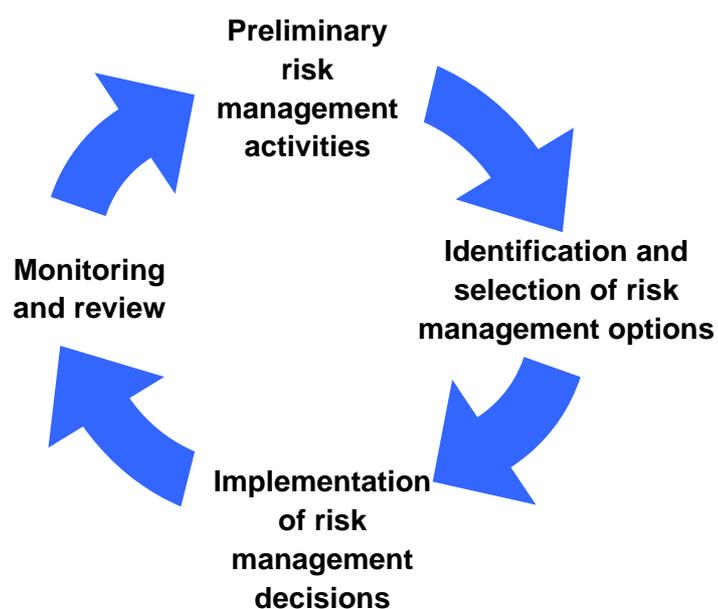


# Food safety risk management in New Zealand

A review of the New Zealand Food Safety Authority's risk management framework and its application

By

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## Abbreviations

A1 milk	Milk high in A1 beta-casein
A2 milk	Milk high in A2 beta-casein
ADI	Acceptable Daily Intake
ALARA	As Low As Reasonably Achievable
BCM7	Beta-casomorphin-7
CCCF	Codex Committee on Contaminants in Foods
DFVA	Danish Food and Veterinary Administration
DM-1	Type 1 diabetes mellitus
ECDC	European Centre for Disease Prevention and Control
EFSA	European Food Safety Authority
EMA	European Medicines Agency
ESR	Institute of Environmental and Scientific Research
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FDA	Food and Drug Administration
FSAI	Food Safety Authority of Ireland
FSANZ	Food Standards Australia New Zealand
FVO	Food and Veterinary Office
GBS	Guillain-Barre Syndrome
HRC	Health Research Council
IHD	Ischaemic heart disease
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
MoH	Ministry of Health
NFA	National Food Administration
NFI	National Food Institute
NTD	Neural tube defects
NZFSA	New Zealand Food Safety Authority

OIE	International Office of Epizootics (now called the World Organisation for Animal Health)
RASFF	Rapid Alert System for Food and Feed
RMF	Risk Management Framework
SCF	Scientific Committee on Food
SPS Agreement	Agreement on the Application of Sanitary and Phytosanitary Measures
WHO	World Health Organization
WTO	World Trade Organization

## Summary

Following public concern about the safety of A1 milk and criticism from some quarters of the New Zealand Food Safety Authority's (NZFSA's) handling of the release of a report by Professor Boyd Swinburn on beta-casein A1 and A2 in milk and possible effects on human health, NZFSA decided to commission two reviews. This is the report of the first of these and deals with NZFSA's framework for managing food safety risks. The second will review the science available to support a possible causal relationship between consumption of A1 milk and human disease and is being carried out by the European Food Safety Authority (EFSA) at the request of NZFSA. The present review has examined NZFSA's recently updated Risk Management Framework (RMF) and how it has been applied in some recent high-profile food safety issues in New Zealand. These include the A1/A2 milk issue, *Campylobacter* in poultry, the artificial sweetener aspartame, the imported foods regime, Roquefort cheese and other products made from raw milk and mercury in fish. The RMF has also been compared with international guidelines on best practice and the food safety systems used in Denmark, Ireland and Sweden.

### *Risk management framework (RMF)*

The RMF consists of four interconnected elements: 1) Preliminary risk management activities, 2) Identification and selection of risk management options, 3) Implementation of risk management decisions and, 4) Monitoring and review. Each of these elements is then further subdivided into several individual tasks. In addition to the RMF itself, the document contains an introductory section explaining the need for an agreed risk management process and two annexes providing more detailed information on risk assessment and risk communication. The way in which the RMF is applied is illustrated with many examples of its use in handling recent food safety issues in New Zealand.

The RMF is a well written document that provides a very good structure for systematically and flexibly managing the wide variety of food safety risks currently encountered in New Zealand and also for handling new risks. It takes into account scientific and other developments and the practical experience gained in the seven years since the previous RMF was published and it is a considerable improvement on the earlier text. The RMF is designed to cover all the different types of food-borne hazard that NZFSA has to deal with and has the built-in flexibility to achieve this. The RMF strongly emphasises the importance of sound science and a multi-disciplinary approach to food safety and points out the need to consider the whole of the food chain from "farm to fork". The RMF is comprehensive, but a number of recommendations for additions aimed at making it easier to understand for those not familiar with the subject are given below.

The RMF provides a sound basis for dealing with situations in which the scientific basis for carrying out risk assessments varies widely. It also points out the importance of both communicating and dealing with uncertainty in risk assessments and explains how NZFSA does this. Although there is a need to give clear messages to consumers, the food industry and other stakeholders, it is important that NZFSA's information about risks associated with foodstuffs is balanced and that uncertainties associated with the risk assessments are clearly communicated. The RMF includes a requirement for communication with interested parties during all phases of the risk management process and provides an appropriate framework for priority setting. It also provides a sound basis for defining public health goals, but it is not clear from the document who defines these goals in New Zealand.

The RMF provides a good basis for setting food safety standards for a wide range of hazards and foodstuffs and also points out the need to take into account the standards adopted by the international standard-setting bodies. Although it is a relatively small country, through its active participation in the work of the Codex Alimentarius Commission (CAC) and the World Organisation for Animal Health (OIE), New Zealand plays an important role in shaping the decisions of these international standard-setting organisations - to use a boxing expression, New Zealand “punches far above its weight”. This is of benefit both in protecting the health of New Zealanders and in reflecting the country’s interests in the development of standards for food moving in international trade.

Although they, in principle, use the same risk management framework as that used in New Zealand, the food safety authorities in Denmark, Ireland and Sweden are organised in different ways. In Denmark, Ireland and Sweden, the food safety authorities’ mandates are defined in national legislation, but this is not the case in New Zealand. NZFSA emphasizes in its information material that it has two key functions: a) to protect and promote public health and safety and, b) to facilitate market access for New Zealand’s food and food by-products. Some consumers believe that there is a potential conflict between these two functions. Therefore it is important to clarify to consumers what the second function involves and to assure them that carrying it out will in no way compromise the role of NZFSA to protect public health. The role of NZFSA in the nutrition area and in the promotion of health by providing advice on healthy diets seems unclear to many outside NZFSA and the Ministry of Health (MoH).

NZFSA resembles the food safety authorities of Denmark and Ireland insofar as they all rely to a considerable extent on external scientific support for their risk management activities. In 2005 NZFSA established the NZFSA Academy to assist in the provision of advice from experts in areas where NZFSA either does not have the expertise within its own staff or where confirmation of the advice of its own experts would be valuable. From time to time, NZFSA establishes expert groups or seeks more specific assistance in relation to particular issues. Rather than setting up a number of permanent committees dealing with specific scientific areas of expertise, NZFSA has preferred to have the capability available to set up *ad hoc* working groups as and when the need arises. NZFSA’s international contact networks are important for its ability to keep abreast of international developments in the field of food safety and can facilitate its work in detecting new or re-emerging food safety issues at the earliest possible stage. A policy of openness and transparency is essential for NZFSA in building and maintaining public trust and can also help to ensure that food business operators comply with food legislation and established codes of practice.

A high degree of flexibility is incorporated into the RMF and changes in the organisational structure of NZFSA need not affect it. Having been created as a separate public service department as recently as July 2007, it is too early to draw firm conclusions about the advantages and disadvantages of the present organisational structure and no attempt to do so has been made in the present review.

The following recommendations are made:

- The RMF should be regarded as dynamic, rather than static, and subject to continuous improvement, with a formal revision at regular intervals (maximum 3 years).
- A shorter lay version of the RMF should be prepared as a useful source of information for the general public and for educational and training purposes.

- In the introductory part of the document, a list should be added showing the different types of hazard that must be dealt with by NZFSA, including environmental contaminants, natural toxins, residues of pesticides and veterinary drugs, substances formed during food processing and preparation and allergens.
- A glossary containing the most important risk analysis terms should be added to the document and, in its communication with the general public, NZFSA should explain the meaning of some of these terms. In addition, these terms should be defined in New Zealand's basic food legislation (the Food Act), preferably using the internationally accepted definitions adopted by the Codex Alimentarius Commission (CAC).
- The advantages of using a preventive approach to food safety, i.e. trying to eliminate or control problems at source, for example by strict control on the use of pesticides and veterinary drugs and by trying to control contamination with *Campylobacter* in poultry production, should be emphasised in the RMF.
- In order to achieve a better balance in the document and to increase understanding of their importance, the text on the last two steps of the RMF, *Implementation of risk management decisions* and *Monitoring and review*, should be expanded.
- The role that the food industry can play in identifying and assessing the practicality of different risk management options should be expressed more clearly in the RMF.
- A short description of how the NZFSA deals with the problem of allergy/hypersensitivity/intolerance to food components should be added to the RMF.
- In the RMF it should be clarified who defines public health goals in New Zealand.
- The roles that NZFSA and Food Standards Australia New Zealand (FSANZ) play in setting different types of food standard that apply in New Zealand should be clarified in the RMF.
- In the interests of openness and transparency it is recommended that NZFSA's mandate be defined by the Government in a document that is more readily accessible to the public than Cabinet documents. In defining the NZFSA's mandate it is recommended that the Government clarify to all stakeholders that its primary role is to help to ensure the safety of foods produced in New Zealand (regardless of whether they are consumed in the country or exported) and also to help to ensure that imported foods are safe.
- In the interests of openness and transparency regarding its policy, it is recommended that the Government, in its basic food legislation, consider giving NZFSA a clearer mandate to apply a precautionary approach when dealing with uncertainty in risk management. In addition, NZFSA should provide more information on how it applies such an approach in risk management.
- NZFSA should continue to develop its policy of openness and transparency by providing more information to relevant consumer and other stakeholder groups via its web site and other channels, including the results of inspections of food business operations and other control activities.
- NZFSA should consider introducing the Danish ("Smiley") symbol system for informing potential customers of the results of the latest inspection of food premises, such as shops and restaurants, as a means of improving compliance and helping consumers to choose shops and restaurants maintaining high standards of food hygiene.

- The current division of responsibility between NZFSA and MoH for supplying advice to the general public on nutrition and healthy dietary habits should be reviewed, bearing in mind the need for a holistic approach to dietary recommendations, especially in cases where consumption of the same type of food may involve both health risks and health benefits.
- It is strongly recommended that NZFSA, and other organisations in New Zealand, continue to play an active role in the food safety work of relevant international organisations, in particular FAO, WHO, CAC and OIE.
- In the RMF, the roles played by NZFSA's Business Groups other than the Science Group in risk management should be specified. NZFSA should carefully examine the vulnerability and sustainability of the current arrangement of having a relatively small Science Group, bearing in mind the very wide range of scientific issues it is called upon to tackle.
- The current organisational structure of NZFSA should be reviewed after a period of not more than 3 years.
- The international contact networks that NZFSA has established should be strengthened and expanded, where possible through formal arrangements.

#### *The A1/A2 milk issue*

Deletion of the Lay Summary by NZFSA prior to placing the Swinburn report on A1/A2 milk on its web site resulted in some loss of transparency, since it made it more difficult for lay persons, including non-specialist journalists, to understand some parts of the conclusions and recommendations in the report. However, it did not result in the loss of any essential information, since the full text of the report itself and the Executive Summary were placed on the web site at the same time as the Press Release. NZFSA's decision to delete the Lay Summary was an error of judgement and led to damaging and unnecessary speculation that NZFSA was trying to withhold important information from the public, even if this was not the case. NZFSA's decision to present his report on a day that Swinburn was unavailable for media interviews also reduced transparency and is difficult to justify, especially since a very long time had already elapsed between the commissioning of the report and its finalisation. Furthermore, it fuelled suspicion that NZFSA was trying to hide something. Some details in NZFSA media release were formulated in ways that are open to different interpretations or were incorrect. However, this reviewer does not subscribe to the theory advanced by Professor Woodford suggesting that NZFSA was withholding important information from the public and had an ulterior motive in the formulation of its media release.

NZFSA spread information about the Swinburn report, including its recommendations for support of further research, and made it publicly available via its web site. Therefore it can be assumed that research workers in relevant fields, at least in this part of the world, are well aware of Swinburn's recommendations about the need for further research and also know about possible sources of research funding. However, neither NZFSA nor MoH took any specific action to gather together research workers in relevant disciplines for a discussion about support for new research. MoH's current dietary advice to different population groups shows that it regards milk as an important component of a healthy diet. Since there is a risk that the media treatment of the A1/A2 milk issue could result in some consumers replacing milk in their diet with other beverages with less nutritional value, it might have been expected that MoH would have been active in the media discussion about the Swinburn report and the A1/A2 issue in general. However, MoH appears to have maintained a very low profile throughout the whole

affair, apparently regarding it as primarily a food safety issue. The following recommendations are made:

- NZFSA should continue to develop its risk communication skills to enable it to better inform the public when faced with the difficult task of sending clear and unambiguous messages and at the same time communicating uncertainty.
- As soon as EFSA has completed its review on the science of A1/A2 milk, NZFSA should bring together a group of experts in relevant fields to discuss the report and the possible need for further research in this area.

### *Campylobacter in poultry*

The strategy that has been developed by NZFSA and is being implemented by the food industry to tackle the serious problem of *Campylobacter* contamination of poultry meat is based on sound science and follows NZFSA's RMF. The hazard-based goal of the strategy, a 90% reduction in levels of *Campylobacter* contamination of broiler carcasses, is clear and methods for following it up have been put in place. Likewise, the interim public health goal, involving a 50% reduction in the number of cases of human campylobacteriosis within a five-year period, is clear, as are the methods to monitor progress. Initial results from 2008 indicate that the situation is improving. However, although this is encouraging, it is far too early to conclude that the goals will be reached on time. The following recommendations are made:

- In order to reduce the problem of *Campylobacter* infection, the poultry industry should seriously consider the practicality of de-stocking the entire flock in each poultry house at the same time (the "all-in-all-out" principle).
- The food industry and trade should consider giving financial incentives to poultry producers/processors that provide *Campylobacter*-free poultry and products thereof.
- The food industry should redouble its efforts to ensure that raw poultry products are packaged in such a way as to avoid cross-contamination during distribution and NZFSA should verify that current legal requirements for leak-proof packaging are met.
- NZFSA should continue to use its international contacts to follow developments in this area and evaluate any new methods that become available to mitigate the problem of *Campylobacter* in poultry meat.
- If its current strategy does not produce satisfactory results on time, NZFSA should re-examine its position on commercial freezing of *Campylobacter*-contaminated broilers as a method to reduce the numbers of *Campylobacter* on chicken meat. Alternatively, other decontamination steps should be applied, e.g. heat-treatment.
- Together with relevant agencies and stakeholders, NZFSA should continue to identify and deal with food-borne sources of *Campylobacter* other than poultry.
- NZFSA should encourage further research into attribution to enable better epidemiological understanding of the causative *Campylobacter* organism and thus enable much more targeted controls of the health risk.
- NZFSA should intensify its information to both consumers and commercial caterers about the problem of *Campylobacter* in poultry meat and how to deal with it (avoidance of cross-contamination, adequate heat-treatment prior to consumption, etc.).

### *Aspartame as a food additive*

NZFSA has handled the different aspects of the aspartame issue in a sound and professional manner. The preliminary risk assessment carried out by NZFSA on the basis of the information then available was later confirmed by the in-depth assessments carried out by EFSA and the US Food and Drug Administration. NZFSA has provided consumers and other stakeholders with relevant and understandable information about aspartame and responded to questions from consumers, the media and others. The following recommendations are made:

- NZFSA should continue to base its risk management of food additives on the best scientific evidence available, monitor developments in the toxicology of food additives, including aspartame, and provide consumers and other interested parties with information about any new developments in this area.
- NZFSA should continue to correct any obviously false or misleading information appearing in the media or other arenas and, in doing so, concentrate on correcting the information without commenting on the individuals spreading the information.

### *Imported foods regime*

The revised import regime developed by NZFSA is based on sound science and is a considerable improvement on the earlier arrangement. If properly enforced, it should provide adequate protection against the import of foods that constitute health risks. NZFSA's handling of the issue of residues of veterinary drugs in farmed fish and contaminated animal feed/vegetable protein from China was effective and made good use of its international network of contacts in other food safety agencies around the world, in particular those in North America. The following recommendation is made:

- NZFSA should list details of foods that have been rejected/detained at import control and refused entry into New Zealand, make this information publicly available and also transmit it to neighbouring countries.

### *Roquefort cheese and other raw milk products*

NZFSA has followed its RMF in handling the issue of health risks posed by cheeses made from raw milk, in particular Roquefort cheese. It has obtained a good scientific basis for its decision making and has consulted different stakeholders during the process. New Zealand has also fulfilled its World Trade Organisation obligations in its handling of the issue. NZFSA has put in place a survey to check that processing standards for cheeses prepared from raw milk have been complied with by measuring the levels of *Escherichia coli*. A very important component of the risk management strategy is the provision of information to vulnerable groups, e.g. pregnant women, who should avoid this type of product. The following recommendations are made:

- In addition to surveying *E. coli* levels in raw milk cheeses, NZFSA should check that its information on the risks associated with the consumption of raw milk cheeses is reaching the relevant target groups and that they understand it.
- NZFSA should closely monitor the incidence of food-borne infections caused by *Listeria* spp. and take action if the number of such cases associated with consumption of raw milk cheeses increases.

### *Mercury in fish*

NZFSA's risk management of the mercury in fish issue takes into account the latest risk assessment carried out by the Joint FAO/WHO Expert Committee on Food Additives. The decision to change the earlier risk management strategy and to put much more emphasis on clear and balanced dietary recommendations to vulnerable consumer groups, especially pregnant women, was sound and is consistent with the approach taken in other countries, e.g. Denmark, Ireland and Sweden. It is recommended that:

- NZFSA should follow up its risk communication efforts by checking that its recommendations are reaching the target groups and that they are understood and followed.
- NZFSA should continue to collect data on current levels of mercury in fish consumed in New Zealand, including imported fish. If the levels found differ significantly from those on which the current recommendations are based, the recommendations should be revised accordingly.
- NZFSA should continue to collect data on fish consumption and, if intake decreases in a manner considered negative from a health point of view, take steps together with the health authorities and others to stimulate consumption of relevant fish species.
- If resources are available, NZFSA should initiate a study to measure the levels in the hair of women of childbearing age to check that their total mercury exposure does not exceed tolerable levels.

## Acknowledgements

The author would like to thank all those who have given of their time to provide information on which to base the present report. Particular thanks are due to:

- Dr Andrew McKenzie, Dr Steve Hathaway, Mrs Sandra Daly, Ms Carole Inkster, Ms Carol Barnao, Mr John Reeve, Dr Peter van der Logt, Dr Roger Cook, Mr Gary Bowering, Mr Matthew Green, Ms Jenny Reid, Veterinarians Brent Pearce and Mike Hanlon and others on the NZFSA staff
- Professor Boyd Swinburn, Deakin University, Melbourne, Australia
- Professor Keith Woodford, Lincoln University, Canterbury
- Dr Andrew Clarke, A2 Corporation Limited
- Dr Jeremy Hill, Fonterra Co-operative Group Limited
- Mr Michael Brooks, Poultry Association of New Zealand Inc.
- Ms Elizabeth Aitken, Ministry of Health
- Ms Belinda Allan, Ms Jean Park, Mrs Wendy McGowan, Ms Alison White and Mr Steffan Browning, all members of NZFSA's Consumer Forum
- Professor Jack A. Heinemann, University of Canterbury
- Mr Simon Terry, Sustainability Council of New Zealand
- Professor Ian Shaw, University of Canterbury
- Professor Jim Mann, University of Otago
- Dr Stephen L.W. On, Institute of Environmental Science and Research, Christchurch,
- Mr Nigel Harris, United Fisheries Ltd., Christchurch
- Deputy Chief Executive Dr Alan Reilly, Dr Wayne Anderson, Mr Jeffrey Moon, Dr Mary A.T. Flynn and other members of the staff of the Food Safety Authority of Ireland
- Mr Knud Østergaard and other members of the staff of the Danish Food and Veterinary Administration and Dr Alicja Mortensen and Dr Agnes Pedersen from the Danish National Food Institute
- Dr Lars Plym Forshell, Dr Roland Lindqvist, Dr Nils-Gunnar Ilbäck, Chief Legal Officer Goran Aner and other former colleagues at the Swedish National Food Administration.

I would also like to express my sincere thanks to Dr Andrew McKenzie, Mrs Sandra Daly and others at NZFSA for the excellent practical arrangements they made in connection with my visits to New Zealand and for promptly meeting all my requests to arrange meetings with representatives of other government departments, consumer organisations, the food industry, and other stakeholders and also experts at academic and research organisations.

## 1. Background to the present review

Consumer concern in New Zealand in recent years about the safety of “A1 milk” was the main reason for commissioning this review of how the New Zealand Food Safety Authority (NZFSA) manages different food safety risks. New Zealand has a major dairy industry and exports of dairy products are important for the country’s economy and any discussions on the safety of milk are therefore of great interest to industry, government and consumers alike. Commercial organisations selling “A2 milk”, an alternative to “A1 milk”, have a particular interest in this subject.

Milk contains six major proteins, four of which are casein proteins. Beta-casein is the most common of the caseins and of special interest for this review are two forms of beta-casein called A1 beta-casein and A2 beta-casein. Digestion of A1 beta-casein produces a peptide called beta-casomorphin-7 (BCM7), comprising a string of seven amino acids. Digestion of A2 beta-casein, on the other hand, does not give rise to significant amounts of BCM7. Milk high in A1 beta-casein has been referred to as A1 milk and milk high in A2 beta-casein as A2 milk and these terms will be used with these meanings in the present report. Whether an animal produces A1 or A2 milk or a mixture of both depends on the species and breed of animal. The New Zealand dairy herd produces predominantly A1 milk, but A2 milk is also produced and marketed in New Zealand.

In January 2003, an article in the New Zealand Medical Journal (Laugesen and Elliot 2003) triggered increased media interest in the A1/A2 milk issue. The article and subsequent advertising of A2 milk products associated A1 milk with ischaemic heart disease (IHD), type 1 diabetes mellitus (DM-1), schizophrenia and autism. At that time, the prime regulatory interest of NZFSA in this issue was in ensuring that any health claims applied by industry to A2 milk complied with New Zealand legislation. In November 2003, the New Zealand Commerce Commission advised that A2 Corporation Ltd. and its licensed A2 producers had agreed to amend their promotional material following a warning from the Commission.

Following the health claims made publicly for A2 milk and the implication that A1 milk might pose human health risks, NZFSA became aware that some consumers were concerned that the milk they were drinking might not be safe and, as a result, some of them might substitute less healthy alternatives (e.g. high-sugar drinks) for milk. This prompted NZFSA to issue a press statement in January 2003 entitled “*Milk is still part of a balanced diet*” (NZFSA 2003). Later in 2003, as a result of the continuing public claims being made about A2 milk, and in view of growing consumer concern, NZFSA decided to commission an independent review of the literature to assess the scientific validity of the statements being made. The review was carried out by Boyd Swinburn, Professor of Public Health Nutrition at Deakin University, Melbourne, Australia. He produced a draft report in October 2003. This was then reviewed by four experts, amended by Swinburn in the light of the reviewers’ comments and finalised on 13 July 2004. The final report (*Beta-casein A1 and A2 in milk and human health*, Swinburn 2004) included both an Executive Summary and a Lay Summary: the Lay summary was not peer-reviewed. On 3 August 2004 NZFSA issued a Press Release (NZFSA 2004a) and placed the report, including its Executive Summary, but not the Lay Summary, on its website. On the day NZFSA released his report Professor Swinburn had other prior engagements and was not available for interviews by the media. Later, on 18 August 2004, NZFSA also placed the Lay Summary on its web site. In the overall conclusions (Section 5) of his report Swinburn wrote, among other things:

*“In my opinion, the warranted actions at present by the relevant government agencies involve:*

- *Funding further research, especially clinical research*
- *Communicating the current evidence and the uncertainty to the public about the A1/A2 hypothesis and its implications for milk consumption*

- *Monitoring new evidence as it is published and reviewing public health action*
- *Monitoring the claims being made to the public about health benefits of A2 milk and ensuring that they are within the food claims regulations*

*I do not believe that there is sufficient evidence as yet to warrant more specific population measures such as:*

- *Changing dietary advice to the general population*
- *Changing recommendations for specific dietary advice for those with (or at risk of) DM-1, IHD, autism or schizophrenia*
- *Requiring labelling of casein sub-type on dairy products*
- *Recommending changing dairy herds in order to improve public health outcomes*

*A New Zealand dairy herd that produced predominantly A2 milk would have no apparent negative health effects and could potentially have significant population health benefits if the A1/A2 hypothesis proves to be correct. Current claims for the health benefits of A2 milk need to remain restricted and comply with the appropriate regulations on food claims.*

*In discussion with their medical advisors, people with established IHD or at high risk of IHD, families with children at (genetically) high risk for DM-1, and families with autistic children may be motivated to reduce or eliminate their intake of A1  $\beta$ -casein. This would be done as a precautionary approach (or possibly as a trial in the case of autism) in the face of substantial uncertainty about the potential benefits. The evidence does not support such dietary changes as a recommended clinical approach with a known likelihood of benefit.”*

It has been suggested by the advocates of A2 milk that NZFSA’s delayed release of the Lay Summary, the unavailability of Professor Swinburn for media interviews when his report was released and some of NZFSA’s communications about the safety of milk indicate problems with the application of NZFSA’s risk management decision-making process for food safety issues.

