An Overview of Microbial Food Safety Risk Assessment†

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ABSTRACT

This is an overview of the application of risk assessment for evaluating and managing foodborne microbiological health risks. Risk assessment comprises four steps: hazard identification, hazard characterization, exposure assessment, and risk characterization. The process provides a framework for systematic and objective evaluation of all available information pertaining to the foodborne hazard. The outcome of microbial risk assessment is an estimation of the magnitude of human health risk in terms of the likelihood of exposure to a pathogenic microorganism in a food and the likelihood and impact of any adverse health effects after exposure. Characterization of the uncertainties and variability in the information used and the risk estimate itself is part of the overall process. Risk assessment thus provides an objective scientific basis for decision making in ensuring the safety of the food supply. This approach to evaluation and management of microbial food safety risks is still in the developmental stages, but as it evolves it will facilitate the process of establishing microbiological criteria for foods in international trade and guidelines for national standards and policies. Furthermore, a detailed risk assessment can be used to identify critical gaps in our knowledge base, characterize the most important risk factors in the production-to-consumption food chain, help identify strategies for risk reduction, and provide guidance for determining priorities in public health and food safety research programs.

Key words: Risk assessment, risk analysis, microbial food safety

Recognition of the significant impact of microbial foodborne disease in terms of human suffering and economic costs to society and industry, combined with an increasing global food trade, has underlined the need to change our approaches to management of the safety of the food supply (11, 14, 33). Traditional management strategies have generally evolved through subjective evaluations of food safety and food safety risk criteria on the basis of national interests and policies and with respect to the local manufacture, marketing, and consumption of foods. Such strategies are no longer defensible nor feasible in a global environment that demands international fair trade, consumer choice, industrial competitiveness, and assurances of safe food. Diminishing fiscal resources for management of food safety and public health concerns also warrant the development of new approaches for assessment of foodborne risks and implementation of appropriate, cost-effective strategies for risk prevention or risk reduction. A structured risk assessment process is needed to estimate the magnitude of human illness associated with foodborne pathogens and to help determine food safety priorities (11). This article provides a brief overview of current microbial risk assessment concepts and their applications in microbial food safety.

A formal process for estimating risk was introduced in U.S. federal agencies in the late 1970s as a means of standardizing the basis for regulatory decision making, specifically in areas concerning potential human exposure to chemical substances with known adverse effects at high doses but unknown effects at low doses (24). The process is predictive, that is, it is used to estimate the likelihood that a defined adverse outcome (harm or loss) will occur in a particular situation or circumstance, based on previous knowledge. Risk assessment methodologies are now used routinely to evaluate risks in many diverse fields, ranging from toxicology and ecology to engineering and economic investment. The outcome of a risk assessment process should ideally provide a clear and balanced representation of the information relevant to a specific situation, described in terms of the probability and impact of an adverse event. It provides the basis for what is known as risk analysis, a comprehensive approach to management of risks through three separate but closely linked interdependent and interactive activities: risk assessment, risk management, and risk communication (17, 21, 22).

The application of risk assessment for evaluation and management of microbial human health risks is a relatively recent development. Most significantly, risk assessment, within the context of the overall risk analysis process, has been advocated by world trade agreements as a rational approach by which to developing consistent, science-based standards for the equitable trade of foods between nations while ensuring the safety of the food supply (33). Definitions of terms, principles, and guidelines for microbial risk

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assessments are currently in the developmental stage, undergoing discussion and debate within national and international agencies. Even among the various disciplines that commonly use the risk assessment process, terminologies and definitions can differ (1). However, regardless of semantics, the objective of the risk assessment process is to answer three risk questions: What can go wrong?, How likely is that to happen?, and What would the consequences be if it did go wrong? (15). Risk assessment for microbial hazards is aligned with the more established risk assessment “paradigms” that deal with chemical and environmental hazards (14, 21, 22, 33). However, unique parameters are required to accommodate the inherent variability and uncertainties encountered with living organisms. These include, for example, the dynamics of growth and inactivation of microorganisms throughout the food chain; the diversity of microorganisms and of the human immune response to microbial agents; and the role of the consumer in dramatically altering the potential risk outcome through food handling and preparation practices.

