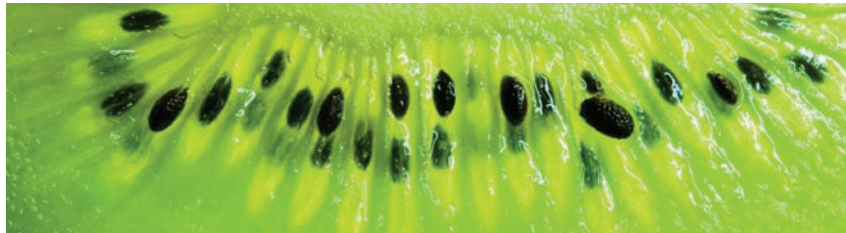
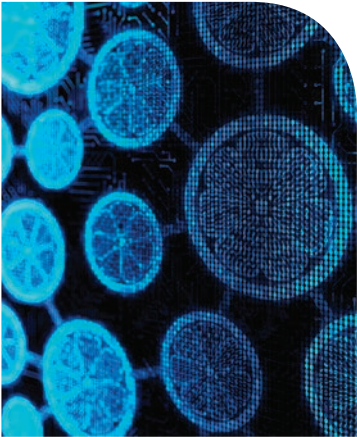


Risk Analysis in Food Regulation



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



© Food Standards Australia New Zealand 2013

ISBN: 978-0-642-34581-3

Food Standards Australia New Zealand (FSANZ) supports and encourages the dissemination and exchange of information. Information in this publication is provided under a Creative Commons Attribution 3.0 Australia (CC BY 3.0) Licence, except for the Food Standards Australia New Zealand logo. An electronic version of this work is available on the FSANZ website at www.foodstandards.gov.au and, for New Zealand, www.foodstandards.govt.nz.



Attribution

You may copy, distribute, transmit and adapt the material in this publication by the CC BY 3.0 licence for commercial and non-commercial purposes; but you must attribute the work in the following manner:

© Food Standards Australia New Zealand.

This attribution must not, in any way, suggest that FSANZ endorses you or your use of the work.

For more information email info@foodstandards.gov.au

FSANZ Australia

PO Box 7186
Canberra BC ACT 2610
Australia
T +61 2 6271 2222
F +61 2 6271 2278

FSANZ New Zealand

PO Box 10559, The Terrace
Wellington 6143
New Zealand
T +64 4 978 5630
F +64 4 473 9855

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



Contents

Foreword	3
Acronyms and abbreviations	7
1 Introduction	10
1.1 Maintaining a safe food supply	10
1.2 The food regulatory system and FSANZ's role	10
2 Identifying food-related health risks	14
2.1 Terminology	14
2.2 Agents and factors associated with health risks in food	15
2.2.1 Chemicals	16
2.2.2 Microbiological agents	16
2.2.3 Physical factors	16
2.3 Other aspects to consider regarding health risks in food	17
2.3.1 New technologies	17
2.3.2 Novel foods and ingredients	17
2.3.3 Changes in nutrient profile	17
2.3.4 Special purpose foods	18
2.3.5 Allergenic foods	18
2.3.6 Food intolerance	18
3 Recognising the varied nature of food-related health risks	20
3.1 Introduction	20
3.2 Traditional foods and production methods	20
3.3 New foods, additions to food and new production methods	20
3.4 A whole-of-chain view	21
3.5 Considering both health risks and benefits	22
3.6 Maintaining vigilance	22



4	Addressing food-related health risks	24
4.1	The risk analysis framework	24
4.2	The Codex risk analysis framework	24
4.3	The FSANZ approach to risk analysis	26
4.3.1	Working in the Codex framework	26
4.3.2	Applying risk analysis	28
4.3.3	FSANZ's risk appetite	29
4.3.4	Underlying principles	29
4.3.5	Identifying and gathering data and other information	32
4.3.6	Prioritising food-related health risks	33
4.3.7	Review and evaluation	34
4.3.8	Responding to rapidly emerging issues	34
5	Assessing food-related health risks	36
5.1	Risk assessment in a food context – overview and general principles	36
5.2	Steps in risk assessment	39
5.2.1	Hazard identification	40
5.2.2	Hazard characterisation	41
5.2.3	Exposure assessment	44
5.2.4	Risk characterisation	48
5.3	Special risk assessment cases	51
5.3.1	Bovine spongiform encephalopathy	51
5.3.2	Allergenic foods	51
5.3.3	Special purpose foods	52
5.3.4	Other nutritive substances	52
5.3.5	New technologies	53
5.4	Impacts on consumers' behaviour	54
5.5	Variability and uncertainty in food risk assessments	55
5.6	Risk assessment outputs	56



6	Managing food-related health risks	58
6.1	General approach to risk management	58
6.2	FSANZ's risk management process	59
6.2.1	Preliminary risk management activities	60
6.2.2	Formulating risk management options and selecting preferred options	62
6.2.3	Implementing risk management decisions	63
6.2.4	Monitoring and evaluation	65
6.3	Factors influencing risk management decisions	66
6.3.1	Health and safety issues – risks and benefits	66
6.3.2	Behavioural and social issues	66
6.3.3	Regulatory analysis	67
6.3.4	Governmental and international agreements and international food regulations	69
6.3.5	Rapidly emerging food incidents	70
6.4	Options for managing food-related health risks	70
6.4.1	Regulatory measures	70
6.4.2	Non-regulatory measures	76
6.5	Monitoring and evaluation activities	77
6.5.1	Monitoring activities	77
6.5.2	Evaluation activities	79
7	Communicating food-related health risks	82
7.1	Risk communication	82
7.2	Communication strategies	83
7.2.1	Risk perception	83
7.2.2	General matters	84
7.2.3	Applications and proposals	85
8	Case studies	88
8.1	Approval to use the food additive Advantame	88
8.2	Cyanogenic glycosides in cassava-based snacks	91
8.3	Methylmercury in fish	94
8.4	Approval to add calcium to several non-dairy foods	97
8.5	Raw milk products	100
	Reading	104
	Appendix 1 – Glossary	106
	Appendix 2 – Regulatory framework for food	112



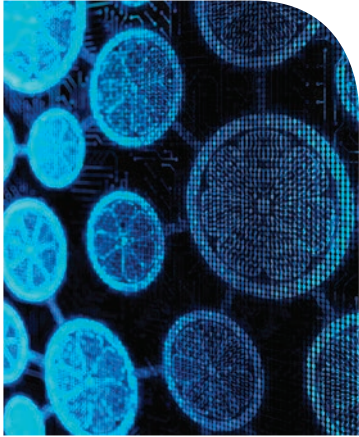
Acronyms and abbreviations

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

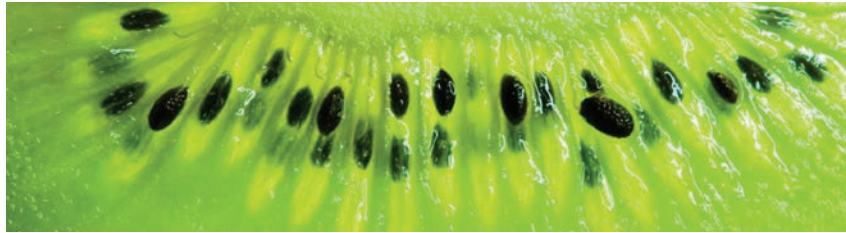


IFIS	Imported Food Inspection Scheme of the Department of Agriculture
ISFR	Implementation Sub Committee for Food Regulation
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LOAEL	Lowest-Observed-Adverse-Effect Level
LOR	Limit of reporting
ML	Maximum Level
MOE	Margin of Exposure
MPI	Ministry for 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

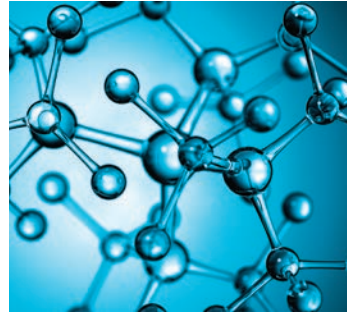




Introduction



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.

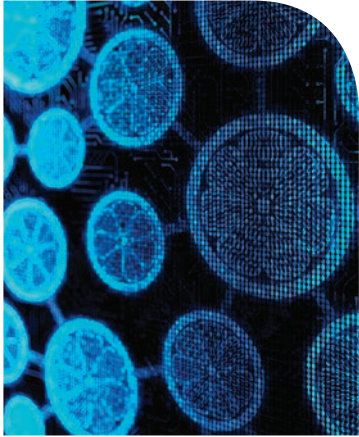
Recommendations to approve a standard or variation to a standard are presented to the FSANZ Board. The Board's decisions are notified to the Forum and, if the Forum does not request a review of the Board's decision, the standard is gazetted and registered as a legislative instrument.

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.

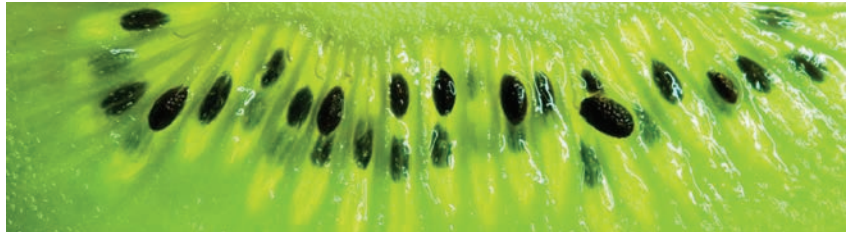
Risk analysis can lead to effective regulatory decisions, even when available information is limited. Its use encourages communication between all interested parties including consumers. FSANZ is open and transparent about its risk analysis processes in order to increase community understanding about 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.

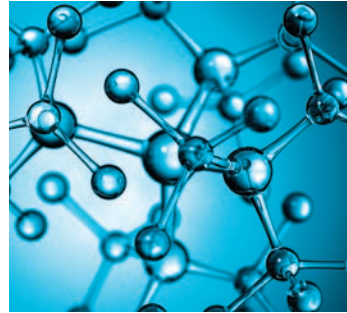




Identifying food-related health risks



2



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.

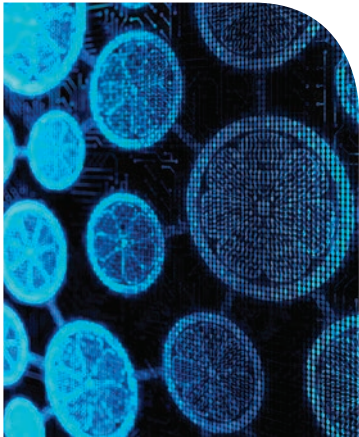
2.3.5 Allergenic foods

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.

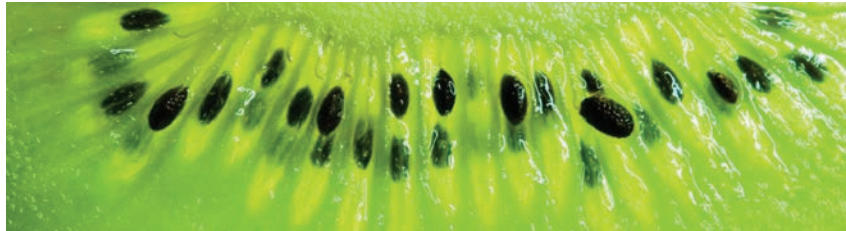
2.3.6 Food intolerance

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.

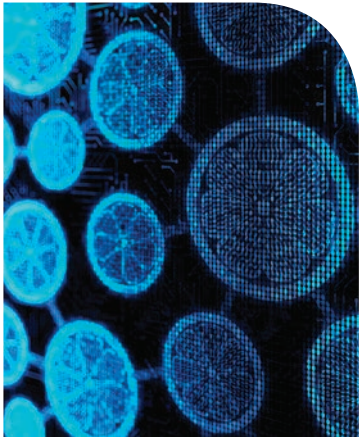
When a chemical is added to a food for a specific purpose, for example, where a preservative is added to minimise the growth of pathogenic microorganisms, the benefits associated with the use of this chemical is considered in terms of ensuring the safety of the food as well as the potential risks associated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

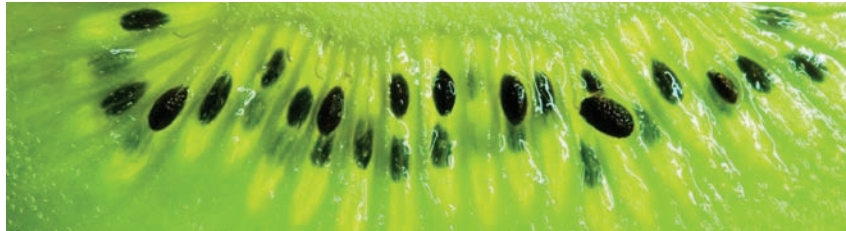
3.6 Maintaining vigilance

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.





Addressing food-related health risks



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 risk². 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.

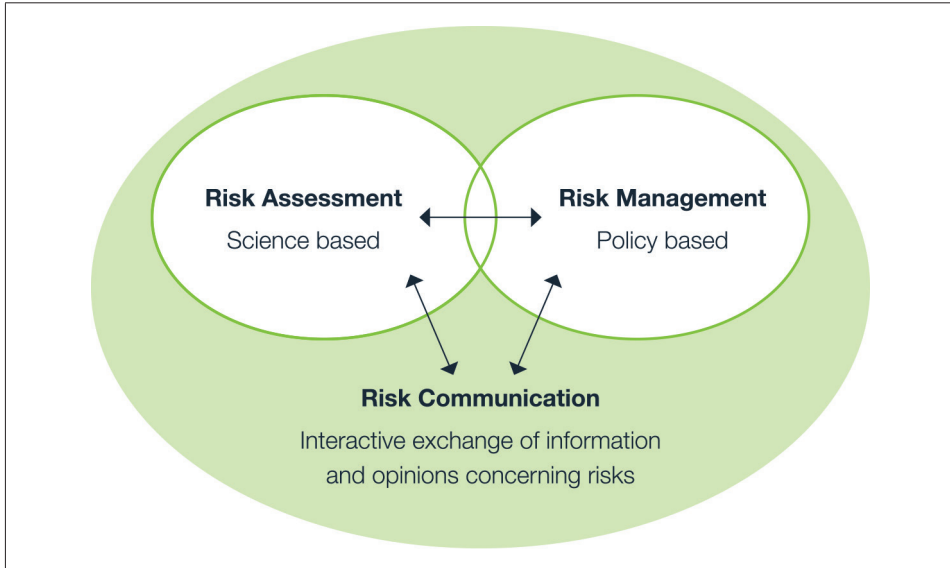
The risk assessment and risk management components of the Codex risk analysis framework operate together as an iterative process with active communication between risk assessors and risk managers. A diagrammatic representation of this framework is shown in Figure 1.

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 procedures³, 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 framework⁴



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 food⁵ 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.

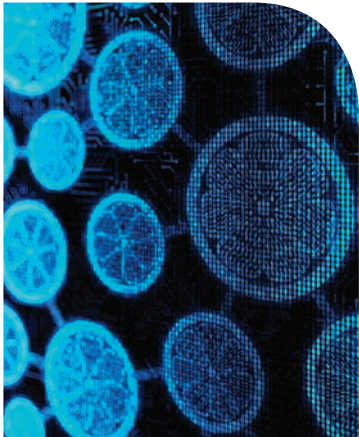
4.3.8 Responding to rapidly emerging issues

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.

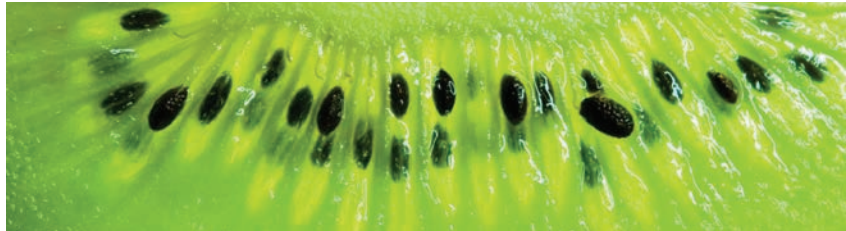
The general principles of risk analysis apply in responding to rapidly emerging issues. However, time constraints may affect the sequence of steps undertaken. These steps will be determined on a case-by-case basis with the information available. If national action is required in Australia, the National Food Incident Response Protocol⁷ 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>





Assessing food-related health risks



5 Assessing food-related health risks

5.1 Risk assessment in a food context – overview and general principles

Risk assessment involves a process of identifying, analysing and characterising food-related health risks. Each risk assessment is done on a case-by-case basis, using the best available scientific evidence to decide whether an identified food-related hazard might pose any public health and safety issues. Risk managers use the outcomes of risk assessments to formulate responses to food health and safety concerns.

Risk assessments aim to estimate the likelihood and severity of an adverse health effect occurring from exposure to a hazard. They can examine substances deliberately added to food (e.g. food additives, processing aids, agricultural or veterinary chemicals), substances that occur inadvertently in food (e.g. environmental contaminants, naturally-occurring toxins or pathogenic microorganisms), novel foods, nutritive substances and the impact of new technologies. In this context, risk is a function of both the hazard and the level of exposure to that hazard. A food risk assessment therefore consists of an assessment of the hazard and an assessment of exposure which together enable characterisation of the risk.

The above model can be applied to assessing potential risks resulting from exposure to chemicals, microbiological agents and nutrients. However, there are some specific features of microorganisms and nutrients that make risk assessment of these substances different from that of the general class of chemicals. For example, microbiological risk assessments identify the likelihood of the microbe's association with food and the severity of the consequences of its presence, such as gastroenteritis, long-term illness or death. Identifying and describing microbiological hazards is complicated by the broad range of factors that may influence the associated risk of an adverse effect, including the intrinsic variability of the pathogen and host related factors that influence pathogenicity.

The model can also be applied to assessing whole foods. The first step in assessing potential risks from whole foods that are complex mixtures of constituents [e.g. foods derived from genetically modified (GM) crops, foods that have undergone irradiation or whole novel foods] is to compare the food to the conventional counterpart food with a history of safe use as the benchmark—a process termed a safety assessment. Any identified hazards are further characterised to determine their effect on the safety of the food⁸.

8 FSANZ (2007) *Safety Assessment of Genetically Modified Foods – Guidance Document*.
http://www.foodstandards.gov.au/consumer/gmfood/safety/documents/GM%20FINAL%20Sept%2007L%20_2_.pdf



The risk assessment should address the food health and safety issue and questions developed by the risk managers in consultation with the risk assessors (see Section 6.2.1). The scope of the assessment will be defined by these parameters.

The risk assessment process is often iterative. Risk assessment outputs are communicated to risk managers to inform the development and selection of appropriate risk management options. The risk characterisation step may need to be repeated numerous times for each proposed risk management scenario. This may apply particularly when there is the potential for the proposed risk management strategies to precipitate changes in consumer behaviour.

Scientific evidence used in a risk assessment may include unpublished reports in addition to publicly available studies such as scientific journal articles. Irrespective of the source, in all cases, FSANZ uses the best available scientific evidence and exercises professional judgement about the quality and relevance of the data and information, including that obtained from peer reviewed literature.

