New Zealand's Food Safety Risk Management Framework

NEW ZEALAND FOOD SAFETY AUTHORITY

Te Pou Oranga Kai o Aotearoa

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Foreword

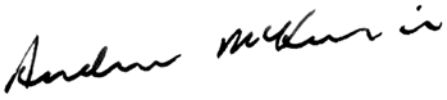
The last decade has seen an unprecedented level of change in the approach to food safety. The drivers for this change have been diverse and are generated by all stakeholders active in the food chain including consumers, government, industry and the academic community. As a consequence, food safety authorities around the world are continuing to evolve structural, legal and operational responses to chart new courses in their efforts to protect consumers against foodborne illness.

The New Zealand Food Safety Authority (NZFSA) is no exception and this document describes the generic Food Safety Risk Management Framework that we consistently apply to address all food safety issues. Much of our work is about understanding and dealing with foodborne risks to consumers, and transparent and agreed processes are needed to incorporate risk-based approaches to our activities wherever practicable.

Food safety risk management can be described in general terms as the process of evaluating available food control options in consultation with interested stakeholders and then implementing regulatory standards or other risk management measures and activities as appropriate. Our Food Safety Risk Management Framework ensures that all aspects of internationally recognised risk analysis practice, ie, risk assessment, risk management and risk communication, are combined with monitoring and review in a logical manner to maximise the benefits available from a risk-based approach to food safety.

Robust science is a key input to all components of New Zealand's Food Safety Risk Management Framework. This is provided from a range of sources including our own NZFSA Science group, contracted science providers, and international liaison. The cyclical nature of our Framework reflects the continual quest for better scientific data and the importance of basing risk management decisions on sound scientific judgment.

The Framework can only ensure that stakeholder goals are achieved if food safety control measures are underpinned by well-functioning operational systems. We are proud of our record in this area and will continue to ensure that the outputs of the Framework are effectively supported by the routine activities of all our business groups.



Andrew McKenzie
Chief Executive

Introduction

NZFSA, working alongside businesses and third party agencies active in the food sector, plays a vital role in ensuring the New Zealand food supply is safe.

To fulfil this role, NZFSA applies a robust and transparent framework – the Food Safety Risk Management Framework - to systematically manage the food safety risks that need to be addressed in an ever-changing food chain environment. The Framework underpins all of the work that NZFSA undertakes towards realising the priority of safe food.

New Zealand's Food Safety Risk Management Framework consists of four steps, each supported as appropriate by effective two-way risk communication:

1. preliminary risk management activities
2. identification and selection of risk management options
3. implementation of control measures
4. monitoring and review.

This document describes these four steps and the rationale for them, and gives examples of how they are put into practice by NZFSA[1].

NZFSA recognises that any process of managing risks will always reflect the current state of scientific knowledge, and that there is a need to continually invest in all aspects of risk management in order to achieve ongoing improvements in food safety.

1 This document reflects the practical experience gained by NZFSA during recent years. It updates *Food Administration in New Zealand: A Risk Management Framework for Food Safety,* which was published jointly in 2000 by the New Zealand Ministry of Health and the Ministry of Agriculture and Forestry, and the *Risk Management Framework* published by NZFSA and updated in April 2008.

Why the need for an agreed process for risk management?

A time of change

Food safety is of fundamental importance to producers, consumers and regulators of food, as well as being a pre-requisite for overseas market access; yet food safety issues can also court controversy. During the last decade, increased knowledge has become available about the risks to consumers associated with many biological, chemical, physical and nutrient-related hazards in the food chain[2]. This growth in knowledge has occurred in parallel with the successful application of many new food safety regulatory systems and programmes. Nevertheless, foodborne illness continues to be a major global problem. Governments must respond to assure the safety of food provided to domestic consumers and to those in foreign markets.

Global drivers of change

NZFSA's mandate is to protect consumers by providing an effective food regulatory programme covering food produced and consumed in New Zealand, as well as imports and exports of food products. NZFSA therefore gives high priority to managing the risks associated with both existing and emerging hazards in the global food chain, where these have potential to impact adversely on public health, and on trust and confidence in New Zealand's food and related products both domestically and internationally.

Global drivers of change in food safety are particularly important influences on the New Zealand situation because food exports are very significant to our economy. Despite its own substantial food production, in recent years New Zealand has also imported at least one-fifth of its food by value to satisfy increasingly diverse and sophisticated demand from domestic consumers.

Along with the growth in international trade in food, there has been vast expansion in the geographical origin, nature, range, preservation requirements and intended end uses of foods produced and consumed globally. This places ever-increasing demands on the resources of NZFSA when it comes to managing risks that impact on the New Zealand food chain. This is especially true when identifying emerging hazards associated with changing agricultural practices and new processing technologies, and applying appropriate control measures. Further, many foods that may have some potential to generate adverse health effects are at the same time essential components of a healthy diet, with the result that they can pose particularly complex risk management and communication challenges.

Domestic drivers of change

The seamless nature of the international and domestic food environment means that new and emerging hazards elsewhere in the world inevitably impact on domestic New Zealand stakeholders and consumers.

Specific concerns raised by domestic consumers add to the range of potential hazards that must be addressed by NZFSA. Examples of areas of increased consumer awareness and concern include nutritional deficiencies in diets and allergens in foods.

NZFSA has an increasing focus on nutrition and works to facilitate New Zealand consumer choices that support better health.

Figure 1: Global and domestic drivers of change in food safety

2 A variety of technical and scientific terms are used throughout this document. The meanings that NZFSA attributes to these terms are set out in the glossary at pages 32-34.

NZFSA's food safety priorities

NZFSA has identified high level outcomes that reflect the priority it gives to responding to drivers of change in food safety.

High level outcomes for NZFSA

- **Outcome 1:** Improved safety and suitability of food
- **Outcome 2:** Effective government role in facilitating commerce and market access
- **Outcome 3:** Consumer food practices and choices that support better health[3]

Consumer food practices and choices present complex challenges and may involve risk management and communication decisions that deal with competing elements, eg, the potential of developmental risks in children from low levels of mercury in fish, compared with the general nutritional benefits of fish consumption. The need to make such complicated decisions creates demands for high-quality scientific input and specialist risk communication skills.

NZFSA also works towards ensuring that government plays an effective role in facilitating commerce and market access. This is driving closer cooperation between NZFSA and industry in identifying priority areas for applied research and regulatory change so as to accommodate innovative and cost-effective technologies. NZFSA aims to target the steps in the food chain where prevention or control is most practical and cost-effective. The New Zealand Government's promotion of economic, environmental and social sustainability also influences NZFSA domestic regulatory policies.

In a modern food safety system, there is an onus on the food producer and processor to produce safe food. While NZFSA is responsible for developing regulatory measures, and for carrying out associated activities such as providing consumer information, New Zealand industry players themselves must implement and verify relevant food control measures to the satisfaction of government. Both the control measures and the levels of official supervision needed are under constant review by NZFSA in terms of effectiveness and efficiency.

As scientific and technical knowledge of hazards and controls inevitably changes and advances, existing standards and other measures already in place to manage food safety risks can become outdated. It is therefore essential that NZFSA implements an ongoing process of monitoring and review, and where appropriate, modernises existing measures to take advantage of progress.

Finally, there will always be food safety hazards that emerge without warning in both the New Zealand and international contexts. NZFSA needs to have a trusted and systematic process on which it can rely, to effectively respond to, and manage, the unexpected.

Public health goals

Around the world, government agencies concerned with food safety are adopting specific public health goals as part of government policy. Monitoring and review of foodborne disease statistics not only demonstrates achievement of food safety outcomes; it also provides information on the effectiveness of underlying regulatory systems and the necessary allocation of food safety resources proportional to risk.

When setting outcomes related to public health, NZFSA strives to find ways to demonstrate that a change (or no change) can, with a reasonable degree of certainty, be attributed to the actions of NZFSA.

In 2008, NZFSA established three goals against which it can monitor progress in improving the safety and suitability of food for consumers. These are:

- a 50% reduction in the reported annual incidence of foodborne campylobacteriosis by 2013 from a baseline of 160 per 100,000 population to 80 per 100,000 population
- a 30% reduction in the reported annual incidence of foodborne salmonellosis by 2013 from a baseline of 14.2 per 100,000 population to 10.6 per 100,000 population
- no increase in the average reported annual incidence of foodborne listeriosis over the five year period to 2013.

Achievement of these goals over time will be highly dependent on systematic application of risk analysis principles and guidelines according to an agreed risk management process.

3 Drawn from the *NZFSA Statement of Intent, 2009-2012* which can be accessed at: www.nzfsa.govt.nz

Overseas public health goals

NZFSA's public health goals can be compared to those recently established by other countries. In the United States, the public health goals of 'Healthy People 2010' include a 50% reduction in general cases of campylobacteriosis and cases of post-diarrhoeal haemolytic uraemic syndrome (HUS) in young children by 2010[4]. In the United Kingdom, food safety goals (which contribute to public health goals) include a 50% reduction in the incidence of broiler chickens which test positive to *Campylobacter*, and a 50% reduction in the incidence of pigs that test positive to *Salmonella*, at the end of slaughter by December 2010[5].

Emergence of food safety risk analysis

In recent years, risk analysis has emerged as a core food safety discipline. It is employed to answer a basic set of questions:

- what can go wrong?
- how likely is it to go wrong?
- how serious would it be if it went wrong?
- what can be done to reduce the likelihood and/or seriousness of it going wrong?

The components of risk analysis

Risk analysis is supported by a set of internationally-agreed principles and guidelines that are now applied by many countries.

Risk analysis comprises three components (see Figure 2):

- risk assessment: a scientifically based process consisting of hazard identification, hazard characterisation, exposure assessment and risk characterisation. (This process and its application by NZFSA are described in more detail at pages 16-18 and in Annex 1).
- risk management: the process of weighing risk management options in the light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures (described in more detail at pages 19-25).
- risk communication: the interactive exchange of information and opinions concerning risk between all interested parties throughout the risk analysis process (described in more detail at page 12 and in Annex 4).

NZFSA's Food Safety Risk Management Framework combines the three components of risk analysis with the good practice of monitoring and review to ensure that any risk management options achieve what is expected and align with broad risk management goals.

Prevention, reduction or elimination of risks can take many forms and may involve taking into account scientific findings alongside other considerations such as the health expectations of society, the rights of consumers to make choices about the food they eat, and the likely costs and benefits of potential control measures.

Figure 2: Components of risk analysis

4 'Healthy People 2010' is managed by the Office of Disease Prevention and Health Promotion of the United States Department of Health and Human Services. The website for "Healthy People 2010" can be accessed at: www.healthypeople.gov

5 United Kingdom Food Standards Agency, *Strategic Plan to 2010 – Putting Consumers First,* page 4.

Government management of food safety risks

Since the early 2000s, food safety authorities around the world have undergone structural change so as to better support risk analysis. NZFSA has been no exception and, from 2002 to 2007, initiated significant policy and structural changes to support a risk-based approach to food safety issues. Recent regulatory reform in New Zealand has also promoted greater stakeholder participation in the development of risk management controls, and increased the focus on public health outcomes, rather than prescriptive regulatory requirements.

In 2007, NZFSA became a stand-alone public service department and has since continued to fine-tune its risk-based approach to food safety. New work programmes reinforce NZFSA's 'production-to-consumption' approach to food safety. They draw on an increasing range of expertise as inputs to risk-based decisions, eg, in areas of economics, human and veterinary medicine, nutrition, statistics and risk modelling, food technology, public policy and social sciences. This multidisciplinary approach is important if consumers are to have full confidence in the activities undertaken by NZFSA.

As a signatory to the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (the WTO SPS Agreement), New Zealand also has responsibilities to pursue a risk-based and equitable international trading environment for food. Consequently, NZFSA has developed a comprehensive strategy for incorporating the risk analysis guidelines developed by the international food standards agency, Codex Alimentarius Commission (Codex), in its regulatory systems wherever appropriate.

Ultimately, NZFSA recognises that a regulator has a special responsibility to put health risks in perspective in all aspects of its activities, while factoring in legitimate concerns expressed by stakeholders relating to economic, political, social and environmental considerations. In times of limited fiscal and technical resources, NZFSA must prioritise its risk management activities to those areas that pose the greatest foodborne risks to New Zealand and international consumers.

New Zealand's Food Safety Risk Management Framework

A process for ensuring food safety

NZFSA, working alongside businesses and third party agencies active in the food sector, plays a vital role in meeting expectations that the New Zealand food supply is safe.

