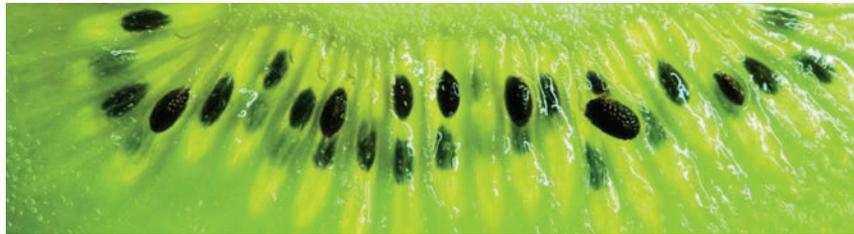
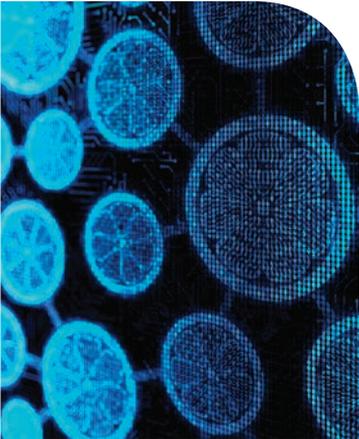
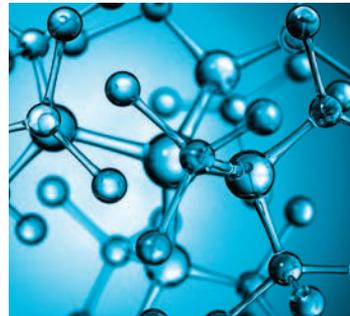


Risk Analysis in Food Regulation



FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa



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ISBN: 978-0-642-34581-3

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Foreword

Risk analysis is an internationally recognised process adopted by other food regulatory bodies across the world. It has three parts—risk assessment, risk management and risk communication.

At the heart of the process is scientific evidence, with Food Standards Australia New Zealand (FSANZ) relying on the best available evidence to make its decisions. This is true of every risk analysis process undertaken at FSANZ, whether it is applied to assessing applications to vary the *Australia New Zealand Food Standards Code* or managing food safety incidents.

Scientific evidence provides the basis for making judgements on risk. FSANZ will communicate advice on these matters in its decision making documents.

This publication details our approach to the key elements of risk analysis and provides case studies demonstrating how the process has been applied.

I extend thanks to Dr Samuel Godefroy; Director General, Food Directorate of Health Canada, an international expert in risk analysis, who peer-reviewed this publication and the many FSANZ staff involved in its preparation and finalisation.

Steve McCutcheon

Chief Executive Officer

Food Standards Australia New Zealand



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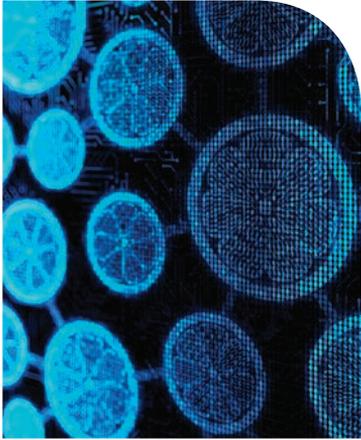
Acronyms and abbreviations

ABARES	Australian Bureau of Agricultural and Resource Economics and Sciences
ABS	Australian Bureau of Statistics
ADI	Acceptable Daily Intake
AI	Adequate Intake
ALARA	As Low as Reasonably Achievable
ALOP	Appropriate Level of Protection
APVMA	Australian Pesticides and Veterinary Medicines Authority
ARfD	Acute Reference Dose
ATDS	Australian Total Diet Study
BMD	Benchmark Dose
BSE	Bovine Spongiform Encephalopathy
CCCF	Codex Committee on Contaminants in Food
COAG	Council of Australian Governments
Codex	Codex Alimentarius Commission
EAR	Estimated Average Requirement
EPA	Environmental Protection Authority
FAO	Food and Agriculture Organization of the United Nations
FDA	Food and Drug Administration of the USA
Forum	COAG Legislative and Governance Forum on Food Regulation (formerly the Australia and New Zealand Food Regulation Ministerial Council)
FSANZ	Food Standards Australia New Zealand
GAP	Good Agricultural Practice
GELs	Generally Expected Levels
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
HACCP	Hazard Analysis Critical Control Point
HBGV	Health-Based Guidance Value