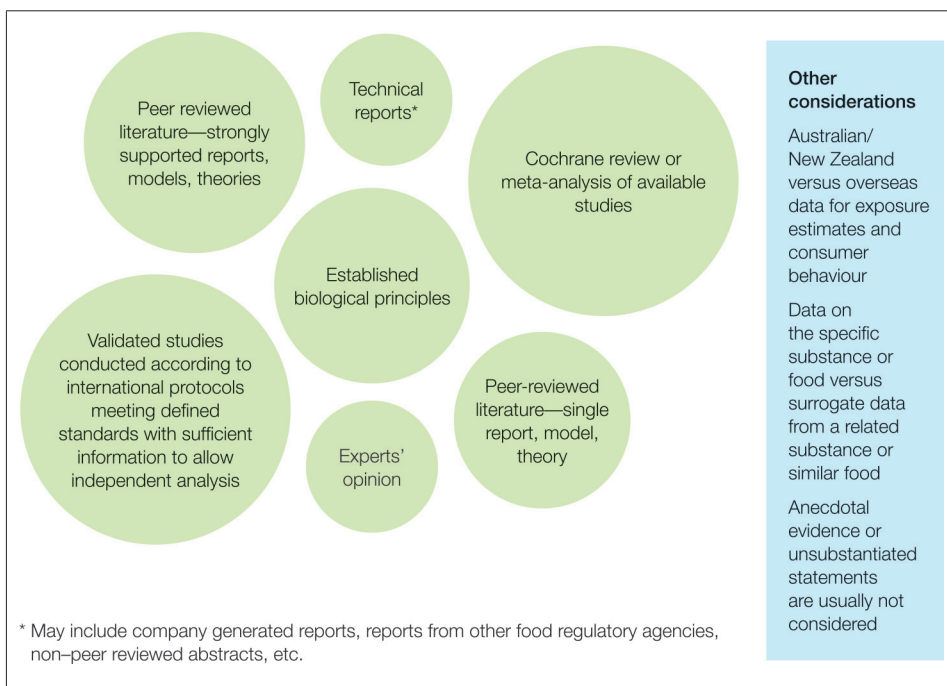
In assessing the quality of individual studies, including epidemiological studies, FSANZ will typically assess various elements of the study design and method. These might include: the purpose of the study; appropriateness of the study design for the purpose; appropriateness of the instruments used to measure the outcome variables of interest; the duration of the study; and the appropriateness of the statistical analyses undertaken. This is not an exhaustive list but is indicative of study parameters that must be considered.

While grading of the evidence is more traditionally applied when evaluating evidence from epidemiological studies, there are increasing efforts to adapt this approach for other types of studies e.g. toxicological studies. In general, studies designed and conducted in accordance with the principles and intent of good laboratory practice (GLP) are accorded a higher weighting as there is the expectation that these studies have been conducted with good quality control.

An indication of the relative weighting that FSANZ may give to different sources of evidence is illustrated in Figure 2, using circles of differing size.



Figure 2. Different sources of evidence used by FSANZ and relative weighting given



Drawing a conclusion about the level of risk using the available scientific evidence requires both scientific judgement and reference to any agreed practices on addressing uncertainty imposed by limited or incomplete information. Examples include practices such as (i) the use of safety (or uncertainty) factors to account for species differences and human variability; and (ii) the use of 90th or 95th percentile dietary exposure levels to represent high level consumers.

Peer review is an important quality control mechanism used by FSANZ to maintain the scientific integrity of its regulatory decisions (see the *FSANZ Science Strategy 2010–2015*⁹). Each risk assessment prepared by FSANZ is internally peer reviewed to ensure conclusions are scientifically robust. In addition, stakeholders have the opportunity to comment on risk assessments via a public consultation process. For more scientifically complex or contentious risk assessments, advice may be sought from experts in the preparation of the assessment and/or an external peer review may also be sought from national or international experts.

9 The intention of the *FSANZ Science Strategy 2010–2015* is to facilitate the identification of strategies that lead to continuous improvement in FSANZ's food regulatory science. FSANZ (2010) *FSANZ Science Strategy 2010–2015*. <http://www.foodstandards.gov.au/science/strategy/Pages/default.aspx>

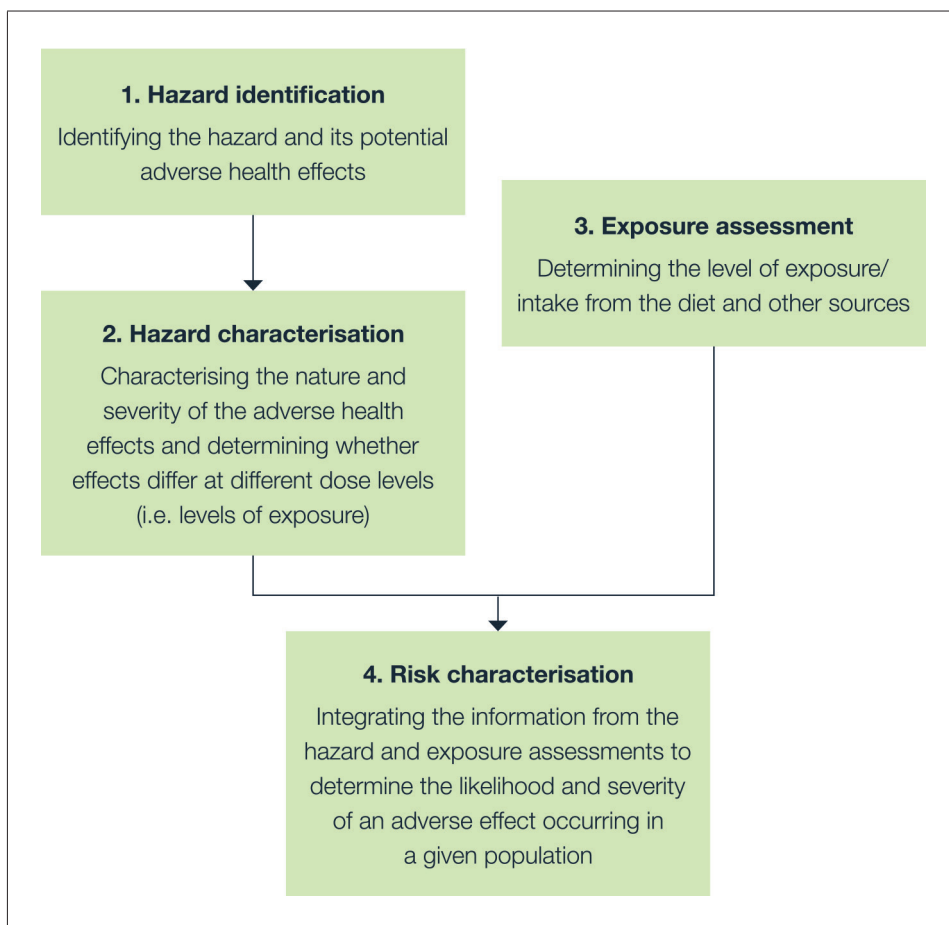
Collectively, this peer review process ensures that the scientific basis of a risk assessment is transparent, robust and benchmarked against international best practice risk assessment methodologies.

5.2 Steps in risk assessment

The risk assessment process used by FSANZ follows the Codex framework (see Section 4.2) and involves four key steps: hazard identification and hazard characterisation (together called hazard assessment, when considering chemical entities), exposure assessment and risk characterisation.

The four key steps of risk assessment are shown in Figure 3 and described in more detail below.

Figure 3. The four key steps in risk assessment



5.2.1 Hazard identification

Hazard identification seeks to clearly describe the hazard being assessed and to identify potential adverse health effects that could occur as a result of exposure to the chemical (food additive, contaminant etc.), nutrient, other food component or microorganism in food.

Inadequate intake of essential nutrients, by definition, leads to adverse effects whereas intake in the range that covers human requirements provides a health benefit. Some, but not all, essential nutrients also have adverse effects when intake is excessive. The hazard identification process for nutrients therefore requires consideration of the health effects at low, moderate and high intakes. Other nutritive substances that are not essential nutrients may also be assessed using this approach. These are discussed separately (see Section 5.3.4).

Hazard identification involves examining the available scientific data on the health effects of the chemical, nutrient, other food component or microorganism, specifically, relevant toxicological, microbiological, physiological, epidemiological or other technical information. If possible, the biological mechanism by which the adverse health effect occurs is also described.

Chemicals

For non-nutrient chemicals (food additives, processing aids, contaminants, agricultural and veterinary chemicals and active novel constituents), hazard identification involves examining their characteristics (including physical and chemical properties and method of manufacture and composition). Toxicity studies (in laboratory animals, for example) and relevant human studies, if available, are also considered to determine adverse health effects.

Laboratory animal studies provide information on the absorption, distribution, metabolism and excretion pathway of the chemical, possible adverse effects following a single exposure (acute toxicity) and adverse effects (e.g. cancer) following long-term exposure (chronic toxicity). In assessing any adverse effects observed in laboratory animals, consideration is always given to their relevance for humans. Relevant human studies may include volunteer studies, occupational or accidental exposure studies and epidemiology studies. Adverse effects or poisoning case reports for humans may also be available.

In the case of whole novel foods, if an initial comparative safety assessment identifies a potential hazard, then the potential toxicity of the hazard will be investigated. In addition to traditional toxicity studies or observational data in humans, FSANZ also considers the composition of the material (the types and concentrations of substances that consumers would ordinarily be exposed to in the diet), the manufacturing process (in terms of the potential to concentrate any deleterious substances) and any history of safe consumption of the equivalent material outside of Australia and New Zealand.



Nutrients

Nutrients are food chemicals required for human health that must be supplied in the diet because the body cannot manufacture them or can only manufacture insufficient quantities. The adverse effects that result from consuming too little of an essential nutrient over a prolonged period of time are well characterised. Some, but not all nutrients also have adverse effects when intake is excessive (usually over a long time frame). Therefore for nutrients, hazard identification primarily involves an examination of data from human studies, particularly those that involve the target populations, at inadequate or excessive levels of intake. A wide range of data may be examined including epidemiological, clinical, and other studies relating to physiological and biochemical effects and response.

Microbiological agents

Hazard identification of microbiological agents involves reviewing microbiological, clinical and surveillance data, as well as epidemiological information. Scientific information is obtained on the microorganism, its preferred growth conditions, and factors specific to the food and how it is produced (e.g. moisture content, cooking) which may influence the organism's growth, survival or death. Surveillance and epidemiological data may assist in identifying the foods most commonly associated with the organism, the likely level of exposure and mode of transmission, as well as identifying any susceptible population groups. An analysis of the adverse health effects including the nature, severity and causal mechanism of the illness is also considered. Adverse health outcomes may vary from acute, short-term conditions such as gastroenteritis, to serious long-term illness, systemic disease, or may even result in death.

5.2.2 Hazard characterisation

Hazard characterisation seeks to characterise toxicological responses in laboratory animals and/or humans to various levels of exposure (i.e. doses). This is often referred to as a dose-response assessment. Hazard characterisation will identify the critical health effects associated with exposure and, if possible, establish a dose-response relationship.

An important part of hazard characterisation involves assessing relevant studies, including toxicological and epidemiological studies for their quality and relevance.

Chemicals

The hazard characterisation focuses on the most sensitive adverse effect. It is generally accepted that for most chemicals there is a level of exposure, known as a threshold dose, below which adverse health effects do not occur. Hazard characterisation focuses on establishing a 'safe' level of exposure; that is, a level below this threshold level of exposure. This level can be used to establish what is generally referred to as the 'health-based guidance value' (HBGV), which reflects the level of a chemical that can be ingested over a defined time period (e.g. lifetime or 24 hours) without appreciable health risk.



For most chemicals, HBGVs are established on the basis of traditional toxicity studies. These studies use a range of dose levels to identify the highest dose at which adverse health effects do not occur—the no-observed-adverse-effect level (NOAEL). In some cases, and particularly for certain contaminants, agricultural chemical residues and nutritive substances, the NOAEL may be based on human studies. To establish the HBGV based on the NOAEL, 'safety' (or 'uncertainty') factors are applied. A factor of 100 is generally applied when the NOAEL is determined from adequate long-term studies in animals.

However, for some chemicals, such as those considered to be genotoxic and carcinogenic, a threshold of toxicity cannot be readily identified. In such cases, an alternative to the NOAEL approach can be used, which involves dose-response modelling to determine a benchmark dose or BMD. This may also be expressed as the BMDL that is the lower confidence limit of the BMD. The BMD is a level producing a low but measurable adverse response, corresponding to a pre-determined increase (usually 5 or 10%) in a defined adverse effect.

The HBGVs commonly established to take account of long term exposure are the acceptable daily intake (ADI) for food additives or agricultural and veterinary chemical residues and the provisional tolerable (daily, weekly, monthly) intake (PTDI, PTWI, PTMI) for contaminants. For some chemicals, a HBGV is established for short term exposure, usually during one meal or one day, without appreciable risk to the consumer [the acute reference dose (ARfD)].

The HBGVs that FSANZ uses in its risk assessments may be derived from several different sources, depending on the type of chemical under review:

- The Office of Chemical Safety and Environmental Health of the Department of Health assigns ADIs and ARfDs for agricultural and veterinary chemicals^{10 11}.
- FSANZ may establish a HBGV based on data provided by external individuals, organisations or companies as part of their application to amend the Code.
- The Joint FAO/WHO Expert Committee on Food Additives (JECFA) sets HBGVs for both additives and contaminants and FSANZ will endeavour to harmonise the HBGVs it uses with these wherever possible.

The HBGVs established during the hazard characterisation step are subsequently used in the risk characterisation step of the risk assessment to compare with the estimated dietary exposure levels.

10 OCS (2012) *Acceptable Daily Intakes for Agricultural and Veterinary Chemicals*.
<http://www.health.gov.au/internet/main/publishing.nsf/Content/ocs-adi-list.htm>

11 OCS (2012) *Acute Reference Doses for Agricultural and Veterinary Chemicals*.
<http://www.health.gov.au/internet/main/Publishing.nsf/Content/ocs-arfd-list.htm>



Nutrients

Nutrient-related hazards are usually characterised using the HBGVs called Nutrient Reference Values (NRVs) set for Australia and New Zealand by the National Health and Medical Research Council of Australia (NHMRC) and New Zealand Ministry of Health to assess population nutrient intakes¹². To assess nutrient inadequacy either the Estimated Average Requirement (EAR) or the Adequate Intake (AI) is used, depending on the available evidence for the specific nutrient. These are measures of adequate intake in healthy populations. Macronutrients, including protein, have an Acceptable Macronutrient Distribution Range that provide an upper and lower limit on the range of intake (expressed as a per cent of energy intake) that is advisable. To assess whether population intakes might be excessive, the Upper Level of Intake (UL) is available for some micronutrients and is the highest average nutrient intake likely to pose no adverse health effects to almost all individuals in the general population. As intake increases above the UL, the potential risk of adverse effects increases. A small number of minerals also have a Tolerable Daily Intake (TDI). On occasion, FSANZ might use the TDI rather than the UL for assessing whether intake of these minerals is excessive¹³.

There are currently many chemical forms of vitamins and minerals that can be added to food in Australia and New Zealand. If permission to add a new form is sought, its bioavailability must be assessed and compared with the current permitted forms. Bioavailability in a nutritional context is the proportion of the ingested nutrient that is absorbed and utilised through normal metabolic pathways. The bioavailability and bioconversion of different forms of nutrients is usually taken into account in one of two ways. For vitamins, such as folate, niacin, vitamin A or E, there are standard 'equivalence' factors that are applied to different vitamins (i.e. different forms of the vitamin exhibiting proportionally equivalent vitamin activity), or foods, to allow for bioavailability and bioconversion. The equivalents are totalled and compared to NRVs expressed in units of equivalents (e.g. niacin equivalents). For minerals, the NRVs have been increased by a factor to allow for the typical bioavailability in the Australian and New Zealand dietary pattern. As the bioavailability of a nutrient is also influenced by interactions with other nutrients and food components, processing and preparation of food, and host-related intestinal and systemic factors, consideration must be given to various characteristics of the food group intended to contain the added nutrient and the target and non-target populations.

12 NHMRC (2006) *Nutrient Reference Values for Australia and New Zealand Including Recommended Dietary Intakes*. <http://www.nhmrc.gov.au/guidelines/publications/n35-n36-n37>

13 Codex Alimentarius Commission (2011) *Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Foods for Special Dietary Uses*. In: Codex Alimentarius Commission Procedural Manual Ed. 20. Joint FAO/WHO Food Standards Programme, Rome. <http://www.codexalimentarius.org/procedures-strategies/procedural-manual/>



Microbiological agents

The severity of the adverse effect from microbiological hazards can be influenced by the strain and subtype, food production, processing and storage, and the food matrix in which the hazard is present. The food matrix is particularly relevant as it may influence the ability of the microorganism to survive the hostile environment of the stomach. Factors related to the host that need to be considered include underlying conditions that may predispose the host to infection, illness and immune status. A dose-response relationship may exist describing the relationship between the number of microorganisms ingested and the severity and/or frequency of the associated adverse health effects. However, issues such as strain variability and host susceptibility provide an increased level of uncertainty.

The infectious disease process following exposure to a microbiological hazard is multiphasic. Each organism ingested is assumed to have a distinct probability of surviving host barriers (such as the gastric acid of the stomach) to reach a target site for colonisation and cause illness i.e. non-threshold dose-response. Infection may be asymptomatic or, depending on a wide range of virulence and host factors, result in various adverse responses (acute, chronic or intermittent). Although most commonly associated with gastroenteritis, exposure to pathogens can result in long-term illness and, in some cases, death.

For a limited number of pathogenic microorganisms, dose-response data has been gathered from human-feeding studies. These studies usually involve exposing healthy adult volunteers to high numbers of microorganisms and measuring the response (infection and/or illness). Mathematical models are then fitted to the data to estimate the response at much lower doses. The use of adults for developing dose-response models leads to uncertainty about the suitability of the dose-response models for application to children or other population sub-groups. Alternatively, dose-response data may be based on epidemiological studies, in vitro studies or animal studies. Epidemiological studies have been used to determine adjustments in the dose-response models to account for population sub-groups.

5.2.3 Exposure assessment

FSANZ generally undertakes dietary exposure or nutrient intake¹⁴ assessments, though in some cases may consider other sources of exposure. An exposure assessment seeks to provide an estimate of the magnitude, frequency and duration of exposure to the hazard or, the magnitude of nutritional intake found in the diet.

14 For nutritional risk assessments the term *intake* is used instead of *exposure*, however for the purpose of this section the term exposure covers chemical, nutritional and microbiological dietary assessments.



Chemical exposure assessments (including nutrients)

FSANZ estimates dietary exposures using dietary modelling—a technique, supported by a customised computer program, to combine food consumption data with food chemical concentration data to estimate dietary exposure to food chemicals such as food additives, processing aids, contaminants, novel food ingredients, agricultural and veterinary chemical residues and nutrients.

FSANZ uses methods for calculating dietary exposure that are used internationally. A detailed description of FSANZ's dietary exposure assessment methodologies is provided in the *Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes*¹⁵.

Food consumption data for dietary modelling purposes is most commonly derived from the most recent Australian and New Zealand National Nutrition Surveys (NNSs). These surveys collected data on food and beverage consumption amounts using a 24 hour recall method over one or two non-consecutive days. From time to time, FSANZ may also commission consumption and consumer behaviour surveys to fill evidence gaps and to confirm behavioural assumptions. This is particularly important when new products have entered the market since the NNSs were carried out or where the NNS contains limited data for use in specific dietary exposure assessments.

Data on the concentration of chemicals and nutrients in food is derived from different sources depending on the purpose of the assessment and the nature of the chemical. Food additive, processing aid, novel food or other ingredient concentrations can be derived from manufacturers' actual or proposed use levels or analytical survey data. In the absence of other data, the maximum permitted levels specified in the Code might be used to estimate dietary exposure noting this would tend to overestimate the concentration in food because actual levels present in the food may be lower. For agricultural and veterinary chemical residues, maximum residue limits from the Code can also be used to estimate dietary exposure, or alternatively, data from agricultural trials of the chemical on crops or in animals or analytical surveys. Data on food contaminant concentrations can be sourced from monitoring surveys, including total diet studies. Data on the concentration of nutrients in food are available from Australian food composition databases compiled by FSANZ, New Zealand food composition databases, or directly from specific analytical surveys.