NZFSA fulfils this role by using the four-step Food Safety Risk Management Framework to work through food safety issues using a process that is iterative and dynamic.

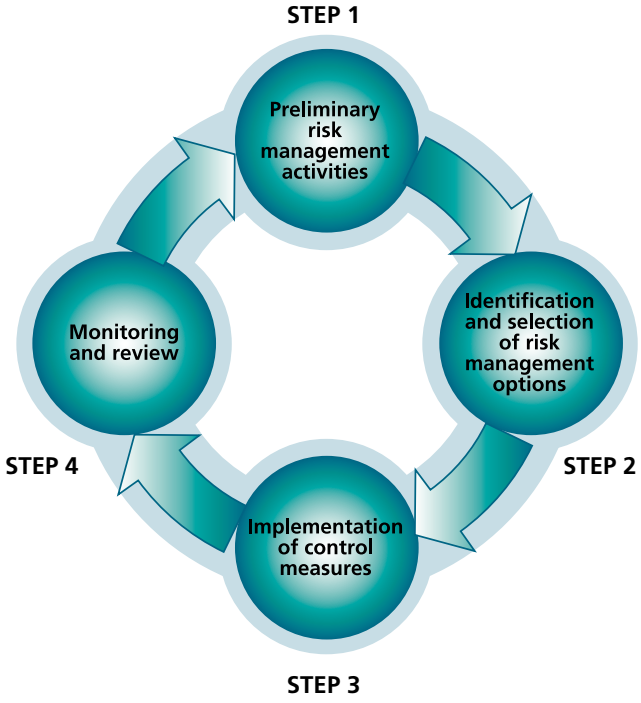


Figure 3: Components of New Zealand's Food Safety Risk Management Framework

Each of the fours steps of the Framework is described in detail at pages 14-31.

The Framework provides for the evaluation of potential risks associated with existing, new or re-emerging hazards. To manage these risks, risk managers identify and select appropriate control measures. These measures include both mandatory regulatory standards and other non-mandatory measures and activities.

The Framework also incorporates the monitoring of existing and known hazards in the food chain and the periodic review of regulatory standards and other measures that have already been implemented. This often leads to the revision, and possible removal and cessation, of some existing measures.

While inputs may vary substantially for each food safety issue, NZFSA initiates the risk management process and sees it through to completion. The benefits of consistent application of a risk management process include:

- establishment of food control systems that are risk-based and achieve the levels of protection that consumers expect
- decisions about management options that are proportionate to the health risks involved
- innovation and flexibility that can be built into the measures and activities undertaken
- due regard being given to both the costs and benefits of control measures and other activities undertaken to manage risks
- risk communication strategies that are implemented at all appropriate stages.

While the Framework focuses on food safety, its general steps can also be applied to deal in a logical and transparent way with matters relating to the suitability of food.

The Framework facilitates interaction between government, industry, consumers and other stakeholders on issues relating to the management of risks, while allowing NZFSA to act in a consultative manner that is independent of sector interests. The Framework allows science to be appropriately merged with other inputs in the development of standards and other risk management activities.

NZFSA's Food Safety Risk Management Framework is recognised as an example of best practice by trading partners. It closely matches systems of analysis developed by international organisations concerned with food safety, including the Food and Agriculture Organization and the Codex Alimentarius Commission. This is important because risk management decisions made by international organisations increasingly influence the New Zealand food safety regulatory environment and impact directly on domestic and international markets. Some key international sources and influences on the Framework are listed at page 41.

What needs to be managed?

The Food Safety Risk Management Framework is concerned with:

- **hazards:** biological, chemical or physical agents in, or conditions of, food with the potential to cause adverse health effects[6]
- **risk:** a function of the probability of an adverse health effect[7] and the severity of that effect, consequential to a hazard(s) in food.

Examples of the hazards with which the Framework is concerned include:

Type of hazard	Examples
Microbiological	• pathogenic bacteria that cause foodborne disease • foodborne viruses • fungi • parasites • protozoa
Chemical	• residues of veterinary drugs including growth promotants and animal feed additives • residues of pesticides or fertilizers • natural toxins • environmental contaminants • chemicals from packaging materials • food additives and processing aids
Nutrient–related	• nutrients or related substances in food that have the potential to cause adverse health effects, depending on inadequate or excessive levels of intake
Physical	• extraneous matter, eg, metal or glass fragments

Many of these hazards are present at low levels in food without posing any appreciable risk to public health. Such foods are usually regarded as acceptable, because there is reasonable certainty that under normal conditions of consumption the food will not cause any harm. Other hazards can be present in food without posing any risk to the general population, but may be of some risk to sub-groups of the population (including the very young, frail elderly, pregnant, and immune-compromised).

Some hazards have been continually present in the New Zealand food chain for many years. Others are newly emerged, or have re-emerged, due to reasons that include:

- changes in production systems and technologies, eg, relating to animal husbandry, crop production and food processing
- new and emerging zoonotic illnesses
- expansion in international trade, which introduces new foods or new food sources to a food chain
- changes in lifestyle and consumer demands, including greater consumption of ready-to-eat foods
- microbial adaptation.

The role of the risk manager

While all stakeholders have a role in the Food Safety Risk Management Framework, it is NZFSA as the risk manager that initiates the application of the Framework, and then drives the progression through all of its four steps.

In practice, staff in different business groups within NZFSA assume the role of risk manager, depending on the specific hazard being addressed. Usually it is staff in the NZFSA Standards group, the Approvals and Agricultural Compounds and Veterinary Medicines (ACVM) group, or the Joint Food Standards team within the Science group, who assume the role of risk manager. Staff in these groups hold relevant qualifications in diverse disciplines including veterinary science, food technology, nutrition, and pharmacology.

The risk manager initiates and co-ordinates scientific and other inputs as needed. To ensure that any scientific analysis undertaken delivers results that are apt and clearly understood, the risk manager consults closely with the risk assessors in the NZFSA Science group. The risk manager also solicits input as needed from other NZFSA groups, including Policy, Legal, Communications, Compliance and Investigation, and the NZFSA Verification Agency (the Verification Agency).

6 This definition includes nutrient-related hazards, which are nutrients or related substances in food that have the potential to cause adverse health effects depending on inadequate or excessive levels of intake.

7 The adverse effect can range from negligible to severe (including death), and the probability of the adverse effect occurring can vary from negligible to very high. In the context of food, some risks may be more serious than others, and some sub-groups within the population may be more susceptible to risks than other persons.

It is essential that the risk manager continually identifies interested and impacted parties and ensures that clear, interactive dialogue/consultation is maintained with these parties.

Other functions of the risk manager, which are integral to the overall success of the Framework, include:

- identifying and defining the food safety issue to which the Framework needs to be applied
- setting, prioritising and articulating the goals of the risk management process. This involves taking account of public health goals, as well as relevant economic, consumer, political, environmental and legal considerations
- posing the questions that need to be answered at all steps in the Framework. These questions shape how the food safety issue is scoped and addressed. They also define what, and how, intelligence and scientific evidence is gathered and assessed (eg, whether a risk profile and/or risk assessment are needed)
- agreeing guidelines for dealing with uncertainties
- commissioning a risk assessment, in consultation with scientists, where required. Risk assessments can take a variety of forms, depending on the specific hazard and the risk management questions being posed. They may be formal and comprehensively cover hazard identification, hazard characterisation, exposure assessment and risk characterisation. At other times, they may be more informal and flexible in their content[8].
- reviewing the outputs of the risk assessment (where this has been undertaken), considering other relevant factors, and reaching decisions on the options for managing risk
- taking responsibility for formulating and selecting the control options that are most likely to achieve the risk management goals
- developing principles and practices to be followed during implementation of options
- ensuring processes are in place for verification of options, where applicable
- ensuring that application of the Framework is a continuing process that monitors and takes account of newly generated data, and evaluates and reviews risk management decisions as appropriate
- strategic development and management.

The role of science

An international consensus has developed that, to the extent practicable, there should be clear role differentiation between those who undertake the scientific evaluation and risk assessment steps in frameworks for managing risks, and those who make risk management decisions and implement related measures and activities. The intent of this role differentiation is to protect the integrity of scientific evaluation and risk assessment as objective and unbiased activities.

NZFSA, along with a number of other food safety authorities, has reinforced this role differentiation in its organisational structure. The Science group is the main repository for scientific expertise in NZFSA and provides scientific advice to the other business groups. Where necessary, the Science group contracts scientific inputs from external providers. Participation in international standard-setting organisations and their working groups is another important source of cutting-edge scientific information[9].

Figure 4 demonstrates the range of scientific inputs available at each step in the Food Safety Risk Management Framework. Decisions about the nature and quantity of scientific inputs which are required will be made on a case-by-case basis depending on the specific hazards and risks involved. For example, rather than being completed routinely, risk assessments are undertaken only when there is a justifiable need. In other instances, risk management decisions are based on alternative intelligence and scientific sources, such as knowledge and experience of good hygiene practice (GHP), or one element of the risk assessment process, such as an exposure assessment.

8 Refer pages 16-18 and Annex 1 for further information on risk assessments.

9 Participation in international standard-setting work is also an important source of information for NZFSA staff tasked with developing and reviewing regulatory standards and other risk management measures and activities.

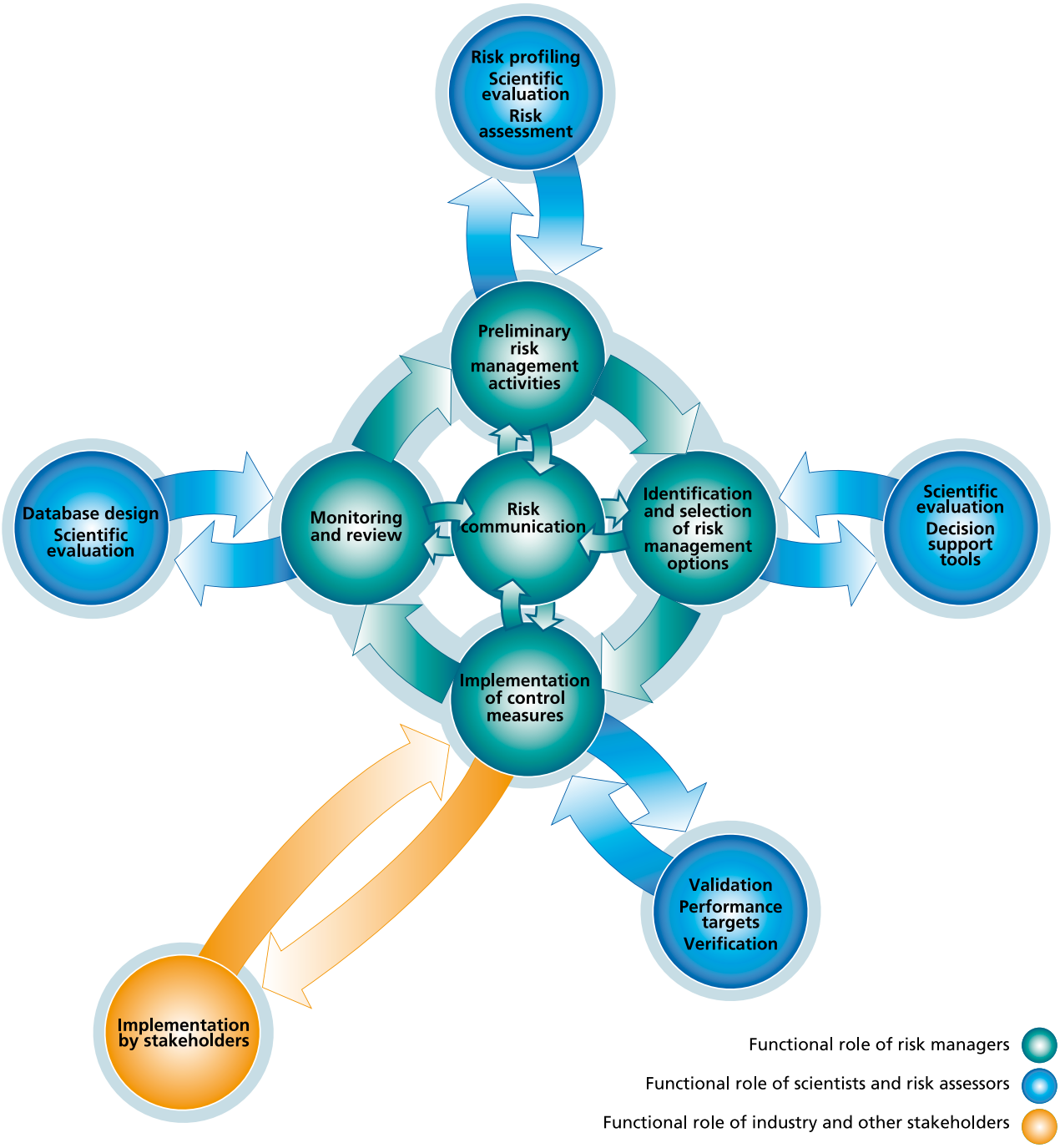


Figure 4: Scientific inputs to the Framework

The role of risk communication

Risk communication is an essential component in the risk analysis process. It can both support the overall process of risk management, and be an effective risk management tool in its own right.

