



**Workshop on the Application of Risk
Management Principles
in Public Health Law
27 March 2001**

Summary Report

September 2001

**The Application of Risk Management Principles
in Public Health Law**
**Summary Report of the Workshop, held 27 March 2001 at the Stamford
Hotel Sydney Airport**

Introduction

On 27 March 2001, the Legislation Reform Working Group (LRWG) conducted a workshop on *the Application of Risk Management Principles in Public Health Law*. The workshop built on the earlier report on the *Application of Risk Management Principles in Public Health Law*, commissioned by the LRWG from Dr Chris Reynolds, School of Law Flinders University.

The workshop, which was held at the Stamford Hotel at the Sydney Airport, brought together a diverse group of invited participants who discussed a variety of perspectives on this issue. The workshop itself emerged in recognition of the need to:

- provide a forum for discussion of the application of risk management principles, an emerging issue in the development of legislation particularly in the areas of public health and environmental issues;
- provide an opportunity to share information and learnings; and
- build on the work of LRWG and examine the practical issues of jurisdictional action.

The program for the workshop was structured to encourage progression from conceptual frameworks through to practical implementation issues at the jurisdictional level.

Dr Reynolds began the workshop by speaking on the theoretical framework of risk and public health legislation. Dr Reynolds was followed by Ms Lisa Wardlaw-Kelly from the Australia New Zealand Food Authority, who spoke on the Challenges for Regulatory Decision Making and Accountability drawing on the ANZFA experience. The final speaker in this session was Ms Therese Manning from the NSW Environment Protection Agency who spoke on the General Principles of Risk Assessment in Environmental Management.

Jurisdictional perspectives were presented by Mr Peter Kennerly, from the New Zealand Ministry of Health, who spoke of the “Development of a Public Health Risk Management Methodology to Inform Decision Making”; Mr James Edis, who gave a presentation on risk management legislation in the ACT; Mr Jim Dadds who spoke on the current and possible legislative requirements in South Australia and a joint presentation from Ms Kate Purcell and Associate Professor Mark Ferson on the application of risk management principles to public health legislation in the NSW context.

The final session of the workshop involved participants breaking into four groups in order to consider and then report back on some set questions around: how risk management principles can be incorporated into public health policy making; how concepts of risk management principles can be translated into everyday practice and/or guidance for decision makers; consideration of what are seen to be the challenges to incorporating risk management principles into public health legislation and how risk assessment/management can be incorporated into a jurisdiction’s Public Health Act.

This paper provides a summary of the presentations and discussion at the workshop, which has been undertaken by Dr Reynolds in consultation with the presenters.

Session 1: The Conceptual Framework (10.00 AM- 12.30 AM)

Chris Reynolds, School of Law Flinders University, Adelaide

A Theoretical Framework - Risk and Public Health Legislation

Any discussion of risk management will be shaped by the context in which it is considered. And it's worth starting by taking a quick glimpse of the legislation that will be focussed upon in today's workshop as well as its origins.

The public health acts of the States and Territories found their origins in the early to mid 19th century British urban reform movements that led to the British Public Health Act 1848. This first model in many ways still reflects the way that the public health community still operate our core public health controls in Australia.

What can be said about it? Firstly, that it responded to the concerns about the health risks of the urban environment. But it did so in a reactive way - generally by providing a remedy to a detected and complained about problem. It put in place a split responsibility of public health between the local and the central (in Australia the State government and the local councils) - a theme that remains today

But the Act was premised on a miasmatic view of disease - it was smells, or the miasmas emanating from insanitary conditions, that spread disease. And while that may have been wrong as a scientific idea, it did lead to a focus on the conditions that were seen to be offensive and which also were responsible for spread of disease.

In Australia in the new century, there have not been many cases where there has been a dramatic departure from this early model. Some State Acts still bear very close similarities to their 19th century predecessors. Others have a more modern approach - though the basic framework remains.

If such a thing could be imagined, a typical State or Territory public health act might provide -

- A mechanism for determining central and local council responsibilities.
- A power to remedy insanitary conditions or nuisances.
- The power to licence some activities of public health concern - but not the places licensed for environmental concerns that are dealt with under environmental legislation.
- Powers to call up codes of practice and possibly to determine standards - but generally in specific cases such as public swimming pools, septic tanks or cooling towers.
- A statutory authority, and perhaps an advisory body, to make decisions and advise on policy.
- Some public health powers over water, waste, houses unsafe for human habitation.
- Possibly some residual powers to regulate some activities such as rag picking, or campsites.

- And, of course, a series of powers in relation to infectious and notifiable diseases.

Where formal decisions are to be made under these Acts they are generally silent on how the decision making process is arrived at. Where standards are set - and they are not generally set - but where they are - the Acts are similarly silent on the process of setting them.

There are some exceptions to this, notably, the ACT *Public Health Act 1997*. Here the authorised officer is required to take a number of matters into consideration before deciding whether or not to issue the notice. These are:

- the number of persons affected or potentially affected, by the condition, state or activity;
- the degree, or potential degree, of public health risk, damage to public health or offensiveness to community health standards resulting from the condition, state or activity;
- any reasonable precautions that a person causing the relevant condition, state or activity has or has not taken to avoid or minimise the adverse affect, or the potential adverse affect, of the condition, state or activity;
- any reasonable precautions that a person adversely affected, or potentially affected, by the relevant condition, state or activity has or has not taken to avoid or minimise the effect, or potential effect, of the condition, state or activity on his or her health or on the health of another person for whose care, support or education the person is responsible.¹

So how can it be ensured that the Public Health Acts systematically deal with risk in decision making? This leads to the issues that are being considered today.

The discussion should start with some terminology. There are many different ways of describing risk and the processes that are part of its management overall. There are so many forms of words and so many ideas. All I can do today is to present some of those that that were referred to in the report². In particular, the report used the definitions for the NZ Final Report on the Development of A *Public Health Risk Management Methodology to Inform Decision Making* (1999)³.

Risk: The chance of something happening that will have an impact upon objectives. It is measured in terms of consequence and likelihood. The exposure to the possibility of such things as ... loss ... physical damage, injury or delay. Risk is a combination of the likelihood of occurrence of an adverse event and the magnitude of the consequences.

Risk assessment: A combination of *risk analysis* – which is a systematic use of available information to determine how often specified events may occur and the magnitude of their consequences and *risk evaluation* - which is the process used to

¹ (ACT) *Public Health Act 1997* s 69(2).

² This is the Final Report The Application of Risk Management Principles in Public Health Legislation, National Public Health Partnership, June 2000.

³ Department of Public Health, Wellington School of Medicine 30 June 1999.

determine risk management priorities by comparing the level of risk against predetermined standards, target levels or other criteria.

Risk management. The culture, processes and structure which come together to optimise the management of potential opportunities and adverse affects.⁴

What is being attempted is to find some sort of balance between costs and benefits of actions that might be taken under statute in the public health interest. But that's always going to be controversial. For a start, risks aren't seem the same way - and statements about risk, and actions responding to risk are not merely a scientific process. Also, calculations of costs and benefits are subjective. They are sometimes uncertain and the costs and benefits are never equally distributed across a community. Those who get the benefits may not have to bear the costs. Those who pay the costs may not get any of the benefits. For example, children with a higher likelihood of getting asthma may pay the costs, while those who own and most obviously benefit from a process live in leafy suburbs far away.

What could be done - it seemed to us - was to examine Australian and New Zealand public health laws and consider how a process that was friendly to risk could be created. A system that allows for decision makers to incorporate ideas about risk in their decisions. Such a system could:

- allow for decision makers to incorporate ideas about risk in their decision;
- take account of community concerns;
- take account of scientific uncertainties and articulates values and objects;
- can balance competing issues; and
- provide an explicit and transparent process for developing standards.

