RANKING FOOD SAFETY RISKS
A DISCUSSION DOCUMENT

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by

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1 INTRODUCTION

1.1 The NZFSA's Risk Management Framework for Food Safety

The New Zealand Food Safety Authority (NZFSA) has adopted a structured approach to food safety risk management. Details of the generic approach have been published in the document "Food Administration in New Zealand: A Risk Management Framework for Food Safety" (Ministry of Health/Ministry of Agriculture and Forestry, 2000). Figure 1 outlines the risk management process. The NZFSA's risk management framework adopts the following definitions:

- A **hazard** is a biological, chemical or physical agent in food that has the potential to cause an adverse health effect in consumers.
- **Risk** is a function of the probability of adverse health effects and the severity of those effects in the population consuming that food.
- **Risk management** is the process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant to health protection of consumers and promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.

The four-step framework for food safety risk management is shown in Figure 1.

Figure 1: Risk Management Framework

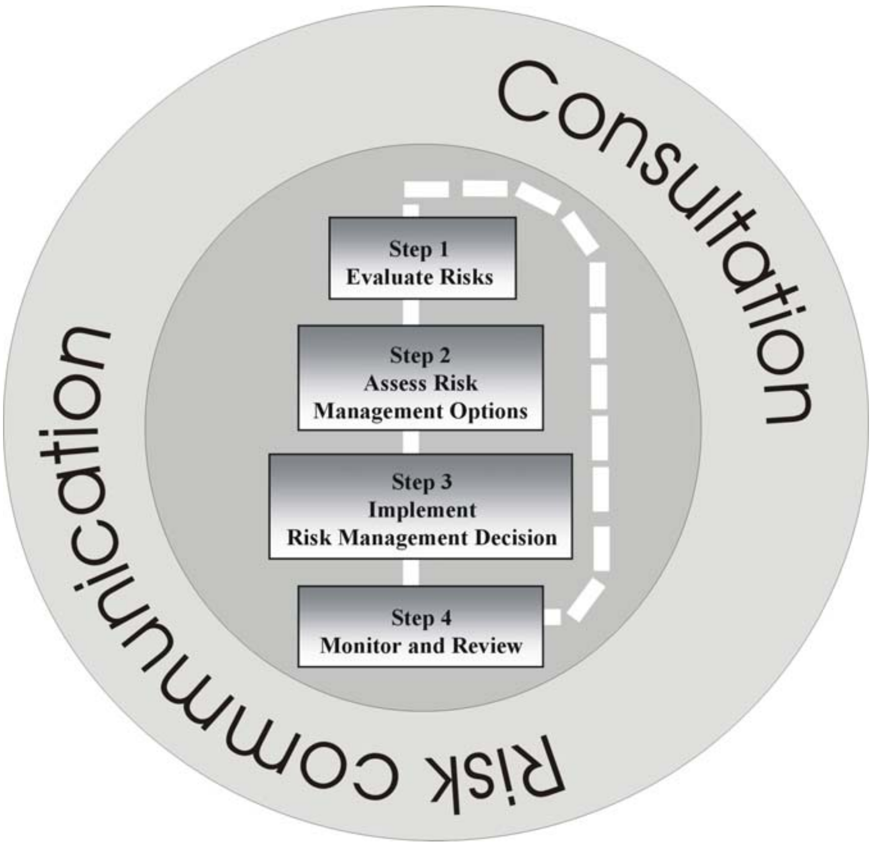

Figure reproduced from "Food Administration in New Zealand. A risk management framework for food safety" (Ministry of Health/Ministry of Agriculture and Forestry, 2000).

In more detail, the four-step process is:

1. Risk evaluation

- identification of the food safety issue
- establishment of a risk profile
- **ranking of the food safety issue for risk management**
- establishment of risk assessment policy
- commissioning of a risk assessment
- consideration of the results of risk assessment

2. Risk management option assessment
- identification of available risk management options
- selection of preferred risk management option
- final risk management decision

3. Implementation of the risk management decision

4. Monitoring and review.

Since 2000 effort in Step 1: Risk Evaluation has involved preparing risk profiles for microbiological hazards in particularly foods ('food safety issues'). This process is now well established and attention moves to the next step in the risk evaluation process – the ranking of the food safety issue for risk management.

1.2 The Current Project

For regulators to make the best use of food safety resources, they need to identify, assess and compare the risks posed by various contaminant/food combinations and prioritise opportunities for reducing risks through targeted food safety initiatives (Taylor and Hoffman, 2001). The process of comparing risks and ordering or grading them in some manner is known as risk ranking or comparative risk assessment (CRA).

This document reviews existing models and practical examples of risk ranking exercises, which are principally from overseas. The information in this document will provide a basis for development of a consultative approach to ranking of risks associated with hazards in New Zealand consumed foods. The intention was to cover risk ranking as a process, without being restricted to ranking of food safety issues.

Information on risk ranking was retrieved by:
- On-line searching using search tools for the scientific literature (PubMed, Embase);
- Review of back issues of the key scientific journal "Risk Analysis"; and,
- Internet based searches of general and government sources.

In this document risk ranking refers to a process that uses scientific information to compare the magnitude of the risks associated with a set of problems or issues, and is as objective as possible. This process is treated as distinct from risk prioritisation, which may involve additional non-scientific information and considerations, such as political and social criteria.

1.3 Objectives of Risk Ranking

Risk ranking or comparative risk analysis (CRA) is driven by the premise that if the relative risks of a range of problems can be established, then risk reduction efforts can be directed at the worst problems first. CRA has been applied mainly to environmental problems and has been used at national and sub-national levels overseas to inform environmental policy development. CRAs conducted to date have four main objectives (Konisky, 1999):
1. Involve the public in priority setting and identify and incorporate their concerns;
2. Identify the greatest (environmental) threats and rank them accordingly;
3. Establish (environmental) priorities; and,
4. Develop action plans/strategies to reduce risks.

While, risk ranking and CRA are often regarded as synonymous, the objectives outlined by Konisky go beyond the ranking of risks and incorporate the subsequent risk management activities of risk prioritisation and the development of risk reduction strategies. The approach taken in this document restricts the objectives of risk ranking to the first two of Konisky above. These two objectives are well aligned with the conditions for risk decision-making proposed by Webler *et al*. (1995):
- Decisions should be based on the best available scientific knowledge; and,
- Citizens with an interest in the situation should have some say in the decision.

