

# FOOD

STANDARDS

Australia New Zealand

## The Analysis of Food-Related Health Risks



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Te Mana Kouna Kai – Ahitereiria me Aotearoa

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## Foreword

Australia and New Zealand have one of the safest food supplies in the world.

Ensuring the safety of food in Australia and New Zealand involves cooperation among government, industry, consumers and health professionals. Within this cooperative arrangement, Food Standards Australia New Zealand (FSANZ) is responsible for maintaining the *Australia New Zealand Food Standards Code* (the Code), which contains standards related to the composition, labelling, safe handling and primary production of foods. These food standards are constantly evolving as new products emerge and new policy guidance is developed. Changes to the Code are gazetted into State, Territory and, in most cases, New Zealand food law generally without variation and thus provide a high level of uniformity across Australia and New Zealand.

The objectives which FSANZ must address in developing food standards are identified in the *Food Standards Australia New Zealand Act 1991*. The most important of these objectives is the protection of public health and safety, and it is this objective which is the focus of this document. The development of new food products, together with changes to consumer lifestyle and eating habits, continue to raise new public health and safety issues in relation to food. An important part of FSANZ's role is assessing and managing these issues through a structured risk analysis process which incorporates scientific, economic, social and policy considerations.

The Analysis of Food-Related Health Risks outlines the broad approach used by FSANZ to analyse the health risks associated with food. I extend my thanks to the experts who peer-reviewed this document and to the staff of FSANZ who contributed. More detailed discussion of the use of risk analysis for particular types of foods, food ingredients, food contaminants, or substances added to food is available in other FSANZ documents.

**Steve McCutcheon**

*Chief Executive Officer*

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## Acronyms and abbreviations

ADI	Acceptable Daily Intake
AI	Adequate Intake
ALARA	As Low as Reasonably Achievable
ALOP	Appropriate Level of Protection
ANZFSC	Australia New Zealand Food Standards Code (the Code)
ANZFRMC	Australia and New Zealand Food Regulation Ministerial Council
APVMA	Australian Pesticides and Veterinary Medicines Authority
AQIS	Australian Quarantine and Inspection Service
ARfD	Acute Reference Dose
ATDS	Australian Total Diet Study
BSE	Bovine Spongiform Encephalopathy
BMD	Benchmark Dose
COAG	Council of Australian Governments
Codex	Codex Alimentarius Commission
DIAMOND	<b>D</b> iet <b>A</b> ry <b>M</b> odelling <b>O</b> f <b>N</b> utritional <b>D</b> ata (FSANZ computer program)
EAR	Estimated Average Requirement
FAO	Food and Agriculture Organization of the United Nations
FDA	Food and Drug Administration of the USA
FSANZ	Food Standards Australia New Zealand
GELs	Generally Expected Levels
HACCP	Hazard Analysis Critical Control Points
IFIS	Imported Food Inspection Scheme
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LO(A)EL	Lowest Observed (Adverse) Effect Level
ML	Maximum Level
MRL	Maximum Residue Limit
NNS	National Nutrition Survey
NRV	Nutrient Reference Value
NO(A)EL	No Observed (Adverse) Effect Level
NRS	National Residue Survey
OBPR	Office of Best Practice Regulation
OCS	Office of Chemical Safety in Department of Health & Ageing
PMM	Post Market Monitoring
PTD(W)	Provisional Tolerable Daily (Weekly) Intake

RDI	Recommended Dietary Intake
SPS agreement	Sanitary and Phytosanitary Measures agreement of the WTO
TBT agreement	Technical Barrier to Trade agreement of the WTO
TSE	Transmissible Spongiform Encephalopathy
UL	Upper Level
WHO	World Health Organization of the United Nations
WTO	World Trade Organization of the United Nations
vCJD	Variant Creutzfeldt-Jakob Disease

# 1 Introduction

There is a community expectation in Australia and New Zealand that food will be safe, and, in general, for most of the people most of the time, this expectation is met. The safety of food, however, is dependent on many factors, not all of which can be controlled through government legislation and regulations. Much of the shared responsibility for food safety lies with the agricultural sector and the processed food industry to ensure that reliable procedures are in place to produce consistently safe primary produce and processed foods. Part of this shared responsibility also lies with food outlets and consumers to ensure food is 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 individual diets. The range and diversity of food available to consumers has greatly expanded in recent decades, as has the interest by consumers in food matters, including the safety of food. As a result, the amount of advice on healthy food choices has also expanded. Although generally well-intentioned, such advice can confuse and, in some cases, mislead consumers. Assessments of the safety of food need to be based on sound scientific evidence, so that consumers can remain confident about the safety of the food supply.

The challenge for food regulators is to maintain a food regulatory system that delivers safe food for the population, enables consumers to make informed choices and also maintains public confidence in the food regulations. Public confidence in the food regulations will depend, firstly, on evidence that there is a low level of risk and, secondly, on assurance that adequate systems are in place to monitor and analyse food, and to respond when situations of potential harm occur. Providing evidence that there is a low level of risk requires a method of analysing food risks that is evidence-based and transparent, and results in effective management strategies which can be communicated clearly to consumers.

FSANZ, using a widely accepted method called *risk analysis*, identifies, assesses and manages food-related health risks within a structured framework. Risk analysis can be used across a broad range of circumstances and can lead to effective management strategies even when the available data are limited. Its use encourages communication between all interested parties including consumers. It can also identify areas where more data are required in order to refine the risk analysis. Risk analysis is used by FSANZ in an open and transparent manner in order to increase community understanding of the decision-making and to encourage an informed debate about the potential health risks associated with food.

The intention of this document is to focus on risk analysis in relation to potentially adverse health effects related to food. In some circumstances, FSANZ must also consider the benefit of certain foods or food ingredients alongside its assessment of risk. This is an emerging area of work and is therefore not considered in the scope of this document. However, it is intended to be included in future reviews of this document.

## 2 Identifying Food-Related Health Risks

### The use of risk-related terms

There is no standardised terminology relating to food-related health risks, which can cause difficulties in describing and communicating the nature of the risk. The Codex Alimentarius Commission has provided some definitions of risk analysis terms (See Chapter 4); however, there are variations in their use globally and there are additional terms used. In this paper, the terms used are described in general terms without providing formal definitions. More detailed discussion regarding terminology can be found in the papers listed in *Further Reading*. The terms *safe*, *risk* and *risk factor* are described in this chapter. Other terms are described in other chapters.

The term *safe* in the context of food generally means there is a reasonable certainty of no harm under the normal conditions of consumption of that food. Contrary to the expectation of some in the community, it does not mean 'no risk', although, in most cases, the risk will be very low and, for most people, will be regarded as acceptable.

The term *risk* in relation to food generally encompasses two elements: the nature of the adverse effect, also described as the hazard; and the likelihood that the adverse effect will occur which in turn is closely related to the likely extent and level of exposure to the hazard. The adverse effect can be immediate, such as gastroenteritis, or long-term, such as development of liver damage or cancer e.g. colon cancer. Adverse effects may also range from negligible to severe, including death, as well as exhibit a temporal dimension. The likelihood can range from negligible to very high.

The term *risk factor*, as used in this document, refers to chemical, microbiological or physical agents found in foods or added to food which may give rise to a potential risk. This term has been used in preference to the term *hazard*, as used by Codex, which is suitable only for microbiological agents, physical agents and chemical contaminants. The term *hazard* is not suitable to describe nutritive substances and food additives and, therefore, the broader term *risk factor* has been used. The term *hazard* is used in some sections of this document relating to chemical and microbiological assessment as it is widely accepted for these scientific disciplines.

## Factors associated with health risks in food

Food risks can result from a broad range of microbiological, chemical or physical factors (see Table 1). Each of these groups of factors can contain a diverse range of agents, many of which are well known, although some are only relatively recently recognised as contributing to food risk. In some cases, factors which can contribute to food risk also provide a benefit to the whole community or to particular groups within the community, either through improvements to food production or processing (e.g. agricultural chemicals or food additives), or to improvements in well-being (e.g. nutritive substances). For these factors, an assessment of the benefits as well as the risks, and achieving an appropriate balance, will be necessary.

**Table 1. Risk factors in food**

Microbiological factors	Chemical factors	Physical factors
Bacteria (Infectious and toxin-producing)	Environmental contaminants	Metal
Protozoa and helminths	Food additives and processing aids	Glass
Viruses	Naturally-occurring toxins	Stones
Moulds	Nutritive substances*	Plastics
	Dietary macro-components*	Wood
	Agricultural and veterinary chemicals	Bones and bone fragments
	Packaging contaminants	
	Allergens	
	Novel food and ingredients	
	Prions	
	Nanoscale materials	

\* Can contribute to benefit as well as risk

### Microbiological risk factors

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, as well as viruses and parasites, also pose an increasing public health risk. A more recent biological risk factor is the prion, a protein infectious agent most notably associated with bovine spongiform encephalopathy (BSE) in cattle and variant Creutzfeldt-Jakob disease (vCJD) in humans.

### **Chemical risk factors**

There are many chemical risk factors associated with foods although, in most cases, these are relatively well regulated. They include chemicals used in primary production, such as agricultural and veterinary chemicals; chemicals which are found naturally in foods, such as toxins; chemicals used in food production, such as food additives and processing aids; chemicals which may contaminate foods such as environmental chemicals or chemicals from packaging materials; and novel food ingredients, nutritive substances or novel dietary macro-components, which are added to foods with the intention of achieving a health benefit, or altering the profile of the final food, such as phytosterols, vitamins or minerals.

### **Physical risk factors**

Physical risk factors may occur in food as a result of contamination through manufacturing and processing failures, such as metal fragments from machinery, although the number of such incidents is declining. In general, these incidents are managed well by food companies and if the food is considered to be unsuitable for human consumption, it is recalled from sale. Food companies may consult with FSANZ or relevant State and Territory Agencies regarding the potential human health risk, if necessary.

### **Unknown risk factors**

In some cases, the identity and character of the factor(s) which result in an increased food-related health risk may not be known. Examples include many of the natural toxins in foods or the proteins in food that cause allergy.

In the case of foodborne illness caused by microbiological risk factors (see Table 1) in particular, new strains of microorganisms and even previously unknown risk factors (such as prions) continue to emerge, and careful analysis of cases of foodborne illness remains an important part of the surveillance of the food supply.

While a lack of understanding of the nature of a particular risk factor may limit the analysis of the health risk, it does not prevent the use of suitable control measures in most cases.

## **Other risks associated with food**

### **Risks associated with new technologies**

When a new technology is used to produce food, an examination may be necessary to determine whether use of the new technology can introduce a new risk factor or increase the presence of an existing risk factor in the food. New technologies that alter the characteristics

of the food, such as genetic modification or food irradiation, may change the composition of the food. New technologies that replace an existing or traditional method of food production can also lead to a change in the levels of a hazard, such as the levels of pathogenic microorganisms, and therefore impact on the overall risk associated with the food.

### **Risks associated with a change in nutrient profile**

Enhancing the nutrient profile of foods through voluntary or mandatory fortification, with the intention of achieving a potential health benefit for a target population group, also has the potential to introduce new health risks. These health risks may include increasing intake of a particular nutrient or a related substance through consumption of the foods or altering consumption patterns to include the fortified foods, which 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 the more vulnerable population groups.

### **Risks associated with novel foods**

Novel foods have the potential to encompass a broad range of foods and food ingredients, including plants and animals and their extracts, single chemicals or macro-components, micro-organisms (including probiotics), food ingredients derived from new food sources, and foods produced by a new process. Analysis of the risks associated with this broad range of foods and food ingredients, some of which may have beneficial properties, will generally require consideration of issues beyond those addressed by the more conventional assessments. In some cases, the normal data used for a risk assessment, such as toxicity tests, may not be available, although in such cases information on composition, metabolism, non-foods use (e.g. use in dietary supplements or complementary medicines), safety of related substances, and history of use in other countries may be sufficient to demonstrate safe use.

### ***Functional ingredients***

While functional ingredients such as phytosterols are added to food to provide a health benefit, it needs to be established that their presence in food does not also inadvertently introduce any new health risks, either as a result of the presence of the functional ingredient itself or by altering the levels of other food ingredients. As the demand for functional ingredients increases and their use in foods becomes more widespread, the analysis of the risk will need to be broadly-based to ensure safe use of these foods. In some cases, monitoring of the levels of the ingredient in the food supply may be necessary to confirm the assumptions used

in the assessment, particularly in relation to potential levels of dietary exposure to functional ingredients.

### **Risks associated with allergenic foods**

Allergenic foods present a special case for risk analysis - the adverse effect is highly specific to sensitised individuals and can range from mild to severe gastrointestinal effects, headaches, respiratory problems or skin reactions to potentially life-threatening anaphylaxis. While there has been a significant increase in our understanding of how factors such as the level of exposure can influence risks associated with food allergy, the main focus of managing these risks by regulatory agencies such as FSANZ has been on providing information, mainly through food labelling, to allow food allergy sufferers to identify and avoid potentially allergenic foods. Research is continuing on better recognition of allergens, on whether a threshold level (a level at which no adverse effect occurs) can be established for known allergens, and on the factors which influence adverse health effects.