It is here that there are lessons to be learned from related areas of legislative interest like food regulation and environmental protection where there are defined processes for getting up standards and where communities are involved in decision making. There are also lessons to be learned from the common law - which has had to deal with questions of reasonableness as an element of negligence actions. In particular, the High Court case *Wyong Shire Council v Shirt* (1980),⁵ considered the problem of distinguishing between a “reasonable” and “unreasonable” risk of injury in the following way. There should be a consideration of:

- the magnitude of the risk;
- the degree of the probability of its occurrence;
- the expense, difficulty and inconvenience of taking alleviating action; and
- any other conflicting responsibilities which the defendant may have.⁶

Public health legislation can learn from some of these processes - and can build them into its legislative framework. But they can also be a problem - process requirements may promote long delays, and raise questions about how promptly legislation can be made to respond to issues. The NSW case *Parramatta Council v Lutz*⁷ (1988) well illustrates the political and legal costs associated with delays, some of which are imposed by the process that councils

⁴ Page 8, - as discussed, there is a range of definitions canvassed, of which those cited here are only some.

⁵ (1980) 146 CLR 40.

⁶ Per Mason J at p48.

⁷ (1988) 12 NSWLR 293.

consider themselves obliged to undertake in order to discharge their statutory obligations of fairness and due process.

Additional process requirements may also lead to an increase in administrative review of decisions. If more steps are added to the process, there is more opportunity to challenge a decision on the grounds that the process was not properly complied with. The 1996 Federal Court case *Tobacco Institute of Australia Ltd and others v National Health and Medical Research Council and others*⁸ (the *Passive Smoking* case) demonstrates this point.

One thing seems very clear - We are living in a period of accountability, where the possibility of legal cases emphasising statutory accountability is increasingly present. These can come from a range of sources

- The coroners court.
- Administrative challenges.
- Duty of care cases such as the *Wallis Lake* case.⁹

All of these possibilities make it important that due diligence and systematic processes are in place. This means that there is seemingly more work at a time when there are less people to do it. Potentially there are more delays to a system that people expect will respond quickly to these concerns.

However, increasing accountability and community expectations are arguments for making the public health regulatory system more explicit and more sophisticated in its structure. It is the case that if you look at the body of public health law in Australia today - as expressed in the public health acts - the words "traditional and unsophisticated" do spring to mind. When you compare them with the environment protection laws administered by EPAs you seem to be comparing enactments that are generations apart. When you look at the ideas in the model food proposals, you get a similar picture.

But it should be added that this does not necessarily reflect any limitation in the way in which public health is actually administered by public health officers under the existing enactments. And it should also be recognised that some Australian jurisdictions have provisions that would seem to address many of the questions that will be considered today.

What was to be done? - The aim of the report was to present the ingredients of a model public health act that made thinking about risk explicit and that was friendly to the processes of risk assessment and its management. It sought to take the best bits from the 8 public health laws across Australia and also from the environment protection laws and the natural resources laws.

This was brought together and is possibly most clearly seen on pp78-79

Essentially there are 3 ideas -

- How could public health legislation be generally focussed on the idea of risk?
- More particularly - how might it deal explicitly with the assessment of risk?

⁸ (1997) 142 ALR 1.

⁹ *Ryan v Great Lakes Council* 1998 Federal Court.

- And then how can it be said to manage it in its general every day operation?

It advocates a view that measuring and understanding risk requires both quantitative and qualitative approaches. It warns of the problems - possibly seen in US legislation - where risk has become an ideological issue. It also warns against the option of making process issues so complex as to frustrate timely and efficient public health responses.

When thinking about the specific question of risk one is often drawn into a wider question - how should 21st century public health law look? In that respect, the report really carried on the work that so many of you and the LRWG more generally has been doing over the past 4 years.

Lisa Wardlaw-Kelly, Australia New Zealand Food Authority, Canberra
Challenges for Regulatory Decision Making and Accountability - the ANZFA Experience

Thank you for giving me the opportunity to speak here today. I really believe that the topic is an important one. Risk management should mean “a stitch in time saves nine” rather than – “we should have known that would happen!” It provides an ideal framework for public health decision-making but unfortunately there is a huge amount of confusion about it. As Chris mentioned in his paper – definitions and models abound. Today is an important step in bringing people together to talk about risk management in the context of public health law. Let’s see if some progress can be made together.

Today, I’m going to tell you a little about where I’m from and what we do there and then I’ll talk about the integrated risk management model we are in the process of developing at ANZFA, and how it relates to the issues and concepts discussed in the two reports which were circulated prior to the workshop.

The following three concepts are the central themes of my presentation. They represent key challenges for risk management at ANZFA.

- Risk management is a core responsibility not a supplementary one.
- Establishing the context is paramount.
- Not only do we need to provide credible scientific analysis but we also need an integrated approach to risks in order to address community concerns.

First of all risk management needs to be integral to the process of developing regulation. Secondly decisions about risks need to be made with a thorough appreciation of the context within which they are being made. Thirdly, we need an evidence based approach which considers impacts on the public.

All regulatory agencies face questions as to how much weight to give to consumer, business or other governments’ concerns which conflict with scientific analysis. Risk management cannot make those judgements for us but it can provide a framework for systematically considering all relevant issues and making explicit the assumptions that are used in weighing up the different interests and perspectives.

Basically, my talk will be about the challenges in getting from point A, (which is ANZFA's statutory obligation to apply risk analysis principles in developing standards), to point Z, (to have effective food regulation in place which protects public health and safety and supports consumer confidence in the food supply.)

The Australia New Zealand Food Authority is a regulator. That means that although ANZFA develops regulatory measures they don't enforce them –enforcement of the food standards code is a State, Territory and New Zealand government responsibility. ANZFA does, however, consider enforcement issues as a part of developing 'good regulation'. Our role includes:

- Maintaining the food standards code.
- Developing codes of practice.
- Coordinating food surveillance.
- Conducting research and surveys.
- Assessing policies about imported food.
- Coordinating food recalls.

ANZFA have Objects in the *Australia New Zealand Food Authority Act 1991* as well as specific objectives for developing food regulation. In summary, ANZFA (the Authority) was established through the *ANZFA Act* to ensure a high standard of public health protection throughout Australia and New Zealand through achieving the following goals:

- (a) a high degree of consumer confidence in the quality and safety of food produced, processed, sold or exported from Australia and New Zealand;
- (b) an effective, transparent and accountable regulatory framework within which the food industry can work efficiently;
- (c) the provision of adequate information relating to food;
- (d) the promotion of consistency between domestic and international food regulatory measures.

The Act also sets out our objectives for developing food regulatory measures. These objectives are in descending order of priority. When applying risk management to the development of regulation, these objectives are always the primary ones. They are:

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

There are other factors which must be considered under the Act. They include:

- (a) the need for standards to be based on risk analysis using the best available scientific evidence;
- (b) the promotion of consistency between domestic and international food standards;
- (c) the desirability of an efficient and internationally competitive food industry;
- (d) the promotion of fair trading in food.

You will note that ANZFA has an explicit statutory obligation to base standards on risk analysis using the best available scientific evidence.

ANZFA aims to develop best practice regulatory approaches, which rely on epidemiological evidence and scientific analysis. The regulatory process also involves other forms of evidence and analysis, which can be less straightforward. Both the circulated papers pointed to the challenges presented by the need to make value judgements about the impact of risk and risk management options on those who will be affected by them.

ANZFA is currently seeking to develop an integrated process for regulatory decision making which is based on a systematic analysis of the risks and the impact of proposed risk treatment options. This process will be used not only in developing food regulatory measures but also in carrying out other activities, including policy development, research and education initiatives. It will be applied to both internal and external activities. It will not be restricted to scientific analysis but covers every kind of activity undertaken at ANZFA. Hence the term 'integrated risk management'.