The "best" decision has been described as the one that is both scientifically competent and democratically accepted (Webler *et al*., 1995).

1.4 The Risk Ranking Process

A risk ranking exercise has three main components (Konisky, 1999):
- Problem list
- Criteria for evaluating problems. Criteria must consider the types of risks analysed (human health, quality-of-life, trade, economic), the scope of the risks considered (inherent, residual) and the participants conducting the ranking (public, expert). Criteria may be a mixture of quantitative and qualitative descriptors.
- Ranking. Process of sorting data and drawing conclusions on relative severity of problems. This inevitably involves comparing problems against several criteria at once.

These components have been incorporated into a five-step risk ranking method that was developed in a project undertaken for the US EPA (Florig *et al*., 2001). The process is summarised in Figure 2.

Step A and Step B are intended to be iterative before proceeding to Step C. Step B implies decisions about the criteria to be used.

This model only specifies stakeholder involvement in the ranking process, but decisions as to the criteria (risk attributes) will also require stakeholder input. Nevertheless this model will serve to structure this discussion document.

Figure 2: EPA five-step risk ranking process

Step A:
Define and categorise the risks to be ranked

Step B:
Identify the risk attributes that should be considered

Step C:
Describe the risks in terms of the attributes in risk summary sheets

Step D:
Select participants and perform the risk rankings

Step E:
Describe the issues identified and the resulting rankings

The New Zealand Ministry for the Environment has carried out a scoping study for CRA (MfE, 1996), in which they propose a six-step process:

1. Problem definition (develop set of desired environmental outcomes, identify environment problems and risks).
2. Risk analysis (categorise risks, identify risk attributes, describe risk in terms of attributes)
3. Risk ranking (perform ranking, merge results, summarise the results)
4. Risk reduction evaluation (identify risk reduction options, identify criteria to evaluate options, describes options in terms of criteria)
5. Ranking of risk reduction potential (re-rank risks in terms of risk reduction potential, focus on risks with high risk reduction potential)
6. Publication of list of identified priorities (explain analytical and ranking methods, list data sources and assumptions, show techniques and assumptions for future estimation of risk)

While the approaches of the MfE and the EPA share common themes, the MfE approach goes beyond risk assessment/evaluation into areas of risk management and prioritisation. We view these as two quite distinct activities and the current discussion document will only deal with aspects relating to the first three steps of the MfE six-step process. However, the MfE process does identify one element not included above - the development of a set of desired outcomes.

More complex mathematical risk ranking models have been proposed (e.g. Long and Fischhoff, 2000) but at this stage of the NZFSA process a non-mathematical model was considered more useful for consultation.

2 STEP A: DEFINITIONS AND CATEGORIES OF RISK

Problems can be defined in many ways, including:

- by hazard (*Campylobacter, Salmonella)*,
- by source (farm derived, processing derived),
- by pathway (chicken, cheese, environmental), or
- by target group (whole population, young children).

The risk ranking process is significantly simplified if a consistent approach is taken in the definition of the problem list. One of the earliest large-scale CRAs was the US Environmental Protection Agency's analysis of environmental issues in the USA, published under the title *Unfinished Business: A comparative assessment of environmental problems* (EPA, 1987). While certainly a landmark study, the EPA's efforts have been criticised for not adopting a consistent approach to classification of problems (Morgan *et al.*, 2000) and included a mixture of pollutants (air pollutants, drinking water pollutants), pollution sources (oil spillages, mining wastes) and receptors (consumers, workers).

The current approach to the development of risk profiles for the foods New Zealanders eat uses a consistent approach to the definition of problems ("specific food safety problems"; Ministry of Health/Ministry of Agriculture and Forestry, 2000) as the problem is consistently defined in terms of a specific hazard or related group of hazards (e.g. shiga-like toxin producing *Escherichia coli*) in a particular food or related group of foods. Despite this, the issue of risk categorisation is important to risk ranking and is further discussed in subsequent sections of this report.

2.1 Categorisation of Risks

Often the number of potential risks which the risk managers are responsible for may be too large to make overall risk ranking feasible. This problem can be overcome by categorisation of the risks under consideration, followed by ranking of categories on a single or number of axes (Morgan *et al.*, 2000). Defining the categories by which hazards are grouped requires value choices and can have important implications for the resultant rankings. Development of an explicit basis for choosing a risk-categorisation scheme is seen as crucial if an agency wishes to use the results of a risk ranking project as an input into risk management.

Two main approaches to categorisation are discussed by Morgan *et al*. (2000):

(1) Similarity-based view. This view holds that the inclusion of a particular instance in a category is based on the similarity of that instance to some abstract specification. This may be achieved in three ways:

- Instances may be included in a category due to a 'family resemblance' to an idealised category member of 'prototype'.
- Categories are constructed on the basis of similarity comparisons between the individual instances ('exemplars').
- Categories result from the use of cognitive schema that include the prototype and the individual exemplars.

(2) Explanation-based view. In this view categorisations are constructed on the basis of relationships which exist between instances and categories. Instances which initially appear to have nothing to do with each other may be linked to form a category through some underlying scenario or knowledge structure.

In relation to food safety, an example of the similarity-based view might be categories based on hazards which are bacterial, viral or parasitic. An explanation-based view might create another category of microbiological hazards for which foodborne transmission is believed to be significant.

MfE (1996) suggested some additional means to classify problem areas; by receptor and by departmental responsibility. A classification based on receptor approach may question whether the risk is to a particular ecosystem, geographical area or political area. Classification by departmental responsibility may be particularly relevant to the consideration of foodborne risks. For example, food contaminated through contact with contaminated irrigation water will invoke different departmental responsibilities to food contaminated through handling by an infected food handler.

Morgan *et al*. (2000) defined a set of desirable attributes for an ideal risk categorisation system. These are reproduced in Table 1.