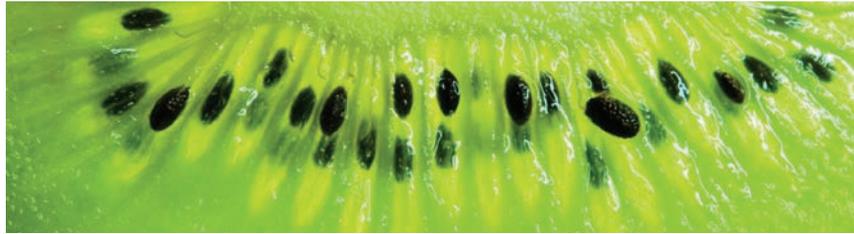


IFIS	Imported Food Inspection Scheme of the Department of Agriculture
ISFR	Implementation Sub Committee for Food Regulation
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LOAEL	Lowest-Observed-Adverse-Effect Level
LOR	Limit of reporting
ML	Maximum Level
MOE	Margin of Exposure
MPI	Ministry for Primary Industries (New Zealand)
MRL	Maximum Residue Limit
NHMRC	National Health and Medical Research Council
NNS	National Nutrition Survey (Australia or New Zealand)
NOAEL	No-Observed-Adverse-Effect Level
NRS	National Residue Survey in Department of Agriculture
NRV	Nutrient Reference Value
OBPR	Office of Best Practice Regulation in Department of Finance
OCS	Office of Chemical Safety in Department of Health
OGTR	Office of the Gene Technology Regulator
PTD(W)I	Provisional Tolerable Daily (Weekly) Intake
RDI	Recommended Dietary Intake
RIS	Regulation Impact Statement
SPS agreement	Agreement on the Application of Sanitary and Phytosanitary Measures of the WTO
SDC	Standards Development Committee
TBT agreement	Agreement on Technical Barriers to Trade of the WTO
UL	Upper Level of Intake
WHO	World Health Organization
WTO	World Trade Organization of the United Nations
vCJD	Variant Creutzfeldt-Jakob disease

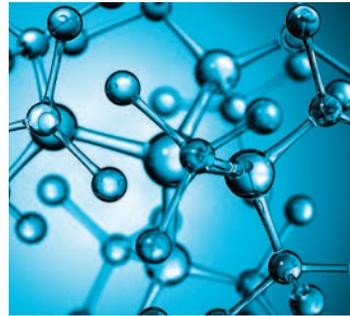




Introduction



1



1 Introduction

1.1 Maintaining a safe food supply

The safety of our food depends on many factors, some of which are beyond regulatory control. While the food industry has primary responsibility for ensuring the safety of food, government and consumers also share this responsibility.

The agricultural sector and processed food industry have procedures in place to produce consistently safe primary produce and processed foods. In turn, food outlets and consumers are responsible for ensuring food is stored, handled and prepared in ways that do not introduce new risks.

Maintaining the safety of food requires constant vigilance by government, industry and consumers as the food supply changes as a result of new technologies, expanding trade opportunities, ethnic diversity in the population and changing diets.

The range and diversity of food available to consumers has greatly expanded in recent decades, as has consumer interest in food matters, including safety. There is also a proliferation of consumer advice on food safety issues and healthy food choices. This information comes from sources with varying levels of knowledge and/or credibility and this means there is potential for consumers to be misled or confused. Food regulators play an important role in providing information from competent, authoritative sources that is based on appropriate scientific evidence.

Food regulators aim to ensure health and safety risks from food are negligible for the whole population, and that consumers can make informed choices. When this is achieved, public confidence in the effectiveness of food regulation is maintained. However, this confidence depends on evidence that there is an acceptable level of risk and, on assurance that adequate systems are in place to monitor and analyse food, and to respond when a risk is identified. Providing evidence that there is an acceptable level of risk requires a way to assess food risks that is evidence-based and transparent, and results in effective management strategies which can be communicated clearly to consumers.