An exciting prospect for microbial food safety lies in the exploitation of the risk assessment process beyond simply providing an estimate of risk to developing a decision-support tool for management of all aspects of food safety. Rodricks (24) espouses the perspective that risk assessment provides a framework within which all available information and knowledge pertaining to the risk can be organized in a highly systematic way, not only to characterize the nature and size of the risk, but also to describe the degree of scientific certainty that can be attached to the various sets of data, models, and assumptions used to produce the risk. This is a broader view of the nature and content of the risk assessment process than has been customarily adopted by regulatory agents. From this perspective, risk assessment can serve as a valuable analytical tool to enhance our understanding and control of foodborne pathogens. By using the framework to systematically describe all of the factors and circumstances that contribute to a risk outcome, the process can help identify where critical data and/or understanding are lacking in the production-to-consumption food chain and where more research might be warranted. This approach also provides further information to help risk managers determine where in the food chain intervention strategies would be most effectively implemented, with reduction of risk to human health as a final measure of efforts to control, reduce, or eliminate pathogens in the food supply.

DEFINITIONS OF TERMS AND RISK ASSESSMENT PROCESS

At the international level, terms, definitions, principles, and guidelines for food safety risk assessment, including potential biological, chemical, and physical hazards, are in the process of elaboration under the auspices of the Codex Alimentarius Commission (CAC). The CAC acts internationally to coordinate all food standards work under its charter to help risk managers determine where in the food chain; the diversity of microorganisms and of the human immune response to microbial agents; and the role of the consumer in dramatically altering the potential risk outcome through food handling and preparation practices.

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Risk is a function of the probability of an adverse health effect and the magnitude of that effect, consequential to a hazard in food.

Hazard is a biological (chemical or physical) agent in or on property of food that has the potential to cause an adverse health effect.

Risk analysis is a process to scientifically evaluate the probability of occurrence and severity of known or potential adverse health effects resulting from human exposure to foodborne hazards (risk assessment); to weigh policy alternatives in light of the results of risk assessment and, if required, to select and implement appropriate control options (risk management); and to exchange information and opinions interactively among risk assessors, risk managers, and other interested parties (risk communication).

Risk assessment is the scientific evaluation of the probability of occurrence and severity of known or potential adverse health effects resulting from human exposure to foodborne hazards. The process consists of (1) hazard identification, (2) hazard characterization, (3) exposure assessment, and (4) risk characterization. The definition includes quantitative and/or qualitative expressions of risk. Quantitative risk assessment uses numerical parameter measurements, including, for example, point estimates or distributions, and yields a numerical expression of risk. Qualitative assessments use categorical/descriptive representations of probability and risk. In both cases, emphasis is placed on describing the uncertainty and variability in the information used to derive the risk estimate. Ideally, quantitative assessments are desirable; however, recognizing that in many cases insufficient quantitative data for microbial pathogens will be lacking, qualitative evaluations within the framework will allow incorporation of new information as better data are acquired.

Ultimately, any decision regarding the management of risk is a complex process involving not only the scientific evaluation of risk, but also social, cultural, and/or economic considerations (17, 22, 26). The linkages between risk assessment, risk management, and risk communication are schematically shown in Figure 1, adapted from the procedures manual of the Animal and Plant Health Risk Assessment Network of Agriculture and Agri-Food Canada (19). Risk assessment provides the scientific basis for decision making by describing and quantifying the probability and impact of an adverse human health effect. Overall, the risk analysis approach can be described as interactive because it requires communication between assessors, managers, and other individuals affected by the issue; iterative in the sense that decisions may evolve through several steps with scientific, regulatory, and public input; and normative because the
Risk Assessment
- Scientific
- Hazard identification
- Risk characterization

Risk Management
- Process initiation
- Weigh policy alternatives
- Select & implement control options

Risk Communication
- Interactive exchange of information and opinions concerning risks

FIGURE 1. Schematic diagram of risk analysis, a process that involves the merging of scientific assessment, practical management, and ongoing communication (19).

decisions made during the risk analysis process must take into consideration values and standards (19).