Table 1: Desirable attributes of an ideal risk categorisation system for risk ranking

LOGICALLY CONSISTENT • Exhaustive so that no relevant risks are overlooked • Mutually exclusive so that risks are not double counted • Homogeneous so that all risk categories can be evaluated on the same set of attributes
ADMINISTRATIVELY COMPATIBLE • Compatible with existing organisational structures and legislative mandates so that lines of authority are clear and management actions at cross purposes are avoided • Relevant to management so that risk priorities can be mapped into risk management actions • Large enough in number so that regulatory attention can be finely targeted, with a minimum of interpretation by agency staff • Compatible with existing databases, to make best use of available information in any analysis leading to ranking
EQUITABLE • Fairly drawn so that the interests of various stakeholders, including the general public, are balanced
COMPATIBLE WITH COGNITIVE CONSTRAINTS AND BIASES • Chosen with an awareness of inevitable framing biases • Simple and compatible with people's existing mental models so that risk categories are easy to communicate • Few enough in number so that the ranking task is tractable • Free of the 'lamp post' effect, in which better understood risks are categorised more finely than less understood risks

Reproduced from Morgan et al. (2000)

Morgan *et al*. (2000) argue that an ideal risk categorisation scheme should reflect the risk management objectives of the organisation which has commissioned the risk ranking exercise. The risk management goals of the New Zealand Food Safety Authority are set out in "Food Administration in New Zealand. A Risk Management Framework for Food Safety" (Ministry of Health/Ministry of Agriculture and Forestry, 2000).

While the huge diversity of hazards involved in an environmental CRA mean that categorisation is not only important, but necessary, it appears to offer less value when considering the relatively narrow topic of microbiological food contaminants or even the wider topic of all food contaminants. However, categorisation should be considered as part of the ranking exercise, as it may offer opportunities to group risks in useful ways.

2.2 Inherent vs. Residual Risk

Inherent risk refers to the risk, which would exist in the absence of current controls.

Residual risk refers to the current level of risk, assuming reasonable compliance with current regulations and other controls.

Environmental CRAs have mainly focused on residual risk and this seems to be the most likely approach for consideration of foodborne contaminants. Chemical and microbiological risk assessments generally depend on actual field data or scenarios based on a particular risk management scenario. An example of the latter is the calculation of theoretical maximum daily intakes (TMDIs) during the assessment of pesticides and veterinary medicines. This approach assumes that the residue of interest is present in all samples of a food at the maximum residue limit. This allows an *in extremis* assessment of a particular control scenario.

This distinction is between inherent and residual risk is recognised in the document "Food Administration in New Zealand. A Risk Management Framework for Food Safety",

> "It is important to note that in many cases a risk estimate is arrived at in the context of existing sanitary measures."

In other words, risks derived will generally be those residual risks existing after the application of existing sanitary measures.

3 STEP B: CRITERIA FOR EVALUATION OF RISK: RISK ATTRIBUTES

In the five-step model of risk ranking described in Section 1 risk is described as a multi-attribute concept. People are concerned about a large number of attributes, but high correlations amongst risk attributes in general allow the variation amongst risks to be captured by just three independent factors (Florig *et al*., 2001):

- unknown risk;
- dread risk;
- societal and personal exposure.

Florig *et al.* proposed that these three factors could be represented by a small number of proposed attributes. The choice of attributes was based on the strength of the argument for relying on the attribute, the comprehensibility of the attributes to participants in the risk ranking process, and the quality of data for assessing risks on the attributes. To represent unknown risk “quality of scientific understanding” and “time between exposure and health effects” are used. To represent dread risk “greatest number of deaths in a single episode” and “ability to control exposure” are used; and to represent societal and personal exposure, mortality and morbidity are used.

These attributes were developed to rank the numerous health risks associated with a model school. However they do suggest some criteria that would be relevant to food safety risks:

- uncertainty (quality of scientific understanding);
- time between exposure and health effects (low for microbiological food safety risks, although some sequelae may involve longer periods);
- severity in terms of mortality (dread risk);
- ability to manage the risk (control exposure);
- a variety of mortality and morbidity data (see section 3.1).

Public perceptions of food safety issues have received attention by researchers, particularly with regard to foods from modern biotechnology. A more general study has examined whether the factor analysis used to describe perception of risk by the general public was also be applicable to food safety issues. The factor analysis was developed by Paul Slovic and colleagues and described risk perception as having three primary components: unknown risk; dread risk; and, societal and personal exposure (as described above; Slovic *et al*., 2000). A mail survey in the United Kingdom in 1991 explored the factors that characterised risk amongst members of a consumer panel (Sparks and Shepherd, 1994). The risks considered included nutrition-related components (fats, sugar), additives, packaging, genetic modification, irradiation, pesticides, and bacterial contamination. The results showed that the variability in risk ranking could indeed be largely described in term of three variables: severity, unknown (i.e. uncertainty), and number of people exposed. Bacterial contamination of food, as well as *Salmonella* and *Listeria*, were ranked high on the severity index, but low on the unknown index, suggesting that they were perceived as relatively well understood (this might be a result of campaigns to control these bacteria in foods in the UK). The severity for bacterial contamination was ranked as similar to pesticides, veterinary drug and hormone residues. This suggested that the axiom that the public underrate microbial hazards compared with chemical hazards, is not true. The research also provided evidence of the optimistic bias effect (i.e. personal susceptibility to a risk is lower than for others) with respect to food safety.

The MfE scoping study (MfE, 1996) discussed similar concepts in terms of 'dimensions of risk'. It was concluded that risk can be seen through two fundamentally different dimensions. These are 'probabilistic risk', which relies on hard data and is generally carried out by technical experts and involves the estimation of probabilities of adverse events and their severity. The second dimension takes a wider perspective and views risk as a cultural or social construct, and often involves the public in the assessment process. The scoping study suggested six attributes which may be used to describe a values-based assessment of the nature of consequences of action. These attributes were:

- Character. This attribute addresses issues such as; are all deaths in a population viewed equally? How does death compare to various disease states? Does the source of the risk (voluntary or involuntary) matter?
- Magnitude. This attribute addresses the issue that, while the probability of one person in 1000 dying is the same as 10 people in 10,000 dying in a single event, society will react differently to a point catastrophe claiming a number of lives than a sporadic occurrence claiming the same number of lives.
- Distribution in population. This attribute considers inequities in risk, for example, exposure of a small group of people may produce a very small population risk, but a considerable individual risk.
- Time scale. Some risk with consequences in the future may be seen as less important. For example, future occurrence of cancer is often seen as less serious than current incidence, due to an expectation that medical technology will produce future solutions. In contrast, some risks occurring in the future are seen as more serious, such as the depletion of natural resources.
- Whether they are old or new. New risks tend to receive more focus than old risks and the burden of proof for a new activity generally falls on those who claim it is safe, whereas for old activities the burden of proof generally falls on those who claim it is unsafe.
- Manageability. Criteria for manageability may include; existing public awareness, existing legal authority, existing control programmes, availability of control techniques, effectiveness of control techniques, cost of control techniques, and personal and professional experience and judgment.

