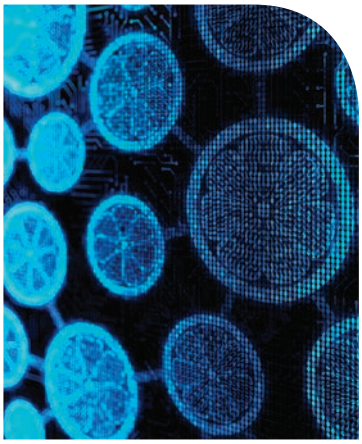
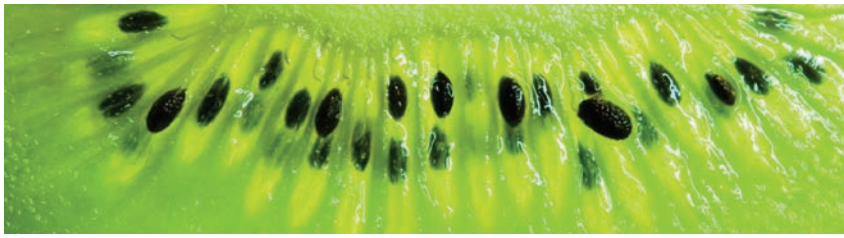


Managing food-related health risks



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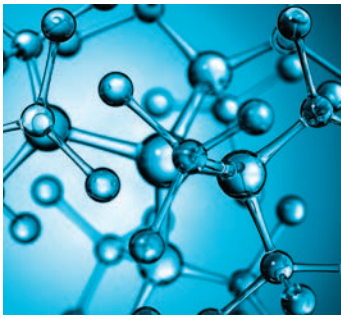


6 Managing food-related health risks

6.1 General approach to risk management

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

Risk management in FSANZ is broadly consistent with Codex, FAO/WHO and other food regulatory agencies. It is a consultative and decision-making process that identifies the problem; considers the risk assessment, social, economic and other factors; and develops, weighs and selects the option of greatest net benefit to the community. This process may also evaluate the implemented decision.

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

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

6.2 FSANZ's risk management process

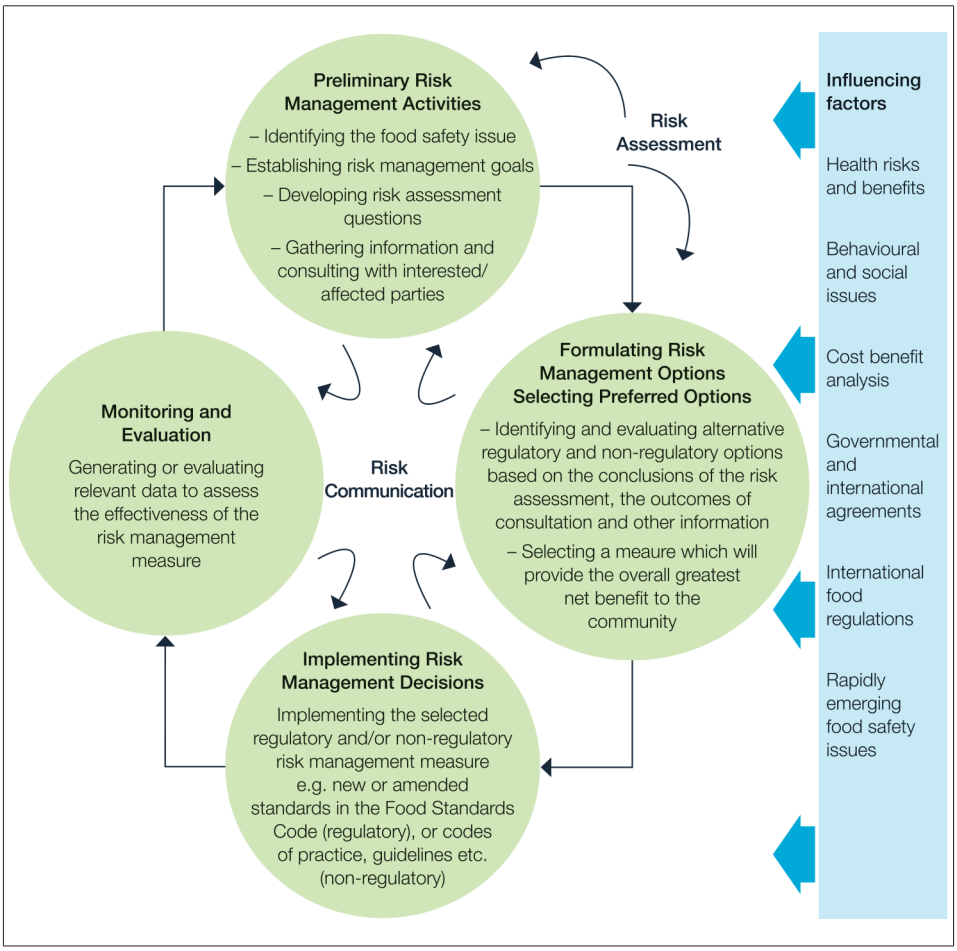
FSANZ's risk management process is guided by a risk management framework comprising four overarching components. These are: preliminary risk management activities; formulating risk management options and selecting preferred option(s); implementing risk management decisions; and monitoring and evaluation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