### **Risks associated with 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 are generally related to an underlying condition which is aggravated by a relatively high exposure to a particular food or food ingredient. Chemicals which have been associated with such reactions include monosodium glutamate, biogenic amines (such as tyramine and histamine), and salicylates. There is currently little information on the underlying causes and the factors which can influence the prevalence and severity of food intolerance. As with food allergy, management of risks by regulatory agencies such as FSANZ has focused on providing information via food labelling to allow individuals with a food intolerance to avoid foods which contain agents that may cause intolerance.

### 3 General Approaches To Food-Related Health Risks

#### Recognising traditional foods and production methods

The foods that are currently consumed in Australia and New Zealand are a mix of foods that have been traditionally consumed for many generations, together with new foods from other parts of the world and foods that have been more recently developed using new technologies. The views of the community, and of individuals within the community, as to whether these foods are 'safe' is influenced by many factors, such as the nature of the food, its history of use, its acceptance by others, its method of production, and whether its safety has been adequately established using formal tests. Thus, foods, including food ingredients, are accepted or not accepted by the community based on a perceived level of risk, which may be different for different groups or individuals within the community. Generally, foods that have a history of safe consumption provide the highest level of public confidence.

Foods such as meat and fish, commonly used cereals, dairy products, tinned foods, and conventionally produced fruit and vegetables, are generally considered safe as long as well-established manufacturing practices are followed. Some traditionally-consumed foods, such as red kidney beans and even potatoes, can carry an inherent health risk, but such risks are accepted because the food industry and the community know how to mitigate this risk 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 practices. In other cases where there is an inherent risk, such as the presence of food allergens, controls are not so easily implemented, but ingredient labelling can assist vulnerable consumers to identify foods unsuitable for them and minimise any health risk. Unavoidable contaminants, such as mercury in fish, may be a risk to certain groups in the population, in particular, unborn children if the mother consumes high levels of certain fish species during pregnancy. In this case, providing a maximum level (ML) for mercury in fish in the Code and advice on limiting consumption of certain types of fish (but not avoiding fish consumption altogether) is the appropriate risk management approach. These cases illustrate that many foods while providing nutritional benefits also carry some level of health risk. Ensuring the safety of food, even with traditionally-consumed foods, relies on an adequate level of consumer knowledge and appropriate behaviours, in addition to strict industry practices and a rigorous food regulatory system.

## Assessing new foods, additions to food, and new production methods

Under the 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 this case, it is reasonable, that some level of assessment of the safety of the food or ingredient is performed. For food additives and processing aids, there are well-established and uniformly applied safety assessment procedures. For other substances added to food, such as nutritive substances and novel ingredients, general guiding procedures exist. However, each substance is considered on a case-by-case basis. For foods not traditionally consumed or foods from other parts of the world (e.g. native bush foods), the safety assessments rely largely on compositional analysis and a demonstrated history of safe use. For foods produced by new technologies (e.g. irradiated foods or genetically modified foods), safety assessment procedures have been elaborated that examine the methods of production as well as compare the composition of the new foods to conventionally produced foods.

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

## Taking a whole-of-chain view of food production

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 to safe food has enabled the identification of risk factors at each step in the food production process and for controls to be put into place at various production steps to reduce risks associated with the final food. The HACCP (hazard analysis and critical control points) approach to food safety, which identifies and addresses physical, chemical and microbiological hazards in a preventative manner, has led to the development of food safety plans for food industries and business. This approach has been instrumental in identifying unsafe practices and reducing reliance on end-product testing for chemical or microbiological hazards prior to 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 a variety of control measures. This equivalence approach can ensure food safety without unnecessarily hindering innovation in the food industry.

### **Recognising and balancing risks and benefits**

In assessing food risks, there is a need to ensure that the benefits of a nutritious and well-balanced diet are recognised. Circumstances may arise however, where the risks associated with a particular food constituent outweigh the benefits of consuming that food or food constituent for all consumers or for particular individuals or population groups.

For some, if not most foods, low levels of undesirable chemicals or microorganisms may exist without causing any appreciable health risk. In such cases, it is appropriate to use the ALARA principle (as low as reasonably achievable), without removing the food completely from the food supply. In some cases, it may be necessary to provide advice on reducing the consumption of particular foods by some population groups. In the case of microbiological risks, there are many techniques used to reduce the potential microbiological load of food, including the use of preservatives. The generally low level of health risk associated with techniques, such as the use of preservatives, needs to be weighed against the risk associated with the presence of pathogenic microorganisms and the potential for an outbreak of foodborne illness.

In the case of nutritive substances or other novel substances that are added to foods to achieve a purported health benefit, there is a need to ensure that over-consumption of these substances or the displacement of other foods does not lead to an unbalanced diet and thus raise new safety concerns.

### **Maintaining vigilance of the food supply**

Ensuring safe food requires constant vigilance and a pro-active approach to control both known and emerging health risks. Factors in food which lead to known health risks require monitoring to ensure that the established controls are in place and are effective. Emerging health risks, on the other hand, are by their nature less well characterised and therefore difficult to monitor. While not all food-related health risks can be identified before they occur, ongoing research and development in the food industry and elsewhere, as well as active surveillance of foods and investigation of foodborne disease outbreaks, can assist in identifying some of the potential emerging risks. FSANZ plays a significant role in ensuring the safety of food including setting food regulations and conducting surveillance, monitoring and evaluation activities.

The use of certain food components (e.g. food additives), as well as the use of certain food technologies (e.g. irradiation), according to some consumers, contributes to an increase in food-related health risks, despite a lack of supporting scientific evidence. Consumer's perception of risk can be influenced by many factors, including their level of knowledge and understanding of the issue, as well as an individual's level of acceptance of the potential perceived benefit. Perceptions regarding food risks can change slowly over time as new information becomes available. Thus, studies which investigate the linkages between food and health outcomes can be important in changing perceptions and in providing reassurance regarding the safety of food.

## 4 Addressing Food-Related Health Risks

### Risk analysis

Underlying the general approaches to ensuring safe food discussed in Chapter 3 is the need for a systematic approach to examine and assess the public health and safety risks associated with food, and to formulate, implement and communicate risk management decisions. This approach is generally described as *risk analysis*.

Risk analysis is comprised of three distinct but interrelated components namely *risk assessment*, *risk management* and *risk communication*. The components of risk analysis are discussed briefly below and in more detail in Chapters 5, 6 and 7 of this document.

**Risk assessment** involves a science-based approach that utilises experimental and other available data to characterise the risk and arrive at a conclusion regarding the potential risk associated with a food or food ingredient.

**Risk management** assists in defining the risk assessment scope and questions to be addressed, considers options for managing identified food risks in the broader context, taking into account the potential benefits of the food as well as relevant policy, consumer behaviours and economic issues associated with use of the food.

**Risk communication** is the interactive exchange of information and opinions regarding risks, risk-related factors, and risk perceptions among all concerned parties, or stakeholders, throughout the entire risk analysis process. It is an ongoing process that engages stakeholders and the public in decision making to the maximum extent possible. Risk communication is also important to assist in bridging the gap which sometimes exists between the scientific assessment of the health risk and consumers' perception of the health risk.

### The use of risk analysis frameworks

Risk analysis frameworks are a structured way of examining and incorporating the wide variety of factors that impact on a decision-making process, and are widely used in the health sector. There is no single framework which works for all scenarios where there are risks to human health, and, in this regard, food risks may raise issues which are different to other types of health risks. A range of different risk analysis frameworks can be used to consider different food risks. Flexibility and adaptation, therefore, are necessary in using risk analysis frameworks to assess and manage risks.

The risk analysis framework described in this Chapter provides a systematic approach to address food-related health risks, and although its use will vary in particular circumstances, the elements of this framework are applicable across the food chain. One of the important aspects of such a systematic analysis of risk is that both the strengths and weaknesses of each step can be openly discussed and debated. A flexible approach can be taken to deciding what additional data would assist in applying the risk analysis framework to a particular food-related health risk.

### The Codex risk analysis framework

The *Codex Alimentarius Commission* (Codex) was formed in 1961/2 through the *Food and Agriculture Organization* (FAO) and the *World Health Organization* (WHO). Its function is to develop 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 to ensure fair practices in food trade.

Codex has developed a risk analysis framework to guide its work in relation to food safety. This framework sets out an approach for evaluating the potential risk associated with what it describes as food-borne hazards, and for assessing ways of managing any identified risk<sup>1</sup>. The framework also takes into account the need for communication between those involved in risk analysis as well as communication to stakeholders, such as consumers, public health professionals and government agencies. The Codex framework for food risk analysis has three components which are defined as follows:

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

**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 options.

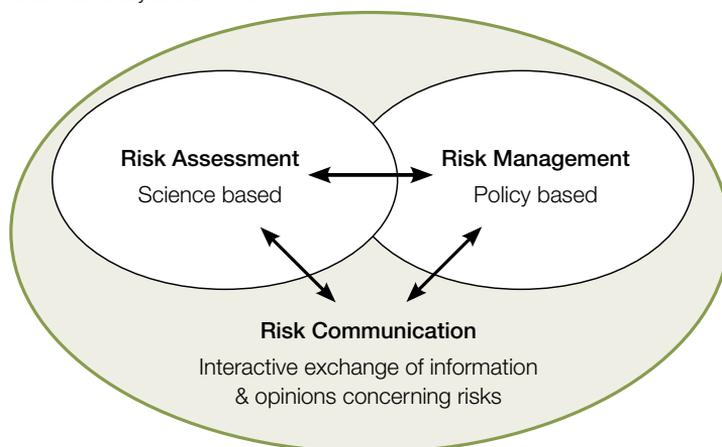
**Risk communication:** The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors, and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation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

<sup>1</sup> Although the Codex risk analysis framework sets out an approach for elaborating food-borne hazards, this was not elaborated specifically for whole foods. 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 focuses on identifying new or altered hazards relative to existing conventional foods, with any identified hazards becoming the focus of further assessment.

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 is extending its work on risk analysis to include development of nutritional risk analysis principles and guidelines. Such work, presently in draft, contributes to the objective of the aforementioned 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.

Figure 1. The Codex risk analysis framework<sup>2</sup>



## The FSANZ approach to risk analysis

### Working within the Codex framework

The approach to risk analysis used by FSANZ is based on the general framework endorsed by Codex, although the diversity of issues under consideration requires some flexibility in the terminology used to describe parts of the process. The Codex framework is essentially a decision-making framework that allows separation of the scientific aspects of risk analysis from the broad range of factors which impact on the ultimate risk management decisions. While the Codex framework defines the risk management process as primarily policy-based, within FSANZ it is recognised that scientific approaches may also be used to inform the selection of risk management options. In this broad sense, the FSANZ approach to risk analysis is consistent with the Codex framework.

<sup>2</sup> URL <http://www.who.int/foodsafety/micro/riskanalysis>

A second aspect of the Codex framework is a description of the four steps of risk assessment. While these steps were used widely for chemical risk factors prior to their endorsement by Codex, the four-step process is now widely accepted and forms the basis of FSANZ's risk assessment procedure for a range of risk factors. Its application in specific circumstances, however, may vary, depending on the nature of the risk factor and its relationship to the food.

### **Underlying principles**

The broad range of food-related risks necessitates a variety of approaches to risk analysis. It is necessary therefore to have guiding principles that ensure consistency between these different approaches. Some of these are discussed below:

#### *Use the best available data and methodologies*

Scientific, economic and other data and information come from both published and unpublished sources, but in both cases, data should be of high quality, credible and objective. Critical evaluation of the available data is an essential element in establishing the basis for the safety of food and subsequent risk management decisions. Where possible, collaboration with other experts or organisations, both national and international should be sought.

#### *Recognise uncertainty in risk analysis*

It is inevitable that decisions in relation to the safety of food will be made in the presence of scientific uncertainty (see Chapter 5 for further discussion). In deciding on the risk management options, it is appropriate to recognise, document and address scientific uncertainty. Depending on the level and nature of uncertainty, a cautious approach to proposed changes to current food regulations may be taken to ensure that the overall risk remains low. On the other hand, uncertainty in the scientific data should not be used as a reason for inaction when there is reasonable evidence to indicate a potential health risk.

#### *Tailoring the risk management approach to the risk*

In managing food-related health risks, 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 risk. In deciding on the risk management approach, 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. Another factor influencing the level of protection in a particular case will be the level of risk which is acceptable to the community.