It's worth mentioning this broader application of risk management because an integrated approach to risk will support stakeholder confidence in ANZFA's processes beyond those relating to specific standards. It will provide the public and their elected representatives with assurances about the way all decisions are made at ANZFA. This extends to ANZFA's consideration of the wider context in which it operates and the critical risks which need to be managed by the agency at a strategic level. Having said this, I will be focusing today primarily on the process for dealing with applications or proposals to vary the food standards code.

First of all a risk management model needed to be developed which could be applied across the range of activities in ANZFA and yet still be highly relevant to food standards development. There were a few practical requirements that were required, including that the model should:

- Be able to link up a range of risk management activities.
- Be sufficiently generic but still relevant to specific tasks.
- Foster a pro-active risk management culture.
- Engender accountability.
- Enhance strategic planning.

The model also needed to establish a common language and methodology for managing risks and to address the three key challenges I mentioned earlier:

- Risk management as a core responsibility not a supplementary one.
- Establishing the context is paramount.
- The model needs to provide for credible scientific analysis and allow us to address community concerns.

In dealing with food standards applications and proposals three related processes had to be integrated:

- The scientific risk analysis process espoused by the international food standards body, the Codex Alimentarius Commission.
- The Australian/New Zealand standard on risk management.
- The Regulation Impact Statement as required by COAG.

The scientific risk analysis process as put forward by Codex, has three main elements; risk assessment, risk management and risk communication. Whilst in the diagram used to represent this process, these three elements are each contained within their own circle, in practice they overlap. If you were to follow the Codex process strictly, you would have to start in the risk management circle and undertake a risk evaluation which includes identifying a food safety problem, establishing a risk profile (a description of the food safety problem and its context, and preparing a risk assessment policy before commissioning a risk assessment.¹⁰

This illustrates how the model could potentially be misinterpreted by those applying it. Unless you have access to the more detailed reports behind the model, you could easily be forgiven for assuming that the process begins with a risk assessment, moves on to risk management and finishes up with risk communication. In fact communication is integral to the process from the outset, and the most important element of risk management, namely considering the problem in its context, precedes the scientific risk assessment.

Although all the logical steps are covered and the resulting analysis would be sound - this is not an overly user-friendly model and for this reason careful thought was given to whether or not to use this model in the integrated risk management system. Another factor which influenced against this model was that it did not easily translate to non-scientific activities and a common language and methodology was required to truly integrate risk management across the agency.

It was recognised, however, that there was a need to keep intact the scientific methodology provided for under the risk assessment element. As such, this component was kept in its entirety and incorporated into the integrated risk management model.

The Australian/ New Zealand Standard includes basically the same steps in its process, although it lacks the specific steps relating to scientific risk assessment. These are the steps included in the process:

- Establish the Context
- Identify Risks
- Analyse Risks
- Evaluate Risks
- Treat Risks
- Monitor and Review (continuous)
- Communicate and Consult (continuous)

The strengths of this model are:

- It is easy to follow;

¹⁰ Food and Agriculture Organisation of the United Nations 'Risk Management and Food Safety', Rome January 1997 p5-6.

- It places emphasis on proper scoping;
- It is suited to a range of risk areas; and
- It can be easily modified.

Those of you who are familiar with the process for developing regulation will have already recognized some of the concepts which are central to the Office of Regulation Review's (ORR) 'Regulation Impact Statement'. The Regulation Impact Statement, or RIS, as I will henceforth refer to it, is a document which regulators are required to prepare before developing a regulatory measure. According to ORR, the RIS formalizes "...some of the steps that must be taken in good policy formulation. [It]...ensures that all relevant information is documented and that the decision-making processes are made explicit and transparent."¹¹ Sound familiar? In many ways it bears a strong resemblance to the risk management process.

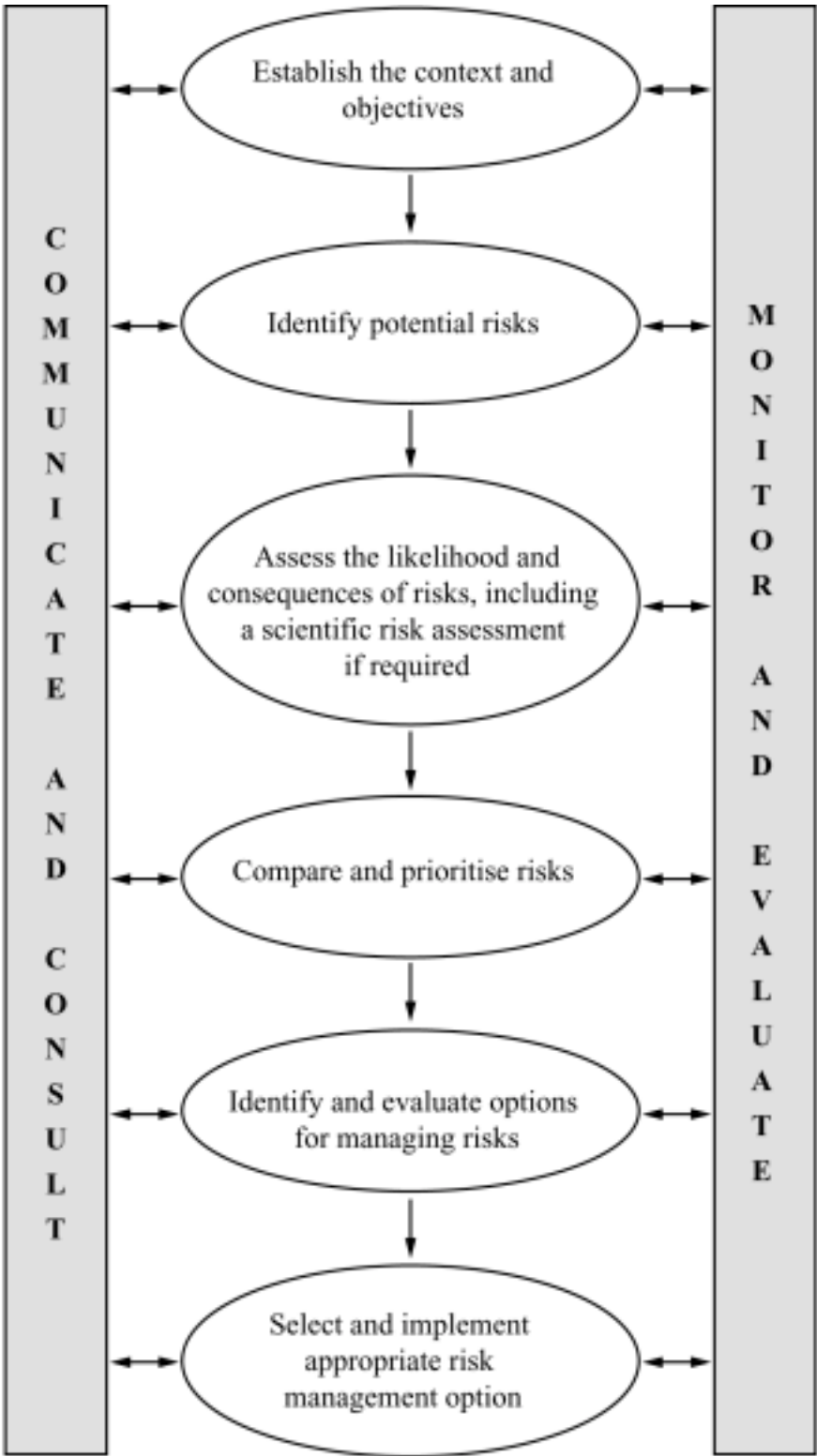
The focus of the RIS is on the impacts of regulatory options on those who will be affected by the regulation. It includes a cost benefit analysis. I will talk later about how the RIS is being integrated into the standards development process.