On 15 September 2007, Keith Woodford, Professor of Farm Management and Agribusiness at Lincoln University, published a book entitled “*Devil in the Milk: Illness, Health and Politics, A1 and A2 Milk*” (Woodford 2007a). In his book Woodford advanced the hypothesis that the peptide beta-casomorphin-7 (BCM7, “The Devil in the Milk”), is a causative agent in a range of human diseases (IHD, DM-1, schizophrenia and autism). Woodford also criticised various aspects of the NZFSA’s handling of the A1/A2 milk issue, including NZFSA’s Press Release and the timing of the release of the Swinburn report. Considerable media interest was generated by the publication of Woodford’s book and questions were asked about NZFSA’s handling of the A1/A2 milk issue. In response to continued public interest in the A1/A2 milk issue, in October 2007 NZFSA proposed two further reviews – the present review, which deals with NZFSA’s risk management framework and its application, and a review of the science of A1/A2 milk and the possible causal relationship between consumption of A1 milk and human disease. The latter review is now being carried out by the European Food Safety Authority (EFSA) at NZFSA’s request.

## 2. Terms of Reference for the review

The Terms of Reference for the present review were proposed by NZFSA. In order to ensure that the review was as independent as possible, the State Services Commission, Treasury and Audit New Zealand were consulted and the Terms of Reference were noted by the Cabinet on 10 December 2007. As announced by the Hon. Lianne Dalziel, Minister for Food Safety, on 13 December 2007 (Dalziel 2007), the expert consultant carrying out the present enquiry will:

- (i) Assess the appropriateness and applicability of NZFSA's Risk Management Framework for making decisions on consumer protection.
- (ii) Undertake an evaluation of the applicability and appropriateness of the NZFSA Risk Management Framework in regard to:
  - a. varying levels of uncertainty in available scientific information and/or risk assessments;
  - b. establishing priorities for policy development and risk management action;
  - c. balancing scientific information on risks with other risk management inputs such as the health expectations of society and the likely cost/benefit of potential control measures;
  - d. the establishment of food safety standards where appropriate;
  - e. the context of international trade rules and New Zealand's international obligations; and
  - f. allocation of decision-making and standard development functions within the organisation, and the business structure for such activity.
- (iii) Compare the Risk Management Framework as applied in New Zealand with international (Codex) guidelines on best practice.
- (iv) Compare the application of the NZFSA's Risk Management Framework in New Zealand with similar risk management systems in other countries.
- (v) Consider and report, in light of the report *Beta-casein A1 and A2 in milk and human health* prepared by Professor Boyd Swinburn, on the application of the principles of the Risk Management Framework in respect of the process by which NZFSA came to the decision to continue to take the position that milk is a good source of nutrition and is safe to drink.
- (vi) Assess the transparency and communication of decisions made in regard to A1-A2 milk, particularly in light of the delayed release of the lay summary prepared by Professor Boyd Swinburn and his non-availability to respond to media queries resulting from the release of his report.
- (vii) Consider whether, in light of the Swinburn report, further steps should have been taken by NZFSA, including referring the report to other Government agencies.
- (viii) Consider and report on the application of the principles of the Risk Management Framework in respect of other recent high-profile risk management and standard setting activities undertaken by NZFSA; in particular the strategy for control of *Campylobacter* in poultry, aspartame as a food additive, the imported foods regime (including for food from China), and the standard development for Roquefort cheese made from raw milk.

The expert consultant will take into account:

- (ix) Published and internal NZFSA documentation of systems and processes
- (x) Current New Zealand legislation and guidance
- (xi) Published documents on risk management systems for (and of) other national food agencies

A review report is to be prepared and presented that contains:

- (xii) A description of the NZFSA system
- (xiii) A description of international best practice in the area
- (xiv) A comparative analysis of the NZFSA system against best practice
- (xv) Commentary on the application in recent risk management decision-making matters.

As announced by the Food Safety Minister on 19 February 2008 (Dalziel 2008), a separate, comprehensive review of existing scientific research into the safety of A1 milk is to be carried out by EFSA and therefore this aspect of the A1/A2 issue is not dealt with in the present review.

To meet the requirement in point (iv) of the above Terms of Reference, NZFSA's Risk Management Framework has been compared with the risk management systems used by the food safety authorities in Denmark, Ireland and Sweden. The mandates of the food safety authorities in all four countries cover both foods for domestic consumption and foods that are exported. Denmark and Ireland were chosen because, like New Zealand, exports of meat and milk products are important for their economies and their populations are of a similar size to New Zealand's. Sweden was chosen as an example of a country where food exports are of much smaller importance and because the reviewer was already well acquainted with the risk management system applied there. The choice of the above countries for comparison with New Zealand was communicated to NZFSA's Chief Executive, Dr Andrew McKenzie, and to the Minister for Food Safety, the Hon. Lianne Dalziel, who considered it acceptable.

### 3. How the review was conducted

During the period 15 January - 1 February 2008 I visited New Zealand and had discussions with and received information from:

- Hon. Lianne Dalziel, Minister for Food Safety
- Dr Andrew McKenzie, Chief Executive of NZFSA, and members of his staff
- Professor Keith Woodford, Lincoln University, Canterbury
- Professor Jack A. Heinemann, University of Canterbury
- Mr Simon Terry, Sustainability Council of New Zealand
- Professor Ian Shaw, Pro-Vice-Chancellor, University of Canterbury
- Dr Stephen L.W. On, Head, Food Safety Programme, Institute of Environmental Science and Research, Christchurch,
- Professor Jim Mann, University of Otago
- Mr Nigel Harris, United Fisheries Ltd., Christchurch
- Dr Andrew Clarke and Mr Anthony Lawler, A2 Corporation Limited and Dr Jock Allison, Consultant to the A2 Corporation
- Dr Jeremy Hill, Fonterra Co-operative Group Limited, Palmerston North
- Mr Michael Brooks, Poultry Association of New Zealand Inc. and Michael Rozen, Ingrams Enterprises (NZ) Pty. Limited
- Ms Elizabeth Aitken, Ministry of Health
- Ms Belinda Allan, Ms Jean Park, Mrs Wendy McGowan, Ms Alison White and Mr Steffan Browning, all members of the NZFSA Consumer Forum

When in Wellington I obtained a copy of Professor Woodford's book "*Devil in the Milk. Illness, health and politics. A1 and A2 milk*". During my visit to New Zealand I also took the opportunity to visit a slaughterhouse and a fish and shellfish processing plant to gain some insight into how NZFSA's food production inspection system operates in practice. Some of the above-mentioned persons have also provided me with further information (e.g. Woodford 2007b, 2008), mostly by e-mail, subsequent to my visit to New Zealand. Professor Boyd Swinburn kindly provided me with information about his review and answered questions via e-mails.

On 20-22 February 2008 I visited Dublin and had discussions with Deputy Chief Executive Dr Alan Reilly, Dr Wayne Anderson, Mr Jeffrey Moon, Dr Mary A.T. Flynn and other members of the staff of the Food Safety Authority of Ireland, who also provided me with a large amount of written material on the Authority's responsibilities and activities relevant to this review.

On 27 February 2008 I visited Copenhagen for discussions with Mr Knud Østergaard, Dr Helle Eriksen, Dr Rikke Benyahia, Dr Charlotte Vilstrup, Dr Gudrun Sandö and other members of the staff of the Danish Food and Veterinary Administration, who provided me with information about their organisation and its activities, and Dr Alicja Mortensen and Dr Agnes Pedersen from the National Food Institute, who provided information on the aspartame issue and other matters.

On 15 February 2008 I visited the Swedish National Food Administration (NFA) in Uppsala and had discussions with Dr Lars Plym Forshell, Dr Roland Lindqvist, Dr Nils-Gunnar Ilbäck and other former colleagues at the Administration. Information on the Swedish programme to reduce *Campylobacter* in broilers was provided by Veterinarian Pia Gustafsson from Svensk Fågel. Dr Ingrid Hansson from the Faculty of Veterinary Medicine and Animal Sciences, Swedish University of Agricultural Sciences, kindly sent me her thesis from 2007 on *Bacteriological and Epidemiological Studies of Campylobacter spp. in Swedish Broilers*. Information on Iceland's

measures to reduce the problem of *Campylobacter* in broilers was kindly provided by its Chief Veterinary Officer Halldór Runólfsson.

On 21 April- 2 May 2008 I paid a second visit to New Zealand, had some further discussions with NZFSA staff, finalised the report and presented it to the Minister for Food Safety and others.

In addition to the above sources, information for this review has been obtained from various web sites, including those of NZFSA and FSANZ, the New Zealand Ministry of Health, the Danish Food and Veterinary Administration, the Food Safety Authority of Ireland, the Swedish National Food Administration, FAO, WHO, EFSA, the European Commission and the Swedish Institute for Infectious Disease Control (Smittskyddsinstitutet). I also had access to a large number of documents from my previous work with FAO/WHO expert bodies, the Codex Alimentarius Commission (CAC) and its subsidiary bodies, the World Organisation for Animal Health (OIE) and the National Food Administration (NFA).

#### 4. New Zealand Food Safety Authority's Risk Management Framework and its applicability and appropriateness

During early 2008 NZFSA further developed its risk management framework (RMF) and in April 2008 it published a document entitled “*Food Safety in New Zealand: Application of a Risk Management Framework*”. This is an update of the publication “*Food Administration in New Zealand: A Risk Management Framework for Food Safety*”, published jointly with the Ministry of Health (MoH) in 2000. The updated RMF (see Appendix 1) and its application is the subject of the present review: it is available on NZFSA's web site ([www.nzfsa.govt.nz](http://www.nzfsa.govt.nz)).

As indicated in its Introduction, in addition to the earlier text, the updated RMF takes into account four international best practice guideline documents from FAO, the World Health Organisation (WHO) and the Codex Alimentarius Commission (CAC), namely:

- *Food Safety Risk Analysis: A Guide for National Food Safety Authorities*. FAO Food and Nutrition Paper No. 87, WHO/FAO, Rome, 2006 (WHO/FAO 2006)
- *Working Principles for Risk Analysis for Application by National Governments*. Codex Alimentarius Commission (CAC) Procedural Manual. 17<sup>th</sup> Edition 2007. FAO, Rome. (Codex Alimentarius Commission 2007)
- *FAO Biosecurity Toolkit*. 2007. FAO. Rome
- *Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)*. CAC/GL-63 2007. FAO. Rome.

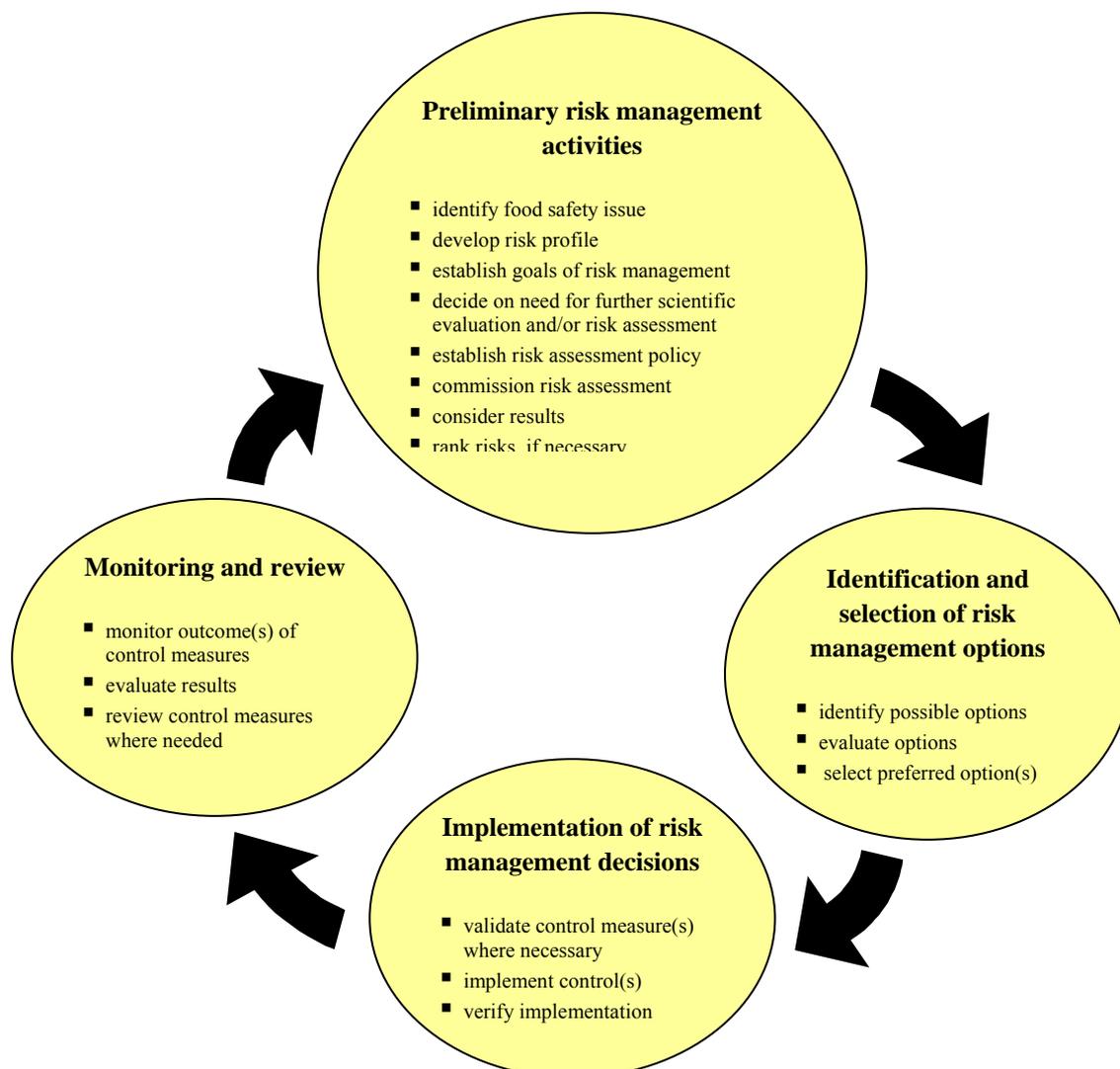
The RMF outlines a process for managing food safety issues as they arise and consists of four interconnected elements: 1) Preliminary risk management activities, 2) Identification and selection of risk management options, 3) Implementation of risk management decisions and, 4) Monitoring and review. Each of these elements is then further subdivided into several individual tasks (see next page). In addition to describing the RMF itself, the document contains an introductory section explaining the need for an agreed risk management process. The two annexes to the RMF provide more detailed information on two of the three components of food safety risk analysis - risk assessment and risk communication, respectively. The way in which the RMF is applied is illustrated with many examples of its use in handling recent food safety issues in New Zealand.

##### 4.1 General comments and recommendations

The comments given in this section of the report refer to the generic RMF itself and comments on its application by NZFSA in various high profile issues are given later in Section 7.

This updated RMF is a well written document that provides a very good structure for systematically and flexibly managing the wide variety of food safety risks currently encountered and also for handling emerging risks that NZFSA must address. The document takes into account scientific and other developments, both in New Zealand and internationally, and the practical experience gained by NZFSA in the seven years since the previous document was published and it is a considerable improvement on the previous text. The RMF is designed to cover all the different types of food-borne hazard that NZFSA has to deal with and has the built-in flexibility to achieve this. The RMF strongly emphasises the need for risk management decisions to rest on a sound scientific foundation and to use a multidisciplinary approach to food safety. Furthermore, it points out the need to consider the whole of the food chain from primary production to the final consumer when managing food safety risks. There are considerable advantages in using a preventive approach to food safety, i.e. trying to eliminate or control problems at source, for example by strict control on the use of

pesticides and veterinary drugs and by trying to control contamination with *Campylobacter* in poultry production, and it is recommended that this also be emphasised in the document.



### Individual tasks at each step in the risk management framework

The RMF is comprehensive, but a number of recommendations are given here with the aim of further improving the document by a) making it easier to understand for those not familiar with the subject, b) filling some information gaps and, c) achieving a better balance in the presentation of the four different steps of the RMF.

In the RMF it is emphasized that the process is cyclical, iterative and on-going. This is important, because in some quarters there is a tendency to regard the process as linear and to overemphasize the importance of standard setting and to put insufficient emphasis on the last two components of the framework – implementation of control measures and monitoring and review to assess the effectiveness of the risk management measures. In the document there is an imbalance between the presentation of the four different steps comprising the RMF, most attention being concentrated to the first two steps. The elaboration of standards, guidelines, codes of practice and other recommendations may lead to little improvement in food safety unless they are enforced or applied in practice. The existence of a well-functioning implementation and enforcement system, including, for example, inspections of food producing, processing and distribution establishments and control of

chemical and biological contaminants (e.g. mycotoxins and residues of pesticides and veterinary drugs) in foods, provides a strong incentive to food business operators to comply with standards and follow recommended practices. It would be of interest to see examples of the types of action taken by NZFSA when it finds contraventions of existing legislation. NZFSA has a modern and effective meat inspection system and this is an example of an area that could be incorporated into the text. Consequently, it is recommended that, in order to achieve a better balance in the document and to increase understanding of their importance, the text on the two steps *Implementation of risk management decisions* and *Monitoring and review* be expanded.

Although it can be expected that the basic four-component structure will be applicable for many years to come, it is recommended that the RMF document be regarded as dynamic, rather than static, and subject to continuous improvement, with a formal revision at regular intervals (maximum 3 years). This is in line with the stated policy of NZFSA to strive for continuous improvement in its working methods.

The RMF points out the importance of providing information in lay terms for the general public and this is relevant to the handling of, among other things, the A1/A2 issue (see Section 7.1). The RMF is a valuable basic food safety document and it is recommended that a shorter lay version, containing the most important points, be prepared as a useful source of information for the general public and for educational and training purposes. Some of the risk analysis terms used in the document are defined and explained in various parts of the text. However, in order to improve the readability of the RMF, it is recommended that a glossary containing the most important risk analysis terms be added to the document. In addition, it is recommended that in its communication with the general public NZFSA explains some of these basic terms. Many food safety risk analysis basic terms (e.g. hazard, risk, risk assessment, risk management, risk communication and risk profile) are used in the RMF document and in other documents produced by NZFSA. In order to promote transparency and wider understanding of the risk management process, it is recommended that these terms be defined in New Zealand's basic food legislation (the Food Act), preferably using the internationally accepted definitions adopted by the Codex Alimentarius Commission (CAC).

The examples given in the RMF should help readers outside NZFSA and unfamiliar with food safety risk management to understand the process and that many different types of hazard have to be addressed. Many of the examples given refer to risks arising from microbiological hazards (e.g. *Campylobacter* and *Salmonella*) and few refer to risks from chemical hazards. This is perhaps understandable in view of the importance of microbiological hazards, but other types of hazard can also pose health risks. It is therefore recommended that in the introductory part of the document a list be added showing the different types of hazard that must be dealt with by NZFSA, including environmental contaminants, natural toxins, residues of pesticides and veterinary drugs, substances formed during food processing and preparation and allergens.

#### **4.2 Applicability and appropriateness of the Risk Management Framework to varying levels of uncertainty in available scientific information and/or risk assessments**

The amounts and quality of the scientific data available for carrying out risk assessments can vary widely. In the case of some naturally-occurring toxins, for example, very few data are available, whereas for food additives and pesticides, where there is a legal requirement for approval prior to placing the products on the market, there are large sets of toxicological data on which to base a risk assessment. The RMF provides a sound basis for dealing with both situations. This is absolutely necessary, since in many cases the scientific basis and/or resources for carrying out a full risk assessment are lacking and for this and other reasons, for example time constraints, it is necessary to make risk management decisions on the basis of a risk profile, rather than a full risk assessment. This

is described in the RMF. The RMF also points out the importance of both communicating and dealing with uncertainty in risk assessments and explains how NZFSA does this. This applies both to communication between risk assessors and risk managers within NZFSA and between NZFSA and those outside it, including consumers, food business operators, academia and other interested parties. The communication by regulatory authorities, such as NZFSA, to the public of uncertainty on food safety issues is often a very difficult matter, as evidenced by the discussions on the handling of the A1/A2 milk issue (see section 7.1). There is a need to give clear messages to consumers, the food industry and other stakeholders and avoid from the health point of view unwarranted changes in food consumption patterns. It is, however, important that NZFSA's information about risks associated with foodstuffs is balanced and that uncertainties associated with the risk assessments are clearly communicated. There is a lot to be said for following the simple recommendation: "*Tell them what you know, tell them what you don't know, and tell them now*". NZFSA appears to follow this principle and, through training and experience, its performance in risk communication has improved.

The RMF takes up the important issue of the application of precaution in risk management and states that, although it applies a precautionary approach, NZFSA does not have a specific policy in this area. The RMF then goes on to explain how NZFSA incorporates precaution when dealing with uncertainty in risk management. One of the key issues here is "How much evidence/indication of a human health problem is needed to trigger the initiation of risk management measures by NZFSA?" Although this may be difficult to describe, and may well vary depending, amongst other things, on the dietary importance of the food concerned, it is recommended that an attempt be made to enlarge on this issue in the RMF as part of a clarification of NZFSA's policy in this area.

New Zealand is a member of the World Trade Organisation (WTO). Article 5.7 of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures ("SPS Agreement") states that "*In cases where relevant scientific evidence is insufficient, a (WTO) Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.*" This Article gives New Zealand the right to take provisional measures to protect its human, animal and plant life or health from hazards in, among other things, foods moving in international trade, even in the absence of adequate scientific evidence on which to base a risk assessment and New Zealand exercises this right. Article 5.7 of the SPS Agreement can be said to sanction a precautionary approach in risk management applied to food moving in international trade. It is logical to apply a similar precautionary approach in the domestic arena.

In order to clarify its policy, the EU has incorporated a "Precautionary Principle" into its "general food law" (Article 7 in EC Regulation 178/2002, European Community 2002). This Principle is similar to the principle expressed in Article 5.7 of the SPS Agreement and also incorporates the need for the measures to be proportionate and a requirement that the measures should be no more trade restrictive than necessary, which are also basic SPS principles. The Government of New Zealand has hitherto chosen not to explicitly incorporate a precautionary approach into its basic food legislation (the Food Act). This means that, although NZFSA states that it is conservative and uses a precautionary approach when dealing with high degrees of uncertainty, it is not specifically mandated by the Government to do so. In the interests of openness and transparency regarding its policy, it is recommended that the Government, in its basic food legislation, consider giving NZFSA a clearer instruction/mandate to apply a precautionary approach when dealing with uncertainty in risk management.

### **4.3 Applicability and appropriateness of the Risk Management Framework to establishing priorities for policy development and risk management action**

Since resources for risk assessment and other components of risk analysis are limited, it is necessary to rank risks for policy development and risk management action. This ranking can place at different stages of the preliminary risk management activities. Although this ranking is primarily a scientific issue and larger or more severe risks should be given priority, many other factors, not always related to the size and severity of the risk, may affect it. These include political and consumer concerns and perceptions, media interest and disputes in international food trade. The updated RMF, which includes a requirement for communication with all interested parties during all phases of the risk management process, provides an appropriate framework for priority setting.

### **4.4 Applicability and appropriateness of the Risk Management Framework to balancing scientific information on risks with other risk management inputs such as the health expectations of society and the likely cost/benefit of potential control measures**

One of the components of the second stage of the RMF (*Selection of preferred risk management option(s)*) involves weighing the estimated reduction in risk that can be achieved by different risk management options and other factors, such as the costs and practicability of introducing the measures, effects on the availability of the foodstuff concerned and international trade obligations, against each other. One of the related key issues here is the health expectations of society. Many consumers are, understandably, reluctant to accept that consumption of food should be associated with any health risks at all. However, because it is impossible to guarantee that certain foods are free from hazards, for example broilers are often infected with *Campylobacter*, it is necessary to establish “appropriate levels of protection” (the term used in the SPS Agreement) or tolerable levels of risk. The RMF describes different approaches adopted to establish appropriate levels of protection. These include the As Low As Reasonably Achievable (ALARA) approach and the “notional zero-risk” approach. The latter is used by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and many other expert advisory bodies when assigning Acceptable Daily Intakes (ADIs) for man for food additives and residues of pesticides and veterinary drugs. Because of the great difficulty in obtaining reliable numerical estimates of the risk posed to man by various hazards present in food and in reaching agreement on tolerable levels of risk, in only very few cases has a figure been quoted for an appropriate level of protection. Instead of defining a tolerable level of risk it is more common, and perhaps easier to accept at the political level, to define a goal for reducing risk from a certain hazard within a given time frame, e.g. a 50% reduction within 5 years in the number of reported cases of campylobacteriosis caused by food. This is reflected in the approach that has been taken by NZFSA in its strategy to tackle the problem of infections attributed to *Campylobacter* in broilers.