NZFSA uses risk communication to bridge any gaps between the evaluation of risk by experts and the views of other stakeholders, including consumers, and to encourage the interactive exchange of findings and comment. When communicating risk management options and decisions, NZFSA takes into account the knowledge, attitudes, values, practices and perceptions of stakeholders. NZFSA aims to foster public trust by communicating clear accessible information which ensures stakeholders understand risk management decisions and the justification for making them.

At times, an effectively-implemented communications strategy, drawing on scientific evidence, can be a primary tool for addressing a food safety issue. Such a strategy can be appropriate in situations where consumers may consider a food poses a greater risk to public health than is supported by the scientific evidence. NZFSA then aims to provide reassurance by publicising the scientific data in readily understood terms, and ensuring people can access this information when making choices about consuming the food.

Communications strategies can also be used in conjunction with other risk management measures. An example of where this combined approach is appropriate is when control measures ensure that hazards in foods are reduced to levels that are safe for the general population, but are not stringent enough to prevent low levels being present that could pose risks to certain vulnerable sub-groups (including the very young, frail elderly, pregnant, and immune-compromised). In such cases, communications strategies can target the vulnerable persons and encourage them to avoid consumption of the food concerned.

Further information about NZFSA's use of risk communications is given in Annex 4.

Cross agency links

NZFSA's sphere of influence extends to all food and food related issues associated with public health, including foodborne diseases and aspects of nutrition directly related to the food supply chain. This scope is reflected in the goals that NZFSA, as the risk manager, sets when applying the Food Safety Risk Management Framework.

A number of other New Zealand government agencies operate in related public health areas, including the Ministry of Health, Biosecurity New Zealand[10], and the Environmental Risk Management Authority (ERMA New Zealand). NZFSA maintains close contacts with these agencies to ensure co-ordinated strategic approaches and work programmes are followed where appropriate, and to avoid duplication in risk management initiatives and interventions.

Sometimes the laws administered by NZFSA lay down formal requirements for consultation with other government agencies (as does for example the Agricultural Compounds and Veterinary Medicines Act 1997 (the ACVM Act)). In other instances, NZFSA has concluded Memorandums of Understanding with government agencies to clarify relationships and responsibilities.

10 Biosecurity New Zealand is part of the Ministry of Agriculture and Forestry, and is also known as MAF Biosecurity New Zealand (MAFBNZ).

NZFSA and Food Standards Australia New Zealand

Following the signing in 1995 of the *Agreement Between the Government of Australia and the Government of New Zealand Concerning a Joint Food Standards System* (the Food Treaty), NZFSA has worked closely with the Australian Commonwealth, States and Territories on matters relating to joint food standards that apply to food sold in both countries.

The Food Treaty established a joint trans-Tasman food standards body – Food Standards Australia New Zealand (FSANZ). FSANZ develops the food standards that comprise the Australia New Zealand Food Standards Code (the Food Code) and which are concerned with the composition and labelling of food sold in Australia and New Zealand. Policy guidelines for the development of these food standards are set by the Australia and New Zealand Food Regulation Ministerial Council, of which the New Zealand Minister for Food Safety is a member. The Council is advised by the Food Regulation Standing Committee, which includes senior officials from NZFSA.

While FSANZ co-ordinates the development of the Food Code, NZFSA is responsible for co-ordinating the input of the New Zealand government into the Food Code development, and for undertaking its implementation and enforcement in New Zealand. NZFSA and FSANZ can conduct their own separate risk analysis of food safety issues (an example being the individual risk assessments that both have undertaken relating to Roquefort cheese), but wherever possible they co-operate and share scientific information and aim to harmonise food safety outcomes. An NZFSA/FSANZ forum, the Australia New Zealand Science and Exposure Assessment Forum (ANZSEAF), has been established to co-ordinate science between the two agencies.

FSANZ has published a guide to the broad approach that it uses to analyse the health risks associated with food[11].

11 Food Standards Australia New Zealand, *The Analysis of Food-Related Health Risks,* 2008.

The four steps of New Zealand's Food Safety Risk Management Framework

The key tasks associated with each of the four steps of New Zealand's Food Safety Risk Management Framework are illustrated in Figure 5. While the risk manager follows a step-wise approach when moving through the Framework, the order and number of steps included may vary.

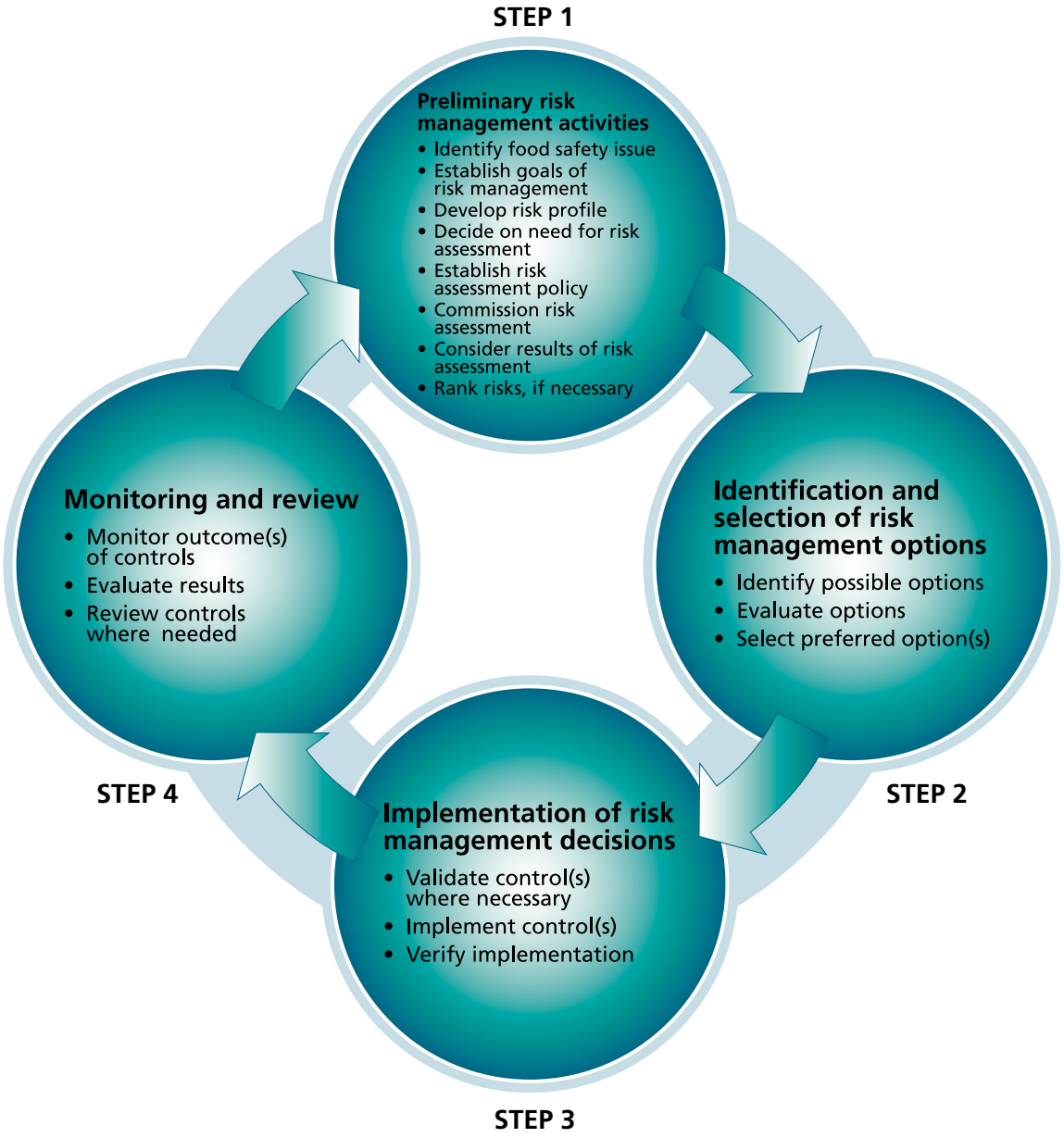


Figure 5: Key tasks in each step of the Framework

Step 1: Preliminary risk management activities

During the initial step in the Framework, the risk manager (often working in consultation with the risk assessor) will require that certain tasks be undertaken:

Step 1 tasks

- identify food safety issues
- establish broad risk management goals
- gather data including, if required, commission risk profiling and/or other scientific evaluation
- decide on the need for a risk assessment and, if required, the form this should take
- if needed, set risk assessment policy and commission the risk assessment
- consider the results of the risk assessment, where applicable
- rank and prioritise the food safety issue for risk management consideration.

Identify food safety issues

Identification of food safety issues that will trigger a risk management response arises from many sources but most issues are identified by NZFSA's ongoing activities, including monitoring and intelligence gathering by the Science and Standards groups. Contributions are made by the Compliance and Investigation group and the Verification Agency who make observations as the 'eyes and ears' of NZFSA during their contact with industry. Information can also be derived from external sources, such as new concerns raised by consumers, or through requests from industry for the evaluation of innovative food production and processing technologies. New hazards identified by the global scientific and food safety community (including risk assessments carried out by international expert groups like the Joint FAO/WHO Expert Meetings) can be another trigger for risk analysis being initiated, as can discussions about equivalence with trading partners.

Establish broad risk management goals

Goals are statements of the intended purpose and end result that risk management options are intended to accomplish. They will be linked to the NZFSA mandate, eg, to reduce the incidence of foodborne illness.

Goals are articulated by the risk manager and used to guide each step of the Food Safety Risk Management Framework. They are generally first set early in Step 1 of the Framework, to help guide the choice of data to be gathered and to influence the parameters for any risk profiling activities. However, because the full nature of risk may not be known until after scientific analysis and other intelligence gathering is complete, goals must be revisited and reviewed on a regular basis. They may require adjustment either later in Step 1 as the data gathering and any risk profiling and risk assessment activities progress; and/or during other steps of the Framework, eg, if new information comes to light during monitoring and review (Step 4 of the Framework).

Commission risk profiles

Risk profiling provides an opportunity to gather scientific data and other information on possible food safety risks associated with a food safety issue and provides a lead for risk managers to assess whether further action is required. Essentially, a risk profile is an exercise in determining 'what we already know' and 'what we need to know' for a particular food/hazard combination.

Risk profiles draw upon information from a range of sources, including information generated overseas, advice from experts, and data gathered through surveys, including sampling testing and behavioural surveys. The risk manager will often commission a risk profile as a specific scientific exercise, involving the NZFSA Science group or other business groups.

Each risk profile should be fit-for-purpose – and in some situations will be a very elemental exercise. Components that may appear in a risk profile include:

- description of the food and the food chain scenario or context
- the biological or chemical characteristics of the hazard
- available scientific information on possible risks (including descriptions of likely adverse health effects)
- identification of gaps or uncertainties in scientific knowledge
- description of current control measures, if any
- implications for trading agreements, such as the WTO SPS Agreement.

Following the completion of the risk profile, risk managers may need to reconsider the broad risk management goals. This is likely to occur in conjunction with a decision on whether or not a risk assessment is a feasible and necessary next step.

NZFSA risk profiles

NZFSA has commissioned an extensive set of risk profiles for hazard/ food commodity combinations of importance in New Zealand. These include:

- *Bacillus* spp. in rice
- *Campylobacter jejuni/coli* in poultry
- ciguatoxins in seafood
- *Clostridium botulinum* in ready-to-eat smoked seafood in sealed packaging
- *Listeria monocytogenes* in soft cheeses
- *Salmonella* (non-typhoid) in and on eggs
- shiga-like toxin-producing *Escherichia coli* in uncooked comminuted fermented meat products
- mycotoxins in the New Zealand food supply
- natural toxins in crop plants.

