Food safety risk assessment: part 1 – risk assessment primer

Words by Dr Dipon Sarkar and Deon Mahoney

This is the first in a series of articles in *food australia* exploring the science (and art) of food safety risk assessment. In this article, we will be focusing on the fundamentals of risk assessment - the basic steps according to the Codex framework, along with the complexities and barriers in the process. While this article focuses on microbial risk assessment, the concepts can be extended to managing other hazards such as allergens and chemicals.

Codex risk analysis

Over the past two decades, there has been a significant push for food safety management systems to move from a reactive hazard-based approach to a harmonised, preventative, risk-based approach.[1] This shift required a reliable, scientifically robust and reproducible process to assess the risk from food safety hazards. The Codex Alimentarius Commission (CAC), under the umbrella of the parent organisations WHO and FAO, developed the risk analysis process in 1999 as the common operational framework to support the development of risk-based food safety control.[2]

Codex defines risk analysis as the structured, systematic process that examines the potential adverse health effect from a hazard and develops options for mitigating that risk.[2] The Codex risk analysis framework consists of three separate but closely related elements – risk assessment, risk management and risk communication. As the name suggests, these elements focus on defining and assessing the risk; identifying the control measures that can be used to effectively manage the risks; and communicating the risks to different stakeholders.

The four steps of conducting a risk assessment according to the Codex framework are:

1. hazard identification,
2. hazard characterisation,
3. exposure assessment and;
4. risk characterisation.

Hazard identification is the first step of risk assessment. It builds on HACCP principles and is focused on identifying the main microbiological, physical, allergenic or chemical hazards associated with a particular food process or product. Hazard characterisation focuses on the detailed relationship between exposure to the hazard and public health outcome, including factors that influence the severity or occurrence of disease caused by the hazard, such as virulence factors, risk populations and food matrix effects. The dose-response relationship is an essential part of hazard characterisation, providing mathematical relationships between levels of hazard consumed (dose) and the probability of a health outcome (response).

Exposure assessment gives a quantitative measure (prevalence and concentration) of the contaminant level in the final product at the time of consumption.[4] The first step in conducting an exposure assessment is describing the food pathway, which illustrates how the exposure will be calculated. The final step of the risk assessment is risk characterisation which integrates findings of the previous three steps and provides

Hazard identification	Hazard characterisation	Exposure assessment	Risk characterisation
Description of hazard (microbe, toxin, etc.) and adverse effects it causes	Description of the hazard's effect, including dose-response – predicting the probability of an adverse effect from a given dose	The qualitative and/or quantitative evaluation of the likely intake of biological, chemical, and physical agents via food as well as exposures from other sources if relevant	Qualitative/quantitative estimate of occurrence and severity of adverse health effects in a given population

Table 1: Summary of the four steps of conducting a microbial risk assessment according to the Codex framework..

a risk estimate and proposes risk management options.[2] Depending on the method used for risk assessment, risk characterisation can be qualitative, quantitative, or semi-quantitative, however quantitative methods are usually used.[4] The estimate can be risk per portion or risk per population, and may involve economic evaluations. A complete risk characterisation consists of the risk summary; understanding the variability of the risk; sensitivity analysis, understanding the uncertainty and validation.

There are two major types of microbial risk assessments - qualitative and fully quantitative.[3] When quality data are lacking, qualitative risk assessment serves as a quick tool to describe risks in descriptive measures, such as 'negligible', 'low', 'medium' or 'high'. The methodology depends on a subjective description of quantities based on expert opinions. Semi-quantitative risk assessment uses either primary data or 'scores' to describe risk. The model complexity and the amount of data required are less in this model compared to fully quantitative models, making food safety risk assessment readily available to non-expert users for educational and decision-making purposes.[4] Quantitative risk assessment is a more complex form of risk assessment, which uses a probabilistic modelling approach to generate numerical estimates of consumer risk.

These formal risk assessment protocols have proven to be beneficial for researchers, academics, and food regulators in the development of food regulations, codes of practice, and guidance material designed to eliminate or reduce risks. However, on the food factory floor, food industry personnel need to perform stripped-down risk assessments on a routine basis – often with limited time, resources, and expertise. These assessments (henceforth referred to as rapid risk assessments) are needed to address the day-to-day scenarios encountered by the food industry and make time-sensitive decisions on product release, raw material acceptance, and ingredient or process change. In reality, these rapid risk assessments are often made based on experience and intuition or with the help of a 3x3 (using subjective estimates of likelihood and consequence) without detailed analysis and consideration of the risk descriptor. The limitation of this approach is that it doesn't necessarily leverage the full breadth of knowledge and scientific advancements that have been made in this field.

The question arises, how can food industry personnel leverage the Codex framework when undertaking rapid risk assessments to make them more robust? Are there tools available that can help? Is the revised hazard analysis process under the HACCP system being effectively used to identify those hazards which are of such significance that they are reasonably likely to cause harm if not effectively controlled?

To explore these topics, and dissect microbial and allergen case studies from a regulatory and industry perspective, AIFST has partnered with industry experts to organise a series of risk assessment workshops. The first workshop was conducted in June 2024 in

Melbourne with further workshops organised in Brisbane and Sydney (dates to be confirmed). The findings from the workshop along with other essential themes of risk assessment will be further explored in this series of risk assessment articles in future editions of *food australia*. Stay tuned!

References

1. Koutsoumanis, K.P., Aspridou, Z., 2016. Moving towards a risk-based food safety management. *Current Opinion in Food Science* 12, 36–41.
2. FAO and WHO. 2023. *General Principles of Food Hygiene. Codex Alimentarius Code of Practice*, No.CXC 1-1969. Codex Alimentarius Commission. Rome. https://doi.org/10.4060/cc6125en
3. FAO and WHO. 2021. *Microbiological risk assessment - Guidance for food.* Microbiological Risk Assessment Series No. 36. Rome. https://doi.org/10.4060/cb5006en
4. Membré, J., 2022. *Microbiological Risk Assessment Associated with the Food Processing and Distribution Chain.* ISTE Ltd, John Wiley & Sons, Inc.

Dr Dipon Sarkar is a food safety consultant working at Victual.

Deon Mahoney is a food safety consultant at Deon Mahoney Consulting and is Adjunct Professor in the School of Agriculture and Food Sustainability at the University of Queensland.