Principles of risk analysis as applied to microbial food safety concerns*

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Each day we are faced with decisions that require us to make conscious or unconscious decisions related to risks we face in our daily lives. For example, the simple act of crossing a street requires an individual to assess the likelihood that automobiles traveling on the street are a hazard and then make a decision on whether to cross the street or wait until the risk is more in line with our willingness to risk injury. However, it has only been in the last 30 years that techniques in risk analysis have advanced to the point where risks associated with hazards associated with foods could studied and systemized such that risk estimates could begin to be articulated in quantitative terms. Furthermore, it has only been in the last ten years that first researchers and then food control agencies and industry began to apply these techniques to the consideration of microbial food safety concerns. Thus, while it has long been a public health principle that food safety hazards should be managed in a risk based manner, it has only been in the last several years that the tools have been developed that allow risks to be measured systematically. However, as these tools have developed, there is increasing interest in developing principles for both determining how microbial risk assessments should be conducted and how the results of those evaluations are used to both manage and communicate microbial food safety risks.

The emerging field of risk analysis is generally considered to consist of three interconnected activities: risk assessment, risk management, and risk communication. Risk assessment is the process whereby the risk associated with a hazard is evaluated either quantitatively or qualitatively. Risk management is the process whereby information related to a risk, including the results of a risk assessment if available, are used to make decisions on how the risk will be controlled and then how that decision is implemented. Finally, risk communication, the process by which information related to the assessment and management of a risk is exchanged among the individuals affected by the hazard, is the medium that allows the assessment and management processes to take place.

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Microbial food safety risk assessments

It is always important to remember that the purpose of risk assessments is as a decision-making tool that is employed to aid the individuals and groups that must discuss and ultimately reach decisions and take actions. As such, risk assessment can take on a number of different forms and formats, depending to the questions that the risk assessors are being asked. For example, four of the types of risk assessments that have been used to address food safety and related microbiological public health concerns are product/pathogen pathway analysis, relative risk ranking, geographical introduction, and risk-risk analysis. The complexity of any particular risk assessment will vary with the complexity of the hazard being addressed, the availability of the data and scientific knowledge, and most importantly the complexity of the risk management questions being posed to the risk assessors by the risk managers. A good risk assessment should be sufficient to answer the question that is being posed, but not so complex that it substantially delays or confuses the need by risk managers, the users of the risk assessment, to reach a decision.

Several key references have been developed that outline the principles of microbial food safety risk assessments and the framework wherein they should be applied to international food safety concerns. The International Commission on Microbiological Specifications for Foods (ICMSF 1) outlined key scientific parameters underlying microbial risk assessments, including comparing the similarities and differences in approaches that are needed to effectively evaluate the risks associated with chemical and microbiological hazards. The Codex Alimentarius Committee on Food Hygiene (CCFH) developed guidance for its member countries on how microbial risk assessment should be conducted, including articulating the 11 general principles for the conduct of a microbiological risk assessment listed below (2). These principles have been widely accepted, and effectively guided risk assessments conducted by national governments and international public health and food safety agencies.

- Microbiological risk assessments should be soundly based upon science.
- There should be a functional separation between risk assessment and risk management.
- Microbiological risk assessment should be conducted according to a structured approach that includes hazard identification, hazard characterization, exposure assessment, and risk characterization.
- A microbiological risk assessment should clearly state the purpose of the exercise, including the form of risk estimate that will be the output.
- The conduct of a microbiological risk assessment should be transparent.
- Any constraints that impact on the risk assessment such as cost, resources or time, should be identified and their possible consequences described.
- The risk estimate should contain a description of uncertainty and where the uncertainty arose during the risk assessment process.

- Data should be such that uncertainty in the risk estimate can be determined; data and data collection systems should, as far as possible, be of sufficient quality and precision that uncertainty in the risk estimate is minimized.
- A microbiological risk assessment should explicitly consider the dynamics of microbiological growth, survival, and death in food and the complexity of the interaction (including sequelae) between human and agent following consumption as well as the potential for further spread.
- Wherever possible, risk estimates should be reassessed over time by comparison with independent human illness data.
- A microbiological risk assessment may need re-evaluation, as new relevant information becomes available.

The second principle has stimulated a great deal of interest and subsequent discussion including several international consultations (3, 4). While the text of the document goes on to explain that the purpose of this principle is to help ensure that risk assessors and risk managers avoid potential sources of bias, it has lead to some confusion. Experience has led both the developers and commissioners of microbial risk assessments to recognize the need for ongoing communication between the risk assessors and risk managers. A useful document recently shared by the US FDA's Center for Food Safety and Applied Nutrition that may provide practical examples of protocols that they employ to help assure effective communication between risk assessment teams and the developer of risk management programs (5).