These risk profiles have guided a range of standard-setting and other activities designed to manage risks. The profiles constitute a 'living library' of up-to-date scientific information specific to New Zealand and are reviewed every five years to assess the need for amendment or modification.

Using risk profiling: aspartame

Public concerns arose in New Zealand during 2007 over the use of aspartame as an intense sweetener in foods, with claims of adverse health effects being widely covered in the media. A rapid response from NZFSA was needed to allay public fears and a full review of scientific information available from other food safety authorities was quickly undertaken. Of particular importance was the scientific report on aspartame published by the European Food Safety Authority in 2002 and an evaluation by NZFSA's Science group of the studies published in 2005 by the European Ramazzini Foundation. NZFSA found no scientific evidence in support of the new public claims of risks to human health and initiated a risk communication programme to this effect. It was not necessary to commission new risk assessment work in New Zealand.

Decide if a risk assessment is needed

A risk assessment is a science-based approach that uses available data to develop an understanding of, or characterise, the risk associated with a particular hazard. It can be quantitative and/or qualitative. It answers specific questions posed by the risk manager on likely risk, eg, about the severity and likelihood of a particular adverse effect, the individuals or population that may be at risk and the degree of uncertainty in the risk estimate. A further explanation of the risk assessment process is given in Annex 1.

Situations where a risk assessment is likely to be required include where:

- the issue is of significant concern to regulators and stakeholders
- little data exists and/or there is much uncertainty (while acknowledging that it may at times be necessary to fill some data gaps before a comprehensive risk assessment can be undertaken).

Risk managers may formally request from risk assessors an assessment that systematically covers the four steps of hazard identification, hazard characterisation, exposure assessment, and risk characterisation. In NZFSA, requests for such risk assessments often require authorisation from the NZFSA Board. At other times, risk assessments may be requested through a more informal process and/or the content may be tailored or reduced, to reflect the specifics of the food/hazard combination concerned and the risk management questions being posed.

Sometimes, food safety issues can be managed without commissioning a risk assessment. In such cases, risk profiling may instead be used directly by risk managers to guide identification and selection of risk management options.

A risk assessment is unlikely to be undertaken where:

- rapid action is needed, such as in an emergency[12]
- there is already sufficient scientific information on likely risks
- embarking on a risk assessment is impractical
- an issue is of minor food safety concern

Alternative scientific evaluation may be sought and other ways of developing available information on risk brought into play, eg, food source attribution data derived from surveillance of foodborne illnesses.

Examples of risk assessments commissioned by NZFSA

Recent risk assessments have determined risks associated with:

- *Salmonella* contamination of sheep meat
- *Cysticercus bovis* in domestic and exported beef
- *Salmonella* spp. in imported fresh broiler chicken meat
- *Campylobacter* in chicken meat
- Roquefort cheese imported from France (made from unpasteurised sheep's milk)

Commission risk assessments

If it is decided to commission a risk assessment, the risk manager should clearly define, in association with the risk assessors, the following aspects of the assessment:

- scope
- purpose
- question/s to be addressed
- expected outputs (qualitative or quantitative)
- the population or sub-population group(s) to be protected
- the priority the work will be accorded.

The previously established risk management goals will help direct the scope of the risk assessment and will likely be refined when the outputs are known. Required resources should also be agreed, and for some simple projects will be able to be provided by individuals. NZFSA may have to contract scientific research to fill data gaps as the risk assessment proceeds.

Risk assessments in emergency management

NZFSA, like all food safety authorities, must at times respond rapidly to emergency situations. Examples of such situations included contamination of New Zealand honey with the toxin tutin; and testing of the New Zealand food chain for melamine following issues with milk products being adulterated with melamine in China. NZFSA's emergency response can be triggered by many sources including: intelligence generated by its own monitoring activities; evidence of an adverse public health incident; or information volunteered by consumers, industry or drawn from overseas experiences.

NZFSA applies the four steps of the Food Safety Risk Management Framework to emergency situations. However, emergency situations almost always involve instances where it is not feasible or appropriate to conduct a comprehensive risk assessment prior to selecting and implementing control measures. Alternatively, if a risk assessment is undertaken it may have to be tailored to address immediate concerns and to quickly satisfy critical gaps in data. In such cases, NZFSA may proceed rapidly to selecting and implementing risk management options, such as a recall of product. A comprehensive risk assessment may be completed at a later date, and, once evaluated, the results would prompt review and, if necessary, refinement of risk management measures.

12 Note the preliminary regulatory response is likely to be revisited if a risk assessment later becomes available.

Set policy for risk assessments

During risk assessment, scientific judgements often entail a choice being made between several reasonable options. Thus gaps in scientific knowledge are bridged through a set of inferences that are agreed in accordance with risk assessment policy. Risk assessment policies are usually generic and are established by risk managers in consultation with risk assessors. These policies preferably should be established before a risk assessment commences.

'Safety factors' in chemical risk assessment

An example of risk assessment policy is when NZFSA applies internationally-accepted default 'safety factors' to estimate acceptable daily intakes (ADIs) for chemical residues in foods. Animal exposure studies are used to determine 'no observed adverse effect levels' and then a safety factor of 10 is applied to account for any variation within a species, such as higher susceptibility of very young and aged members of a population. An additional factor of 10 is applied in case there is any interspecies variation when extrapolating from the animal test species to humans.

Consider the results of risk assessments

Proper interpretation of the outputs of the risk assessment (qualitative and quantitative) by the NZFSA risk manager, in conjunction with the risk assessor, is a vital function. The overall strengths and weaknesses of the risk assessment, including any uncertainties, should be discussed and documentation should include a general summary that can be readily understood by stakeholders.

Rank and prioritise food safety issues

Ranking of food safety issues for risk management action can take place at different stages during preliminary risk management activities. While ranking is essentially a scientific exercise, prioritisation of issues is an NZFSA management role. New work may be prioritised according to drivers other than the rank of food safety risk, eg, consumer interest and/or political concerns within New Zealand or, as periodically happens, disputes over international market access.

NZFSA *Campylobacter* Risk Management Strategy: scientific evaluation and risk assessment

Following development of a comprehensive risk profile on *Campylobacter jejuni/coli* in poultry, NZFSA has implemented a detailed *Campylobacter* Risk Management Strategy with the goal of reducing the incidence of foodborne human campylobacteriosis by 50% between 2008 and 2013.

Due to the severity of the problem, preliminary risk management activities have covered a range of scientific projects. Short-term responses have included scientific collaboration with industry to further develop best practice guidelines for poultry producers and processors. Medium-term responses have included scientific evaluation of the likely level of hazard control associated with a number of hazard-based interventions throughout the food chain. A farm-to-plate poultry risk assessment model has also been developed so that risk-based controls that achieve agreed levels of consumer protection can be regulated in the longer term.

Step 2: Identification and selection of risk management options

In the second step of the Food Safety Risk Management Framework, the risk manager leads the process of identifying and selecting risk management options according to appropriate criteria.

Broadly, the process of identifying and selecting risk management options takes account of the size, extent and impact of the food safety problem/issue. These factors are then considered alongside the benefits and costs of the different available options for mitigation or control, in terms of likely outcomes in terms of public health, the economy, environment, law, ethics, and social and political priorities.

A wide range of possible options for managing food safety risks are available to risk managers. These options can impact at one or more points in the food chain from the grower, harvester or farmer through to the end consumer. They include regulations, standards or specifications issued pursuant to the legislation that NZFSA administers, ie, the Agricultural Compounds and Veterinary Medicines Act 1997, the Animal Products Act 1999, the Australia New Zealand Food Standards Code, the Food Act 1981, and the Wine Act 2003. Non-mandatory measures, such as the development of codes or practice or advice to industry, can also be effective; as can communications strategies targeted at industry and/or consumers. Sometimes a combination of different options will be used to provide the most appropriate solution.

Examples of risk management options

- Categorise products according to risks posed and establish varying levels of regulatory or non-regulatory controls for each category.
- Control or mitigate through new or amended regulation (with which compliance is mandatory). This can include standards and specifications pertaining to domestic, imported and exported foods, and joint trans-Tasman food standards.
- Control or mitigate through non-mandatory means, such as guidance issued by the regulator, information and training for industry, and industry innovation.
- Prevent or try to eliminate problems at source (eg, by placing controls on the use of agricultural compounds or veterinary drugs).
- Monitor the problem to see if further action is appropriate.
- Ban the food that poses unacceptable risk.
- Seize or recall food.
- Require industry to monitor hazards for process control purposes.
- Use risk communications to inform consumers.
- Label ingredients, or label with advisory or warning statements.
- Evaluate but make no change to current food controls.

Possible control measures for *Campylobacter*

The NZFSA *Campylobacter* Risk Management Strategy provides an example of where a range of possible control measures have been evaluated over a period of time to determine whether they would be effective and verifiable in the New Zealand context. Control measures evaluated in relation to broiler chickens have included:

- decontamination of drinking water
- testing of flocks prior to slaughter
- improved process hygiene
- chemical decontamination of carcasses
- performance targets for chilled carcasses
- commercial freezing
- leak-proof packaging at retail
- consumer information.

Criteria for evaluating and selecting risk management options

The process used to evaluate and select risk management options is critical to the overall success of New Zealand's Food Safety Risk Management Framework.

Best practice involves formulating an array of possible risk management options, and then analysing and comparing these options against criteria that will link to the broad risk management goals already set at an earlier stage of the Framework. Risk management options may be suggested by a variety of sources, including the risk manager, risk assessor, industry, consumers, and academia. The options considered will normally be compared against the status quo, as it is important to consider whether any change is actually necessary in order to sufficiently protect consumers. Where regulatory options are included, good practice encourages consideration of the minimum level of intervention and regulation necessary to achieve the desired level of consumer protection.

The achievement and protection of public health goals will be paramount when risk management options are evaluated and selected. The science-based and intelligence gathering tasks undertaken during the first step of the Framework will inform decisions, eg, in terms of how the possible options align with the severity of the risk, the likelihood of it occurring, the population affected, and the desire to reduce or eliminate the risk. Risk managers are likely to have asked the risk assessors to examine the impact of different control measures on minimising risks and this process may continue until one or more risk management options that achieve the desired level of consumer protection are chosen.

The criteria used to analyse and select risk management options will factor in legitimate considerations relating to economic, social, political, environmental, ethical and legal issues and values, including:

- consistency with government policy
- consistency with NZFSA's strategic and operational priorities, eg, as expressed in the NZFSA Statement of Intent
- consequences for international trade
- compliance cost implications for business
- impact on the ability of industry to innovate and be competitive
- acceptability to stakeholders (eg, industry and consumers), noting that different stakeholders may have competing or contradictory interests
- alignment with best practice regulation guidelines, eg, whether options take account of requirements for minimum regulation where possible, and effectiveness, efficiency, equity and clarity
- consistency with existing domestic and international food standards or legislation
- consistency with New Zealand's international obligations, including agreements to which we are signatories. An example could be whether options will be trade-restrictive, perhaps by being disproportionate to the risk identified
- the feasibility of implementation, verification, certification and enforcement
- how evidence can be gathered to demonstrate that options are effective
- other considerations which may be set down in empowering legislation administered by NZFSA.

NZFSA business groups make varying contributions to the process of identifying then using criteria to select risk management options. Examples of this participation include:

- the Standards and Approvals and ACVM groups, and the Joint Food Standards team in the Science group, leading the selection process when the food or food related issues being addressed fall within their areas of expertise
- the Science group, as risk assessors, assessing the impact of different options on reducing or eliminating risk and the feasibility of any proposed control measures in a particular food production or processing context
- the Policy group evaluating options, particularly against criteria relating to economic, political, consumer, and social factors[13]. Policy strives to evaluate the costs and benefits associated with risk management scenarios in a transparent manner. Policy can also lead on formal consultation with stakeholders and government, and formulate advice and recommendations to ministers and government. Where proposed options impact on the Australia New Zealand Food Standards Code, Policy and the NZFSA Joint Food Standards team often combine to work with FSANZ. The Legal team within the Policy group advises on consistency with legislation and, where needed, will draft legal instruments
- the Compliance and Investigation group providing guidance on the compliance and enforcement of options
- the Verification Agency advising on technical matters and the practicality of verification
- the Communications group refining options that are reliant on risk communications strategies, including when vulnerable population sub-groups need to be targeted with specific messages.