### *Involve interested and affected groups*

The involvement of groups which have an interest in the outcome of a risk analysis can enhance the process through the provision of scientific data, by identifying relevant social, ethical and economic factors, and by suggesting alternative management approaches. While the process and rules for such involvement need to be clear, involving interested and affected groups can provide opportunities for building trust as well as helping to lend credibility to the ultimate risk management decisions leading to their successful implementation.

### *Communicate in an open and transparent manner*

Documents outlining risk management options prepared in relation to food-related health risks should generally be publicly available and public submissions on these documents taken into account in the regulatory decisions. Confidential commercial information should be protected but, in general, data that support the safety assessment of the food are not considered confidential. Dialogue with industry, consumers and health professionals on food regulatory matters is integral and is facilitated, including encouraging our 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 and it is necessary to examine the impact of the regulation after a certain period, to ensure that the predicted outcome was achieved and/or that the assumptions used in the assessment were correct. Surveys of the food supply and key groups affected by regulatory changes, such as the food industry, health professionals, enforcement officers or consumers, can generally provide information to evaluate the outcome and determine whether further regulatory action is required.

### **Application of risk analysis**

FSANZ uses risk analysis across a range of situations where food risks need to be assessed and managed, namely:

- in the development of new standards for whole classes of food commodities, such as the primary production and processing standards for seafood and dairy;
- to evaluate existing standards through specific surveillance activities or through on-going monitoring of the food supply. Such survey work can lead to changes to existing standards or other risk management measures if specific health risks are identified;

- to evaluate proposed changes to existing 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; or to approve the addition of a nutritive substance to food;
- to evaluate current food technology practices, if necessary, or changes to current food technology practices, or the impact of new technologies;
- to address questions of the safety of food that arise from unexpected risks in domestic and imported food, which can occur as a result of a failure in food safety control systems; and/or
- to evaluate or change current or proposed food labelling standards.

When considering the development of a new standard or a significant change to an existing standard, a detailed risk analysis will be undertaken. This will be carried out according to FSANZ's statutory timeframes which are designed to allow time for a comprehensive analysis of the available information, and in some cases, to generate new information.

### **Scoping the food-related health risk**

In considering a particular food-related health risk, preliminary activities are undertaken to better understand the nature of the issue and determine the most appropriate way forward. These activities are variously termed *Problem formulation* (Codex terminology) or *scoping* and assist in:

- (i) defining and describing the food-related health risk and its context;
- (ii) identifying the availability of data to undertake a risk analysis;
- (iii) identifying interested and affected groups;
- (iv) identifying related consumer behavioural and economic factors;
- (v) identifying the questions to be answered by the risk assessment;
- (vi) identifying the goals and objectives of the risk management activity;
- (vii) considering possible regulatory and non-regulatory options; and
- (viii) considering the availability of resources to address the issue.

Scoping an issue provides the opportunity to undertake a preliminary analysis using readily available data. This is important in order to understand the magnitude of the problem, the potential health risks, and the consequences of the various options. Scoping is an essential

step to allow prioritisation of different food-related health risks to be considered and to determine the level of risk assessment required, given the resources available.

### **Identifying and gathering data**

The identification and gathering of data can come from many sources. FSANZ uses a variety of sources of such information including data obtained from FSANZ's own surveys as well as external sources such as overseas studies, data generated or obtained by other government agencies (domestic or international) and industry data. Data obtained from various sources assists in identifying those foods which may present a public health risk. Survey activities can also provide important information on the nutrient composition of food that can be used to assess the nutritional status of population groups.

#### *Specific FSANZ surveys*

FSANZ may lead or undertake specific surveys for various reasons such as:

- (i) to investigate possible food risks in relation to local or imported food;
- (ii) to investigate reports where there may be a potential public health risk;
- (iii) to provide evidence for domestic standards where revisions to reference health standards may have occurred;
- (iv) to gain more background data on a particular issue;
- (v) to support the standards development process; or
- (vi) to monitor levels of certain ingredients/substances in the food supply.

These surveys may be in relation to composition, microbiological data or food chemical data. Some surveys are conducted on an ongoing basis and at regular intervals e.g. the ATDS. Specific surveys on particular chemicals (e.g. dioxins, benzene, chloropropanols or caffeine) or microbiological agents (e.g. pathogens in sesame products, soft noodles, or fresh horticultural produce) are conducted as required and where resources allow.

Additionally, surveys of consumer behaviour are conducted where the existing evidence is insufficient for risk assessments. These may relate to individuals consumption or other behaviours that may influence the level of a health risk.

FSANZ is also responsible for the national food composition database and commissions analytical work to update and develop the database on the nutrient content of Australian foods.

<http://www.foodstandards.gov.au/monitoringandsurveillance/foodcompositionprogram/index.cfm>

### **Prioritising the food-related health risk**

Many factors may influence the prioritisation of food-related health risks, including political 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 that are added to food. In these cases, the timelines for assessment are pre-determined, such as where FSANZ statutory timelines apply. Prioritisation becomes important for issues that are identified reactively, such as the unexplained presence of contaminants in food or concerns related to a new technology.

The scoping step should provide preliminary information on, firstly, the likelihood (or probability) of an adverse event occurring and, secondly, on the consequences (severity) of such an event. The likelihood of an event will be influenced by the effectiveness of existing regulations or other risk management measures. The consequences will be influenced by both the nature of the potential adverse 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 risk management measures are in place; or
- undertake a more detailed risk assessment to determine the magnitude of the potential health risk, while applying an interim and conservative risk management approach; or
- take immediate steps to manage the significant health risk associated with the food, while undertaking a more detailed risk assessment.

### **Review and evaluation**

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

### Responding to rapidly emerging issues

When considering an unexpected food safety issue, 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 very rapid, alerting both food regulators and consumers, often at the same time.

The general principles of risk analysis are applicable to responding to rapidly emerging issues. However, time constraints may impact on the sequence of steps undertaken within this framework which will be determined on a case by case basis and the information available. Additional effort may be made to rapidly assess the potential impact of the food safety issue on the population in order to establish a targeted risk assessment approach. This risk assessment approach may be tailored to address any immediate public health and safety concerns, and to rapidly address gaps in the available data that are critical for characterising the risk. Where a cautious approach is required, despite the absence or paucity of data, provisional risk management measures may be applied and revised later as new information becomes available. If action is required on a national basis, the National Food Incident Response Protocol may be used to coordinate action at the national, State and Territory or local levels. [http://www.health.gov.au/internet/main/publishing.nsf/Content/CDA339ACBEE60CF8CA25709600193198/\\$File/response.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/CDA339ACBEE60CF8CA25709600193198/$File/response.pdf)

The need for global action on food-related issues has long been recognised. The International Food Safety Authorities Network (INFOSAN) is a network established by the WHO and FAO to promote the exchange of information and to improve collaboration among food safety authorities around the world. FSANZ is an active participant in international fora that consider risk analysis principles, establish food standards and monitor the food supply, as well as providing training in these matters to countries in the region. The approach to risk analysis and the principles underlying its use are thus becoming more uniform across countries.

## 5 Assessing Food-Related Health Risks

### Risk assessment in a food context

Risk assessment in relation to food involves assessing the likelihood that a specific adverse health effect will occur in individuals or in a population as a result of consuming food. The breadth of the assessment will depend on the circumstances, particularly the urgency of the issue, the potential severity of the adverse effect, and the likely number of affected individuals in the population. Thus, risk assessment can be used in a broad range of scenarios such as examining the impact of an unexpected microbiological or chemical contaminant or ingredient, examining the impact of a new food technology, evaluating a new food additive or novel food, or establishing a standard for a whole food sector e.g. developing primary production standards.

Risk assessment is that part of risk analysis that examines the scientific data on a particular physical, chemical or microbiological hazard in food. This generally includes data from laboratory investigations (toxicological or microbiological studies) or human epidemiological studies when available, as well as data on the level of exposure from dietary and other sources. Combining these sets of data provides the risk assessment outcome, which may take the form of a quantitative assessment of the risk or a qualitative expression of the risk. Commonly, comparative benchmarks are used to express a qualitative assessment of the risk. In some cases, particularly in relation to microbiological risk factors, quantification of the risk may be possible if good exposure data and dose-response information is available, although many factors can influence such estimates.

Thus, the way in which risk assessment is used for chemicals, microbiological agents and nutritive substances in foods, or for foods themselves, differs in some details, but the overall process is similar in each case. However, the way in which the risk is expressed will vary. The language of risk assessment is still evolving and although there is some commonality, many differences still exist within and between agencies.

The overall goal of risk assessment is to understand the risks associated with a particular food or food ingredient. This includes the nature of the known or potential adverse health effects, an estimate of the likelihood of occurrence (however this is expressed), the identity of the population at risk, and an examination of the uncertainties in the available data.

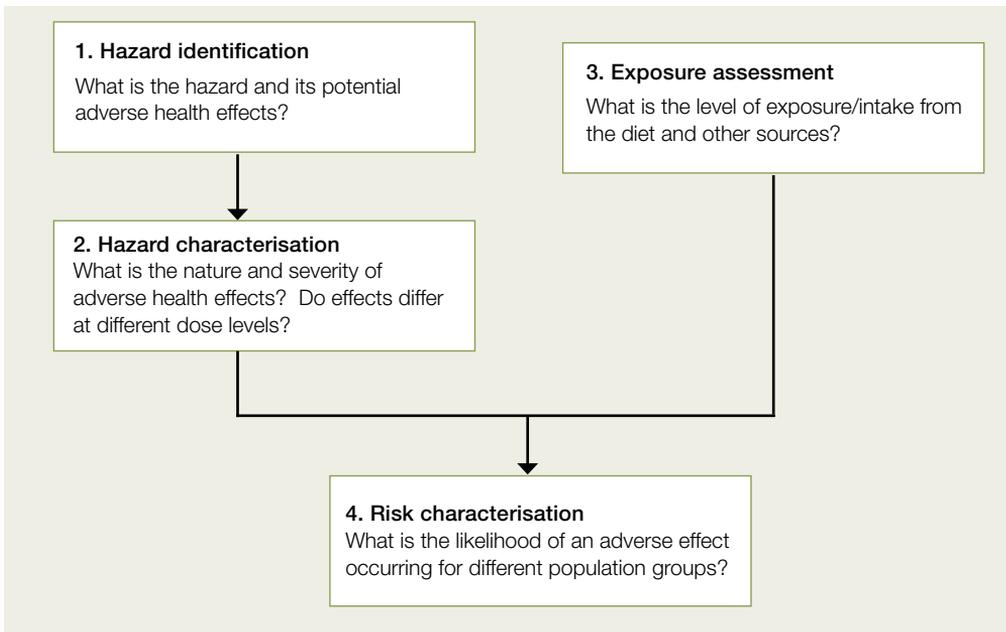
Inferring a level of human health risk from the available scientific data requires both scientific judgement and policy choices regarding the use of the available data. This process is

sometimes called *risk assessment policy*, and refers to the agreed policy on how to use limited scientific data to make regulatory decisions. Examples include matters such as (i) the use of safety (or uncertainty) factors to account for species differences and human variability; (ii) the use of 90<sup>th</sup> or 95<sup>th</sup> percentile dietary exposure levels to represent high level consumers; and (iii) the use of a margin-of-exposure approach to assess the risks associated with genotoxic carcinogens.

### Steps in risk assessment

The risk assessment process used by FSANZ follows the Codex model and involves four stages, namely, hazard identification, hazard characterisation, exposure assessment and risk characterisation<sup>3</sup>. These four stages are shown in Figure 2 and described in more detail below. Sometimes, the first two steps are merged together and referred to as a hazard assessment.

Figure 2. The four steps in risk assessment



<sup>3</sup> The exception to this is in the case of genetically modified foods, where a modified form of risk assessment is applied. Further information on the safety assessment for genetically modified foods can be obtained from the FSANZ Guidance Document on the Safety Assessment of GM Foods.

## Hazard identification

The first step in risk assessment, hazard identification, seeks to identify the potential hazards that may occur as a result of the presence of the risk factors in food, which were described in Chapter 2. Chemical risk assessment focuses on the *hazard* as an intrinsic property of the risk factor, such as the ability to cause cancer, allergy or organ damage, which will only be evident under certain conditions of exposure. Microbiological risk assessment focuses on the *hazard* as the risk factor itself, the likelihood of its association with food, and the consequences of its presence, such as infectious disease or gastroenteritis.

The level of exposure will be the major, but not the only, factor in determining whether the hazard associated with a risk factor will manifest in a particular situation. For those chemical risk factors which also provide a benefit in food, the identification of the potential hazards and their relationship with exposure are critical in balancing the risk and benefit. While for most risk factors in food, an increased level of risk is associated with an increased level of exposure, for nutritive substances, a hazard can also occur if the exposure is too low, although in this case, the hazard is not linked with an intrinsic property of the nutritive substance, but with the absence of adequate amounts of the nutritive substance.