3.1 Selection of Criteria Associated with Societal and Personal Exposure

Virtually any quantitative or qualitative criteria can be applied to risk ranking, although these criteria should relate to the metrics of the risks being ranked. Risk is generally defined a function of the probability of a particular adverse outcome and the severity of that outcome in the exposed population. In the case of environmental (including food) hazards the risk will be a function of:

- Level of exposure or dose. For foodborne hazards, this in turn will be a function of the frequency of consumption of the foods, the quantity of food consumed, the frequency of contamination of the food and the level of contamination.
- The potency of the hazard. Related factors are the dimensions of the dose-response relationship and the severity (or perceived severity) of health outcomes at various dose levels.
- The exposed population, including particular sensitivities of sectors of the population.

Morgenstern *et al*. (2000) reviewed a number of environmental comparative risk assessments performed in a number of countries. The assessment criteria most commonly used were the incidence and the severity of health effects associated with each problem. In some cases the incidence was expressed as a probability. Other CRAs used a combination of risk analysis and public input to classify problems into categories of 'high', 'medium' or 'low'.

Environmental CRAs have generally assessed risk in terms of three endpoints: human health, ecosystems and quality of life. Quality of life considerations include such topics as risk to future generations, fairness, sense of community, recreation, aesthetics, economic damages and peace of mind (Jones, 1997). Of these three, the human health endpoint has most relevance to contamination of the food supply.

Human health risks have also been subdivided into cancer and non-cancer health impacts (Morgenstern *et al*., 2000). In many cases these separate assessments have been combined into a single, integrated ranking.

Incidence is a useful metric as it integrates effects of exposure, potency and population. This is also consistent with the approach of Florig *et al.* (2001) outlined above, as incidence is a measure of morbidity. However, in many cases it is not possible to ascribe the incidence of a particular adverse outcome to a particular hazard. For example, while the incidence of campylobacteriosis in New Zealand is a very good indicator of the total risk associated with *Campylobacter* exposure in New Zealand, it is extremely difficult to apportion this total risk to individual risk factors.

3.2 Criteria Included in Current NZFSA/ESR Risk Profiling

Risk profiles completed for the NZFSA by ESR have classified the risks associated with hazard-food combination on the basis of four criteria or attributes:

- Severity of outcomes associated with the hazard. The hazard is classified in terms of the percentage of cases that result in severe outcomes (death or hospitalisation).
- Incidence of illness associated with the hazard. The incidence level classified here is usually an estimate of the proportion of the incidence due to the food in question, based on invariably very limited data.
- Trade importance. This is generally a yes/no criterion indicating whether the presence of the hazard in the particular food is a current criteria for the food in international trade, and whether the food in question is an export commodity for New Zealand.
- Other considerations. This criterion allows for the inclusion of any prevailing societal attitudes or other qualitative considerations relevant to the hazard-food combination.

3.3 Additional Criteria Proposed by the NZFSA Consumer Forum

The topic of risk ranking was presented to the NZFSA Consumer Forum in November 2002. While there was general support for the approach being taken with the risk profile project, it was felt that a wider range of assessment criteria were desirable for the classification of hazard-food combinations. Suggestions included:

- Food consumption. This criterion would apply a greater weighting to foods which are more commonly consumed.
- Manageability of the hazard in the food. This criterion was proposed to give greater weighting to situations where there was a good expectation that management of the hazard would affect a change.

It should be noted that food consumption will be related to the incidence of illness, as it is a major driver for the assessment of exposure, along with the frequency and level of contamination of the food by the causative agent. However, as discussed previously, food consumption can be targeted to a particular area of risk quite accurately, while incidence can not generally be apportioned with any accuracy to the various components of the total risk.

Manageability will be a key consideration for the prioritisation of risks for risk management activity, however, it is questionable whether this should be included as a risk ranking criteria. The assessment of risk management options is likely to be a separate process and require additional research to provide data for the process.

3.4 Combined Criteria

As criteria for risk ranking, severity and incidence of disease may provide conflicting or difficult to resolve priorities (rare but severe diseases versus common, but mild diseases). One solution to this is to combine these criteria into a single measure. Several such metrics have been used.

3.4.1 <u>Economic burden</u>

Essentially this process assigns economic value to illness, including medical systems costs (GP visits, hospital bed days etc.), the value of time spent being ill (e.g. days off work related to the average wage) or mortality. The value of a statistical life lost can be estimated in a variety of ways; formerly lifetime earnings were considered, but more recent “willingness to pay” estimates are more common. The value of morbidity may also be estimated using a diminished quality of life estimation. This is valuable for long-term sequelae from intestinal infections, such as Guillain-Barré syndrome (GBS) following campylobacteriosis.

These severity linked costs are then multiplied by incidence data. The numerical values obtained will depend on the model used, but provided a consistent model is chosen then relative rankings of economic burden can be derived.

An analysis of the economic burden of foodborne disease in New Zealand has been published (Lake *et al*., 2000; Scott *et al*., 2000). This analysis included both direct and indirect medical costs; the latter included lost productive time (regardless of employment status) and the value of mortality (according to the value of a statistical life) but not loss of quality of life from long-term illness. The latter can be a significant economic value, particularly for certain pathogens such as *E. coli* O157:H7 (Buzby *et al*., 1996).

3.4.2 Health adjusted life years

Health adjusted life years (HALYs) are summary measures of population health that allow the combined impact of death and morbidity to be considered simultaneously (Gold *et al*., 2002). This umbrella term includes quality adjusted life years (QALYs) and disability adjusted life years (DALYs). Essentially health is regarded as a continuum along a scale of 0 to 1.0, representing the extremes of death and full health.

These two measures perform a similar function, but QALYs were developed according to an economic model and linked to utility theory, which has an underlying principle of the greatest good for the greatest number. This conflicts with some ethical concerns in some situations.