1.2 The food regulatory system and FSANZ's role

The food regulatory system in Australia and New Zealand is multi-jurisdictional. The three key elements of the system are policy development, standards development and implementation/enforcement. The system encompasses all levels of government: the Australian and New Zealand governments, the states and territories of Australia and local governments.



The food policy framework is set by the Council of Australian Governments (COAG) Legislative and Governance Forum on Food Regulation (the Forum, formerly the Australia and New Zealand Food Regulation Ministerial Council). The Forum comprises health and agriculture ministers from state and territory governments, and the Australian and New Zealand governments.

In Australia, food legislation is enforced by the Australian states and territories and local government agencies. The Department of Agriculture is responsible for the compliance of imported food and providing import and export inspection and certification. When a food must be recalled from distribution, sale and consumption due to a potential health or safety risk, FSANZ coordinates and monitors this activity, in consultation with the food manufacturer or importer and state and territory governments. In New Zealand, ensuring compliance with the food legislation for both domestic and imported foods is the responsibility of the New Zealand Ministry for Primary Industries (MPI). MPI is also responsible for coordinating food recalls. Further details about the regulatory framework for food are available at Appendix 2.

FSANZ is responsible for standards setting, developing and maintaining the *Australia New Zealand Food Standards Code* (the Code). The Code is comprised of standards for the use of substances added to foods such as food additives and novel substances, contaminants, the composition of some foods, labelling, primary production and processing, and food hygiene.

FSANZ must consider its objectives in setting standards under the *Food Standards Australia New Zealand Act 1991* (the Act). In descending order of priority they are:

1. Protection of public health and safety.
2. Provision of adequate information relating to food to enable consumers to make informed choices.
3. Prevention of misleading or deceptive conduct.

In developing standards, FSANZ also needs to genuinely consider other matters including:

- ensuring our standards are based on risk analysis using the best available scientific evidence
- promoting consistency between domestic and international food standards
- the competitiveness of the Australian and New Zealand food industry
- promoting fair trading in food.



Whilst FSANZ performs an important food regulatory function as the food standards-setting body, the Office of the Gene Technology Regulator (OGTR) in Australia and the Australian Pesticides and Veterinary Medicines Authority (APVMA) also have regulatory functions which are relevant to food. These involve the use of genetically modified organisms and agricultural and veterinary chemicals, respectively. In New Zealand, the respective roles are fulfilled by the Environmental Protection Authority (EPA) and MPI.

Under the Inter-Governmental Agreement established by COAG, FSANZ is required to apply minimum effective regulation enabling a safe and healthy food supply. FSANZ must also have regard to the policy guidelines established by the Forum on food standards issues.

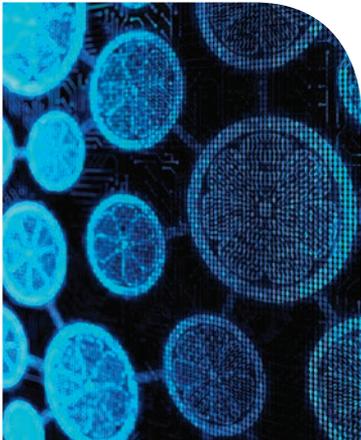
Recommendations to approve a standard or variation to a standard are presented to the FSANZ Board. The Board's decisions are notified to the Forum and, if the Forum does not request a review of the Board's decision, the standard is gazetted and registered as a legislative instrument.

In setting food standards, FSANZ uses risk analysis, an internationally accepted process that identifies and assesses food-related risks, and manages and communicates these. Risk analysis can be used for many situations where risks need to be assessed and managed. FSANZ uses risk analysis in developing new food standards, evaluating proposed changes to existing food standards, for monitoring and surveillance activities, assessing food technology practices and considering emerging food safety issues. Further details about the application of risk analysis are provided in Section 4.3.2.