When making decisions about risk management options, NZFSA strives to involve all stakeholders to the greatest extent possible. As a general principle, all parts of the food chain are taken into account when selecting control measures.

Allergies and intolerances

A food allergy is an adverse response of the body's immune system to a food or food component, known as an allergen. All foods have the potential to cause an allergic reaction which may be life threatening and foods containing such allergens should be avoided by people who are known to react to them.

A food intolerance or insensitivity is an unfavourable reaction to a food or food component that involves the body's digestive and metabolic systems, rather than the immune system. Foods that trigger intolerances or insensitivities should be avoided, or their consumption limited, by those affected.

As it is generally impossible to limit the availability of foods that trigger allergies and intolerances, risk management of allergens focuses on equipping affected individuals with the information they need to understand and manage their diets.

Labelling is a key tool. The Food Code requires that common food allergens and/or substances capable of causing intolerance (eg, cereals containing gluten, egg, crustacean, milk, peanuts and soybeans, fish, and nuts) be declared on food labels. Mandatory advisory statements can also be required on food packaging, where an ingredient is known to provoke an unfavourable reaction. In the case of royal jelly, the Food Code requires a mandatory warning statement.

NZFSA produces and/or funds risk communication resources (often working alongside interest groups and medical professionals) which raise awareness amongst consumers of the causes of allergies and how to avoid the foods that trigger them. An example is the Manufactured Food Database, funded by NZFSA, which lists manufactured foods suitable for consumption by those with some common allergies and intolerances.

The Verification Agency can check compliance with relevant labelling requirements when verifying the risk based management programmes of some industry operators and NZFSA's Compliance and Investigation group can also be called upon to survey food business compliance with labelling requirements. NZFSA can recall foods that are incorrectly labelled.

13 The NZFSA Science group also has expertise in social sciences.

Level of protection

In Step 2 of the Food Safety Risk Management Framework, the process of selecting risk management options may be influenced by determination of an appropriate level of protection (ALOP) for consumers that is deemed acceptable for the particular hazard/food combination.

A 'zero risk' or no risk level of protection will not necessarily be the chosen level of consumer protection because it may result in an outcome relating to a particular food or food-related product that is unacceptable to consumers, industry, or other stakeholders for a variety of reasons. An example would be if achieving a 'zero risk' level of protection resulted in banning the sale of a food, for which there is considerable consumer demand and/or existing production and trade and if this would be a disproportionate response to the level of risk posed to human health. Another example would be if achieving a 'zero risk' meant introducing restrictions on the existing production or processing of a food which would be so onerous that they would be impractical or prohibitively expensive to implement. See Annex 3 for further information about levels of consumer protection.

International trade

In imported food situations the WTO SPS Agreement, to which New Zealand is a signatory, influences the factors that can be considered in NZFSA's decision-making about risk management options and appropriate levels of consumer protection. The SPS Agreement requires that decisions on control measures are no more restrictive than necessary and take account of the need to minimise adverse effects on trade. NZFSA must also avoid unjustifiable or arbitrary distinctions in levels of ALOP chosen in different food safety situations. In adhering to international obligations, such as the WTO SPS Agreement, NZFSA remains very mindful of its role in protecting public health.

Examples of approaches to establishing levels of consumer protection

- The NZFSA *Campylobacter* Risk Management Strategy incorporates an 'as-low-as-reasonably-achievable' (ALARA) level of risk reduction, in aiming to significantly reduce the incidence of foodborne campylobacteriosis.
- In NZFSA's Science Report 'Modelling of exposure of New Zealanders to *Salmonella*', there is direct comparison/ranking of risks using surveillance data and food attribution studies so as to apportion risks from different *Salmonella* serotypes in a range of foods and prioritise those at unacceptable levels for specific food chain interventions.
- NZFSA uses a generic 'notional zero-risk' as the required level of consumer protection for chemicals such as food additives or veterinary drugs that are intentionally added to the food supply. This means standards are developed on the basis that any allowable residues can be ingested daily over a lifetime without any appreciable health risk.
- In the case of threshold approaches, which can be applied to potentially carcinogenic chemicals in the food supply, the generic level of consumer protection is no more than one additional case of disease above background per million consumers. This was how the NZFSA standard for residues of xylazine metabolytes in deer velvet was set.

The role of the Food Safety Risk Management Framework in equivalence

Judgement of the equivalence of different food safety control measures for exported food is of vital importance to New Zealand because of our high volume of exported food products. Where food standards in an exporting country differ from those in an importing country, the WTO SPS Agreement states that *'Members shall accept the sanitary measures of other Members as equivalent, even if these measures differ from their own or those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary protection'.*

Systematic use of the Framework has allowed NZFSA to achieve judgements of equivalence by trading partners for a significant number of alternative, cost-effective food safety control measures for exported food. In the case of the cattle tapeworm *Taenia saginata,* traditional and labour-intensive post-mortem meat inspection procedures were historically imposed on New Zealand at high cost to industry. A risk assessment was able to show that alternative cost-effective risk management options achieved the same level of consumer protection.

NZFSA likewise accepts the equivalence of food safety programmes and control measures implemented by other countries which are the source of foods imported into New Zealand, where these programmes and measures result in an appropriate level of consumer protection.

Dealing with uncertainty

Uncertainty and gaps in scientific knowledge are intrinsic to risk analysis. As a result, a precautionary approach to food safety may be applied in various ways during risk assessment and risk management activities. A precautionary approach means acting with caution where there is scientific or technical uncertainty about the effects of taking a particular course of action. Precautionary positions may be taken in a number of ways, eg, when using safety factors to establish acceptable daily intakes for chemical residues in food.

Different approaches may be taken to risk management in the face of scientific uncertainty in varying political, social and economic contexts. In some cases, consumer fears have driven bans on trade even though these have not been scientifically supported by international standard-setting processes, eg, when the European Union banned the importation of hormone-treated beef from all countries including New Zealand. In other cases, a conservative approach to standard setting may be taken by NZFSA if the ramifications of a single detection of a high profile pathogen (eg, *E. coli* O157) in exported product might trigger a worst-case reaction from trading partners.

When working in the face of scientific uncertainty, NZFSA aims to manage risks in a manner that is rational, practical, and based on scientific principles.

If there is likely to be a significant risk to human health from a particular hazard or situation, NZFSA will take appropriate risk management action that is proportional to:

- the potential risk
- the consequences of the risk management option(s) chosen
- the degree of uncertainty in the scientific evaluation.

The NZFSA risk management response will prevent or limit exposure while more conclusive information is gathered about the actual risks faced and the control measures likely to be most effective. Where this precautionary response impacts on traded products, there is an obligation under the WTO SPS Agreement to actively pursue additional scientific information, and to undertake timely review of interim control measures.

If there is considerable concern amongst consumers regarding a particular issue about which there exists some degree of uncertainty, NZFSA strives to recognise this in its response, eg, by undertaking targeted consultation and risk communication. NZFSA will clearly inform consumers where significant gaps in scientific knowledge exist, so that consumers can make decisions accordingly[14].

14 Further information about NZFSA's application of the precautionary approach can be found on the NZFSA website amongst the policy statements in the Policy and Law section.

Examples of dealing with uncertainty

Pyrrolizidine alkaloids in honey

Monitoring by NZFSA under the National Residue Monitoring Programme has shown that the speciality vipers' bugloss honey naturally contains pyrrolizidine alkaloids. There are more than 100 different types of these alkaloids arising from different flowers and while the data shows that the individual substances have quite varied toxicity, information across the whole spectrum is very limited. In view of these gaps, a precautionary approach to risk management has been taken. The chemical risk assessment used data from the most toxic of the known alkaloids to establish an acceptable daily intake (ADI) and dietary intake information on honey was used to assess a worst-case exposure scenario. It was found that even with this precautionary approach, there was no appreciable risk to New Zealand consumers given the level of exposure in the New Zealand diet and therefore no standards have been set.

Shiga toxin-producing *E. coli* in uncooked comminuted fermented meat

E. coli O157 and other shiga toxin-producing *E. coli* in uncooked comminuted fermented[15] meat have caused severe illness in a number of countries. However, surveillance data to date has revealed no such cases in New Zealand and contamination levels in fresh beef and pork are very low. Despite this, a hazard-based processing standard that mirrors overseas standards for this product was put in place as a precautionary measure. The processor is required to monitor the microbiological quality of raw materials and apply processing parameters that are sufficient to deactivate any pathogens that may be present.

The value of consultation

NZFSA recognises that stakeholders can make a valuable contribution during any of the four steps of the Framework and initiates consultation whenever this serves a helpful purpose.

As stakeholders can provide significant input when identifying and assessing risk management options (eg, because industry can share its hands-on knowledge of production, processing, distribution and trade), the consultative process often assumes particular prominence during Step 2 of the Framework.

Consultation with stakeholders offers a number of benefits, including:

- ensuring interested or affected parties have an opportunity to comment and influence decision-making
- discussing with business operators proposed risk management options that may impact on their operations
- identifying intelligence that may:
  - prompt the Framework to be applied to a new issue
  - assist with selection of risk management options
  - help to shape the criteria used to evaluate those options. For example, industry stakeholders can advise on the practicality and cost implications of possible risk management options
- fostering confidence in, and understanding of, risk management decisions taken by NZFSA. This may also assist with the later implementation of decisions
- ensuring NZFSA is transparent and provides justification for its decisions.

15 Uncooked comminuted fermented meat products or UCFM, eg, salami, are fermented and not heat treated. Therefore contamination of such products with *E. coli* O157 may constitute a risk to the consumer.

The range of stakeholders with whom NZFSA consults is large, and varies according to the risks being managed. Examples of stakeholders consulted include:

- the Minister for Food Safety
- Food Standards Australia New Zealand (FSANZ)
- food industry associations and forums
- food businesses
- representative community groups and individual consumers
- the scientific and academic community
- trading partners
- international food safety agencies
- third party agencies who undertake evaluation, verification and enforcement roles such as territorial authorities and public health units
- other government agencies.

Consultation takes many forms, ranging from formal public discussion papers through to informal dialogue between the risk manager and industry or interest groups. Public discussion papers are frequently prepared at Step 2 of the Framework to present clear rationale for the proposed risk management option/s selected and to initiate dialogue with stakeholders. Regulatory Impact Statements which describe the likely impacts on affected parties are often included in discussion documents and in concurrent briefing papers for Government.

The NZFSA *Campylobacter* Risk Management Strategy provides an example of how ongoing consultation and exchange of information between industry and NZFSA has resulted in effective control measures being implemented in an integrated manner.

Consultation on Roquefort cheese

Roquefort is a semi-hard blue veined French cheese made from unpasteurised ewes' milk. In 2007, a standard was enacted under the Food Act 1981 to permit Roquefort to be imported into New Zealand. The associated risk management decision drew on tasks completed during Steps 1 and 2 of the Food Safety Risk Management Framework.

As a preliminary activity, NZFSA undertook a qualitative assessment into the risk of foodborne illness from hazards associated with the consumption of Roquefort in the New Zealand context. The assessment involved hazard identification (description of the bacterial hazards, such as *Listeria monocytogenes*, that may be present in Roquefort and cause disease); hazard characterisation (description of the adverse health effects caused by human infection with the identified hazards, including recognition that certain sub-groups of the population could be more at risk from infection by some hazards); exposure assessment (exposure was measured throughout the farm to table continuum); and risk characterisation (estimates of likely illness in New Zealand consumers associated with eating Roquefort). The qualitative outcome of the risk assessment was that the overall risk to the New Zealand population from consuming Roquefort was low, but that certain sub-groups with reduced immunity could face a greater risk from consuming it.

NZFSA then identified and evaluated several risk management options that could reduce the risks posed by Roquefort to all sectors of the population, including the sub-groups most at risk. These options included verification of: testing of raw milk; specified pathogen control steps during processing of Roquefort; and that Roquefort meets European Commission (EC) microbiological criteria on importation to New Zealand. Risk management options also included providing information to New Zealand consumers about the risks associated with Roquefort consumption.

A final risk management decision was made after due consideration of relevant factors. The decision allowed for Roquefort to be imported on the basis that several control measures would be combined to reduce risk. These measures are: certification that Roquefort is produced according to EC requirements covering microbiological, food safety and process hygiene criteria; monitoring in New Zealand to check that Roquefort meets the criteria for *E.coli* prescribed in the Food Code; and providing information for vulnerable consumers most at risk from eating Roquefort. This risk management decision was the subject of formal consultation through a discussion paper process.

