

Risk Assessment as a Tool for Food Safety Managers: The Case of Microbial Contaminants

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Abstract

The Food and Agriculture Organization (FAO) and World Health Organization (WHO) risk analysis framework and principles are being implemented in different national and international settings. Risk analysis is comprised of risk assessment, risk management and risk communication. Microbiological risk assessment is a new discipline; the number of peer-review published microbiological risk assessments is low and the format is still variable. The presentation and discussion of formalized microbiological risk assessments will inform the debate at both the international and national levels. The ultimate goal is to define better risk management options and mitigate the spread of microbiological food-borne diseases. The WHO and the FAO have initiated international work to improve the standardization and dissemination of microbiological risk assessment and to develop more efficient and open interaction between risk managers and risk assessors.

Introduction

Food safety is an essential public health issue for all countries. Food-borne diseases are widespread and represent a serious threat to health in both developing and developed countries. Approximately two million children die annually from diarrheal diseases, while hundreds of millions suffer from frequent episodes of diarrhea and its debilitating consequences, mostly caused by food or water-borne pathogens (WHO, 2000). Diarrhea is the most common symptom of food-borne illness, but other serious consequences include kidney failure, brain and nerve disorders, and death.

Available data indicate that the frequency of food-borne disease in the past 10 to 20 years has been on the rise the world over. In the 1980s and 1990s, emerging pathogens have caused new and increasing problems (WHO, 1995; TAUXE, 1997). Examples include Salmonella, Campylobacter, Yersinia, Enterohemorrhagic E. coli (EHEC) and Listeria monocytogenes. Up to 30% of the population in industrialized countries may be affected by food-borne illness each year and the problems are likely to be even more serious in developing countries (MEAD et al., 1999).

A very significant part of food safety problems appears related to microbiological hazards, and current food control systems have not adequately dealt with these. The allocation of resources in microbiological food safety initially focused on the introduction of general tools of "Good Hygienic Practices" (GHP) through all production and preparation stages as well as efficient use of pasteurization, cold-chain and food additives to prevent growth of or kill

pathogenic microorganisms. A more focused control of the relevant hazards was introduced through systems such as HACCP (Hazard Analysis and Critical Control Points). In spite of these improvements, the problems seem to have increased, making the traditional food control measures appear insufficient. The disease increase has prompted a search for the causes behind this evolution. New production systems in the primary production as well as in the manufacturing sector are likely to have had an influence. However, it is likely that the real problem is not that these new systems are inherently less safe, but that the hygienic consequences of introducing them were not evaluated. Other changes in the food production chain from farm to table, including changes in kitchen habits at the consumer level have also been mentioned in this context, as have increases in food trade and tourism.

For whatever reason, it appears that there is an increase in microbial food-borne disease, and whether or not this can be substantiated in valid, comparable data, it is clear that the problems at hand in all regions of the world call for concerted action using science-based methodology. The development of a risk analysis framework over the last decade can be seen as an attempt to provide such methodology.

Risk Analysis and Microbiological Food Safety

Risk analysis comprises risk assessment, risk management and risk communication (FAO and WHO, 1995). The risk analysis process is generally initiated by government authorities. Although important components can be developed in an international cooperative framework, the full risk analysis process is typically a national initiative. Risk can be defined as “a function of the probability of an adverse effect and the magnitude of that effect, consequential to a hazard(s) in food” (FAO and WHO, 1995).

Most often, the initiating part of risk analysis is risk management. The word management stems from the Italian verb *maneggiare*, meaning to ride a horse with skill. In contrast to the confusion over use and meaning of some of the other vocabulary in the risk analysis realm, the perception of this concept is generally straightforward. In Codex Alimentarius terminology, risk management is the process of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures (FAO and WHO, 1996).

Risk communication is the exchange of information and opinions concerning risk and risk-related factors among risk assessors, risk managers, consumers and other interested parties (FAO and WHO, 1999a).

Microbiological risk assessment (MRA) provides a scientific description of food-borne risks related to the occurrence of pathogenic microorganisms in the whole food chain. MRA has four components: hazard identification, hazard characterization, exposure assessment and risk characterization (FAO and WHO, 1999b).

Over the past decade, there has been an acknowledgement internationally that various areas of potential microbiological risk need to be assessed and managed on the basis of science-based approaches. The risk assessment framework in the area of genetically modified microorganisms was primarily initiated through work conducted by the Organization of Economic Cooperation and Development (OECD) in the mid 1980s (OECD, 1986). These principles were later elaborated and formalized in European Commission (EC) Directives 90/219/EEC and 90/220/EEC. Likewise the regulation of microbial pesticides in the EC is governed by Directive 91/414/EEC, wherein microbial risk assessment plays a major role.

The new international trade agreements developed in connection with the World Trade Organization (WTO) also emphasize science-based risk analysis. In particular, the Sanitary

and Phytosanitary (SPS) Agreement (Article 2, paragraph 2) establishes that sanitary - measures should be based on scientific principles and should not be maintained without sufficient scientific evidence.