In all cases, hazard identification involves examining the available scientific data on the nature of the chemical, microbiological or nutritive substance, evaluating the epidemiological, toxicological or other data used to identify the potential hazard, and, if possible, investigating the mechanism by which the risk factor is responsible for the observed hazard.

In the case of a new food, such as a novel food, genetically-modified food or an irradiated food, hazard identification generally involves an examination of composition of the food, including the presence of natural toxins, allergens and pathogens, together with an examination, in some cases, of the method of production or processing of the food. Production and processing may introduce new risk factors or change the levels of existing risk factors.

### *Chemical risk factors*

For chemical risk factors, hazard identification usually involves extensive examination of animal and *in vitro* toxicity studies or, in some cases, epidemiological data, in order to identify the potential adverse effects of the chemical. Structure-activity relationships and *in vitro* studies may also be useful. The term 'toxicity' is often used to refer to a hazardous property of the chemical and its ability to cause adverse effects when present in food at a particular level. In reality, extensive toxicity data are generally only available for certain types of chemicals in

food, such as food additives, since these require pre-market approval and are sponsored by the food or chemical industry.

The availability of data on the safety of novel food ingredients has increased in recent years, as a result of a requirement for pre-market approval in Australia/New Zealand and in other countries. For other chemicals, such as contaminants and natural toxins, both the amount and quality of the available toxicity data are variable.

For most chemicals associated with food, the principal adverse health concerns are those resulting from long-term exposure, although short-term exposure may be a concern for some contaminants, natural toxicants and for residues of certain agricultural chemicals.

#### ***Nutrient risk factors***

For nutrient risk factors, hazard identification usually involves an examination of data primarily from human studies and experience. A wide range of data may be examined including epidemiological data, clinical and other studies that demonstrate physiological and biochemical effects and response. For nutrients, the principal adverse health concerns are those resulting from long-term excessive or deficient intakes.

#### ***Microbiological hazard identification***

Describing microbiological hazards is more complex due to the broader range of factors that may influence the associated health risk. For microbiological risk factors, hazard identification involves reviewing microbiological, clinical and surveillance data, as well as epidemiological information. Scientific information is obtained on the hazard, its preferred growth conditions and factors within the food which may influence the hazard's growth, survival or death. Surveillance and epidemiological data may assist in identifying the foods most commonly associated with the hazard, the likely level of exposure and mode of transmission, as well as identifying any susceptible populations. An analysis of the adverse health outcome including the nature and severity of the illness is also considered. For microbiological hazards, the adverse health outcomes are normally short-term, such as gastroenteritis, but may develop into serious long-term illness or systemic disease.

#### **Hazard characterisation**

Hazard characterisation seeks to define the parameters that may influence whether the identified hazard will result in a health risk under the expected levels of exposure – this is often referred to as a dose-response assessment, particularly for chemicals and nutritive substances, since the level of dietary exposure/intake is the major parameter influencing the

health risk. For chemicals and nutrients, factors that influence bioavailability, such as the food matrix or consumption of other foods within the same meal, will also impact on the potential health risk, as well as other factors such as metabolism and the mechanism of toxicity. For microbiological hazards, the relationship between dose and response is even more complex and a number of other factors need to be considered. The severity of the adverse effect can be influenced by strain and subtype variability, by food production, processing and storage, the food matrix in which the hazard is present as well as host factors such as immune status.

For both chemical and microbiological risk factors, hazard characterisation will identify the critical health effects associated with exposure; if possible, establish a dose-response relationship; and the most appropriate dose-response model if extrapolation to the normal exposure level is required.

### *Chemical risk factors*

For chemicals such as food additives and agricultural and veterinary chemical residues, there is generally reasonable information on the level of absorption from the gastrointestinal tract as well as the fate of the chemical in the body, including its metabolism, rate of excretion and whether it accumulates in particular organs. In some cases, the mechanism by which it causes toxicity is also partially understood. Effects that are observed in just one animal species may be the result of a species-specific mechanism that is not observed in humans. For contaminants and for nutritive substances, the amount of available information is likely to be less. When more information is available, there will be a better understanding of why and how a particular adverse health effect occurs and the factors that can influence its severity. However, a characterisation of the hazard associated with the chemical can be undertaken with limited animal toxicity data and data on dietary exposure, as long as the uncertainties in the data and the assumptions used are acknowledged.

For most chemicals, it is generally accepted that a level of exposure, known as a threshold level, exists below which adverse health effects do not occur, largely due to homeostatic mechanisms that maintain cellular equilibrium. Hazard characterisation focuses on establishing, if possible, a 'safe' level of exposure; that is, a level below this threshold level of exposure, generally referred to as the 'reference health standard'. For the majority of chemicals, reference health standards are established on the basis of toxicity studies conducted in experimental animals. These studies use a range of dose levels to identify the dose at which adverse health effects do not occur – the so-called no-observed-[adverse]-effect level (NO[A]EL). The NOEL or NOAEL is the highest-dose level that produces no observed adverse effects in the most sensitive test species. In a small number of cases, and

particularly for nutritive substances, the NOEL may be based on human studies. Where toxicity studies conducted in animals are available, the appropriateness of the experimental model to examine a toxicological end-point considered relevant for humans, should be considered. In order to establish the reference health standard based on the NOEL, it is necessary to use 'safety' (or 'uncertainty') factors to address (i) the uncertainty introduced by using animal models to predict human adverse effects; (ii) the uncertainty caused by the inevitable variability in the response of individuals in the population to a chemical hazard; and (iii) the uncertainty introduced by using incomplete toxicity databases. The overall size of the safety factor applied is determined on a case-by-case basis; however, a factor of 100 is generally applied when the NOEL is determined from adequate long-term studies in animals (derived from a factor of 10 applied for animal-to-human extrapolation, and a factor of 10 applied for individual variation in the human population).

An alternative to the NOEL approach is to make use of dose-response modelling to determine a so-called 'benchmark dose' or 'BMD', (which may also be expressed as the BMDL which is the lower confidence limit of the BMD), which is a level corresponding to a pre-determined increase (usually 5 or 10%) in a defined effect. The benchmark dose approach can be used broadly but has been particularly useful for chemicals which are considered to be genotoxic and carcinogenic, since, in these cases, a threshold of toxicity cannot be readily identified.

The reference health standards commonly used are the 'acceptable daily intake' or 'ADI' (for food additives or agricultural and veterinary chemical residues), the 'provisional tolerable daily (weekly, monthly) intake' or 'PTDI (PTWI, PTMI)' (for contaminants). For agricultural and veterinary chemicals and sometimes for contaminants, the 'acute reference dose' (ARfD) is also used to estimate the amount of a residue of an agricultural chemical that can be ingested over a short period of time, usually during one meal or one day, without appreciable health risk to the consumer. The reference health standards or the benchmark dose levels are used in the risk characterisation step of the risk assessment to compare with the estimated dietary exposure levels.

In the case of novel food ingredients, the nature of the adverse effect to be examined in humans, such as the gastro-intestinal effects of novel carbohydrates, will require a careful consideration of the appropriateness of the animal model used. In some cases, establishing a reference health standard may not be possible due to a paucity of data. In these cases, factors such as composition, method of production, history of safe use in other countries, potential for toxicity in humans, and routes of metabolism become important considerations in characterising the potential hazard.

### *Nutrient risk factors*

For some nutrients, a range of reference health standards or nutrient reference values (NRVs) have been set for use in individual or population assessments for Australian and New Zealand populations, to assess both the risk of nutrient inadequacy and the risk of adverse effects from excessive nutrient intake (NHMRC 2006). FSANZ uses Australia New Zealand NRVs in assessing the risk to population groups. Comparisons of estimated nutrient intakes with the Estimated Average Requirement (EAR), where they exist, are used to examine the probability that a group's usual intake is inadequate. Comparisons of nutrient intakes with an Upper Level of Intake (UL), where they exist, are used to assess the probability of excessive intakes and potential risk of adverse effect. These results are considered together with other data, where available, that support or otherwise provide evidence of health impacts.

### *Microbiological hazard characterisation*

For microorganisms, a dose-response relationship generally exists, describing the relationship between the number of microorganisms ingested and the frequency of the associated adverse health effects. However, issues such as strain variability and host susceptibility provide an increased level of complexity. An additional factor that is particularly relevant to microbiological hazards is the food matrix, which may influence the ability of the microorganism to survive the hostile environment of the stomach.

The infectious disease process following exposure to a microbiological hazard is complex. Each organism ingested is assumed to have a distinct probability of surviving barriers 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 (either acute, chronic or intermittent). Although most commonly associated with gastroenteritis, exposure to pathogens can result in sequelae (long-term illness) and, in some cases, death.

For a limited number of pathogenic microorganisms, dose-response data have 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. Alternatively, dose-response data may be based from epidemiological studies, in-vitro studies or animal studies.

The output from a hazard characterisation is an estimate of the likelihood of an adverse health effect arising in the population.

### **Exposure/intake assessment**

Exposure or intake<sup>4</sup> assessment seeks to provide an estimate of the magnitude, frequency and duration of exposure to the risk factors found in the environment. Generally, this is restricted to dietary exposure but ideally exposure from all sources would be included in an exposure assessment. If possible, a quantitative estimate is sought, although in some cases, the estimate may be qualitative.

Food consumption data from National Nutrition Surveys (NNS) data, supplemented by other sources of consumption data in some instances, are combined with food chemical or nutrient concentration data to estimate dietary exposures for a 'population based' assessment.

At FSANZ, dietary exposures are estimated 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, contaminants, novel food ingredients, agricultural and veterinary chemical residues and nutritive substances. There are several sources of both food consumption data and food chemical data, and also several methods of integrating the two data sets to estimate dietary exposure. The method used will depend primarily on the purpose of the dietary exposure assessment, the food chemical, and the data available (see below).

Although the framework for assessing dietary exposure is similar for both chemical and microbiological hazards, there are complexities unique to the way risks associated with exposure to microbiological hazards are assessed. Because microbiological hazards can grow, survive, or die in food, how food is produced, processed, stored and prepared will affect the amount of hazard present in the food. Various models for the quantitative assessment of microbiological agents are being developed around the world and FSANZ is working with other countries through the WHO to develop a model which will be internationally accepted. The current method for undertaking exposure assessment for microbiological agents is discussed below.

### ***Food consumption data***

Australia and New Zealand both conduct NNSs under the auspices of respective health departments. The Australian 1995 and 2007 children's and the New Zealand 1997 adults

<sup>4</sup> For nutrient risk assessments the term *intake* is used instead of *exposure*, however for the purpose of this section the term *exposure* is used to cover chemical, microbiological and nutrient dietary assessments.

and 2002 children's NNS's collected data on food and beverage consumption using a daily food consumption (24hr recall) method. A single 24hr recall record was collected from all participants in each survey, with a second 24hr recall being collected for 10-15% people, with the exception of the 2007 children's survey when a second 24hr recall was collected from every child in the survey. In the 2002 and 2007 children's surveys, supplement use was also recorded. A food frequency questionnaire may also be used to assess the usual frequency of food consumption over the previous 12 months and has been used in some, but not all, these NNSs.

FSANZ also commissions consumption and consumer behaviour surveys from time to time to fill evidence gaps. This is particularly important where new products have entered the market since the last NNS was carried out or where the NNS contains limited data for use in specific dietary exposure assessments.

The food industry can also provide data on market size, profile and market share data for different food product categories. These data are commonly used to ensure that the most representative foods are sampled in analytical surveys and to revise consumption information where changes in consumption patterns may have occurred since the last NNS, or where more distinction within specific food product categories is needed.

#### *Food chemical and nutrient data*

Data on the concentration of chemicals and nutrients in food are derived from different sources depending on the purpose of the assessment. Food additive, novel or other ingredient concentrations can be derived from the Code (maximum permitted levels), manufacturers' use levels or analytical survey data. For agricultural and veterinary chemical residues, maximum residue limits from the Code can also be used, or alternatively, data from agricultural trials of the chemical on crops or in animals or analytical surveys. Data on the concentration of nutrients in food are available from food composition databases (the Australian nutrient database (NUTTAB); the New Zealand food composition database, NNS survey databases) or directly from specific analytical surveys. Data on other nutritive substances, such as amino acids or nucleotides, may be more difficult to obtain.

For contaminants, the maximum levels in the Code are not normally used for dietary exposure estimates as they tend to grossly over estimate dietary exposure. Data on food contaminant concentrations can be difficult to obtain because contaminants are not normally intentionally added to foods, however, data can be obtained from analytical surveys, including total diet studies. Various factors can influence the extent of contamination, such as geographical and climatic conditions, agricultural practices, local industrial activity and food processing, food

preparation and storage practices. Dietary exposure assessments for contaminants, usually take the whole diet into account, however, for some contaminants the data on concentration levels are not extensive and may not cover all foods likely to contain the contaminant at low levels.