15 FSANZ (2009) *Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes*. http://www.foodstandards.gov.au/science/riskanalysis/exposure/documents/Principles%20_%20practices%20exposure%20assessment%202009.pdf



Food consumption and chemical and nutrient concentration datasets are often incomplete, variable in quality or inadequate for use in a dietary exposure assessment. When limitations are identified, assumptions about the data are made and additional information may be available to underpin these, all of which is documented in the risk assessment. The data may include market share data for foods, both across the food supply or in a specific food category. Information on food consumption, chemical concentration or market share data from other comparable countries can also be used where there may already be a permission for, or history of use of, a specific food, ingredient or chemical.

Nutrient concentration data should comprise both naturally occurring forms of the nutrient and that added as fortificants. In addition, nutrient concentrations of complementary medicines (as defined in Australia) and dietary supplements (as defined in New Zealand) may be needed in some situations to allow total nutrient intakes from food and these other sources to be calculated.

Bioconversion might be an important consideration in some cases. If bioconversion from another compound occurs, then both the form of the chemical present in the food and its precursor(s) need to be included in an exposure assessment. For example, a dietary exposure assessment of vitamin A would include beta-carotene and retinol. The form must also be taken into account for many non-nutrient chemicals, for example organic arsenic versus inorganic arsenic.

The nature of the food chemical and the hazard it poses will determine whether a chronic dietary exposure estimate is required (exposure over time) or an acute estimate (exposure over a meal or one day). Depending on the purpose of the assessment, dietary exposure to a chemical may be estimated for the whole population, for consumers of the food only, for high consumers and/or for specific population sub-groups.

When undertaking a dietary exposure assessment, FSANZ may use a tiered or stepped approach, particularly where data and resources are limited. Initial estimates of dietary exposure tend to be very conservative and serve to identify those cases that warrant a more detailed assessment. A more refined and accurate dietary exposure assessment, using more detailed consumption data, improved or more concentration data and more sophisticated dietary modelling techniques, is conducted where initial estimates indicate HBGVs may be exceeded. Generally, FSANZ uses a 'semi-probabilistic' dietary modelling approach which combines the detailed food consumption data from NNSs with single point chemical concentration data. A distribution of exposures for a population is derived and population statistics (mean and various percentiles of dietary exposure) are reported. Occasionally, where further refinement and characterisation of the dietary exposure assessment is required, and where suitable data is available, FSANZ may conduct a probabilistic dietary exposure assessment. Probabilistic modelling combines detailed food consumption data



from the NNSs with a range of chemical concentration data and derives a probability, or likelihood, of a level of exposure for a population sub-group.

When there are significant uncertainties in the data used in an assessment, FSANZ will apply conservative assumptions. When determining exceedances of the HBGVs, the use of conservative assumptions will help ensure that the dietary exposure is not under-estimated. Similarly, when determining whether the intake of nutrients is sufficient, as compared to the relevant NRV, the use of conservative assumptions will ensure that the dietary exposure is not over-overestimated.

The dietary model is often run multiple times. The first model describes the baseline situation. Subsequent models predict the dietary exposure in the population under other scenarios, as a result of possible changes to the Code. For food components such as nutrients that have beneficial as well as adverse effects, the focus of the iterative dietary exposure assessment might be on obtaining an acceptable level of intake by the target population while ensuring intake by the non-target population is not at excessive levels that have the potential to cause adverse effects.

Microbiological exposure assessments

An assessment of exposure to microbiological hazards takes into account the ability of a pathogen to grow, survive or be inactivated in the food. Various factors need to be considered including: data on the prevalence and level of hazard in the food, the amount and frequency of the food consumed, the population consuming the food, the characteristics of the hazard and the effect that food production, processing and handling has on the hazard (actual levels as well as the likelihood of the hazard being present). Food consumption data can be sourced from two areas: food production statistics and food consumption surveys like those discussed above.

Data on the prevalence and level of hazard in the food at various stages of the food supply chain also needs to be gathered. This may be problematic as there may be little or no data available. Sometimes unpublished information can be obtained from government laboratories, the food industry or other regulatory agencies. In some cases, it may be necessary to undertake microbiological surveys of food to obtain appropriate information. Data also needs to be gathered on the food, how it is produced and stored and how these factors may influence the level of hazard present in the food at the time of consumption.

FSANZ may develop predictive mathematical models to predict the growth, inactivation and survival of a microbiological hazard throughout the food chain, taking into account the impact that factors such as food processing and storage and the amount of food consumed have on the level of exposure. Different quantitative models may be developed depending on the amount of data and resources available. Deterministic models produce single



outputs from single sets of data, while stochastic, or probabilistic models, use frequency distributions to cover a range of possible values. Probabilistic models incorporate variability and uncertainty into model inputs and provide a range (distribution) of possible exposure levels. Probabilistic models therefore seek to better represent the variability and randomness of events observed in the natural environment, which can assist with identifying steps in the exposure pathway that have most influence on risk.

The type of model used will depend on many factors such as what information is needed to make a risk management decision, the availability and quality of relevant data and the urgency for requiring the risk assessment outputs (recognising that developing complex quantitative models often requires significant resources and time to complete).

5.2.4 Risk characterisation

Risk is a function of both the hazard and the level of exposure to that hazard. For this reason, both elements are equally important in determining the level of risk of an adverse effect in consumers. Risk characterisation—the last step in risk assessment—seeks to integrate information from the hazard and exposure assessments to generate a risk estimate. For chemicals and nutrients, this often involves comparing the dietary exposure estimates for different population groups with the HBGVs and, for nutrients, the NRVs, noting in some cases other sources of exposure may also be considered. For microorganisms, there are generally no set values; therefore, a range of methods including qualitative, semi-probabilistic and probabilistic modelling may be used to best describe the risk to consumers.

The risk characterisation may apply to the whole population or for a specific population sub-group, depending on the nature of the adverse health effect and the pattern of dietary exposure. Specific risk characterisation information for at risk groups e.g. infants, pregnant or lactating women, the elderly, immuno-compromised or individuals with special dietary needs, may need to be considered separately in the risk assessment.

The risk characterisation may be repeated numerous times for each of the different risk management scenarios that have been identified. These scenarios might relate to differences in the concentration of the hazard in the food.

Chemicals

Different approaches are used for risk characterisation of chemicals depending on the nature of the chemical and whether a toxicity exposure threshold can be identified from animal or human studies.

A threshold approach can generally be used in most cases where there is a non-cancer endpoint. Whether a threshold of toxicity can be identified or not, the ALARA principle should apply, whereby exposure to the chemical in question should be as low as reasonably achievable without withdrawing the food completely from the market.



When a threshold of toxicity is evident, the risk characterisation involves comparing the dietary exposure estimates for consumers at the mean and high levels of consumption to an appropriate HBGV. According to current generally accepted definitions for HBGVs (see Section 5.2.2), exposure below the HBGV is considered to be *without appreciable health risk* for a food additive, novel food ingredient or pesticide and veterinary drug residue and to be of low risk and *tolerable* for a food contaminant.

When a threshold of toxicity is not evident, risk characterisation may involve a margin-of-exposure (MOE) approach to provide an estimate of relative risk. The MOE approach compares the BMD [or the lowest-observed-adverse-effect level (LOAEL), if the BMD is not available] with estimated dietary exposure to the chemical. While a large MOE (e.g. >10,000) generally indicates a low risk, the MOE is not a quantification of risk, and needs to be accompanied by some narrative to describe the way in which it has been derived and the limitations of this approach.

Occasionally, estimated dietary exposures may exceed the HBGVs for food contaminants or older chemicals (food additives, pesticide and veterinary drug residues) that may have a long history of apparent safe use, but which were not assessed against current regulatory standards. In this scenario, a detailed case-by-case approach involving a re-examination of both the hazard and exposure assessments, together with any new scientific information, is needed.

A small or transient dietary exposure above a HBGV does not necessarily mean the exposed population is at significant additional health risk as a result of that exposure. However, if the risk characterisation indicates there is an exceedance of a HBGV that may pose a health risk, FSANZ will adopt a conservative approach to ensure the protection of public health and safety, reflecting FSANZ's low overall risk appetite. The approach may include regulatory or non-regulatory actions proportionate to the identified risk, to reduce dietary exposure to the substance.

Nutrients

Risk characterisation of nutrients must consider both food safety and health aspects for all population groups. Good quality evidence in humans is required to accurately characterise any risks and benefits to health of nutrients. Corroborating evidence from *in vitro* and animal studies of potential adverse effects (and to a lesser extent potential beneficial health effects) is also used to strengthen the evidence. Evidence of a plausible biological mechanism associated with consumption of the nutrient and the health effect is also considered in the totality of evidence.

Estimating the proportion of the population with nutrient intakes below the EAR, where it exists, can be used to estimate the proportion of the group whose usual intake is inadequate. Estimates of intakes that are above the UL, where it exists, or TDI, where it exists for minerals,



are used to assess the probability of excessive intakes and potential risk of adverse effects. For population nutrient intake assessments that indicate a small proportion of intakes below the EAR or above the UL, there is little likelihood of any adverse health effects.

The risk characterisation must also consider the variability in population food intakes and therefore nutrient intakes (also see Section 5.5). For example, the dietary intakes for one group in a population might be inadequate while at the same time, a substantial proportion of a different group in the same population might have intakes exceeding the UL. This could become problematic when considering possible food fortification options. If exceedance of the UL is likely, the extent and duration of the exceedance needs to be considered based on the proposed level of addition of the nutrient to various foods. Further assessment of the basis for the UL can also be undertaken to determine if the endpoint on which the UL is based is relevant for the population group with the high intakes and also to assess the nature of the risk associated with an exceedance of the UL. As with other chemicals and food contaminants, where an exceedance occurs, FSANZ will adopt a cautious approach that aims to protect public health and safety.

Microbiological agents

Risk characterisation of microbiological hazards integrates dose-response and exposure information to provide an estimate of illness and other adverse health effects that may occur in a given population (general or sub-population).

Risk estimates may be expressed either qualitatively i.e. in a descriptive manner such as a risk ranking or descriptive categorisation (high, medium or low) or quantitatively i.e. expressed mathematically. Mathematical expressions of risk may describe the likelihood of illness for an adult or a child from a single meal. It may also be expressed in terms of the probability of illness per 100,000 individuals or the predicted annual incidence of human illness in a total population.

Determining a risk estimate, whether it is qualitative or quantitative, depends on many factors including the initial scope of the problem as determined by risk managers, the selection (and rejection) of scientific and other data and the exposure pathways (i.e. a pathogen present in a raw product may be consumed in a number of different types of food). The risk estimate must be viewed with knowledge of all factors affecting the determination of the final result, the associated data sources and assumptions, and taking into account any uncertainties/limitations.

The microbiological risk characterisation also identifies factors in the food chain that reduce the risk to consumers. In the case of a quantitative risk assessment, the cost of introducing additional control measures can be readily assessed against the benefit of reductions in human illness. The best interventions, that minimise costs and maximise the benefit, can then be determined.



5.3 Special risk assessment cases

5.3.1 Bovine spongiform encephalopathy

The risk to human health associated with the prion responsible for bovine spongiform encephalopathy (BSE) has historically been difficult to assess due to the high level of uncertainty around many aspects of the disease and its science. When initially recognised as a potential foodborne disease, the nature of the BSE agent and its infectivity was to a large extent unknown. However, it is now clear that the BSE agent is only spread to cattle through the feeding of contaminated ruminant protein and does not naturally spread between cattle. The human form of the disease, variant Creutzfeldt-Jakob disease (vCJD) was acquired when people consumed BSE-contaminated meat products, and although rare has also been acquired through blood transfusion. Uncertainties that still exist in the understanding of these types of diseases include the mode of action of prions in causing BSE and vCJD in humans, the dose-response relationship, and the existence of a threshold dose level. There is now, however, better information on the characterisation of prions, the relative susceptibility of various species, the identity of those animal tissues containing the highest concentration of BSE and, therefore, a better understanding of the foods that potentially may pose a risk of containing BSE. There is now also solid evidence that controls, if implemented effectively across the cattle/beef supply chain, can be successful in eliminating BSE from animal herds and preventing contamination of food. Therefore, the approach is to assess the BSE risk status of a country by examining its through-chain controls for the production and processing of meat and meat products, as well as surveillance of cattle herds.

5.3.2 Allergenic foods

Food allergies are adverse reactions that involve the immune system of some individuals. A small number of foods are responsible for most food allergies in the population. Milk, egg, wheat, soy, peanut, tree nuts and fish are some of the allergenic foods widely consumed around the world. In allergic individuals, proteins in these foods trigger various symptoms ranging from mild to severe. Assessment of the risk associated with allergenic foods has unique features due to the nature of allergy itself, in that the risk from allergenic foods is specific to allergic individuals. Also, allergic individuals vary widely in their sensitivity in the amount of allergenic food that triggers an allergic reaction (allergen thresholds). However, clinical evidence on allergen thresholds is being developed internationally to support risk assessments in this area. This is particularly relevant to assessing the risk from ingredients and products derived from allergenic sources, and from the unintended presence of allergens in food products.



5.3.3 Special purpose foods

The ingredients of special purpose foods generally require premarket approval, as these foods are intended for vulnerable populations as a sole source of nutrition (e.g. infant formula products) or to supplement the normal diet (see Section 2.3.4). The safety and composition of these products is assessed with a particular focus on the target population and the intended special purpose of the food. Specific data relevant to the particular population group will be required, such as that described for nutrients above. In general, an even more cautious and conservative approach is taken in relation to the acceptable level of risk for foods in this category i.e. the level of uncertainty must be low (see Section 5.5) or the risk(s) capable of being easily managed (see Chapter 6). If the consumer of a special purpose food is well defined, and the products are unlikely to be consumed by a non-target audience, assessing risks in the non-target population group is likely to be less of a concern, than when nutrients are added to general purpose foods.

5.3.4 Other nutritive substances

Other nutritive substances that are not essential nutrients, such as some amino acids, might be added to food with the intention of achieving a beneficial health effect. Characterising risks associated with these substances will depend on whether the hazard assessment has found any beneficial or adverse effects and whether a HBGV can be established against which dietary intakes can be compared.

In cases where risks or threshold effects are found, then FSANZ may need to identify or establish a HBGV. Intakes can then be compared to the HBGV for beneficial or adverse effects, as described in Section 5.2.4. It may be necessary to conduct separate risk assessments for the target and non-target populations. When a HBGV cannot be established, an estimate of dietary intake may be provided for information purposes only.

The focus remains on assessing the likelihood of adverse effects occurring in the target and non-target populations and the likelihood of the beneficial health effects occurring in the target population at the estimated levels of consumption. This can be assessed empirically by pooling and analysing the results of various studies or by assessing the strength of the evidence to support the true existence of a beneficial health effect or the likelihood of a risk. As is the case for nutrients, good quality evidence from studies in humans as well as in vitro and animal studies is required to accurately characterise any risk and benefit to health of these nutritive substances.



5.3.5 New technologies

Food irradiation

Irradiation of foods produces some minor chemical and nutrient changes in foods depending on the dose used. Risk assessments of irradiated foods are undertaken on a case-by-case basis and include consideration of the following:

- the history of safe consumption of irradiated foods in other countries
- conclusions from previous assessments by expert committees, the WHO, other regulatory agencies and safety assessments conducted by FSANZ
- an assessment of the technological need to irradiate foods and data on the safety of irradiated foods that has become available since the previous assessments
- compositional (nutrient) data on irradiated foods compared to their non-irradiated counterparts and the level of consumption of those foods (and nutrients) in Australia and New Zealand.

Genetically modified foods

The safety assessment of genetically modified foods is based on the concept that their safety can be assessed, to a large extent, by comparison to the conventional counterpart having a history of safe use, and taking into account both intended and unintended changes. The objective is to identify new or altered hazards relative to the conventional counterpart. Any identified hazards then become the focus of further assessment. The objective of further assessment is to determine if there is any risk associated with any of the identified hazards under the intended conditions of use; and if any new conditions of use are needed to enable safe use of the food.

The safety assessment is characterised by:

1. case-by-case consideration of GM foods—this is necessary because the key issues requiring consideration will often depend on the type of food being evaluated and the nature of the genetic modification
2. consideration of both the intended and unintended effects of the genetic modification
3. comparisons with conventional foods having an acceptable standard of safety.

The goal of the safety assessment is not to establish the absolute safety of the GM food but rather to consider whether the GM food has all the benefits and risks normally associated with the conventional food.



The safety assessment relies on: (i) consideration of the molecular characterisation of the genetic modification; (ii) phenotypic characterisation of the new organism, compared with an appropriate comparator; (iii) assessment of novel substances, including proteins, that may be expressed in the food; and (iv) compositional analysis of the new food or the specific food product.

Nanotechnology

The use of technologies such as nanotechnology to produce nanoscale materials provides an opportunity for innovation in various areas of the food sector including production, processing, preservation and packaging. However, the use of nanoscale materials may also potentially lead to a new or increased risk in food.

FSANZ considers that its risk assessment framework is generally sufficient for assessing new or novel nanoscale materials. Assessment of the safety of a new material—nanoscale or non nanoscale—generally includes an evaluation of the toxicokinetics and metabolism of the substance as well as the toxicity of the substance as determined through studies in animals and, where available, humans. When ingested orally, soluble or biodegradable nano particles are understood to behave differently than those that are poorly soluble and non-biodegradable, especially those that remain particulate in nature in the final food. Therefore, pharmacokinetic studies following oral ingestion that allow the differentiation of solubilised material from particulate material will be particularly useful in conducting a health and safety assessment of nanoscale materials in food products or food contact materials.

5.4 Impacts on consumers' behaviour

The addition of some substances to foods may precipitate changes in consumers' behaviour with consequential health and safety risks. This may need to be considered as part of the risk assessment, whereby the risk characterisation is repeated for each possible risk management scenario.

The potential to precipitate changes in consumers' behaviour is usually related to functional and nutritive substances, where the new addition is signalled to consumers through labelling and product marketing. Changes in dietary behaviour may occur when consumers adopt new sources of the substance in place of traditional sources of the same substance, and in that change may lose other nutritional benefits from the traditional source. Changes in broader dietary and physical activity outcomes may occur through compensatory consumption behaviour based on beliefs about the new substances. These broader behavioural aspects are typically explored through surveys and experiments. The *FSANZ Application Handbook* also requests data and information on these types of behavioural impacts.



5.5 Variability and uncertainty in food risk assessments

Variability and uncertainty are inherent in the risk analysis process. Variability refers to the differences within a particular parameter (e.g. in concentrations of haemoglobin in people, in the concentration of a particular additive in different samples of the same type of food, or differences in infectivity and virulence between strains of microorganisms). Uncertainty is the lack of perfect knowledge (i.e. data) to define the true value of the parameter (e.g. determination of the absolute NOAEL for a chemical). Variability cannot be reduced but can be better understood and described. In contrast, uncertainty can be reduced (though never completely eliminated) through additional and more accurate data. Risk assessors implicitly deal with variability and uncertainty as part of their scientific decision-making. While it is unnecessary and impractical to document every single aspect of variability and source of uncertainty in a risk assessment, it is important to consider both in the context of the impact on the overall risk characterisation.