A number of major risk assessments have or are in the process of being completed conducted both internationally and within different countries. There has been a substantial amount of activity in the United States where the development of risk assessment is increasingly part of the process for the development of new food safety regulations. Major microbial food safety risk assessments developed by U.S. food safety regulatory agencies include:

- *Salmonella* Enteritidis in eggs and egg products (USDA/FSIS)
- *Listeria monocytogenes* in ready-to-eat foods (DHHS/FDA and USDA/FSIS)
- *Vibrio parahaemolyticus* in oysters (DHHS/FDA)
- Enterohemorrhagic *Escherichia coli* in ground beef (USDA/FSIS)
- *Listeria monocytogenes* in deli meats (USDA/FSIS)
- Fluoroquinoline resistance in *Campylobacter* (DHHS/FDA)

The FAO and WHO have been effectively working together to facilitate advances in microbial risk assessments and to address the risk assessment needs of Codex Alimentarius through the establishment of the Joint Expert Meetings on Microbial Risk Assessment (JEMRA). They have several risks assessments nearing completion including:

- *Salmonella* in broilers
- *Salmonella* Enteritidis in eggs
- *Listeria monocytogenes* in ready-to-eat foods
- *Campylobacter* in broilers

- Enterohaemorrhagic *Escherichia coli* in ground beef
- *Vibrio* spp. in seafood

Microbial food safety risk management

As the ability to conduct microbial risk assessment emerged, there is strong interest in determining how these tools can be used effectively and appropriately to enhance food safety decision-making. This, in combination with the demands for more transparent international and national food safety criteria as a result of the Sanitary and Phytosanitary Agreement of the World Trade Organization, has led to increased international activity in establishing a framework for food safety risk analysis and general principles for microbiological risk management. This is particularly true within Codex Alimentarius wherein the Committee of General Principles has been working on "Draft Working Principles for Risk Analysis within the Framework of Codex Alimentarius" (6) and the Committee on Food Hygiene has been developing the "Draft Principles and Guidelines for the Conduct of Microbiological Risk Management" (7). While still in the early stage of development, the draft principles for microbiological risk management listed below are of particular interest since they provide a framework for developing and implementing food control programs that have been specifically designed to take into account the ability to develop a microbial risk assessment if needed. The ability of risk assessment to link food control programs to likely public health outcomes has also led to the development of new metrics such as Food Safety Objectives (FSOs) and the reexamination of old metrics such as microbiological criteria.

- Protection of human health should be the primary consideration in the conduct of microbiological risk management.
- Microbiological risk management should take into account the entire food chain, including feed and imported food and feed.
- Industry has the responsibility for producing and marketing safe products.
- Microbiological risk management should follow a structured process, generally described in four chronological steps: preliminary microbiological risk management activities, identification and evaluation of microbiological risk management options, implementation of microbiological risk management decisions, monitoring, and review.
- The basis of microbiological risk management decisions should be transparent and include clear, interactive communication with all interested parties.
- There should be a functional separation between microbiological risk assessment and microbiological risk management, while it is recognized that some interactions are essential to a pragmatic approach.
- Risk managers should establish, and follow a microbiological risk management policy.

- Risk managers should establish, and follow, a microbiological risk assessment policy in order to ensure that the microbiological risk assessment is systematic, complete, and transparent.
- The effectiveness of microbiological risk management decisions should be periodically assessed and microbiological risk management decisions should be revised if appropriate.

Anticipating the impact that the ability to conduct microbial risk assessments would have on the way risk management decisions are developed and implemented, the ICMSF has articulated a framework for relating food safety activities to public health consequences (8). They demonstrate how a risk analysis approach can be used to translate a public health goal to a food safety objective that in turn can be related through a relatively simple conceptual model to performance criteria, process criteria, and microbiological criteria. They also provide detailed information on the techniques, requirements, and limitations of associated with using different types of microbiological testing approaches to verify the effectiveness of food control systems. Many of these concepts were adopted in the subsequent FAO/WHO consultation on the interface between risk assessment and risk management (4).

Concluding remarks

The past ten years have brought dramatic changes in our ability to evaluate the risks associated with foodborne microbiological hazards. These advances have in turn stimulated a great deal of interest in developing more systematic framework for conducting food safety risk management. This comes at a time when there has been an increased demand both within nations and internationally to develop food control systems that are transparent, can be objectively verified, and for which the equivalence of different approaches can be established. This will undoubtedly lead to increased interest in the application of microbial risk assessment techniques. However, it is critical that these applications be based on sound science and that they serve to enhance public health and not simply become another barrier to effective food safety risk management implementation.