### *Dietary exposure estimates*

The nature of the food chemical and hazard it poses will determine what type of dietary exposure estimate is undertaken, for example 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 only (eaters of the foods containing the chemical), for high consumers and/or for specific population sub-groups.

The total diet studies conducted in Australia and New Zealand are examples of special dietary exposure estimates where the concentration of the food chemical is analysed in the food as consumed. Estimated dietary exposure to a range of pesticide and veterinary drug residues and contaminants in the food supply, as well as dietary exposures to nutritive substances and food additives may be reported in the total diet study, (more information on total diet studies is provided in Chapter 6).

The dietary exposure estimate may take account of the market share that a food containing a specific chemical has in the relevant food category, for example, the proportion of fruit juice that is fortified with a nutrient of interest. Market share information is used to estimate dietary exposure to a food chemical for a population over a period of time. Past and present market share information for foods, where there appears to have been a significant change in consumption in recent years, can be very useful for specific dietary exposure estimates. For example, changes to the proportion of milk consumed that is full, semi and low fat milk may be taken into account in estimates of fat or energy intakes. The proportion of the food group in which the added food chemical such as a food additive or novel food ingredient is proposed to be used may also be used in the calculation to obtain a more realistic estimate. FSANZ may be able to use market share data quantitatively in estimates of dietary exposure (e.g. by weighting chemical concentration levels for groups of foods). Alternatively, it may be used qualitatively to assist in making assumptions or interpreting results.

In addition to a population based estimate of dietary exposure, FSANZ may assess dietary exposure for groups of individuals with certain behaviours. For example, the likely dietary exposure should a consumer always consciously avoid or always consciously select foods containing the food chemical.

Consumer research also provides useful information to underpin the assumptions used in dietary exposure assessments. Research on consumption behaviours can assist in determining if consumers specifically avoid or choose to consume specific foods containing a certain food chemical; if they eat more of a certain food that contains a particular food chemical because they think it is better for them. This helps with determining assumptions in modelling about whether consumers substitute a particular food with a new one or if they simply add it to their normal diet. These data may be used in extensions of modelling or in providing evidence to make more realistic assumptions when constructing the models.

#### *Use of computer modelling*

The computer-modelling program developed by FSANZ (called DIAMOND: **DietAry M**odelling **O**f **N**utritional **D**ata) assists in calculating the dietary exposure to food chemicals and nutrients such as food additives, pesticide residues, contaminants, nutritive substances and food ingredients. DIAMOND uses the food consumption data from NNSs and the concentration data described above. Different models may be run, based on point estimates (deterministic models) or distributions of food consumption and concentration data (probabilistic models) or a combination of both, for example a distribution of food consumption amounts from a NNS combined with a single food chemical concentration (semi-probabilistic model).

#### *Food microbiological data*

Assessing the level of exposure to microbiological hazards is complex due to their ability 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 processing and handling has on the hazard. 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 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 need to be gathered on the food, how it's produced and stored and how these factors may influence the level of hazard present in the food at the time of consumption.

FSANZ may work with research agencies to develop predictive mathematical models to predict the growth, inactivation and survival of a microbiological hazard throughout the food chain, taking into account the impact of factors such as food processing and storage and the amount of food consumed has 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 are useful for complex models as they incorporate variability and uncertainty into the results and provide a range of possible exposure levels.

### **Risk characterisation**

The last step in risk assessment, risk characterisation, seeks to integrate the information from the previous steps and to provide an estimate of the likely occurrence and severity of any potential adverse health effects in a given population under defined exposure conditions. This includes an analysis of the inherent uncertainties in the process, which can arise from the availability and quality of the data used, the applicability of the experimental model(s) used and the assumptions used in the absence of data.

It is also expected that the risk characterisation will provide information which can be used for risk management to manage identified risks. This information can be of a quantitative or qualitative nature depending on the nature of the issue and the quality of the available data. The information provided needs to take into account the quality, the completeness and relevance of the scientific information available, as well as the context in which this information will be used to address risk management goals. The initial scoping of the food-related issue (see Chapter 4) by both risk managers and risk assessors should have established the broad parameters to be considered in the risk characterisation in order to address the risk management goals.

The risk characterisation can be quite broad, e.g. for the whole population or for a specific sub-population, 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.

### ***Chemical risk factors***

For chemical risk factors, different approaches are used for risk characterisation depending on the nature of the chemical and whether a toxicity exposure threshold can be identified from the

available animal or human studies. While toxicity thresholds are likely to exist for all chemicals, given the efficient mechanisms in place to maintain cellular homeostasis, in some cases, the threshold may be lower than can be practically measured, such as for chemicals which induce cancer following an initial mutational event (so-called genotoxic carcinogens). For non-cancer endpoints, a threshold approach is generally used. Whether a threshold can be identified or not, a fundamental principle is that exposure to chemicals should be as low as reasonably achievable (ALARA) without withdrawing the food completely from the market, except in the case of those nutrients where essentiality applies. The ALARA principle is particularly important for contaminants, where there is often a so-called 'irreducible level' for the contaminant in the food, below which a reduction cannot be achieved in practice.

When a threshold is evident, a reference health standard can generally be established based on either a NOEL or BMD derived from long-term studies. Part of the risk characterisation in these cases involves a comparison of the exposure of mean and high level consumers (for the whole population or a particular at-risk group) to an appropriate reference health standard. Exposure below the reference health standard is considered to be *without appreciable health risk* for a food additive, novel food ingredient or pesticide and veterinary drug residue; to be of low risk and *tolerable* for a food contaminant; and in relation to the upper level to be *unlikely to lead to adverse health effects* for nutritive substances, according to the current generally accepted definitions for the respective reference health standards described earlier in Chapter 5. However, such comparisons must also take into account any uncertainties/limitations inherent in the exposure data; the quality of data used; the nature of the adverse effect on which the reference health standard is based; the length of exposure if known; and whether the reference health standard refers to short-term or long-term exposure.

When a threshold is not evident, risk characterisation may involve using a so-called margin-of-exposure (MOE) approach to provide an estimate of relative risk. The MOE approach compares the benchmark dose (BMD) (or the lowest-observed-effect level (LOEL), if the BMD is not available) with the normal level of 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. It may be useful for ranking and priority setting by risk managers.

The level of complexity of the risk characterisation in a particular case will depend on the circumstances – if exposure is very low, limited data on the potential hazard may be sufficient if the metabolism of the chemical and the toxicity of related chemicals are well understood. Similarly, if the data indicate a low hazard, an extensive assessment of dietary exposure may

not be necessary. In general, as the level of exposure increases, so does the requirement for more detailed hazard identification and characterisation data and vice versa.

For some chemicals, there will always be only a small amount of data on hazard identification, either because it is a common chemical with a history of safe use or it is a chemical generally found at very low levels in food, such as a flavouring agent or a chemical which migrates from packaging materials. In the latter case, more extensive use is made of structure-activity relationships, common metabolic data and structural similarities. The concept of a *threshold of toxicological concern*, which represents a level of human exposure below which it can be considered there are no significant risks to health, has not been formally accepted by FSANZ but has been used by the Joint (FAO/WHO) Expert Committee on Food Additives (JECFA) for flavouring agents and by the US Food and Drug Administration (FDA) for chemicals migrating from packaging materials.

#### ***Nutrient risk factors***

Nutrients, including nutritive substances, by definition, fulfil a nutritional purpose and therefore an adequate intake of the nutrient is either essential, or at least desirable, for a healthy life. For nutrient risk factors, the risk characterisation must consider both food safety and health aspects for all population groups. Practical and ethical considerations make a comprehensive set of key data difficult to obtain and the level of uncertainty in the available data is in some cases considerable. Intake data can also be difficult to obtain since nutritive substances can be found naturally in food, in fortified foods and in complementary medicines (as defined in Australia) and dietary supplements (as defined in New Zealand). It is possible, if there is significant variability in the population, that the dietary intake levels for one population group may be experiencing signs of adverse health effects from inadequacy while at the same time a different group in the same population has intakes that exceed the UL. This could become problematic when considering possible food fortification options. If exceedance of the UL appears to occur or increase, further assessment of the basis for the UL can be undertaken to check that the endpoint on which the UL is based is relevant for the population group with high intakes and also to assess the nature of the risk associated with an exceedance of the UL. Depending on the assessment outcome, a number of risk management approaches may be necessary in such cases.

#### ***Microbiological risk characterisation***

For microbiological hazards, risk characterisation integrates exposure and dose-response information to provide an estimation of adverse health effects likely to occur in a given population. In microbiological risk assessments, estimates generally apply to the population

of a country, or specific population groups if there are different levels of risk between population groups e.g. immuno-compromised individuals could be at greater risk than the general population.

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 likelihood of illness per 100,000 individuals in a population per year or the predicted annual incidence of human illness in a total population.

The microbiological risk characterisation also identifies factors in the food chain that impact upon these estimates.

## **Special risk assessment cases**

### **Transmissible spongiform encephalopathies**

The human health risk associated with the prions responsible for bovine spongiform encephalopathy (BSE) and other transmissible spongiform encephalopathies (TSEs) remain difficult to assess using the present risk assessment framework because of the high level of uncertainty in many aspects of the assessment. When initially recognised as a potential foodborne disease, the nature of the risk factor involved was unknown and even now many aspects of what are now recognised as prions remain unclear. Other uncertainties include the mode of action of prions in causing BSE and variant Creutzfeldt - Jakob disease (vCJD) in humans, the dose-response relationship, and the existence of a threshold dose level. There is now, however, good information on the identity of all of the animal tissues which contain prions and, therefore, the potential foods which may contain prions. Given the potentially fatal consequence of ingesting food containing the BSE prion, and the high levels of uncertainty regarding the risk assessment, risk management measures to date have been cautionary.

### **Allergenic foods**

The risk associated with allergenic foods is difficult to assess within the present risk assessment framework because of a number of factors. Firstly, information on the nature of the proteins responsible for food allergy varies depending on the allergenic food, and therefore the risk factor is generally considered to be the food itself rather than the allergenic protein(s) in the food. Food processing can significantly influence the allergenicity of the food or its derivatives. Secondly, the dose-response relationship is highly variable in the human

population, making it difficult to identify thresholds for adverse effects, and thus safe levels of exposure. Thirdly, the acute sensitivity of some individuals and potentially fatal consequences of ingesting allergenic foods limits the value of population-based risk assessments. Because of these uncertainties, risk management measures to date for allergenic foods have been designed to be targeted towards the affected sub-population.

### **Special purpose foods**

Special purpose foods are those foods which are intended to provide for the particular dietary needs of special, often vulnerable, groups in the population. In some cases, such as infant formula products or certain medical foods, these foods may be the sole source of nutrition. In other cases, these foods may contribute to meeting particular dietary needs such as formulated supplementary foods. Regulatory permission is generally required before certain substances can be added to these foods and may require data which are relevant to particular population groups. In general, a more conservative approach is taken in relation to the acceptable level of risk for foods in this category.

### **Dealing with uncertainty and variability**

Uncertainty and variability in risk assessment occur in a multitude of ways and can significantly influence the value of the risk assessment and its interpretation. Uncertainty arises when there is insufficient information available to accurately determine the value of a particular parameter within a model. Variability refers to the inherent variation in the parameters within the model. Uncertainty can be reduced through additional research and more accurate data, while variability cannot be reduced but it can be better understood. It is important, therefore, to both document the uncertainty and variability and also to make some judgement regarding their impact on the overall risk assessment.

The most common source of uncertainty is limited or poor quality data on potential health effects and/or on the dietary exposure. If the data are unsuitable to identify the potential adverse health effects, it is difficult for the assessment to progress unless, in the case of chemicals, the exposure is so low that a more limited safety database is acceptable. The uncertainty in the quality of safety data can be particularly critical when establishing reference health standards. Uncertainty in the level of dietary exposure is common because of paucity of up-to-date national dietary survey data. However, the level of dietary exposure, on the other hand, can generally be estimated even with relatively poor data if appropriate assumptions are made. Additionally, FSANZ commissions or requires from applicants more detailed data as

required. In a limited number of cases, with poor exposure data, the level of uncertainty can be so great that a realistic risk assessment is not possible.

The most common sources of variability in risk assessment are, firstly, inter-species and inter-individual variation in relation to understanding the nature of the potential adverse effects and their impact on humans, and secondly, the variation in both type and quantity of food consumed by individuals within a given population.

The reliance on studies conducted in animals to examine potential adverse effects as a surrogate for human studies requires an examination of the relevance of these data in order to better understand any differences and interpret the data correctly. In most cases, studies in animals are conducted at high dose levels in order to increase the power of the study to identify potential adverse effects and to identify, if possible, exposure thresholds for the adverse effects. Understanding the impact of high-to-low dose extrapolations is also an important part of risk assessment. Within the human population, there is considerable variability in the responses of individuals to both chemical and biological risk factors. Safety factors (or uncertainty factors) are commonly used to address inter- and intra-species variation.