The FAO/WHO risk analysis framework and principles are being implemented in different national and international settings. The Joint FAO/WHO Food Standards Program is the basis for the Codex Alimentarius Commission (Codex), and food safety standards, guidelines and recommendations established by Codex are generally recognized as the basis for harmonization of sanitary measures. The aim of risk analysis is to provide a means for a science-based evaluation of risks associated with foods and the preventative measures which could be used to lower them. In this respect, it is likely that decision systems modeled after the FAO/WHO risk analysis framework will be the tools of food safety managers in the future.

Microbiological Risk Assessment

Microbiological risk assessment is an essential element of risk analysis, as it describes food-borne risks related to the occurrence of pathogenic microorganisms in the whole food chain. The novelty of this concept is that risks are assessed throughout the food chain on the basis of sound science, combining qualitative and quantitative data in the areas of epidemiology and pathogenicity of microorganisms with data from monitoring of food and food animals, food production and handling.

According to the Codex definition, risk assessment should be commissioned, scoped and targeted by risk managers through a risk assessment policy. It is, however, necessary to remember that different types of problem warrant different types of assessment. In principle, some risk assessments can be done over a very limited time span, whereas others (typically) need a full MRA, including all four components and a significant input of specialized man-hours.

The 4 phases or steps of microbiological risk assessment can be outlined as follows:

1. **Hazard Identification:** the identification of agents capable of causing adverse health effects which may be present in a particular food or group of foods. The purpose of hazard identification in MRA is to identify the microorganism(s) or microbial toxin of concern and to collect evidence that it is indeed a potential hazard when present in the particular food. Epidemiological, biological, and other pertinent information and expert knowledge are used to link biological agents and their sources in food to illness in consumers.
2. **Hazard characterization:** the qualitative and/or quantitative evaluation of the nature, severity and duration of the adverse effects associated with the identified agents. A dose-response assessment should be performed if data are obtainable. Key factors to consider relate to the microorganisms, the mechanisms and dynamics of infection and the sensitivity of the host. Important issues are: the description of the relationship between different doses and their relative effect (the dose-response relationship), the impact of the composition of food, the virulence of strains and the sensitivity of (sub-populations of) consumers at risk. A number of limiting factors have been identified which contribute to the uncertainty in the description of the dose-response relationship, such as: the absence of human data, incomplete epidemiological information, difficulties in extrapolating from animal data to humans and a lack of mechanistic models. Important additional input into hazard characterization are estimates of the rates of infection, morbidity and mortality of the relevant disease. Collecting this kind of data is typically the

domain of public health officials, which again underlines the importance of ensuring that food safety is recognized as an important public health issue.

3. **Exposure assessment:** the determination of the numbers/quantities of pathogens or toxins ingested by the consumer and the prevalence of such ingestion(s). This is the part of MRA where food companies can make important contributions through the provision of data. Most (theoretical) data should be developed taking into account not only processing during manufacture but rather the whole distribution chain from primary production of raw materials to the preparation and use by the consumer. This aspect of MRA involves determination of the probability and extent of exposure to a population, possibly including consideration of sub-populations exposed to varying quantities of the microorganism. Several factors such as quantities of product sold, quantities consumed, consumption habits, etc. need to be taken into consideration. Some such data could be obtained through improved coordination with nutrition/consumption studies, to develop knowledge of consumption data relevant to food-borne microbiological risks. Another important aspect is the behavior of the pathogen in the product, with a view to estimate the pathogen level(s) at the time of consumption. To this end data on the killing effect of various processing steps are available for many products, and growth and die-off models, taking into account different parameters, have been developed. However, for a large proportion of foods, pathogens contaminate the food after a lethal processing step. This will occur either in the processing line before packaging or during the distribution or preparation by the final user (e.g. retail, vending, kitchens, etc.). Post-process contamination is thus an important element to consider in exposure assessment and knowledge of potential sources and of routes of contamination is essential.
4. **Risk characterization:** the quantitative and/or qualitative estimation (with attendant uncertainties) of the probability of occurrence and severity of known or potential adverse health effects in a given population. It may consist of different estimates, based on different scenarios or assumptions, which may help the risk managers to evaluate the effectiveness of various control options. Risk characterization is the last step in risk assessment, on the basis of which a risk management strategy can be formulated. Bringing together the information of the previous stages, it provides an estimate of risk to a given population or sub-population. Given the inherent variability and uncertainty embedded in such estimates, they must be presented with a clear and generally understandable narrative explaining the nature of the results, including range of uncertainty and constraints influencing the estimates, such as data gaps and time limitations. This can help risk managers in their difficult task of evaluating and comparing different types of risk (biological, chemical, physical) and balancing costs and benefits.

It is important to recognize that risk assessment is an analytical process based on technical information and statistical probabilities. The quality of a risk assessment will only be as good as the data going into the calculations. Hence much emphasis should be focused on data needs and data generation. One of the strengths of a formalized risk assessment is that it will allow a scientifically based presentation of data needs in a specific area.