Variability

Some examples of how variability is dealt with include: parameter measurements (e.g. toxicology endpoints, food chemical concentrations) which are described statistically with an indication of variability (standard deviations or error); chemical assays including limits of detection and quantification; in setting HBGVs, 10-fold inter and 10-fold intra-species safety factors are typically applied to the NOAEL to account for inter and intra-species variation and dietary intakes are determined for different population groups to take into account variability in the total human population. For microbiological hazards, an additional source of variability is the effect of the food vehicle and its environment on the rate of growth of the microorganism, which can be incorporated into the models underpinning quantitative risk assessments.

Uncertainty

Uncertainty is commonly dealt with in a risk assessment by making conservative assumptions in both the hazard and exposure assessments. Such a conservative approach is commensurate with our low overall risk appetite. For example, there may be insufficient data to confirm the relevance to humans of an adverse effect observed in laboratory animals. Consideration would therefore need to be given as to whether it is appropriate to derive a HBGV from such data. Under this scenario, a conservative assumption would be that the adverse effect is relevant to humans. In an exposure assessment, the assumption might be that the substance of interest, say a proposed new food additive such as a high intensity sweetener, will replace *all* existing sweeteners. In the absence of other information, such an assumption will result in a conservative risk estimate.



It is important that the level and nature of uncertainty, and any conservative assumptions that may have been applied, are articulated in the risk assessment. The uncertainty needs to be understood by the risk manager and be fully considered in risk management decisions. Typically, the uncertainty is documented in risk assessments by including descriptive text. However, not all potential sources of uncertainty (or data gaps) will have a large impact on risk estimates and an assessment of the relative importance is also included. A quantitative approach may be possible in some cases.

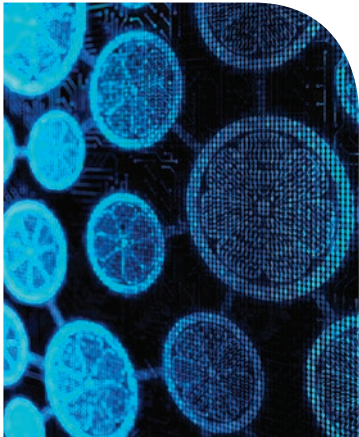
5.6 Risk assessment outputs

It is important that the outputs of the risk assessment provide information in a way that facilitates risk management decision-making. For chemicals and nutrients, where it is possible to compare dietary exposure estimates (typically derived using a semi-probabilistic modelling approach) with HBGVs, outputs will generally be quantitative. For microorganisms, where there are generally no set values and often only limited data available, outputs are more likely to be qualitative.

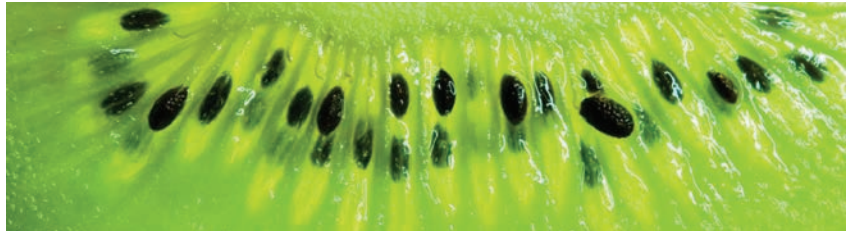
Irrespective of the format in which the risk assessment outputs are presented, the results of the risk assessment are one of a number of considerations informing risk management, others being public health policy guidance, consumer behaviours and economic and regulatory inputs. Risk assessment outputs therefore need to be considered and interpreted within the context of other available information.

While the separation of risk assessment and risk management is an important principle in risk analysis, in reality the risk analysis process is iterative and cooperative. At FSANZ, risk assessors and risk managers work together to develop risk management goals and objectives and the options to achieve these goals and to formulate the risk assessment questions (see Section 6.2.1). By working this way, risk managers are aware and understand the limitations of the risk assessment and how to interpret the risk assessment outcomes.

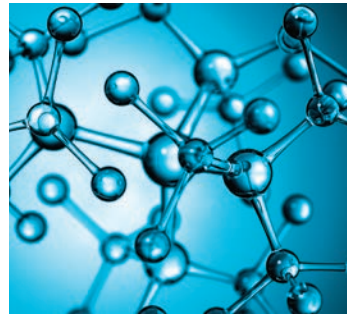




Managing food-related health risks



6



6 Managing food-related health risks

6.1 General approach to risk management

Codex defines risk management as the process of weighing policy alternatives in consultation with interested parties, considering risk assessment and other factors for the health protection of consumers and the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options (see Section 4.2).

Risk management in FSANZ is broadly consistent with Codex, FAO/WHO and other food regulatory agencies. It 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. This process may also evaluate the implemented decision.

Risk management begins before risk assessment, runs concurrently with it and continues beyond it. Risk managers work in a team along with others with expertise in risk assessment, risk communication, food technology, public health nutrition, economics, behavioural and social science, food labelling and food regulation.

Risk communication is initiated early as ongoing communication with all interested and affected parties is an important part of the process. Risk communication specialists work with the team to develop a communication plan. The plan aims to identify communication objectives, key messages, key audiences, and any information materials that may need to be developed. Risk communication is addressed in further detail in Chapter 7.



6.2 FSANZ's risk management process

FSANZ's risk management process is guided by a risk management framework comprising four overarching components. These are: preliminary risk management activities; formulating risk management options and selecting preferred option(s); implementing risk management decisions; and monitoring and evaluation (see Figure 4 below).

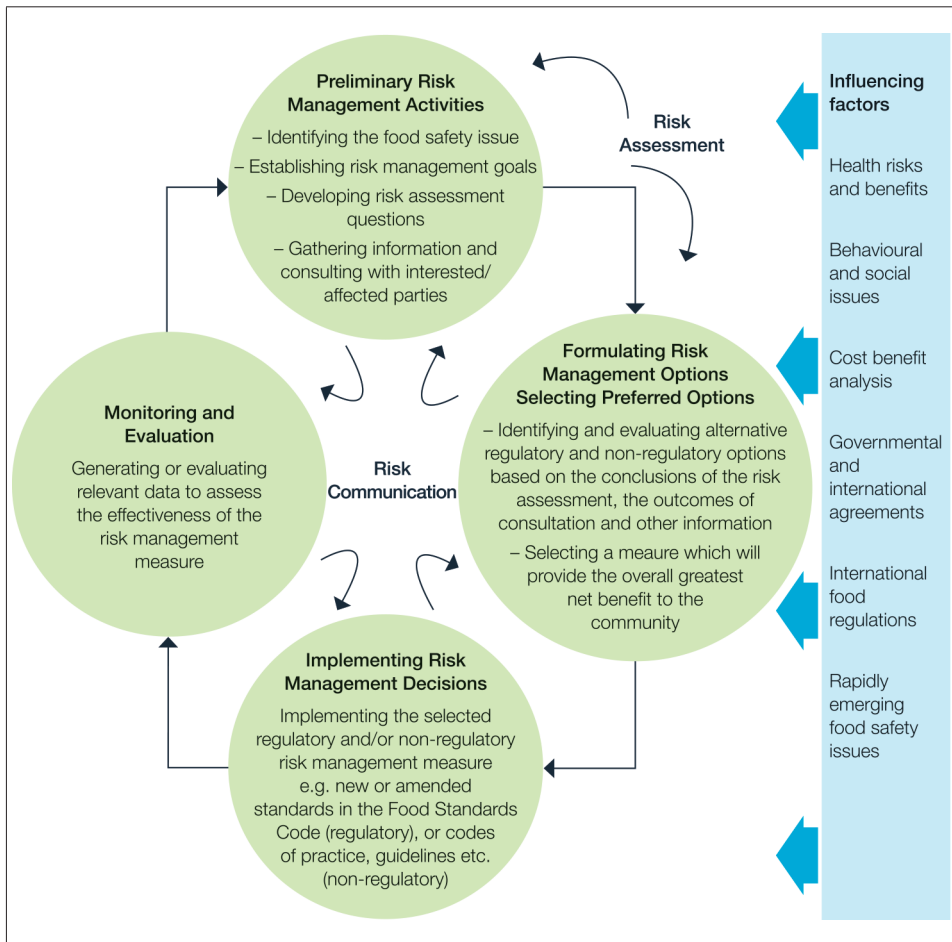
Sitting under each of these components are a number of inter-related and overlapping activities including:

- identifying the food safety issue
- determining whether a risk assessment is required; what that assessment should examine and the questions that need to be answered by the assessment
- gathering information and identifying the issues
- consulting with stakeholders
- determining, analysing and evaluating options to manage/reduce the assessed risks
- selecting and implementing the option of greatest net benefit to the community (a Regulation Impact Statement can inform this process, see Section 6.3.3)
- monitoring and evaluating the outcome, as appropriate.

The risk management framework illustrates how outcomes of preliminary risk management activities inform the need for, level and scope of a risk assessment and how the risk assessment outputs affect the development and selection of appropriate risk management options. Key factors that could influence risk management option selection are listed and these are discussed further in Section 6.3. It is important to measure the effectiveness of the selected risk management strategy through monitoring and evaluation. Efforts will be tailored according to the agency's needs and resources available. In addition, monitoring and evaluation can lead to identification of further food-related health and safety issues that need to be managed.



Figure 4. Framework depicting the key components of FSANZ's risk management process



6.2.1 Preliminary risk management activities

Identifying the food health and safety issue

Risk managers must first identify the food health and safety issue. They do this by undertaking an initial scoping exercise and situation analysis. Establishing ongoing dialogue between risk managers, risk assessors and others on the team is critical to this process. A preliminary scan of available information helps to describe the current situation and issues, clarify what will be included and excluded from consideration and identify key stakeholders.



Preliminary information may also provide some insight into the likelihood of an adverse health effect and the consequences of such an event, and thus allow the prioritisation of the food safety issue. It can also help in determining the availability of resources to address the issue.

The scoping step will also help determine what information and resources are required to identify and characterise any risk and to undertake further risk management activities. This, in turn, will help determine whether a risk assessment is required or feasible; and, if one is required, the scope and level of detail necessary. Similar steps are undertaken to determine the level of health benefit assessment, where this applies.

A scoping exercise can result in a determination that the health risk is insignificant or appropriate measures are already in place. In this case, no further action is required.

Establishing risk management goals and planning how to achieve them

Once information is gathered and the regulatory problem is clearly identified and described, risk management goals are determined.

These goals will reflect FSANZ's key objective in setting standards, which relates to protecting public health and safety (see Section 18 of the FSANZ Act), as well as specific objectives to manage the particular problem and food-related health risk.

Options for achieving these goals may include developing new standards or amending existing standards in the Code to reduce risk to a level acceptable to the community. However, some food safety issues may be addressed with non-regulatory interventions.

Developing risk assessment questions

If a risk assessment is required, the risk manager should be able to clearly explain why it is required and its scope. During ongoing discussions, risk assessment questions should be developed according to case requirements in consultation with risk assessors and other technical experts on the team. Discussions throughout the risk assessment process will give risk managers a good understanding of any limitations or uncertainties that might arise from the risk assessment. This means risk managers have all the relevant information they need to interpret risk assessment outcomes in the context of other relevant information.

Gathering information and consulting with stakeholders

How much information risk managers require varies from case to case. Information may come from a range of sources; in addition to scientific risk assessments, it may be in the form of food policy guidance, behavioural and social science research, economic and regulatory analysis, international regulations and public consultations. Targeted consultations with key stakeholders may also be needed to help gather specific information and clarify issues.



Sometimes, expert groups may need to be established to provide expert advice. In other cases, targeted analytical surveys of certain foods (which may inform a subsequent risk assessment) may be required. Research may also need to be conducted on food products and food labels and peer reviewers or consultants may be engaged to provide information or expert opinions.

Key issues that may emerge as a result of information gathering include: possible effects on the food industry, government agencies, health professionals and consumers and consumer choice; whether the benefits of any regulation outweigh the costs to the community; and whether regulations are achievable and enforceable and prevent or create barriers to trade.

Preliminary risk management activities are iterative. As more information becomes available and new issues are identified, further assessment or consultation may be needed.

6.2.2 Formulating risk management options and selecting preferred options

The second part of the risk management process involves formulating risk management options, evaluating them and then selecting the preferred option(s). Risk assessment outcomes and information gathered in the preliminary stages of the risk management are used to do this.

A range of options can be developed, including regulatory or non-regulatory measures or a combination of both. The status quo is also an option.

In developing options, risk managers must consider the context of the problem. For example:

- Does the risk need to be dealt with urgently?
- Is it likely to be widespread in nature and involve a range of foods?
- Will it affect specific vulnerable population groups, e.g. infants and young children?
- What is the nature of the risk (e.g. risk of adverse effects)?
- What is the likelihood and severity of the risk (e.g. low chance/probability and low severity vs. high chance/probability and high severity)?
- What is the nature of any uncertainty associated with the risk assessment?

In developing options, FSANZ must also evaluate and compare the effects, costs and potential net benefits of the alternative options for the key stakeholder groups. These groups could include (among others) consumers (including any specific groups such as pregnant women, infants or young children), the food industry, government enforcement agencies, health professionals, health educators, retailers and patient support groups. The impacts of different options could be intended or unintended and not only relate to health and safety



of consumers. They could also be legal, environmental, regulatory, economic, behavioural or social in nature. Depending on the availability of appropriate information, this analysis may involve comparing the weight or priority of different issues that different stakeholders consider most important. Using this approach, it is possible to determine the net benefit to the community. Other factors that could affect which risk management option is selected are discussed in Section 6.3.

A range of factors influence whether the appropriate risk management strategy is a regulatory or non-regulatory measure, including the nature of any adverse health effect, the likelihood of it occurring and the number of individuals potentially affected. Other factors include the anticipated effectiveness of the proposed risk management strategy and the costs and benefits of the different options to key stakeholder groups. For regulatory measures, consideration must also be given to the practicalities of implementation, measurement and enforcement.

Like many of the aspects of risk analysis, the process of developing and evaluating risk management options is iterative. Elements of risk assessment such as exposure assessments and risk characterisation may be run simultaneously for a number of different scenarios that might occur as a consequence of each of the proposed risk management strategies. The results of these are used to further refine and inform the development of options.

For larger or more complicated issues, FSANZ may establish specialist committees to provide advice on risk management options, e.g. the Standards Development Committee (SDC) for primary production and processing standards. Members of such committees may include representatives from key stakeholder groups including industry, Australian jurisdictions and the New Zealand government, consumers, academia and independent experts.

A final decision on what option(s) to use is reached after analysing and comparing each option against criteria linked to risk management goals, the risk assessment conclusions and effects on key stakeholders. Data gaps can restrain options. Ultimately, the preferred option should deliver the greatest net benefit to the community.

Performance indicators may need to be established that are specific, measurable, attainable and relevant. Early consideration of performance indicators makes evaluating the effectiveness/outcome of the chosen control measure easier.

The risk management options available to FSANZ are described in further detail in Section 6.4.

6.2.3 Implementing risk management decisions

FSANZ is required to consider both regulatory and non-regulatory approaches to risk management. Regulatory measures involve amending existing standards or incorporating new standards into the Code. Non-regulatory measures might involve developing industry codes of practice and guidelines.



A combination of regulatory and non-regulatory measures may be implemented, particularly when all parts of the food supply chain i.e. paddock to plate are involved. In such cases, industry, individual food businesses and independent third parties (that assess and audit risk management activities) may all have a shared responsibility for implementation.

For regulatory measures, a draft standard (or amendment to an existing standard) is prepared for incorporation into the Code. This part of the process is a legal responsibility undertaken by FSANZ's Office of Legal Counsel, in response to drafting instructions provided by the risk management team. The draft standard must be approved by the FSANZ Board, which is responsible for the final risk management decision(s). The decision must then be presented to the Forum before it can be gazetted and become law. If the Forum requests a review of FSANZ's decision, then FSANZ has three months to re-affirm, amend or withdraw its approval of the draft standard. A longer review period may be granted for complex issues.

Once a standard or variation to a standard is gazetted, it is adopted by reference into the laws of the Australian states and territories, and into the *Imported Food Control Act 1992*. In New Zealand, a food standard reflecting the changes is issued and gazetted in that country. The Forum has general oversight of the implementation of regulatory measures. Enforcement of regulatory measures is the responsibility of state/territory departments and food agencies in Australia and the New Zealand MPI.

Risk managers, in consultation with jurisdictions, will also consider the need for other strategies to support the implementation of the regulatory measure e.g. transition periods, user guidelines, and communication strategies such as developing explanatory information on the FSANZ website.

Non-regulatory risk management measures should be considered, generally when the health risk is lower such that the development of a regulatory measure is not warranted. Non-regulatory measures include industry codes of practice, guidelines, education/advice, and standards developed by other recognised bodies e.g. Standards Australia. These may also be referred to by various other terms.

FSANZ may develop such non-regulatory measures or provide advice to other organisations in their development.



Non-regulatory measures may be implemented singly or in combination with other non-regulatory measures or, indeed, regulatory measures, as part of an overarching risk management strategy. Non-regulatory measures may still need to be considered by the FSANZ Board as meeting a specific purpose, such as protecting public health and safety. If the measures are directly linked to the implementation of a new food standard or the amendment of an existing food standard (such as an ML or a labelling requirement), then they are also considered by the Forum before they are approved into food law.

As an example, consumer guidance is in place to assist certain population sub-groups to avoid or limit exposure to mercury in fish. This guidance was developed in liaison with state/territory and New Zealand regulatory partners and approved by the FSANZ Board so that the key messages on both the risk and benefits of fish consumption were available to consumers before final implementation of the guideline.

6.2.4 Monitoring and evaluation

Monitoring and evaluation is important to assess whether a measure is effective. FSANZ directs its efforts in this regard when a need has been identified and according to available resources. For example, a structured, formal evaluation program may be required to monitor the beneficial health effects on a population group over time following a decision to fortify the food supply. In other cases, a periodic review of data as and when it becomes available through regular surveillance activities may be sufficient to assess the ongoing effectiveness of a regulatory measure.

Monitoring and evaluation involves generating, gathering and evaluating relevant data (such as chemical concentration or food consumption data) and using this information to assess the effectiveness of the control measures. Data gathering should be considered at the beginning of the risk analysis process and repeated throughout because it can identify further risks that need to be managed. It can also lead to the revision of risk assessments or provide data that reduces the level of uncertainty in the risk analysis. Data and information obtained through monitoring and evaluation can also be used to inform subsequent risk management decisions. The monitoring and evaluation activities undertaken by FSANZ and other agencies involved in maintaining a safe food supply in Australia and New Zealand are described in Section 6.5.



6.3 Factors influencing risk management decisions

As outlined in Section 6.2.2, FSANZ must take into account a number of different factors that could affect which risk management option(s) are selected. These factors are discussed in detail below.

6.3.1 Health and safety issues – risks and benefits

The primary objective of FSANZ in developing or amending a food standard is the protection of public health and safety. This is generally interpreted as maintaining a safe food supply from which consumers can choose a diet according to their individual needs and preferences.

Risk assessment conclusions should identify and quantify any adverse health effects associated with consuming the food relevant to the general population, sub-groups or individuals. Additionally, and particularly for certain nutritive substances, the possibility that the proposed change could lead to consequential behavioural changes among consumers will be addressed in the risk assessment (see Chapter 5). In some cases, it may be appropriate to identify and quantify beneficial health effects.

Every assessment is different and so risk management strategies will vary. For example, when considering mercury in fish, the benefits of consuming fish as part of a healthy diet, as recommended in Australian and New Zealand dietary guidelines, must be considered alongside the risks associated with potentially higher mercury intakes from consuming certain types of fish.