Step 3: Implementation of risk management options

Once risk management options have been selected, Step 3 of the Food Safety Risk Management Framework provides for their implementation at all appropriate points in the food chain.

The measures selected for implementation will relate to the production, processing, importation, transportation, storage and sale of food and food related products. The risk manager is responsible for ensuring that processes are in place to ensure implementation occurs in a timely and effective manner.

Consideration as to how implementation will occur, and who will have responsibility, will have already occurred during Step 2 of the Framework, and is likely to have had some influence on the selection of risk management options.

Approaches to the implementation of risk management options

A variety of approaches can be taken to implement risk management options. Sometimes, the means used for implementation will be mandatory. For example, food businesses can be required by law to implement HACCP-based[16] risk management plans that address food safety hazards and unsafe practices, and give effect to requirements relating to production and processing. In such cases, there may also be mandatory requirements for evaluation, audit and verification of industry risk management plans; or for testing, inspection, certification and approval of end product.

At other times, the means of implementation will be voluntary, including when codes of practice and guidelines which address food safety hazards and practices are developed by regulators in partnership with industry, which individual food businesses can then choose to adopt.

Risk management options can also involve NZFSA and/or industry taking an educative approach, and developing communication strategies to raise awareness and inform affected parties, including industry operators and consumers.

More than one of these implementation means may be combined, as farm-to-plate approaches to food safety promote the design of integrated food safety strategies that make the best use of industry and government resources.

The role of industry in implementation

Since the 1990s, NZFSA's food safety management approach has been based on a regulatory model[17] that identifies key players, or tiers, within the food industry. These players are:

1. NZFSA as the regulator/risk manager
2. independent or third party verifiers
3. industry operators
4. consumers who have an expectation that their food will be safe and suitable.

Adoption of the regulatory model meant a shift away from the former prescriptive 'command and control' form of government intervention in food safety which, prior to the 1990s, involved the government acting not only as the rule maker and enforcer, but also taking responsibility for ensuring product safety, eg, through the use of official inspection.

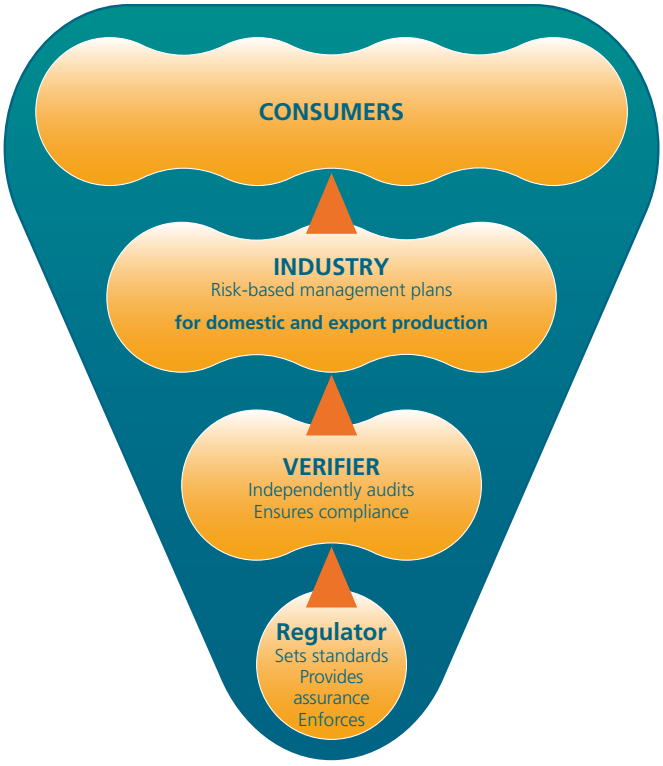


Figure 6: The New Zealand food safety regulatory model

16 Hazard Analysis and Critical Control Point. For a full explanation, refer to the glossary.
17 For further information on the regulatory model, refer to the publications in the Policy and Law section of the NZFSA website.

Under the regulatory model, NZFSA takes a lead role in developing and setting risk management control measures, and auditing and monitoring the overall food safety system for effectiveness and efficiency. However, the prime responsibility for implementing many control measures, and for producing food that is safe and fit for purpose, rests with food industry operators. Where possible, the risk management options that NZFSA develops will be outcomes based, allowing industry freedom to innovate and flexibility to choose the methods they use to comply.

The functions undertaken by industry to manage risks in the food chain can include:

- developing risk management plans to address hazards in a preventative manner
- implementing verification and monitoring systems
- applying sampling plans
- staff training
- communicating as necessary with suppliers, customers and consumers.

The role of NZFSA in implementation

While industry operators have the primary responsibility for implementing many risk management control measures, NZFSA still has a role to play in implementation. Examples are given below of some of the means by which NZFSA engages in the implementation of risk management activities.

Legal measures

Where the risk management option selected involves the development of new or revised legal measures, such as regulations, standards or specifications that apply to food produced in New Zealand and/or overseas, the risk manager will guide the development, drafting and government approval of these measures. This process will draw on the expertise of NZFSA legal and policy staff. NZFSA also ensures industry operators are consulted or informed about new or amended legal measures.

Implementation tools and industry partnerships

NZFSA business groups, such as the Standards and Approvals and ACVM groups, develop tools to assist industry to implement risk management measures. This is often done in partnership with industry. Implementation tools include generic codes of hygienic practice for different food and food-related commodities, templates for risk-based management plans, and guidelines on quality assurance systems.

To give industry time to become familiar with new or revised requirements, NZFSA may build in a transition period prior to the time when control measures must be enacted. Evidence suggests that, when non-compliance occurs, it is more often related to inadequacy of information or understanding about what is expected, rather than any deliberate intent to avoid compliance. NZFSA staff proactively develop partnerships with industry to facilitate successful implementation of control measures. Staff include those from the Science, Standards and the Compliance and Investigation groups, and the Verification Agency. Staff work with industry through a number of means, including meetings with individual operators or with industry bodies; workshops; calibration exercises; and verification trials.

Approval activities

The NZFSA Approvals and ACVM group fulfils an implementation function by administering various registrations, approval and listing processes. These include the registering of food premises; approval of risk-based management plans developed by industry, and recognition of third parties such as laboratories, verifiers and evaluators.

Verification

The NZFSA Verification Agency verifies that control measures have been effectively implemented by some industry operators, especially where overseas markets require, as a condition of market access, that verification is undertaken by a 'competent authority' rather than by an independent third party. Occasionally, the Verification Agency may also become directly involved in the implementation of risk management measures, such as those related to supervisory meat inspection.

Enforcement

The NZFSA Compliance and Investigation group undertakes independent audits of regulatory functions and can apply sanctions where control measures have been incorrectly implemented by industry. When the group uncovers failures in the implementation of control measures, it has a toolbox of responses at its disposal. Responses can be educative, such as when an informative letter is sent to an

industry operator advising of non-compliance and providing information on where to go for assistance. At other times, more stringent enforcement or sanction responses are applied. These can require more frequent verification visits; recall of products; partial or complete plant closures; notices of direction by the NZFSA chief executive under empowering legislation; or prosecution. Agreed procedures are followed when determining the type of response to make, and are linked to the scope and seriousness of the specific non-compliance.

Communications

Strategies developed by the NZFSA Communications group ensure messages about risks in the food chain are conveyed readily and effectively to interested parties, including business operators and consumers. The group also fosters the ongoing exchange of information with key interest groups.

For further information about the work of the NZFSA Communications group, refer to Annex 4.

The role of independent third parties in implementation

Third parties, that are independent of industry operators and NZFSA, have a vital role in ensuring that risk management measures are effectively developed and implemented by industry operators.

Third parties are contracted by many industry operators who work under the jurisdiction of the Animal Products Act 1999 to evaluate and assess the validity of their risk management programmes, and to ensure these comply with legal requirements. Third parties also undertake verification and auditing of industry-operated risk-based management programmes mandated under the Animal Products Act and other laws that NZFSA administers, including the Food Act 1981 and the Wine Act 2003. Independent laboratories that perform testing, eg, to demonstrate that products meet safety and suitability requirements required for export assurances, are another example of third parties that play a role in the implementation of risk management activities.

Step 4: Monitoring and review

Monitoring

During Step 4 of the Food Safety Risk Management Framework, monitoring activities are undertaken at appropriate points in the food chain, as directed by the risk manager. Monitoring is used to gather information on levels of hazards, and to review the effectiveness of any related regulatory measures and other risk management activities.

This step is essential because it ensures the risk manager proactively and regularly checks what has been achieved, and whether any implemented risk management measures and activities are working as intended and align with broad risk management goals. During this step in the Framework, the risk manager often draws on the analytical and scientific expertise of the risk assessor.

Monitoring may be carried out ahead of the implementation of risk management activities, so as to establish baseline levels for hazards, or it may follow their implementation. Sometimes, baseline surveys will be conducted prior to the implementation of risk management options, and will then be repeated at later dates to measure trends and changes.

NZFSA has an extensive programme for monitoring hazard levels in the food chain.

Regular monitoring by NZFSA

- **National Microbiological Database (NMD):** An example of a world-leading monitoring activity, which provides for regular microbiological monitoring of the effects of slaughter, dressing, cutting, and boning processes. It offers continuous stream of information on the safety status of major classes of New Zealand meats (primary processing of adult cattle, very young calves, sheep, deer, goats, poultry, ostriches, and pigs). Results assist in studying the effects of different risk management activities and what they achieve in terms of microbiological outcomes, and are used to demonstrate the low level of contamination on fresh meat produced under New Zealand conditions. Aside from the reassurance this provides to consumers in New Zealand, data derived from the NMD has allowed the NZFSA Science group to carry out analyses which have demonstrated that additional and costly microbiological monitoring required by importing countries is not necessary. This has led to equivalence agreements with importing countries that have subsequently saved New Zealand's food export industry significant revenue.
- **Food Residue Surveillance Programme:** This checks compliance with chemical food safety standards across a wide range of locally-produced and imported foods. Run intermittently in any given year, with each round focusing on specific food/residue combinations in their 'as produced' form (eg fruits immediately post harvest and before processing).
- **National Residue Monitoring Programme:** This provides food safety assurances on exported animal products, including farmed and wild animals, honey and fish. Runs continuously throughout the year.
- **New Zealand Total Diet Survey:** This evaluates the level of exposure of the New Zealand population to chemical residues, contaminant elements and selected nutrients in the food supply. Food is analysed in 'as consumed' form (eg, fruits peeled and meats cooked). Occurs about every five years.
- **Monitoring of imported foods:** An annual programme is run for non-urgent monitoring of imported foods for specific hazards or suitability factors. A scanning list also allows for monitoring of imported foods for emerging and possibly unexpected hazards that may pose an immediate risk. An example of the latter is the sampling and melamine testing of dairy products and ingredients imported from China that occurred in 2008.
- **Monitoring of labelling compliance:** The *Ongoing Food Label Monitoring Survey/ Australia and New Zealand,* conducted by FSANZ, provides regular data on compliance with labelling requirements set by the Food Code. The NZFSA Compliance and Investigation group also conducts surveys into specific components of labelling.

National human health surveillance activities administered by the New Zealand Ministry of Health are an important input into the monitoring and review activities undertaken by NZFSA. Where possible, food chain data is combined with human health surveillance data assembled by the Ministry of Health to determine the effectiveness of food safety regulatory activities in consumer protection terms. In some cases, NZFSA initiates and funds sentinel studies[18], where data on specific hazards in the food chain is lacking and the resultant level of foodborne disease is unknown. In liaison with the Institute of Environmental Science and Research (ESR), NZFSA also assists with analysis of human health statistics on gastrointestinal illness.

Robust surveillance data is the starting point for applying the scientific process of food source attribution. This methodology is key to determining which types of foods are proportionately responsible for foodborne illness due to a particular pathogen. Together with Massey University, the NZFSA Science group has an advanced operational research programme in this area. In New Zealand, the proportion of priority enteric diseases caused by food is approximately 60% for campylobacteriosis and salmonellosis, 80% for listeriosis, and 40% for norovirus.

Collecting and evaluating data on hazards and risks on a periodic basis provides NZFSA with information to determine whether its risk management decisions and implementation of measures to manage risks have resulted in the achievement of stated goals. This information can reduce uncertainties and prompt revision of risk assessments, or commissioning of new scientific research. Monitoring identifies new food safety problems as they emerge, thereby triggering the application of the Food Safety Risk Management Framework to newly recognised problems.

