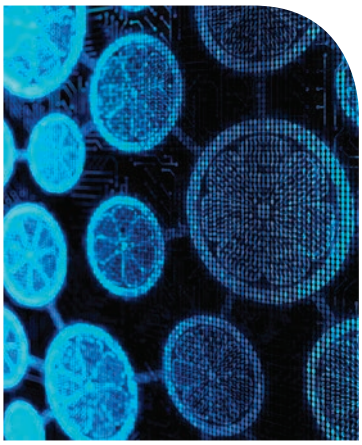
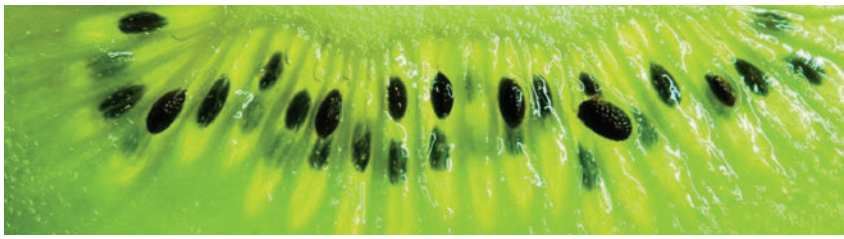


Addressing food-related health risks



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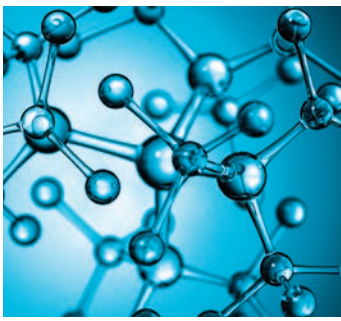


4 Addressing food-related health risks

4.1 The risk analysis framework

Risk analysis is a systematic approach to examining and assessing public health and safety risks associated with food. This approach underpins the general approaches discussed in Chapter 3 and is used to formulate, implement and communicate risk management decisions.

Risk analysis is comprised of three interrelated components—*risk assessment*, *risk management* and *risk communication*. Due to the wide range of health and safety risks associated with food, the risk analysis process for food must be flexible.

4.2 The Codex risk analysis framework

Codex was established in 1963 by the Food and Agriculture Organization (FAO) and the World Health Organization (WHO). Codex develops international food standards and guidelines under the Joint FAO/WHO Food Standards Programme, the main purpose of which is to protect the health of consumers and ensure fair practices in global food trade.

The Codex risk analysis framework sets out an approach for evaluating the potential risk associated with food-related hazards, and for assessing ways to manage any identified risk[2]. It allows separation of the scientific process of risk assessment from the broad range of factors that affect risk management decisions. It also takes into account the need for communication between those involved in risk analysis as well as communication with stakeholders, such as consumers, public health professionals and government agencies, including enforcement agencies. The Codex framework comprises the three key components of risk analysis:

Risk assessment: A formal scientifically based process consisting of the following steps: (i) hazard identification; (ii) hazard characterisation; (iii) exposure assessment; and (iv) risk characterisation.

2 Although the Codex risk analysis framework sets out an approach for elaborating standards to address foodborne hazards, this was not elaborated specifically for whole foods. For example, for genetically modified foods, a modified risk assessment approach is used, based on the principle that their safety can largely be assessed by comparison to their conventional counterparts having a history of safe use. This approach, which is referred to in FSANZ as a 'safety assessment' rather than a 'risk assessment' focuses on determining whether any new or altered hazards are present, relative to existing conventional foods, with any identified hazards becoming the focus of further assessment.

Risk management: The process, distinct from risk assessment, of weighing policy alternatives in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control measures.