The RMF points out that, although final responsibility for choice of the preferred risk management option rests with the risk manager, there is a need to involve all stakeholders in the identification and selection of risk management options. With their detailed knowledge of food production, processing and distribution, the food industry and trade may well be able to make valuable contributions when identifying and assessing the practicality of different risk management options. Therefore, it is recommended that this be expressed more clearly in the section of the RMF document dealing with the identification and selection of risk management options.

Certain individuals in the population are allergic/hypersensitive/intolerant to some components naturally present in foodstuffs (e.g. fish and shellfish, milk, eggs and nuts) or intentionally (e.g. food additives) or unintentionally (e.g. contaminants) added to them. Allergic reactions to food components can have serious, sometimes life-threatening, consequences, but this issue is hardly mentioned in the RMF. Labelling, which is primarily the responsibility of Food Standards Australia New Zealand (FSANZ), consumer education and control of foods sold as being especially suitable

for persons who are allergic/hypersensitive/intolerant to certain food components (e.g. gluten) are important in dealing with this problem. Therefore, it is recommended that a short description of the role that NZFSA plays in dealing with this issue be added to the RMF.

Although defining public health goals is a difficult and sensitive issue and selecting the best risk management option often involves balancing quite different factors against each other, the RMF provides a sound basis for carrying out these tasks. However, it is not clear from the document who defines public health goals in New Zealand (Government, Ministry of Health, NZFSA?) and it is recommended that this matter be clarified in the RMF.

#### **4.5 Applicability and appropriateness of the Risk Management Framework to the establishment of food safety standards, where appropriate**

NZFSA's role *vis á vis* food standards in New Zealand is complicated by the fact that responsibility for setting several types of food standards (e.g. standards for food additives, microbiological limits, labelling, GMOs and heavy metals) rests with another organisation, namely FSANZ. This is not brought out clearly in the RMF and therefore it is recommended that the roles played by NZFSA and FSANZ in setting different types of food standard be clarified in the RMF and that reference be made to other sources of information on this subject, for example NZFSA and FSANZ web sites.

The RMF provides a good and flexible framework for the setting of food safety standards for a wide range of hazards and foodstuffs. It also points out the need to take into account the standards adopted by the international standard-setting bodies, in particular the Codex Alimentarius Commission (CAC) and World Organisation for Animal Health (OIE). In this connection it would be of interest to get some idea about the extent to which NZFSA uses the risk assessments carried out by international expert groups, such as the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the Joint FAO/WHO Expert Meeting on Pesticide Residues (JMPR), or carries out its own risk assessments. Likewise, an indication of the extent to which it adopts Codex Maximum Residue Levels (MRLs) for residues of pesticides and veterinary drugs would be useful.

#### **4.6 Applicability and appropriateness of the Risk Management Framework to the context of international trade rules and New Zealand's international obligations**

New Zealand is a Member of the World Trade Organisation (WTO) and a party to the SPS Agreement. Article 2 of the SPS Agreement states, among other things, that to harmonize sanitary and phytosanitary measures on as wide a basis as possible WTO Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist. Members shall also play a full part, within the limits of their resources, in the relevant international organisations and their subsidiary bodies, in particular the CAC, OIE, and the international and regional organisations operating within the framework of the International Plant Protection Convention.

By basing its RMF on guidelines from FAO/WHO and the CAC (for details see below under Section 5), participating actively and constructively in the food safety work of the CAC and OIE and by taking due regard to the standards, guidelines and recommendations adopted by these organisations when framing its national legislation, NZFSA, and thereby New Zealand, fulfils its obligations under the SPS Agreement.

Codex and OIE standards are specifically recognised by the SPS Agreement as the international benchmarks for food safety and for zoonoses and animal health, respectively. Thus these standards are very important for a country like New Zealand, with interests in both protecting the health of its citizens (and its animal population) and also ensuring fair practices in international trade in food and

access to export markets for its foods. In addition to its above-mentioned contributions, New Zealand has also played another important role in Codex by hosting and chairing two Codex Committees, namely the Codex Committee on Meat Hygiene (chaired by Dr Andrew McKenzie) and the Codex Committee on Milk and Milk Products (chaired by Dr Steve Hathaway). New Zealand also plays an active role in the OIE. For example, Dr Barry O'Neil, Deputy Director General of MAF Biosecurity New Zealand, is currently President of the OIE's Administration Committee, its highest decision-making body and Dr Stuart MacDiarmid chairs the OIE's Science Code Commission. NZFSA's Dr Andrew McKenzie is a member of the OIE Working Group on Animal Production Food Safety. Thus, although it is a relatively small country, through its active participation in the work of the CAC and the OIE, New Zealand plays a major role in shaping the decisions of these international standard setting organisations - to use a boxing expression, New Zealand "punches far above its weight". This is of benefit both for protecting the health of New Zealanders and in reflecting New Zealand's interests in the development of Codex standards for foods moving in international trade. It is strongly recommended that NZFSA, and other organisations in New Zealand, continue to play an active role in the food safety work of the international organisations, in particular FAO, WHO, CAC and OIE.

The RMF used by NZFSA also appears to fulfil the requirements laid down by major trading partners, such as the USA and the EU, with whom New Zealand has bilateral trading agreements or arrangements.

#### **4.7 Applicability and appropriateness of the Risk Management Framework to allocation of decision-making and standard development functions within the organisation, and the business structure for such activity**

Apart from the Science Group, which provides scientific input into the RMF, relatively little is said in the RMF about the roles of risk managers in other Groups within NZFSA that provide risk management inputs. It is therefore recommended that further clarification on this issue be included in the RMF, perhaps through reference to other documents available on NZFSA's web site. A high degree of flexibility is incorporated into the RMF and changes in NZFSA's organisational structure need not affect it. Having been created as a separate public service department as recently as July 2007, it is too early to draw firm conclusions about the advantages and disadvantages of the present organisational structure with a number of different Business Groups directly under the leadership of the Chief Executive and no attempt to do so has been made in the present review. It is, however, recommended that the current organisational structure be reviewed after a period of not more than 3 years. In addition, having compared the organisational structure of NZFSA with that of the corresponding authorities in some other countries, the following comments and suggestions are made.

Sound science is a vital input into many components of the RMF. The Science Group at NZFSA consists of a small, highly competent group of scientists covering a range of different disciplines. However, NZFSA's extensive needs for scientific inputs cannot be met by NZFSA's staff alone and a large amount of scientific support is obtained from external sources. For example, the Institute of Environmental and Scientific Research (ESR) has prepared a series of risk profiles under contract to NZFSA and extensive surveys of chemical and microbiological hazards in specific foods at different points in the food chain (e.g. *E.coli* O157:H7 in bobby calves, natural toxins in honey and microbiological hazards in fresh produce) and the Total Diet Surveys have all been carried out externally. However, almost all of the microbiological risk assessments have been produced by NZFSA staff, sometimes in collaboration with external scientific experts. Although "small is beautiful", it is recommended that NZFSA carefully examine the vulnerability and sustainability of the current arrangement of having a relatively small Science Group, bearing in mind the very wide range of scientific issues it is called upon to tackle and that it must spend a lot of time designing project specifications and following up the progress of contracted projects. In addition, the Group

must assess the quality of the reports from work contracted out and ensure that conflicts of interest do not arise in those carrying out such work. In the RMF, and in the CAC Guidelines (Codex Alimentarius Commission 2007), the importance of a functional separation between risk assessment and risk management is emphasised, in order to preserve the integrity of the risk assessment process. Since risk assessment and risk management are both carried out within NZFSA, it is important that the current functional separation of these two components of risk analysis be retained and also that the results of risk assessments, including attendant uncertainty, are clearly documented. However, although risk assessment and risk management should be functionally separated, it is vital that there is close cooperation and good communication between those responsible for these two components of risk analysis. This appears to be the case at NZFSA.

NZFSA has already established national and international networks with other food safety authorities and academic and research organisations. The Science Group administers and funds the Enteric Zoonotic Disease Research Steering Committee, a task previously carried out by MoH. This Committee has a wide brief in respect to zoonotic pathogens, but the main emphasis is on an integrated approach to prevention and control of enteric zoonoses that are transmitted via the food chain. The Committee includes stakeholders from various government ministries, academia and industry and sets strategic priorities, promotes and coordinates research and provides a centre of scientific expertise. Recently, much emphasis has been placed on research issues related to *Campylobacter* and a holistic approach has been taken, i.e. food-borne, environmental and occupational sources are all covered. The Committee coordinates efforts to provide a holistic risk model for source attribution of campylobacteriosis in New Zealand.

In 2005 NZFSA established the NZFSA Academy to assist in the provision of advice from experts in areas where NZFSA either does not have the expertise within its own staff or where confirmation of the advice of its own experts would be valuable. It was also recognised that from time to time, NZFSA needs to establish expert groups or seek more specific assistance in relation to particular issues. In these circumstances, a group of already identified experts, such as would be available through an 'Academy', could greatly assist in timely and effective advice. Rather than setting up a number of permanent committees dealing with specific scientific areas of expertise, NZFSA has preferred to have the capability available to set up *ad hoc* working groups as and when the need arises. The role of the Academy as included in the terms of reference is to:

- Provide a means of identifying experts that might be needed in specific scientific and other areas in a timely and effective manner.
- Provide advice to NZFSA on issues that may be raised with Academy members.
- Alert NZFSA to emerging issues that may be of interest to NZFSA in their fields of expertise.
- Provide statements and complement NZFSA communications and positions as appropriate in specific scientific or other areas.

NZFSA's international networks are important for its ability to keep abreast of international developments in the field of food safety and it is recommended that these networks be strengthened and expanded, where possible through formal arrangements. This is especially important since these international networks can facilitate the work of NZFSA in detecting new or re-emerging food safety issues at the earliest possible stage.

## **5. Comparison of NZFSA's Risk Management Framework with international (Codex) guidelines on best practice**

As indicated in its Introduction, the updated RMF takes into account four guideline documents from FAO, WHO and the CAC namely:

- *Food Safety Risk Analysis: A Guide for National Food Safety Authorities*. FAO Food and Nutrition Paper No. 87, 2006. WHO/FAO, Rome, 2006
- *Working Principles for Risk Analysis for Application by National Governments*. CAC Procedural Manual. 17<sup>th</sup> Edition 2007. FAO, Rome.
- *FAO Biosecurity Toolkit*. 2007. FAO. Rome
- *Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)*. CAC/GL-63 2007. FAO. Rome

The RMF is consistent with the guidelines and recommendations provided in the documents cited above and it is noted that a NZFSA staff member, Dr Steve Hathaway, has played a significant role in the developing this international body of advice. However, as is appropriate, the examples given in the RMF reflect the particular interests and specific situations in New Zealand. NZFSA staff have played, and continue to play, a key role in developing Codex Principles and FAO/WHO Guidelines for the application of risk analysis to food safety issues. This has been done through very active and constructive participation in FAO/WHO expert bodies and the CAC and its subsidiary bodies, in particular the Codex Committee on General Principles (CCGP), the Codex Committee on Food Hygiene (CCFH), the Codex Committee on Meat Hygiene (CCMH) and some of the Committee working groups.

## 6. Comparison of the application of the Risk Management Framework in New Zealand with risk management systems in Denmark, Ireland and Sweden

This Section contains some general comparisons of the application of the Risk Management Framework (RMF) in New Zealand and the risk management systems in Denmark, Ireland and Sweden. More detailed comments on the handling of a number of high-profile food safety issues (e.g. *Campylobacter* in poultry, aspartame and mercury in fish) in the four countries are given in Section 7.

### 6.1 Food safety risk analysis at the European Union level

Denmark, Ireland and Sweden are all members of the European Union (EU) and to better understand how the food safety systems in these countries operate it is necessary to have some basic knowledge of EU food legislation and the way in which it is developed and enforced. The following is a very short summary of some of the most important points relevant to a discussion of the RMF and its application.

#### *Step 1: Preliminary risk management activities*

Although some food safety problems may be of special importance for only one or a few of the 27 EU Member States, most problems are relevant for many of them. For this reason, the European Commission, in consultation with the Member States, identifies food safety issues that should be addressed at the EU level and initiates preliminary risk management activities. In some cases, the aim may be to introduce EU legislation (food standards, regulations on inspection, etc.): the Commission has a monopoly on initiating such legislation. When there are a large number of risks to be addressed and resources are inadequate to deal with them simultaneously, the Commission decides on the priority ranking, after consulting the Member States.

If the Commission wishes to propose new or amended food legislation which may have an impact on human health, for example regulations on food additives and chemical and microbiological contaminants, it must first obtain a risk assessment/scientific opinion. The risk assessments/opinions that form the scientific basis for EU legislation are mainly carried out by the European Food Safety Authority (EFSA), but evaluations of veterinary drugs and their residues are carried out by the European Medicines Agency (EMA). EFSA is an independent organisation with responsibility for risk assessment and risk communication, but not risk management. It covers the whole of the food chain and deals with not only human health but also animal and plant health issues. EFSA's independence ensures a functional separation of risk assessment and risk management, as recommended in the Codex guidelines on the application of risk analysis to food safety matters (Codex Alimentarius Commission 2007). EFSA's risk assessments are carried out by its nine Scientific Panels, which consist of independent scientists chosen on the basis of their expertise and not representing their countries or employers. Some of these experts come from regulatory agencies, while others are from academic or research organisations or are independent consultants. All the experts are required to make a declaration of interest and these declarations are placed on the EFSA web site ([www.efsa.europa.eu](http://www.efsa.europa.eu)). EFSA places great emphasis on transparency and all the scientific Opinions (risk assessments) produced by its Scientific Panels are placed on its web site immediately after finalisation. In addition to carrying out risk assessments, EFSA helps to promote networking on risk assessment and risk communication between the food safety organisations in EU Member States. EFSA's network of contacts embraces not only the corresponding organisations in the Member States but also other European Community organisations, such as EMA and the European Centre for Disease Prevention and Control (ECDC), international organisations, such as FAO, WHO, OECD and OIE and their expert bodies and government agencies in countries outside the EU, such as the USA, Canada, Australia, New Zealand and Japan.

EFSA plays an increasingly important role in risk communication in food safety matters within the EU. It provides information directly to the media, consumers, industry and other stakeholders via its web site, press releases, etc. It also provides the national food safety authorities with information on which they can base messages tailor-made to their national conditions and interests.

In addition to contributing to risk assessment at the EU level through the participation of their experts in the work of EFSA, the EU Member States also carry out risk profiling and risk assessments at the national level on issues that are not currently being dealt with at the European level. In particular, the exposure assessment component of risk assessment is usually based on work carried out at the national, rather than European, level.

### *Step 2: Identification and selection of risk management options*

At the EU level, risk management options are identified by the Commission in consultation with the Member States and representatives of the food industry, consumers and other stakeholders. The Commission's proposals for risk management measures, including food standards and other legislation, are discussed in groups under the Commission, the Council (which consists of representatives of the governments of the EU Member States) and the directly elected European Parliament. This means that the issue of an Appropriate Level of Protection (ALOP) is dealt with at the EU political level. After usually extensive discussion, often resulting in amendments to the original texts, proposals for EU food legislation are adopted by the Council and the European Parliament. European Community *Regulations* apply directly in all Member States and EC *Directives* apply after being transposed into national legislation. In the EU most food safety legislation is harmonised nowadays, i.e. the same rules apply in all 27 Member States.

The EU participates actively in the work in the international standard-setting bodies, such as the CAC and its subsidiary bodies and the OIE. When doing so, the Member States and the European Commission strive to present co-ordinated positions as far as possible. When developing its own standards, the EU takes account of those adopted by the CAC and other international standard-setting bodies. However, in a few cases its standards differ from the international standards and this has led to them being challenged in the WTO. A case in point is the EU ban on the import of beef from cattle that have been treated with certain hormones, even though it meets the Codex standard for veterinary drug residues.

The EU "General Food Law" (EC Regulation 178/2002, European Commission 2002) contains Articles on, among other things, definitions of risk analysis terms, risk analysis as a basis for food law, the Precautionary Principle, transparency, international standards, obligations on food business operators, the Rapid Alert System for Food and Feed (RASFF), crisis management and emergency measures. The same Regulation also contains Articles on the establishment of EFSA. It also clearly states (Article 17) that primary responsibility for food safety rests with the food business operators. It defines (Article 7) what is meant by the Precautionary Principle and gives conditions for its application in food safety issues.

### *Step 3: Implementation of risk management decisions*

Article 17 of EC Regulation 178/2002 states that the Member States shall enforce food law and monitor and verify that the relevant requirements of food law are fulfilled by food business operators at all stages of production, processing and distribution. For that purpose, the Member States shall maintain a system of official controls and other appropriate activities, including public communication on food risks. Through inspections carried out by its Food and Veterinary Office (FVO), the European Commission verifies that the Member States fulfil their obligations. The FVO also verifies that third

countries, for example New Zealand, fulfil their obligations as defined in bilateral agreements with the EU. The reports of all the FVO inspections are placed on the European Commission's web site. Each Member State is required to develop and implement both annual and multi-annual food control programmes and the results of these control programmes are submitted to the Commission annually.

The EU has a large number of regulations on food control, including meat inspection and control of foods imported into the EU from third countries. Control of imported foods takes place at the external border of the EU and concentrates mainly, but not exclusively, on foods of animal origin. In principle, a food legally produced in or imported into one EU Member State may circulate freely within the whole Community and there is no border control between EU Member States. When a batch of imported food is found to be out of compliance, e.g. it is found to contain mycotoxins or residues of veterinary drugs or pesticides above maximum permitted levels, control is intensified and if the problem persists the Commission takes up the matter with the exporting country/countries.

Although the EU Member States are required to implement the same EU food safety legislation, they are free to decide the structure of their food safety organisations. As described below when examining the situation in Denmark, Ireland and Sweden, this can differ quite widely from country to country.

#### *Step 4: Monitoring and review*

Under EU legislation the Member States are required to carry out food safety surveillance and monitoring activities covering, for example, residues of pesticides and veterinary drugs in foods and the intake of food additives. The regulations prescribe minimum levels of monitoring and many countries carry out additional studies in areas of particular national concern. Member States are also required to monitor outbreaks of food-borne disease and report the results to EFSA, which produces an annual report on food-borne disease in the EU and it co-ordinates its work in this area with that of ECDC. If it is found that the risk management measures introduced in the EU are not resulting in the intended level of health protection, they are reviewed and modified or supplemented.

From the above it can be seen that the EU applies the principles of risk analysis in its food safety work and that its risk management framework is essentially the same as that recommended by FAO, WHO and the CAC and used by NZFSA. Discussions with staff of the food safety agencies in Denmark, Ireland and Sweden confirm that, in principle, they all apply the food safety risk management framework recommended by FAO/WHO in the *Food Safety Risk Analysis: A Guide for National Food Safety Authorities* (WHO/FAO, 2006). However, they have not documented this as clearly as NZFSA has done in its updated Risk Management Framework document. It must also be remembered that for the EU Member States most of the standard setting takes place at the EU level and also that some of the standard setting for New Zealand (e.g. labelling, food additives, microbiological limits, GMOs and heavy metals) is carried out not by NZFSA but by FSANZ. However, the implementation of the legislation is the responsibility of the competent authorities in the individual countries.

## **6.2 Food safety risk management in Denmark**

In Denmark central responsibility for food safety risk management rest with the Danish Food and Veterinary Administration (DFVA), which is part of the Ministry of Food, Agriculture and Fisheries. DFVA covers the whole of the food chain from farm to fork and, in addition to food safety, is also responsible for animal health issues. Its mandate is defined in legislation (Bekäntgörelse om Födevarestyrelsens opgaver og beføjelser 1479 af 15 December 2005 and Födevareloven 526 af 24 June 2005). In addition to responsibility for food safety, this mandate includes responsibility for issuing official dietary guidelines and the promotion of healthy dietary habits.

DFVA is the largest of the four organisations considered here, with over 1800 employees. Administration, development, coordination and the formulation of rules and regulations take place in the head office of DFVA just outside Copenhagen. DFVA Head Office has 12 Divisions include the following: Control Coordination, International Trade, Microbiological Food Safety and Veterinary Medical Products, Nutrition, Communication, Legal Affairs and International Coordination. The International Trade Division is responsible for, among other things, border control and export certification. Food control and veterinary inspection are handled by the three regional DFVA centres which are located in different parts of the country. DFVA is the Danish contact point for the EC Rapid Alert System for Food and Feed.

In order to make inspections more risk-based, DFVA has developed a system for risk classification of food establishments and this is used as a basis for deciding the frequency of inspections. It has also developed a system (“Smileys”) by which potential customers are informed of the results of the latest inspection of shops and restaurants via a symbol on an inspection report that must be prominently displayed on the premises. The “Smileys” symbolize that the inspector either a) had no remarks, or b) has emphasized that certain rules must be obeyed, or c) issued an injunction order or prohibition, or d) issued an administrative fine, reported the company to the police or withdrew an approval. An “Elite Smiley” is awarded to enterprises who have received the best level of performance (i.e. no remarks) on the last four inspections and no remarks during the last twelve months. More information about the system is available in English on DFVA’s web site ([www.fvst.dk](http://www.fvst.dk)).

Much of the scientific basis (risk profiles, risk assessments, etc.) for DFVA’s work is provided by the National Food Institute (NFI) and the National Veterinary Institute, which are part of the Technical University of Denmark. In this way Denmark has achieved a clear functional separation of risk assessment and risk management. The NFI has approximately 335 employees working in five Departments – Nutrition, Food Chemistry, Food Production Engineering, Microbiology and Risk Assessment and Toxicology and Risk Assessment. The NFI is a WHO Collaborating Centre for Antimicrobial Resistance in Food-borne Pathogens, a WHO Collaborating Centre for Food Contamination Monitoring and an EFSA Zoonoses Collaboration Centre. Denmark plays a very active role in the Nordic cooperation on food safety matters and also in the food safety work of EFSA, FAO and WHO.

DFVA provides much information and advice to different stakeholders, including consumers, via its web site and in the form of brochures to specific population groups, reports on special food safety issues and other printed materials. Those wishing to get more information about DFVA and its activities are referred to its web site ([www.fvst.dk](http://www.fvst.dk)). More information about NFI is available on the Technical University of Denmark’s web site ([www.food.dtu.dk](http://www.food.dtu.dk)).

### **6.3 Food safety risk management in Ireland**

In Ireland the Food Safety Authority of Ireland (FSAI) has national responsibility for leading and coordinating work on food safety. It comes under the aegis of the Minister for Health and Children. FSAI is a statutory, independent body and emphasises the need to base food standards on sound science and risk assessment. Its mandate is defined in the Food Safety Authority of Ireland Act of 1998 and subsequent amendments to that Act. The mandate emphasizes the role of the FSAI in ensuring that food produced in Ireland (whether marketed there or exported) and food distributed and marketed there (including imported food) meets the highest standards of food safety and hygiene reasonably available and complies with legal requirements and recognised codes of good practice. The FSAI is also responsible for providing advice to Ministers, regulators, the food industry and consumers on food safety and healthy dietary habits. It provides a large amount of information via its web site

([www.fsai.ie](http://www.fsai.ie)) and also in the form of an annual report, a newsletter, brochures, scientific reports, codes of practice and other types of printed material. FSAI is involved in a large number of training activities directed towards different stakeholders and with the objective of improving food safety in Ireland. It arranges and participates in scientific meetings, seminars, workshops and other activities to provide information on and discuss food safety issues and works with the food industry and trade to gain their commitment in the production of safe food.

In addition to the Chief Executive's Office, FSAI has five Divisions – Audit and Compliance, Consumer Protection, Service Contracts and Food Science and Standards. The Authority's legal work is largely handled by an external legal practice and much of the work in producing informational and educational materials is contracted out. Compared with its equivalents in Denmark and Sweden, FSAI is a relatively small organisation, with just under 100 employees, and much of the food safety work in Ireland is carried out by organisations working under contract to the FSAI. The Authority is directly involved in enforcement activities relating to food additives, ionising radiation of food, novel food, genetically modified food, nutrition and dietetics. It is also the national contact point for the EC Rapid Alert System for Food and Feed (RASFF). In 2006 FSAI had service contracts with 37 official agencies, including the Department of Agriculture and Food, the Health Service Executive, The Department of Communications, Marine and Natural Resources, the Marine Institute, the National Standards Authority of Ireland, the Office of the Director of Consumer Affairs and over 30 Local Authorities. FSAI's service contract with the Department of Agriculture and Food focuses on the food safety controls in food premises licensed for the export market, including meat plants, milk and milk product premises and egg and egg product premises, the control of imported foods of animal origin through Border Inspection Posts, the operation of the National Residue Control Plan, the work of the Pesticide Control Service and the Department's role under the EC Zoonoses Directive (for further details see [www.fsai.ie/service\\_contracts](http://www.fsai.ie/service_contracts)). The Health and Safety Executive (HSE) is contracted by FSAI to inspect food businesses (e.g. manufacturers and packers, distributors, retailers and caterers), sample foods, carry out controls on the importation of foods of non-animal origin. FSAI has developed a Code of Practice for the HSE on risk characterisation of food businesses (Food Safety Authority of Ireland 2006a).

FSAI has also signed Memoranda of Understanding with various organisations to facilitate cooperation and exchange of information related to food safety, including the Irish Food Board, the Food Standards Agency Northern Ireland, the Radiological Protection Institute of Ireland, the Customs and Excise Service the Irish Sea Fisheries Board and the Food Safety Promotion Board (*safe food*) and the Irish Agriculture and Food Development Authority.