In some situations, monitoring can demonstrate planned reduction in levels of exposure to specified hazards over time. For example, the NMD results reveal gradual improvements are occurring in process hygiene indicators and levels of microbiological contaminants.

Monitoring for pyrrolizidine alkaloids

Monitoring by NZFSA has shown that exposure to pyrrolizidine alkaloids in honey is highly unlikely to constitute a health risk to New Zealand consumers. However, it is possible that these compounds are also present in other food types, eg, cereals, and exposure across a total diet might possibly breach the acceptable daily intake. Consequently, NZFSA has initiated a wider monitoring programme to support its risk management decision not to set a maximum limit for the speciality vipers' bugloss honey.

Review

It is good practice for risk management decisions, and the implementation of related control measures including regulatory standards, to be reviewed on a regular basis. Monitoring data provides vital input to this practice. Reviews take account of factors such as:

- whether safety and suitability goals have been achieved
- the efficiency of implemented measures, including cost compliance issues
- the ease of implementation of the measures
- whether there have been any unintended effects
- the impact of measures on different population groups or at different points in the food chain
- levels of compliance with measures (if non-compliance is higher than anticipated, this may indicate a need for revision)
- the sustainability of measures.

Opportunities are provided for industry and consumers to participate in the review process and to influence decisions about whether risk management measures should be maintained or changed.

NZFSA's monitoring and review activities are greatly enhanced by effective communication networks and linkages with offshore food safety authorities. Trading agreements often contain obligations related to monitoring and, where possible, NZFSA links up with international organisations which operate early warning systems for foodborne disease, for example the World Health Organization International Food Safety Authorities Network (INFOSAN).

18 Sentinel site surveillance involves a limited number of selected reporting sites (communities) from which the information collected may be extended to the general population. A concentration of resources in the defined sites produces a rich source of information, producing more accurate final estimates than those normally available from broader national surveillance programmes.

Tutin in honey: the Framework in action

Around the Easter 2008 period, 22 New Zealand consumers were poisoned by eating honey from the Coromandel that was contaminated with tutin, a toxin derived from the tutu plant.

NZFSA rapidly applied the Food Safety Risk Management Framework to manage the serious risk this posed both to public health and, potentially, to New Zealand's export trade in bee products. The NZFSA Standards group took the lead in driving the progression through all four steps of the Framework.

Preliminary risk management activities (Step 1 of the Framework) included NZFSA initiating sampling to ascertain the extent of the problem. Much of the North Island honey crop sampled was found to contain low levels of tutin and hyenanchin (a by-product closely related to tutin), with dangerously high levels of tutin in some parts. NZFSA also commissioned toxicological testing to increase understanding of the relative toxicity of tutin and hyenanchin with a view to setting limits for consumption. This confirmed that, while hyenanchin is of little toxicological concern, honey contaminated with tutin poses considerable risk to health.

Risk management options were then formulated (Step 2 of the Framework), in consultation with bee products industry representatives. One risk management option considered was to maintain the status quo and to rely on the potential for prosecution in the event of a repeat event (the beekeeper whose honey was the source of the Easter 2008 poisoning was prosecuted under the Food Act 1981); however this option was discarded because of the seriousness of the risk posed by tutin contamination. The risk management option of informing beekeepers of strategies for avoiding contamination with tutin was also not considered to offer sufficient control on its own.

The preferred option selected to control the risk posed by tutin in honey involved setting a maximum level for tutin in honey for sale for human consumption and for export. After considering various legal mechanisms that could give effect to this option, a new standard under the Food Act 1981 was proposed. Extensive consultation was then undertaken with honey producers, consumers, and other stakeholders, through a public discussion paper and submissions process; at regional public meetings; and through targeted discussions with industry representatives.

NZFSA drafted the new food standard, and it was given ministerial approval. The Australia and New Zealand Food Regulation Ministerial Council was advised that New Zealand would be promulgating a 'temporary New Zealand-only standard', as provided for in the Food Treaty, as contaminants are covered by the Food Code.

Implementation of a risk management option – which in this case involved industry meeting its obligations under the new standard (Step 3 of the Framework) – was assisted by NZFSA providing all registered beekeepers with both a copy of the standard and a guide to compliance. The new standard came into effect in January 2009.

Monitoring and review activities (Step 4 of the Framework) are underway. NZFSA has commissioned further scientific research to validate its understanding of toxic honey, eg, as to whether a component other than tutin contributes to toxicity in honey, and regarding any long term chronic toxicity associated with tutin. The Compliance and Investigation group is surveying the implementation of the new standard. NZFSA is also seeking feedback from industry on the operation and impact of the standard, as part of a formal review process which commenced in mid 2009, six months after the new standard came into effect. These monitoring and review activities may result in future refinements to the standard.

Glossary of acronyms and abbreviations

Acceptable Daily Intake (ADI): A measure of the amount of a specific substance (usually a food additive, or a residue of a veterinary drug or agricultural compound) in food or drinking water that can be ingested (orally) over a lifetime without an appreciable health risk. ADIs are expressed by body mass, usually in milligrams (of the substance) per kilograms of body mass per day.

Agricultural compound: A generic term for any substance intended for preventing, destroying, attracting, repelling or controlling any pest, including unwanted species of plants or animals during the production, storage, transportation, distribution and processing of food, agricultural commodities or animal feed. The term includes pesticides, fungicides, insecticides, herbicides and chemicals which may be administered to animals for the control of ectoparasites. It includes substances applied to crops either before or after harvest to protect the commodity from deterioration during storage and transportation, or disinfestations of raw primary produce.

Agricultural compound residue: Any specified substance in food, agricultural commodities, or animal feed resulting form the use of an agricultural compound (from known, unknown or unavoidable sources). Includes any derivatives of an agricultural compound, such as conversion products, metabolites, reaction products and impurities considered to be of toxicological significance.

Agricultural Compounds and Veterinary Medicines (ACVM): The Approvals and ACVM group is a business group within NZFSA. The Agricultural Compounds and Veterinary Medicines Act 1997, which NZFSA administers, is also sometimes referred to as the ACVM Act.

As Low as Reasonably Achievable (ALARA): Often used in reference to chemical or radiation exposure levels.

Allergens: Substances in food which trigger adverse effects (such as allergies or intolerances) in affected individuals, eg, eggs, nuts, cows' milk and sulphites. These substances may adversely affect a small portion of the population, but the reaction can be severe.

Appropriate Level of Protection (ALOP): The level of protection deemed appropriate to protect human, animal or plant life or health.

Attribution: The extent to which a change (or no change) in an outcome, can, with a reasonable degree of certainty, be attributed to the actions of a food safety authority.

Australia New Zealand Food Standards Code (the Food Code): Sets out compositional and labelling standards for food sold in New Zealand and Australia.

Australia New Zealand Science and Exposure Assessment Forum (ANZSEAF): A forum established by NZFSA and FSANZ to co-ordinate science between the two agencies.

Campylobacteriosis: An illness caused by the bacterium *Campylobacter*.

Codex Alimentarius Commission (Codex or CAC): The international food standards setting body established jointly by the Food and Agriculture Organization and the World Health Organization.

Contaminant: Any substance or thing which is undesirable, potentially harmful, or unexpected in a particular product or process and is, or may be, present in or in contact with animal material, or animal product or food.

Disability Adjusted Life Years (DALYs): A measure of overall disease burden. Originally developed by the World Health Organization, it is becoming increasingly common in the field of public health and health impact assessment. It is designed to quantify the impact of premature death and disability on a population by combining them into a single, comparable measure. In so doing, mortality and morbidity are combined into a single, common metric.

Equivalence: The World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (to which New Zealand is a signatory) states that 'Members shall accept the sanitary measures of other Members as equivalent, even if these measures differ from their own or those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary protection'.

Exposure assessment: Qualitative and/or quantitative evaluation of the likely intake of biological, chemical and physical agents via food as well as exposures from other sources if relevant.

Food: Any substance, whether processed, semi-processed or raw, which is intended for human consumption and includes drink, chewing gum and any substance which has been used in the manufacture, preparation or treatment of 'food' but does not include cosmetics, tobacco or substances used only as drugs.

Food additive: Any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result, (directly or indirectly) in it or its by-products becoming a component of or otherwise affecting the characteristics of such foods. The term does not include 'contaminants' or substances added to food for maintaining or improving nutritional qualities.

Food intolerance or insensitivity: An unfavourable reaction to a food or food components that involves the body's digestive and metabolic systems, rather than the immune system. Foods that trigger intolerances or insensitivities should be avoided, or their consumption limited, by those affected.

Food Standards Australia New Zealand (FSANZ): Joint trans-Tasman food standards body established by the *Agreement Between the Government of Australia and the Government of New Zealand Concerning a Joint Food Standards System* (the Food Treaty) in 1995.

Goals: Statements of the intended purpose and end result that risk management options are intended to accomplish.

Good Agricultural Practice(s) (GAP): A collection of principles to apply for on-farm production and post-production processes, resulting in safe and healthy food and non-food agricultural products, while taking into account economic, social, and environmental sustainability.

Good Hygiene Practice(s) (GHP): All practices regarding the conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain.

Good Manufacturing Practice(s) (GMP): The part of quality assurance that ensures products are consistently produced and controlled to the quality standard defined by the manufacturer. Good manufacturing practice includes both production and quality control.

Good Operating Practice(s) (GOP): Covers the practices and procedures designed to ensure the consistent production of products that are safe and suitable for their intended purpose, and that meet relevant regulatory requirements. It includes several interacting components - good hygienic practices, effective processing operations and effective quality assurance systems.

Hazard: Biological, chemical or physical agents in, or conditions of, food with the potential to cause adverse health effects. This definition includes nutrient-related hazards, which are nutrients or related substances in food that have the potential to cause adverse health effects depending on inadequate or excessive levels of intake.

Hazard Analysis and Critical Control Point (HACCP): A system which identifies, evaluates and controls hazards which are significant, and the measures for their control to ensure the safety of food. HACCP focuses on prevention rather than end-product testing.

Hazard characterisation: The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents which may be present in food. For chemical agents, a dose-response assessment should be performed. For biological or physical agents, a dose-response assessment should be performed if the data are obtainable.

Hazard identification: The identification of biological, chemical, and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods.

Listeriosis: An illness caused by the bacterium *Listeria monocytogenes*.

Monitoring: The collection, analysis and reporting of information and/or data. Monitoring can be described as the performance and analysis of routine measurements, aimed at detecting changes.

Nutrient-related hazard: A nutrient or related substance in food that has the potential to cause an adverse health effect depending on inadequate or excessive level of intake.

Performance objective: A quantitative expression of the frequency and/or concentration of a hazard in a food at a specified step in a food chain that should not be exceeded if the required level of consumer protection is to be met.

Review: Involves systematically and objectively analysing the success of ongoing and completed programmes, projects, systems and standards to determine relevance, efficiency, effectiveness, impact and sustainability.

Risk: A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard in food.

Risk analysis: A process consisting of three components: risk assessment, risk management and risk communication.

Risk assessment: A scientifically-based process consisting of the following steps:

(i) hazard identification
(ii) hazard characterisation
(iii) exposure assessment
(iv) risk characterisation

Risk-based: Based on a specific knowledge of risks to human health.

Risk characterisation: The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterisation and exposure assessment.

Risk communication: The interactive exchange of information and opinions concerning risk among risk assessors, risk managers, consumers and other interested parties.

Risk estimate: The quantitative estimation of risk resulting from risk characterisation.

Risk management: The process of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures.

Risk profile: The description of the food safety problem and its context.

Salmonellosis: An illness caused by the bacterium *Salmonella*.

Stakeholder: A person, group or organisation that has a direct or an indirect interest in an organisation because it can affect or be affected by the organisation's actions, objectives and policies.

World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (WTO SPS Agreement): This agreement can be viewed at: www.wto.org

Annex 1: Risk assessment

This annex supplements information provided at pages 10 and 16-18 of this document.

Risk assessment represents an evaluation of the probability of occurrence (likelihood) and severity (magnitude) of known or potential adverse health effects that result from human exposure to hazards in foods. Although the ideal goal is a quantitative estimate of risk, qualitative expressions of risk are common in many situations, such as when ranking levels of risk as high, medium, or low.