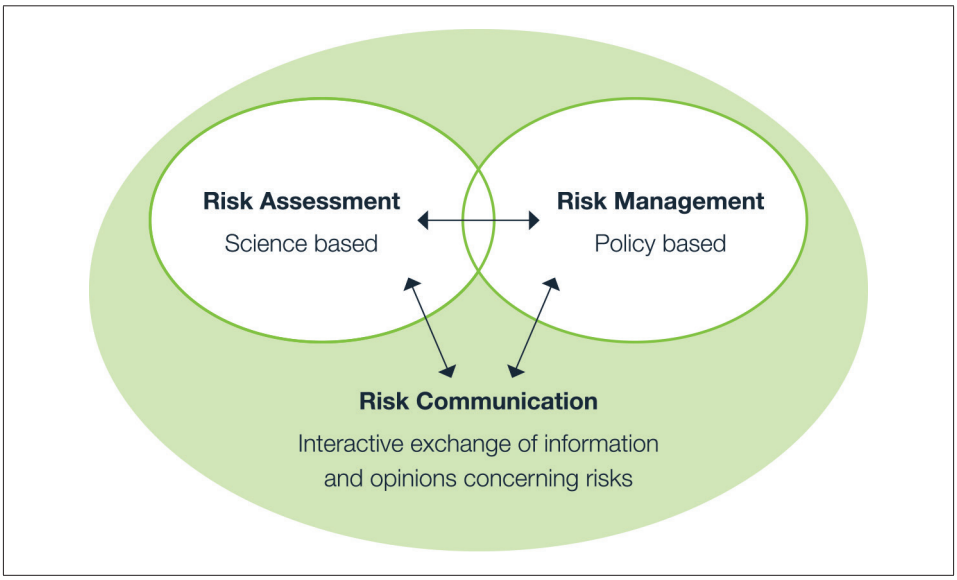
Risk communication: The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors, and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.

The risk assessment and risk management components of the Codex risk analysis framework operate together as an iterative process with active communication between risk assessors and risk managers. A diagrammatic representation of this framework is shown in Figure 1.

Codex has extended its work on risk analysis to include development of nutritional risk analysis principles and guidelines. This work contributes to the objective of the framework by basing the food safety and health aspects of Codex standards and related texts on risk analysis. Nutritional risk analysis differs from traditional risk analysis by recognising that food and their constituents can confer a benefit or risk to health, depending on the amount consumed. In line with Codex procedures[3], nutritional risk analysis considers the risk of adverse health effects from inadequate and/or excessive intakes of nutrients and related substances and the predicted reduction in risk from proposed management strategies. In situations that address inadequate intakes, a reduction in risk through addressing inadequacy might be referred to as a nutritional benefit. When applied in a nutritional risk analysis context, the high level risk analysis terms given above are prefaced by ‘nutritional’.

3 Codex Alimentarius Commission (2011) *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*. In: Codex Alimentarius Commission Procedural Manual Ed. 20. Joint FAO/WHO Food Standards Programme, Rome. http://www.codexalimentarius.org/procedures-strategies/procedural-manual/

Figure 1. The Codex risk analysis framework[4]



4.3 The FSANZ approach to risk analysis

4.3.1 Working in the Codex framework

FSANZ's approach to risk analysis is based on the Codex framework described in Section 4.2 although the diversity of issues considered requires some flexibility in the terminology used to describe parts of the process.

The four steps of risk assessment were applied to chemical hazards before their endorsement by Codex. This process is now widely accepted and is the basis of FSANZ's risk assessment procedure for a range of hazards (including nutrient-related hazards). However, how the process is applied can vary, depending on the nature of the hazard and its relationship to the food.

The components of risk analysis as used by FSANZ are discussed briefly below and described in more detail in Chapters 5, 6 and 7.

4 http://www.who.int/foodsafety/micro/riskanalysis

Risk assessment involves a process of identifying, analysing and characterising risk. In line with the Codex framework, risk assessment consists of the same four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation.

Risk management at FSANZ is a consultative and decision-making process that identifies the problem; considers the risk assessment, social, economic and other factors; and develops, weighs and selects the option of greatest net benefit to the community. The process may also involve evaluation of the implemented decision.

Risk communication is the interactive exchange of information about risk between risk assessors and risk managers, and among FSANZ, news media, interested groups and the general public. It is an ongoing process that aims to engage interested groups and the general public in decision making to the maximum extent possible. Risk communication is also important to help bridge the gap which sometimes exists between the scientific assessment and consumers' perceptions of risk.

In the context of nutritional risk analysis, FSANZ uses the Codex framework and prefaces the high level risk analysis terms given above with the term 'nutritional'. FSANZ prefaces the risk assessment steps *hazard identification, hazard characterisation*, and *risk characterisation* with 'nutrient-related'. In the case of nutrients and related substances with a potential beneficial health effect, the risk assessment step *exposure assessment* is more appropriately termed 'intake assessment'. However in this document, the term *exposure assessment* covers chemical, nutritional and microbiological dietary assessments.