Figure 1¹² shows the risk management model that has been developed. As you can probably tell, the model is largely based on the Australian New Zealand Standard, with some modifications. I'll briefly take you through the steps involved, using a hypothetical example of risk management, which I will draw upon to make this explanation more interesting for you.

¹¹ Office of Regulation Review 1998, *A Guide to Regulation* (second edition) pA2.

¹² See the powerpoint slides distributed earlier.

Figure 1



Hazelnuts: A Case Study

The hypothetical application asked ANZFA to consider the amount of lead permitted in hazelnuts. The applicant wanted Australia's levels to be doubled to the international level so that they could import hazelnuts to Australia.

Establish the Context – As the standard says, the risk management process occurs within the framework of the agency's strategic, organisation and risk management contexts. This step establishes the nature of those contexts and defines the basic parameters within which risk will be managed. It is basically the scoping stage of the process. If there are general or specific objectives relevant to the activity, or as discussed in Chris' paper, Objects included in an Act, these should be expressed at this stage. This is also the stage where criteria for evaluating risks are set.

In our hypothetical example, aspects to be looked at were:

- statutory objectives;
- international obligations;
- community concerns; and
- the interests of local growers.

The criteria that were set emphasised public health and safety but also stated that the standard should not restrict access to 'safe' hazelnuts.

Identify potential risks – This step seeks to systematically identify all relevant risks. Identification should cover all risks whether or not they are under control of the organisation. We added 'potential' in order to remind people to be pro-active in thinking about risks. Not just the ones that are staring us in the face but the ones that might be around the corner.

For hazelnuts, the risks included over-exposure to lead through consumption of hazelnuts, economic hardship in areas which produced hazelnuts for the local market and international trade sanctions if we refused to bring our standard into line with others.

Assess the likelihood and consequences of risks, including a scientific risk assessment if required – To avoid confusion due to the same terms being used differently, in the model this step was expressed more literally, and referred explicitly to the scientific risk assessment.

In terms of the hazelnut example this step would include:

- a toxicological risk assessment;
- A non-scientific assessment of the likelihood and consequences of other risks such as community concern and international trade wars.

Compare and prioritise risks - involves comparing the level of risk found during the above process with the risk criteria established at the beginning. According to the criteria that was established for the hazelnuts case, any health and safety risk would be ranked above a trade consideration, as this is required by our Act. However, if there was found to be no risk to health, then other risks may be prioritised. In this case it might mean balancing the local community's concerns with international obligations. Once again, our previously established criteria would assist in this process – I think we said that in the absence of health risks, the standard should not restrict access to 'safe' hazelnuts.

Identify and evaluate options for managing risks – basically this equates to the ‘options’ and ‘impacts’ part of the RIS. Once again, this was expressed a little more literally than in the standard and separated the step on ‘treat risks’ into this and the next step.

For the hazelnuts, permissions could be left relatively tight, or they could be loosened in line with international practice. Either way, it could be simply recommended that the standard be changed, or that it could mitigate the non-scientific risks by involving the public in the process, by making our processes open and transparent and/or by giving growers and their communities a period of time to adjust.

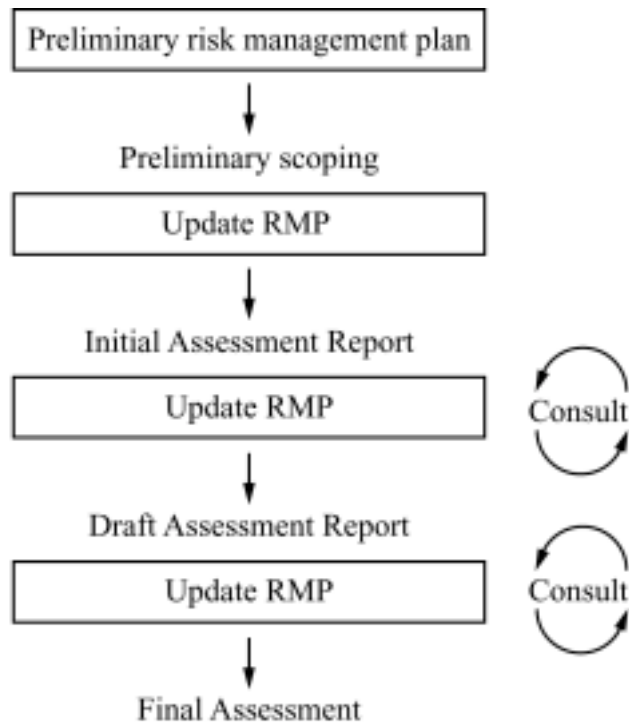
Select and Implement Option – After considering the relative threats and opportunities presented by each option or combination of options, one plan would be selected for implementation. There would be consultation with the community on the recommended option and if appropriate – it would be implemented!

Monitor and Review – Few risks remain static. It is necessary to monitor risks, the context and risk treatments and the whole risk management system to make sure they reflect any new developments.

Communicate and Consult – from the beginning, with everyone. Open and honest communication is the cornerstone of good risk management. It helps to make sure that all necessary information is available at every stage and ultimately it helps in implementing the regulation that have been developed.

Figure 2 is a representation of how the risk management process is going to align with ANZFA’s new process for developing regulation. It shows that, harking back to my introduction, risk management is a core responsibility – it is central to the process – not an ‘add on’ or afterthought. After each period of consultation, the risk management process is revisited to take on new information about context, risks and options.

Figure 2



Instead of writing a series of different reports, the new process will mean that one report will evolve from its preliminary form, through an initial and draft stage to the final report. Each stage will involve appropriate consultation and communication and at each stage the risk management plan will be reviewed and updated. This will ensure that our analysis of the risks, the context and the impacts will always reflect the latest available information. We also propose to integrate the Regulation Impact Statement into our processes. Each of the reports I referred to above will follow the format of a RIS. With sections titled, ‘Problem’, ‘Objective’, ‘Options’, ‘Impacts’, ‘Recommendations’ and Implementation’. Since the RIS process and the risk management process are so similar, this will mean that most of the information that needs to go in the report will have been generated through the risk management process. It will save on time and energy as well as ensuring that there is a best practice, risk based approach to developing regulation.

To Conclude and just to reiterate the key concepts I wanted to get across today. They are:

- That risk management needs to be central to what we do;
- A proper scoping is essential; and
- We need to think about *all* risks in their context.

I hope our experiences at ANZFA have shed some light on the subject of risk management for you. As I said at the beginning, it should be a case of “a stitch in time saves nine” rather than – “we should have known that would happen!” I look forward to a healthy discussion during the rest of the workshop.

Therese Manning, NSW Environment Protection Agency, Sydney
General Principles of Risk Assessment in Environmental Management

I thought that I should start by looking at some of the objectives of the New South Wales environment protection legislation and provide some background thinking on why these objectives were put both in the NSW Act and also in other environment protection laws.

Objects in environmental legislation

The Objectives of environment protection legislation in NSW are:

- To protect, restore and enhance the quality of the environment in NSW, having regard to the need to maintain ecologically sustainable development.
- To reduce the risks to human health and prevent the degradation of the environment, by a variety of means.

The Act also raises the issue of ecologically sustainable development. This includes, the precautionary principle, conservation of biodiversity and inter-generational equity.

The Act specifies that the ways in which the second object can be met include: promoting pollution prevention; encouraging waste minimisation; and recycling. To provide some context, the objects have been set out below:

Objectives of the Environment Protection Authority, as set out in the *Protection of the Environment Administration Act 1991*.