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

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

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

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



6.2.1 Preliminary risk management activities

Identifying the food health and safety issue

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

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

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

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

Establishing risk management goals and planning how to achieve them

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

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

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

Developing risk assessment questions

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

Gathering information and consulting with stakeholders

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

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

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

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

6.2.2 Formulating risk management options and selecting preferred options

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

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

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

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

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

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

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

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

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

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

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

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

6.2.3 Implementing risk management decisions

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

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

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

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

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

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

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

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

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

6.2.4 Monitoring and evaluation

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

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

6.3 Factors influencing risk management decisions

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

6.3.1 Health and safety issues – risks and benefits

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

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

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

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

6.3.2 Behavioural and social issues

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

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

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

6.3.3 Regulatory analysis

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

FSANZ follows COAG[16] best practice regulation principles and guidelines to ensure that (where possible) the costs and benefits and net effect of the various options identified as part of the proposals and applications process are provided to decision makers. For some regulatory proposals and applications, this may involve preparing a Regulation Impact Statement (RIS). A regulation impact statement comprises seven elements:

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

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

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

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

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

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

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

6.3.4 Governmental and international agreements and international food regulations

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

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

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

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

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

(i) new data for the domestic situation that was not available at the time the international standard was set becomes available for assessment

(ii) the domestic environment (climate and growing conditions) results in different levels of risk from contaminants, natural toxicants or nutrient levels in foods

(iii) domestic consumption patterns result in different dietary exposures

(iv) particular manufacturing and production processes have been adapted to meet specific domestic requirements.

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

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

6.3.5 Rapidly emerging food incidents

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

6.4 Options for managing food-related health risks

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

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

6.4.1 Regulatory measures

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

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

End-product standards

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

Pre-market assessment of certain foods and food ingredients

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

Food additives and processing aids

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

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

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

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

Novel foods and nutritive substances

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

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

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

Genetically modified foods

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

Irradiated foods

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

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

Contaminants and natural toxicants

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

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

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

Agricultural and veterinary chemicals in Australia

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

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

Microorganisms

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

Plants and fungi

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

Food labelling

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

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

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

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

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

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

Outcome-based standards

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

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

Food safety programs

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

Food handling practices

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

Processing requirements

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

Primary production requirements

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

6.4.2 Non-regulatory measures

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

Codes of practice

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

A code of practice could be developed where:

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

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

Guidelines and protocols

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

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

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

Consumer information/advice

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

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

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

6.5 Monitoring and evaluation activities

6.5.1 Monitoring activities

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

Monitoring can:

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

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

Australian Total Diet Study

The ATDS[20] is conducted approximately every two years with support from Australian jurisdictions and examines Australians' dietary exposures to a range of substances that may include agricultural or veterinary drug residues, environmental contaminants, natural toxicants, certain food additives and nutrients. The ATDS allows FSANZ to monitor the food supply and provides data to inform risk assessment activities. The ATDS collects and analyses foods that best represent the Australian diet nationwide. To achieve more accurate dietary exposure estimates, the foods examined in the ATDS are prepared to a 'table ready' state before they are analysed to provide quantitative data on the levels of chemicals in foods as consumed. As a consequence, both raw and cooked foods are examined.

Other FSANZ surveys

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

OzFoodNet

OzFoodNet[21] was established by the Department of Health as a national network to monitor public health events that can be indicators of foodborne hazards. It seeks to improve the accuracy and timeliness of notification of foodborne-related infections particularly those that cross state, territory and national borders, and to provide comprehensive interpretation of state and territory surveillance data. It also facilitates the coordination of state and national investigations of clusters and outbreaks of disease, and provides a focus for studies examining the risk factors associated with foodborne disease.

20 http://www.foodstandards.gov.au/science/monitoring/pages/australiantotaldiets1914.aspx
21 http://www.ozfoodnet.gov.au

National Residue Survey

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

Imported Food Inspection Scheme

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

State, Territory and New Zealand surveys

Health, agriculture and environment departments in each of the Australian jurisdictions and New Zealand may conduct surveys on a variety of food chemical and microbiological contaminants. Under the Implementation Sub Committee for Food Regulation (ISFR), FSANZ, the Australian jurisdictions and New Zealand have established a coordinated food survey plan[24]. This plan coordinates surveillance activities across jurisdictions and New Zealand—this makes more efficient use of resources and undertaking more statistically robust studies using commonly agreed methodologies. It enables a higher level of scrutiny and peer review, collaboration amongst jurisdictions in the areas of sampling and analysis, less duplication of surveillance activities and discussion of results with a view to ensuring consistent risk management options, as appropriate.

6.5.2 Evaluation activities

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

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

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

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

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

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

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

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