FSAI has a Scientific Committee consisting of 15 experts in the food safety field in Ireland. The Committee has five sub-committees dealing with 1) Food Additives, Chemical Contaminants and Residues, 2) Microbiology, 3) GMO and Novel Foods, 4) Nutrition and 5) TSE. These expert groups provide the FSAI with risk profiles, risk assessments and other scientific advice on which to base its risk management and risk communication activities. Several members of these expert bodies are also members of EFSA's scientific expert groups. Members of the Scientific Committee are required to state their interests and this information is publicly available.

FSAI has a Food Safety Consultative Council, consisting of representatives from different stakeholder groups, including primary producers, the food industry and trade and consumers. It also has an Industry Forum comprising an Artisan Food Producers Forum, a Food Service Forum, a Mollusc Shellfish Safety Committee and a Retail Forum.

FSAI has an extensive international network of contacts with other organisations and individuals in the food safety area and is active in international organisations, such as FAO, WHO, Codex and OIE.

Those wishing to get more information about FSAI and its work are referred to its web site ([www.fsai.ie](http://www.fsai.ie)).

#### **6.4 Food safety risk management in Sweden**

In Sweden the National Food Administration (NFA) is the central supervisory authority for matters related to food, including drinking-water. Its responsibilities are post-harvest/post-slaughter and the Swedish Board of Agriculture (SBA) and National Fisheries Board (NFB) have responsibility for primary production. However, an on-going official enquiry in Sweden is looking into the consequences of creating a single agency with responsibility for the whole of the food chain by amalgamating the whole or parts of the current NFA, SBA, NFB and the National Veterinary Institute. NFA's mandate is defined in the Swedish Government's Decree with Instructions for the National Food Administration, the latest amendments to which were issued in 2007. The mandate emphasizes that NFA's primary role is to protect the interests of the consumers by working for safe food of good quality, fair practices in the food trade and healthy eating habits. NFA is an independent government agency and the Director-General reports to the Minister of Agriculture, Fisheries and Food.

In Sweden responsibility for food control is divided mainly between NFA, which has responsibility for control of imports at Border Inspection Posts and control at slaughterhouses and large food-producing establishments, and the 290 independent municipal health and environment protection authorities. The latter are responsible for control of all establishments not under NFA control, e.g. small producers, wholesale and retail distribution and catering establishments. The populations of the municipalities vary from about 700 000 in Stockholm to about 3 500 in some rural areas and the resources available for food control in different municipalities also vary widely. For this reason, NFA has earlier proposed that a more centralised (state) food control system, similar to that introduced in neighbouring Denmark, should be introduced, but it seems unlikely that any change will take place in the near future. NFA has developed a system for risk classification of food business operators which forms the basis for deciding the frequency of inspections and the level of food control fees.

Risk profiles and assessments are produced by NFA's own staff, mainly in its Research and Development Department, which has Divisions for Chemistry, Microbiology and Toxicology with their own laboratory facilities. Risk management is carried out in the Food Standards Department and the Food Control Department. Thus, as in NZFSA, although risk assessment and risk management are carried out within the same organisation, they are carried out in different parts of the organisation. NFA also has about 50 external scientific advisors, with expertise in areas not covered by its own staff, e.g. clinical medical disciplines. It has also two expert committees with external membership dealing with Diet and Health and Paediatric Diet and Health, respectively. NFA collaborates in networks with experts from other government agencies (e.g. the National Veterinary Institute, the Swedish Institute for Infectious Disease Control, the National Board of Health and Welfare, the National Board of Agriculture and the Environment Protection Board), academic institutions (e.g. the Swedish University of Agricultural Sciences, Karolinska Institute and the Universities of Stockholm, Uppsala and Lund). There is also a Swedish Zoonoses Centre, administered by the National Veterinary Institute and comprising representatives from all relevant organisations. NFA also participates actively in the long established Nordic cooperation in food safety matters, including risk assessment, legislation and food control.

NFA has about 500 employees, including about 200 working in meat inspection service at slaughterhouses throughout the country. In addition to the Director-General's Office, NFA has five Departments for Research and Development, Nutrition, Food Standards, Food Control and

Administration, respectively. NFA provides information to the media and to different stakeholder groups via its web site, its publications and press services and through a telephone and e-mail answer service. It also organises courses, workshops, etc. and provides information and support to the municipal food control authorities. NFA maintains contact with different stakeholder groups through regular meetings with representatives of consumers and the food industry and trade. NFA is the Swedish contact point for the EC Rapid Alert System for Food and Feed. In Sweden the results of official inspections and other food control activities, such as control of pesticide and veterinary drug residues are public information. Those wishing to obtain more information about NFA and its work are referred to its web site ([www.slv.se](http://www.slv.se)).

## 6.5 Conclusions and recommendations

As shown above in this Section of this report, although they, in principle, use the same risk management framework as that used in New Zealand, the food safety authorities in the different countries are organised in different ways. What, if anything, can New Zealand learn from these other countries? NZFSA is judged to be achieving very good results with relatively small resources and this was also the conclusion of an external review of its work (Scott & McKenzie 2005). Thus changing the current system in New Zealand should only be done after careful consideration of the likely benefits and consequences of such changes. From an analysis of the systems used in Denmark, Ireland and Sweden the following observations and recommendations made.

### *NZFSA's mandate*

The ways in which the different countries apply the Risk Management Framework takes into account their different mandates and organisational structures. In Denmark, Ireland and Sweden, the food safety authorities' mandates are defined in national legislation. This is not the case in New Zealand, where NZFSA's mandate is given in a series of Cabinet papers. NZFSA emphasizes in its information material that it has two key functions: a) to protect and promote public health and safety and b) to facilitate market access for New Zealand's food and food by-products. Some consumers believe that there is a potential conflict between these two functions. Therefore it is important to clarify to consumers what the second function involves and to assure them that carrying it out will in no way compromise the role of NZFSA to protect public health. In Denmark, Ireland and Sweden the mandates of the food safety authorities emphasise that their primary role is to work for safe food and in the consumer interest. In New Zealand the way in which the mandate is expressed may give the impression that equal weight is attached to food safety and facilitating access of New Zealand foods to foreign markets. Closer examination of NZFSA's work shows that its primary contribution to facilitating access of New Zealand's foods to foreign markets is by helping to ensure that they are safe and certifying that they comply with the requirements laid down by importing countries. This is essentially the same role as played by the food safety authorities in Denmark, Ireland and Sweden, although in Ireland certification is carried out by the Ministry of Agriculture and Food.

In the interests of openness and transparency it is recommended that NZFSA's mandate be defined by the Government in a document that is more readily accessible to the public than Cabinet documents. In defining NZFSA's mandate it is recommended that the Government clarify to all stakeholders that its primary role is to help to ensure the safety of foods produced in New Zealand, regardless of whether they are consumed in the country or exported, and also to help to ensure that imported foods are safe.

In Denmark, Ireland and Sweden the food safety authorities (DFVA, FSAI and NFA) have a clear mandate to provide advice to the public on nutrition issues and healthy dietary habits. The respective roles of NZFSA and MoH in the nutrition area and in the promotion of health by providing advice on healthy diets are unclear to many outside these organisations. It is therefore recommended that the current division of responsibility between NZFSA and MoH for supplying advice to the general public

on nutrition and healthy dietary habits should be reviewed, bearing in mind the need for a holistic approach to dietary recommendations, especially in cases where consumption of the same type of food may involve both health risks and health benefits.

#### *Scientific support for the work of NZFSA*

NZFSA resembles the food safety authorities of Denmark and Ireland insofar as they all need a considerable amount of external scientific support for their risk management activities. Much of this support in the EU is provided by EFSA and, since EFSA publishes all of its risk assessments on its web site, this information is also readily available to the NZFSA. FSAI has established a Scientific Committee consisting of 15 experts in the food safety field in Ireland with five sub-committees dealing with 1) Food Additives, Chemical Contaminants and Residues, 2) Microbiology, 3) GMO and Novel Foods, 4) Nutrition and 5) TSE. In addition to its group of about 50 external scientific advisors, the National Food Administration in Sweden has an Expert Committee on Diet and Health and an Expert Committee on Paediatric Nutrition and similar expert bodies also exist in Denmark. Instead of establishing permanent groups of experts on different subjects, NZFSA prefers to use the experts in NZFSA Academy and set up *ad hoc* working groups to deal with special topics as and when the need arises.

#### *Openness and transparency*

Openness and transparency are essential for any organisation trying to build and maintain public trust and can also be an important factor in ensuring that food business operators comply with food legislation and established codes of practice. It is therefore recommended that NZFSA continues to develop its policy of openness and transparency by providing more information to relevant consumer and other stakeholder groups via its web site and other channels, including the results of inspections of food business operations and other control activities. It is furthermore recommended that NZFSA consider introducing the Danish (“Smiley”) system for informing potential customers of the results of the latest inspection of food premises, such as shops and restaurants, as a means of improving compliance and helping consumers to choose shops and restaurants maintaining high standards of food hygiene.

## **7. Application of the New Zealand Food Safety Authority's Risk Management Framework in recent high-profile issues and comparisons with some other countries**

### **7.1 The A1/A2 milk issue**

#### *7.1.1 The Swinburn review*

As described in Section 1 of the present report, in early 2003 NZFSA decided to commission an independent review of the literature to assess the health claims being made about A2 milk and in view of subsequent consumer concern about the safety of A1 milk. There was a discussion among experts within NZFSA concerning the choice of person to carry out the review and the views and suggestions of the Ministry of Health (MoH) were sought. There was agreement between NZFSA and MoH that Boyd Swinburn, Professor of Public Health Nutrition, Deakin University, Melbourne, was a suitable person for the task, in view of his expertise, his earlier role as Medical Director for the Heart Foundation and his availability.

The Terms of Reference for the review were developed by NZFSA, discussed with MoH and Professor Swinburn and finalised by NZFSA in agreement with MoH. The Terms of Reference did not specifically mention consideration of beta-casomorphin-7 (BCM7). NZFSA expected the review to focus on peer-reviewed published material, so to the extent that BCM7 was covered in the literature in conjunction with milk and the suggested issues then it could expect to have been part of the review. The Terms of Reference for the Swinburn review were as follows:

*The expert consultant is to undertake the following:*

- (i) Identify the extent of available research in the area of beta-casein A1 and beta-casein A2 in milk and in any closely related and relevant areas; and*
- (ii) Evaluate the implications of such research; and*
- (iii) Be available to review any further research material in this area that might be published up until June 2004.*

*In particular, a document is to be prepared and presented that contains:*

- (i) a descriptive list of all available research in the area of beta-casein A1 and beta-casein A2 in milk or closely related areas (such as casein in milk) identified from sources available to the consultant including as may be provided by the NZFSA, by companies and from literature searches.*
- (ii) a critical analysis and evaluation of the research identified. As far as possible this should take into account the related areas of nutrition, human health, cardiovascular disease, diabetes and neurological disorders such as schizophrenia and autism.*

The A2 Corporation provided comments to NZFSA about the Terms of Reference for the Swinburn review and also sent Swinburn a list of scientific publications which it considered should be included in his review. On 23 August 2004, following publication of the Swinburn report, the A2 Corporation (via Jock Allison) complained that it was incomplete, since not all the information it had supplied had been considered in the review. On 20 September 2004 NZFSA (via Andrew McKenzie) replied that, since Swinburn had received the material from A2 Corporation, it could be concluded that it was not reviewed because it lay outside the scope of the review and that Swinburn was in the best position to

have judged the relevance of material located by both his own research and that of others, including the A2 Corporation. What scientific information should be included in a review of the science of A1/A2 milk is a scientific issue and outside the Terms of Reference of the present review. As mentioned above, EFSA is currently carrying out a review of the science of A1/A2 milk and any relevant scientific information should be considered there. The present reviewer has recommended to a representative of the A2 Corporation that they send any scientific information they consider relevant to EFSA.

Swinburn sent a draft report to NZFSA in October 2003 and it was shared internally. In view of the importance of the report, NZFSA decided to get the draft peer reviewed by scientists having expertise in the different areas covered by the report (IHD, DM-1, schizophrenia, autism). It took some time to locate suitably qualified scientists who were willing to take on the task, but finally in February 2004 the following four reviewers were confirmed: Dr Paul Shattock, Autism Research Unit, University of Sunderland, U.K., Professor Inga Thorsdottir, Unit for Nutrition Research, University Hospital, Iceland, Professor Norman Sharpe, Medical Director, National Heart Foundation of New Zealand and Professor Robert Scragg, Auckland University. The reviewers were provided with the Terms of Reference and the draft report and their views on its accuracy, completeness and appropriateness of conclusions were sought. Swinburn revised the draft report in the light of the comments received from the reviewers and added a Lay Summary (as recommended by one of the reviewers) and finalised the report on 13 July 2004 and sent it to NZFSA.

On 3 August 2004 NZFSA issued a Media Release (NZFSA 2004a, Appendix 2) and placed the report and its Executive Summary (see Appendix 3 to the present report), but not the Lay Summary (see Appendix 4 to the present report), on its web site. As he had previously informed NZFSA, on the day NZFSA released his report Professor Swinburn had other prior engagements and was not available for interviews by the media. Following a request from Professor Woodford, NZFSA also placed the Lay Summary on its web site on 18 August 2004. Since then NZFSA has published a series of media releases (e.g. NZFSA 2005, 2007a, 2007b, 2007c) on its web site to correct what it regards as incorrect or misleading information in the media about the A1/A2 milk issue and to encourage consumers to continue to include milk as part of a healthy diet. It has also continuously updated the information package placed on A1/A2 milk on its web site (NZFSA 2008).

### ***7.1.2 Comments on NZFSA's handling of issue***

#### *Official position prior to the Swinburn review*

The official dietary recommendations from the MoH, the lead authority for such advice in New Zealand, include advice to include milk in a healthy diet, especially the diets of pregnant women and children, because of its content of essential nutrients. The recommendations do not differentiate between A1 and A2 milk, but recommend low-fat milk for some population groups. Thus the official (MoH and NZFSA) position prior to the Swinburn review was that milk was an important component of the diet. However, MoH and NZFSA did not have an official position on the relative merits of A1 and A2 milk from a health point of view.

#### *Deletion of the Lay Summary from the Swinburn report*

There has been considerable media discussion and speculation about the reasoning behind NZFSA's decision to delete the Lay Summary from the Swinburn report prior to placing it on the web site. Swinburn himself has expressed dissatisfaction about this action. This is understandable, since he had gone to the trouble of producing the Lay Summary in response to a comment from one of the peer reviewers and it was removed without consulting or informing him. According to NZFSA, the

decision not to publish the Lay Summary was a collective decision by NZFSA decision makers – Executive Director, Joint Food Standards, Dairy and Primary Products Group (now Standards Group), Communications and Science – on the basis that it added little, if anything, to the Media Statement, the Questions and Answers, the Executive Summary and the full report, all of which were placed on NZFSA’s web site. NZFSA says it was concerned not to treat the interested public paternalistically, since it considered that those most interested were likely to want to read the full report in any case, those less interested could read the Executive Summary and others would have enough information from the media coverage and material produced by NZFSA. However, Professor Swinburn alone, and not NZFSA, was responsible for the content of his report, including the Lay Summary and thus NZFSA could not be held responsible if some readers found it paternalistic or a considered the Lay Summary to be an unnecessary repetition of what was already stated in the Executive Summary. By deleting the Lay Summary, and especially doing so without discussing with or informing Swinburn, NZFSA laid itself open to criticism that it was withholding important information from the public.

Deletion of the Lay Summary by NZFSA prior to placing the Swinburn report on its web site resulted in some loss of transparency, since it made it more difficult for lay persons, including non-specialist journalists, to understand some parts of the conclusions and recommendations in the report. However, deletion of the Lay Summary did not result in the loss of any essential information, since the full text of the report itself and the Executive Summary were placed on the web site on 3 August 2004. Summaries of scientific reports, be they Lay or Executive, should not contain any information, conclusions or recommendations that are not contained in the body of the report itself. The Lay Summary, being shorter, contains less detail than the Executive Summary. Comparison of the Lay Summary and the Executive Summary (compare the texts in Appendices 3 and 4 to the present report) shows that some parts (e.g. the last paragraph) are word-for-word identical and other parts are similar, the main difference being that some medical terms in the Executive Summary are replaced by lay terms in the Lay Summary. It is interesting to note that, although he makes a big issue of the deletion of the Lay Summary, in Chapter 11 (which deals with NZFSA’s handling of the Swinburn report) of his book (Woodford 2007a) Professor Woodford makes no mention of the fact that the Executive Summary was placed on NZFSA’s web site at the same time as the report and that parts of it are identical with the Lay Summary.

In the view of this reviewer, although NZFSA did not withhold any information of importance, its decision to delete the Lay Summary prior to placing the Swinburn report on its web site was an error of judgement, since a) the addition of a Lay Summary was one of the suggestions from the peer review of the draft report, b) it made it somewhat more difficult for the general public and the media to understand the main conclusions of the report, c) its deletion led to damaging and unnecessary speculation that NZFSA was trying to withhold important information from the public, even if this was not true, and d) the deletion was carried out without consulting or informing Professor Swinburn. In the updated NZFSA RMF (see Section 4 of the present report) the importance of providing information to lay audiences is emphasized and this should have been borne in mind when presenting the Swinburn report.

#### *Unavailability of Professor Swinburn when his report was released*

In an e-mail exchange with NZFSA, Swinburn had made it clear that, although he would be in New Zealand on 3 August 2004, he would not be available on that day for interviews with the media since he had prior commitments. However, due to a mistake by a staff member at NZFSA, it was initially believed that he would be available on that day. Although the mistake was detected prior to the planned date for releasing the report, it was decided to go ahead with the release on 3 August anyway. In a comment in an e-mail to Swinburn it was indicated by a staff member that NZFSA was not altogether disappointed that there would be no media interviews, since it was expecting some negative

media reactions. NZFSA's decision to present his report on a day that Swinburn was unavailable for media interviews reduced transparency and is difficult to justify, especially since a very long time had already elapsed between the commissioning of the report and its finalisation. Furthermore, it fuelled suspicion that NZFSA was trying to hide something.

One can only speculate about the consequences of Swinburn's unavailability for media interviews on the day his report was released, since it depends on what questions the media would have raised, his replies and how the media reported the whole issue. According to his later statements, it seems likely that Swinburn would have emphasised the need for more research and the need to communicate to the public the uncertainty about the A1/A2 milk hypothesis and its implications for milk consumption. However, he could not have departed from his conclusions that there was no need for the authorities to change their current dietary advice to the general population or the recommendations for specific dietary advice for those with (or at risk of) DM-1, IHD, autism or schizophrenia. Although Swinburn was not available for media interviews on the day the report was released, he has had the opportunity to have contact with the media on later occasions and he has himself contacted the media. Recently (14 April 2008) he sent an Open letter to New Zealand dairy farmers to a number of rural newspapers/magazines in New Zealand in which he said that farmers should be encouraged to switch their herds to the A2 variant. It is interesting to note that in that letter when talking about the possible links between A1 milk and certain human diseases he states, among other things, that "The uncertainty of the evidence also makes it difficult to communicate to the public about what they should be doing – there is a significant risk of miscommunication and spooking the public off milk which is a valuable and nutritious part of the kiwi diet". No doubt NZFSA would agree with that statement.

Swinburn's report contained several different conclusions/recommendations (see Section 1 of the present report), including, a) there is insufficient evidence to warrant changing dietary advice to the general population or for specific dietary advice for those with (or at risk of) DM-1, IHD, autism or schizophrenia, b) health claims being made about A2 milk should be monitored, c) current evidence and the uncertainty about the A1/A2 hypothesis should be communicated to the general public and, d) funding further research, especially clinical research. NZFSA chose to put most emphasis on the first of these, while others with a specific interest in A2 milk chose to emphasize others.

#### *NZFSA's media release of 3 August 2004*

When considering NZFSA's media release of 3 August 2004 (NZFSA 2004a, see Appendix 2) it is important to bear in mind that the Terms of Reference, the main body of the final report and the Executive Summary (but not the Lay Summary) were all placed on the web site at the same time as the media release was issued.

The first sentence of the media release: "*Consumers are advised to keep drinking milk as a nutritious food, no matter whether it's A1 or A2, as there is no food safety issue with either type of milk, says NZFSA Director of Food Standards, Carole Inkster.*" presents NZFSA's advice to the public, based on its reading of the Swinburn report's conclusions and the current official (MoH) dietary recommendations. The Swinburn report did not review the nutritional value of milk, but NZFSA considered this to already be well established by MoH, the lead authority for such questions in New Zealand.

Unlike academic and research organisations, government authorities like NZFSA have a duty to provide advice to the general public on matters of diet and health and in doing so it is important that they send as clear and unambiguous messages as possible. Thus it was justified for NZFSA in its media release to present what it regarded as Swinburn's main conclusion from the public health point of view, namely that "*Further public health actions, such as changing dietary advice or requiring*

*labelling of milk products, are not considered to be warranted at this stage.*” It follows from this and the current recommendations from MoH that New Zealanders should continue to include milk as part of a healthy diet and no distinction is made between A1 and A2 milk in this connection.

I do not subscribe to the theory, advanced by Professor Woodford and given much attention by the media, suggesting that NZFSA was withholding important information from the public and had an ulterior motive in the formulation of its media release. However, some parts of the media release were formulated in ways that were open to different interpretations or were incorrect.

The assertion that *“there is no safety issue with either type of milk”* can be interpreted in different ways. If it is interpreted, as some do, as meaning that there is no scientific debate about possible negative health effects of A1 milk it is not correct and is also contradicted by the quotes from Swinburn’s report given lower down in the same media release. According to NZFSA, the phrase *“there is no safety issue with either type of milk”* was intended to provide the public with assurance that their choice to use either (A1 or A2) milk product was not going to result in the safety issues that are otherwise associated with unsafe food, such as sickness or hospitalisation.

The statement that: *“The report, Beta casein A1 and A2 milk and human health, is available in full from the NZFSA web site”* was not correct, since, although the full text of the body of the peer-reviewed report and the Executive Summary were available on the web site, the Lay Summary had been removed.

The recommendation in the Swinburn report that: *“the appropriate government agencies have a responsibility to communicate the current state of evidence to the public, including the uncertainty about the evidence.”* was to some extent satisfied by the text lower down in NZFSA media release and by making the report and the Executive Summary available on the website. NZFSA considers that it delivered on this recommendation with the material published at the time of release of the report and the extensive media coverage at the time. It featured on all media, including print, radio and TV.

Sending clear and unambiguous messages to the public on food safety issues and at the same time communicating uncertainty is a big challenge, especially in an aggressive media climate. Nevertheless, NZFSA must try to achieve this and it is important that NZFSA’s information about the conclusions from scientific studies and reviews is balanced and that uncertainties associated with the conclusions are also clearly communicated. It is therefore recommended that NZFSA continues to develop its risk communication skills to enable it to better inform the public when faced with the difficult task of sending clear and unambiguous messages and at the same time communicating uncertainty.

#### *Response to Swinburn’s recommendation on the need to fund further research*

In Section 5. Overall conclusions to his report Swinburn stated *“In my opinion, the warranted actions at present by the relevant government agencies involve: Funding further research, especially clinical research .....*”

NZFSA has provided the following information about its action on this issue.

“NZFSA’s, own experts discussed this issue and came to the view that research involving human trials was very costly and beyond any funding available to NZFSA. It was up to the research community, together possibly with those in dairy milk industry, to develop proposals and submit them through the usual/known channels for public health research funding. These channels are well known in New Zealand, the main one being the Health Research Council (HRC), the Crown agency responsible for the management of the Government’s investment in public good health research. Ownership of the HRC resides with the Minister of Health, with funding being primarily provided from Vote Research,

Science and Technology. The HRC website sets out its funding and purchase strategy and opportunities for funding research through partnership initiatives (joint ventures as well as grants) and through an Annual Funding Round. The Annual Funding Round accommodates a wide range of research from emerging researcher to broader, more established programmes. This is common knowledge among those working in the public health field in New Zealand. As a result, NZFSA did not send the report to any research body or funding body but instead, widely publicised its availability so that those interested in pursuing research of this kind could draw on the information in the report to frame research proposals. NZFSA did not have a Scientific Advisory Committee at the time and nor was the NZFSA Academy up and running. The academic arena in New Zealand is very well connected and those interested appeared to be following the matter closely. The issue, at least in part, is attributed to a debate amongst academics in the *New Zealand Medical Journal* (NZMJ) of 24 January 2003 (vol.116 No.1168) titled “*Balancing research for new risk factors and action for the prevention of chronic diseases*” by Robert Beaglehole and Rod Jackson (Beaglehole and Jackson 2003). It was about research, commenting on a paper in the same issue of the NZMJ by M. Laugesen and R. Elliott titled “*Ischaemic heart disease, Type 1 diabetes, and cow milk A1  $\beta$ -casein*” (Laugesen and Elliot 2003). Beaglehole and Jackson suggested that “it would be prudent, however, to suggest other observational study designs before embarking on the difficult, complex and expensive clinical trials, even if they could be designed and implemented satisfactorily. Further animal studies alone will never be sufficient for public policy decisions.” They concluded by encouraging Laugesen and Elliott to pursue this research but not at the expense of “policy and programmatic research” that had the potential to “significantly and quickly reduce ethnic inequalities in chronic disease outcomes” in New Zealand.

After this publication, in February/March of 2003, NZFSA approached some of the leading academics as to availability to undertake the review and later, others were approached about the peer review. Many academics in the field were therefore aware of the debate surrounding A1-A2 milk.

In light of the foregoing (previous involvement of MoH, interest within the academic world, widely known funding channels for public health, publication and broad media coverage of the issues in 2003 and again in 2004) no separate discussions were held with MoH on the matter of research. No other government agencies were approached formally.”