To the extent practicable, NZFSA keeps the risk assessment process separate and distinct from the risk management so as to protect the integrity and objectivity of the risk assessment. NZFSA strives to ensure:

- each risk assessment is fit for its intended purpose and transparent in its documentation
- the scope is clearly stated
- there is an open exchange of ideas between risk assessors, risk managers and other stakeholders
- factors that impact on the risk assessment are identified, eg resource constraints and data gaps, and assumptions and uncertainties are explained
- the reporting style allows risk managers and other stakeholders to properly understand the risk assessment and an interpretive summary is provided for lay readers.

The risk assessment process

Food safety risk assessment is a scientifically-based process that can consist of up to four steps (refer Figure A). Steps 2 and 3 can be carried out in any order. Depending on the hazard/food combination concerned and the risk management questions being posed, at times the content of a risk assessment will not fully incorporate all four steps.

Hazard identification

Hazard identification concerns the possible presence of biological, chemical or physical agents capable of causing adverse health effects. This is a qualitative exercise that utilises a 'weight-of-evidence' approach and it may include ranking different hazards in a food in order of their likely importance. (As a consequence, low-ranking hazards may not be included in subsequent risk assessment because of resource implications). In the case of chemicals in food, hazard identification may include quantitative evaluation of toxicological data from animal studies. In the case of biological hazards in food, epidemiological data on the possibility of foodborne illness is essential.

Hazard characterisation

Hazard characterisation determines the nature of the adverse health effects. In the ideal situation this will include a dose-response assessment. However, accurate dose-response data at the point of consumption are difficult to obtain for microbiological hazards and risk assessments will often rely on qualitative hazard characterisation. Dose-response studies for chemical hazards using animal models contain both quantitative and qualitative elements, especially in extrapolation of data from high-dose chemical toxicity studies in animals to low-dose exposures in humans.

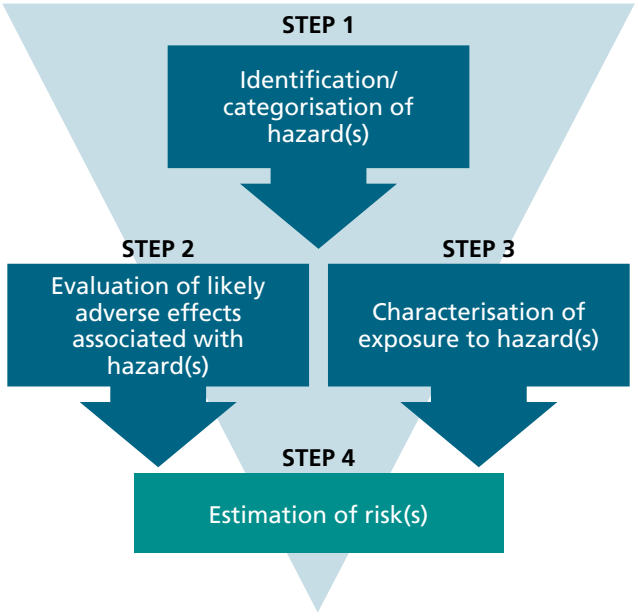


Figure A: The risk assessment process

Exposure assessment

Exposure assessment is the dietary intake of hazards that is likely to occur. Exposure of a defined consumer population to a specific hazard may have a qualitative or a quantitative base. Inadequate information on dietary intake and/or the distribution/level of hazards within the food at the point of consumption will limit the ability to conduct a risk assessment.

Risk characterisation

Risk characterisation is the integration of the above activities into an estimation of the probability and severity of adverse effects likely to occur in a given population. 'What if' scenarios can be used to evaluate the impact of different assumptions and different ranges of input data on model outcomes. The outcome for each new 'what if' scenario is compared to the baseline outcome to determine the degree of change.

Uncertainty

Uncertainty (the quality of being unknown) in a risk assessment should be clearly separated from variability (a characteristic of natural phenomena that differs from one observation to the next). When data is lacking, uncertainty can be represented in a risk assessment by use of a range of possible data values. Uncertainty also arises from various conceptualisations when modelling a system. Risk assessors must ensure that risk managers understand the sources and degree of uncertainty in the risk assessment and the impact it has on risk estimates.

Annex 2: Categorisation of control measures

With the widespread commitment to risk analysis at the international and national level, it is important to establish the difference in the types of measures now available for food control, as follows:

- **Good Hygiene Practice (GHP)-based control measures** are generally qualitative in nature and are based on empirical scientific knowledge and experience. They are usually prescriptive and may differ considerably between countries.
- **Hazard-based control measures** are developed from scientific knowledge of the likely level of control of a hazard at a step (or series of steps) in a food chain, have a quantitative base and can be validated as to their efficacy in hazard control at the step. There is an obvious expectation of consumer protection but the actual degree of protection will be unknown.
- **Risk-based control measures** are developed from risk assessments or other information on risk, eg, surveillance data, on the basis of specific knowledge of the likely levels of consumer protection that will result. They have a quantitative base and should be able to be validated against an identified level of consumer protection.

A modern food safety programme will be made up of food control measures in all these categories. However, the inclusion of an increasing proportion of risk-based measures that have been developed and implemented according to an agreed risk management process will have marked benefits for all stakeholders. In the ideal situation, a proposed food safety programme should be broad enough to encompass all parts of the food chain and standards should be implemented wherever they will be the most effective in reducing risks.

Annex 3: Acceptable level of consumer protection

Desired levels of consumer protection can be expressed in a number of ways. The tolerable number of cases of illness due to a particular hazard in a food in a particular population over a specific time period may be used, eg, no more than one case of disease Y per 100,000 people in the general population per year. However, it is more likely that NZFSA will express the desired public health goal in terms of a percentage improvement over current (unacceptable) levels. In other situations, the risk per edible portion of a food is a useful parameter to anchor a decision on control measures. Measurement of the societal impact of a foodborne disease, eg, using disability-adjusted life years (DALYs) as a comparative unit, provides a means of comparing risks from disparate sources when deciding on a desired level of consumer protection.

Performance objectives as risk management options

Where hazards exist continuously in a food chain, risk-based control measures can benefit from the establishment of regulatory 'targets' that are called performance objectives. A performance objective is a quantitative expression of the frequency and/or concentration of a hazard in a food at a specified step in a food chain that should not be exceeded if the required level of consumer protection is to be met. It is envisaged that use of risk assessments within a framework for managing risks will lead to decisions on performance objectives that provide considerably increased flexibility to industry in design of food hygiene programmes.

However, food safety authorities around the world are finding it difficult to reach public policy decisions on acceptable levels of consumer protection for commonly occurring foodborne illnesses, eg, those due to *Campylobacter* and *Salmonella*, which are a necessary input to setting performance objectives. Decision-making on acceptable levels of consumer protection for severe foodborne illnesses of very low frequency, for example those due to *E. coli* O157 and *Cronobacter spp.,* is even more difficult. (This is in contrast to decisions on risks from certain chemical hazards in the food supply, including agricultural compounds and food additives, where a predetermined 'notionally zero risk' policy is the norm).

On the other hand, food safety authorities in a number of countries are leaning towards setting food safety goals that reflect continuous improvement in levels of consumer protection. In striving to achieve these goals, regulatory targets that are hazard-based rather than risk-based are set at specific steps in the food chain. Systematic application of a Food Safety Risk Management Framework for managing risks and improving attribution surveillance data allows the risk manager to monitor progress and modify targets as needed. If continuous improvement in public health is not achieved, the stringency of hazard-based targets can be increased.

Annex 4: NZFSA approach to risk communication

NZFSA has a documented risk communication strategy and develops specific implementation plans to engage on food safety and suitability issues with both external stakeholders and staff within NZFSA.

The nature and urgency of the risk information to be conveyed will drive each implementation plan. This can range from predominantly one-way communication with the public to urgently advise or warn about a particular risk, to full two-way engagement with a number of stakeholder groups over a reasonable period of time. Risk communications also service international reporting obligations.

Stakeholder interests may be significantly affected by regulatory risk management decisions, and participation and involvement of stakeholders throughout all phases of the Food Safety Risk Management Framework is therefore important.

Risk communication messages

Before formulating risk communication messages, it is necessary to identify the various stakeholder groups that will be predominantly affected by a food safety issue or emergency, and to properly understand their knowledge, motivations, opinions and perceptions. Risk communicators, risk managers and risk assessors within NZFSA all contribute to this task.

When communicating on risk issues, NZFSA strives to fully understand risk perception factors. Humans tend to be wary of similar things for similar reasons and the study of risk perception identifies the psychological factors by which we subconsciously 'decide' what to fear – and how concerned to be. The public's judgement of benefits and risks often differs from expert analysis and may be significantly affected by information flows. As a result, it is necessary to identify the most appropriate ways to communicate with different stakeholders.

NZFSA uses a range of tools and channels to communicate. Media campaigns, release of information on the NZFSA website, email alerts and 0800 telephone information services can be particularly appropriate when communicating about risk events that are of high interest to the public or to industry. Other vehicles which can be effective in raising public awareness include: meetings with stakeholder representatives, media releases and briefings, contributions to the Science Media Centre (which journalists can access for information on food safety and suitability), periodicals, fact sheets, pamphlets, advertising and technical reports.

NZFSA can choose to adopt a variety of approaches to risk communications. Approaches can be proactive or responsive.

A *proactive approach* may be taken when scientific data indicates a food issue is a high risk to public health and/or New Zealand's international reputation. In most such cases, consumer perceptions will align with the scientific findings, meaning there is also concern about the issue in the community. In 2008 NZFSA took a proactive approach when communicating about possible contamination of the food chain by melamine, and the discovery of honey contaminated with tutin. When a proactive approach is taken, information is initiated by NZFSA, and disseminated rapidly as the situation unfolds, with frequent updates. This ensures the public can focus on the management of the risk itself, rather than any perception of inadequate information. There is a constant flow of information about the risk management steps being taken by NZFSA.

Sometimes a food issue poses a significant risk, but there is only low awareness of the issue in the community. In this case, proactive strategies aim to encourage consumers to change behaviour, possibly by avoiding or limiting consumption of certain foods. This type of strategy has, eg, been used by NZFSA to encourage the very young, frail elderly, pregnant, and immune-compromised to avoid eating Roquefort cheese after a risk assessment found they were more at risk from eating unpasteurised milk cheeses than the rest of the population. NZFSA messages about the importance of consuming flour in cooked form, rather than raw form, (eg, that children should avoid eating baking batter containing raw ingredients) is another example of a proactive approach, and follows an outbreak of salmonellosis linked to raw flour.

NZFSA may take a *responsive approach* when the community perceives an issue to be of greater risk than the scientific evidence supports. In such cases, NZFSA aims to

put forward the best available science-based information in a form that can be readily understood by a layperson. Examples of issues that have been addressed with a responsive approach include adverse health claims about the intense sweetener aspartame, and allegations of high levels of pesticide residues in imported foods.

At other times, NZFSA risk communications need to deliver information about the suitability, as opposed to the safety, of food. This type of message has, for example, been used when providing explanations about labelling ingredients and related nutritional information to help consumers make choices that suit their needs.

The clarity and impact of key messages for each stakeholder group is monitored by NZFSA to the extent practicable. Research can be used to gauge whether all relevant target groups have been reached and understand key messages. Behaviour change as a result of risk communication is also evaluated if appropriate. Involvement of stakeholders throughout a risk analysis process helps with acceptance of a final risk management decision, even if not all stakeholders are in agreement.

Cross-agency responses

Risk communication in an emergency situation requires an issue-specific implementation plan. NZFSA has developed a broad emergency communication process and supporting manual so it can move quickly into response mode when necessary. The process is shared with the Ministry of Agriculture and Forestry (MAF) and its Biosecurity agency (MAFBNZ) and can accommodate a range of responses.

Where risk communication needs to span multiple sectors, the joint NZFSA/MAF/MAFBNZ approach clearly differentiates the likelihood of animal health impacts versus the likelihood of human health impacts when there is an epidemic of exotic disease, such as 'highly pathogenic' avian influenza. Even so, public reactions can be unpredictable. In an outbreak of avian influenza in Southeast Asia, the Japanese government clearly informed their public that foodborne risks from imported poultry products were negligible but consumers still markedly reduced their purchase of chicken meat and eggs. Similar declines in consumption of pig meat have been reported in some countries since the advent of the Influenza A (H1N1) virus or 'swine flu', although international scientists have stated that pig flu viruses are not transmitted by food, including hygenically-prepared pork or pork products.

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