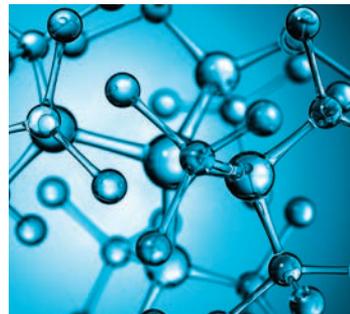
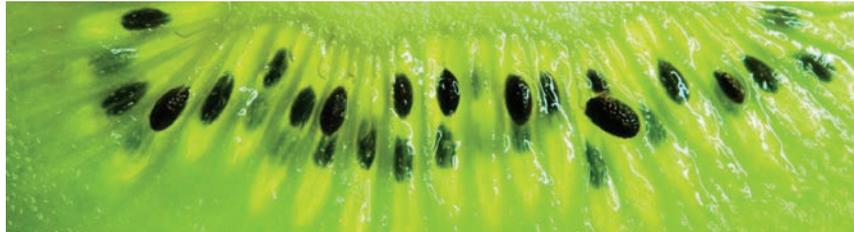
Risk analysis can lead to effective regulatory decisions, even when available information is limited. Its use encourages communication between all interested parties including consumers. FSANZ is open and transparent about its risk analysis processes in order to increase community understanding about the decision-making process and to encourage an informed debate about the potential safety risks associated with food.

This publication describes how FSANZ uses risk analysis in developing and reviewing regulatory measures. In some cases, FSANZ may determine that a non-regulatory measure(s) may adequately protect the public from food-related health risks. While there is a focus on safety, in some circumstances, FSANZ must also consider the beneficial health effects of certain foods or food ingredients alongside an assessment of safety. Thus the assessment of beneficial health effects is considered, where applicable. Chapters 2 and 3 of this publication discuss factors associated with health risks and general approaches to dealing with such risks. Chapter 4 follows with an overview of the risk analysis framework. Subsequent chapters (Chapters 5, 6 and 7) examine each of the three components of the risk analysis framework (risk assessment, risk management and risk communication) in further detail. Chapter 8 comprises case studies that illustrate how FSANZ has applied risk analysis to manage different risks in foods.





Identifying food-related health risks



2 Identifying food-related health risks

2.1 Terminology

The terminology in this document is largely consistent with that provided by the *Codex Alimentarius Commission* (Codex)¹. It is well established and used globally in relation to food. Commonly used terms are provided in the glossary at Appendix 1 and a more detailed discussion about terminology can be found in the papers listed under *Reading* at the end of this document.

The meaning of *hazard* can vary slightly depending on the context in which it is being used. For example, a hazard associated with a chemical is really any adverse effect arising from the presence of that chemical in a food. In the context of this publication however, the term *hazard* refers to a chemical (including nutrient), microbiological or physical agent in food with the potential to cause an adverse health effect.

The term *risk* in relation to food relates to the likelihood and severity of an adverse effect from exposure to a hazard. The adverse effect can be immediate, such as gastroenteritis, or longer-term, such as development of liver damage or cancer e.g. colon cancer. Adverse effects can also range in severity including death. The likelihood can range from negligible to very high.

The term *safe* in the context of food generally means there is a reasonable certainty of no harm under normal conditions of consumption. This underscores the importance of understanding human behaviour, and any effects on the normal conditions of consumption. It is important to note that safe does not mean zero risk, although, in most cases, the risk will be very low and, for most people, will be regarded as acceptable.

Nutritional risk analysis is another area of work in FSANZ. Nutritional risk analysis has the added dimension that consideration must be given to the risks directly posed by inadequate intakes. Codex has amended the term *hazard* to refer to inadequate intake as a cause of adverse effects to apply to nutrients and related substances. These include nutrients (e.g. vitamins and minerals, which are essential and have requirements for intake), as well as other nutritive substances that are not essential nutrients such as certain amino acids, nucleotides and related substances that are intentionally added to food to achieve a nutritional purpose. Therefore, in the context of nutritional risk analysis, the terms *nutrient-related hazards* and *nutritional risk* are used in this document.