#### *Comments on NZFSA’s and MoH’s reponse to Swinburn’s recommendation*

NZFSA spread information about the Swinburn report, including its recommendations for support of further research, and made it publically available via its website. Therefore it can be assumed that research workers in relevant fields, at least in this part of the world, are well aware of Swinburn’s recommendations about the need for further research and also know about possible sources of research funding. However, neither NZFSA nor MoH took any specific action to gather together research workers in relevant disciplines for a discussion about support for new research to investigate a possible causal relationship between A1 milk and certain diseases.

It should also be pointed out that, although the safety of A1 milk is of particular importance to New Zealand in view of the economic importance of its export of milk products, the issue should also be of considerable interest to countries in other parts of the world where A1 milk is an important component of the diet and/or of great economic importance, e.g. Northern Europe. Almost four years have now past since the Swinburn report was published and EFSA is currently carrying out a review of the science of A1/A2 milk at NZFSA’s request. It is recommended that, as soon as EFSA has completed its review on the science of A1/A2 milk, NZFSA should bring together a group of experts in relevant fields to discuss the report and the possible need for further research in this area.

### *Further reflections*

The A1/A2 milk issue has both food safety and nutritional aspects. The lead authority for dietary advice to the public in New Zealand is MoH, but NZFSA also has some responsibility in this area. The division of responsibility is defined in a Memorandum of Understanding, which is currently under review. MoH's dietary advice to different population groups (infants, young children, pregnant women, etc.) shows that it regards milk as an important component of the diet, especially for children and pregnant women, due to its content of calcium and other important nutrients. Since there is a clear risk that the media treatment of the A1/A2 milk issue could result in some consumers replacing milk in their diet with other beverages with less nutritional value, it might have been expected that MoH would have been active in the media discussion about the Swinburn report and the A1/A2 issue in general. However, MoH appears to have maintained a very low profile throughout the whole affair, apparently regarding it as primarily a food safety issue, without nutritional aspects.

In discussions with different stakeholders in New Zealand it has become clear that the current division of responsibility between NZFSA and MoH for providing advice to the general public on nutrition and healthy diets is confusing to many outsiders. Therefore it is recommended that it be reviewed, bearing in mind the need for a holistic approach to dietary recommendations, especially in cases where consumption of the same type of food may involve both health risks and health benefits, for example the issue of mercury in fish. It is important to avoid a situation in which one authority gives out information emphasising health risks and another authority's information emphasises the health benefits.

## 7.2 Control of *Campylobacter* in poultry

### 7.2.1 Background information

*Campylobacter* species are the commonest bacterial cause of gastrointestinal illness in New Zealand and in many other countries, including Denmark, Ireland and Sweden. The most important organisms in this respect are *Campylobacter jejuni* and to a lesser extent *Campylobacter coli*. (In the following text the *Campylobacter* bacteria causing food-borne illness are, for the sake of simplicity, referred to simply as *Campylobacter* or *Campylobacter* spp.: in fact the situation is much more complex and different strains of *Campylobacter* have different capabilities to cause disease.) *Campylobacter* spp. are widespread in the intestinal tract of warm-blooded animals used for food production and they may therefore contaminate raw meat, raw milk and products thereof. *Campylobacter* spp. are also commonly found in the alimentary tract of healthy birds, including domestic poultry. This relates to the high optimum growth temperature (42°C), which is approximately the same as the normal body temperature of poultry. *Campylobacter* spp. are sensitive to freezing, heating (pasteurization/cooking), acidic conditions (pickling), disinfectants and irradiation. Unlike *Salmonella*, *Campylobacter* are generally unable to multiply in foods and therefore do not tend to cause large outbreaks of food poisoning.

The number of bacteria of *Campylobacter* spp. that must be ingested to cause disease (the infective dose) is considered to be low, ranging from 500 to 10 000 cells and may be lower in children than it is in adults. The incubation period for campylobacteriosis is usually two to five days. Clinical disease following infection with *Campylobacter* spp. varies from a mild, self-limiting enterocolitis lasting for 24 hours to severe illness lasting up to 10 days. Symptoms include general muscle pain, stomach cramps, nausea, headache or fever followed by sudden watery diarrhoea that may contain blood. The great majority of patients infected with *Campylobacter* spp. recover without any specific treatment. Complications are relatively rare, but infections have been associated with Guillain-Barré Syndrome (GBS), reactive arthritis, Reiter's syndrome, haemolytic uremic syndrome (HUS) and, following septicaemia, localised infection of nearly any organ. GBS occurs following approximately 0.1% of cases of campylobacteriosis. In the management of human campylobacteriosis, fluid replacement is of primary importance. Antimicrobial therapy is necessary in only a minority of patients with more severe disease and in those who are immunologically compromised. For the minority of patients who do require treatment, the greatest threat to the continued use of antimicrobial agents for human therapy is the development of antimicrobial resistance among pathogenic organisms such as *Campylobacter* spp. The use of antimicrobial agents in animal production contributes to increased antimicrobial resistance in *Campylobacter* spp. and other pathogenic bacteria. However, antibiotics are not used in poultry production in New Zealand.

### 7.2.2 Incidence of human campylobacteriosis

The reported incidence of human campylobacteriosis in New Zealand is much higher than that reported in some other developed countries. There has been a rising trend in the number of cases since the 1980s, reaching a peak in 2006 when there were 15873 notifications and 969 hospitalisations. In 2006, the rate of notified campylobacteriosis in New Zealand was 383.5 per 100,000. In the same year, the rates for Denmark, Ireland and Sweden were 60, 43 and 67 per 100,000, respectively and over 60% of the cases in Sweden had acquired the infection while abroad. In New Zealand, and in many other countries, there is a marked seasonal variation in the number of cases of campylobacteriosis, with a peak in the summer months. It must be borne in mind that a large proportion of cases are not reported and thus the above figures represent only the tip of the iceberg. Using the widely used multiplier of 7.6 times the number of notified cases, it has been estimated that the true incidence of campylobacteriosis in New Zealand in 2006 was about 120,000 (Baker and Wilson 2007). Thus the campylobacteriosis situation in New Zealand is clearly unacceptable. In addition to the suffering caused to affected

individuals, it places a heavy burden on the health services. It also has serious economic consequences, estimated by Baker *et al.* (2006) to be about 75 million NZ\$ per annum, and may also damage the reputation of New Zealand as a producer of safe food.

### 7.2.3 NZFSA risk management strategy for *Campylobacter* in poultry

Although several different foods have been implicated in food-borne campylobacteriosis, contaminated poultry meat has been recognised as the major cause of such infections in New Zealand and the same is true for many other countries. Therefore, in order to tackle the problem of human campylobacteriosis in New Zealand, NZFSA developed a *Risk Management Strategy for Campylobacter in poultry 2006-2009*; this Strategy has been updated and the latest version is the *Risk Management Strategy for Campylobacter in poultry 2007-2010*. The Strategy is well documented and much information about its development and progress in its application is available to the public via NZFSA's web site. The document includes annexes on completed and current scientific work, key milestones for 2007-2008 and a *Campylobacter* intervention table and decision tree. A *Campylobacter* Working Group meets regularly and senior management at NZFSA is provided with monthly progress reports. The Strategy has been developed using NZFSA's Risk Management Framework (RMF) described in Section 4 of the present report. Some brief information about and comments on the Strategy are given below, presented using the four steps of the RMF.

#### *Preliminary risk management activities*

NZFSA has commissioned an impressive series of risk profiles, risk assessments, discussion documents and other scientific projects on *Campylobacter*, including the risk profiles "*Campylobacter jejuni/coli* in poultry (whole and pieces)", "*Campylobacter jejuni/coli* in mammalian and poultry offals" and "*Campylobacter jejuni/coli* in red meat". Most of this scientific work has been carried out by other organisations, for example the Institute of Environmental and Scientific Research (ESR) and Massey University, working under contract to NZFSA. Quantitative and comparative risk models have also been developed and the "Preliminary Relative Risk Assessment for *Campylobacter* in New Zealand" compares the exposure to *Campylobacter* from various reservoirs. A number of research projects have been carried out covering, among other things, transmission routes for campylobacteriosis in New Zealand, a systematic review of the aetiology of human campylobacteriosis in New Zealand and packaging of poultry in New Zealand. In summary, it can be said that NZFSA's Strategy is built on a sound scientific foundation.

Estimates of the different causes of food-borne disease in New Zealand show that campylobacteriosis ranks highest and it is therefore logical that this problem has been given highest priority.

#### *Identification and selection of risk management options*

The *Risk Management Strategy for Campylobacter in poultry 2007-2010* shows how the risk management options have been identified and selected. A document "Evaluation of short to medium-term interventions for reducing exposure to consumers from *Campylobacter*" assesses interventions and is being updated continuously. A "whole food chain" approach has been used and interventions at different points along the whole of the food chain, including primary production, slaughtering, retail distribution and food storage and preparation in the home, have been considered. Consultation with various stakeholders has taken place. This includes regular meetings with the poultry industry and food retailers and presentations to NZFSA's Consumer Forum.

The interventions considered include on-farm measures to reduce infection of live broilers with *Campylobacter*, use of various chemicals (e.g. acidified sodium chlorite or trisodium phosphate) in water used during post-slaughter processing, introduction of leak-proof packaging for distributing poultry meat products and commercial and/or domestic freezing of poultry meat. The possibility of

tackling the problem by irradiating broiler carcasses, which would probably be effective, does not appear to have been pursued, probably due to the generally negative attitude of consumers in New Zealand to irradiation.

The current level of human campylobacteriosis in New Zealand is considered to be unacceptable. NZFSA has introduced an interim performance target that will contribute to achieving a 50% reduction in the number of human cases of food-borne campylobacteriosis over a 5 year period. The approach seeks to achieve the greatest reductions in *Campylobacter* numbers as early as possible in the food chain. The performance target mandated by NZFSA from 7 April 2008 represents a 90% reduction in current broiler carcass contamination levels. The poultry industry considers that meeting this target will involve considerable costs, but NZFSA has indicated that it will take strong action against producers that do not meet the target. The standards to reach the goal are set out in the National Microbiological Database, which stipulates acceptable levels of *Campylobacter* in broiler rinsates. In addition to setting and enforcing these standards for the food industry, NZFSA has also provided a lot of information and advice to consumers on the importance of avoiding cross-contamination in domestic kitchens and of thorough cooking of poultry prior to consumption.

#### *Implementation of risk management decisions*

In addition to developing and implementing mandatory standards, NZFSA has developed voluntary standards together with the poultry industry. The standard for *Campylobacter* in broiler rinsates in the National Microbiological Database and the Codes of Practice for Processing of Poultry are mandatory. The Broiler Growing Biosecurity Manual is an example of a voluntary standard that was developed together with the industry. Verification is performed by NZFSA's Verification Agency.

#### *Monitoring and Review*

Monitoring of human disease in New Zealand is carried out by ESR and the system is described in "Notifiable and other diseases in New Zealand. Annual Report 2006". That report also contains an analysis of *Campylobacter* notifications. NZFSA's *Risk Management Strategy for Campylobacter in poultry 2007-2010* also contains details on monitoring, as does the New Zealand Public Health Surveillance Report. Monitoring of flock prevalence of *Campylobacter* is carried out to assess the effectiveness of the interventions introduced at farm level. Provision is made in NZFSA's Strategy for review of regulatory and other measures in the light of progress, or lack thereof, in reducing campylobacteriosis in New Zealand.

#### **7.2.4 International co-operation**

NZFSA has a worldwide network of contacts dealing with the problem of contamination of foodstuffs with *Campylobacter* and other pathogenic organisms and it has used these contacts in developing its strategy to deal with the problem. For example, it has used the MED-VET-NET to help in the elaboration of a risk model for New Zealand and get informal feedback on different possible intervention strategies.

New Zealand, and in particular NZFSA, is held in high regard in international bodies that deal with zoonoses, including the CAC and its subsidiary bodies and the OIE. Proof of this is the fact that, together with Sweden, it has been asked to lead the work under the CAC's Committee on Food Hygiene to develop a new international "Code of Practice for *Salmonella* and *Campylobacter* in Young Chickens (broilers) and Chicken Meat". This work is ongoing. The Chief Executive of NZFSA is also a member of the OIE Working Group on Animal Production Food Safety, which is also dealing with the issue of pathogenic bacteria in broilers.

#### **7.2.5 Comparisons with some other countries**

*Campylobacter* in poultry and human campylobacteriosis are worldwide problems and by no means restricted to New Zealand. However, for reasons that are not entirely clear, the size of the problem in New Zealand appears to be much greater than that in many other developed countries and perhaps something can be learnt from the way in which other countries are tackling the problem. In consultation with industry and other stakeholders, the food safety authorities in Denmark, Ireland and Sweden have developed strategies for dealing with the problem several years ago and they have been updated in the light of the experience gained. All of the strategies consider the whole of the food chain from farm to fork and include strict hygiene and bio-security measures at the farm level. They also emphasize the importance of information to consumers about the importance of good hygienic practices in the kitchen and proper heat treatment of raw poultry prior to consumption. The strategies have been successful in reducing the problem, but it has not been eliminated and therefore the authorities and industry are intensifying their efforts to find further ways to deal with it. In Denmark and Sweden all broiler flocks are sampled for *Campylobacter* prior to slaughter and some companies pay higher prices to farmers delivering *Campylobacter*-negative flocks.

*Campylobacter* are sensitive to freezing and Georgsson *et al.* (2006) have shown that freezing is an effective method to reduce *Campylobacter* contamination of broilers. In a recent paper on strategies to reduce human campylobacteriosis in Sweden, Lindqvist and Lindblad (2008) estimated that diverting all *Campylobacter*-positive flocks to freezing would result in 43% as many cases as the baseline. The second best diversion option (54% of baseline cases) was to direct all chickens from the two worst groups of producers (in terms of percentages of positive flocks delivered) to freezing. In Denmark there is a voluntary practice of allocating *Campylobacter*-negative flocks to the production of fresh products and *Campylobacter*-positive flocks to frozen product production. In Iceland there is a mandatory requirement to freeze carcasses of broilers found to be *Campylobacter*-positive in pre-slaughter testing. According to Iceland's Chief Veterinary Officer, the freezing requirement works well there: because there is a large price difference between fresh and frozen products there is a strong incentive for the producers to keep their flocks *Campylobacter*-free.

Baker and Wilson (2007) have proposed that a ban on the sale of fresh chicken and a switch to frozen poultry (or similar intervention to lower contamination levels by a similar amount) should be introduced in New Zealand. For various reasons (e.g. cost, practicability, consumer preference for chilled rather than frozen broilers, uncertainty about effectiveness), neither NZFSA nor the New Zealand poultry industry seems keen to adopt this approach at present and NZFSA has not mandated it.

A surveillance programme for broilers operated by the Swedish Poultry Meat Association commenced in 1991 and involved sampling of all flocks at slaughter. An extended five-year programme was initiated in 2001, based on the Swedish Board of Agriculture's Regulation 1993:42 on Organised Health Control. In her thesis: "Bacteriological and epidemiological studies of *Campylobacter* spp. in Swedish broilers" Hansson (2007) identified three key measures for reducing *Campylobacter* incidence at farm level, namely a) a high level of general tidiness on the farm and a high standard of the hygiene barrier protecting the broilers, b) avoidance of thinning, in which part of the flock is kept for further rearing and, c) avoidance or minimization of other livestock on the farm. In Sweden there is a strict "all-in-all-out" regime, which means that for a certain period of time there are no broilers on the premises. In its strategy document, the Food Safety Authority of Ireland (Food Safety Authority of Ireland 2002) has listed many different interventions to reduce *Campylobacter* contamination of broilers. These include de-stocking the entire flock in each house at the same time (the "all-in-all-out" principle).

### 7.2.6 Conclusions

The strategy that has been developed and is being implemented by NZFSA to deal with the unacceptably high number of cases of human campylobacteriosis in New Zealand is based on sound

science. Much of the scientific basis for the strategy has been provided by external organisations, in particular ESR, working under contract to NZFSA. The Strategy considers the whole of the farm-to-fork food chain and considers interventions at several points along the chain. The Strategy follows the four steps of NZFSA's Risk Management Framework in a clear manner. The hazard-based goal of the strategy, involving a 90% reduction in the current level of *Campylobacter* in broiler rinsates is clear and methods for following it up have been put in place. Likewise, the interim public health goal, involving a 50% reduction in the number of cases of human campylobacteriosis within a five year period ending 2010, is clear and methods to monitor progress are in place. The Strategy has been developed in consultation with stakeholders, including representatives of the poultry industry, the retail food trade and consumers and also academia and other government organisations. Many other countries are faced with similar problems caused by *Campylobacter* in poultry and NZFSA has made good use of its international networks, including the MED-VET-NET, to obtain feedback from other experts in the field on its strategy. Proof of the high regard with which NZFSA is held internationally is that, together with Sweden, it has been asked to lead the work under the CAC's Committee on Food Hygiene to develop a new international "Code of Practice for *Salmonella* and *Campylobacter* in Young Chickens (broilers) and Chicken Meat". Extensive risk communication has been carried out and a large amount of material is publicly available via NZFSA's web site. Initial results from 2008 indicate that the situation is improving. However, although this is encouraging, it is far too early to conclude that the goals will be reached in time.

NZFSA plans to closely monitor progress in achieving the interim goals and take corrective action immediately if there are indications that the situation is not improving as intended. This includes taking action against poultry-producing units that fail to make progress in reducing *Campylobacter* infection in their flocks.

### 7.2.7 Recommendations

The following recommendations are made:

- As the practices of thinning and point selling during production represents serious risks of introducing *Campylobacter* spp. into flocks, the poultry industry should seriously consider the practicality of de-stocking the entire flock in each house at the same time (the "all-in-all-out" principle).
- The food industry should redouble its efforts to ensure that raw poultry products are packaged in such a way as to avoid cross-contamination during distribution and NZFSA should verify that current legal requirements for leak-proof packaging are met.
- NZFSA should continue to use its international contacts to follow developments in this area and evaluate any new methods that become available to mitigate the problem of *Campylobacter* in poultry meat.
- If its current strategy does not produce satisfactory results on time, NZFSA should re-examine its position on commercial freezing of *Campylobacter*-contaminated broilers as a method to reduce the numbers of *Campylobacter* on chicken meat. Alternatively, other decontamination steps should be applied, e.g. heat-treatment.
- Even if the interim goals set by NZFSA for reducing contamination of broilers with *Campylobacter* are achieved, there will probably still be a large and unacceptable residual problem of campylobacteriosis in New Zealand (a 50% reduction in the estimated total incidence of 120 000 cases in 2006 would still leave 60 000 campylobacteriosis cases per year). Therefore NZFSA should, together with other relevant agencies and stakeholders, continue to identify and deal with other food-borne sources of this infection in New Zealand.

- NZFSA should encourage further research into attribution to enable better epidemiological understanding of the causative *Campylobacter* organism and thus enable much more targeted controls of the health risk.
- Even if NZFSA's interim goals for reducing contamination of broilers with *Campylobacter* are achieved, some poultry meat on the New Zealand market will still be contaminated with *Campylobacter*. Therefore NZFSA should intensify its information to both consumers and commercial caterers about the problem and how to deal with it (avoidance of cross-contamination, adequate heat-treatment prior to consumption, etc.).
- The food industry and trade should consider giving financial incentives to poultry producers/processors that provide *Campylobacter*-free poultry and products thereof.

## 7.3 Aspartame as a food additive

### 7.3.1 Background information

Aspartame has been used as a low-calorie sweetener in foods and as a table-top sweetener for more than 20 years in a large number of countries throughout the world, including New Zealand. It was first authorised for use in the USA and several European countries during the 1980s and was approved for use throughout the European Union in 1994. Its safety has been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) on several occasions, most recently in 1981 when it was assigned an Acceptable Daily Intake (ADI) for man of 0-40 mg/kg body-weight. Its safety has also been evaluated by the European Commission's Scientific Committee on Food (SCF), which assigned it the same ADI, and by expert bodies in many countries, including the USA, Canada, Australia and New Zealand.

Aspartame has undergone extensive testing in animals and studies in humans, including four animal carcinogenicity studies conducted during the 1970s and early 1980s. These studies, together with studies on genotoxicity, were evaluated by regulatory bodies worldwide and it was concluded that they did not show evidence of genotoxic or carcinogenic potential for aspartame. Since its approval, however, the safety of aspartame has been repeatedly questioned, with discussions focusing not only on the safety of aspartame itself, but also on the safety of its breakdown products, aspartic acid, phenylalanine and methanol. In response to such questions, the SCF undertook a further review of all the data on aspartame in 2002 and concluded that there was no need to revise the outcome of their earlier risk assessment. A comprehensive review of the safety evaluations of aspartame was recently presented by Magnuson *et al.* (Magnuson *et al.* 2007).

In 2005 and 2006 the European Ramazzini Foundation of Oncology and Environmental Sciences (ERF) reported the results of a new carcinogenicity study on aspartame (Soffritti *et al.* 2005, 2006). The ERF considered that the results of their study indicated that aspartame is a 'multipotential carcinogenic agent'. The European Food Safety Authority (EFSA) was asked by the European Commission to assess the results of the ERF study. EFSA asked its Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (the AFC Panel) to review the study as a matter of high priority. The AFC Panel assessed the new carcinogenicity study, using not only the ERF publications but also a more extensive report provided to EFSA by the ERF at the end of 2005 and further data from the same study provided by the ERF in April 2006. The Opinion of the AFC panel (EFSA 2006) was adopted on 3 May 2006 and is available on the EFSA website ([www.efsa.europa.eu](http://www.efsa.europa.eu)). For those interested in more details of the Opinion, the Summary is attached as Appendix 6 to the present report. The Panel considered that the study had flaws which bring into question the validity of the findings, as interpreted by the ERF. In particular, the high background incidence of chronic inflammatory changes in the lungs and other vital organs and tissues and the uncertainty about the correctness of the diagnoses of some tumour types were major confounding factors in the interpretation of the findings of the study. The Panel took note of the previous evaluations of aspartame by the SCF and other expert bodies, the negative results of recent carcinogenicity studies carried out by the US National Toxicology Program on aspartame in transgenic mice. The Panel was also informed about a recent epidemiological study carried out by the US National Cancer Institute in which no increase in brain or blood related cancers was reported to be associated with aspartame consumption. The Panel also took note of the comprehensive studies on the substance indicating that aspartame does not have genotoxic activity. In summary, the AFC Panel concluded, on the basis of all the evidence currently available from the ERF study, other recent studies and previous evaluations that there is no reason to revise the previously established ADI for aspartame of 40 mg/kg body-weight.

In 2007 the RMF published a second carcinogenicity study on aspartame (Soffritti *et al.* 2007). Prior to expressing an opinion on it, EFSA has repeatedly requested more detailed information on this study from the ERF, but to date its request has not been met. EFSA has now decided to ask the AFC Panel to make a statement (rather than an Opinion, since it has not been given access to the data it requested from ERF) about the second ERF study.

### 7.3.2 Handling of the aspartame issue by NZFSA

The following is a brief summary of the way NZFSA handled the aspartame issue in recent years and is based on documentation provided by NZFSA and information from other sources.

#### *Risk assessment*

In July 2005 NZFSA became aware of the (first) ERF carcinogenicity study on aspartame in rats and John Reeve, its Principal Advisor (Toxicology), reviewed the then available information about it and in an Internal NZFSA Memo of 16 August 2005 concluded: “Overall I do not believe this data changes anything with regard to aspartame, and I believe it remains a safe artificial sweetener. We should however await the outcome of the EFSA review of this information”. When EFSA’s AFC Panel Opinion was published in May 2006, Reeve examined it and agreed with its reasoning and conclusions. He was also aware of the fact that the US Food and Drug Administration (FDA) and the Canadian food safety authority had also reviewed the ERF study and concluded that it did not demonstrate that aspartame is a carcinogen.

In June 2007 NZFSA became aware of a second ERF carcinogenicity study, which became available online on 13 June 2007 (Soffritti *et al.* 2007). After examining the report of this study, Reeve concluded that it suffered from the same problems as the first ERF study, the conclusions from which had been rejected by himself, EFSA’s AFC Panel and the US FDA. An addendum to the review by Magnuson *et al.* (Magnuson *et al.* 2007) concludes that the second ERF study also fails to provide convincing evidence of aspartame carcinogenicity.

Thus the AFC Panel, US FDA, NZFSA and several other expert bodies have all reached the same conclusion regarding aspartame, namely that the many studies carried out so far do not demonstrate that aspartame is a carcinogen and that it can be safely used as a food additive, with an ADI of 40 mg/kg body-weight (JECFA, EFSA) or 50 mg/kg body-weight (FDA). Studies carried out in several countries have shown that the actual intake of aspartame is well below the ADI, even among persons consuming large amounts of aspartame-sweetened foods.

The outcome of NZFSA’s review of the ERF studies was that they did not bring any reason to alter the current regulatory view on aspartame and with no need to alter the ADI it saw no reason to seek a review by FSANZ to have the current regulations on the use of aspartame as a food additive changed. Thus there was no reason to initiate further risk management action. Food Standards Australia New Zealand (FSANZ) did not carry out its own assessment of the ERF studies but relied on the review of carried out in the USA and the extensive EFSA critique.