Similarly, it is possible that a particular intervention may bring about beneficial health effects in one population sub-group, but may introduce new risks in a different population sub-group. For example, fortification of certain foods may assist some consumers in reaching an adequate intake of a nutrient, while others could exceed the UL for this nutrient. In the case of a nutritionally poor diet however, the benefit (or risk reduction, in this case) of increasing the dietary intake of a nutrient can be measured in relation to the EARs for each population sub-group, where these have been estimated.

6.3.2 Behavioural and social issues

In some situations, successful risk management strategies are dependent on certain groups adopting responsive behaviours. Different options can result in or impose behaviour change in some individuals, groups or institutions. For example, the mandatory fortification of bread-making flour required the food industry to adopt new manufacturing practices. The use of mandatory declarations on food labels of known allergens in foods allows allergic individuals to avoid certain foods. Food labelling is a risk management strategy used to help consumers understand the risks (and benefits) associated with the food they consume. For labelling to be effective, it must be noticed, understood, and used to make food consumption choices.



Risk managers may draw on existing knowledge about likely behaviour and responses to proposed risk management options, with particular reference to international experiences. In some cases, information may not exist and could be collected as part of stakeholder consultation processes or through surveys or research.

Risk managers may also draw on broader social research and understanding to develop appropriate risk management options. This is particularly the case in applying new and novel technologies to food e.g. irradiation and nanotechnology. In these cases, understanding the community's level of acceptance, concerns and perceived risks may help to identify issues that need to be addressed in risk assessment, and to decide how best to engage and communicate with the community. FSANZ typically draws on existing published literature, although additional empirical research is sometimes undertaken.

6.3.3 Regulatory analysis

The costs and benefits of alternative risk management options can be a significant factor in deciding a management strategy.

FSANZ follows COAG¹⁶ best practice regulation principles and guidelines to ensure that (where possible) the costs and benefits and net effect of the various options identified as part of the proposals and applications process are provided to decision makers. For some regulatory proposals and applications, this may involve preparing a Regulation Impact Statement (RIS). A regulation impact statement comprises seven elements:

1. statement of problem
2. objectives
3. statement of options
4. impact analysis (costs and benefits)
5. consultation
6. evaluation and conclusion
7. implementation and review.

¹⁶ The Council of Australian Governments (COAG) is the peak intergovernmental forum in Australia. COAG members include the Prime Minister and state and territory premiers and chief ministers.



The objective of a RIS is to assure that from the set of possible non-regulatory and regulatory options, the option with the greatest net benefit to the community is identified for decision makers. The RIS considers all possible options, including the status quo, non-regulatory or self-regulatory options. FSANZ works with the Office of Best Practice Regulation (OBPR), which is the Australian Government's independent body for promoting and monitoring effectiveness and efficiency of regulation, to ensure the RIS is in accordance with COAG best practice regulation principles and guidelines.

Typically, a RIS is required for proposals and applications where the impact is not minor or machinery in nature. At the initial scoping stage of the risk analysis process, a preliminary assessment report is submitted to the OBPR to allow them to determine whether a RIS is required. FSANZ must always seek an OBPR opinion on whether a RIS is required unless the OBPR has provided written advice that a class or type of application is exempt from RIS requirements. Such exemptions are only provided for changes that are deregulatory in nature and almost certainly will be to the benefit of industry and the wider community.

A written protocol exists between the OBPR and New Zealand Treasury to deal with issues that have a trans-Tasman impact. This process, set out in the protocol, provides that draft RISs are sent by ministerial councils and national standard-setting bodies to the OBPR for advice prior to the RIS being made available for public comment. Where a trans-Tasman issue is involved, the OBPR will refer the draft consultation RIS to the New Zealand Treasury for comment. Similarly, the OBPR will forward the decision-making RIS to the New Zealand Treasury for comment. The aim is to ensure that potential impacts to New Zealand are adequately identified and analysed.

A RIS is required to set out the costs and benefits for industry, consumers and government with the aim of being as holistic as possible. The OBPR encourages evidence to be presented quantitatively where possible but the RIS may also include qualitative evidence. Information required for a RIS may include the cost of outbreaks of illness, affected sub-groups, the costs associated with the possible range of risk management options and affected parties. Information is gathered from a range of sources, such as internal research, consultation, stakeholder feedback, commissioned consultants, academics and national and international statistical agencies, regulators and industry organisations.

FSANZ applies economic tools including cost effective and cost benefit analyses to inform the RIS and often draws upon methodology from health and agricultural economics and anticipates that techniques from the field of behavioural economics may become increasingly important in the future. When a RIS is required, it must be approved as compliant with the COAG Guidelines before its release by the OBPR.



6.3.4 Governmental and international agreements and international food regulations

Australia and New Zealand are members of the World Trade Organization (WTO) and are subject to the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS agreement) and the Agreement on Technical Barriers to Trade (TBT agreement).

The SPS agreement is primarily intended to protect human health and animal/plant life from risks arising from the spread of diseases or pests, or from additives, contaminants or toxins in food/feed. The agreement requires that food regulatory measures adopted by member countries are justified on the basis of a robust risk assessment. These risk assessments should be based on sound scientific principles and take into account the methodologies used by relevant international organisations. Regulatory measures which could be influenced by the SPS agreement include MLs for chemical or microbiological contaminants; requirements for warning and advisory statements on labels; and compositional requirements for standardised foods.

The TBT agreement acts as an important instrument to ensure that technical regulations, standards and conformity assessment procedures do not create unnecessary obstacles to trade. Compliance with technical regulations is mandatory. Under the TBT agreement, technical regulations may be developed for one or more objectives of the agreement, one of them being the protection of human health or safety. Regulatory measures that could be influenced by the TBT agreement include packaging and marking and labelling requirements.

In developing food regulatory measures, FSANZ must have regard to the promotion of consistency between domestic and international food standards. In terms of food safety, the relevant international standard setting body is the Codex Alimentarius Commission. Standards set by Codex provide a benchmark against which national food measures and regulations can be assessed. FSANZ contributes to the work of a number of Codex committees.

In certain situations however, FSANZ might receive an application to amend the Code (e.g. an application seeking permission to use a new food additive) before an international standard exists. There are also situations where domestic food standards will necessarily vary from international standards. This could include circumstances where:

- (i) new data for the domestic situation that was not available at the time the international standard was set becomes available for assessment
- (ii) the domestic environment (climate and growing conditions) results in different levels of risk from contaminants, natural toxicants or nutrient levels in foods
- (iii) domestic consumption patterns result in different dietary exposures
- (iv) particular manufacturing and production processes have been adapted to meet specific domestic requirements.



In terms of Australian government agreements, under the Inter-Governmental Agreement established by COAG, FSANZ has to apply minimum effective regulation in providing a safe and healthy food supply.

FSANZ must also have regard to the *Trans-Tasman Mutual Recognition Act 1997*, which gives effect to mutual recognition principles whereby goods that can legally be sold in Australia can also be sold in New Zealand, and vice versa (with some exceptions); any relevant New Zealand standards and bi-national policy guidelines established by the Forum.

6.3.5 Rapidly emerging food incidents

In the case of food emergencies, a rapid response, including consideration of risk management strategies, may be required. Often there is limited information and time to undertake a risk assessment in any detail. The decision on risk management options needs to be made in close consultation with enforcement agencies, industry and other food regulators. In some cases, in Australia, the National Food Incident Response Protocol will be activated and decisions on risk management options will be made under this arrangement. As outlined in Section 4.3.8, the protocol provides a framework for coordinating timely and appropriate action in Australia, in response to a national food incident at the national, state and territory and local level.

6.4 Options for managing food-related health risks

When the risk assessment and other information gathered indicates the existing level of protection is not acceptable, a range of risk management options is available to achieve what is known as an 'appropriate level of protection' or 'ALOP'¹⁷. This concept is sometimes also referred to as the 'acceptable level of risk'.

The acceptable level of risk could change over time with technological advances in areas such as analytical testing, which enables detection of a substance in food at lower and lower levels. Alternatively, public attitudes to the food risk may influence food policy.

6.4.1 Regulatory measures

Standards in the Code can be divided into end-product standards and outcome-based standards. Both aim to manage a food-related health risk to achieve an acceptable level of health protection.

¹⁷ WTO Sanitary and Phytosanitary (SPS) Agreement defines ALOP as 'the level of protection deemed appropriate by the Member establishing a SPS measure to protect human, animal or plant life or health within its territory'.



End-product standards

End-product standards apply to the final food product. For example, Standard 1.3.1 – Food Additives, lists permissions for using additives and the levels at which they may be present in the final food. In general, the outcomes of these standards can be readily measured and assessed against the requirements of that standard.

Pre-market assessment of certain foods and food ingredients

To manage any potential risks, a pre-market assessment is required for food additives, processing aids, nutritive substances, genetically modified (GM) foods, novel foods, and irradiated foods. Food substances such as these, which involve the use of nanotechnology, will also require pre-market approval if potentially unsafe. For risk managers, the outputs of this pre-market assessment are a key factor in determining a risk management strategy which ensures the safe use of these food substances.

Food additives and processing aids

As outlined in Section 6.3.4, risk managers must also have regard to relevant overarching food policy guidelines in formulating and selecting from alternative risk management options. When permitting the use of certain food additives and processing aids, FSANZ must have regard to the policy guideline, *Addition to Food of Substances other than Vitamins and Minerals*¹⁸, specifically the policy principle for technological function. An important policy principle that needs to be addressed relates to assessing that the substance meets the proposed technological function (i.e. the 'stated purpose') when it is added to food.

Food additives are intentionally added to a food to achieve specific technological function(s). Depending on the outcomes of the risk assessment, permissions for food additives can be broad or restricted to certain food categories only. Maximum permitted levels may also be set. In general, food additives must be identified on the label when present in foods by listing the specific food additive name or a number determined by Codex in the ingredient list, as well as the function(s) of the food additive.

Processing aids are necessary in the manufacture of certain foods although they are not always present in the final food product. Like food additives, permission to use a processing aid can be general, or restricted to specific foods. Processing aids used in food manufacture are not required to be identified on the label of the food unless they contain nominated allergens.

18 Legislative and Governance Forum on Food Regulation (2008) *Policy Guideline: Addition to Food of Substances other than Vitamins and Minerals*. <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>



Novel foods and nutritive substances

When assessing novel foods and nutritive substances, FSANZ considers the risk assessment outcomes as well as the principles outlined in the policy guideline *Addition to Food of Substances other than Vitamins and Minerals*, in this case principles relating to 'for any other purpose'. Other relevant policy guidelines for nutritive substances include *Fortification of Food with Vitamins and Minerals*¹⁹.

The pre-market assessment for novel foods can result in certain specified conditions of use being listed in the Code e.g. the use of a particular name, certain labelling requirements, restrictions to particular food types, or use in defined quantities in a food. Labelling requirements for novel foods are considered when permissions for novel foods are assessed.

Nutritive substances are substances which are intentionally added to food to achieve a nutritional purpose. Nutritive substance permissions are restricted to specific foods and the level of use is related to a percentage of the Recommended Dietary Intake (RDI) or other relevant HBGV, where these exist. Additional labelling requirements may also be established.

Genetically modified foods

Genetically modified foods, or foods produced using gene technology as defined in the Code, are not permitted in the food supply unless they have been approved following a pre-market safety assessment. In the early 1990s, it was recognised that it would not be appropriate to apply traditional risk assessment methods, typically used for single chemical substances, to assessing whole foods. The principles on which GM food safety assessments are based were therefore developed at the international level following broad scientific discourse on how to assess the safety of whole foods which lack a history of safe use. Approved GM foods are subject to mandatory labelling requirements set out in the Code.

Irradiated foods

Foods that are permitted to be irradiated are listed in the Code. Regulatory measures include specifying minimum and maximum radiation levels, the conditions under which irradiation may be used, and labelling requirements.

19 Legislative and Governance Forum on Food Regulation (2009) *Fortification of Food with Vitamins and Minerals*. <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>



Contaminants and natural toxicants

Any risk associated with the presence of a chemical contaminant or a natural toxicant in food may be managed by establishing an ML for the substance, as an outcome of the risk assessment. This may form part of a wider risk management strategy also involving additional labelling requirements. For example, for a chemical contaminant, an ML is established only when it serves an effective risk management function and only for those foods which provide a significant contribution to the total dietary exposure. When established, MLs for chemical contaminants have been set at levels which are reasonably achievable from sound production and natural resource management practices. The Code includes MLs for several food contact materials that can migrate from packaging. This provides FSANZ with the mechanism to regulate chemicals that migrate from packaging that may pose a risk to human health and safety.

In general, the ALARA principle applies for chemical contaminants in food, and there are many controls other than food regulations to minimise their presence. The ALARA principle is particularly important for contaminants, where there is often a so-called 'irreducible level' for the chemical contaminant in the food, below which a reduction cannot be achieved in practice.

Natural toxicants can be found in some basic foods, such as edible oils, cereals, honey, and lupin products.

Agricultural and veterinary chemicals in Australia

The safe use of agricultural and veterinary chemicals in Australia is managed by the Australian Pesticides and Veterinary Medicines Authority (APVMA). The APVMA determines maximum residue levels (MRLs) for each chemical in association with a crop or veterinary use, to ensure that the chemical is used appropriately for the agricultural conditions [Good Agricultural Practice (GAP)] and treatment of animals. The APVMA then assesses, and FSANZ confirms, that any residue of the chemical or nominated metabolites in foods as a result of its use on a crop or in food-producing animals, does not pose a safety concern. MRLs are subsequently listed in the Code and apply in Australia only. Limits for agricultural and veterinary chemical residues in New Zealand are set by the New Zealand MPI.

MRLs may also be included in the Code to facilitate trade, provided that a risk assessment determines the residues do not pose any public health concerns.



Microorganisms

To manage risks related to foodborne microorganisms, microbiological criteria are included in the Code for some foods or classes of food. Limits may be for general hygiene indicators (such as standard plate count and coliforms) or for pathogenic microorganisms (such as *Salmonella* and *Listeria*). Information is also provided on mandatory sampling plans and methods of analysis.

Plants and fungi

There are a large number of plants and fungi which are unsuitable for use in food because of their intrinsic toxicity. To manage risks, the Code prohibits these from being intentionally added to food or offered for sale as food, or otherwise places restrictions on their use.

Food labelling

Food labelling is an important risk management strategy to address potential food-related health risks. Labelling is different from other control measures as it places responsibility on the consumer to heed the label information. When used as a risk management strategy, labelling needs to be recognised and comprehended by targeted population sub-groups to elicit the right choices. The levels of existing knowledge, accessibility, motivation to use labels, literacy and numeracy may need to be considered in the context of labelling for effective risk management. Drawing on existing research or doing new studies can assist in testing the effectiveness of labelling as a risk management strategy. In some cases, information in addition to that on the label can be provided by other means (e.g. education initiatives targeted to specific audiences).

Labelling that addresses potential risks to health and safety includes mandatory warning and advisory statements. Warning statements, which require a prescribed labelling statement, are reserved for well-characterised, potentially life-threatening risks when the target population is likely to be unaware of the potential risk. For example, in the Code, a prescribed statement is required on royal jelly products or foods containing royal jelly: 'This product contains royal jelly which has been reported to cause severe allergic reactions and in rare cases, fatalities, especially in asthma and allergy sufferers'.

Mandatory advisory statements (statements of an advisory nature where specific wording is not prescribed) are used to advise the general or target population of a potential risk associated with a food e.g. a statement to the effect that the food is not suitable for children, pregnant or lactating women, and individuals sensitive to caffeine, on formulated caffeinated beverages.

Mandatory allergen declarations are important for addressing a potentially significant health risk for food-allergic individuals, as these declarations alert them to the presence of an allergen in a food. The allergens that are required to be declared on food labels are listed in the Code.



Other labelling requirements that can also assist in addressing health and safety risks include directions for preparing, storing or using food and date marking of food. Advice about levels of intake is required on food labels when excessive consumption of certain substances permitted to be added to the food could present a health risk (e.g. formulated caffeinated beverages).

For some food labelling, the emphasis is to provide information to allow consumers to make informed food choices and to help reduce the risk of misleading and deceptive information on food labels. An example of this is country of origin labelling. This form of labelling provides information to consumers on the country where the food was produced, made or packaged, which enables them to make an informed choice. Nutrition content claims and health claims are another form of food labelling that can provide information for consumers about food products; regulating their use also reduces the risk of misleading and deceptive claims on food labels. These forms of labelling relate more to the second and third objectives of our Act in relation to developing or amending food standards.

Outcome-based standards

Outcome-based standards are more general in relation to the appropriate level of health protection. For example, Chapter Three – Food Safety Standards, and Chapter Four – Primary Production and Processing Standards are focused on control measures for risks associated with microbiological and chemical hazards in food. These standards only apply in Australia. New Zealand has a separate food safety regulatory program set by the MPI.

These standards use a variety of risk management strategies and place responsibility for compliance on the food industry.

Food safety programs

The Code requires certain food businesses to develop and implement food safety programs based on a systematic identification and control of hazards as identified in the hazard analysis critical control point (HACCP) system.

Food handling practices

The Code requires food businesses to ensure that people undertaking or supervising food handling operations have knowledge and skills in food safety and food hygiene. The relevant standards consider factors related to the receiving, handling, storage and display of food, as well as to food premises and equipment.

Processing requirements

Certain food commodities (e.g. milk, cheese, eggs and some meats) have specific processing requirements to mitigate any inherent risks to public health and safety. The Code provides detailed processing requirements in these cases.



Primary production requirements

The Code also provides specific requirements in relation to the production of certain primary produce including eggs, dairy, seafood, poultry meat, ready-to-eat meat, seed sprouts and specific cheeses. Primary production standards are broad-based and consider all aspects of production including general safety requirements, potential contamination and handling, storage, transportation, packaging, disposal, hygiene requirements, as well as premises and equipment.

6.4.2 Non-regulatory measures

Non-regulatory measures that aim to manage an identified health risk are not specified in the Code. These include measures such as industry codes of practice, guidelines, educational materials such as fact sheets developed by FSANZ and standards developed by other recognised bodies such as Standards Australia.

Codes of practice

Codes of practice or guidelines can be developed by industry alone or developed jointly with FSANZ. A code of practice is a non-binding measure used to regulate food activities and food practices in the community. It is usually developed as an alternative to a food standard or as a supplement to a food standard.

A code of practice could be developed where:

- there is clear evidence that established practices adequately protect public health and safety and the level of risk is acceptable to the community without the need for a standard and/or
- a standard exists but further advice is needed to facilitate compliance and foster consumer confidence.

Compliance with codes of practice is generally the responsibility of industry although, in some cases, there may be a degree of oversight by the relevant jurisdiction.

Guidelines and protocols

In some cases, FSANZ may develop guidelines to help industry meet the requirements for good agricultural and/or good manufacturing practices. For example, this measure is used to set levels for certain chemical contaminants in food. The concept of 'generally expected levels' or 'GELs' was introduced to encourage those agricultural or manufacturing practices that support the ALARA principle and to encourage the continuance of active monitoring and surveillance of chemical contaminants. GELs are derived where there are no provisions in the Code and where sufficient monitoring or surveillance data is available for specific contaminant/food combinations to set the guideline levels. GELs provide a benchmark against which unacceptable contamination of food can be identified and provide a trigger



for remedial action if the GEL is exceeded. Hence, GELs can either complement the legally enforceable MLs for chemical contaminants or provide a benchmark in situations where MLs are not considered necessary.