DALYs were developed jointly by the World Bank and the World Health Organisation as part of the Global Burden of Disease study. They are intended to quantify the burden of disease and disability in populations, and to help set priorities for resource allocation.

One scientist has proposed the use of DALYs as a tool for making decisions about Food Safety Objectives (Havelaar *et al*., 1999). In this paper the DALYs lost to campylobacteriosis in the Dutch population was calculated as an example.

A similar exercise could be performed for New Zealand but would need analysis of incidence data and the development of a consistent model.

4 STEP C: PREPARATION OF SUMMARY SHEETS

This step in the process seems trivial but involves some important considerations. The material to be presented to any risk ranking process will be based on decisions in Steps 1 and 2. The information presented to the risk ranking participants will need to be trusted and some form of independent validation or review exercise may need to be undertaken.

Appendix 1 reproduces a risk summary sheet from Florig *et al.* (2001) related to the risk category of 'School bus accidents' in their Centerville Middle School test bed.

Such summary sheets were also proposed by MfE (1996). They suggested a two-step process in which "in the first instance the analyses of environmental risk should take the form of 'green papers'. These papers provide a detailed description of the risk according to the selected risk attributes, including any predicted changes in the risk in the future" (MfE, 1996). The green papers would be considered by a Technical Advisory Group and condensed into summary sheets, which would include:

- A non-technical qualitative description of the risk, including a short paragraph on what the risk category includes.
- A more detailed quantitative or qualitative evaluation of the risks in terms of each selected attribute.
- A brief discussion of the degree of uncertainty or indeterminacy associated with the attribute and any other special circumstances (MfE, 1996).

It is possible that the 'green papers' envisaged by MfE would be at a level of detail similar to the risk profiles currently produced by ESR for the NZFSA.

5 STEP D: PARTICIPANTS AND THE RISK RANKING PROCESS

5.1 Participants

While no reports have been located concerning involvement of stakeholders in priority-setting for food safety issues, there is a considerable literature on the involvement of the general public in setting health care priorities and environmental issues.

The need to include public values within a comparative risk ranking exercise has been recognised as fundamental to the process (Jones, 1997). Even if objective information is available for risk ranking, such as mortality data, judgments will be made regarding the relative value placed on, for example, deaths amongst elderly with existing conditions versus deaths amongst the general population.

A survey of 373 citizens attending medical clinics in central Sydney, Australia found that at least 75% of people felt that public preferences should be used to inform priority-setting across health care programmes, medical procedures and population groups (Wiseman *et al*., 2003). This survey did not state the degree to which public preferences would determine the final priorities, and other surveys have found that the general public considered that the views of experts (i.e. doctors and health professionals) should take precedence in making decisions or establishing priorities. Survey respondents also identified a number of other groups (besides the general public) who should be consulted for priority setting, including nurses and other health professionals, researchers, special interest and lobby groups.

This study helps to define some questions to be considered before proceeding with the risk ranking consultation process:

- Which stakeholder groups should be involved?
- To what degree should stakeholder groups influence the final decisions?

Two focus group style workshops held by the UK National Consumer Council in 2001 elicited the views of low-income consumers with respect to farming and food (see: http://www.ncc.org.uk/pubs/feeding_in.htm). A significant point to emerge from the workshops was that participants valued the opportunity to be consulted, and expressed a wish to be heard, but there was a deep scepticism that policy-makers would take notice. Although the workshop covered a variety of food related issues, specific food safety concerns were pesticide use, GM foods, additives used in food processing and problems for people with particular dietary needs, including pregnant women and those with allergies.

The 1996 MfE comparative risk assessment scoping study proposed involvement of three separate groups in the CRA process; a Steering Committee, a Public Advisory Group, and a Technical Advisory Group (MfE, 1996). The Steering Committee would be key decision-makers (or their representatives) who will have involvement in or responsibility for implementing policies arising from the CRA, and representatives of the Advisory Groups. The Committee would have primary responsibility for the development and implementation of the project work plan.

The Public Advisory Group was seen as consisting of individuals drawn from interest groups such as iwi, community organizations, local government, industry and environmental organizations, as well as the general public. This group was viewed as being involved in all aspects of the project.

The Technical Advisory Group were viewed as having responsibility for commissioning and co-ordinating collection and dissemination of technical, scientific and specialized information necessary for the ranking of risks and the setting of environmental priorities. The group may also be asked to participate in the risk ranking exercise. The generic organizational structure proposed by MfE is reproduced in Table 2.

Table 2: Generic organizational structure for a CRA project as proposed by MfE (1996)

	Steering Committee			Public Advisory Group	Technical Advisory Group		
Make-up	Decision-makers who will be involved in implementing the results of the CRA			Representative from community and interest groups	Environmental professionals and key stakeholders with applicable skills – can be split into sub-groups		
Functions	Project oversight	Project co-ordination	Public relations/ Communications	Perception assessment	Risk analysis	Risk forecasting	Risk management
Core activities	• Develop initial terms of reference • Hire project co-ordinator • Monitoring of project progress	• Day-to-day co-ordination of project activities • Selection of working group members • Resourcing of working groups	• Maintenance of projects public profile • Advice on style, format and language of technical papers, etc. • Publishing recommendations	• Represent public interests and values • Participate in all aspects of project including peer review and risk ranking	• Advise on technical aspects of environmental problems • Perform risk analyses and provide technical advice to other groups	• Predict and monitor changes in the identified risks • Predict impacts of risk management proposals	• In conjunction with key stakeholders, scope policies and methods to deal with identified risks

Reproduced from MfE (1996)

5.2 The Risk Ranking Process

Perceptions of risk vary extensively between different groups, largely due to different criteria used by these groups to determine relative risk. Scientific risk data generally includes substantial uncertainties and, consequently ranking of risk may devolve to a mixture of objective and subjective criteria. Ranking is likely to include a degree of value-judgment and non-expert input is increasingly being included when judgments of this sort have to be made.