1 Codex Alimentarius Commission (2011) *Definitions of Risk Analysis Terms Related to Food Safety*. In: Codex Alimentarius Commission Procedural Manual Ed. 20. Joint FAO/WHO Food Standards Programme, Rome. <http://www.codexalimentarius.org/procedures-strategies/procedural-manual/>



2.2 Agents and factors associated with health risks in food

The food supply can be a source of numerous health risks as outlined in Table 1. Many of these are well known although some have been recognised only relatively recently as contributing to risk. Some nutrient-related hazards can contribute to risk but can also contribute a health benefit if consumed in adequate amounts. In this sense, nutrients and related substances, functional ingredients and certain foods that enhance nutrient profile are identified as potentially beneficial according to the context in which these foods and substances are discussed. For these substances, a comprehensive assessment by FSANZ will therefore consider issues beyond safety and include evaluation of a potential health benefit.

Where it is determined that a food is unsuitable for human consumption, it is usually withdrawn from sale. FSANZ can assist food companies in Australia when food recalls are necessary. In New Zealand, food recalls are coordinated by MPI.

Table 1. Agents or factors in food that could contribute to risk (and benefits, where appropriate)

Chemicals	Microbiological agents	Physical factors
Environmental contaminants	Bacteria (Infectious and toxin-producing)	Metals
Food additives and processing aids	Protozoa and helminths	Glass
Naturally-occurring toxins	Viruses	Stones
Agricultural and veterinary chemicals	Moulds	Plastics
Packaging materials	Prions	Wood
Allergens		Bones and bone fragments
Nanoscale materials		
Nutritive substances*		
Dietary macro-components*		
Novel foods and ingredients*		
GM ingredients with enhanced nutritional profile*		

* Can have a nutritive component and contribute to health benefit as well as risk.



2.2.1 Chemicals

All food is made up of a complex mixture of chemicals. Chemicals are also sometimes added to food e.g. additives such as food colours or processing aids. These and other chemicals present in the environment or present as a result of processing or packaging are subject to regulatory assessment.

Some foods also contain naturally-occurring toxins, for example, from plants or other organisms. Exposure to chemicals can also occur from herbicides or pesticides used in agriculture, and veterinary drugs used in food producing animals.

Novel foods or novel food ingredients are considered non-traditional foods that do not have a history of human consumption in Australia and New Zealand, or are produced using non-traditional methods, and for which there may be potential health and safety concerns. Nutritive substances are intentionally added to food to achieve a nutritional purpose. Novel food ingredients (such as phytosterols), or nutritive substances (such as vitamins and minerals), are chemicals generally added to foods with the intention of achieving a beneficial health effect, as an alternative to conventional ingredients, or to enhance the nutritional profile of the final food. These are discussed in further detail in Section 2.3.2.

2.2.2 Microbiological agents

The most common foodborne illnesses are caused by pathogenic bacteria such as *Campylobacter jejuni* and *Salmonella* species although more serious illness can be caused by enterohaemorrhagic *Escherichia coli* and *Listeria monocytogenes*. Other foodborne bacteria (including toxins produced by enterotoxin producing bacteria), as well as viruses and parasites, also pose an increasing public health risk. Another biological hazard is the prion, a proteinaceous infectious agent (abnormal form of the host prion protein) most notably associated with Bovine Spongiform Encephalopathy (BSE) in cattle, Scrapie in sheep and variant Creutzfeldt-Jakob disease (vCJD) in humans. Some microorganisms, such as probiotics, may contribute a health benefit. In this case, an assessment of these substances as novel food ingredients may be appropriate. See Section 2.3.2.

2.2.3 Physical factors

Physical factors that could potentially contribute to a health risk may occur in food as a result of contamination through manufacturing and processing failures. An example of this is the presence of metal fragments in food from machinery. The presence of physical impurities is not normally subject to a risk analysis. In general, these are isolated incidents that are managed well by food companies. In addition, Australian and New Zealand regulations that apply to all foods intended for commercial sale adequately cover the presence of foreign objects in food and broader food safety considerations generally.