The Food Industry Recall Protocol which applies in Australia only is an example of a protocol developed by FSANZ. It provides advice to businesses on how to write a food recall plan and how to conduct a food recall if necessary.

Consumer information/advice

Providing information and/or advice to consumers in the form of web information, technical papers or through public forums is another non-regulatory measure. For example, FSANZ may provide:

- information to community organisations about safe food handling e.g. for fundraising
- information to at-risk groups about safe eating practices e.g. *Listeria* advice for pregnant women
- advice on how to use food labels effectively.

Consumer information/advice is often used to support other regulatory or non-regulatory measures such as labelling.

6.5 Monitoring and evaluation activities

6.5.1 Monitoring activities

Monitoring may be undertaken after regulatory or non-regulatory measures are introduced to assess the effect of the control measures over time. It may involve repeating surveys of the food supply at different times to determine trends. In particular, it may help establish possible causal links between apparent changes in estimated dietary exposure and the adopted risk management strategies.

Monitoring can:

- determine changes in the status of particular foods in the market
- provide confirmation of the estimated dietary exposures used in the risk assessment, once the food ingredient is available on the market, by examining actual use data
- provide information on exposure in non-target populations and on unintended consequences
- be used to review assumptions made during the risk assessment and risk management processes.



FSANZ undertakes monitoring activities in the form of the ATDS, other targeted surveys of the food supply, and through surveys of relevant sectors e.g. food handlers, consumers and industry. Other Australian government departments, both at the Commonwealth and state and territory level, and in New Zealand also undertake monitoring activities that generate data and information that may be used to inform FSANZ risk analysis processes.

Australian Total Diet Study

The ATDS²⁰ is conducted approximately every two years with support from Australian jurisdictions and examines Australians' dietary exposures to a range of substances that may include agricultural or veterinary drug residues, environmental contaminants, natural toxicants, certain food additives and nutrients. The ATDS allows FSANZ to monitor the food supply and provides data to inform risk assessment activities. The ATDS collects and analyses foods that best represent the Australian diet nationwide. To achieve more accurate dietary exposure estimates, the foods examined in the ATDS are prepared to a 'table ready' state before they are analysed to provide quantitative data on the levels of chemicals in foods as consumed. As a consequence, both raw and cooked foods are examined.

Other FSANZ surveys

FSANZ may also undertake survey work relating to specific areas of the Code e.g. food additive standards or in response to emerging issues and national food incidents. These surveys may be of foods or consumer behaviours e.g. to confirm behavioural assumptions. These surveys are conducted as required and as resources permit.

OzFoodNet

OzFoodNet²¹ was established by the Department of Health as a national network to monitor public health events that can be indicators of foodborne hazards. It seeks to improve the accuracy and timeliness of notification of foodborne-related infections particularly those that cross state, territory and national borders, and to provide comprehensive interpretation of state and territory surveillance data. It also facilitates the coordination of state and national investigations of clusters and outbreaks of disease, and provides a focus for studies examining the risk factors associated with foodborne disease.

20 <http://www.foodstandards.gov.au/science/monitoring/pages/australiantotaldiets1914.aspx>

21 <http://www.ozfoodnet.gov.au>



National Residue Survey

The National Residue Survey (NRS)²² is conducted by the Department of Agriculture. This ongoing survey tests predominantly foods that are destined for export (including animal, grain, horticulture and fish products), for residues of agricultural and veterinary chemicals and environmental contaminants. The survey supports Australia's food industry and primary producers by monitoring residues and ensuring that they remain below set limits also helping to identify potential problems and indicating where follow-up action is needed.

Imported Food Inspection Scheme

The Imported Food Inspection Scheme (IFIS)²³ is administered by the Department of Agriculture. The IFIS monitors food imported into Australia to ensure it meets Australian requirements for public health and safety and is compliant with the Code. This may involve analytical testing against a published list of potential hazards. The Department of Agriculture decides on the level and frequency of inspection and testing of imported food consignments, based on risk assessment advice provided by FSANZ.

State, Territory and New Zealand surveys

Health, agriculture and environment departments in each of the Australian jurisdictions and New Zealand may conduct surveys on a variety of food chemical and microbiological contaminants. Under the Implementation Sub Committee for Food Regulation (ISFR), FSANZ, the Australian jurisdictions and New Zealand have established a coordinated food survey plan²⁴. This plan coordinates surveillance activities across jurisdictions and New Zealand—this makes more efficient use of resources and undertaking more statistically robust studies using commonly agreed methodologies. It enables a higher level of scrutiny and peer review, collaboration amongst jurisdictions in the areas of sampling and analysis, less duplication of surveillance activities and discussion of results with a view to ensuring consistent risk management options, as appropriate.

6.5.2 Evaluation activities

FSANZ has considerable experience in evaluating the effectiveness, costs and net benefits of regulatory or non-regulatory measures as well as the processes involved in formulating and implementing the measures themselves. From time to time, FSANZ may also undertake other types of evaluation activities such as program evaluations, as a means of identifying processes that work well and areas requiring further development.

22 <http://www.daff.gov.au/agriculture-food/nrs>

23 <http://www.daff.gov.au/biosecurity/import/food/inspection-scheme>

24 <http://www.health.gov.au/internet/main/publishing.nsf/Content/foodsecretariat-isc-food-survey-plan-11-14>



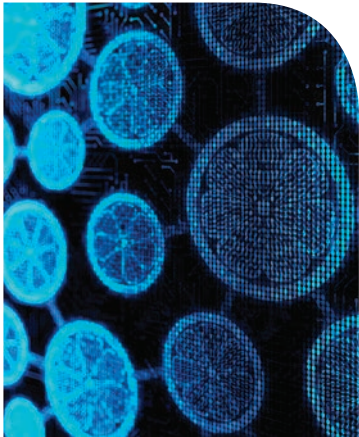
The focus of this section however, is on those evaluation activities undertaken to examine whether regulatory or non-regulatory measures are operating as intended, whether they are effective, and whether there are any unexpected outcomes or problems arising from their implementation. These types of evaluations are also known as impact evaluations and would be undertaken in collaboration with our regulatory partners.

Information from food surveillance and monitoring activities forms an integral part of the evaluation process by providing information on the current baseline situation and the impact of new food regulatory and non-regulatory measures.

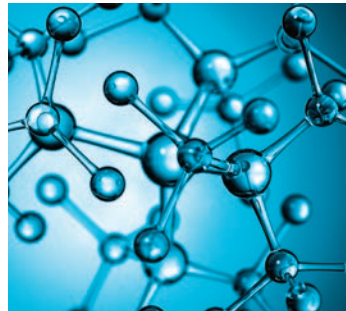
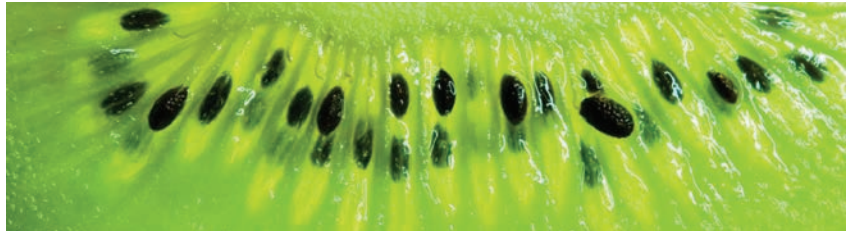
Such evaluations can only be performed effectively if the data collection starts at an early stage e.g. in the form of performance indicators, and if the risk management objectives are clearly stated and measurable. Although a baseline scenario or control group should be established before any regulatory change to evaluate the net effect of regulation of such change, in many cases, the ability to retain a control group following changes in the Code is not possible.

In line with current evaluation practice, evaluation at FSANZ is applied selectively. Larger scale projects that provide the highest contribution towards organisational learning and accountability in areas of high risk are those most often targeted for evaluation.





Communicating food-related health risks



7 Communicating food-related health risks

7.1 Risk communication

Risk communication involves the interactive exchange of information about risk between risk assessors and risk managers, and among FSANZ, news media, interested groups and the general public.

Risk communication, which is an essential part of the risk analysis process, begins at the earliest stages of a potential food-related health and safety issue. This is to ensure that appropriate strategies can be developed to communicate information internally and externally, including to consumers.

In the Codex risk analysis framework, risk communication is considered in both risk assessment and risk management (see Figure 1 in Section 4.2). The interactive and ongoing exchange of information and opinions quickly between the risk assessors and risk managers involved in risk analysis is vital for successful outcomes. Communication with external stakeholders, including the broader community, is also essential to inform FSANZ's decision-making processes and to ensure transparency, trust and a high level of confidence in the food regulatory system.

Communication with stakeholders is a two-way process. FSANZ prepares communication strategies to give stakeholders the information they need to better understand the health and safety risks associated with foods and managing those risks. Stakeholders are also given opportunities to contribute to FSANZ's consideration of issues. Externally-focused risk communication has as much to do with building productive relationships with stakeholder groups as with disseminating information. Therefore, appropriate methods of exchanging information with a broad range of interested and affected people need to be established early in the process.

Everyone connected to the risk analysis process is responsible in some way for risk communication. While specialist communicators may be responsible for preparing media releases, a communication strategy or publishing material on the website or on social media, the project manager has overall responsibility for the communication.



Much of the externally-focused risk communication involves a strategy which seeks to:

- identify the target audience
- design messages for those audiences
- use the most appropriate communication vehicles for interacting with those audiences.

Risk communication should aim to provide clear, accurate, relevant and easy to understand information to audiences at appropriate points in the risk analysis process.

It should give an honest appraisal of identified health risks, the uncertainties associated with that appraisal, and the steps being undertaken to address the identified risks.

7.2 Communication strategies

Communication strategies for engaging external stakeholders vary according to the complexity of the issue, the degree of public interest and how long the risk analysis and formal consultation processes will take. For example, amending a pesticide MRL may involve a strategy comprising only public notifications in newspapers and on the FSANZ website. Developing a new food standard dealing with all aspects of a primary industry sector would take several years to complete and would require public consultations, detailed consideration of the target audiences, messages and communication vehicles. Another challenge of a large project would be to keep stakeholders interested and aware of the status of the project during periods of inactivity.

7.2.1 Risk perception

Communication strategies are developed according to four levels of risk, based on scientific evidence (as determined by FSANZ) and perceived risk (as seen by the community), as shown in Table 2. Some consumers may hold a perception that the use of certain food components (e.g. food additives), and technologies (e.g. irradiation), may contribute to an increase in health risk. In developing appropriate communication strategies, it is important to note that consumers may hold these particular beliefs regardless of the available scientific evidence. Consumers' perception of risk can be influenced by many factors, including their level of knowledge and understanding of the issue, as well as their level of acceptance of the potential perceived benefits to public health and/or safety. Perceptions about food risks can change slowly over time as new information becomes available and familiarity with the issue grows. For this reason, consumer research that investigates and provides contemporary information on the links between food and health outcomes play an important component in risk communication, as it can provide reassurance to consumers about the health and safety of food.



7.2.2 General matters

Individual communication strategies are not mutually exclusive and may be used in combination. The strategies indicate the main direction and level of communication activity required for a particular health risk. They are 'preferred' strategies, which does not preclude adopting other strategies if the need arises.

Table 2. Communication strategies

Level	Risk combinations	Communication strategy
1	LOW risk – LOW perceived risk	PASSIVE
2	LOW risk – HIGH perceived risk	RESPONSIVE
3	HIGH risk – LOW perceived risk	EDUCATIVE
4	HIGH risk – HIGH perceived risk	PROACTIVE

It is necessary to have a good understanding of how a risk is perceived by the public in order to identify which communication strategy should be applied to a particular food issue.

This understanding may be developed by monitoring media and online debate, or through research designed to measure and assess public risk perceptions. Such studies may have been initiated to answer specific risk assessment or risk management questions, but can also collect data useful in constructing risk communication messages and strategies. In addition to new research, existing studies on the factors influencing consumer perceptions of risk will form an important evidence base.

Communication vehicles that can be employed in each of the strategies vary. They may include media liaison, web publishing, interactive web forums, fact sheets²⁵, reports, meetings, conferences, advice line, displays, launches, email bulletins and advertising.

Passive communication strategies

Passive communication strategies involve notifying and alerting interested and affected individuals and groups to the food issue. These strategies are used generally when the scientific evidence supports a low level of risk and where there is a low perceived risk by the community e.g. the proposed use of processing aids.

25 <http://www.foodstandards.gov.au/consumer/safety/faqsafety/Pages/default.aspx>



Responsive communication strategies

Responsive communication strategies are used where the community, or a section of the community, perceives a much greater risk in a food issue than the scientific evidence would indicate. In these cases, the degree of communication activity will be increased and will include media releases; proactive media liaison; providing regular and updated web material; and using social media.

Educative communication strategies

Educative communication strategies are particularly useful when the scientific evidence shows a high risk for the food issue, of which the community is unaware. Education campaigns are developed in an attempt to effect behaviour changes in the target groups e.g. increasing knowledge and awareness in pregnant women about mercury in fish.

Proactive communication strategies

Proactive communication strategies are used when the scientific evidence and the community awareness of the food issue indicates a high risk. In these situations, media and stakeholder interaction is initiated early, and is put in place when all parties agree there is significant public health and safety risk e.g. BSE.

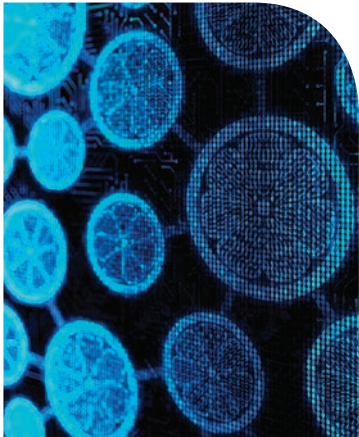
7.2.3 Applications and proposals

Stakeholder views are sought for all applications and proposals to change the Code. This occurs through a formal call for submissions process in one or more rounds of public consultation. All submissions are made publicly available and taken into account during FSANZ's consideration of applications and proposals.

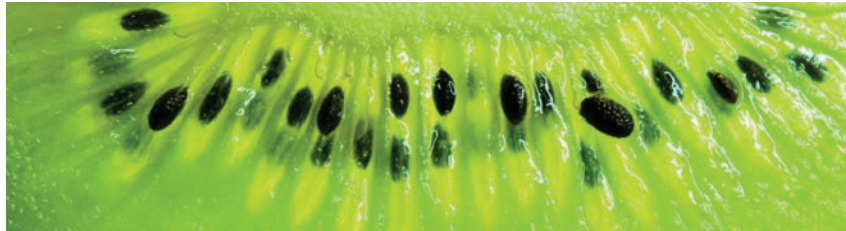
Application and proposal reports are also publicly available except when information is considered confidential commercial information under the provisions of the FSANZ Act²⁶.



26 <http://www.foodstandards.gov.au/foodstandards/changingthecode/>



Case studies



8 Case studies

Risk analysis provides a structured framework for examining and assessing public health and safety risks associated with food. However, the broad range of potential risks in different types of food requires that the risk analysis approach be sufficiently flexible in identifying and managing such risks. This is illustrated in the following case studies.

8.1 Approval to use the food additive Advantame

Assessing an application for a new food additive

8.1.1 The regulatory problem

In 2009, an application was received to amend Standard 1.3.1 – Food Additives in the Code. The Applicant sought approval to use Advantame, a new intense sweetener, in a range of foods and beverages. These included table top sugar substitutes (powdered only) and a range of powdered beverages including fruit flavoured drinks, milks and flavoured milk drinks, instant tea and coffee, and protein drinks. The Applicant advised FSANZ that the purpose of using Advantame as a food additive would be to provide assistance to people as part of their weight management or weight loss regime by lowering the calories in foods while maintaining flavour.

FSANZ was required to conduct a pre-market safety assessment under Standard 1.3.1 of the Code, before Advantame could be sold in Australia or New Zealand. At the time the application was received, no other country had completed a toxicological assessment. Therefore no acceptable daily intake (ADI) for Advantame had been established.

8.1.2 The risk

FSANZ conducted a comprehensive risk assessment. This included an independent evaluation of more than 50 detailed toxicity studies, including studies on kinetics, metabolism, acute toxicity, repeat-dose toxicity, genotoxicity, immunotoxicity, reproductive toxicity and developmental toxicity. Four human studies were also evaluated. The toxicity of Advantame was well characterised based on the extensive database. An ADI of 5 milligrams per kilogram of body weight per day (mg/kg bw/day) was established.

FSANZ sought an external peer review of the toxicological report. The reviewer concurred with FSANZ's conclusions and commented that FSANZ's evaluation was scientifically defensible.



Food additive permissions in the Code apply to food produced or sold in both Australia and New Zealand. Therefore a dietary exposure assessment was conducted for both countries using food consumption data reported in the 1995 Australian National Nutrition Survey, the 1997 New Zealand National Nutrition Survey and the 2007 Australian National Children's Nutrition and Physical Activity Survey.

To enable the dietary exposure assessment to be conducted, the Applicant provided proposed maximum levels of Advantame likely to be used as a sugar replacement in the range of food products requested. Where permission to add Advantame at certain concentrations to specific foods was proposed, the whole group of foods to which the specific food belongs was included in the dietary exposure assessment and assumed to contain Advantame at that concentration. For example, while permission was requested to add Advantame to 'powdered flavoured milk drinks' the category of 'liquid milk products and flavoured liquid milks' was included in the assessment. Overall, this resulted in a much broader range of foods being included in the assessment than had been requested and consequently a highly conservative estimate of dietary exposure was made.

Despite the conservative nature of the dietary exposure assessment, the estimated dietary exposures were well below the ADI of 5 mg/kg bw for all groups of Australian and New Zealand consumers assessed (including children). On this basis, FSANZ concluded that there were no public health and safety issues for Australian and New Zealand consumers associated with the proposed addition of Advantame to food.

8.1.3 The response

Although there were no public health and safety issues associated with the proposed addition of Advantame to food, FSANZ considered two options to ensure its appropriate use. The first option involved establishing maximum permitted levels in Schedule 1 of Standard 1.3.1 of the Code. The second option was to give approval for Advantame use according to Good Manufacturing Practice (GMP) in Schedule 2 of Standard 1.3.1.

Schedule 1 permissions usually apply when the risk assessment determines that an exceedance of the ADI could be possible for a population group and it would be appropriate to restrict levels of the food additive in foods. However, FSANZ calculated that a 60 kg person would have to consume 300 mg Advantame/day to exceed the ADI of 5 mg/kg bw. As Advantame is 20,000 times sweeter than sucrose, this would be equivalent to a consumption of 6 kg of sucrose per day. A 19 kg child would have to consume the equivalent of 1.9 kg of sucrose per day, which is unrealistic in the context of a normal diet.



Therefore, FSANZ concluded that the second option, to recommend GMP permissions for Advantame in Schedule 2 of Standard 1.3.1, would be the most appropriate option because:

- the risk assessment found there was no specific risk that needed to be managed by setting maximum permitted levels in foods
- it would allow Advantame to be used in a wider range of food preparations to suit a variety of broader food applications
- due to the intense sweetness of Advantame, which means that only minimal amounts are needed to sweeten foods, the use of Advantame is self-limiting
- when used at the levels proposed by the Applicant, the dietary exposure for the highest consumer was well below the ADI.

General labelling requirements in the Code, including the mandatory declaration of food additives, would ensure that adequate information regarding foods containing Advantame would be provided to consumers. Advantame would need to be declared in the ingredient list by its food additive class name 'sweetener' followed by its specific name or food additive number.