While the typical food-related microbiological risk assessment relies on existing data, not all MRA studies are retrospective in nature. Examples of prospective MRAs are assessments of genetically modified microorganisms, of foods with functional ingredients (functional foods) or even of new technologies, such as the use of non-thermal preservation systems. In these cases, MRA is needed to forecast the expected risk associated with these new practices.

International Publications in Microbiological Risk Assessment

There are two different types of publications on MRA: full risk assessment, which is normally not presented in peer-reviewed journals, and the traditional peer-reviewed journal articles. The latter typically only deal with parts of risk assessments, and generally do not present a final estimate of the risk (for instance, BUCHANAN et al., 1997; NOTERMANNNS et al., 1998; CASSIN et al., 1998). Nevertheless, such papers present valid and scientifically scrutinized elements to be used in risk assessments within risk analysis frameworks.

The documentation of a full-blown risk assessment is not likely to pass through the usual peer-review system of international scientific journals. However, other systems are emerging to obtain peer review of such studies, the first example most likely being the risk assessment of shell eggs and egg products (BAKER et al., 1998). This MRA is presented in its entirety on the United States Department of Agriculture web site (<http://www.fsis.usda.gov/OPHS/ophspubs.htm>), and parts are making their way into traditional scientific literature. In the future a balance needs to be struck between peer-reviewed articles and underlying full reports. In this connection it is very important that every presentation of risk assessments includes a description of the “tool box” required to undertake the particular study, i.e. the assumptions, the models and the software used.

The traditional scientific method of building upon the assumptions of other scientists should be considered with serious reservations in the case of microbiological risk assessments. In particular, the use of undocumented assumptions, or those based on “expert judgment”, which have been presented in other scientific publications could lead to a nontransparent process and presentation of risk assessment. Externally-derived assumptions should be discussed thoroughly in the context of the assessment in question, so that the reader can openly evaluate any inconsistencies.

In general, the role of predictive modeling in risk assessment, such as it is used in exposure assessment, and the use of other mathematical modeling techniques, such as Monte Carlo simulation, should be scrutinized. Taking into consideration the biological variability inherent in all microbiological systems, it is necessary to validate the (use of) models. It is also essential to describe or refer to the data which the model was built upon and the assumptions underlying the mathematical equations.

The transparency of the risk assessment process is extremely important. In the traditional Codex set-up of risk analysis, risk managers have important tasks before, and sometimes also during, the risk assessment process. While this interaction is key, it is at the same time imperative that the two tasks be functionally separated and that any inconsistencies, such as hidden limitations in the scope of the exercise, be avoided. There is a need for a more general development of a protocol for risk assessment, also applicable to scientific approaches not directly linked to risk management.

Future Interactions between Microbiological Risk Assessment and Risk Management

In the future, an important outcome of the risk analysis process is likely to be the establishment of food safety objectives. A working definition of a food safety objective could be: a government-defined target, in the form of microbiological criteria or prevalence rates of pathogens in raw or ready-to-eat foods, considered necessary to protect the health of consumers. Future risk assessments will emphasize the necessity to identify opportunities for intervention for further use in the risk management process. In this context, more

attention will need to be focused on presenting the estimates to risk managers with adequate information about assumptions made, data used and the limits of both.

From the international scientific literature on MRA, it is clear that one important future focus, which has implications for food safety management activities, will be on data needs and data generation. An interesting new concept, which could have implications for data needs, is to consider the risk assessment process in two stages: initially look at the effect of all factors, and then select key factors to be investigated in more detail.

Risk assessment of microbiological hazards in foods has been identified as a priority area of work for the WHO and the FAO and for the Codex Alimentarius Commission. The FAO and the WHO are jointly launching a work program with the objective of providing expert advice on risk assessment of microbiological hazards in foods to their member countries and to the Codex Alimentarius Commission. To this end, the two organizations convened a joint expert consultation in July 2000 to evaluate the available information on risk assessment of *Salmonella* spp. in poultry and eggs and *Listeria monocytogenes* in ready-to-eat foods. The report of the consultation contains the exposure assessment and hazard characterization aspects of these assessments (see <http://www.who.int/fsf/mbriskassess/index.htm>). In response, the Codex Committee on Food Hygiene has suggested more focused questions for the continued work of the expert group before the final report, which will be delivered in 2001. A second round of similar work has been initiated for *Vibrio* spp. in sea-food and for *Campylobacter* spp. in poultry.

Conclusion

Microbiological risk assessment is a new discipline, and limited work has been presented internationally over the last few years in this area. In many cases this work only presents parts of risk assessments and a number of constraints still hamper full deliberations in the area, not the least of these being the scarcity of good data. Open and transparent international cooperation will enable significant improvement in data acquisition and model development, as well as a system of international exchange of expertise and risk assessment data.

Trends in national food safety initiatives show a paradigm shift, moving away from "vertical" detailed legislation, placing more emphasis on risk analysis and "horizontal" general rulings. The importance of cooperation among different public health and food safety authorities is now emphasized in many countries, and the concept of a total overview of the problems "from farm to table" is taking over. The use of MRA to qualify the decision process will be a major global task of the future.

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