General stepwise processes for comparative risk assessments have been described in Section 1.4. The MfE document makes a number of practical points for the actual risk ranking step in their proposed six step process:

- Public confidence is increased if more than one group performs the rankings;
- The dynamics of individual groups are likely to work best if the members have similar levels of experience and expertise;
- Where different groups produce similar rankings there is greater confidence in the conclusions;
- The values people express, and hence the results of a ranking exercise, can be sensitive to the way in which information is provided and the way in which questions are posed and discussed;
- The most likely outcome is the sorting of risk categories into several broad classes. Experience in the United States suggests that it can prove divisive and unproductive for groups to precisely rank risk categories whose ranks are overlapping;
- It is important that the documentation supporting the final risk rankings reveals something of the process that gave rise to them and the strength or fragility of the consensus.

The format of the consultation is likely to be a focus group. Traditional methods for gaining public input, such as opinion polls, have not been successful (MfE, 1996). It appears that conventional surveys cannot provide people with the background needed to understand complicated risk related issues.

It may be useful to stage the consultation so that participants have time to consider and absorb the information presented to them, and participate in the ranking exercise after an interval.

The development of a process for risk ranking will depend on the objectives of the NZFSA for the process. Therefore a detailed process has to been developed within this document.

6 STEP E: RISK COMMUNICATION: DESCRIBING THE ISSUES INVOLVED AND THE RESULTING RANKINGS

The risk ranking exercise will need to be documented as fully as possible, to capture participant's views and also to describe the process for the rankings chosen and the uncertainties involved.

Feedback of this material will be an important part of the consultation process.

The MfE scoping study identified the following aspects which should be communicated at the conclusion of the ranking exercise (MfE, 1996). It was envisaged that this would be in the form of a report:

- Offer an explicit description of analytical and ranking methods.
- List the groups involved in the process.
- List data sources and assumptions.
- Show techniques and assumption used for future estimations of risk.
- Show risk rankings.
- Explain how the risk rankings of different groups differed and why.
- List risk reduction options for each problem area with a summary of the risk reduction potential for each specific option.
- List the environmental priorities identified by the exercise and explain how the potential priorities for action relate back to the original environmental vision and its associated goals.

As discussed previously, the MfE scoping study went beyond risk ranking to consider risk management options and priority setting. The current report does not consider these aspects and, consequently, the last two aspects of risk communication listed by MfE would not be relevant.

7 EXAMPLES OF APPLICATION OF RISK EVALUATION CRITERIA TO THE RANKING AND/OR PRIORITISATION OF HAZARDS

7.1 Overviews of Communicable Diseases

The Public Health Laboratory Service, now the Health Protection Agency, in the United Kingdom organised periodic reviews of priorities in communicable diseases; those for 1997 and 1999 have been located. Although these were supposed to occur every two years, more recent surveys have not been located.

The process for this overview was to conduct a mail survey of approximately 1,000 key professionals involved in communicable disease control in the United Kingdom. Respondents were asked to assess relative priority on the basis of five criteria: present burden of ill health, social and economic impact, potential threat to health, health gain opportunity, and public concern and confidence.

In 1999 to top ten priorities were: HIV/AIDS, meningococcal disease, *Chlamydia trachomatis*, influenza, tuberculosis, *E. coli* O157, methicillin resistant *Staphylococccus aureus*, salmonellosis, transmissable spongiform encephalopathy's and *Helicobacter pylori*.

7.2 Food Safety Research Consortium (FSRC)

While still in its early stages, the goals of this research consortium appear to be quite close to the goals of the current study, that is, to develop a robust methodology for the ranking of risk associated with hazards in the food supply. The consortium is a multi-disciplinary collaboration made up of people from Resources for the Future, University of Maryland School of Medicine and Iowa State University (http://www.rff.org/fsrc/projects.htm). The consortium is developing a risk ranking model to support the allocation of "resources more in accordance with the distribution of risks and the opportunities to reduce risk across the food supply".

While still under development it is planned that the model will incorporate data on:

- Foodborne illness surveillance.
- Food-pathogen combinations.
- Medical symptoms, complications and outcomes.
- Economic impact.
- Social values relevant to judging the significance of a potential hazard to population health.

The project team intends to:

- Develop a model structure for ranking the relative public health impacts of various foodborne pathogens and pathogen/food combinations.
- Conduct a ranking exercise based on currently available data.
- Identify gaps in the data required to complete such a ranking.
- Seek input on the model from the FSRC Expert Panel and other public and private sector experts.
- Convene a consensus conference to review and amplify the work of the project team.

- Make the resulting model available through print and electronic formats (http://www.rff.org/fsrc/projects.htm).

7.3 USDA Economic Research Service (ERS)

The ERS have developed an on-line Foodborne Illness Cost Calculator to support their work on the estimation of the costs of illness and premature death resulting from foodborne pathogens (http://www.ers.usda.gov/data/foodborneillness/).

The calculator provides a summary of cost calculations related to foodborne pathogens (only the *Salmonella* model is loaded at present) and outlines the assumptions made to achieve these estimates. It is possible to change these assumptions on-line and examine the impact of various assumptions on the total cost estimates and risk rankings (based on cost).

7.4 United States Environmental Protection Agency

The USEPA carried out early pioneering work in the ranking (comparative risk assessment) of environmental issues. Their first initiatives is this area were published in *Unfinished Business: A Comparative Assessment of Environmental Problems* (EPA, 1987). In this assessment a range of environmental problems was assessed in terms of four types of risk: human health – cancer, human health – non-cancer, ecological, and economic welfare. It should be noted that the human health aspects of the EPA CRA largely related to consideration of chemical hazards.

Carcinogenic risk evaluation

The EPA approach to determination of human health cancer risks associated with a particular problem area began with the identification of a short list of chemicals, which represented the emissions associated with each problem. Contaminants were then characterised according to their carcinogenic potency. EPA cancer potency factors (Pf) were used. Exposures were then assessed in each problem area, including estimation of contaminant doses and the likely population exposed.

The upper bound excess cancer risk was calculated from the equation:

Risk = Dose x Potency x Population

The risk is report in terms of the estimated incidence per year.

The degree of uncertainty associated with the risk evaluation was assessed qualitatively.

Non-cancer risk evaluation

The non-cancer risk evaluation methodology followed the same general approach as the approach for the cancer endpoint. Three variables were considered; the population exposed, the hazardous index (HI – estimated, based on the severity of the health effects endpoint), and the exposure, based on the ratio of the dose (exposure divided by body weight) to the reference dose (RfD). The reference dose is derived from the toxicological No Observable Adverse Effect Level (NOAEL).