Although the use of the risk analysis framework will vary, its elements apply across the food supply. One of the important aspects of this systematic approach is that the strengths and weaknesses of each step can be openly discussed and debated. A flexible approach can be taken to deciding what additional information would assist in applying the risk analysis framework to a particular food safety risk. It is also worth noting that the outcomes of risk analysis do not always result in regulatory change, rather a number of regulatory and non-regulatory options, including taking no action, may be considered as part of the risk management process.

4.3.2 Applying risk analysis

FSANZ uses risk analysis to:

- develop new food standards for whole classes of food commodities, such as the primary production and processing standards for eggs, seafood, dairy, poultry and seed sprouts
- evaluate proposed changes to existing food standards, such as the approval of a food additive, extension of use of a food additive, a novel food or a genetically modified food; to establish limits for microbiological or chemical contamination; to approve the addition of a nutritive substance to food[5] or a compositional change to special purpose foods
- evaluate existing food standards (including food labelling standards that address health and safety risks) using specific surveillance activities or on-going monitoring of the food supply. Such survey work can lead to changes to existing standards or other regulatory and non-regulatory measures if specific risks are identified
- evaluate current food technology practices, if necessary, or changes to current food technology practices, or the impact of new technologies
- address questions about the safety of food that arise from risks in domestic and imported food, which can occur as a result of a failure in food safety control systems
- identify and consider emerging food-related health risks and manage our response to domestic or imported food incidents (such as the detection of an unapproved substance or high levels of a contaminant) in a systematic and timely manner
- evaluate existing and proposed food standards where health and safety risks have changed because of new evidence or changes in consumer understanding, preferences and behaviours.

The abovementioned activities that relate to the development or review of food standards are generally undertaken as a result of an application made by an external body or individual to amend the Code, or a proposal instigated by FSANZ or requested by the Forum to amend the Code.

5 Nutritional risk analysis uses food composition and food consumption data to assess the nutritional risks and potential health benefits from adding the nutritive substance to food.

4.3.3 FSANZ's risk appetite

FSANZ defines *risk appetite* as the amount and type of risk that it is willing to pursue or retain. This definition is based on the *AS/NZS ISO 31000:2009 Risk Management – Principles and Guidelines.* As an agency, our risk appetite is the level of risk that we are prepared to accept in fulfilling our statutory objectives, without taking action to reduce that risk. The level of risk that remains after risk management action is taken to reduce that risk is known as the *residual risk*.

It is recognised that organisations can benefit from having a clear and concise statement relating to the extent of their willingness to take risk in pursuit of their business objectives. The statement can also provide a basis on which to evaluate and monitor the amount of risk being faced to determine whether the risk has risen above an acceptable range. Articulating risk appetite is complex and developing a risk appetite statement requires involvement at the FSANZ Board and management levels.

FSANZ undertakes its risk analysis processes to achieve its objectives in a low overall risk range. Our lowest risk appetite relates to meeting our key objective in setting standards, which is protecting public health and safety through a safe food supply. In meeting this objective, we adopt a conservative approach. This is particularly the case where there is a level of uncertainty in the risk assessment due to a paucity of data or when dealing with susceptible population sub-groups. In such cases, FSANZ operates with a zero to negligible tolerance for residual risk. We have a slightly higher risk appetite in relation to fulfilling our other objectives that relate to providing adequate information and preventing misleading or deceptive conduct. In discharging our duties relating to these two objectives, we adopt a more managed approach, balancing risk, benefits and costs with a moderate tolerance for residual risk.

4.3.4 Underlying principles

Different approaches to risk analysis are required because of the wide variety of food risks. The following guiding principles have been developed to ensure consistency between these different approaches:

Good practice for process management and 'good policy'

The risk analysis process should be conducted according to the principles of 'good policy'. Initial steps should include a problem analysis and a set of feasible policy options for decision making. The environment should be defined and stakeholders should be identified and consulted.

The quality of the process should be ensured by following the advised quality assurance process, within time and budget, including good process management and a clear division of responsibilities in the risk analysis team.

To ensure rigour, the analysis should be based on the best available evidence and should be objective, transparent and complete. The analysis should be in writing and should explain the relevant issues and the context for these. It should be understood by the audience and supported by the agency. Depending on the timeframe, the comprehensiveness of the advice may vary, but recommendations need to be informed by evidence and articulated clearly.