2.3 Other aspects to consider regarding health risks in food

2.3.1 New technologies

New technologies can potentially lead to a new or increased risk in food. For example, technologies such as genetic modification of crops, nanotechnology or food irradiation could change the composition of the food or the way it is used. New technologies that replace an existing or traditional method of food production can also lead to a change in the potential hazard, for example, by increasing the levels of pathogenic microorganisms. This in turn might have an impact on the overall risk associated with the food. In general, an assessment of risks associated with the use of such new technologies is done on a case-by-case basis.

2.3.2 Novel foods and ingredients

Novel foods encompass a broad range of foods and food ingredients, including plants and animals and their extracts, single chemicals or macro-components, microorganisms (including probiotics), food ingredients derived from new food sources, and foods produced by a new process. Information on composition, metabolism, non-food uses (e.g. use in dietary supplements or complementary medicines), safety of related substances, and history of use in other countries may be used to assist in assessing the risk. Again, an assessment of risks is generally done on a case-by-case basis.

Functional ingredients

Functional ingredients such as phytosterols are added to food for a possible beneficial health effect. However, it is necessary to establish that their presence does not also inadvertently introduce any new risks to human health. These new risks could arise because of the functional ingredient itself, altered levels of other constituents or through changes in consumption behaviour due to the nature and content of product labels. As the demand for functional ingredients increases and their use in foods becomes more widespread, risk analysis will need to be broad to ensure the safe use of these foods. One way to achieve this might involve systematic monitoring of the levels of the ingredient in the food supply over time (post-market monitoring). This would assist in confirming the assumptions used in the assessment, particularly in relation to possible changes in levels of dietary exposure to functional ingredients.

2.3.3 Changes in nutrient profile

Enhancing the nutrient profile of foods through voluntary or mandatory fortification to improve the nutritional status of a target population group, also has the potential to introduce new risks to health. For example, increasing the intake of a particular nutrient or a related substance through fortification, or altering the consumption patterns to include or avoid fortified foods may lead to a nutrient imbalance. Although the potential for both



of these scenarios is low in the general population, both need to be considered when addressing food fortification, particularly for vulnerable population sub-groups. The signalling of nutrient fortification through labelling may result in changes in consumption behaviour that may need consideration.

2.3.4 Special purpose foods

Special purpose foods are specially formulated to deliver adequate nutrition to physiologically vulnerable individuals and to satisfy particular dietary requirements for population sub-groups. These groups can be at risk of dietary inadequacy due to a particular physical disease, disorder or disability, or a specific life stage (e.g. infancy). In some cases, the foods may be the sole source of nutrition, such as infant formula products, or products formulated for a particular medical purpose e.g. tube feeds. Formulated meal replacements, formulated supplementary foods and formulated supplementary sports foods, which are becoming increasingly available in Australia and New Zealand, are also special purpose foods. Regulatory permission is generally required before nutrients or other nutritive and related substances can be added to special purpose foods. As these foods may be the sole source of nutrition in certain situations, assessment of any potential risks associated with adding such substances to special purpose foods is done on a case-by-case basis.

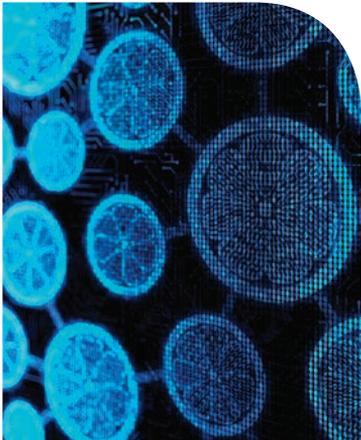
2.3.5 Allergenic foods

Allergenic foods present a special case for risk analysis. The adverse health effect resulting from exposure to the allergen is specific to sensitised individuals. Adverse effects can range from mild to severe gastrointestinal, respiratory or skin reactions, to potentially life-threatening anaphylaxis. The main focus of managing the risks from allergenic foods by regulatory agencies such as FSANZ has been on providing information, mainly through food labelling, to allow allergic consumers to identify and avoid allergenic foods. Research is continuing to improve recognition of new allergens, establish allergen thresholds (amount of allergen below which no adverse effect occurs in susceptible individuals), and identify factors that influence the severity of allergic reactions.