6 Objectives of the Authority

(1) The objectives of the Authority are:

- (a) to protect, restore and enhance the quality of the environment in New South Wales, having regard to the need to maintain ecologically sustainable development, and
- (b) to reduce the risks to human health and prevent the degradation of the environment, by means such as the following:
 - promoting pollution prevention,
 - adopting the principle of reducing to harmless levels the discharge into the air, water or land of substances likely to cause harm to the environment,
 - minimising the creation of waste by the use of appropriate technology,
 - regulating the transportation, collection, treatment, storage and disposal of waste,
 - encouraging the reduction of the use of materials, encouraging the re-use and recycling of materials and encouraging material recovery,
 - adopting minimum environmental standards prescribed by complementary Commonwealth and State legislation and advising the Government to prescribe more stringent standards where appropriate,
 - setting mandatory targets for environmental improvement,
 - promoting community involvement in decisions about environmental matters,

- ensuring the community has access to relevant information about hazardous substances arising from, or stored, used or sold by, any industry or public authority,
- conducting public education and awareness programs about environmental matters.

(2) For the purposes of subsection (1) (a), ecologically sustainable development requires the effective integration of economic and environmental considerations in decision-making processes. Ecologically sustainable development can be achieved through the implementation of the following principles and programs:

(a) the precautionary principle namely, that if there are threats of serious or irreversible environmental damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation.

In the application of the precautionary principle, public and private decisions should be guided by:

- (i) careful evaluation to avoid, wherever practicable, serious or irreversible damage to the environment, and
- (ii) an assessment of the risk-weighted consequences of various options,

(b) inter-generational equity namely, that the present generation should ensure that the health, diversity and productivity of the environment are maintained or enhanced for the benefit of future generations,

(c) conservation of biological diversity and ecological integrity namely, that conservation of biological diversity and ecological integrity should be a fundamental consideration,

(d) improved valuation, pricing and incentive mechanisms namely, that environmental factors should be included in the valuation of assets and services, such as:

- (i) polluter pays that is, those who generate pollution and waste should bear the cost of containment, avoidance or abatement,
- (ii) the users of goods and services should pay prices based on the full life cycle of costs of providing goods and services, including the use of natural resources and assets and the ultimate disposal of any waste,
- (iii) environmental goals, having been established, should be pursued in the most cost effective way, by establishing incentive structures, including market mechanisms, that enable those best placed to maximise benefits or minimise costs to develop their own solutions and responses to environmental problems.

The Scientific Approach

The Act recognises that decisions often have to be made in the absence of scientific certainty, and that a systematic approach needs to be adopted.

What do we know about science?

- Science is the pursuit of systematic and formulated knowledge or the state of knowledge that has been accumulated to date on a particular subject.
- We usually don't have full knowledge about a particular subject.
- The pursuit of knowledge and understanding in a particular area is dynamic.

Rarely do we get the full knowledge on a particular issue.

We also know that the scientific method is an iterative and continuing process, that involves:

- Making some observations.
- Generating a hypothesis to explain the observations.
- Conducting experiments to test the hypothesis.
- Modifying the hypothesis in light of the new data.

What do we really know? As more knowledge about a subject is collected, our understanding of how it works is revised. Such revisions can result from studies but they can also result from when something goes badly wrong or when things go unexpectedly right.

There are many examples of problematic chemicals that have been widely used in the community. These include, DDT, BSE, impurities in herbicides, DES, damming of rivers, and the impact of CFCs on the ozone layer. Improvements in monitoring and measuring also shape how one can make and interpret observations and respond to them.

In undertaking experiments designed to test hypotheses, that might in turn assist in risk assessment and standard setting, it is important to take account of both false positives and false negatives. The possibility of false negatives is particularly significant environmentally, if it is found that (despite the prediction) there is in fact a problem. Repairing environmental damage is far more problematic than preventing it.

Other Approaches

Decision-making does not occur within a purely scientific context. Rather it requires other matters to be considered and also demands a framework within which these issues are considered. These matters are

- economic
- social
- political
- technological
- alternatives
- intergenerational equity
- natural justice

It is with all these difficulties in mind that the environment protection legislation requires decision makers to consider (among other things)

- the precautionary principle
- intergenerational equity
- conservation of biological diversity and
- appropriate valuation of the environment

To summarise, We need to make decisions about potentially risky situations and despite not having all the understanding we need. Thus, environmental protection legislation has been designed to require a cautious approach. We must try to find the balance between being

unduly cautious, and not being sufficiently cautious. Decision makers have to find that balance as best they can. It is a developing process and we are still learning it.

Session 2 Challenges in Applying Risk Management Principles (1.00 PM - 3.00 PM)
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Peter Kennerly, New Zealand Department of Health, Wellington
The Development of a Public Health Risk Management Methodology to Inform Decision Making in New Zealand

The focus of New Zealand's proposed Public Health Bill is on public health risk management. It is not concerned with financial risk management or information risk management but with managing risks to public health.

An amendment to the existing *Health Act* 1956 will require drinking water suppliers to develop and implement public health risk management plans for their supplies. In our consultation meetings with supply managers, they strongly supported the concept of a public health risk management plan.

The New Zealand report *The Development of a Public Health Risk Management Methodology to Inform Decision Making*¹³ provides a useful starting point for considering risk management in legislation. Our approach to public health risk management in legislation has the following components.

1 *Risk and Intervention Assessment Methodology*

To be developed, consulted on, and mandated by an Order in Council, to be used in reviewing existing regulations, and before any new regulations can be passed and before the Director General takes action under the proposed *Public Health Act*. The methodology aims to provide:

- Robustness
- Consistency
- Transparency

2 *Duty of the Director General to Consider Alternative Interventions*

This is based on section 32 of the *Resources Management Act* 1991 (NZ) - this requires an evaluation of costs and benefits and recognises that a variety of other means are available and also that the responses must be proportionate to the need.

Specifically, section 32 provides:

Duties to consider alternatives, assess benefits and costs, etc.---

(1) In achieving the purpose of this Act, before adopting any objective, policy, rule, or other method in relation to any function ... any person described in that subsection shall---

(a) Have regard to---

¹³ See foot note 3.

- (i) The extent (if any) to which any such objective, policy, rule, or other method is necessary in achieving the purpose of this Act; and
- (ii) Other means in addition to or in place of such objective, policy, rule, or other method which, under this Act or any other enactment, may be used in achieving the purpose of this Act, including the provision of information, services, or incentives, and the levying of charges (including rates); and
- (iii) The reasons for and against adopting the proposed objective, policy, rule, or other method and the principal alternative means available, or of taking no action where this Act does not require otherwise; and

(b) Carry out an evaluation, which that person is satisfied is appropriate to the circumstances, of the likely benefits and costs of the principal alternative means including, in the case of any rule or other method, the extent to which it is likely to be effective in achieving the objective or policy and the likely implementation and compliance costs; and

(c) Be satisfied that any such objective, policy, rule, or other method (or any combination thereof)---

- (i) Is necessary in achieving the purpose of this Act; and
- (ii) Is the most appropriate means of exercising the function, having regard to its efficiency and effectiveness relative to other means.

3 *A Precautionary Approach*

This is based on section 7 of the *Hazardous Substances and New Organisms Act* 1996 (NZ) - all persons exercising functions, powers and duties under the Act, shall take into account the need for caution in managing public health risks, where there is scientific uncertainty or incomplete information about those effects. This section provides:

Precautionary approach---All persons exercising functions, powers, and duties under this Act, including but not limited to, functions, powers, and duties under sections 29, 32, 38, 45, and 48 of this Act, shall take into account the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects.

4 *A General Duty on all Persons to Prevent, Remedy or Mitigate Public Health Risks*

This idea is based on the *Resource Management Act* and the *Hazardous Substances and New Organisms Act*, though under these Acts the duty is not enforceable. Under the proposed *Public Health Act* it will be, to the extent that infringement notices could be issued for non-compliance with the duty. In particular, section 13 of the *Hazardous Substances and New Organisms Act* provides as follows:

General duty---

- (1) Every person who imports, possesses, or uses a hazardous substance or new organism shall ensure that---
 - (a) Any adverse effect caused by an act or omission of that person in relation to that substance or organism on any other person or the environment is avoided, remedied, or mitigated; and

(b) No action or omission by that person will contravene any requirement or control on that substance or organism imposed by this Act.