7.5 USDA/FSIS (Petersen *et al.*, 1996)

Petersen *et al.* (1996) prioritised 25 infectious agents transmissible to man through consumption of undercooked beef through application of a health planning method (Hanlon method). Such health planning methods are used by government or hospital administrators to provide relative rankings of different health care programmes. Essentially the method involves allocating scores to criteria selected for each issue e.g. severity, exposure, feasibility of interventions etc.

This approach used in this paper is described as the Pathogen Evaluation System (PES). It calculates a Priority Rating (P), where:

$$P = (A + B) \times E_c$$

'A' represents the extent of affected population and is the sum of two scores representing the most likely affected population and the estimated total case numbers per year.
'B' represents the perceived or actual seriousness of the problem and is the sum of scores representing urgency (a reflection of consumer concern), percent case specific mortality, usual duration of illness, and intensity/discomfit of gastrointestinal and extraintestinal symptoms and sequelae.
'E_c' is an exposure factor derived from scores for rate of detection by current inspection procedures, ability to multiply in or on raw beef and to reach an infectious dose, infectious dose for the general population, and percent prevalence in or on final product. The sum of the E_c score are divided by 35 (the theoretical maximum) and then scaled into bands between zero and 1.5.

In the analysis of Petersen *et al*. (1996) *E. coli* O157:H7 received the highest priority ranking, largely due to its hazard rating (A + B). The four top priorities (*E. coli* O157, *Salmonella*, *Listeria*, *Campylobacter*) matched the four foodborne pathogens targeted in the US Healthy People 2000 initiative and this was taken as support for the PES process. The fifth highest priority was *Toxoplasma*.

One hurdle to apply this type of process is that much of the quantitative data required is not available.

7.6 University of Tasmania

Ross and Sumner (2002) from the University of Tasmania have developed a spreadsheet-based risk assessment tool, which allows the ranking of microbiological hazards based on indices of public health risk. The tool requires the answering of qualitative questions related to:

- Hazard severity
- Susceptibility of consumer
- Frequency of consumption
- Proportion of population consuming

- Size of population of interest
- Proportion of product contaminated
- Effect of process
- Potential for recontamination
- Increase from level at processing required to reach an infectious or toxic dose for the average consumer
- Effectiveness of post processing control systems
- Effect of preparation for meal

The qualitative answers to these questions are equated to weighting factors, which are multiplied to give a 'comparative risk'. Comparative risk factors are then logarithmically scaled to lie between 0 and 100.

Essentially this tool represents a simplified version of a quantitative risk assessment, but one in which point estimates for various factors are used, instead of the more realistic distributions that can be coped with using more complex and sophisticated mathematical models. In addition it provides no information of the uncertainty associated with risk rankings.

This tool was used to rank a number of risks associated with seafood (Sumner and Ross, 2002). Risk rankings ranged from 24 (for mercury in predaceous fish for the general Australian population) to 72 (for algal toxins during an algal bloom for recreational gatherers). These rankings were validated by the actual number of reported cases or food poisoning incidents attributed to each hazard/food combination in Australia.

7.7 Lower Columbia River Estuary Partnership

This environmental risk ranking exercise (see http://www.lcrep.org/ranking_criteria.htm) defined criteria for ranking of risks under two major headings; human and ecosystem health, and quality of life. The criteria were:

7.7.1 Human and Ecosystem Health

Extent of the Problem: How widespread is the problem?

Consequences of Delay: What happens if we do not address the problem? Will the cost to repair the problem escalate? Will we reach a point of irreparable harm? Will we affect disproportionately the health of future generations?

Nature of the Impact or Effect: What is it and how bad is it?

Permanence: How permanent is the impact? Is it recoverable; if so, how long to recover?

Likelihood of Occurrence: How likely is an environmental event to occur?

Trends: Is the situation worsening, stable, improving, or unknown?

Uncertainties: Do we have ample data, and how good are the data we have? How secure are we in the assumptions underlying the assessment- i.e. the continuance of regulations or programs which may be controlling the risk?

Relationship to Other Issue Areas: Is this a fundamental or underlying issue- i.e. one that is the cause of other problems (issues) on the list? Are there synergistic effects?

7.7.2 Quality of Life

Economic Well Being: Are there lost jobs, increased health care costs, or lowered incomes?

Fairness: Are the costs and benefits unequally distributed?

Future Generations: Have the costs of today's activities been shifted to people unable to vote or not yet born?

Peace of Mind: Do we feel individually threatened by the impacts of this environmental problem or do we feel that we have done less than we should to address it?

Recreation: Are recreational opportunities and enjoyment reduced because of lack of access to recreational lands or a loss in aesthetic values?

Sense of Place: Does the problem result in a loss of heritage, or will the heritage of the place remain intact? Is the continuity of place and history evident? Is the rate of change affecting the sense of place? Does the problem result in a loss of mutual respect, cooperation, or the ability or willingness to solve problems together? Is there a reduced feeling of connection, belonging, or responsibility to a specific geographic area?

It should be noted that this was not a structured ranking process and the ranking criteria were provided ‘to prompt one’s thinking’. Separate ranking exercises were carried out by the general public, focus groups and ‘technical’.

7.8 Centreville Middle School

This fictional school was developed by scientists to explore risk ranking for the US EPA and the USDA. The model used for this ranking has already been described in Section 1 (Florig et al., 2001). A set of health risks and their attributes were described according to this fictional school and its students. Although common and uncommon infectious diseases and food poisoning were included, the types of risk were quite broad including commuting to school and school bus accidents. Thus, while the actual risks may not be directly relevant to he food safety area, the process provides some useful direction.

A set of students (218) taking a risk analysis course at Harvard School of Public Health were asked to rank the risks (Morgan *et al*., 2001). Two processes were used:

1. Holistic ranking: ranking of risks directly; and,

2. Multiattribute ranking: indications of the relative importance of different risk attributes, and the investigators used this information to construct implied rankings of the risks.

Participants were asked to perform some ranking exercises individually before each session. Then the whole group was given a lecture on the psychology of risk perception and the multiattribute nature of risk. This was followed by group sessions in which the ranking exercises were repeated, to achieve group consensus.