8.1.4 Communication

The application was assessed as a Major Procedure, requiring a minimum of two rounds of public comment. Public submissions were invited on each of the two assessment reports. FSANZ took all submitters' comments into consideration in completing the assessment and reaching its conclusions.

On gazettal of the new food regulatory measure, FSANZ notified the public through its food standards notification circular, public notices and publication in newspapers.

Due to intermittent media and consumer interest on sweeteners generally, FSANZ continues to publish and update information about the use of intense sweeteners in the food supply.



8.2 Cyanogenic glycosides in cassava-based snacks

Responding to an incident of a naturally occurring toxicant in food

8.2.1 The regulatory problem

Cassava (*Manihot esculenta* Crantz) is a hardy plant that is an important food source in some developing countries. Cassava contains compounds called cyanogenic glycosides, which can cause potential health risks to consumers. These are naturally occurring sugars that have cyanide in their structure. The main cyanogenic glycoside in cassava is linamarin (93%). A small amount of lotaustralin (7%) is also present.

In January 2008, Japanese authorities notified Australia that the cyanogenic glycoside concentrations in a cassava-based snack food manufactured in New South Wales were higher than normal and 'a danger to damage human health' (translation). At the time this issue emerged, a standard for cassava-based snack food did not exist in Australia. Within 24 hours of notification being received from Japan, the National Food Incident Response Protocol was activated. This case study demonstrates that the general principles of risk analysis can still apply in responding to rapidly emerging issues, although time constraints may affect the sequence of events and depth of information that can be obtained and assessed.

8.2.2 The risk

It is important to process cassava appropriately before consumption to reduce the levels of cyanogenic glycosides. If it is not adequately processed, it can retain high levels of cyanogenic glycosides which are broken down by gut microflora in humans to form hydrogen cyanide (or hydrocyanic acid, HCN). Processing methods include peeling, grating, soaking in water and mild heat treatment. Processing allows the natural conversion of linamarin to HCN, which due to its volatility, is released into the air.

Symptoms of acute toxicity include headaches, dizziness, stomach pain or mental confusion. In developing countries where cassava is a staple food, toxicity has also been implicated in the aetiology of several chronic diseases including Konzo, a motor neuron disease affecting legs, arms and speech and tropical ataxic neuropathy (TAN), characterised by symptoms affecting the mouth, eyesight, hearing or gait, mainly of older people.

Using available toxicity studies on linamarin, FSANZ was able to establish an acute reference dose (ARfD) for linamarin of 0.7 mg/kg bw. This was based on death in hamsters at doses greater than 70 mg/kg bw. A 100-fold inter and intra-species safety factor was applied. This ARfD was converted to an ARfD for total HCN of 0.08 mg/kg bw.



As a follow-up to the testing of Australian-made products done by Japan, Australia sampled and analysed a total of 300 samples of domestically produced and imported cassava-based snack foods (i.e. ready-to-eat cassava chips). While there were equally high levels of total HCN found, results also showed significant variation in the levels (<10–145 mg/kg).

A dietary exposure assessment was conducted using the concentration data obtained from the 300 products surveyed and consumption data reported in the 1995 Australian National Nutrition Survey and the 1997 New Zealand National Nutrition Survey. As consumption of ready-to-eat cassava chips was not reported separately, consumption data for equivalent salty snacks was used, assuming that consumption amounts for cassava-based snacks would be similar.

Two types of dietary exposure assessment were conducted: deterministic and probabilistic. The results of the deterministic dietary exposure assessment were compared with the ARfD. The mean concentration of total HCN of 63 mg/kg could result in dietary exposures above the ARfD for all groups assessed. Children 2–4 years of age showed the highest risk of exceeding the ARfD. At the minimum concentration of 10 mg/kg, 2–4 year old children remained at risk.

When compared to the ARfD, the results of the probabilistic exposure assessment indicated that, at the mean concentration of total HCN of 63 mg/kg, the likelihood of 2–4 year old children exceeding the ARfD was 56%. At the minimum concentration of 10 mg/kg, the likelihood decreased to 2–4%.

As HCN has a short half-life, there was an additional consideration whereby the consequences of exceeding the ARfD was also dependent on whether exposure occurs in one sitting or over the course of a day. However, the 97.5th percentile consumption of salty snacks for 2–4 year olds was estimated at around 100 g. It was reasonable to assume that this quantity could be easily consumed in one sitting.

The results of the assessment indicated that inadequate processing of raw cassava could result in there being detectable levels of total HCN remaining in ready-to-eat cassava chips. Even the lower end of the total HCN concentrations detected in a range of products available in Australia might present a public health risk, with children of 2–4 years of age being at most risk.



8.2.3 The response

The National Food Incident Response Protocol provides a framework for coordinating timely and appropriate action in Australia, in response to a national food incident. Preliminary toxicological expert advice indicated that at the levels detected by Japan, consumption of between 100–200 g might manifest in mild symptoms. The manufacturer of the product was informed and agreed to voluntarily recall the product in question.

In February 2008, a preliminary risk assessment was completed by FSANZ using a guidance level of 25 mg/kg (this risk assessment was later refined as described in Section 8.2.2 above). Manufacturers and importers of products found to have concentrations above 25 mg/kg were advised that these levels were not acceptable and asked to consider a course of remedial action. Most companies responded by voluntarily withdrawing their product.

Significant variability in levels of total HCN in ready-to-eat cassava chips had been observed, even between different batches of the same product. Stronger controls over ingredients and processing practices would help to ensure levels of total HCN were maintained as low as reasonably achievable.

FSANZ prepared Proposal P1002 – Hydrocyanic acid in ready-to-eat cassava chips to assess the public health risks associated with HCN in these products. In June 2009, and following a balanced consideration of public submissions received, an ML of 10 mg/kg for total HCN in ready-to-eat cassava chips was established in Standard 1.4.1 of the Code. In addition, upon risk assessment advice from FSANZ, the Department of Agriculture instituted testing of imported products at the border.

8.2.4 Communication

Initial risk communication messages to the public were in the form of media releases issued by jurisdictions across Australia. Messages were formulated based on the analytical results for total HCN in cassava chip products available at that stage of the incident. Consumers, especially children, were advised to avoid eating large quantities of cassava-based chips/crackers.

Follow up materials were produced for the FSANZ website with more of a focus on advice regarding cooking raw cassava and advice about the limits set in the Code for cassava chips.



8.3 Methylmercury in fish

Monitoring contaminants and re-evaluating our risk assessment as new data becomes available

8.3.1 The regulatory problem

Mercury is a heavy metal released into the environment from a range of natural and man-made sources. Methylmercury (an organic form of mercury) is formed from inorganic mercury by microbial action in aquatic systems (both fresh and marine water), sediments and soils. Methylmercury enters and accumulates in the aquatic food chain, with predatory and long living species higher up the food chain accumulating higher levels. These species include marlin, swordfish and shark.

The consumption of fish and seafood is the major source of human exposure to methylmercury in most populations. Methylmercury levels will differ significantly across different fish species. Typical levels in some types of fish can cause potential health risks to consumers. The developing foetus is thought to be at particular risk from methylmercury exposure due to the toxic effects of methylmercury on foetal brain development.

At its 61st meeting in June 2003, JECFA re-assessed mercury and revised the PTWI for methylmercury from a level of 3.3 micrograms per kilogram of body weight per week ($\mu\text{g}/\text{kg}$ bw/week) to 1.6 $\mu\text{g}/\text{kg}$ bw/week. The new level was considered safe for the developing foetus. This prompted FSANZ in 2003 to re-evaluate its risk assessment for mercury. FSANZ had evaluated mercury in 2000 as part of Proposal P157 – Metal contaminants in food. At that time, FSANZ determined that the most effective risk management strategy would be to provide advice to pregnant women and women intending to become pregnant on the amounts and types of fish that could be safely consumed. This advice needed to be updated based on the revised PTWI, and this formed the basis of the updated risk assessment.

8.3.2 The risk

The toxic effects of methylmercury in humans are well documented. Methylmercury is readily absorbed following ingestion and can induce toxic effects in several organ systems. However, the nervous system (central and peripheral) is the most sensitive to methylmercury toxicity, with the developing nervous system the most vulnerable.

In 2003, following the JECFA review, FSANZ re-evaluated its risk assessment for mercury. A dietary exposure assessment was undertaken using more recent analytical data on mercury concentrations in fish, which had become available subsequent to Proposal P157, and consumption data reported in the 1995 Australian National Nutrition Survey and the 1997 New Zealand National Nutrition Survey. The revised risk assessment also considered



specific mercury concentrations and consumption levels for specific types of fish and other seafood, whereas for the previous assessment, there were two concentrations used for two groups of fish determined as predatory and non-predatory.

Various scenarios were assessed to estimate dietary exposure to methylmercury. The first scenario used all of the analytical data on mercury concentrations, including concentrations exceeding MLs in the Code. This scenario assessed the assumption that strict enforcement of fish exceeding MLs did not take place. Other scenarios were run to assist in determining whether lowering the MLs in the Code could decrease the dietary exposure. For example, one scenario excluded concentration data points above 1 mg/kg (the higher ML for fish in the Code). Another scenario excluded concentration data points above 0.5 mg/kg (the lower ML for fish in the Code)²⁷.

For this assessment, two PTWI levels were used to reflect different sensitivities in the population to the toxic effects of methylmercury. The lower level of 1.6 µg/kg bw was applied to women of childbearing age (as a proxy for pregnant women and women intending to become pregnant). A FSANZ review of the toxicological data determined that a PTWI of 3.3 µg/kg bw was applicable for use for the rest of the population including children.

The potential risk to public health of methylmercury exposure was established by comparing the dietary exposure estimates for the Australian and New Zealand populations to their respective PTWIs. For most population groups in Australia and New Zealand, the estimated dietary exposures were below the PTWI, and only exceeded the PTWI in the worst case scenario i.e. where concentrations below the level of detection ('Not Detected') are assigned a concentration equal to the Limit of Reporting (LoR). For those with high exposures to methylmercury (i.e. those at the top 5% of exposures), the estimated dietary exposures exceeded the PTWI for all Australian population groups assessed but none of the New Zealand population groups. This is due to differences in the types of fish consumed in the two countries. There were similar results when concentration data above 1 mg/kg or 0.5 mg/kg were excluded from the exposure assessment.

Based on these results, it was determined that some risk management was still needed and the number of serves of each species of fish that could be consumed without exceeding the HBGV was calculated per week, fortnight or month for each relevant population group. Revised consumption advice was generated for each specific type of fish using specific concentrations, as opposed to the advice based on two types of fish given previously.

²⁷ FSANZ sets maximum levels for mercury in fish in Standard 1.4.1 of the Code. An ML of 0.5 mg/kg has been set for most fish excluding the following: gemfish; billfish (including marlin); southern bluefin tuna; barramundi; ling; orange roughy; rays and all species of shark, for which an ML of 1 mg/kg has been set. The ML can be used to restrict the sale and consumption of fish that does not fall within the established limit.



8.3.3 The response

The risk management of methylmercury exposure is complex as the risks associated with exposure to methylmercury through the consumption of certain types of fish must be considered noting also the benefits of consuming fish as part of a healthy diet.

Fish consumption has many nutritional benefits. Fish are considered a good source of protein, omega 3 fatty acids and iodine. Fish are also low in saturated fat. As a result, fish consumption is often encouraged by health professionals. In considering the risks and benefits, the aim was to restrict the level of methylmercury in fish to protect public health and safety, while not setting the levels so low so as to restrict the availability of fish in the marketplace (and their concomitant nutritional benefits).

In relation to risk management options following the revised risk assessment, it was noted that the level of mercury in the fish is difficult to control in their natural environment, and MLs for mercury were already in place in the Code. It was determined that providing revised advice to the population (and, in particular pregnant women and women intending to become pregnant) on fish consumption would be the best way of managing potential health risks of methylmercury in fish.

Methylmercury in fish has been a known hazard for many years and is the subject of previously completed risk analyses at the international level. In 2010, a Joint FAO/WHO Expert Consultation on the Risks and Benefits of Fish Consumption was held to examine the health risks associated with methylmercury and other chemical contaminants in fish and the health benefits of fish consumption. The work outlined in this case study precedes this expert consultation and further consideration of the HBGVs by the Codex Committee on Contaminants in Food (CCCF). This case study illustrates that risk management responses need to be reviewed and updated as new scientific evidence becomes available, particularly for vulnerable population sub-groups such as pregnant women, children and consumers with high levels of fish consumption. It further illustrates the cyclic nature of the risk analysis process and also demonstrates that food-related health risks may be addressed through a mix of regulatory and non-regulatory interventions.

8.3.4 Communication

An advisory statement on mercury in fish, detailing the number of serves of different types of fish pregnant women and women planning pregnancy could safely consume was first issued by FSANZ in 2001.



Following the re-evaluation in 2003, the risk management approach included revised consumer information. The advisory statement again targeted pregnant women and women intending to become pregnant, providing advice on four specific species of fish that should be consumed in limited quantities only, while also highlighting the nutritional benefits from eating fish. Advice was also added at this time for the general population, including children. The advice was published on the FSANZ website and was distributed to key health professionals (e.g. doctors, dietitians) and the fishing industry for their information. In addition, FSANZ developed a fact sheet targeted to health professionals and others requiring further technical information on mercury, the risk assessment and the development of the consumer advice brochure.

A number of jurisdictions in Australia have also provided advice on fish and mercury.

8.4 Approval to add calcium to several non-dairy foods

Assessing the risks and benefits associated with voluntary nutrient fortification

8.4.1 The regulatory problem

In 2001, an application was received to amend Standard 1.3.2 – Vitamins and Minerals. The applicant sought permission for the voluntary addition of calcium to: fruit- and vegetable juices; fruit- and vegetable drinks; fruit cordial (later withdrawn); soups; and savoury biscuits. The applicant sought permission to add calcium at a level that would allow a claim of good source of calcium, that is, 25% of the calcium RDI per reference quantity²⁸ (similar to a serving) of the food.

Vitamins and minerals are not permitted to be added to general purpose foods unless the addition of the specific vitamin or mineral is permitted in Standard 1.3.2. At the time, Standard 1.3.2 permitted the voluntary addition of calcium to breakfast cereals and most dairy products but not to non-dairy foods.

8.4.2 The risk

The identified public health and safety risks associated with calcium addition to the requested range of foods included:

- over-consumption of the nutrient in multiple foods
- the displacement of other more nutritious foods already in the food supply
- other behavioural changes.

²⁸ As defined in clause 1 of Standard 1.3.2.



At the time the application was received, nutritional risk analysis, incorporating an assessment of both the risks and benefits associated with the addition of a nutrient, was still a developing area of work. Specifically, our assessment considered the:

- suitability of the nutrient for potential fortification
- existing inadequacy of calcium intakes of the total population and population sub-groups
- risk of excess calcium intake for the total population and population sub-groups
- suitability of the foods proposed to be fortified
- risk of dietary displacement (i.e. increased consumption of fortified foods in place of natural sources of calcium, such as milk)
- risk of nutrient deficits or imbalances resulting from milk substitution, specifically in relation to riboflavin and zinc
- potential for increase in sugar consumption, specifically risk of dental caries and over-nutrition
- risk of calcium not being bioavailable in the requested foods.

FSANZ assessed the inadequacy of calcium intakes of the total population and population sub-groups and found that about one third of the Australian and New Zealand populations had inadequate calcium intakes, in particular Australian and New Zealand adolescent and adult females, non-dairy consumers and New Zealand Maori.

The risk of people consuming excessive amounts of calcium from a diet containing calcium-fortified foods was considered minimal. The main concern about dietary displacement was whether calcium-fortified fruit- and vegetable juices and drinks would displace milk in the diet. However, an independent survey of 1200 Australians as well as overseas data indicated minimum risk of long-term substitution of calcium-fortified beverages for milk, because these beverages were considered to be sufficiently different from milk in nutrient profile, taste and usage. In addition, FSANZ modelled a 'worst-case' scenario assuming a 50% reduction in milk consumption due to substitution with calcium-fortified non-dairy beverages, which showed only a small decrease in the intake of nutrients obtained from milk such as riboflavin and zinc.



8.4.3 The response

FSANZ approved draft variations to Standard 1.3.2 to permit the voluntary addition of calcium to fruit- and vegetable juices and drinks, soups and savoury biscuits, up to a maximum claim per reference quantity of 25% RDI, equivalent to a 'good source' claim.

During the assessment of this application, a new policy guideline on the *Fortification of Food with Vitamins and Minerals*²⁹ was developed by the then Australian and New Zealand Food Regulation Ministerial Council. The release of the guideline prompted further consideration of whether the proposed fortification would:

- promote consumption patterns inconsistent with nutrition policies and guidelines of Australia and New Zealand (i.e. reduce milk consumption and increase fruit juice consumption)
- promote increased consumption of foods high in sugar, salt and fat.

Stakeholders had particular concerns about: the suitability of the foods proposed to be fortified; their potential to displace other foods and nutrients in the diet; and that the fortification itself could mislead consumers as to the foods' nutritional quality. FSANZ addressed these issues by seeking additional information from key stakeholders, undertaking further assessments and engaging expertise to assist in examining the likely impact of the proposed calcium-fortified foods on food consumption patterns.

Further work was also undertaken to address the concern that calcium claims on the label could mislead consumers about the nutritional quality of fortified foods. The potential risk of consumers perceiving fortified foods to be 'healthier' than unfortified counterparts was acknowledged. Labelling requirements at the time were considered sufficient to provide consumers with adequate information on the presence and total amount of calcium in foods. Any possible risk of consumers being misled from label claims was considered to be outweighed by the potential benefit derived from additional sources of calcium in the diet.

8.4.4 Communication

There were two calls for public comment during the assessment of this Application. Submissions were received from a variety of stakeholders including government enforcement agencies, food manufacturers and health professionals. The comments raised in submissions were taken into consideration in completing the assessment and reaching its conclusions.

²⁹ Ministerial Policy Guideline on the *Fortification of Food with Vitamins and Minerals* is available at: <http://www.health.gov.au/internet/main/publishing.nsf/Content/foodsecretariat-policy-guidelines#5>



Initial messages were targeted to dietetic and health professionals. FSANZ also notified the public of its decision to permit calcium to be added to the requested foods through its food standards notification circular, public notices and through the media. Follow up materials were produced for the website to support education initiatives to help raise awareness of general labelling information and the role of fortified food in the diet.

8.5 Raw milk products

Using risk analysis to develop a regulatory framework to support the safe production of raw milk products

8.5.1 The regulatory problem

Requirements for the primary production of milk and processing of dairy products specified in the Code essentially specify that dairy products sold in Australia must be pasteurised. In recent years, however, permissions have been given for a small number of raw milk cheeses following risk assessment work that demonstrated that these products would present a low risk to public health and safety with implementation of appropriate milk production and processing controls.

Rather than continue with a case-by-case assessment of specific raw milk cheeses, a risk analysis approach was taken to develop a through-chain regulatory framework that would support the safe production of raw milk products.

8.5.2 The risk

A wide range of microbiological hazards may be associated with raw milk. If these hazards are not managed, all raw milk products can present a high level of risk to public health and safety. The level of risk posed can be reduced by implementing production and processing controls. A number of qualitative and quantitative risk assessments identified the:

- milk production factors that impact on the prevalence of pathogens in raw milk
- factors that have the greatest contribution to pathogen control during cheese manufacture (the primary raw milk product)
- key parameters for determining pathogen reduction, and conditions for growth and no growth
- level of risk associated with each category.