Summary

This contribution describes the different steps of a microbiological risk analysis from the risk assessment through to the risk management of food safety. The precise description and the systematic measuring of risk in a given framework are important as these risks relate directly to health concerns and public health goals. Therefore, decisions concerning food safety must be based on firm scientific data. Different organizations like the International Commission of Microbiological Specification of Foods (ICMSF), the Codex Commission of Food Hygiene (CCFH) and the Joint FAO/WHO Meetings on Microbiological Risk Assessment (JEMRA) ensure the exchange and standardization of guidelines, which serves the international trade, the legislative authorities and the consumer as well.

Zusammenfassung

Dieser Beitrag beschreibt die verschiedenen Schritte einer mikrobiologischen Risikoanalyse, vom Risiko Assessment bis zur Verwendung des Ergebnisses im Risiko Management der Lebensmittelsicherheit. Auf das saubere Beschreiben und systematische Messen der Risiken in klar abgestecktem Rahmen wird hohen Wert gelegt, da diese direkt mit den gesundheitlichen Aspekten des Lebensmittelkonsums und mit Zielen der «Public Health» verbunden sind. Entscheidungen betreffend die Lebensmittelsicherheit müssen deshalb wissenschaftlich gut fundiert sein. Verschiedene internationale Organisationen wie die International Commission of Microbiological Specification of Foods (ICMSF), die Codex Commission of Food Hygiene (CCFH) und die Joint FAO/WHO Meetings on Microbiological Risk Assessment (JEMRA) sorgen für einen Austausch und eine Vereinheitlichung der Richtlinien, und dienen damit dem internationalen Handel, den gesetzgebenden Organen ebenso wie dem Konsumenten.

Résumé

Cette contribution décrit les différentes étapes d'une analyse des risques microbiologiques, de l'établissement du risque jusqu'à l'utilisation des résultats dans le cadre de la gestion de la sécurité alimentaire. La description précise et la détermination systématique des risques dans un cadre strictement défini est très importante car ces risques sont directement liés à la santé des consommateurs et à la définition d'objectifs de santé publique. Les décisions concernant la sécurité alimentaire doivent donc être basées sur des données scientifiques solides. Différentes organisations internationales comme l'International Commission on Microbiological Specifications for Foods (ICMSF), la Commission d'Hygiène Alimentaire du Codex (CCFH) et les réunions communes FAO/WHO sur l'évaluation des risques microbiologiques (JEMRA) contribuent aux échanges et à une unification des recommandations, et aident de ce fait les échanges commerciaux, les autorités de même que les consommateurs.

Key words

Microbiological risk analysis, microbiological risk assessment, microbiological food safety management

References

1 *International Commission for the Microbiological Specifications of Foods (ICMSF):* Potential application of risk assessment techniques to microbiological issues related to international trade in food and food products. J. Food Protection **61**, 1075–1086 (1998)

2 *Codex Alimentarius:* Food hygiene – Basic texts. 2nd Edition. Joint FAO/WHO Food Standards Programme Codex Alimentarius Commission (2001), http://www.fao.org/DOCREP/005/Y1579E/Y1579E00.HTM

3 *FAO/WHO:* The interaction between assessors and managers of microbiological hazards in food. Report of a WHO expert consultation (2000), http://www.who.int/foodsafety/publications/micro/en/march2000.pdf

4 *FAO/WHO:* Principles and guidelines for incorporating microbiological risk assessments in the development of food safety standards, guidelines, and related texts. Report of a Joint FAO/WHO Consultation (2002), http://www.who.int/foodsafety/publications/micro/en/march2002.pdf
5 *CFSAN:* Initiation and conduct of "major" risk assessments within a risk analysis framework. Food and Drug Administration, Center for Food Safety and Applied Nutrition, College Park, MD, USA (2002)
6 *Codex Alimentarius, Committee of General Principles:* Draft working principles for risk analysis for application within the framework of Codex Alimentarius (2003), ftp://ftp.fao.org/codex/alinorm03/Al03_33.pdf, pp. 40–46
7 *Joint FAO/WHO food standards programme, Codex Committee on Food Hygiene:* Proposed draft principles and guidelines for the conduct of microbiological risk management. Report of the 34th session of CCFH, October (2001) ftp://ftp.fao.org/codex/ccfh34/fh01_07e.pdf
8 *International Commission on Microbiological Specifications of Foods (ICMSF):* Microorganisms in foods 7: Microbiological testing in food safety management. Kluwer Academic/Plenum Publishers, New York (2002) (see page 118)

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