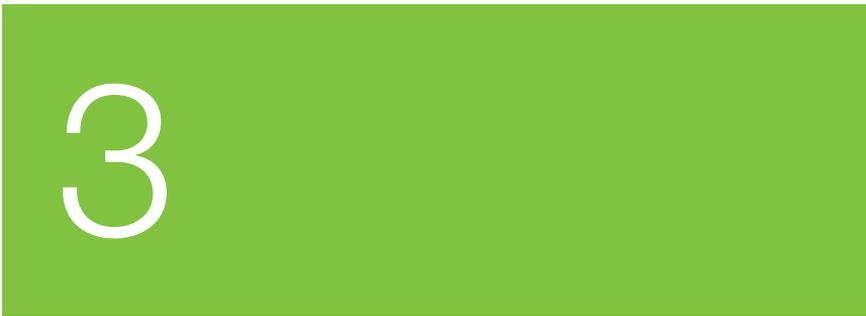
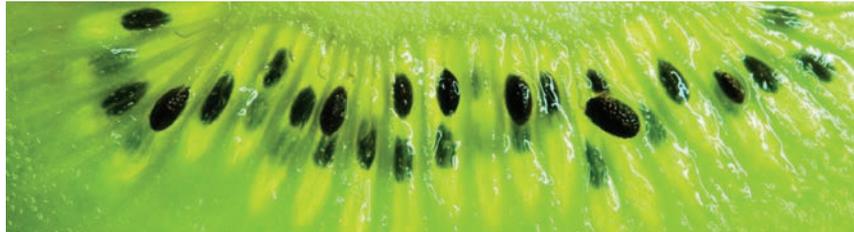
2.3.6 Food intolerance

Foods can also cause a variety of mild to moderate adverse reactions in some individuals as a result of the presence of natural or added substances. Such reactions are highly individualistic and in some instances may be related to an underlying condition which is aggravated by a relatively high exposure to a particular food or food ingredient. Foods and food chemicals that have been associated with intolerance reactions include glutamates, biogenic amines (such as tyramine and histamine) and salicylates. There is currently a scarcity of information on the underlying causes and the factors which contribute to food intolerance.





Recognising the varied nature of food-related health risks



3 Recognising the varied nature of food-related health risks

3.1 Introduction

In the main, foods consumed today are a mix of plant, animal and microbially derived substances that have been traditionally consumed for many generations and foods that have been more recently developed by plant breeding or the use of new technologies.

This chapter further discusses potential risks in different types of food and how these differences, together with other issues, can affect the approach to risk assessments.

3.2 Traditional foods and production methods

Familiar foods with a history of safe human consumption, manufactured using well accepted, conventional methods of production are generally associated with the highest level of public confidence. This includes foods such as meat and fish, commonly used cereals, dairy products, tinned foods, and conventionally produced fruit and vegetables.

While some traditional foods e.g. potatoes, can carry a risk, these risks are accepted because they are well understood, and industry and the community know how to mitigate them through appropriate food preparation. Similarly, the risk of microbiological contamination of food is addressed by strict industry practices and by community education on hygienic food preparation.

In cases where traditional foods pose a risk for susceptible individuals, such as the presence of food allergens, controls are not so easily implemented but labelling can help vulnerable consumers identify unsuitable foods and minimise any health risk.

Environmental contaminants, which may be present in some traditionally consumed foods, can be a risk to the health of population sub-groups. For example, unborn children may be at risk if pregnant women over-consume certain fish with higher levels of mercury. In such a case, providing a maximum level (ML) for mercury in fish in the Code and consumer advice on fish consumption is an appropriate risk management approach.

When traditional foods provide nutritional benefits but also carry some level of risk, an assessment of both health benefits and health risks is necessary.

3.3 New foods, additions to food and new production methods

Under current food regulations, where there is no history of human use by a broad sector of the community, there is no presumption of safety for a food, food ingredient, or substance added to food. In these cases, a pre-market assessment is generally necessary. For food



additives and processing aids, FSANZ has well established and uniformly applied risk assessment procedures. For other substances added to food, such as novel and nutritive substances, general guidance exists although each substance is considered on a case-by-case basis.