There is uncertainty and variability associated with dietary exposure assessments, primarily in relation to the data sets used. There is variability in chemical concentration data, however, generally only one or two concentration levels (e.g. mean or median, and maximum) are used in the dietary exposure assessment. Variability in food consumption data are accounted for by using individual dietary records from each survey respondent in national dietary surveys in the dietary exposure calculations using DIAMOND. There is uncertainty in concentration data where small data sets are used or data for some foods do not exist. There are uncertainties in food consumption data where only one day of data may be available for respondents and day to day variation in consumption patterns may not be able to be taken into account. Additionally, for some obscure or occasionally consumed foods, there may not be many consumers to enable a robust dietary exposure estimate to be made. This may be exacerbated when sub-population groups are assessed (e.g. by age or gender). The result of the uncertainties is that assumptions are made when constructing dietary models that need to be documented clearly along with the results. For example, it might be assumed that the concentration of a chemical in one type of food represents the concentration in a broader group of similar foods where concentration data are not available for all foods of interest.

For microbiological hazards, there are additional sources of variability such as the effect of the food vehicle and its environment on the rate of growth of the microorganism. For both

microbiological hazards and nutritive substances, the health status of individuals is a variable which can have a significant impact on the level of risk within a given population.

The inherent variability within the risk assessment model should be documented, or referenced, in a risk assessment report. The uncertainties in the data and any assumptions made also need to be documented. If the level of uncertainty is too great, a decision may be taken to delay the assessment until new data are available.

### **Using the outputs of risk assessment**

It is important that the outputs of the risk assessment provide adequate information for risk management decision-making. The information which feeds into the risk characterisation, therefore, while largely science-based, needs to be considered within the context of broader public health policy.

While the separation of risk assessment and risk management is an important principle in risk analysis, risk assessors must have sufficient knowledge of the risk management goals, and the options to achieve these goals, in order to provide useful advice. Similarly, risk managers must understand the limitations of risk assessment and how to interpret the risk assessment outcomes in the context of other available information.

In cases where the risk management options may involve economic costs, e.g. changes to food labelling, particular information, such as the number of individuals affected or the severity of the adverse health outcome, may be needed in the risk characterisation in order that an appropriate analysis of the costs and benefits can be undertaken at the risk management stage.

The advice provided to risk managers should include answers to the questions raised by the risk manager and a concise statement of the potential hazards and level of exposure, an estimate of the potential risk to the particular population affected, an appraisal of the uncertainties and their impact on the overall risk assessment.

## 6 Managing Food-Related Health Risks

### Risk management in relation to food

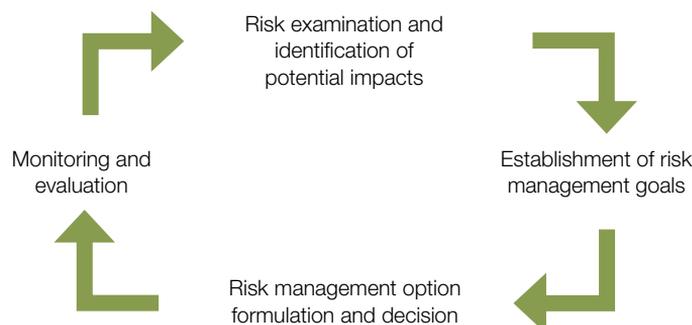
Risk management in relation to food can be considered as comprising of four key steps. The first step examines the nature and potential impact of the food-related health issue. The second step establishes the broad risk management goals and the steps to be undertaken to achieve these goals, including whether a risk assessment is necessary and what questions should be answered by a risk assessment. The third step considers possible risk management options and makes a risk management decision. The fourth step implements any necessary controls and monitors the impact and effectiveness of these controls.

In addition to developing risk management options, risk managers have a large role at the initial stage of the risk analysis process in considering the issue and developing questions to be answered by the risk assessment as well as at the final implementation stage and follow up monitoring and evaluation, which occurs following data generation and analysis. An ongoing dialogue between risk assessors and risk managers throughout the risk analysis process is necessary to ensure a mutual understanding of the risk management goals.

### Steps in risk management

The risk management process used by FSANZ essentially involves four stages, namely, examination of the risk and potential impacts, establishment of risk management goals, risk management option formulation and decision and monitoring and evaluation. These stages are shown in Figure 3 and described in more detail below.

Figure 3. The steps in risk management



### **Risk examination and identification of potential impacts**

The first step in risk management is to examine the nature and potential impact of the food-related health issue. This step includes: defining and describing the food-related health issue; identifying data and data gaps; identifying interested and affected groups; and consideration of resources and prioritisation of the food-related health issue. This step is important to attain a good understanding of the issue and to gather as much preliminary information as possible in relation to the food-related health issue.

### **Establishment of risk management goals**

The second step of risk management is to establish the broad risk management goals and the steps to be undertaken to achieve these goals. This step includes determining whether a risk assessment is necessary and, if so, what questions the risk assessment needs to answer.

A risk assessment may not be necessary if:

- (i) the risk is well described by definitive data;
- (ii) a risk management decision can be made without a risk assessment; or
- (iii) if the food-related health risk is relatively uncomplicated.

The broad risk management goals developed during this step may include developing regulatory standards, establishing benchmark levels of risk, or assessing the impact of a new technology.

### **Risk management option formulation and decision**

The third step considers possible risk management options and makes a risk management decision. This step includes consideration of issues which may impact on the options including human health issues (risks and benefits), consideration of relevant over-arching policy guidance, practicality and enforcement of risk management options, social and consumer issues and cost and benefit analysis. In determining appropriate options, the risk manager must also consider the context of the problem (e.g. is it urgent or likely to be wide-spread in nature and involve a range of foods), the nature of the risk (e.g. low versus high and the toxicological endpoint), the likelihood and severity of the risk (e.g. low risk and low severity vs. high risk and high severity), uncertainty associated with the risk assessment and the most appropriate options (e.g. regulatory or non-regulatory).

As part of the decision-making process a Regulatory Impact Statement (RIS) addressing the issue of cost effectiveness is also prepared. It analyses the benefits and efficacy of alternate (regulatory and non-regulatory) options for achieving the stated objectives. FSANZ consults

the Office of Best Practice Regulation (OBPR) to ensure that the RIS is in accordance with the Council of Australian Governments (COAG) guidelines.

The development of risk management options for food emergencies usually require a rapid response with limited time to consider the broader issues mentioned above.

### **Monitoring and evaluation**

The fourth step implements any necessary controls and monitors the impact and effectiveness of these controls. As part of the development of options, consideration needs to be given to the practicality of the intervention i.e. can the intervention be implemented, measured and enforced. Evaluation and monitoring of controls implemented provides information on the effectiveness of the controls.

### **Factors influencing risk management decisions**

In developing risk management decisions, FSANZ must consider the objectives of the Authority as detailed in the Food Standards Australia New Zealand Act 1991 (the Act).

These objectives include:

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

In addition to these objectives FSANZ must also have regard to:

- (i) the need for standards to be based on risk analysis using the best available scientific evidence;
- (ii) the promotion of consistency between domestic and international food standards;
- (iii) the desirability of an efficient and internationally competitive food industry;
- (iv) the promotion of fair trading in food; and
- (v) any written policy guidelines formulated by the Council for the purposes of this paragraph and notified to the Authority.

In considering these objectives, FSANZ takes into account a number of different issues including human health, consumer behaviour, economic, governmental and international agreements.

### **Human health issues – risks and benefits**

The first objective of FSANZ in developing and varying a food standard is the protection of public health and safety. This is generally interpreted as working towards maintaining a safe food supply to allow for informed choice of a balanced and nutritious diet for all members of the population. The composition of a balanced and nutritious diet will, of course, vary with life stages and for certain sub-populations and individuals. Managing the risks associated with foods requires a number of different approaches which recognise this variability. The enormous benefits of a balanced and nutritious diet, however, need to be recognised and considered against any identified risks when implementing risk management strategies. Balancing the risks and benefits of food-related issues varies according to issue, and as such, risk management strategies will vary. For example, for mercury in fish, it is important to consider the benefits of consuming fish as part of a healthy diet, and in-line with dietary guidelines, against those risks associated with high mercury intake from some types of fish.

Similarly, changes to food which aim to improve the nutritional quality of food need to be considered against potential risks associated with the changes to food. In this case, it is possible that the beneficial effect of a particular action may apply to one sub-population group while the harm associated with this action may apply to a different sub-population group (e.g. fortification may assist some consumers in reaching adequate intake of a nutrient, while others may exceed the upper level for this nutrient). In the case of a nutritionally poor diet however, the benefit (or risk reduction, in this case) of increasing dietary intake of nutritive substances can be measured in relation to the EARs.

The risk assessment results should identify and quantify any health risks associated with the proposed change to the food, and in some cases may also be able to identify and possibly quantify health benefits.

### **Consumer issues**

Managing food-related health risks in some circumstances requires a level of consumer understanding and acceptance. There are many examples of situations where it is important to be able to predict consumer behaviour in order to manage the risk effectively. Food labelling, whether it is for consumer information related to health matters, food safety and/or to enable consumers to make informed food choices, requires that consumers will understand the information on the label and that it assists them in choosing appropriate food. Other circumstances where understanding consumer behaviour is important in risk management include the addition of nutritive substances or novel food ingredients in food products where the intent of the addition is to provide a health benefit, or where the composition

of a standardised food is proposed to be changed. Well designed consumer research can be used to refine risk management strategies. For example, consumer research may be used to trial a proposed management strategy with the findings being used to refine the strategy or conclude that the proposed strategy would not achieve the desired outcome and thus alternative strategies are required.

Predicting consumer behaviour is not easy but information can be obtained through consumer research using surveys, interviews, observations and experiments, or information from the overseas market where the proposed change is already in place. It may be necessary to undertake monitoring in some circumstances in order to confirm consumer behaviour.

### **Economic issues**

Another significant factor in implementing a food-related health risk management strategy is the economic cost. Certain risk management strategies, such as changes to current food labelling or mandatory fortification, will impose a compliance cost on the food industry. In this case, the cost imposed on the food industry, particularly small business, needs to be weighed against the anticipated reduction in health risk, and will depend on the nature and severity of the risk and the consumer's anticipated response in relation of the labelling change. Composition changes to standardised foods also have an economic cost which needs to be considered together with the anticipated consumer response.

Economic costs may also be associated with control of contaminants in food – both chemical and microbiological. The general approach to contaminants in food is to reduce the level of contamination to levels which are as low as reasonably achievable (the so-called ALARA approach), even if, in the case of chemicals, a safety threshold can be established. This is based on the premise that contaminants in food are undesirable and that safety data always carries a level of uncertainty. However, economic costs rise as regulatory limits on contaminants are imposed or existing limits are reduced. A balance of a reasonably achievable level is needed, such that human safety is ensured, costs are manageable and the withdrawal of the food completely from the food supply is avoided where possible.

Industry groups can provide significant information and insight to assessing the practicality of risk management options. FSANZ consults widely with industry and other stakeholder groups on any proposed risk management options. Standards Development Advisory Groups consisting of industry groups may also be established for significant pieces of work. These groups assist in informing the selection of risk management options.

In addition, FSANZ follows the Council of Australian Governments (COAG) best practice regulation principles and guidelines to ensure that regulatory proposals and applications yield net benefits to the community. Regulatory Impact Statements of FSANZ are subject to clearance from the OBPR which is the Australian Government's independent body for promoting and monitoring effectiveness and efficiency of regulation. Depending on the nature of the proposal and advice from the OBPR, FSANZ applies economic tools like cost-analysis, cost effective and cost benefit analyses to inform the impact assessment.

### **Governmental and international agreements**

Australia and New Zealand are members of the World Trade Organization (WTO) and 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 WTO agreement of most relevance to food regulation is the SPS agreement which requires that regulatory measures adopted by member countries must be based on scientific principles and not maintained without sufficient scientific evidence. Member countries are required to base their measures on an assessment of the risks to human health, and these assessments should take into account the methodologies used by relevant international organisations. In the case of the safety of food, the relevant international standard setting body is Codex. Codex standards are the benchmarks against which national food measures and regulations are evaluated. Regulatory measures which could be influenced by the SPS agreement include, amongst others, MLs for chemical or microbiological contaminants, requirements for warning and advisory statements on labels, and compositional requirements for standardised foods. FSANZ also takes into account the recommendations arising from various Codex Committees that have a risk management function, as one of the core functions under the FSANZ Act is to achieve consistency, wherever possible, between domestic and international standards.