When considering the aspartame issue it is important to bear in mind that some groups of consumers consider that aspartame has certain positive aspects and in its presentation to the Health Select Committee NZFSA pointed out that: *Like our colleagues in the Ministry of Health, we believe that aspartame has a place in the diet of New Zealanders who wish to reduce their intake of sugar, either because they are diabetic or are concerned about their weight, but still enjoy a sweet taste. Organisations such as the New Zealand Nutrition Foundation and the Dietetic Association support our stance in this regard.*

### *Risk communication*

There has been considerable media interest in New Zealand in the question of the safety of aspartame. NZFSA has provided information to consumers and other interested parties on aspartame, not only in relation to the ERF carcinogenicity studies but also on other safety issues about aspartame and its metabolites, including methanol. The information has been supplied in several different ways:

- Information has been placed on NZFSA's website, including an information package entitled *Aspartame – what is it and why is it used in our food*, which also gives links to what other food safety authorities (EFSA, USFDA, Canadian Food Inspection Agency, FSANZ) say about aspartame and NZFSA's responses to media reports. This information package is updated as new information becomes available. Information has also been given in NZFSA's publication *Food focus*.
- Information has been provided at meetings of NZFSA's Consumer Forum
- Responses have been given to questions from the media and others
- Input has been provided for the FSANZ fact sheet on aspartame.
- Information was provided when the Parliamentary Health Select Committee looked at aspartame as a result of a petition by Ms Abby Cormack.

As shown above, aspartame is one of the most studied food additives of all and is considered by a large number of both international (e.g. JECFA and EFSA) and national (e.g. US and Canada) expert bodies that have evaluated it to be safe for use as a food additive. Despite this, for a variety of reasons, some of them not scientific, representatives of a few consumer activist groups in New Zealand refuse to accept this assessment and their views are often given wide publicity in the media. This is clear from comments in the media, discussions on aspartame that have taken place in NZFSA's Consumer Forum and at the Parliamentary Health Select Committee meeting that looked at aspartame as a result of a petition by Ms Abby Cormack and in discussions this reviewer had with two members of the Consumer Forum representing Safe Food Campaign and The Soil and Health Association. These members made it clear to me that they had little or no faith in any of the above-mentioned international or national expert bodies that had evaluated aspartame or any studies that have been financed by industry, preferring instead to place more faith in anecdotal reports of negative health effects of aspartame. These views are not shared by the other members of the Consumer Forum I have been in contact with.

### **7.3.3 Handling of the aspartame issue by the food safety authorities in Denmark, Ireland and Sweden**

Denmark, Ireland and Sweden are all members of the European Union (EU) and within the EU regulations on food additives, including sweeteners such as aspartame, are harmonised through a series of EU Directives. The risk assessments which form the scientific basis for these regulations are nowadays carried out by one of the Scientific Panels of EFSA, usually the AFC Panel. EFSA Scientific Panels consist of independent scientists chosen for their expertise in different scientific fields and, when working on the Panels, they do not represent their countries or employers. Readers seeking further information on EFSA and its Scientific Panels and their Opinions are referred to the EFSA website: [www.efsa.europa.eu](http://www.efsa.europa.eu).

As described above, when it was known that ERF was to publish new studies on the carcinogenicity of aspartame, the European Commission asked EFSA to assess them as a matter of high priority. The AFC panel did so and its Opinion was published in May 2006. Since the food safety authorities in Denmark, Ireland and Sweden knew that EFSA was going to carry out an assessment of the ERF studies, including the additional information it had obtained from the ERF, they did not carry out their

own risk assessments, but awaited the outcome of the AFC Panel's work. When the Panel presented its assessment in May 2006, the authorities provided information to the public in their respective countries via their websites and other channels. Scientists from both Denmark and Ireland were members of the AFC Panel and were therefore directly involved in the assessment of the ERF studies.

#### **7.3.4 Reviewer's comments on NZFSA's handling of the aspartame issue**

In my view NZFSA has handled the different aspects of the aspartame issue in a sound and professional manner. The preliminary risk assessment carried out by NZFSA on the basis of the information then available was later confirmed by the in-depth assessments carried out by EFSA and the USFDA. In line with its risk management framework, NZFSA has provided consumers and other stakeholders with relevant and understandable information about aspartame and responded to questions from the media, consumers and others. Despite the fact that it has provided scientific information, explained how food safety risk assessments are carried out and answered questions from representatives of the Safe Food Campaign and the Soil & Health Organisation of New Zealand Inc., it seems unlikely that NZFSA will be able to convince them of the safety of aspartame, since these doubters have an entrenched position from which they seem unlikely to depart.

#### **7.3.5 Recommendations**

It is recommended that NZFSA should continue to base its risk management of food additives on the best scientific evidence available, monitor developments in the toxicology of food additives, including aspartame, and continue to provide consumers and other interested parties with information about any new developments in this area.

It is further recommended that NZFSA continue to correct any obviously false or misleading information appearing in the media or other arenas and, in doing so, concentrate on correcting the information without commenting on the individuals spreading the information.

## **7.4 Imported foods regime (including foods from China)**

### **7.4.1 Background information**

A revised regime for the control of imported foods and food-related products is currently being introduced in New Zealand. (see Imported foods and food-related products. A Blueprint for Change and Implementation, NZFSA, May 2007).

The current regime focuses on “prescribed” or high risk foods and the current list of such foods was established in 1996 and contains foods that do not appear to contain hazards that would be considered high risk. Under the Food Act only foods that are prescribed foods or covered by an emergency food standard can be monitored (i.e. inspected, sampled, tested) at the border. As a result, most foods are considered low risk and are imported without restriction. There is limited monitoring of “low risk” foods, mostly in the form of specific food safety projects.

In the new regime there is a shift away from relying primarily on controls at the New Zealand border to a system that assesses and recognises controls in place overseas to ensure that the products meet or are equivalent to New Zealand standards for domestic food. The intention is to place more responsibility on the countries that produce and export food to New Zealand. This move is in line with international developments and the systems introduced in, for example, the EU. In the new system being introduced in New Zealand imported foods will be classified into three regulatory levels of interest – high, medium and low, considering food safety risk and other factors. Risk profiling and risk assessment will be applied to assist in the ranking/classification of foods and the ranking will determine the requirements to be met in order to import that food. Standards appropriate to the different regulatory levels of interest will be developed to manage the risks identified. High risk foods will be subject to pre-entry assurance requirements. Requirements for imported foods will be linked to those of the Bio-security Import Health Standards. The new regime will take into account New Zealand’s international trade obligations, in particular those following from its membership of the WTO and the SPS Agreement. The new system will also take into account the Trans Tasman Mutual recognition Agreement.

It should also be emphasized that, although NZFSA is responsible for control of imported foods, it is the importers responsibility that they meet the standards established in New Zealand

The new regime will also incorporate a “Scanning list” which NZFSA will use to increase the monitoring of particular foods above what is required by the category of regulatory interest in which a food has been placed. Scanning is the process that will identify food products that need additional attention and the reasons why and will trigger their inclusion on the Scanning list. Scanning includes monitoring of imports at the border, intelligence gathering (including use of international networks of food safety authorities) and specific programmes or projects, e.g. residue surveillance programmes.

Although the new regime relies more heavily on assurances from the exporting countries, some inspection, sampling and testing will continue at the point of entry into New Zealand and if products are found to be out of compliance with New Zealand standards they will be denied entry. In addition, this will lead to intensified control of further shipments of the product (and possibly similar products) from the same source.

### **7.4.2 Farmed fish from China**

During 2007 there were a number of “scares” related to foods produced in China, leading to consumer concerns in New Zealand that unsafe food may have been imported into the country. One of these concerns was related to residues of veterinary drugs in land-based farmed seafood (catfish, shrimp,

dace, eel and basa). The US Food and Drug Administration found low levels of residues of certain veterinary drugs (antimicrobials) that are not approved for use in the USA in farmed seafood from China and therefore intensified its control of these foods presented for import into the USA. The levels found were very low, often close to the level of detection and they were not considered to represent and immediate risk to public health and it was not considered necessary to recall the foods that had already been imported into the USA. The EU has earlier reported similar problems with contamination of seafood from China and some other Asian countries with low levels (trace amounts) of residues of veterinary drugs not approved in the EU.

When NZFSA became aware of the situation through its contacts with the US FDA it increased its control of the products concerned. In May 2007 NZFSA found six residues of triphenylmethane dyes and their metabolites and nine residues of nitrofurantoin antibiotic metabolites. However, the levels of all of these residues were judged to be without health significance. NZFSA has now widened its import control to cover also farmed fish products coming from countries other than China.

In tackling the above problem with seafood from China NZFSA has used its international “intelligence system” to gather information about the problem, intensified its import control of the products concerned, carried out a health risk assessment of the results obtained and communicated the results and assessment to consumers and other stakeholders.

#### **7.4.3 Contaminated pet food and vegetable protein from China**

In the spring of 2007 it was discovered that certain producers in China were adding melamine to wheat gluten, rice protein and chicken feed products to give the impression that it contained more protein than it did. Such products were exported to North America and South Africa and led to a North America-wide recall of an enormous amount of pet food following reports of serious illness and deaths in cats and dogs. In the USA contaminated feed was also used to produce feed for farm animals and fish feed.

In May NZFSA started to investigate vegetable protein imports from China for the presence of melamine and cyanuric acid after the USA had reported the illegal presence of melamine in wheat gluten imported as an ingredient in pet food. NZFSA confirmed that none of the pet food implicated in the incidents in North America had been imported into New Zealand. Neither had wheat gluten been imported from the Chinese company implicated in the USA incident. NZFSA has also reminded the importers of pet food and vegetable proteins of their responsibility to ensure that the products they import comply with New Zealand regulations.

#### **7.4.4 Roquefort cheese from the EU**

Following a recent change in New Zealand’s import regulations (see Section 7.5 of this report) it is now permitted to import Roquefort cheese made from raw milk. Although responsibility for the safety of such cheese rests with the manufacturer and the certifying food control authority in the country where it is produced, as a precautionary measure NZFSA has in place survey to check the levels of *Escherichia coli* in such products as a means of ensuring correct maturation procedures have been complied with.

#### **7.4.5 Conclusions**

The revised import regime developed by NZFSA is based on sound science and is a considerable improvement on the earlier regime. If properly enforced, it should provide adequate protection against the import of foods that constitute health risks.

### 7.4.6 Recommendations

It is recommended that NZFSA lists details of foods that have been rejected/detained at import control and refused entry into New Zealand, makes this information publicly available and also transmits it to neighbouring countries.

## 7.5 Roquefort and other raw milk products

### 7.5.1 Background information

It is virtually impossible to avoid some contamination of raw milk with pathogenic bacteria arising from faecal contamination during milking or from infected animals. The introduction of pasteurisation of milk has resulted in a vast improvement in the safety of milk and milk products. However, in some countries, e.g. France, there is a long tradition of preparing cheeses from raw milk and in some circles the taste of such products is regarded as far superior to that of cheeses made from pasteurised milk. Earlier New Zealand legislation prohibited the sale of cheeses and other products made from unpasteurised milk on the grounds of risks to immuno-compromised consumers, particularly from tuberculosis. Cheese and other products prepared from raw milk may contain pathogenic bacteria and in this respect the presence of *Listeria* spp is of particular concern. Consumption of cheese made from raw milk and contaminated with *Listeria monocytogenes* by pregnant women has been reported to result in severe infection of the foetus or newborn infant resulting in abortion or death of the newborn child. Some people are also especially vulnerable to severe *Listeria monocytogenes* infection as a result of pre-existing illness. More information about the effects of *Listeria* spp. in foods can be found on NZFSA's web site.

### 7.5.2 NZFSA's handling of the issue

#### *Preliminary risk management activities*

The French Government made an application to permit the sale of Roquefort cheese in New Zealand: this cheese is made from raw ewe's milk.

Under contract to NZFSA, ESR produced the following risk profiles:

- Pasteurisation of dairy products: times, temperatures and evidence for the control of pathogens. November 2003.
- *Listeria monocytogenes* in low moisture cheese. July 2005.
- *Listeria monocytogenes* in soft cheese. November 2005.

Further information for a risk assessment was collected through a visit of a delegation from NZFSA to France in January 2006. In August 2006 NZFSA's Science Group produced a risk assessment entitled "*Estimating the risk to New Zealand consumers from the consumption of Roquefort cheese*" as an internal report.

#### *Identification and selection of risk management options*

In March 2007 NZFSA developed a document ("*Risk management decision: importation of Roquefort cheese*") with proposals for control measures (including monitoring the cheese for *E. coli* levels) and the Minister for Food Safety was briefed prior to a visit of the French Minister for Trade. In May 2007 NZFSA sent out a "*Proposal to amend Food Standards to allow for the importation of Roquefort cheese and raw milk extra-hard grating cheeses: Consultation Process and Invitation for Public Comment*" to a long list of stakeholders. The responses to this invitation were summarised in a NZFSA

document in June 2007. NZFSA then developed sampling and testing criteria for scanning Roquefort cheese for *E. coli* levels and a proposal to change the relevant New Zealand legislation

#### *Implementation of the regulatory decision*

The amended legislation (Food (Milk and Milk Processing) Standards 2007 and Food (Prescribed Food) Standard 2007) was issued under the provisions of the Food Act 1981.

#### *Monitoring and review*

NZFSA has started monitoring *E.coli* levels in Roquefort cheese using the sampling and testing criteria it has developed.

#### *Risk communication*

One of the most important risk management measures in connection with allowing the importation of cheeses made from raw milk is to provide information about the health risks for vulnerable consumer groups (pregnant women, babies and toddlers, the frail elderly and persons whose immune system is compromised) and make sure that it reaches relevant groups. NZFSA has provided information on this subject via its web site and through other channels, including information (flyers) to be displayed in shops where these cheeses are sold. Since pregnant women are a particularly vulnerable group, information has also been spread via the health services.

### **7.5.3 Reviewer's comments on NZFSA's handling of the issue**

NZFSA has followed its Risk Management Framework in handling this issue. It has obtained a good scientific basis for its decision making from the risk profiles produced by ESR and has consulted different stakeholders, including consumers, during the process. In this connection it is interesting to note that New Zealand consumers seem to be willing to accept a small increase in risk (compared to cheeses made from pasteurised milk) in order to obtain the benefits of a wider selection of cheese on the market. New Zealand has also fulfilled its obligations under WTO and the SPS Agreement in its handling of the issue. NZFSA has also put in place a survey to check the processing standard of cheeses prepared from raw milk by measuring the levels of *E.coli*.

In view of the very serious health effects of *Listeria* spp. on vulnerable groups, in particular pregnant women/the foetus and newborn children, it is recommended that, in addition to surveying *E. coli* levels in raw milk cheeses, NZFSA checks that its information on the risks associated with their consumption is reaching the relevant target groups and that they understand it. Furthermore, it is recommended that NZFSA closely monitors the incidence of food-borne infections caused by *Listeria* spp. and takes action if the number of such cases associated with consumption of raw milk cheeses increases.

## **7.6 Mercury in fish**

### **7.6.1 Background information**

Mercury is released into the environment from a number of natural (e.g. volcanoes) and man-made (e.g. the chlorine-alkali industry) sources. Inorganic mercury can be converted to methyl mercury by microbial activity in soils and sediments. Methyl mercury is taken up by aquatic organisms and is magnified in the food web. Predatory species high in the food chain, e.g. predatory fish, can accumulate high levels of methyl mercury.

The toxic effects of methyl mercury were first reported among children born to women eating heavily contaminated fish from Minimata Bay in Japan, which was polluted with mercury from industrial sources. The most severe effects involved damage to the nervous system, which is especially vulnerable during prenatal development. Epidemiological studies carried out in different countries (including the Seychelles and the Faroe Islands) on populations eating large amounts of fish have shown that normal levels of methyl mercury in fish (not associated with industrial pollution) pose some health hazards, especially associated with the developing brain.

Evidence that consumption of “normal” amounts of fish contaminated due to industrial pollution or from natural sources may give rise to negative health effects has led to both international and national efforts to assess the risks from exposure to methyl mercury via fish as a basis for standard setting and dietary recommendations to consumers. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) has carried out toxicological evaluations (risk assessments) of methyl mercury on several occasions, beginning in 1972. In its most recent evaluation (2003), JECFA recommended a Provisional Tolerable Weekly Intake (PTWI) of 1.6 micrograms per kg body-weight for methyl mercury, equivalent to 112 microgrammes per week for a 70kg woman. JECFA considered that the proposed PTWI was sufficient to protect developing foetuses, the most sensitive group in the population. The Codex Committee on Food Additives and Contaminants (CCFAC) has proposed Guideline Levels of 0.5 mg/kg and 1 mg/kg, respectively, for mercury in different fish species and these Guideline Levels have been adopted by the Codex Alimentarius Commission. Estimating human exposure to methyl mercury is a complex issue. Different fish species accumulate methyl mercury to different degrees and the degree of methyl mercury exposure depends not only on the amount of fish consumed, but also the species, the size/age of the fish and its geographical source. The growing foetus is especially sensitive to the effects of methyl mercury and thus pregnant women are the most vulnerable population group.

Risk communication is a very important aspect of managing the risks associated with methyl mercury in fish. Fish makes an important contribution to nutrition, especially in certain regional and ethnic diets. Omega-3 fatty acids present in fish reduce the risk of coronary heart disease and strokes and also have positive effects on cognitive development. When JECFA presented its toxicological evaluation of mercury in 2003 it reaffirmed its position that fish is an important part of a balanced nutritious diet and that this has to be appropriately considered in public health decisions when setting limits for methyl mercury in fish or fish consumption. Therefore it is very important that communication with consumers about the health risks associated with fish consumption is balanced and the positive health effects of fish consumption are clearly communicated at the same time. Achieving this balance is difficult and in some cases providing information about the risks associated with methyl mercury and/or other contaminants in fish has led to an unfortunate, and from the health point of view unwarranted, general decrease in fish consumption.

### **7.6.2 NZFSA’s handling of the methyl mercury in fish issue**

In New Zealand in 2005 there were three separate pieces of advice to pregnant women related to the issue of methyl mercury in fish from NZFSA, the Ministry of Health and FSANZ, respectively, and

they were not the same. NZFSA was then given the task of providing the scientific basis for a set of common dietary recommendations. A brief description of how NZFSA has handled the mercury in fish issue is given below, structured according to NZFSA's RMF.

#### *Preliminary risk management activities*

The original advice from NZFSA was based on the above-mentioned JECFA PTWI of 1.6 microgrammes per kg body-weight and fish consumption data from the New Zealand Total Diet Survey (2003/2004). Subsequent to the original assessment, NZFSA collected much better and more up-to-date information about the levels of total mercury in commercial fish species caught and consumed in New Zealand, including trout from the volcanic area and albacore tuna. (Over 90% of the mercury found in fish is present as methyl mercury but, since it is easier to analyse total mercury than methyl mercury, most studies of mercury levels in fish measure total mercury.) Using information about mercury levels in fish in New Zealand, the size of a normal serving and the JECFA risk assessment, NZFSA then constructed a table showing how many servings of different fish species could be recommended to comply with the JECFA PTWI. This table divided the fish species into four groups – a) no restriction necessary, b) three servings per week acceptable, c) one serving per week acceptable and d) one serving per two weeks acceptable.

#### *Identification and selection of risk management options*

For many years the *Australia New Zealand Food Standards Code* has contained a limit (Maximum Level) of 1mg/kg for fish species known to contain high levels of mercury (such as swordfish, southern bluefin tuna, barramundi, ling, orange roughy, rays and shark) and a limit of 0.5 mg/kg for all other fish species. In addition, FSANZ had issued a fact sheet entitled *Mercury in Fish: Advisory Statement for Pregnant Women*, which advised pregnant women or women intending to become pregnant to limit their consumption of the large predatory fish to four small to moderate (150g) portions per week.

In July 2005 FSANZ held a workshop on mercury in fish and the following amended approach to dealing with the problem was proposed:

1. Delete the Maximum Levels (MLs) for mercury in fish and delete the prescribed sampling plan from the *Code*. This would remove the regulatory burden from enforcement agencies and industry for an issue that is not practical to manage through compliance with MLs;
2. Increase the resources and bi-nationally coordinate consumer education and information on mercury in fish to assist consumers to consume fish as part of a healthy diet;
3. Evaluate the information/education of consumers to ensure that target consumers are aware of the issues and are consuming fish appropriately as part of a healthy diet;
4. Publish information on the typical range of mercury levels in various species of fish e.g. as Generally Expected Levels (GELs). This will provide information to industry and enforcement agencies to assist them in investigating and correcting gross contamination incidents;
5. Maintain a regular, low-level mercury in fish monitoring programme as part of the National Coordinated Surveillance Plan. This will ensure that analytical capability is maintained and that complaints of gross contamination can be rapidly investigated, while also ensuring that data is continually gathered to contribute to information about the typical range of mercury levels in fish;
6. Continue to participate in discussions on the issue of MLs in fish at the Codex Committee on Contaminants in Foods (CCCF) to facilitate consideration of a global approach.

#### *Implementation of risk management decision*

As mentioned above, in risk communication about mercury in fish it is important to balance information about risks from methyl mercury and the benefits of consuming fish as part of a healthy

nutritious diet. In line with the above recommendations from the FSANZ workshop, NZFSA has chosen to use improved risk communication with vulnerable consumer groups (especially pregnant women) as the main means of dealing with the problem of mercury in fish. The Maximum Levels (MLs) remain unchanged and can be used to prevent the sale of fish with mercury levels exceeding them. NZFSA also used its international contacts to get information on the strategies used in other parts of the world (e.g. the USA and EU) in dealing with the problem. NZFSA revised its recommendations to consumers on mercury in fish, in consultation with the Ministry of Health (MoH), the fishery industry and other stakeholders and presented them at NZFSA Conference in October 2006. NZFSA recommendations on fish intake for pregnant women are available on its web site (<http://www.nzfsa.govt.nz/consumers/chemicals-toxins-additives/mercury-in-fish/index.htm>) and are also included in its brochure with dietary advice to pregnant women (NZFSA 2006); the recommendations are also used in information issued by the MoH to pregnant women. The recommendations list fish species in three groups – those that can be consumed without restriction, those for which 3-4 servings a week are acceptable and those for which one serving per 1-2 weeks is acceptable. The recommendations point out that fish is a highly nutritious food for everyone, particularly pregnant women because omega-3 fatty acids are important for the development of the central nervous system in babies. It is also pointed out that fish is an excellent source of protein, iodine and some vitamins.

### *Monitoring and review*

NZFSA continues to monitor the levels of mercury in domestically caught fish and the web site table is updated as new data come in. NZFSA is putting in place a project to monitor imported fish for mercury, since, although most fish sold in New Zealand is caught locally, there is an increasing trade in whole fish, particularly from Asia. In addition, most canned fish is processed outside New Zealand and could contain fish from anywhere in the world. Information on fish intake is being collected as part of the New Zealand Total Diet Surveys. NZFSA is also closely following international developments on the risk assessment of methyl mercury and the discussions in the Codex Committee on Contaminants in Food on mercury in fish.

### **7.6.3 Strategies used in some other countries**

Many countries are facing the same problem as New Zealand in relation to mercury in fish, i.e. how to protect vulnerable consumers from health risks while at the same time ensuring that this does not result in an unwarranted decrease in fish consumption, which could be negative from the health point of view. In some countries, e.g. Sweden, the situation is further complicated by the fact that certain fatty fish are contaminated with other environmental contaminants, e.g. dioxins and PCBs.

In all the European Union countries, including Denmark, Ireland and Sweden, the European Community maximum levels for mercury in fish apply. There is a general limit of 0.5 mg/kg for fishery products and muscle meat of fish, but for over 20 listed fish species a higher limit of 1 mg/kg applies (European Commission 2006). In addition to checking that these limits are complied with, Denmark, Ireland and Sweden provide recommendations on fish consumption to different population groups, and in particular pregnant women, via their web sites, brochures and other information and educational materials (see, for example, Danish Food and Veterinary Administration 2006, Swedish National Food Administration 2007, Food Safety Authority of Ireland 2004, 2007). The Swedish recommendations are currently being revised and the revised recommendations will place greater emphasis on the health benefits of fish consumption. As in New Zealand, it is recommended that most species can be eaten without restriction, whereas the consumption of some named predatory species should be restricted to a certain number of portions per week or month. The species named in these recommendations and restrictions take into account the species that are consumed and caught in the

respective countries. In Sweden, in addition to the restrictions recommended because of the presence of mercury in fish, other restrictions on the consumption of fish and fish liver are recommended because of contamination of fatty fish from the Baltic Sea and some inland waters with dioxins and PCBs.

It has been found that the recommendations to restrict the intake of certain fish species and/or fish from certain waters have resulted in some consumers greatly reducing their intake of fish in general. Since this could have negative health effects, many food safety authorities are reviewing their recommendations on fish consumption in order to get a better balance in the information about the risks and benefits of fish consumption. As recently pointed out by Reilly (2007), one of the keys to a healthy diet is to obtain an appropriate balance between the intake of both omega-6 and omega-3 fatty acids and seafood is the predominant source of the latter in the diet. Therefore, from a nutritional point of view, a general increase, rather than a decrease, in fish consumption is desirable.

#### **7.6.4 Conclusions and recommendations**

NZFSA's risk management of the mercury in fish issue is based on a sound scientific foundation and takes into account the latest risk assessment carried out by JECFA. New Zealand has continued to take an active part in the discussions in CCCF on the issue of mercury in fish. The decision to change the earlier strategy of trying to deal with the problem and to put much more emphasis on risk communication was a wise one. However, the problem of elevated levels of mercury in fish will continue and therefore it is important that NZFSA, FSANZ and the health authorities in New Zealand continue to follow developments in this area and therefore the following recommendations are made:

- NZFSA should follow up its risk communication efforts by checking that its recommendations are reaching the target groups and that they are understood and followed.
- NZFSA should continue to collect data on current levels of mercury in fish consumed in New Zealand, including imported fish. If the levels found differ significantly from those on which the current recommendations are based, the recommendations should be revised accordingly.
- NZFSA should continue to collect data on fish consumption and, if intake decreases in a manner considered negative from a health point of view, take steps together with the health authorities and others to stimulate consumption of relevant fish species.
- If resources are available, a study to measure the levels in the hair of women of childbearing age should be carried out to check that total mercury exposure in New Zealand does not exceed tolerable levels.