(2) The duty imposed in accordance with subsection (1) of this section is not of itself enforceable against any person, and no person is liable to any other person for a breach of that duty.

(3) Notwithstanding subsection (2) of this section, a compliance order may be served on any person requiring that person to cease or prohibiting that person from commencing anything done or to be done by or on behalf of that person that in the opinion of the enforcement officer relates to any hazardous substance or new organism and is or is likely to be dangerous to such an extent that it has or is likely to have an adverse effect on the health and safety of people or the environment.

5 "Risk Generators" are required to demonstrate Compliance by Certification

Those people who are the subject of specific regulatory requirements will have to demonstrate compliance with those requirements - perhaps using the model of 3rd party auditors or assessors as provided for under the New Zealand *Building Act*.

6 Monitoring and Reporting Regime on the State of Public Health

This is required currently under the *Health Act 1956* (NZ) but it is proposed to be extended to cover the effectiveness and performance of the health sector and other sectors to the extent that their legislative functions affect public health.

7 Reserve Powers for Public Health Emergencies

These may arise in circumstances other than declared civil defence, biosecurity, or hazardous substances and include a limited overriding of other legislation.

Concluding

The Risk and Intervention Methodology will consider more than technical issues - it will include social, cultural, technological issues, and will not bind decision makers, or remove the political dimension. Recommendations will be made to the Director General or Minister of Health but will make the basis for decisions clear to the public. Experience in New Zealand shows that there can be public/political distrust if experts in Wellington making decisions affecting people.

I would recommend:

- Concentrating on "public health" risk management.
- Ensuring wide consultation and involvement around processes so that people understand that issues wider than the technical/scientific have been considered.
- Use the existing and familiar legislative models where this is possible.
- Suggest considering the difference between using public health legislation to introduce risk management methodology on the one hand and embedding risk management

approaches in the culture of public health practice before proceeding to reflect it in legislation.

James Edis ACT Health Authority, Canberra
Risk Management Legislation in the Australian Capital Territory

I will discuss the considerations that are used in the decision making process when declaring public health risk activities.

Section 18 of the ACT Public Health Act 1997 provides for the following declaration:

- (1) The Minister may, by instrument, declare an activity that may result in the transmission of disease, or that may otherwise adversely affect the health of individuals in the context of the wider health of the community, to be a *public health risk activity*.

Section 18 provides a graduated regulatory scheme with each activity regulated on the actual / perceived level of risk associated with it. Section 18(2) and (3) provide:

- (2) A declaration under this section may, in relation to a public health risk activity, declare 1 or more procedures in relation to that activity to be public health risk procedures.
- (3) A declaration must indicate—
 - (a) for a declared public health risk activity—whether the activity is licensable, non-licensable or registrable; and
 - (b) for a declared public health risk procedure—whether the procedure is licensable or non-licensable.

There are a number of *public health risk activities* that have been declared. There is a broad range of activities covered. This demonstrated the flexibility of the approach. These activities are:

- Operation of a Cooling Tower or Warm Water System.
- Carrying on of a Hairdressing Business.
- Carrying on of a Boarding House Business.
- Operation of a Drinking Water Utility.
- Operation of a Public Swimming or Spa Pool.
- Operation of a Private Hospital.
- Operation of a Centre for opioid detoxification using opioid antagonists.

In declaring a public health risk activity, the following considerations are relevant:

- Location Identification. (Registration or licensing may not be needed if the activity's location is easily identified).
- The possible impact on the health of individuals in contact with the activity in the context of the wider health of the community. (Impact refers to the nature of the activity and the consequences if something goes wrong).

- The skill and training required to properly conduct the activity safely. (This is particularly relevant in cases where the activity involves medical treatment).
- The premises and equipment required to conduct the activity safely.

Categories of Regulation Determined by Risk. The Act allows for a range of interventions - from highest to lowest. Each level brings different imposts on the person carrying out the activity. In relation to registrable activities, there is a right to be registered if the person pays the required fee, provides the required information and is deemed qualified to conduct it and there is no other reason not to register (eg the person has not committed a relevant offence). Codes of Practice can apply to any of the following categories.

The categories are:

- Licensable Public Health Risk Activity.
- Licensable Public Health Risk Procedure.
- Registerable Public Health Risk Activity.
- Registerable Public Health Risk Activity - Location Specific
- Non-Licensable Public Health Risk Activity.
- Non-Licensable Public Health Risk Procedure.

Enforcement and Administration: The Act contains elements that are flexible. They allow for specific or general controls over an activity or individual carrying on an activity.

Accreditation approval rewards proactive activities and persons. The Act:

- Allows for the issue of improvement and prohibition notices.
- Is able to place conditions on the licence or registration.
- Provides for compulsory adherence to determined Codes of Practice.
- Provides for the approval of accreditation schemes.
- Creates an offence for carrying on an activity without the required licence or registration.
- Creates an offence for not carrying on an activity in accordance with the declared Code of Practice.

Codes of Practice: Codes are developed in consultation with the industry, often at the request of industry. They have the same status as regulations without the need for formal drafting by Parliamentary Counsel. Licences or registrations may require compliance with a code as a condition. This will depend on the circumstances of particular cases. Thus the key features of the code may be summarised as follows:

- Industry based development.
- May be quickly and easily amended in light of new procedures or technology.
- Improvement notices may be issued for non-compliance with a Code of Practice.
- No requirement for licence or registration to be connected with a Code if desired.

- Disallowable instruments under the Subordinate Laws Act 1989.
- Penalty for non-compliance up to \$250,000.

It should be noted that the penalty is significant by public health standards.

Declared Codes of Practice: The following have been declared as codes of practice:

- Drinking Water Quality Code of Practice.
- Cooling Towers and Warm Water Systems Code of Practice.
- Public Health (Hairdressing) Code of Practice.
- Swimming and Spa Pools Code of Practice.

There are also Draft Codes of Practice which are being developed:

- Infection Control Code of Practice. (these are based on provisions that previously were regulations)
- Health Care Facilities Code of Practice. This Code relates to information flow - both to government and consumers and seeks to maintain the quality of systems.

To provide an indication of the scope and structure of these Codes, the following is extracted from the *Drinking Water Quality Code Of Practice 2000*

Introduction

This document is intended to provide a framework for reporting and water quality management relating to the supply of drinking water in the Australian Capital Territory. The Department of Health and Community Care has formulated this Code of Practice so that any risks associated with drinking water quality can be identified and managed to minimise the threat to the health of the people of the ACT.

The process of risk minimisation will be facilitated through the identification, evaluation and implementation of actions in order to reduce the risk to human health. In achieving the goal of protecting public health through risk management, scientifically sound, cost-effective, integrated actions are the Departments primary concerns while taking into account social, cultural, ethical, political, and legal considerations.

Scope

1. The supply of drinking water in the ACT is declared a 'A Licensable Public Health Risk Activity' under the *Public Health Act 1997*.
2. Operators of water systems (water utilities) are required to obtain a licence under the *Public Health Act 1997* and that licence may include standard conditions.
3. The licence holder is be required to comply with this Code of Practice.
4. The Code of Practice consists of three sections; Australian Capital Territory Water Quality Protocol, Water Incident Notification Protocol and Water Incident Response Protocol.