Use the best available evidence

Scientific, economic and other evidence may be obtained from both published and unpublished sources. Scientific data may come from laboratory based studies; toxicological studies; microbiological studies; relevant human studies such as volunteer studies; occupational exposure studies; poisoning case reports and epidemiology studies; and consumer and social research using survey, experimental and qualitative studies. Whether from published or unpublished sources, information should be of high quality, relevant, credible and objective. Critical evaluation of the available information is essential to establish the basis for the safety of food and subsequent risk management decisions. In certain cases, FSANZ may seek collaboration with external experts or other organisations at the national or international level.

Recognise uncertainty in risk assessment

Some degree of scientific uncertainty is inevitable when food regulation decisions are made (see Section 5.5 for further discussion). It is therefore helpful for uncertainty to be recognised, documented and addressed in risk assessment, to aid in the process of developing and deciding on the most appropriate risk management option. Depending on the available evidence and any inherent uncertainty, a cautious approach in making decisions on risk management options may be warranted to ensure that the overall health risk remains acceptable.

Tailor the risk management approach to the risk

In managing potential risks in food, there are generally a number of options available, depending on the nature of the risk. Quantifying and comparing different risks is difficult, but qualitative comparisons are generally possible using criteria such as the severity of the outcome and the likelihood of the adverse effect. In deciding between risk management options, consideration needs to be given to the level of potential risk which, in the case

of food, will also depend on the importance of the food in the context of the total diet and consumers' likely behavioural responses to the chosen risk management option. The level of risk that is acceptable to the community is another factor that can influence risk management decision-making.

Involve interested and affected groups

Involving groups that have an interest in the outcome of a risk analysis process can enhance the process. These groups can provide scientific data, identify relevant social, ethical and economic factors, comment on the feasibility and practicality of proposed risk management approaches and propose alternatives. Involving interested and affected groups can also build trust as well as lend credibility to risk management decisions, which in turn can lead to the successful implementation of any measures. The process and rules for such involvement need to be clear.

Communicate in an open and transparent manner

Documents stating risk management options that address food-related health risks should be publicly available and submissions on these documents taken into account in the regulatory decisions. Confidential commercial information should be protected but, in general, data supporting the assessment of the food is not regarded as confidential. Dialogue with industry, consumers and health professionals on food regulatory matters is integral to FSANZ's processes and is facilitated, including encouraging stakeholders to comment on documents outlining risk management options.

Review the regulatory response

In some cases, it is not easy to predict with certainty the outcome of a regulatory decision regarding food. For this reason, it may be necessary to examine the effect of the regulation after a certain period, to ensure the predicted outcome was achieved. In this context, risk management is an ongoing process that takes into account any newly generated data, such as post-market monitoring data, in reviewing the regulatory decision.

Surveys of the food supply such as the Australian Total Diet Study (ATDS) can provide information to inform a review of a particular regulatory action. Surveys of key groups affected by regulatory changes, such as the food industry, health professionals, enforcement officers or consumers, can also provide information to evaluate the outcome and determine whether further regulatory action is required.

4.3.5 Identifying and gathering data and other information

Scientific, economic and other data and information used for a risk analysis can come from many sources. Applicants seeking to vary the Code have to submit certain types of information, data and studies with an application, as described in the *FSANZ Application Handbook*[6]. FSANZ also has access to a variety of information sources including FSANZ's own surveys, overseas studies, information from other government agencies (domestic or international) and industry data. FSANZ has a framework for addressing emerging and ongoing food safety risks. The framework provides some guidance for considering such information and data and for escalating consideration of particular emerging food safety risks. Survey activities can also provide important information on the nutrient composition of food and food consumption, which can be used to assess the nutritional status of population sub-groups.

FSANZ surveys

FSANZ may lead or undertake specific surveys to:

(i) investigate possible food risks in relation to local or imported food

(ii) investigate reports where there may be a potential public health and safety risk

(iii) provide evidence for reviewing or amending domestic standards where revisions to health-based guidance values (HBGVs) may have occurred

(iv) gain more background data on a particular issue

(v) support the standards development process

(vi) monitor levels of certain ingredients/substances in the food supply.