## 7.7 Other issues

In addition to the high-profile issues specifically mentioned in the Terms of Reference for this review, the reviewer has received information about how NZFSA has applied the RMF in dealing with several other recent issues, including:

- Folic acid fortification
- *Salmonella Brandenburg* in sheep meat
- Shiga-toxin producing *E.coli* (STEC) in uncooked comminuted fermented meats (UCFM)
- Brodifacoum in feral pigs
- Yessotoxin in shellfish
- TSE Programmes

The documentation of the handling of these issues has not been studied in detail, but the overall impression is that, as in the issues examined in Section 7 of this report, the handling of the above food safety problems has followed the procedure given in NZFSA's RMF. The risk management decisions have all been based on sound science and consultation with interested parties has taken place during the process. In general the process is well documented.

Of the issues named above, the question of mandatory fortification of foods with folic acid is especially complex. It has been the subject of much scientific and public discussion in many other countries around the world, including the USA, Canada, the UK, Ireland and Sweden. It is well established that increasing folic acid intake in the period prior to conception decreases the risk of severe abnormalities of the central nervous system that can develop in the foetus during the first weeks of pregnancy. These abnormalities (anencephaly and spina bifida) are called neural tube defects (NTD) and can result in death of the foetus/newborn child or severe lifelong handicap. There are several different ways of increasing the intake of folic acid by the target group, including dietary advice to increase the intake of folic acid-rich foods, consumption of dietary supplements containing folic acid and voluntary or mandatory fortification of certain foods with folic acid. One of the problems in trying to achieve an increased folic acid intake in the period prior to conception is that many pregnancies are unplanned. Experience in a number of countries has shown that the most effective way of achieving an increase in folic acid intake is fortification of some basic foods, for example grain/flour/bread and several countries, including the USA, Canada, Chile and Ireland, have introduced such fortification of specified foods. Other countries permit voluntary fortification of a range of foods with folic acid and others, such as Sweden, have discussed introducing mandatory fortification for many years, but have hitherto decided against it. A reason for delaying the decision on folic acid fortification in the UK was concern that increased folic acid intake would mask vitamin B-12 deficiency and Sweden has hesitated to introduce mandatory fortification due to uncertainty about whether high folic acid intake by the general population could lead to an increase in the incidence of colorectal cancer.

In New Zealand, the main responsibility for the question of mandatory fortification of foods with folic acid rests with FSANZ. However, NZFSA has commented on a proposal from FSANZ for such fortification and pointed out the possible, but unproven, risk that high intake of folic acid may increase the risk of colorectal cancer. In addition to the issues related to NTD, increased folic acid intake may be beneficial in preventing cardio-vascular disease, although this is not so well established. As can be seen from the above brief and simplified description, the issue of mandatory fortification is extremely complex and involves many aspects over and above purely scientific considerations. More information about folic acid fortification can be found on NZFSA and FSANZ web sites and in the FSAI Report of the National Committee on Folic Acid Food Fortification (Food Safety Authority of Ireland 2006b).

During my first visit to New Zealand in January 2008 I was contacted by Mr Simon Terry, from the Sustainability Council of New Zealand, and Professor Jack Heinemann from the University of Canterbury. They expressed dissatisfaction about NZFSA's handling of the issue of approval of High Lysine Corn LY038, a genetically modified organism (GMO). Approval of GMOs is considered by FSANZ in the first instance. NZFSA subsequently commissioned ESR to examine the evaluation carried out by FSANZ and they reported that they considered it to be satisfactory. The reasons for their objections are given in a document entitled "Food Safety Credibility. The Regulatory Response to GM Lysine Corn" (Sustainability Council of New Zealand 2007). It is outside the terms of reference of this review to carry out a detailed examination of the data submitted to support an application for approval of a GMO and the FSANZ assessment of this particular product. It can, however, be noted that EFSA's GMO Panel is examining what appears to be the same product and has requested further information from the petitioner. EFSA's GMO Panel has not yet expressed an opinion on the product: when it has done so, the opinion will be published on EFSA's web site ([www.efsa.europa.eu](http://www.efsa.europa.eu)).

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## Appendices

### Appendix 1

## Food Safety in New Zealand: Application of a Risk Management Framework

### Summary

This document updates *Food Administration in New Zealand: A Risk Management Framework for Food Safety*, published jointly in June 2000 by the New Zealand Ministry of Health and the Ministry of Agriculture and Forestry. It reiterates the need for an agreed process for systematically managing the myriad food safety issues that a regulator must address in an ever-changing food safety environment and includes practical experience that has been gained by NZFSA over the past seven years. It also recognises that the state of scientific knowledge will always be limited and there is a need to continually invest in new risk assessments and all aspects of risk management if there are to be continual improvements in food safety. As the independent competent authority in New Zealand, NZFSA manages risks to food safety through regulation and provides official assurances on exports of animal products, including milk products and seafood.

### Foreword

The last decade has seen an unprecedented level of change in the approach to food safety. The drivers for such change are diverse and have been generated from all stakeholders in the food chain including the consumer, government, industry and the academic community. As a consequence, Food Safety Authorities around the world are engaged in structural, legal and operational responses that are still incomplete in terms of charting new courses to protecting consumers against foodborne illness.

The New Zealand Food Safety Authority (NZFSA) is no exception and this document describes the application of a generic Risk Management Framework (RMF) to systematically address all food safety issues. Much of the work of NZFSA is about understanding and dealing with foodborne risks to consumers, and transparent and agreed processes are needed to incorporate risk-based approaches in regulatory 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 standards or other regulatory activities as appropriate. Wherever possible, regulatory decisions should be based on risk assessment and all aspects of risk management should be immersed in a 'sea of risk communication'. Systematic application of an RMF ensures that all aspects of risk analysis, ie risk assessment, risk management and risk communication, are brought together in a systematic and logical manner and this maximises the benefits available from a risk-based approach to food safety.

Robust science is a key input to all components of NZFSA's RMF and this is provided from a range of sources including NZFSA itself, contracted science providers and international liaison. The cyclical nature of the RMF reflects the continual quest for better scientific data and the soundest scientific expert judgment as a basis for risk management decisions.

It is important to recognise that systematic application of an RMF to food safety issues will only achieve stakeholder goals if food safety control measures are underpinned by well-functioning operational systems. NZFSA is proud of its record in this area and we will continue to ensure that the outputs of the RMF are solidly supported by the routine regulatory activities of all NZFSA business groups.

Andrew McKenzie

CHIEF EXECUTIVE

2008-04-29

## **Why the need for an agreed risk management process?**

### **A time of change**

Food safety is an accepted consumer requirement but one that courts controversy. The last decade has seen vastly increased knowledge on risks to consumers associated with biological, chemical and physical hazards in the food chain, along with demonstrated success in the application of new regulatory systems and food safety programmes. Nevertheless, foodborne illness continues to be a significant problem in all countries and governments are responding in a number of ways to assure the safety of food provided to domestic consumers and to those in offshore markets.

### **Global drivers of change**

Global drivers of change are particularly important in the New Zealand situation, given that high volumes of exported food are a major part of our economy. New Zealand is also importing a greatly increased range of food from different countries and this now constitutes 20% by value of food consumed.

Along with the increasing volumes of imported and exported food, the geographical origin, nature, range, preservation requirements and intended end uses of foods are now vastly expanded. This places ever-increasing demands on NZFSA resources, especially in terms of identifying emerging hazards associated with changing agricultural practices and new processing technologies, and applying appropriate control measures.

### **Domestic drivers of change**

The seamless nature of the international and domestic food environment means that new and emerging hazards anywhere in the world inevitably impact on domestic stakeholders. Specific concerns of domestic consumers add to the range of potential hazards that must be addressed by NZFSA, which aims to target the steps in the food chain where prevention or control is practical and cost-effective. Areas of increased consumer awareness include nutritional deficiencies and allergens.

In a modern food safety system, there is an ever-increasing onus on the food producer and processor to produce safe food. While the Food Safety Authority is responsible for developing regulatory standards and carrying out other regulatory activities such as consumer education, industry players themselves must implement and verify relevant food control measures to the satisfaction of government. Both the standards themselves and the level of official supervision needed are under constant review by NZFSA in terms of effectiveness and efficiency.

NZFSA's Statement of Intent includes an emerging focus on nutrition and facilitating consumer choices that support better health. This is a complex regulatory area and may involve risk management decisions that have to deal with competing elements, for example the potential of developmental risks in children from low levels of mercury in fish compared with the general nutritional benefits of fish consumption. Regulatory decisions such as this have ever-increasing demands for high-quality scientific input and specialist risk communication skills.



**Figure 1: Global drivers of change in food safety**

#### **NZFSA Statement of Intent 2008–2011**

- Improved safety and suitability of food
- Improved business opportunities through safe and suitable food
- Consumer food practices and choices that support better health

NZFSA also has a mandate to improve business opportunities wherever practicable. 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. Government promotion of economic, environmental and social sustainability (non-harmonised under international food trade agreements) also influences NZFSA domestic regulatory policies.

### **Emergence of food safety risk analysis**

Risk analysis has recently 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**

Risk analysis is supported by a set of internationally agreed principles and guidelines that are now applied by many countries. Three components – risk assessment, risk management and risk communication – are described.

Prevention, reduction or elimination of risks can take many forms and may involve balancing of scientific findings against other questions such as the health expectations of society and the likely costs of potential control measures. Risk communication involves a continuous and interactive exchange of information between all parties throughout the risk analysis process.

Since the early 2000s, Food Safety Authorities around the world have undergone structural change so as to better support risk analysis.



**Figure 2: Components of risk analysis**

### **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:

#### **GHP-based control measures**

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**

These 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**

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 can be validated against a required level of consumer protection.

A modern food safety programme will be made up of food control measures in all these categories. However, 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.

### **Consumer health goals**

Food Safety Authorities around the world are adopting specific consumer health goals as part of government policy. Monitoring 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.

Attribution is a key consideration when setting consumer health goals and represents 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 the Food Safety Authority.

NZFSA has recently established three consumer health goals for New Zealanders:

- 50% reduction in reported annual incidence of foodborne campylobacteriosis after 5 years
- 30% reduction in reported annual incidence of foodborne salmonellosis after 5 years
- no increase in reported annual incidence of foodborne listeriosis over 5 years.

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

In support of NZFSA's goals for reduction in rates of foodborne illness attributable to specific pathogens, 'intermediate' outcomes are expressed in terms of hazard reduction at specific steps in a food chain, as follows:

- one log average reduction in *Campylobacter* on chilled broiler meat against the 2007 baseline, following implementation of a new regulatory standard in early 2008 (interim target)
- 50% reduction in prevalence of *Salmonella* positive broilers after five years
- 50% reduction in prevalence of *E. coli* O157:H7-positive bobby calves after five years.

### **Consumer health goals**

NZFSA goals can be compared with those recently established in other countries. In the United States, the consumer health goals of 'Healthy People 2010' include a 50% reduction in both general cases of campylobacteriosis and cases of post-diarrhoeal haemolytic uraemic syndrome (HUS) in young children by 2010. In the United Kingdom, food safety 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.

### **Risk management and government**

During the years 2002–2007, significant policy and structural changes that supported a risk-based approach to food safety issues were put in place by NZFSA. Regulatory reform also promoted increased stakeholder participation in

standard development and increased the focus on public health outcomes rather than prescription of regulatory process.

Since 2007, NZFSA has been a stand-alone Department of State and has continued to fine-tune the risk-based approach to food safety. New work programmes reinforce the 'production-to-consumption' approach to food control and draw on an increasing range of expertise as inputs to risk-based decisions, eg in areas of economics, human medicine, genomics, information technologies and social sciences. This multidisciplinary approach is important if consumers are to have full confidence in the regulatory activities of NZFSA.

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

Finally, NZFSA recognises that a regulator has a special responsibility to put health risks in perspective in all aspects of its activities. In times of limited technical resources, NZFSA must prioritise its risk management activities to those areas constituting the greatest foodborne risks to consumers. Further, many foods that may have some potential to generate adverse health effects are also essential components of a healthy diet and these situations can comprise complex risk management challenges. The consequences of accepted food practices, eg, adding nitrates to preserve ready-to-eat meats and generation of acrylamides when cooking starch-based prepared foods such as potato chips, also need further research to determine if there are any quantifiable risks associated with levels of exposure in the normal diets of New Zealanders.

## **NZFSA's Risk Management Framework**

**Effective application of risk analysis in food safety is dependent on agreed principles and processes. The most important aspect of risk management in this regard is the consistent and transparent application of a Risk Management Framework (RMF) to all food safety issues.**

While inputs may vary substantially for each issue, risk managers initiate the risk management process and see it through to completion. The benefits of systematic application of an RMF include:

- establishment of food control systems that are risk-based and achieve required levels of consumer protection
- regulatory decisions that are proportionate to the health risks involved
- providing for innovation and flexibility in application of control measures
- allowing due regard to be taken of the costs as well as benefits of regulatory activities.

An RMF facilitates interaction between government, industry, consumers and other stakeholders on many levels and NZFSA can act in a consultative manner that is independent of sector interests. Science can be appropriately merged with other inputs in the development of standards and other risk management activities.

Risk management decisions made by international organisations increasingly influence the NZFSA regulatory environment and impact directly on the domestic marketplace. This creates a strong impetus for an NZFSA RMF that uses risk analysis guidelines adopted by international agencies.

The RMF is a four-step process for risk managers to work through all food safety issues as they arise. This includes the periodic review of old standards and the evaluation of scientific information on new or 're-emerging' hazards that may require regulatory action by NZFSA.

An RMF provides a systematic means whereby knowledge on risk, and evaluation of other relevant factors, are used to choose and implement appropriate food control measures. While all stakeholders have a role, NZFSA as the risk manager is the central player. The process is cyclical, iterative and on-going, with monitoring and review likely to lead to new control measures over time (see Figure 3).



**Figure 3: Components of the RMF**

#### **Sources of NZFSA's RMF**

*Food Administration in New Zealand: A Risk Management Framework for Food Safety*, Joint Ministry of Health and Ministry of Agriculture and Forestry Food Harmonisation Project, 2000, MOH Wellington.

*Food Safety Risk Analysis: A Guide for National Food Safety Authorities*, FAO Food and Nutrition Paper No.87, 2006, WHO/FAO Rome.

*Working Principles for Risk Analysis for Application by National Governments*, CAC Procedural Manual, 17th Edition, 2007, FAO Rome.

*FAO Biosecurity ToolKit*, 2007, FAO Rome.

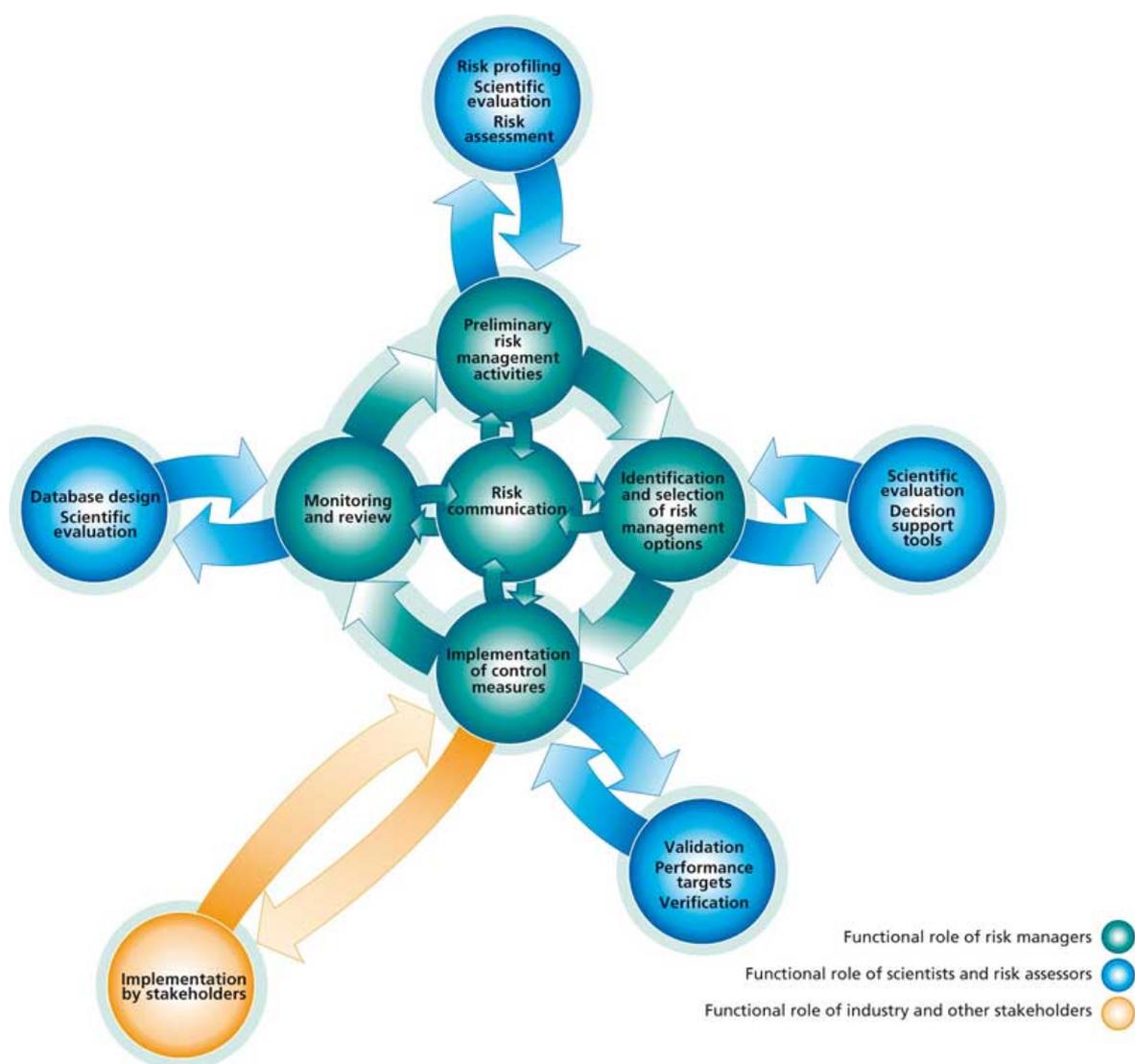
*Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)*, CAC/GL 2007, FAO, Rome.

#### **Role of science**

**An international consensus has now developed that, to the extent practicable, risk assessment should be functionally separate from the standard-setting process carried out by risk managers. The intent of this is to protect the integrity of risk assessment as an objective and unbiased scientific activity.**

NZFSA, along with a number of other Food Safety Authorities, has reinforced this functional separation in its organisational structure. The Science Group is the key repository of 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 for the Science Group.

Scientific inputs are required at all steps in the RMF (as shown in Figure 4).



**Figure 4: Scientific inputs to the RMF**

### Step 1: Preliminary risk management activities

This initial step in the RMF consists of a number of tasks (see Figure 5):

- identification of food safety issues
- risk profiling
- establishing broad risk management goals
- deciding on the need for a risk assessment
- if needed, setting risk assessment policy and commissioning of the risk assessment
- considering the results of the risk assessment
- ranking and prioritisation of the food safety issue for risk management action.

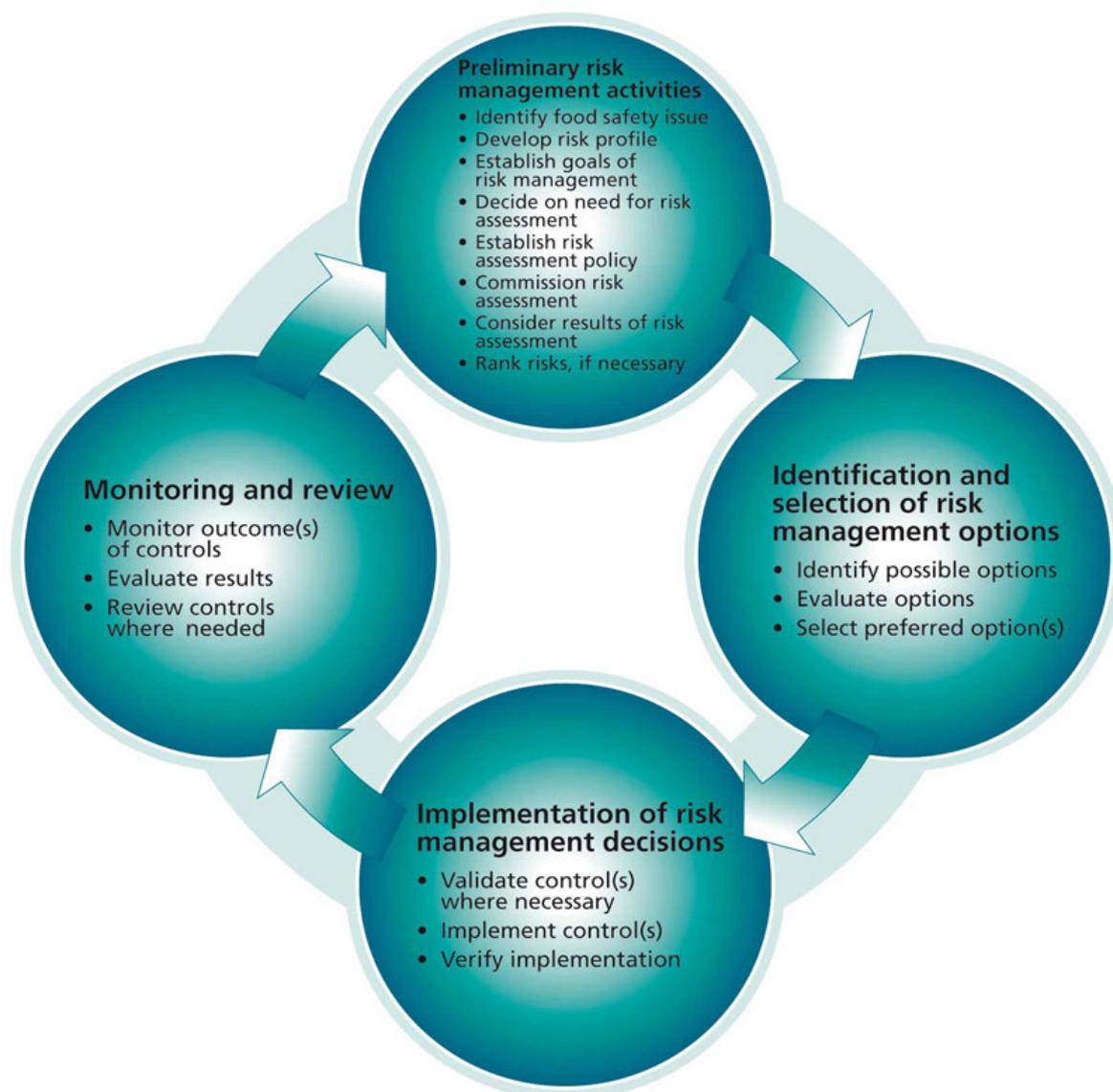
Food safety issues that require a risk management response arise from many sources but most are identified by NZFSA's ongoing activities. External sources include new concerns raised by consumers, requests from industry for the evaluation of new food production and processing technologies, new hazards identified by the global scientific community, and equivalence discussions with trading partners.

Risk profiling provides an opportunity to gather relevant information on an issue and this provides a lead for further action. Each risk profile should be fit-for-purpose – in some situations a very elemental exercise. Components that may appear in a risk profile include:

- description of the food and the food chain scenario
- the biological or chemical characteristics of the hazard
- assembly of scientific information on possible risks
- identification of gaps in scientific knowledge
- description of current control measures
- WTO SPS Agreement implications.

Risk profiling may be used directly by risk managers to guide identification and selection of risk management options, for example where:

- rapid action is needed
- there is sufficient scientific information for action
- embarking on a risk assessment is impractical.



**Figure 5: Individual tasks at each step in the RMF**

#### NZFSA risk profiles

Working closely with ESR, 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 regulatory activities within the RMF process. The profiles constitute a ‘living library’ of up-to-date scientific information specific to New Zealand and are reviewed every five years.

[\*Risk profiles commissioned by NZFSA\*](#)

Following the risk profile, risk managers need to decide on broad risk management goals. This is likely to occur in conjunction with a decision on whether or not a risk assessment is feasible and necessary but should precede actual commissioning of a risk assessment. The broad risk management goals will help direct the scope of a risk assessment and will likely be refined when the outputs of risk assessment are known.

At this stage of the RMF, it is important to recognise that many food safety issues can be actioned without commissioning a risk assessment. Rather, more intense scientific evaluation may be sought and other ways of developing available information on risk may be brought into play, eg food source attribution data derived from surveillance of foodborne illnesses.

#### **Scientific evaluation of aspartame**

Public concerns arose during 2007 in New Zealand over the use of aspartame as an artificial sweetener in foods, with claims of adverse health effects being widely expressed in public 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 by the European Ramazzini Foundation in 2005. 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. Commissioning new risk assessment work in New Zealand was not needed.

During risk assessment, scientific judgements often entail a choice among several reasonable options. Thus gaps in scientific knowledge are bridged through a set of inferences that are called ‘risk assessment policy’. Risk assessment policies are usually generic and are established by risk managers in consultation with risk assessors. They preferably should be established before a risk assessment commences.