One of the matters FSANZ must have regard to in developing food regulatory measures is the promotion of consistency between domestic and international food standards. To support this goal, FSANZ contributes to the work of a number of Codex committees and regulatory measures are aligned as far as possible. However, there are situations where food standards established domestically will vary from international standards. These situations include: where FSANZ may receive an application to amend the Code (e.g. new food additive permission) prior to or after an international standard being developed; where new domestic data is available for the risk assessment; different climate and growing conditions result in different contaminants, natural toxicants or nutrient levels in foods; consumption patterns result in different dietary exposure assessments; and manufacturing and production processes vary which may result in higher requirements for some preservatives.

FSANZ is also required under the Inter-Governmental Agreement established by the Council of Australian Governments (COAG) to apply minimum effective regulation in the provision of a safe and healthy food supply as well have regard to national policy guidelines established by the *Australia and New Zealand Food Regulation Ministerial Council* on food standards issues.

### Options for managing food-related health risks

The first decision for a risk manager is whether the situation requires a risk management strategy or any additional risk management, if a pre-existing measure is already in place. In many cases, no additional risk management is required if the current level of risk is considered negligible or the current risk management strategy is sufficient to maintain an acceptable level of health protection. The concept of 'appropriate level of protection' or 'ALOP' is defined in the WTO SPS Agreement 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'. The ALOP concept is sometimes also referred to as the 'acceptable level of risk'. Risk management of public health issues can range from general to specific depending on the level of available information, the feasibility and practicality of available risk management options, and the current food policy. The acceptable level of risk will therefore change as technology improves and also as public attitudes to food risk influence food policy.

Where the level of protection is not considered acceptable, there are a range of risk management options available for preventing or reducing health risks associated with food. These options can be: regulatory, i.e. those which are specified in the Code, such as end-product standards or outcome-based standards; or non-regulatory, such as industry codes of practice, guidelines or information/advice campaigns. Both regulatory and non-regulatory options need to be considered, particularly with regard to the need to implement minimum effective regulation, as discussed above.

#### Regulatory measures

Regulatory measures are those specified in the Code and are generally divided into end-product standards and outcome-based standards, although such divisions are somewhat arbitrary since both are directed towards an acceptable level of health protection.

#### End-product standards

End-product standards are those where the regulation generally applies to the end-product, namely, the final food product for example Standard 1.3.1 Food Additives. In general, the

outcomes of applying the standards can be more readily measured and therefore compliance is more straightforward, although a higher level of inspection is necessary.

### *Approving foods and additions to food*

Pre-market approval is required for certain foods and for substances added to foods or used in food production for which there is no presumption of safety. This includes food additives, processing aids, nutritive substances, genetically-modified foods, novel foods and irradiated foods. For each of these foods or substances, a pre-market safety assessment is undertaken, and this forms a major part of the approval process.

Food additives must fulfil one or more of the technological functions of food additives specified in the Code. Food additives are listed in the Code and may be allowed broad or restricted use in foods. A general permission in foods allows use up to the level required to fulfil the specified technological function in the final food under good manufacturing practice. A more restricted permission allows use in specified foods and only up to the maximum use levels specified in the Code. Food additives are also required to be identified on the label when present in foods above a minimum level, generally by listing a specific food additive number determined by Codex in the ingredients list. However, an exemption applies where a food additive is in an ingredient which constitutes less than 5 percent of the final food or where the food additive does not perform a technological function in the final food.

Processing aids are used in the manufacture of foods and can be given a general permission for use or restricted to a particular technological purpose in the manufacture of specific foods or foods in general. Processing aids do not have a technological function in the final food and, in most cases, residues are low or not present in the final food. For this reason, processing aids used in the manufacture of food are not required to be identified on the label of the food unless they contain allergens.

Nutritive substances, as defined in the Code, are substances which are intentionally added to food to achieve a nutritional purpose and include vitamins, minerals, amino acids, electrolytes and nucleotides. Nutritive substance permissions are restricted to specific foods and the level of use is related to a percentage of the RDI or other relevant reference health standard, where these exist. The addition of nutritive substances to food is likely to have additional labelling requirements.

Genetically-modified foods as defined in the Code are foods which have been derived or developed from an organism which has been modified by gene technology. Permission for

use is generally given to either all foods, or particular foods derived from, a genetic line of the primary commodity. Labelling requirements may apply.

Novel foods are broadly defined in the Code and can include plants and animals and their extracts, herbs and their extracts, single chemicals or macro-components, micro-organisms (including probiotics), food ingredients derived from new food sources, and/or foods produced by a new process. Permission for use may relate to any of the above and may include conditions of use, such as the use of a particular name, certain labelling requirements, the names of the foods to which an ingredient can be added, and/or well as the amount of the ingredient which can be added.

Irradiation as defined in the Code relates to the processing of food by subjecting it to the action of ionizing radiation. Foods which can be irradiated are listed in the Code together with the minimum and maximum irradiation dose. The conditions under which irradiation may be used are also stated, such as the purpose of the irradiation and specific handling instructions.

#### ***Maintaining the composition of foods***

Compositional requirements apply to standardised foods in the Code. These are in the form of definitions and also statements related to composition and processing. These requirements are in place to avoid deceptive practices as well as, in some case, to maintain public health and safety. Minimum and/or maximum requirements for composition may apply.

#### ***Setting maximum levels for contaminants and natural toxicants***

One tool used in the management of the risks associated with chemical contaminants in food is the establishment of maximum levels (MLs). For a chemical contaminant, a ML is established only where it serves an effective risk management function and only for those foods which provide a significant contribution to the total dietary exposure. Regardless of the presence of an ML for chemical contaminants, the ALARA principle applies for contaminants, and many controls other than food regulations are in place to minimise food contamination. Where established, MLs for chemical contaminants have been set at levels which are reasonably achievable from sound production and natural resource management practices.

Natural toxicants can occur in food as a result of the use of natural ingredients as flavourings or for other technological purposes in food. Natural toxicants can also be found in some basic foods, such as edible oils and lupin products. In some cases, it may be necessary to control the levels of these toxicants by establishing MLs. The Code contains MLs for a number of such toxicants.

### ***Setting maximum limits for agricultural and veterinary chemicals in Australia***

Agricultural and veterinary chemical product use approval in Australia is provided by the Australian Pesticides and Veterinary Medicines Authority (APVMA). Residues of agricultural and veterinary chemicals occur in foods as a result of the use of these chemical products in agriculture and in veterinary practice on food-producing animals. The APVMA determines maximum residue levels or MRLs for these residues when it approves the use of chemical products. These limits are included in the Code for specific residues in food commodities. These standards are applicable in Australia only. Limits for agricultural and veterinary chemicals in New Zealand are set by the New Zealand Food Safety Authority.

Additional limits may also be included in the Code to facilitate trade, provided that the residues do not raise any public health concerns.

### ***Setting maximum levels for microbiological contaminants***

Microbiological criteria are set for some microbiological contaminants in foods. For microbiological contaminants, these criteria are established in the Code for a number of foods and many include details on sampling plans and methods of analysis.

### ***Prohibiting certain plants and fungi***

There are a large number of plants and fungi which are unsuitable for use in food because of their intrinsic toxicity. The Code lists a number of such plants based on their historical association with food, their known therapeutic properties, or the potential for accidental use in food.

### ***Food labelling***

Food labelling is an important risk management strategy and is different from other control measures as it places responsibility on the consumer to heed the label information. Labelling is used not only to address potential health risks but, in some cases, also to allow consumers to make food choices for other reasons. In relation to addressing health risks, labelling is useful when there is a reasonable certainty that consumers will know how to use the information provided. It is particularly useful when the information is required by a particular sub-population, rather than the whole population. Effective food labelling, however, requires that consumers can read and interpret the label information correctly. In some cases, information in addition to that on the label can be provided by other means (e.g. education initiatives).

Labelling which is specifically directed to addressing health risks includes mandatory warning and advisory statements. Warning statements, requiring a prescribed labelling statement, are

generally reserved for well-characterised, potentially life-threatening risks where the target population is unaware of the potential risk. An example of a warning statement prescribed under the Code is the statement 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.’

Advisory statements (labelling statements where the specific wording is not prescribed) are used to advise the general population or a target population of a potential risk associated with a food. For example, 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.

Labelling which identifies the presence of a food allergen in a food product is also important to address a potentially significant health risk, although it applies only to a sub-population. Allergenic foods, including ingredients, which are required to be declared on the label are listed in the Code. The current standard requires these foods and derivatives of these foods to be declared on the label, without any exemptions.

Other labelling which may assist in addressing safety and health risks is labelling which provides direction for preparation, use and storage of food, such as preparation instructions for bamboo shoots or directions such as ‘refrigerate after opening’, as well as the date marking of food. The requirement for mandatory nutrition information panels assists with public health initiatives relating to nutrition specifically in respect of risk increasing nutrients for diet related chronic diseases. Advice regarding recommended levels of intake is required on labels where there is a risk to health of excessive consumption of certain nutrients permitted to be added to the food, for example, formulated caffeinated beverages and formulated supplementary sports foods.

### Outcome-based standards

Outcome-based standards are those that provide more general information regarding the expected outcome in relation to the accepted level of health protection, for example Chapter Three Food Safety Standards. These standards place more compliance responsibility with the food industry. The Code contains outcome-based standards which are directed to the management of the risk associated with microbiological and chemical risk factors in food. These standards are applicable in Australia only. New Zealand has a separate set of food safety standards set by the New Zealand Food Safety Authority.

### *Food safety programs*

The Code addresses the need for certain food businesses to have in place food safety programs based on a systematic identification and control of hazards as identified in the hazards analysis and critical control point (HACCP) system. The relevant Standard requires food businesses to systematically examine all of its food handling operations in order to identify the potential hazards that may reasonably be expected to occur and to develop and implement a food safety program to control any identified hazard or hazards.

### *Food handling*

The Code also addresses food handling practices by requiring food businesses to ensure that persons undertaking or supervising food handling operations have skills in food safety and food hygiene matters; and knowledge of food safety and food hygiene matters. The relevant Standards also consider matters related to food receipt, handling, storage and display, as well as matters related 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, namely, seafood, ready-to-eat meat, dairy products and specific cheeses. Primary production standards are broadly-based and can consider all aspects of production including general safety requirements, contamination and handling, storage, transportation, packaging, disposal, hygiene requirements, as well as premises and equipment.

### **Non-regulatory measures**

Non-regulatory measures are those not specified in the Code and generally include guidelines, industry codes of practice, standards developed by recognised bodies e.g. Standards Australia or information/advice. Various interchangeable terms are used to describe non-regulatory measures and FSANZ may be involved to varying degrees in developing these measures.

### Codes of practice

Codes of practices or guidelines can be developed by industry alone or developed jointly with FSANZ. A code of practice is a nonbinding measure that is used to regulate activities regarding food and food practices within 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 evidence of a low level of health risk, which would not warrant the development of a standard; and/or
- a standard exists but advice is needed to facilitate compliance and foster consumer confidence.

Compliance with codes of practice are 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 assist industry to meet good agricultural and manufacturing practices. One such set of guidelines relates to chemical contaminant levels in food. The concept of 'generally expected levels' or 'GELs' was introduced to encourage 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 are 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 complement the legally enforceable MLs for chemical contaminants as well as providing a benchmark in situations where MLs are not considered necessary.

Another example of guidelines and protocols to assist industry is the Food Industry Recall Protocol. This document provides advice on writing a food recall plan for businesses and how to conduct a food recall if necessary.

### Consumer information/advice

Providing information and/or advice to consumers in the form of fact sheets, technical papers, web-based information or public forums is another effective non-regulatory measure. Consumer information/advice is often used to support other risk management tools, such as labelling e.g. allergen information cards.

Particular information/advice may include:

- information to the community about safe handling and adequate preparation of the product (e.g. information for charities and community organisations relating to food hygiene);
- information to at-risk groups about safe eating practice (e.g. listeria advice for people at risk); and
- information on how to use food labels effectively (e.g. Choosing the Right Stuff – a pocket guide to food labels).

### **Determining risk management options for food-related health risks**

The decision as to whether the appropriate risk management strategy is regulatory or non-regulatory or a combination of both will depend on a number of factors, including the severity of the health risk, the probability of its occurrence, the number of individuals affected and the anticipated effectiveness of the proposed risk management strategy. FSANZ consults early with the OBPR through the consultation Regulatory Impact Statements which contain the description of the problem or health issue, objectives and options. The OBPR provides further advice on the analysis commensurate to the nature of application or proposal. In some cases, it will be influenced by current legislation or food regulatory policies. In other cases, it will require consultation with interested and affected parties, particularly when the responsibility for managing the risk is shared.

The development and determination of appropriate risk management options by FSANZ is open and transparent. FSANZ seeks input from a wide variety of areas including consumers, industry and government agencies. For larger or more complicated issues, FSANZ may establish committees to provide advice on risk management options e.g. Standards Development Committee (SDC) for Primary Production and Processing Standards. Members of these committees may include representatives from key stakeholder groups, industry, jurisdictions, consumers, government and independent experts.

