differences (relatively sensitivities), and lack of knowledge of doses consumed and outcomes for specific cases and outbreaks are contributing factors which complicate model development. Despite these challenges, many of the outcomes of consumption of food-borne pathogens are immediate; this simplifies dose–response modelling relative to most chemical hazards where long-term effects are more common.

Undoubtedly initial predictions will not be so refined as to consider all of the complex factors which may impact disease and often will assume a ‘worst case’ situation. This is a legitimate and valuable starting point which, as long as the limitations are recognized, will move our analytical capabilities and understanding of risk ahead.

6.3. Exposure assessment

Predictive microbiology could help to provide good quantitative information on the prevalence of pathogens which are potential causes of food-borne disease relative to foods of concern. To date the focus has been on bacteria; reasonable predictions of growth, survival and death of selected pathogens in specific conditions already are a reality. Certainly improvements in our predictive capabilities will be made and these tools will be extended to a broader array of organisms, toxins and scenarios of concern. Information on non-bacterial pathogens such as fungi, viruses, protozoa, and parasites is needed. There is good data in the literature on the association of various foods with food-borne illness, yet we know that it only touches the tip of the iceberg. Predictive microbiology should help to identify the full range of food types that will support growth or allow survival of specific pathogens. Improved quantitative information on how numbers and types of pathogenic organisms which may be in food change during production, distribution, storage, preparation, and consumption and as a consequence of competing microflora will be an early and continuing benefit of mathematical predictions. Predictive microbiology is being applied to understanding how numbers and types of microbes are likely to be affected by the structure and composition of the food. As improved management strategies are implemented and the probable numbers of organisms change, this new data must be incorporated in risk assessment and predictive models so that the best current information is considered. Given that there are many foods and food handling scenarios of practical concern, new food formulations and processes continually are being introduced, environmental events may affect food commodities and agricultural practices often change in ways which impact the final product, this is a dynamic and challenging area.

6.4. Risk characterization

Predictive microbiology could be used to improve our estimates of numbers of acute illnesses, chronic sequelae, deaths, cost of illness and to help to predict the likelihood of illness/infection/or death from various food, processing and consumption scenarios.

To get good estimates of the probability of consuming a sufficient number of organisms for illness to occur, one must overlay the distribution frequency for the organism in the food with the dose–response information. This, of course is the essential outcome of risk assessment.

Currently the data and consequent predictions are quite variable, as is illustrated by the salmonellosis data in Table 2. The data are incomplete and differ according to the manner of collection. Data on numbers of cases and the case severity are very different for outbreak data (these are reports to public health officials on outbreaks), laboratory surveillance data (these are reports to the Centers for Disease Control and Prevention by state laboratories which are provided when selected human pathogens are isolated) and other special studies conducted to collect more detailed information on selected pathogens. Given the differences in the underlying data the extrapolations to estimate ‘real’ numbers of cases and deaths (as one would expect) vary vastly. Predictions for other pathogens for which less data are available, are more variable and less certain (CAST, 1994). Estimates of the numbers of deaths are perhaps the most controversial (CAST, 1994).

7. A word about the results

Quantitative risk assessment of a food safety scenario will always be difficult because of the many variables involved in the data needed for hazard and exposure assessment. These include the specific organism and its state, the food handling and consumption circumstances, and the idiosyncrasies of the individual consumer. That this analytical tool can recognize the uncertainty in the data is also a strength when it does not imply more confidence than is reasonable. However, as was noted by Graham (1995) in a historical overview of risk assessment which primarily addressed applications to chemical use and residues, “most real-world risk assessments produce a single risk number that is intended to represent a plausible upper bound on the risk”. The caveat that the numerical estimates are unlikely to be too low and that the true risk may be negligible, is not always communicated clearly to the public and is a factor which has contributed to increased scrutiny and criticism of risk assessment. Graham (1995) also indicated that dissatisfaction with risk assessment is due to the use of arbitrary exposure scenarios, the excessive reliance on animal

Table 2

Salmonellosis data from the U.S. Centers for Disease Control and Prevention sources, and extrapolations to estimate numbers of annual cases and case severity

	Outbreak data ^a , 1983–1987	Laboratory surveillance data, 1990 ^b	Sentinel county studies ^c , 1979 and 1984	Extrapolations based on	
				Outbreak data ^d	Special surveillance studies ^{e,d}
Outbreaks	68	NA ^c	NA	NA	NA
Cases	6249	44,000	40,000	2,000,000	400,000– 4,000,000
Severity					
Deaths	8	ND ^f	500	2000	1000
Hospitalizations	ND	ND	18,000	34,000	36,000
Physician seen	ND	ND	22,000	101,000	44,000
No medical attention	ND	ND	NA	1,863,000	1,919,000

[This table is modified from Table 5.2 of CAST (1994).]

^aBean et al., 1990a,b.

^bBean and Griffin, 1990.

^cCohen and Tauxe, 1986.

^dRoberts, 1989.

^eNA = not applicable.

^fND = not done.

testing, the lack of formal uncertainty analysis, and the neglect of inequities in the distribution of risk. Each of these are potential sources of criticism with application of risk assessment to microbiological food safety analysis. Baird-Parker (1995), commenting on application of dose–response models and consumption scenarios indicated: "... these workers are to be congratulated for tackling microbiological risk assessment in a logical way", even though it was acknowledged that many of the specific assumptions were probably wrong. As we begin to apply risk assessment to the analysis of food safety data, some assumptions must be made and are certain to tend toward evaluating 'worst case scenarios' in order to err on the side of safety. We must not be too critical of this approach yet must also recognize the bias and communicate it clearly. Where alternative approaches are available which would responsibly minimize the conservative bias, they should be employed (see Bogen, 1994).

One practical and useful outcome of risk assessment is to allow importance analysis to identify points in the food handling continuum from food source to consumption where improvements in handling will reduce risk the most (Cassin et al., 1996). With proper analysis of the data it also will be possible to determine where further research effort will be useful or in fact will yield minimal benefit. Po (1996) described the use of meta analysis in the pharmaceutical industry to achieve this outcome.

8. The future

Risk assessment relative to microbiological food safety issues has begun and will continue. It is exciting to recognize that improvements in the databases and accessibility of the databases to those interested in quantitative predictions will dramatically help to enhance risk assessment. Data management has experienced significant growth in all industrial segments and, as such, it is an area where we can expect significant advances. Availability of interactive databases with input from industry, public health agencies, regulatory agencies, and academia, including data from around the world will allow large strides to be made in the ability to apply quantitative risk assessment to enhancing food safety.

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