These surveys may be in relation to food composition, food chemical or microbiological data. In addition to the ATDS, FSANZ may commission specific surveys on the nutrient content of Australian foods, specific chemicals (e.g. dioxins, benzene, chloropropanols or caffeine) or microbiological agents (e.g. pathogens in sesame products, soft noodles, or fresh horticultural produce). Such surveys are conducted as required and as resources allow, in many cases in collaboration with Australian jurisdictions and New Zealand. FSANZ may also examine the New Zealand evidence base (such as the New Zealand Total Diet Study), where appropriate, to supplement Australian data.

6 FSANZ (2011) *Food Standards Australia New Zealand Application Handbook.* http://www.foodstandards.gov.au/code/changes/pages/applicationshandbook.aspx

Surveys of consumer behaviour are conducted where the existing evidence is insufficient for risk assessment or risk management decisions. These could include:

(i) gathering evidence on behavioural assumptions in risk assessments

(ii) investigating potential consequential changes in behaviour triggered by proposed changes in food standards

(iii) gathering evidence on possible responses to risk management options.

Economic data and information can be generated internally using models and surveying stakeholder groups. Organisations such as the Australian Bureau of Statistics (ABS) and the Australian Bureau of Agricultural and Resource Economics and Sciences (ABARES) also produce useful statistics. Economic data and information can also be sourced from external studies conducted by academics and consultants using cost benefit analysis and health, agricultural and behavioural economics techniques. Useful papers and data are also created by overseas regulators.

4.3.6 Prioritising food-related health risks

Many factors may influence the prioritisation of potential risks in food, including policy and social factors, which are not easy to predict. In some cases, there will also be legislative requirements, such as those in place for the pre-market approval of certain foods and substances added to food. In these cases, the timelines for assessment are pre-determined e.g. FSANZ statutory timelines for completing the assessment of applications to vary the Code.

As part of the preliminary risk management activities, an initial scoping exercise should be undertaken to provide some information on, firstly, the likelihood (or probability) of an adverse health effect and, secondly, on the consequences (and in some circumstances, severity) of such an event (see Section 6.2.1). The likelihood of an event will be influenced by the effectiveness of existing regulations or other measures. The consequences will be influenced by both the nature of the potential adverse health effect as well as by the number of individuals affected. Taken together, this information will allow the prioritisation of food-related issues based on the potential for an adverse event.

The outcome of the scoping and prioritisation process may be one of the following:

- take no action if the health risk is considered insignificant and/or appropriate measures are in place or
- undertake a more detailed risk assessment to determine the magnitude of the potential risk, while applying an interim and conservative risk management approach or
- take immediate steps to manage the significant risk associated with the food, while undertaking a more detailed risk assessment.

4.3.7 Review and evaluation

The outcomes of the risk analysis process, as well as the process itself, may need to be regularly reviewed and evaluated to ensure expected outcomes are delivered and that the process is working effectively. The collection of data through various surveillance and monitoring programs is integral to the review and evaluation.

Data collection should be considered from the outset of the risk analysis process, to support the development of objectives that are measurable and indicators that are appropriate. The early collection of data can assist in establishing a baseline situation against which the impact of the selected risk management strategy can be evaluated.

4.3.8 Responding to rapidly emerging issues

When considering an unexpected food safety issue, which, by its nature may involve a poorly defined or little-known hazard, the extent and depth of the risk analysis will depend on a number of factors, particularly the time constraints on responding to the issue. Food-related issues which start locally may quickly become national issues and, in many cases, international issues. The two factors which play a significant role here are communications and trade. The extensive global trade in food means that any local issue can quickly become an issue in many parts of the world. The ease of international communication also means that the reporting of food-related issues is rapid, alerting both food regulators and consumers, often at the same time.

The general principles of risk analysis apply in responding to rapidly emerging issues. However, time constraints may affect the sequence of steps undertaken. These steps will be determined on a case-by-case basis with the information available. If national action is required in Australia, the National Food Incident Response Protocol[7] may be used. The protocol provides a framework for coordinating timely and appropriate action in response to a national food incident at the national, state and territory and local level.

7 Commonwealth Department of Health and Ageing (2012) *National Food Incident Response Protocol.* http://www.health.gov.au/internet/main/publishing.nsf/Content/foodsecretariat-isc-food.htm