The role of the risk assessor is to compile and analyse scientific information objectively, systematically, and apparently. The risk assessment framework of hazard identification, exposure assessment, hazard characterization, and risk characterization provides a structured approach to presentation and evaluation of relevant information in a consistent manner. The framework should be flexible enough, however, to accommodate different risk management needs, the nature and purpose of an assessment, and any limitations imposed by time constraints or information gaps. The risk assessment process is initiated by identifying and understanding what information the risk manager needs to make a decision and to help others understand that decision. Depending on the issue, a comprehensive and detailed quantitative assessment may be warranted, or the assessment may be specifically focused on one or more aspect of the risk situation; in some cases, a qualitative estimate of risk may be sufficient.

Hazard identification is identification of biological agents that are capable of causing adverse health effects and may be present in a particular food or group of foods (7). Epidemiological, biological, and other pertinent information and expert knowledge are evaluated to ascertain the link between a biological agent in a specific food and illness in consumers. This step focuses on the agent and the consequences of its presence in a food, consistent with the definition of hazard in the hazard analysis/critical control point (HACCP) system (23). In other risk frameworks, the focus is usually on identifying the adverse effects of a substance. However, certainty regarding the adverse effect of a microbial pathogen at likely exposures is expected to be common among microbial risk assessments. This is in contrast to assessments of, for example, potential carcino-gens, which must consider the possibility that the agent in question is harmless.

At some stage in risk assessment, it is important to determine whether the particular biological agent/food is associated with health effects that are of sufficient importance to warrant further scientific study, i.e., a detailed assessment, or, in some situations, immediate management action may be required. This concept was elaborated by the U.S. National Research Council (22) and incorporated as a part of the hazard identification step to account for the influence of regulatory mandates and other considerations on the conduct of risk assessments for ecological hazards. Restrictions on data acquisition or availability, or response time, may preclude the appropriateness or timely delivery of a comprehensive risk assessment. This concept emphasizes the need for close interaction and open communication between the risk assessor and the risk manager and other stakeholders in the risk assessment issue.

Hazard characterization is the qualitative and/or quantitative evaluation of the nature of the adverse effects associated with biological agents that may be present in food. A dose-response assessment should be performed if the data are obtainable (7). Dose-response assessment refers specifically to the determination of the relationship between the numbers of the microorganism ingested (or the concentration of a microbial toxin) and the frequency and severity of defined adverse health effects resulting from ingestion.

For microbial agents, elucidation of the nature of the pathogen/host interaction presents several challenges because of the biological diversity among microorganisms and range of susceptibilities and resistance in the human population. Quantitative descriptions of dose-response relationships have been developed for certain pathogens based on experimental data from human feeding trials (9, 12, 25, 27). Further developments will require collection of better quantitative microbial data and exposure demographics during foodborne outbreak investigations and exploration of different ways of modeling dose-response relationships from the data that are available. However, the limitations at this time may be accommodated by using clearly documented “default” estimates derived on the basis of the best available information and by using a combination of empirical evidence and logical, rational expert judgment.

Exposure assessment is the qualitative and/or quantitative evaluation of the likely intake of the biological agent via a food. If relevant to the risk management issue, this step may include exposures from other sources (7). Exposure assessment estimates the probability of consumption and the amount of the biological agent likely to be consumed. All sources of entry of the hazard into the food product should be evaluated, and consideration should be given to the sensitivity, specificity, and validity of the sampling and testing methods used to collect empirical information. Verifiable effectiveness of any existing control measures should be taken into consideration. The scope of the risk assessment, determined by the risk management need, will determine the comprehensiveness and detail required for the exposure assessment; however, all factors affecting the presence and numbers of the agent, up to the point of
consumption, should be considered. This includes the source, frequency, and level of contamination; consequences of handling throughout the food chain; potential for and consequences of temperature or storage abuse; and anticipated preconsumption preparation practices. The exposure unit should be considered as the unit that could potentially result in illnes; for most biological agents in food, that is normally considered to be a single meal serving size, although a minimum amount could be considered a single mouthful. Because it is not possible to measure precisely the population of the pathogen present in a food at the time of consumption, models must be developed to estimate the likely exposure. Predictive modeling techniques describing and quantifying the growth or inactivation of microorganisms are becoming increasingly sophisticated and provide valuable tools for the derivation of probable exposure estimates (18, 20, 30).