The particular issues covered by the Code are the following:

Part I - Water Quality Protocol

- Publication of Annual Drinking Water Quality Reports
- General Requirements
- Specific Publication Requirements
- Notification Requirements
- Characteristics Required to be Published
- Public Access to Information
- Water Quality Testing - Requirements
- Cryptosporidium and Giardia Monitoring
- Catchment Monitoring
- Drinking Water Quality
- Laboratory Testing
- Water Quality Improvement Plans
- Area of Application
- Transitional Arrangements

Part II - Water Incident Notification Protocol

- Type 1 Incidents (serious incidents that could cause risks to human health and require immediate notification to the Chief Health Officer. They are incidents which, if not immediately addressed, can lead to significant and acute harm to humans).
- Type 2 Incidents (lesser incidents that could cause risk to human health and require notification to the Chief Health Officer or a nominated Officer of the Department of Health and Community Care. They are incidents which may lead to human illness in the medium to long term, but pose no immediate risk.)

Copies of all codes on the ACT Health website at:

www.health.act.gov.au/publications/index.html

Jim Dadds, SA Department of Human Services, Adelaide
Current and Possible Legislative Requirements in South Australia

South Australia passed its current public health act (The *Public and Environmental Health Act*) in 1987. It has 2 parts, sanitation (an old concept in public health terms) and provisions for the notification of disease. It did not follow the models of later Act, such as the ACT *Public Health Act* 1997 and Tasmania's *Public Health Act* 1997. In particular it has no specific provision for public health risk activities, nor does it allow licensing and registration of activities or premises that may be of public health concern.

The South Australian Act has 2 key sections. These are Section 15, which provides:

15. (1) If premises are in an insanitary condition, the authority may, by notice in writing, require an owner of the premises or any other person who is apparently responsible for causing the insanitary condition or allowing the insanitary condition to occur-

- (a) to take specified action to improve the condition of the premises; or
- (b) to desist from a specified activity to which the condition of the premises is apparently attributable.

(2) If residential premises are, by reason of their insanitary condition, unfit for human habitation, the authority may include in a notice under subsection (1), a direction that, after a date specified in the notice, the premises must not be occupied until-

- (a) specified action to render the premises fit for human habitation has been taken; and
- (b) the authority is satisfied that the premises are fit for human habitation.

(3) A person to whom a notice under subsection (1) is addressed shall not, without reasonable excuse, fail to comply with the notice. Penalty: Division 5 fine. Expiation fee: Division 6 fee¹⁴

This is the *insanitary conditions* power that provides the traditional public health response and the link back to the 1800s. The response in these cases has generally been to impose an abatement notice.

The term insanitary conditions is defined as follows:

1. Section 3 (2) Premises are in an insanitary condition if-
 - (a) the condition of the premises gives rise to a risk to health;
 - (b) the premises are so filthy or neglected that there is a risk of infestation by rodents or other pests;
 - (c) the condition of the premises is such as to cause justified offence to the owner of any land in the vicinity;
 - (d) offensive material or odours are emitted from the premises; or
 - (e) the premises are for some other reason justifiably declared by the authority to be in an insanitary condition.

It will be noted that the definition includes the term “risk to health” which is not further defined. Though, it is used in other provisions of the Act. Section 17 provides:

Section 17. (1) If an activity-

¹⁴ \$8 000 and \$300 respectively.

- (a) gives rise to a *risk to health*; or
- (b) results in the emission of offensive material or odours, the authority may, by notice in writing to the person responsible for the activity, require that person to desist from the activity or to observe requirements stipulated in the notice in relation to the carrying on of the activity.

It is an offence for a person who, without reasonable excuse, fails to comply with a notice.

There is also a broad power provided by section 36, though it relates specifically to risks to health from the spread of infection. It provides as follows:

36. (1) Where there is danger to public health from the possible spread of a notifiable disease, the Commission or an authorized officer authorized by the Commission for the purposes of this section may give directions and take such action as may be appropriate to avert that danger.

(2) Without limiting the generality of subsection (1), the Commission or authorized officer may-

- (a) direct that any premises, vehicle or article be cleansed or disinfected;
- (b) direct the destruction of any article, substance or food;
- (c) seize any vehicle, article, substance or food;
- (d) impose areas of quarantine or close premises;
- (e) restrict movement into and out of any place or premises;
- (f) take such other action as may be prescribed.

Responsibility for enforcing sections 15 and 17 lies with the local council. There was a devolution of sanitation powers to councils, while responsibility for disease control moved to become a sole State responsibility.

Guidelines have been developed for local councils in relation to skin penetration, hairdressing and are proposed for legionella.

Offences under these sections follow from a failure to comply with the notice, while there is also an appeal in relations to the notice to a specialist review committee. Where appeals occur, they typically involve neighbourhood disputes in relation to amenity issues. Odour complaints are prominent, as are industrial type backyard activities in residential areas such as fibreglass work or spray painting. Industrial or agricultural activities in areas where buffer zones have been eroded, or where an existing use applies have also been the subject of complaints. These include mushroom farms, chicken processing plants and agricultural spraydrift. Amenity issues such as the keeping of large numbers of birds or cats, or the hoarding of large amounts of rubbish have prompted complaints under the Act from neighbours affected by the activity. These involve a balancing of interests.

In many complaints, it is likely that other regulatory systems, such as planning controls or environment protection provisions have either failed or do not apply. By comparison, the public health provisions are flexible, can provide site specific solutions and can also take into account broader issues.

It should be said that the process of establishing “risk to health” used by environmental health officers in South Australia tends to lack rigour and consistency. The appeals suggest that they do not arrive at a conclusion in a documented and systematic way.

The recently released Discussion Paper on the Act¹⁵ considers the way in which “risk to health” might be approached and makes the following points:

- The concept will always require a qualitative approach, comparing likelihood and seriousness of risk with the costs etc of abating it, which may usefully be informed by established standards for exposure, or calculations of risks of adverse health affects from lifetime exposures where these are relevant. However, each “risk to health” as envisaged by the Act is a ‘stand alone’ issue within its own context and circumstances. There is no single quantitative approach which will help to determine whether or not something is a “risk to health” for the purposes of the *Public and Environmental Health Act 1987*.
- Risk is different to the concept of “hazard”. Many activities, such as the storage or transport of chemicals are hazardous but if undertaken safely do not present a risk to health. However, a hazard may become a risk, typically because the hazard is not being managed safely. In these cases special purpose legislation and licensing conditions (for example those established under the *Dangerous Substances Act 1979*) generally specify the requirements that ensure that health is not put at risk. Failure to comply with these requirements may provide the grounds on which a prosecution can occur under the relevant legislation. It does not follow however that simply because the hazard is being dealt with in accordance with legislated requirements that this precludes it from being a risk to health.
- Health should be defined broadly, to include both specific and non-specific conditions such as headaches, nausea etc. There is nothing implicit in the phrase requiring the risk to be one that relates to serious ill health or to exclude some categories of ill health. This broad reading appears to be consistent with the context in which the term sits (in insanitary conditions for example)
- There does not have to be a victim in the sense that the prosecution or the council must demonstrate that someone’s health has actually been adversely affected by the risk. It is enough that the risk exists. Thus specific (and often difficult) questions of individual causation do not need to be addressed and population based evidence showing that a risk was present is sufficient. This is consistent with the way in which section 19 of the *Occupational Health Safety and Welfare Act 1986 (SA)* - the general duty to provide a safe workplace- functions. It is enough for the prosecution to show that a workplace was unsafe, not that a person has been injured as a result of it.

¹⁵ *Review of the Public and Environmental Health Act 1987: A Discussion Paper 2000*, (Dept of Human Services, SA).