There was good consistency between the two different ranking processes, which the researchers took to indicate validity of the process, in that the procedures captured an underlying construct of riskiness. The risks were also grouped into several sets and considered separately. For one particular group of risks, designated "high variance" i.e. including risks from widely variable sources and severity, there was much lower agreement on rankings. This suggests that risk ranking exercises within a more restricted category are more likely to be successful i.e. reach consensus.

7.9 Environmental CRAs

Several international environmental CRAs have been reviewed to identify consistent patterns, and also compare with the "Unfinished Business" exercise conducted by the US EPA (Morganstern *et al*., 2000). The non-US CRAs principally occurred in developing countries and economies in transition. A clear trend was detected toward broader participation in developing the risk rankings.

Aside from differences in the rankings themselves, there was considerable disparity in the processes used to rank risks. All 13 risk rankings considered health risk, while only some considered ecological and/or quality of life end points. When considering health risks, only some of the CRAs considered cancer and non-cancer health risks separately. There were also disparities between US rankings and those in other countries. This was attributed to the so-called "risk transition" i.e. the shift from sanitation and infectious disease problems to those involving industry, vehicles and toxic substances.

This review also pointed out that CRA, methodology may impose certain limitations. For example, by considering aggregate risk across entire populations, high individual risks to sub-populations may be ignored. The rankings reviewed did not consider priority rankings. These may differ: a cost effective opportunity may exist to reduce risks associated with a low risk problem, while there is little that can be done about a higher risk problem.

8 CONCLUSIONS AND RECOMMENDATIONS

No risk ranking exercise has been identified that has close similarity to that planned by the NZFSA, although other ranking exercises do suggest issues to be addressed during the planning process. The following material brings together those issues, and is intended to be an input into the planning conducted by the NZFSA.

8.1 Issues to be Considered during Planning for a Risk Ranking Exercise

8.1.1 Scope

There are a number of food/hazard combinations for which Risk Profiles are in progress or have yet to be commenced. Consequently any risk ranking exercise will be working on a subset of risks for which good information is available. The purpose of the exercise could be twofold:

- rank risks for which a Risk Profile is available;
- establish criteria and a process by which additional risks can be included.

The latter might involve establishing a smaller Public Advisory Group who could be consulted on a more regular basis.

In this document it has been assumed that the risk ranking exercise planned by the NZFSA will not include a consideration of risk reduction potential or risk management options. Nevertheless, it may be useful to discuss these issues while the group is together.

8.1.2 Risk categories

At this stage the NZFSA is considering ranking risks within essentially a single category, which is an explanation-based view: microbiological hazards for which foodborne transmission is believed to be significant.

In the future, should risk ranking be expanded to encompass other foodborne risks, such as chemicals, then the categorisation system will need to be designed to ensure that the categories are compatible.

8.1.3 Risk attributes/criteria

Several attributes or criteria have already been discussed within the Risk Profiles themselves, and in various discussions (e.g. Consumer Forum). These are:

- Incidence (according to categorisation scheme included with Risk Profiles)
- Severity (according to categorisation scheme included with Risk Profiles)
- Ability to manage the risk (e.g. the potential for one risk management measure to address several risks simultaneously).
- Trade importance

An important aspect of ranking on the basis of incidence would be consideration of any trends both in New Zealand and overseas.

A category of “other considerations” is also used in a limited way in the Risk Profiles. These considerations have not been clearly defined, but could the subject of discussion during consultation. These considerations would be most suitable for the risk prioritisation process.

Additional criteria that could be used are:

- Uncertainty. Greater uncertainty about the extent of risk could result in a higher ranking, at least for further investigative work as part of risk management.
- Potential for problems from emerging risks (e.g. new pathogens).
- Potential for affecting particular high risk groups.

Of the criteria above, incidence and severity are the most amenable to ranking on predominantly scientific criteria and should be the basis for a risk ranking exercise, as distinct from risk prioritisation.

8.1.4 Ranking exercise

Any ranking exercise will be dealing with residual risk, so that information on current risk management activity will be an important part of the information presented during a consultation exercise.

It is suggested that the risk ranking be conducted in two phases:

1. Ranking according to scientific criteria (predominantly incidence and severity).
2. Commentary on other criteria as an input into risk management decisions.

Inclusion of the second phase is likely to promote greater trust in the process and acceptance of resulting decisions by participants.

The use of the severity and incidence criteria might be enhanced by the development of DALY analysis of foodborne risk.

8.1.5 Participants and format

The participants in the risk ranking exercise should be a mixture of stakeholders, interested parties (e.g. single issue lobby groups and consumer representatives), as well as members of the general public.

Consideration needs to be given to how Maori interests can be included.

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APPENDIX 1 EXAMPLE RISK SUMMARY SHEET

School Bus Accidents

Summary:
Most school bus-related deaths occur among students who are outside the bus either getting on or getting off. Half of school bus injuries occur among students on the bus. At Centerville Middle School half of the 430 students ride to school, almost identical to the national average. Accidents involving more than one death are very rare. Because CMS buses use the Alvarez Expressway and cross the C&LL rail line, the risk of a catastrophic bus accident in Centerville is estimated to be between four and six times higher than the national average.

School bus accident risk for Centerville Middle School*

Student deaths	*Low estimate*	***Best estimate***	*High estimates*
Number of deaths per year	0.0001	**0.0002**	0.0004
Chance in a million of death per year for the average student	0.25	**0.5**	1
Chance in a million of death per year for the student at highest risk	0.5	**1**	2
Greatest number of deaths in a single episode		**20-50**	
Student illness or injury			
More serious long-term cases per year	0.0002	**0.0006**	0.002
Less serious long-term cases per year	0.0004	**0.0015**	0.004
More serious short-term cases per year	0.001	**0.002**	0.006
Less serious short-term cases per year	0.002	**0.005**	0.015
Other factors			
Time between exposure and health effects		**immediate**	
Quality of scientific understanding		**high**	
Combined uncertainty in death, illness, injury		**1.6 (low)**	
Ability of student/parent to control exposure		**moderate**	

*See "notes on the numbers" for definitions and explanations of assumptions.

Layout of the front page of a four-page risk summary sheet showing the risk name, a summary paragraph, and a table of key risk attributes. Additional pages include a few-paragraph narrative describing the risk in both national and local contexts, and description of actions the school officials have taken to address the risk. A summary sheet was prepared for each of the 22 risk categories defined for Centerville Middle School (Florig *et al.*, 2001)