Risk characterization is the qualitative and/or quantitative estimation of the probability and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization/dose-response, and exposure assessment (7). This step essentially combines all the information gathered to produce a statement of risk. Risk characterization also includes a summary of the uncertainties and variability of the information used to derive the risk estimate.

Risk reduction measures are often considered only in terms of reducing the probability of an event. However, by definition, risk can also be lessened by reducing the severity of an adverse effect. The explicit description and quantification of impact in the risk characterization may lead to consideration of management options that reduce the severity of an adverse outcome, even if the likelihood of occurrence is not reduced. Description of impact also clarifies issues in which the probability of an event is great, but ultimately the impact is negligible in terms of the outcome of concern, i.e., human health. This may be the case in situations in which, for example, a change in food hygiene inspection procedures allows a certain product defect to go undetected but the presence of that defect has no or very little impact on human health. The defect itself may present an aesthetic problem, which represents a different type of adverse outcome or measure of risk, but food safety risk assessments should clearly separate nonsafety concerns from human health risks (13).

A qualitative estimation of risk may be conducted by assigning probability and impact ratings, such as negligible, low, medium, or high, to the risk factors. If such a system is used for rating exposure and dose-response information, specific guidelines and definitions of assigned ranges for each rating must be clearly described and justifiable. Uncertainties in the risk assessment parameters can be similarly rated.

The outcome of a quantitative risk assessment is a numerical estimation of risk. Traditionally, quantitative risk values usually are derived using point estimates as inputs, such as mean values, or produce “worst-case” estimates using extreme values (e.g., 95% confidence intervals). These techniques have limitations in producing realistic outputs, particularly for diverse and dynamic biological systems (6). Alternatively, a probabilistic analytical approach called Monte Carlo simulation can be used to provide distributions of risk rather than a single value (5, 28, 32). Probabilistic models for microbial foodborne hazards have been developed, integrating empirical data, predictive microbiology, dose-response estimates, and Monte simulations, within the risk assessment framework, to quantitatively describe multistage food systems (4, 8, 31). Computer software programs are available that simplify the application of the technique for complex risk problems. Monte Carlo simulation allows the input of probability distributions for each factor that may affect the risk outcome. Random selection of values that represent hypothetical but possible scenarios within the defined parameters of the individual inputs generates a distribution of risk. This approach results in a more realistic risk estimation by incorporating the inherent variability and uncertainties that exist within the data and the models used to describe the risk situation. Further analyses can be performed to estimate the relative importance of each input factor, providing a valuable means of identifying those factors that significantly influence the risk outcome. Manipulation of the model by changing the inputs, or the parameters used to describe an input, can be readily performed to simulate the effect of that alteration on the risk outcome. This provides a means of evaluating the effectiveness of risk mitigation options before actual physical implementation. However, the ease of using Monte Carlo simulation software does not preclude a thorough understanding of the situation being modeled and the basis of probability distribution functions (3, 28, 32).

APPLICATION OF RISK ASSESSMENT TO MICROBIAL FOOD SAFETY

The development and application of risk assessment offers a systematic, objective approach to evaluation of the risks of foodborne illness in a consistent manner, and to providing a scientific basis for the elaboration of food standards in international trade and for national policies. Harmonization of international requirements for HACCP-based programs will require the use of a standardized approach to determine equivalence (2, 13, 23). The HACCP system is rapidly gaining regulatory status as a preventative strategy for managing hazards associated with foods. However, the outcome of a true HACCP-based system should be improved food safety assurance, measured by a reduction in risk to the consumer and not merely a reduction in the level of a hazard in a food (13). Risk assessment provides the linkage between HACCP criteria and a measure of the associated human health risk to help determine which hazards are essential to control, reduce, or eliminate and to verify that critical control points (CCPs) and assigned critical limits effectively result in risk reduction (2, 13, 23).