### **Rapidly emerging food incidents**

In the case of food emergencies risk management, rapid responses are required. In these cases, 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, the National Food Incident Response protocol will be activated and decisions on risk management options will be made under this arrangement.

## Monitoring and evaluation

Monitoring and evaluation of the selected risk management strategy is an important process to measure the effectiveness of any measures adopted. Monitoring and evaluation requires the gathering of information and the analysis of data to ensure the risk management goals are being achieved. This process is on-going and iterative in the risk analysis process and can lead to revision of risk assessments or reduce uncertainties within the risk analysis. The data obtained through monitoring and evaluation can also be used in subsequent risk management decisions.

### Monitoring

Monitoring may be undertaken to examine the current state of the food supply following a regulatory or non-regulatory change in order to assess the impact of the change on consumers over time. It may involve repeating survey activities at different time intervals to determine trends and establish possible causal links between dietary exposure and regulatory or non-regulatory interventions. Monitoring may also be undertaken to determine changes in the status of particular foods in the market. It may also be used to verify the conclusions from the pre-market risk assessment regarding the estimated dietary exposure levels (and theoretically the absence of unexpected health effects). For new food ingredients, dietary exposure must be estimated using projected use data. Monitoring can provide confirmation of the dietary exposure by examining actual use data and can also examine exposure in non-target populations. Similarly, the potential for adverse effects in sub-populations cannot always be examined extensively pre-market.

### Monitoring activities

#### *Australian Total Diet Study*

The Australian Total Diet Study (ATDS) is conducted approximately every two years by FSANZ and, until recently, examined levels of agricultural, chemicals or veterinary drug residues and contaminants in food. The ATDS now examines Australian's dietary exposure to a range of food components which may include agricultural or veterinary chemicals, contaminants, natural toxicants, food additives, nutrients or other substances. The ATDS is a survey tool which allows the monitoring of the food supply, while also providing data to inform risk assessment activities. The ATDS is a unique national study as it collects and analyses foods that best represent the Australian diet nationwide. The foods are prepared as they would be before consumption and then analysed to provide quantitative data on the levels of chemicals in foods as consumed.

### *Other FSANZ surveys*

FSANZ may also undertake survey work in relation to monitoring specific areas of the Code e.g. food additive standards. These surveys are conducted as required and where resources permit.

### *OzFoodNet*

OzFoodNet is a national network that monitors public health events which can be indicators of foodborne hazards. OzFoodNet operates at the national level under the auspices of the Australian Government Department of Health and Ageing. It seeks to improve the accuracy and timeliness of notification of infections and to provide a 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.

<http://www.ozfoodnet.org.au/>

### *National Residue Survey*

The National Residue Survey (NRS) monitors residues of agricultural and veterinary chemicals and environmental contaminants in selected Australian animal products (e.g. meat, honey and fish) and plant products (grain, oilseed and horticulture), predominately foods that are exported from Australia. The survey is conducted by the Australian Government Department of Agriculture, Fisheries and Forestry.

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

### *Imported Food Inspection Scheme*

The Imported Food Inspection Scheme (IFIS), formerly the Imported Foods Program, monitors food being imported into Australia. Imported food must comply with the Food Standards Code in the same way as domestically produced food, with the level of inspection determined by a risk assessment provided by FSANZ. The IFIS is run by the Australian Quarantine and Inspection Service (AQIS) and also may undertake surveys of food chemicals in imported food or on the microbiological status of imported food.

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

### *State, Territory and New Zealand surveys*

Health, agriculture and environment departments in each of the jurisdictions and New Zealand may conduct surveys on a variety of food chemical and microbiological contaminants. FSANZ and the jurisdictions and New Zealand undertake survey work in accordance with a Coordinated Food Survey Plan. This Plan coordinates surveillance activities across Australian jurisdictions and New Zealand under the Implementation Sub Committee (ISC) of the Food Regulation Standing Committee (FRSC), in order to make more efficient use of limited resources and to undertake more statistically robust studies using commonly agreed methodologies. It also allows a higher level of scrutiny and peer review, collaboration of laboratory activities, less duplication of surveillance activities and discussion of results with the view of consistent risk management options if required.

[http://www.health.gov.au/internet/main/publishing.nsf/Content/DB3BB33DE2A105CFCA25743B001416C8/\\$File/isc-workplan.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/DB3BB33DE2A105CFCA25743B001416C8/$File/isc-workplan.pdf)

### **Evaluation**

Evaluation is the systematic application of social and natural science research procedures, using a combination of qualitative and quantitative methods, to assess the design, implementation, and usefulness of interventions, such as food regulations implemented through the Code and other non-regulatory risk management options taken. Evaluation of the Code is intended to examine whether the regulations are operating as intended, whether they are effective, and whether there are any unexpected outcomes or problems arising from their implementation. Information from food surveillance activities and food monitoring activities forms an integral part of the evaluative process by providing information on the current baseline situation and the impact of new food regulatory measures.

Much of the evaluation work undertaken at FSANZ to date has focused on evaluating the effectiveness of the adoption of the harmonised food regulatory system by Australia and New Zealand in 2000. Key regulatory changes, such as the introduction of the Australian food safety standards and the major changes to the general labelling, allergen labelling and food additive standards in Australia and New Zealand, were priorities for evaluation identified in the previous FSANZ Evaluation Strategy of 2001-2003. Assessment of the new primary production and processing standards and generating baseline data prior to proposed changes to labelling for nutrition, health and related claims were more recent priorities identified along with the original work in the more recent Evaluation Strategy of 2004-2008.

The outcomes of these evaluation activities provide a basis for recommending options for future risk management strategies that may include amending standards or developing new food standards and thus promoting continuous improvements in ensuring the safety of food.

## 7 Communicating Food-Related Health Risks

### Risk communication in relation to food

Risk communication is an essential and integral part of the risk analysis process as it drives the iterative process forward in a climate of shared knowledge. In the analysis of food-related health risks, communication allows the sharing of information and opinions related to the scientific evidence and the perceived risks associated with the food-related health risk. Risk communication involves the flow of information both within and between FSANZ and its stakeholders.

The Codex risk analysis framework places risk communication as an overarching consideration for both risk assessment and risk management (see Figure 1 in Chapter 4). The timely exchange of information between risk assessors and risk managers 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 create 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 that provide stakeholders with information to better understand the risks associated with foods and management of those risks and to create opportunities for stakeholders to contribute to FSANZ's consideration of issues. Communication with stakeholders at an early stage of the consideration of the food-related health risk enables appropriate mechanisms for information exchange with a broad range of interested and affected individuals to be established.

Risk communication is ever-present during risk assessment and risk management, and has as much to do with building productive relationships with stakeholder groups as with disseminating information. Moreover, risk communication is a shared responsibility of everyone connected to the risk analysis process. Specialist communicators may be responsible for preparing media releases, a communication strategy or publishing material on the website, but the project manager has overall responsibility for the communication.

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

- (i) identify the target audience(s);
- (ii) design messages for those audiences; and
- (iii) use the most appropriate communication vehicles for interacting with those audiences.

Risk communication aims to provide information that is timely, meaningful, accurate and relevant to interested and affected audiences in a clear and understandable manner.

The risk communication should provide an honest appraisal of identified health risks, the uncertainties associated with that appraisal, and the steps being undertaken to address the identified health risks.

## Communication strategies

### General matters

Communication strategies vary according to the complexity of the food matter, the degree of public interest and the length of time taken to undertake the risk analysis and formal consultation processes. For example, an amendment to a pesticide MRL may involve a strategy comprising only public notifications in newspapers and on the FSANZ website. On the other hand, the development of a new food standard dealing with all aspects of a primary industry sector would take several years to complete and would require 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 progress during periods of inactivity.

FSANZ has categorised communication strategies 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. Individual communication strategies are not mutually exclusive and may be used in combination. The strategies provide an indication of the main direction and level of communication activity required for a particular food-related health risk. The strategies are 'preferred' strategies, which does not preclude the adoption of other strategies should the need arise.

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

To be able to identify which communication strategy should be applied to a particular food issue, it is necessary to have a good understanding of risk as perceived by the public. Social and consumer research is especially useful in this regard to assess community attitudes. Media debate can also be a good barometer of community feeling.

The communication vehicles that can be employed in each of the strategies are wide and varied. They may include media liaison, web publishing, interactive web forums, fact sheets, reports, meetings, conferences, advice line, displays, launches, email bulletins and advertising.

#### *Passive communication strategies*

Passive communication strategies involve notification 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.

#### *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, risk management options such as labelling to enable the consumer to choose or avoid a particular food, may be considered e.g. GM foods.

#### *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. knowledge of mercury in fish by pregnant women.

#### *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.

#### **Applications and proposals**

A more formal process of seeking the views of stakeholders is undertaken when an external body or individual applies to FSANZ to amend the *Code* (referred to as an *Application*) or FSANZ seeks to alter the *Code* itself (referred to as a *Proposal*). In these cases, submissions

are sought in one or more rounds of public consultation. Submissions made in these circumstances are made publicly available. All submissions are considered and addressed by FSANZ.

Reports prepared by FSANZ in relation to Applications and Proposals are also publicly available except where particular information is considered as *Confidential Commercial Information* under the provisions of the FSANZ Act.

**<http://www.foodstandards.gov.au/standardsdevelopment/finalisedapplication2783.cfm>**

**<http://www.foodstandards.gov.au/newsroom/factsheets/index.cfm>**

## 8 Conclusion

The range and diversity of foods available for sale in Australia has increased significantly as the global food system continues to expand. Maintaining the safety of the food supply is a challenging and shared responsibility of the government, industry and consumers. FSANZ has a significant role to play in ensuring a safe food supply by maintaining robust evidence based processes for developing food standards and responding to food safety issues which enables consumers to make informed choices and maintains public confidence in the safety of foods. In order to ensure confidence in the process for developing food regulation, evidence that there is a low level of risk and assurance that adequate systems are in place to monitor and analyse food are required. To undertake this work FSANZ, uses the risk analysis framework.

Risk analysis offers a structured framework for considering the risks associated with food. Incorporating the key components of risk assessment, risk management and risk communication, risk analysis provides a systematic and disciplined approach to establishing and implementing risk management options. FSANZ utilises this framework to assess food-related health risks to provide an estimate of risk to public health, identify appropriate risk management options and to communicate risk and options with stakeholders. The risk analysis framework provides FSANZ with information and evidence required for effective decision making to support the development of standards, manage emerging issues and to provide consumers with adequate information leading to effective food safety outcomes and improvements in public health.

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## Appendix 1 – Regulatory framework for food

### 1. The legal basis for food regulation

The safety of all Australian and New Zealand foods is addressed in the broad provisions of Australian state and territory and New Zealand food and health legislation. This legislation requires that, above all, ‘food must be safe and suitable’; that ‘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’. 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* requires food to be safe and meet the provisions of the *Australia New Zealand Food Standards Code*. The Australian Quarantine and Inspection Service (AQIS) is responsible for implementation of this legislation.

### 2. Establishing food regulation policy

The development of policy in relation to food regulation is the responsibility of the *Australia and New Zealand Food Regulation Ministerial Council (ANZFRMC)*, which comprises ministerial representatives from the Australian Government, New Zealand Government, and Australian state and territory governments. Food regulation policy refers to guidance on the broad principles and direction of food regulation and is developed in the form of guidelines following consultation with stakeholders.

### 3. The Australia New Zealand Food Standards Code

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. It contains joint New Zealand and Australia food standards, as well as some ‘Australia only’ standards. The food standards contained within the Code are developed or varied by FSANZ in accordance with the FSANZ Act, including the policy guidelines provided by ANZFRMC.

## 4. Food Standards Australia New Zealand

FSANZ has a broad range of functions in addition to maintaining the Code – these are listed in the *Food Standards Australia New Zealand Act 1991*. In developing and varying a food standard, FSANZ is required to meet 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; and
- the prevention of misleading or deceptive conduct.

In developing and varying 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; and
- any written policy guidelines formulated by the Ministerial Council.

In developing food standards, FSANZ also has obligations under the *Inter-Governmental Agreement (IGA)* established by the *Council of Australian Governments (COAG)* in 2008. This agreement requires minimum effective regulation be used in the provision of a safe food supply, that regulatory decision-making be based on science, and that a cost-benefit approach be employed where there may be impost on industry.

## 5. Enforcement of food regulations

In Australia, compliance with food legislation for all foods is the responsibility of state, territory and local governments. In addition to complying with this legislation, imported food must also comply with the *Imported Food Act*. Ensuring compliance with this Commonwealth legislation is the responsibility of AQIS.

In New Zealand, ensuring compliance with the food legislation for both domestic and imported foods is the responsibility of the national 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 the WTO trade agreements, namely, the Agreement on Technical Barriers to Trade (TBT) and Agreement on Sanitary and Phytosanitary Practices (SPS).

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