For foods not traditionally consumed by the Australian and New Zealand population but consumed in other parts of the world (e.g. native bush foods), risk assessments rely largely on compositional analysis and a demonstrated history of safe use in humans elsewhere or animals. For those foods for which there is no history of safe use, a full risk assessment is required.

The situation may vary for foods that have been produced using new technologies or by a new use of an existing technology. For example, for genetically modified foods, specific assessment methods have been developed internationally to determine whether the production method has resulted in any changes in the food that could affect safety. However, for foods that have undergone irradiation or have been produced using nanotechnology, different countries have employed a range of different approaches.

For non-traditional foods or food produced by non-traditional methods, additional safeguards may be needed. These could include controls on manufacturing processes and on use in order to mitigate any identified health risk. Controls may also include advice and information for potential consumers to enable them to make informed food choices and to prepare and consume food safely.

3.4 A whole-of-chain view

As food production has become more complex, so too have the tools for establishing the safety of food and the options for managing identified risks. A whole-of-chain approach has enabled the identification of hazards at each step in the food production process and for controls to be put into place at various production steps to reduce risks. The HACCP (hazard analysis critical control point) approach to food safety is an example of this. HACCP identifies and addresses chemical, microbiological and physical hazards in a preventative manner, leading to the development of food safety plans for manufacturing industries and food businesses in general. This approach has been instrumental in identifying unsafe practices and reducing reliance on end-product testing for chemical or microbiological hazards before sale, although some testing to verify the efficacy of the controls is still necessary.

One approach used to assess new and alternative food production methods is based on the concept of *equivalence of food safety measures*. This recognises that the same level of food safety can be achieved by alternative food safety control measures. This approach can ensure food safety without unnecessarily hindering innovation in the food industry. To determine the equivalence of food safety measures consistently, an objective basis of comparison must be identified e.g. comparing the degree of microbial hazard reduction achieved by each measure could be used as an objective basis of comparison.



3.5 Considering both health risks and benefits

The health benefits of a nutritious and well balanced diet have to be recognised in assessing food risks. There may be times, however, when the risks associated with a particular food constituent outweigh any benefits of consuming that food or food constituent for all consumers or for particular individuals or population sub-groups.

For some, if not most foods, low levels of undesirable chemicals or non-pathogenic microorganisms may be present without causing any appreciable adverse health effects. In some cases, and depending on the chemical, the ALARA principle (whereby exposure to a chemical should be as low as reasonably achievable) can be applied where a range of controls can be implemented to minimise their presence. However, targeted advice to population sub-groups on safe levels of consumption may still be necessary.

When a chemical is added to a food for a specific purpose, for example, where a preservative is added to minimise the growth of pathogenic microorganisms, the benefits associated with the use of this chemical is considered in terms of ensuring the safety of the food as well as the potential risks associated with the chemical.

In the case of nutritive substances or functional ingredients specifically added to foods to achieve a beneficial health effect, there is a need to assess any possible health risks that could arise from over-consumption, from the displacement of other equally nutritious foods already in the food supply, or other behavioural changes. While a consideration of the benefits as well as possible health risks might be appropriate in relation to the deliberate or discretionary addition of chemicals and nutritive substances to foods, it would not be as relevant in the context of assessing possible health risks associated with other food constituents such as naturally-occurring toxins.

3.6 Maintaining vigilance

Ensuring food is safe requires constant vigilance and a pro-active approach to control known and emerging health risks. Known food hazards can be monitored to ensure controls are in place and are effective. Emerging food-related public health and safety risks are less well characterised and therefore difficult to monitor. While not all risks can be identified before they occur, ongoing research and development in the food industry and elsewhere, as well as surveillance of foods and investigation of foodborne disease outbreaks, can help identify some of the potential emerging risks. FSANZ plays a significant role in monitoring emerging food-related health risks and ensuring the ongoing safety of food through surveillance and monitoring activities and by maintaining communication with fellow international food regulators.