Decisions about which hazards are essential to control, reduce, or eliminate—acknowledging that microorganism will never be totally eliminated from the general food supply—requires definition of limits dictated by acceptable levels of risk. The notion of an “acceptable” or “tolerable”
level of risk is a value-laden concept that must be addressed by policy makers together with the public (14, 17, 24, 26). Nevertheless, risk assessment can be used to rank specific foodborne hazards in terms of proportion of their toll on human health. Through determination of the magnitude of the human health consequences of foodborne pathogens, cost estimates can be assigned to the human health impact or risk reduction activities. When the pathogens, foods, or processes that contribute most to foodborne disease, or the populations that may be at increased risk of foodborne illness, are identified, informed decisions can be made to prioritize risk reduction efforts. The aim of any food safety activity, including establishment of microbiological criteria, public health programs, research, and food production, manufacture, distribution, handling, and consumption practices, should be continual reduction of risk associated with the consumption of food.

Currently, the use of risk assessment to evaluate and quantify human health risks associated with microbial pathogens in the food supply is still novel, and few examples of quantitative assessments are available in the published literature. Much of the work to date has been in the area of evaluation and quantification of risks associated with enteric pathogens in water supplies, including protozoa, viruses, and bacteria, to help determine drinking water standards and assess the efficacy and cost benefits of water treatment programs (16). Quantitative and semiquantitative approaches to estimation of exposures for selected bacterial pathogens in foods (6, 20, 29) and dose-response relationships for some significant foodborne pathogens (9, 12, 25, 27) have been examined.

More recent efforts have entailed integrating predictive growth models, exposure assessments, and dose-response models with Monte Carlo simulations to analyze the steps of food production systems in terms of their effect on the health risk outcome. Whiting and Buchanan (31), for example, have demonstrated the applicability of the risk assessment framework with a “unit operations” approach to quantitatively estimate the risk of acquiring a *Salmonella enteritidis* infection from thermally processed liquid whole eggs and to identify critical limits of specific processing controls. Cassin et al. (4) applied this approach not only to estimate the risk of illness caused by *Escherichia coli* O157:H7 associated with the consumption of beef hamburgers, but also to identify, for a specific production scenario, those factors between the source of contamination (cattle) and the consumer that most significantly affect the risk outcome. Such applications of the risk assessment framework will help to focus allocation of resources toward the implementation or development of feasible intervention strategies that have a measurable, cost-effective impact on risk reduction.

In attempting to model microbial contamination levels and distribution throughout the food chain, investigators will be faced with the fact that for some stages, there are simply no data available. However, drawing on expert knowledge and critical peer review, reasonable assumptions can be incorporated into the assessment. Analysed appropriately to ascertain the importance of input values to the final risk outcome, the risk model can be used to distinguish critical versus noncritical data needs, providing a direction for further research efforts.

**SUMMARY**

It is increasingly recognized that food safety policies must be based on sound, adequate science, processes, and procedures using the best available information and knowledge in a rational manner. Systematic application of risk analysis methodology is needed to establish microbiological criteria, make overall assessments of risks and benefits in food hygiene programs, and allocate resources proportional to their greatest ability to ensure food safety.

Through rigorous problem definition, incorporation of all available data and knowledge relevant to the issue, and identification of variability and uncertainties, the risk assessment framework provides several benefits beyond estimation of risk. As a structured inquiry into the hazard, exposure, and response parameters, the risk assessment document serves as a database of relevant information and a record of decisions. The assessment can be readily updated as better information is acquired or a food system is changed. As an analytical tool to examine risk factors from production through consumption, it improves understanding of key issues through model development and highlights the stages for which critical data are lacking. Through peer review and collaboration, the risk assessment process will be an invaluable tool to help increase our understanding of the magnitude of foodborne illness, the production-to-consumption food pathway, and the host and pathogen factors involved in foodborne illness and provide direction for effective risk management strategies.

**REFERENCES**