Product	Process and product criteria	Performance criteria	Level of risk
Category 1	Process and product criteria contribute to elimination of pathogens. For cheese: <ul style="list-style-type: none"> • curd cooking at >48°C • extended ripening (≥120 days) at ≥10°C • moisture content ≤39% 	Combination of control measures used during manufacture must provide for a net 5 log reduction of pathogens.	Very low
Category 2*	Process and product criteria must not support pathogen survival and growth. For cheese: <ul style="list-style-type: none"> • rapid acidification • minimum ripening period and temperature • inhibitory pH/salt in moisture profile 	Combination of control measures used during manufacture must ensure no net increase of pathogens.	Low
Category 3	Processing factors do not prevent pathogen survival and intrinsic characteristics of the final product do not inhibit pathogen growth.	Not established.	Medium to high

* The potential pathogen load of raw milk used for the manufacture of Category 2 products is a critical factor. The raw milk needs to meet a stringent level of microbiological quality, achieved through additional on farm controls and verification testing.

8.5.3 The response

Three categories of raw milk products were defined based on the effect that processing factors and final product properties have on pathogen survival and growth.

Category 3	Pathogens survive production process. Final product supports growth.
Category 2	No net increase of pathogens during production. Final product does not support growth.
Category 1	Pathogens are essentially eliminated during production (net 5 log reduction).

↑
Increasing level of risk



Given the increased potential for pathogens to be present, the food safety risk associated with each category increases from Category 1 to Category 3. This category approach provides the basis to determine what raw milk products could be permitted ('approved raw milk products') and what on farm and processing control measures need to be implemented to support their safe production.

8.5.4 Communication

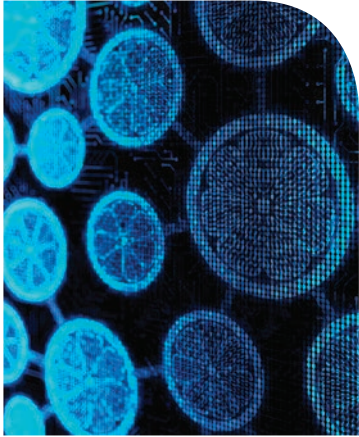
There is strong consumer, industry and regulatory interest in potential permissions for raw milk products. There is a balance between protecting public health and safety, facilitating trade and addressing consumer demand which must be founded on robust scientific assessment. Communicating the approach being taken for assessing raw milk products and the decisions made requires the ongoing provision of clear messages which explain the science, generally delivered in materials such as fact sheets.

FSANZ has provided website information and regular updates about its work. Social media is also one of a suite of tools, which includes FSANZ publications, used to communicate this work. Media releases and regular contact with the media about the issue have also been valuable in confirming the messages about this proposal.

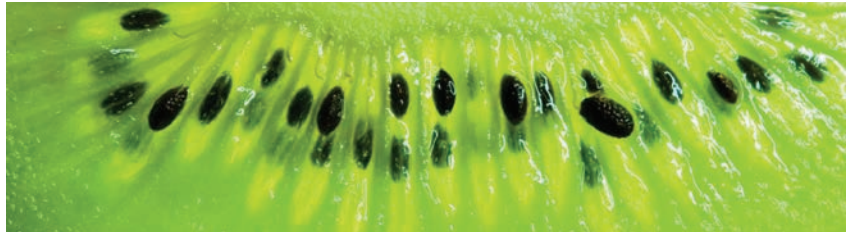
FSANZ's assessment of raw milk products has been progressed through Proposal P1007 – Primary Production and Processing Requirements for Raw Milk Products and Proposal P1022 – Primary Production and Processing Requirements for Approved Raw Milk Products. This work is available on the FSANZ website:

<http://www.foodstandards.gov.au/code/primaryproduction/Pages/default.aspx>.





Other information



Reading

1. Barlow S, Dybing E, Edler L, Eisenbrand G, Kroes R, van den Brandt P (eds.) (2002) Food Safety in Europe (FOSIE): Risk Assessment of Chemicals in Food and Diet. Food and Chemical Toxicology 40.
2. Codex Alimentarius Commission (1999) Principles and Guidelines for the Conduct of Microbiological Risk Assessment. CAC/GL 30.
3. Codex Alimentarius Commission (2007) Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM). CAC/GL 63.
4. 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.
5. 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.
6. FAO/WHO (1995) Report of the Joint FAO/WHO Expert Consultation on Application of Risk Analysis to Food Standards Issues.
7. FAO/WHO (1997) Report of a Joint FAO/WHO Expert Consultation on Risk Management and Food Safety.
8. FAO/WHO (1998) Report of a Joint FAO/WHO Expert Consultation on Risk Communication to Food Standards and Safety Matters.
9. FAO/WHO (2003) Microbiological Risk Assessment Series, No. 3: Hazard Characterization for Pathogens in Food and Water – Guidelines.
10. FAO/WHO (2006) Food Safety Risk Analysis. A Guide for National Food Safety Authorities. FAO Food and Nutrition Paper No. 87.
11. FAO/WHO (2008) Microbiological Risk Assessment Series, No. 8: Exposure Assessment of Microbiological Hazards in Food.
12. FAO/WHO (2009) Microbiological Risk Assessment Series, No. 17: Risk Characterization of Microbiological Hazards in Food – Guidelines.
13. FSANZ (2007) Safety Assessment of Genetically Modified Foods – Guidance Document. Food Standards Australia New Zealand.



14. FSANZ (2009) Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes. Food Standards Australia New Zealand.
15. Health Canada (2000) Decision-Making Framework for Identifying, Assessing, and Managing Health Risks.
16. ILSI Europe (2000) The Acceptable Daily Intake – A Tool for Ensuring Food Safety. ILSI Europe Concise Monograph Series.
17. ILSI Europe (2001) Principles of Risk Assessment of Food and Drinking Water Related to Human Health. ILSI Europe, Brussels.
18. IPCS (2004) Risk Assessment Terminology. International Programme on Chemical Safety. Harmonisation Project Document No. 1. WHO Geneva.
19. Kroes R, Galli R, Munro I, Schilter B, Tran L–A, Walker R, Wurtzen G (2000) Threshold of Toxicological Concern for Chemicals in the Diet: a Practical Tool for Assessing the Need for Toxicity Testing. *Food and Chemical Toxicology* 38 255–312.
20. National Research Council (1983) Risk Assessment in the Federal Government: Managing the Process. National Research Council (USA). National Academic Press.
21. Renwick A, Barlow S, Hertz-Picciotto I, Boobis A, Dybing E, Edler L, Eisenbrand G, Greig J, Kleiner J, Lambe J, Muller D, Smith M, Tritscher A, Tuijelaars S, van der Brandt P, Walker R, Kroes R (2003) Risk Assessment of Chemicals in Food and Diet. *Food and Chemical Toxicology* 41 1211–1271.
22. WHO (1987) Principles for the Safety Evaluation of Food Additives and Contaminants in Food. Environmental Health Criteria No. 70.
23. WHO (2002) Principles and Guidelines for Incorporating Microbiological Risk Assessment in the Development of Food Safety Standards, Guidelines and Related Texts. FAO/WHO consultation. Germany.
24. WHO (2009) Principles and Methods for the Risk Assessment of Chemicals in Food. Environmental Health Criteria No. 240.



Appendix 1 – Glossary

Acceptable daily intake (ADI) ^A

The estimate of the amount of a substance in food or drinking-water, expressed on a body weight basis, which can be ingested daily over a life-time without appreciable health risk to the consumer. The ADI is expressed in milligrams of the chemical per kilogram of body weight (a standard adult person weighs 60 kg).

Acceptable/Tolerable risk

The level of risk that is agreed to be borne after risk management is applied.

Acute reference dose (ARfD) ^A

The estimate of the amount of a substance in food or drinking-water, expressed on a body weight basis, that can be ingested in a period of 24 hours or less without appreciable health risk to the consumer. The ARfD is expressed in milligrams of the chemical per kilogram of body weight.

Adequate intake (AI) ^C

The average daily nutrient intake level based on observed or experimentally-determined approximations or estimates of nutrient intake by group (or groups) of apparently healthy people that are assumed to be adequate.

Adverse health effect ^B

Change in the morphology, physiology, growth, development, reproduction or lifespan of an organism, system or (sub) population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences.

Benchmark dose (BMD)

The dose of a substance which corresponds with a particular level or rate of physiological response. It is derived by modelling the dose-response curve in a range of relevant observable data, and then using that model to estimate a dose that corresponds to a particular level of response. The Benchmark Dose Lower Confidence Level (BMDL₁₀) refers to the dose that corresponds with a 10% response rate for a particular physiological response.

Dietary exposure ^A

See intake.



Dose-response^B

The relationship in which a change in the magnitude of exposure to a chemical, biological or physical agent is associated with a change in the manifestation and magnitude of human health effects.

Dose-response assessment^B

The determination of the relationship between the magnitude of exposure (dose) to a chemical, biological or physical agent, and the severity and/or frequency of associated adverse health effects (response).

Estimated average requirement (EAR)^C

A daily nutrient level estimated to meet the requirements of half the healthy individuals in a particular life stage and gender group.

Exposure assessment

The qualitative and/or quantitative evaluation of the magnitude, frequency and duration of exposure to biological, chemical, and physical agents via food as well as exposures from other sources if relevant. It is the third step in the risk assessment process.

Food additive^A

Any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, the intentional addition of which to food is for a technological purpose.

Good agricultural practice (GAP)^A

For pesticide use, includes the safe use of pesticides under actual conditions necessary for effective and reliable pest control. Actual conditions include on-farm production and post-production processes.

Good manufacturing practice (GMP)^A

For food additives, includes: the quantity of the additive does not exceed the amount needed to accomplish its technological purpose; the quantity of the additive that is not intended to accomplish any technological effect in the food itself is reduced to the extent reasonably possible; the additive is of appropriate food-grade quality and is prepared and handled in the same way as a food ingredient.

Hazard

A chemical (including nutrient), microbiological or physical agent in food with the potential to cause an adverse health effect.



Hazard assessment

The combined hazard identification and hazard characterisation steps of the risk assessment process, when considering chemical entities.

Hazard characterisation

The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents which may be present in food. It includes a dose-response assessment. It is the second stage of the hazard assessment process, and the second step in the risk assessment process.

Hazard identification

A process used to clearly describe the biological, chemical or physical hazard being assessed and to identify the type and nature of the adverse effects that could occur as a result of exposure to the agent. It is the first stage of the hazard assessment process, and the first step in the risk assessment process.

Health-based guidance value (HBGV) ^A

A numerical value that reflects the level of a chemical that can be ingested over a defined time period (e.g. lifetime or 24 hours) without appreciable health risk.

Intake ^A

The amount of a chemical ingested by a person as part of their diet (via food, beverages, drinking water and food supplements).

Margin of exposure (MOE)

The ratio of the No Observed Effect Level (NOEL) or benchmark dose lower confidence limit (BMDL) for the critical effect to the theoretical, predicted or estimated exposure. The calculation usually involves a reference point value (also called a point of departure) derived from the hazard assessment that is then divided by an estimate of human dietary exposure to give a dimensionless ratio that is the MOE.

Maximum level (ML)

The maximum level of a contaminant or natural toxicant that is permitted to be present in a nominated food.

Maximum residue limit (MRL)

The maximum level of a residue of a chemical which is permitted to be present in a food following GAP.



Natural toxicant

A chemical hazard naturally present in a particular food.

No-observed-adverse-effect level (NOAEL)

The highest dose level of a substance that produces no adverse effects in the most sensitive test species.

Novel food

A food or food ingredient that does not have a history of human consumption (in Australia and New Zealand), or is produced using non-traditional methods and which requires an assessment of safety.

Nutrient or related substance

A chemical (including nutrient) or microbiological agent in food with the potential to maintain or cause a favourable health effect.

Nutrient Reference Value (NRV)^c

Outline the levels of intake of essential nutrients considered, on the basis of available scientific knowledge, to be adequate to meet the known nutritional needs of practically all healthy people for prevention of deficiency states.

Nutrient-related hazard

A nutrient or related substance in food with the potential to cause an adverse health effect at inadequate or excessive intake.

Nutritional risk

The likelihood and severity of an adverse effect from an inadequate or excessive intake of a nutrient-related hazard.

Potential health benefit

The likelihood and extent of a favourable health effect from intake of a nutrient or related substance. [*Likelihood* corresponds to the amount of agent consumed].

Processing aid

A substance used in the processing of raw materials, foods or ingredients, to fulfil a technological purpose relating to treatment or processing, but which does not perform a technological function in the final food. It may result in the presence of residues or derivatives in the final product. The proportion of the processing aid should be no more than the maximum level necessary to achieve one or more technological functions under GMP.



Provisional tolerable daily intake (PTDI)/Provisional tolerable weekly intake (PTWI)

The permissible human daily/weekly exposures to food contaminants unavoidable associated with the consumption of otherwise wholesome and nutritious food. The tolerable intake is referred to as 'provisional' as there is often a lack of data on the consequences of human exposure at low levels and new data may result in changes to the tolerable intake.

Recommended Dietary Intake (RDI)

The average daily dietary intake level that is sufficient to meet the nutrient requirements of nearly all (97–98%) healthy individuals in a particular life stage and gender group.

Residual risk

The remaining level of risk after risk management has been applied. (This may or may not be equivalent to acceptable/tolerable risk).

Risk

The likelihood and severity of an adverse effect from exposure to a hazard.

Risk analysis

A structured process to identify, assess, communicate and manage risks consisting of three inter-related components: risk assessment, risk management and risk communication.

Risk appetite

The amount and type of risk that FSANZ is willing to pursue or retain.

Risk assessment

A process of identifying, analysing and characterising risk consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation.

Risk characterisation

The qualitative and/or quantitative estimation, including attendant uncertainties, of the likelihood of occurrence and severity of known or potential adverse health effects in a given population. It is the fourth step in the risk assessment process and integrates information from the hazard and exposure assessments.

Risk communication

Interactive exchange of information about risk between risk assessors and risk managers, and among FSANZ, news media, interested groups and the general public.



Risk management

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 evaluate the implemented decision.

Safety assessment

A structured, comparative process applied to a whole food to determine whether any new or altered hazards are present as a result of the use of certain technologies, e.g. gene technology or irradiation. The food being assessed is compared with a counterpart food having a history of safe use. Any identified hazards are further characterised to determine their risk under specified conditions.

Threshold dose

The dose or exposure below which adverse health effects do not occur. That is, the dose at which an effect just begins to occur.

Uncertainty

A lack of knowledge regarding the true value of a quantity or its variability that can be reduced by additional measurement or information.

Upper Level of Intake (UL) ^c

The highest average daily nutrient intake level likely to pose no adverse health effects to almost all individuals in the general population. As intake increases above the UL, the potential risk of adverse effects increases.

Variability

Real differences between individuals in a 'population', of a certain property over time or space that cannot be reduced by additional measure or information.

Sources

- A WHO (2009) Principles and Methods for the Risk Assessment of Chemicals in Food. Environmental Health Criteria No. 240.
- B FAO/WHO (2011) Codex Alimentarius Commission Procedural Manual Ed. 20. Joint FAO/WHO Food Standards Programme, Rome.
- C NHMRC (2006) Nutrient Reference Values for Australia and New Zealand Including Recommended Dietary Intakes, Canberra.



Appendix 2 – Regulatory framework for food

1. The legal basis for food regulation

Food regulation in Australia and New Zealand is addressed in Australian state and territory and New Zealand legislation. Legislative requirements generally require that food must be safe and suitable; food must not be adulterated, damaged, deteriorated or perished; and that 'food must not be represented in a way that is false, misleading or deceptive'. In other words, under these laws, food producers, processors and manufacturers must ensure the food they supply to the community is safe and appropriately represented to consumers.

Further legislation applies to imported foods at the point of entry. The *Imported Food Control Act 1992* (the Imported Food Control Act) requires food to comply with the *Australia New Zealand Food Standards Code* (the Code), as well as other public health and safety requirements. In addition, the *Quarantine Act 1908* (the Quarantine Act) requires that all food imports comply with quarantine conditions. The Australian Government Department of Agriculture administers both Acts.

2. The Australia New Zealand Food Standards Code

The Code is a compilation of food standards and is adopted into state, territory and, where relevant, New Zealand legislation mainly without variation. The food standards contained within the Code are developed or varied by Food Standards Australia New Zealand (FSANZ) in accordance with the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act), and having regard to the policy guidelines provided by the Legislative and Governance Forum on Food Regulation (the Forum, formerly the Australia and New Zealand Food Regulation Ministerial Council).

3. Establishing food regulation policy

The development of domestic food regulation policy, in the form of policy guidelines for setting food standards, is the responsibility of the Forum, which comprises ministerial representatives (usually health and agriculture ministers) from the Australian Government, New Zealand Government, and Australian state and territory governments.



4. Food Standards Australia New Zealand

FSANZ has a broad range of functions in addition to maintaining the Code—these are listed in the FSANZ Act.

When developing or varying a food standard, FSANZ has three primary objectives:

- the protection of public health and safety
- the provision of adequate information relating to food to enable consumers to make informed choices
- the prevention of misleading or deceptive conduct.

When developing or reviewing standards or variations to standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence
- the promotion of consistency between domestic and international food standards
- the desirability of an efficient and internationally competitive food industry
- the promotion of fair trading in food
- any written policy guidelines formulated by the Forum.

5. Enforcement of food regulations

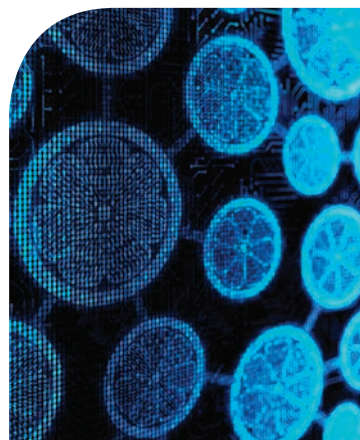
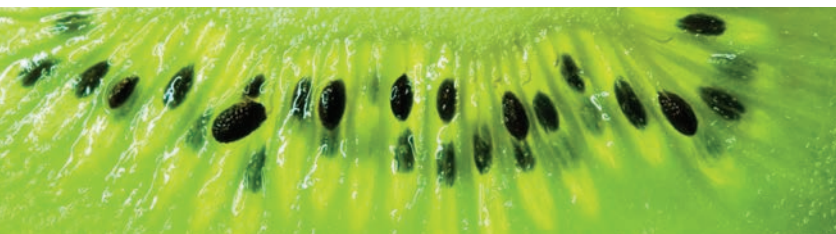
In Australia, enforcing compliance with food legislation is the responsibility of the relevant state, territory and local government agencies. The Department of Agriculture monitors and enforces the Code for imported foods at the border.

In New Zealand, ensuring compliance with the food legislation for both domestic and imported foods is the responsibility of the New Zealand Government.

6. International rights and obligations

Australia and New Zealand must also, as member countries of the World Trade Organization (WTO), fulfil their rights and obligations under WTO agreements, in particular, the Agreement on Sanitary and Phytosanitary Practices (SPS) and the Agreement on Technical Barriers to Trade (TBT).





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

AUSTRALIA

Boeing House
55 Blackall Street
BARTON ACT 2600

PO Box 7186
Canberra BC ACT 2610
Australia

P +61 2 6271 2222
F +61 2 6271 2278
E info@foodstandards.gov.au

NEW ZEALAND

Level 3
154 Featherston Street
WELLINGTON 6011

PO Box 10559, The Terrace
Wellington 6143
New Zealand

P +64 4 978 5630
F +64 4 473 9855
E info@foodstandards.govt.nz