#### **‘Safety factors’ in chemical risk assessment**

The application of internationally accepted default ‘safety factors’ by NZFSA when estimating acceptable daily intakes for chemical residues in foods is an example of risk assessment policy. Animal exposure studies are used to determine ‘no observed adverse effect levels’ and then a safety factor of 10 is applied in case there is any biological variation. An additional factor of 10 is applied in case there is any interspecies variation when extrapolating from the animal test species to humans.

If it is decided to commission a risk assessment, the risk manager should clearly define, in association with the risk assessors, the scope, purpose and expected outputs. The required resources should also be agreed, and in some cases simple projects will be able to be undertaken by individuals. NZFSA may have to contract scientific research to fill data gaps as the risk assessment proceeds.

#### **Risk assessments commissioned by NZFSA**

Recent risk assessments have determined risks associated with:

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

#### **NZFSA *Campylobacter* in Poultry Strategy 2007–2010: A combination of scientific evaluations and risk assessment within an RMF process**

Following development of a comprehensive risk profile on *Campylobacter jejuni/coli* in poultry, NZFSA has implemented a detailed *Campylobacter* Strategy with the goal of significantly reducing foodborne risks to consumers from broiler chickens.

##### [NZFSA's \*Campylobacter\* in Poultry Risk Management Strategy](#)

Because of the severity of the problem, preliminary risk management activities cover a range of scientific projects. Short-term responses include scientific collaboration with industry to develop codes of hygienic practice for both producers and processors. Medium-term responses include scientific evaluation of the likely level of hazard control associated with a number of hazard-based interventions. Meanwhile, a farm-to-plate risk assessment model is being developed so that risk-based controls that achieve agreed levels of consumer protection can be regulated in the longer term.

Proper interpretation of the outputs of the risk assessment by the NZFSA risk manager is a vital function. Risk assessors should clearly describe the uncertainty in a risk estimate and its origins. The overall strengths and weaknesses of the risk assessment should be discussed and documentation should include a general summary that is easily understandable by lay stakeholders.

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.

#### **Domestic Food Review**

NZFSA is undertaking a comprehensive long-term review of regulatory involvement in the

domestic food sector. An important part of the project is application of risk ranking and prioritisation methodology in the early stages. The findings from the ranking and prioritisation models will provide a basis for the transition and implementation plan.

[NZFSA's 'Domestic Food Review'](#)

## **Step 2: Identification and selection of risk management options**

In the second step, potential risk management options are identified and then selected by risk managers according to appropriate criteria. NZFSA strives to involve all stakeholders to the extent possible, as well as providing a clear rationale for the final decisions taken. As a general principle, all parts of the food chain should be taken into account when selecting control measures.

### **Possible control measures for *Campylobacter* in broilers**

The NZFSA *Campylobacter* Strategy identifies numerous control measures that need to be evaluated in the New Zealand context and these include:

- quarantine of the production environment
- decontamination of drinking water
- testing of flocks prior to slaughter
- biological decontamination (bacteriophages)
- improved process hygiene
- chemical decontamination of carcasses
- performance targets for chilled carcasses (see below)
- leak-proof packaging at retail
- consumer education.

During identification and selection of risk management options, risk managers will likely have asked the risk assessors to examine the impact of different control measures on minimising risks. This process may continue until one or more risk management options that achieve the desired level of consumer protection are chosen.

### **Level of consumer protection**

Establishing the level of consumer protection to be achieved by the control measures is a core part of Step 2 in the RMF process. Decisions can be influenced by a wide range of economic, political, social and environmental factors.

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 1 case of disease Y per 100,000 people per year in the general population. 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.

#### **Examples of approaches to establishing levels of consumer protection**

The NZFSA *Campylobacter* Strategy incorporates a risk-balancing approach, ie cost-benefit analysis and an ‘as-low-as-reasonably-achievable’ (ALARA) level of risk reduction, in significantly reducing *Campylobacter* and *Salmonella* contamination of broiler chickens in modern processing systems. This approach is reflected in NZFSA’s goal to have reduced foodborne *Campylobacter* illnesses by 50% by 2010.

##### [NZFSA’s \*Campylobacter\* in Poultry Risk Management Strategy](#)

Direct comparison of risks using surveillance data and food attribution studies were used to apportion risks from different *Salmonella* serotypes in a range of foods and prioritise those at unacceptable levels for specific food chain interventions.

##### [NZFSA’s Science Report ‘Modelling of exposure of New Zealanders to \*Salmonella\*’](#)

NZFSA uses a generic ‘notional zero-risk’ as the required level of consumer protection for chemicals that are intentionally added to the food supply such as food additives or veterinary drugs, ie 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, eg 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 metabolites in deer velvet was set.

Costs and benefits associated with a risk management scenario need to be evaluated in an understandable and transparent manner. As well as economic analysis, the technical feasibility and practicality of available risk management options must be appropriately evaluated. This includes the ability to verify and enforce any regulatory standards that may be decided upon.

#### **Performance objectives as risk management options**

Where microbial 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 an RMF 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, eg those due to *E. coli* O157:H7 and *E. sakazakii*, is even more difficult. (This is in contrast to decisions on risks from certain chemical hazards in the food

supply, such as 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 an RMF and improving attribution surveillance data allows the risk manager to monitor progress and modify targets as needed. If continuous improvement in consumer health is not achieved, the stringency of hazard-based targets can be increased. The disadvantage of this approach is that in the absence of risk assessment, there is no opportunity to compare the effectiveness of different targets (or different control measures) in achieving consumer health goals.

#### **NZFSA *Campylobacter* Strategy 2007–2010**

The NZFSA *Campylobacter* Strategy seeks to significantly reduce foodborne risks to consumers from broiler chickens. A number of risk management options are being developed, including GHP-based, hazard-based and risk-based control measures.

In early 2008, NZFSA regulated a hazard-based target in the form of a quantitative limit for *Campylobacter* on chilled carcasses. This is an interim response to a severe public health problem.

When the farm-to-plate risk assessment has been completed, a risk-based evaluation of available control measures will be undertaken and a performance objective established on this basis.

[NZFSA's \*Campylobacter\* in Poultry Risk Management Strategy](#)

## **International trade**

In imported food situations, the WTO SPS Agreement places specific constraints on factors that can be included in decisions on ‘appropriate levels of protection’ (ALOP) that are chosen by NZFSA. Decisions should take into account the minimisation of trade effects and ensure that selected control measures are not more restrictive than necessary to meet an ALOP. NZFSA must also avoid unjustifiable or arbitrary distinctions in levels of ALOP chosen in different food safety situations.

#### **NZFSA policy on equivalence**

Judgement of the equivalence of different food safety control measures for exported food is of vital importance to New Zealand. 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 RMF has allowed NZFSA to achieve judgements of equivalence 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 and highly cost-effective risk management options, ie lesser intensity meat inspection and a detailed trace-back and farm quarantine system, achieved the

same level of consumer protection.

## Uncertainty

Uncertainty is intrinsic to risk analysis and a precautionary approach to food safety is expressed in various ways during risk assessment and risk management activities. Precautionary positions may be intrinsic to risk assessment policy, eg use of safety factors in establishment of acceptable daily intakes for chemical residues in food, or may be introduced on a case-by-case basis, eg ‘worst-case’ modelling scenarios where pathogens have a low infective dose and/or severe adverse health consequences.

Different approaches may be taken to risk management in the face of scientific uncertainty in different political, social and economic contexts. In some cases, consumer fears have driven actual bans on trade even though this was not 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: H7) in exported product might include a worst-case reaction from trading partners.

NZFSA does not have a specific policy on application of a precautionary approach in the face of scientific uncertainty. Rather, there is an understanding that incorporation of precaution in the RMF will be 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, and the degree of uncertainty in the scientific evaluation. The regulatory response will prevent or limit exposure while more conclusive information is gained on the actual risks faced and the control measures that are likely to be most effective. For products in trade, there is an obligation under the WTO SPS Agreement to actively pursue additional scientific information when a precautionary approach is taken, with timely review of interim control measures.

### **Pyrrolizidine alkaloids in honey**

Monitoring by NZFSA as part of the National Residue Monitoring Programme recently showed that the speciality vipers bugloss honey was contaminated with 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 was taken. The chemical risk assessment used data from the most toxic of the known alkaloids to establish an acceptable daily intake (ADI) and the monitoring information from 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:H7 and other shiga toxin-producing pathogens in uncooked comminuted fermented 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 risk-based processing standard that mirrors overseas standards for this product has been 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 inactivate any pathogens that may be present.

Risk management of genetically modified foods also illustrates a precautionary approach. At present, only a limited number of these foods are traded across New Zealand borders and this is largely a consequence of precaution by risk managers because of the high perceptions of risk by some consumers. In some cases, partial risk assessments and incomplete substantiation of the benefits and risks of genetically modified food have resulted in controversy over their safe use and their safe release into the environment.

### **Step 3: Implementation of control measures**

Industry working throughout the food chain has the primary role in implementation of control measures. Nevertheless, NZFSA may be directly involved in this step in the RMF, such as in supervisory meat inspection. More often, the Verification Agency of NZFSA will verify control measures implemented by industry. The Compliance Group of NZFSA carries out an independent audit of regulatory functions and applies sanctions where control measures have not been properly implemented by industry.

The Approvals and Registration Group of NZFSA also carries out an implementation function by registering food premises and approving food safety plans developed by industry.

NZFSA often develops implementation tools to assist stakeholders in implementing regulatory requirements. Examples are generic codes of hygienic practice for different food commodities, guidelines on quality assurance systems, accreditation systems for laboratories, and assisting with training and education.

Farm-to-plate approaches to food safety promote design of integrated food safety programmes that make the best use of industry and government food safety resources. The NZFSA Campylobacter Strategy is a good example of an alliance between the poultry industry and the regulator to implement the most effective control measures in an integrated manner.

### **Step 4: Monitoring and review**

The aim of monitoring by NZFSA is to gather and analyse data on the level of control of specific hazards throughout the food chain and combine this with human health surveillance data to determine the effectiveness of regulatory activities. This may be carried out ahead of implementation of control measures so as to establish baseline levels or it may follow their implementation.

NZFSA has an extensive programme for monitoring hazard levels in the food chain compared with many countries.

#### **Monitoring of the food chain by NZFSA**

Monitoring programmes carried out by NZFSA include:

- [National Microbiological Database for systematic and ongoing monitoring of premises](#)  
slaughtering cattle, sheep, deer, goats, poultry and ostriches
- [Food Residue Surveillance Programme for compliance with chemical food safety standards](#)  
across a wide range of foods
- [Total Diet Survey for evaluating the level of exposure of the New Zealand population to chemicals in the food supply](#)

- [National Residue Monitoring Programme for exported foods.](#)

Evaluating data on hazards and risks on a periodic basis provides NZFSA with information on the effectiveness of their risk management decisions and actions. It also helps to identify new food safety problems as they emerge. For imported foods, it is not possible to check every unit or lot in a consignment for the presence of hazards and monitoring programmes in the country of origin are sometimes used by NZFSA as a means to improve the limited assurance that can be gained from sampling plans applied at the border.

#### **Human health surveillance**

National human health surveillance activities administered by the New Zealand Ministry of Health are an important part of monitoring and review by NZFSA. In some cases, NZFSA will initiate and fund sentinel site studies where data on specific hazards in the food chain is lacking and the resultant level of foodborne disease is unknown. In liaison with ESR, NZFSA assists in analysis of human health statistics on gastrointestinal illness and has developed food source attribution factors for the most important pathogens, eg an expert elicitation workshop convened by NZFSA developed attribution factors for foodborne campylobacteriosis, salmonellosis, listeriosis and norovirus in New Zealand of 0.6, 0.6, 0.8 and 0.4 respectively.

While not quantitatively linked to foodborne risks per se, there are many opportunities to use monitoring of the food chain to demonstrate that control measures have prevented the level of exposure to biological and chemical hazards from increasing. In other situations, planned reduction in levels of exposure to specified hazards can be demonstrated. The NZFSA National Microbiological Database, continuously applied to all of the major meat slaughter species, is showing gradual improvements over time for process hygiene indicators and gradual reductions in levels of microbial pathogens originating on the farm.

Where monitoring of hazards or risks indicates that food safety goals are not being achieved, risk management strategies and/or control measures will need to be reviewed. Review may also be required when new information on hazards and/or risks arises or new market access requirements are imposed.

#### **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 to not set a maximum limit for the speciality vipers bugloss honey.

Monitoring and review is greatly enhanced by effective communication networks and linkages with offshore Food Safety Authorities. Trading agreements often contain obligations on monitoring and where possible, NZFSA links up with international organisations which operate early warning systems for foodborne disease, eg the World Health Organization INFOSAN system.

## **Annex 1: Risk Assessment**

**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, eg ranking of 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 consisting of four steps (shown in Figure 6). Steps 2 and 3 can be carried out in any order.

#### **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 of different hazards in a food(s) 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 6: 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 in a risk assessment (the quality of being unknown) 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.

### **Sensitivity analysis**

Sensitivity analysis helps NZFSA risk assessors to select those control measures that best achieve risk management goals. Probabilistic software programmes can perform sensitivity analysis by producing graphs or rank correlation statistics between input parameters and output parameters. This allows risk assessors to systematically investigate which input variables have the greatest influence on the outputs of the risk assessment.

## **Annex 2: Risk Communication**

Risk communication encompasses a continuous and interactive exchange of information between all parties involved in food safety. It describes the work done by NZFSA to bridge the gap between the evaluation of risk by experts and the views of other stakeholders, eg safety assessments of genetically modified organisms carried out by Food Standards Australia and New Zealand (FSANZ) have not revealed any evidence of adverse health effects, yet consumers continue to be concerned about transgenic plants in the food supply, especially in relation to possible long-term health and environmental effects. NZFSA takes into account knowledge, attitudes, values, practices and perceptions of stakeholders when communicating risk management options and decisions.

### **NZFSA risk communication strategy**

NZFSA has a fully documented risk communication strategy and develops specific implementation plans that engage with internal (eg administrators, risk managers, risk assessors and risk communicators) and external stakeholders on food safety issues. Stakeholder interests may be significantly affected by regulatory risk management decisions and participation and involvement of stakeholders throughout all phases of the RMF process is essential.

The nature and urgency of the risk information to be conveyed will drive each implementation plan. This can range from predominantly one-way communication to 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 communication must also service international reporting obligations.

A variety of methodologies are used to communicate with the public. Active methods such as media-based information campaigns, websites, email alerts and 0800 telephone information services are employed in risk events that are of high interest to the public and/or industry. Scheduled meetings with stakeholder representatives (eg quarterly meetings with consumer advocates) are a good means of proactively engaging on upcoming issues. Routine publication of periodicals, pamphlets and technical reports by risk communicators are other vehicles by which NZFSA improves public awareness and knowledge.

### **Emergency situations**

Risk communication in an emergency situation requires a tailor-made implementation plan and NZFSA has developed an Emergency Communication Programme and supporting manual to enable the organisation to move quickly into response mode when necessary. The programme is shared with the Ministry of Agriculture and Forestry (MAF) and Biosecurity New Zealand (BNZ) and can accommodate a range of responses.

Where risk communication needs span multiple sectors, the joint NZFSA/MAF/BNZ approach clearly differentiates the likelihood of animal health impacts versus the likelihood of human health impacts when there is an epidemic of exotic disease, eg ‘highly pathogenic’ avian influenza. Even so, public reactions are unpredictable. In the recent 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.

### **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 properly understand their motivations and opinions. Risk communicators, risk managers and risk assessors should all contribute to this task.

When communicating on risk issues, NZFSA strives to fully understand risk perception factors. Humans tend to fear similar things for similar reasons and the study of risk perception identifies the psychological factors by which we subconsciously ‘decide’ what to be afraid of – and how afraid to be. Public perception of risks often differs from expert analysis and the public’s judgement of benefits and risks is significantly affected by information flows. Thus it is necessary to identify the most appropriate media to disseminate information to, and communicate with, different types of stakeholders. Key messages must take into account distributional issues, eg who benefits and in what way, and the importance of the benefit. Key messages must effectively communicate the degree and significance of uncertainty in the risk assessment.

Stringent risk communication efforts are made by NZFSA to nurture public trust and credibility. Above all, information is disseminated as soon as possible in an unfolding food safety situation, with frequent updates, so that stakeholders do not become focused on a perceived suppression of facts rather than management of the risk itself.

The clarity and impact of key messages for each stakeholder group is monitored by NZFSA to the extent practicable. Public opinion research can be used to gauge whether all relevant target groups were reached and if their level of understanding of key messages was adequate. Behaviour change as a result of risk communication is also evaluated if appropriate. Reasoned involvement with stakeholders throughout a risk analysis process helps with acceptance of a final risk management decision, even if stakeholders are not in agreement.

## Appendix 2

### NZFSA Media release

#### A1/A2 milk review released

3 August 2004

Consumers are advised to keep drinking milk as a nutritious food, no matter whether it's A1 or A2, as there is no food safety issue with either type of milk, says NZFSA Director of Food Standards, Carole Inkster.

“Professor Boyd Swinburn’s review of the literature on possible benefits of A2 milk over A1 concludes that there is insufficient overall evidence that either milk has benefits over the other. However, it does note that further work is needed in this area to determine any causative relationships between types of milks and certain diseases.”

The report, *Beta casein A1 and A2 milk and human health*, available in full from the NZFSA web site, examines whether some milk proteins might cause or protect against type 1 diabetes, heart disease, schizophrenia and autism.

Professor Swinburn concludes in the report:

“The hypothesis that a high intake of milk containing A1  $\beta$ -casein promotes conditions as heterogeneous as DM-1 [type 1 diabetes], IHD [Ischaemic heart disease], schizophrenia and autism is intriguing and potentially important. There is some very suggestive evidence from ecological studies for DM-1 and IHD, and there is certainly a possibility that the A1/A2 composition of milk is a factor in the etiology of these conditions. However, this hypothesis has yet to be backed by good human trials. The evidence in relation to autism comes mainly from poorly controlled clinical trials of gluten-free, casein-free diets where some improvement is noted in the autism characteristics and behaviours. The evidence in relation to schizophrenia is very minimal.”

Carole Inkster says Professor Swinburn’s review shows that there is insufficient evidence to demonstrate benefits of one type of milk protein over another.

“We will be liaising with the Commerce Commission over what further steps, if any, need to be taken to ensure that consumers have the information they need to make a fair and informed choice.”

## **Appendix 3**

### **EXECUTIVE SUMMARY OF THE SWINBURN REPORT**

#### **Background**

There are several genetically-determined variants of  $\beta$ -casein, the protein which constitutes about 25-30% of cows' milk proteins. One variant, A1  $\beta$ -casein, has been implicated as a potential etiological factor in type 1 diabetes mellitus (DM-1), ischaemic heart disease (IHD), schizophrenia, and autism. Another variant (A2  $\beta$ -casein) has not been implicated in these diseases.

It is known that nutrition in early life has important health consequences in both childhood and adulthood. Cows' milk is a basic food for most infants and children and a common food for adults in most western societies. Therefore, if some components of milk are causative or protective of the diseases mentioned, it would have major public health implications.

The evidence to support the hypothesis that the A1/A2 composition of milk is an etiological factor in these diseases is reviewed.

#### **Type 1 diabetes mellitus**

There is a consensus that type 1 diabetes mellitus (DM-1) is caused by one or more environmental triggers which, in genetically susceptible people, promotes an autoimmune process that destroys the insulin-secreting, pancreatic  $\beta$ -cells. The evidence that A1  $\beta$ -casein is one such trigger comes mainly from ecological studies. The strength of the correlations between countries of their A1  $\beta$ -casein consumption and their incidence rate of DM-1 is extremely high, although such correlations cannot establish cause and effect and are subject to bias. The clinical studies available (mainly case-control studies of markers of immune reaction) are not very helpful in establishing cause and effect relationships because people with DM-1 (and other autoimmune diseases) have increased immune reactivity to many different antigens. The results from studies using animal models of DM-1 are mixed. The best-designed of the animal studies showed very little effect of a diet high in A1  $\beta$ -casein on the development of diabetes. It is known that A1  $\beta$ -casein is cleaved enzymatically in the gut to produce a molecule ( $\beta$  casomorphin-7) which has some morphine-like actions in the body and it is postulated that this may influence the immune surveillance. A2  $\beta$ -casein, the other main casein variant, does not undergo this cleavage and is not implicated in the disease processes.

## **Cardiovascular diseases**

Ischaemic heart disease (IHD) and stroke represent the clinical outcomes of pathological processes that occur over decades (atherosclerosis) and acutely (thrombosis, arrhythmias). These processes are multi-factorial and several risk factors have been well established (smoking, high blood pressure, high cholesterol etc). The evidence that a high intake of A1  $\beta$ -casein is also a risk factor for IHD rests mainly on the same type of ecological data that the DM-1 case rests on. The correlations, while not as high as for DM-1, are still impressive for such a multi-factorial disease. The available clinical evidence is sparse and unhelpful in determining whether this is a true cause and effect relationship. One animal study showed some support for the atherogenic nature of a diet with a very high A1  $\beta$ -casein supplementation, but the results were far from conclusive and there is difficulty on translating animal studies to human health.

## **Neurological disorders**

There have been several poorly-controlled clinical trials of casein-free, gluten-free diets in people with autism. In general, the diets seem to reduce some of the autistic behaviours, but the bias inherent in the studies (especially lack of blinded assessment) may explain some of the findings. The evidence that A1  $\beta$ -casein is related to schizophrenia is very scant.

## **Implications**

All the conditions discussed are major contributors to mortality and morbidity, so any dietary factor that could reduce the burden they impose should be taken seriously and examined for potential public health and clinical recommendations. It is abundantly clear that much more research is needed in all of these areas, although it is acknowledged that the vested commercial interests in the research and its outcomes adds a major complicating factor to the progression of science, the use of the knowledge, and the communications to the public. The appropriate government agencies have several important responsibilities in this matter: to support further research in the area (especially clinical research); to clearly communicate the state of knowledge and judged risks to the public, and; to take specific actions to promote and protect the health of the public, where appropriate.

The first two actions are clearly warranted based on the evidence to date. In my opinion, however, I do not believe there is sufficient evidence to warrant the government agencies taking further specific public health actions such as changing dietary recommendations, requiring labelling of products containing A1  $\beta$ -casein, or encouraging changes in the dairy herd composition in order to promote and

protect the health of the population. There is a requirement to monitor the health claims being made for A2 milk to ensure that they comply with existing regulations.

Those involved in the dairy and associated industries have to make their own judgements about strategies under their control such as changing dairy herd composition. These decisions will undoubtedly be made on a commercial basis. Changing dairy herds to more A2 producing cows may significantly improve public health, if the A1/A2 hypothesis is proved correct, and it is highly unlikely to do harm.

As a matter of individual choice, people may wish to reduce or remove A1  $\beta$ -casein from their diet (or their children's diet) as a precautionary measure. This may be particularly relevant for those individuals who have or are at risk of the diseases mentioned (type 1 diabetes, coronary heart disease, autism and schizophrenia). However, they should do so knowing that there is substantial uncertainty about the benefits of such an approach.

## Appendix 4

### Lay summary of the Swinburn report

About 25-30% of the protein in cows' milk is  $\beta$ -casein and it comes in several forms depending on the genetic make up of the cows. One of the forms is called A1  $\beta$ -casein and it has been suggested that it might cause or aggravate one type 1 diabetes (which is the type seen most commonly in children), heart disease, schizophrenia, and autism. The other main form of  $\beta$ -casein is called A2 and it has not been not been implicated in these diseases. The evidence to support the hypothesis that the A1/A2 composition of milk is a causative or protective factor in these diseases is reviewed in the report.

The strongest evidence is for type 1 diabetes and heart disease. The main study supporting a relationship with the type of milk consumed was a comparison of 20 countries. Those countries with the highest consumption of A1  $\beta$ -casein had the highest rates of type 1 diabetes and heart disease. The relationship was very strong indeed, but these types of comparisons between countries can be difficult to interpret. There are many other factors that contribute to these diseases and the information is only averaged for the whole country's population. There have been a few other human and animal studies which provide some limited support for the hypothesis. Further research, especially involving human trials, is needed before it can be said with confidence that the A1/A2 composition of milk is important in human health.

The evidence in relation to an effect of A1  $\beta$ -casein on schizophrenia or autism is much less. Some individuals with autism seem to improve on special diets that are free of both casein and gluten.

The A1/A2 hypothesis is both intriguing and potentially very important for population health if it is proved correct. It should be taken seriously and further research is needed. In addition, the appropriate government agencies have a responsibility to communicate the current state of evidence to the public, including the uncertainty about the evidence. Further public health actions, such as changing dietary advice or requiring labelling of milk products, are not considered to be warranted at this stage. Monitoring is also required to ensure that any claims made for A2 milk fall within the regulations for food claims.

Changing the dairy herds to more A2 producing cows is an option for the dairy and associated industries and these decisions will undoubtedly be made on a commercial basis. Changing dairy herds to more A2 producing cows may significantly improve public health, if the A1/A2 hypothesis is proved correct, and it is highly unlikely to do harm.

As a matter of individual choice, people may wish to reduce or remove A1  $\beta$ -casein from their diet (or their children's diet) as a precautionary measure. This may be particularly relevant for those individuals who have or are at risk of the diseases mentioned (type 1 diabetes, coronary heart disease, autism and schizophrenia). However, they should do so knowing that there is substantial uncertainty about the benefits of such an approach.