- The provisions should apply to prevent risks to the health of particular classes of individuals in the population such as people with asthma, as well as risks to the health of the “normal” average population.
- The risk should be a real possibility, not fanciful. Words such as “likelihood” or “probability” (used in the examples cited above but not in the *Public and Environmental Health Act 1987*) infer that the risk should be real but *not* necessarily “more likely than not” (ie the likelihood of the risk occurring does not have to be 50% or greater). It is arguable that, provided there are grounds to state that the activity can have attributed to it a real, as opposed to a trivial, risk to health, it conforms to the requirements set out in the *Public and Environmental Health Act 1987*. Further, it is also arguable that where the risk to health is to “serious ill health”, intervention is warranted even if the likelihood of the ill health occurring might be relatively small. Overall, though, each case will need to be considered on its merits and there is no way in which a clear figure can be put on the threshold size or likelihood of the risk that warrants intervention.
- The precautionary principle could be properly applied in addressing the term “risk to health” especially in deciding whether something was an insanitary condition for the purposes of section 15 of the Act. This principle argues that where full scientific certainty about the health effects of a particular activity is lacking, policy makers are justified on erring on the side of caution in prohibiting that activity.

It also canvassed the possibility of having a risk based offence as its central response to the issue. The following was canvassed in the Discussion Paper

A model for discussion is presented here and is adapted from the *Environment Protection Act 1993 (SA)*.

1 A new offence of causing a *serious risk to health* be inserted with

- A high penalty where a person *knew or was reckless* to the fact that his or her conduct would result in a serious risk to health.
- A lesser penalty where the person has caused the risk but the person was not aware that it would result in a serious risk to health.

2 An offence of causing a *risk to health* with a single penalty - thus a person who causes a risk to health is guilty of an offence.

Definitions

A *risk to health* retains its current scope (ie if it is reasonably possible that the health of a person or persons has been or might have been damaged by the activity)

A *serious risk to health* occurs if it is likely that the activity will result in harm to individuals that is of a high impact or on a wide scale

The terms "risk to health" include cases where actual damage or injury occurs or where it might have occurred.¹⁶

The Discussion paper also raised a number of other issues, including:

- A general statutory duty to protect public health.
- The value of objects in legislation.
- Health impact assessments.
- The application of gateway controls and licensing for activities that present a public health risk.
- Should there be circumstances in which the State, rather than the local council should act? (The New Zealand paper indicated that there should be cases where the response to risks should be centralised.)

Submissions on the Paper closed last August and responses were largely in support, - both for the objects and the application of the precautionary principle. A majority were also in support of graded offences and a general statutory duty of care, though with some discussion on whether a penalty should be attached.

It was felt that the current provisions relating to risk to health should be retained and that guidelines should be developed to deal with ambiguity in relation to the term.

There was also strong support for registration and licensing (especially from regulators). Generally, 'negative licensing' through the operation of codes and guidelines was considered an appropriate form of control for most activities.

In Summary

Any review of the Act needs to establish the right balance between the following:

- the extent to which public health law should have a local application;
- the respective roles of the local and the central authorities;
- the 'safety net' nature of public health powers in light of the development of specific land use and environmental controls; and
- the need to have some flexibility to deal in a holistic way with localised issues.

¹⁶ Editor's note - The South Australian Draft Food Act (which follows the general structure of the national Model Food Act) provides an example of this risk based offences as follows:

Sale of unsafe food

14. (1) A person must not sell food *that the person knows* is unsafe. Maximum penalty:

(a) If the offender is a body corporate—\$500 000.(b) If the offender is a natural person—\$100 000 or imprisonment for four years.

(2) A person must not sell food that the person *ought reasonably to know* is unsafe.

Maximum penalty:

(a) If the offender is a body corporate—\$250 000. (b) If the offender is a natural person—\$50 000.

16 (2) A person must not sell food that is unsafe.

Maximum penalty:

(a) If the offender is a body corporate—\$150 000.

(b) If the offender is a natural person—\$30 000.

Under the Act, food is unsafe if it would be likely to cause physical harm to a person who might later consume it (section 8)

**Kate Purcell Principal Policy Officer, Public Health Legislation Project
NSW Department of Health and Mark Ferson Director, South Eastern Sydney Public Health Unit**

The Application of Risk Management Principles to Public Health Legislation and Some case Studies - the NSW Context

The current NSW *Public Health Act* was passed in 1991. Its problems have been identified as follows:

- No consistent philosophy or approach.
- No coherent structure.
- Not a useful framework to deal with emerging public health risks.

However, there are ways in which risk management can occur in the Act. These are via the following public health powers and orders:

- The power to issue orders and directions during an emergency (sections 4 and 5).
- The power to seize, disinfect or destroy articles that may transmit an infectious disease (under certain conditions) (section 7).
- The power to close premises where the public are required, permitted or accustomed to congregate to preserve the health of the public.
- The Minister can issue directions to public authorities where their action endangers the health of the public (section 10).

Beyond these powers, the Act also provides substantive controls that deal with areas that deal with risk. These include Part 2B of the Act that regulates safety of drinking water, the regulation of swimming pools and spas, the funeral industry, microbial control, skin penetration activities, places of shared accommodation ie “sleeping rooms.”

Powers to control local conditions (eg public health nuisances or insanitary conditions) are found in provisions of the Local Government Act. These include Section 124 which allows councils to issue orders. In particular, Order 15 allows for the following order - not to conduct or to cease conducting an activity on premises where the activity:

- constitutes or is likely to constitute a life threatening hazard or a threat to public health or public safety and
- is not regulated or controlled under any other Act by a public authority

Order 21 allows councils to order persons to:

- do or refrain from doing things specified in the order to ensure that land is, or premises are, kept in a safe or healthy condition

There have been a number of problems identified in the *Public Health Act*. These are:

- gaps in the existing legislative framework; and
- the limited scope for proactive responses under traditional public health legislation

It is proposed that the new NSW Public Health Act will:

- Reflect contemporary public health practices.
- Provide a more coherent framework for regulatory activity.
- Provide a framework to deal with emerging public health risks.

In relation to risk management principles under the new Act, the challenge was to develop a legislative framework for public health that allows flexible and timely responses to emerging public health risks. Models from environment protection and local government legislation were examined, and the following key reforms were proposed. Namely, the new Act will permit a range of regulatory responses, including the following:

- setting standards by regulation;
- operating approvals for prescribed activities;
- registration of prescribed activities;
- mandatory testing for prescribed equipment/installations;
- reporting requirements in prescribed circumstances;
- risk management plans;
- mandatory inspections;
- third party certification for prescribed activities or equipment / installation.

Other key reforms include replacing the role of Medical Officer of Health with a Regional Health Officer (RHO), who will have significant public health expertise and be responsible for local leadership on public health issues. The RHOs functions will include:

- the investigation of matters of significant risk to public health;
- the co-ordination of activities in order to respond to significant public health risks;
- enforcement of public health legislation;
- reporting on matters affecting the health of the public;
- reporting on enforcement of legislation;
- issuing orders similar to those issued under s124 of the Local Government Act.

The Act will also contain:

- Enforcement provisions.
- Consolidate powers of entry.
- Introduce infringement notices.
- Update the penalties.
- Higher penalties for corporations and repeat offenders.

The next steps in the review will be to have the review report with the Minister and, if approved by Cabinet, drafting will commence. Consultation is yet to be determined, but it is anticipated that it will be introduction to Parliament this year.

Mark Ferson provided examples of case studies of responses to public health risk under the current public health legislation

The scope of the current Act is as follows:

- Public health risks: premises, articles, water, emergencies etc.
- Scheduled medical conditions: notification & regulation of individual.
- Control of vaccine preventable diseases.

- Microbial control (legionella).
- Funeral industry matters.
- Tobacco advertising & sales to minors.
- MOH, powers of entry etc.

Mark then provided some case studies relating to the operation of the current Act

Example 1: Tobacco sales to minors

Here, the intent of Act simple – it prevents people selling tobacco products to children. In this case there is a significant educational component, which makes industry and retailers aware of their responsibilities. The role of Public Health Unit staff is to educate retailers, monitor compliance and to enforce the provisions. There is an organisational process in place to support this (this is part of the performance agreement). There is also good central support for this activity, and staff training, resources for it.

Example 2: Exclusion of un-immunised contacts

Here, the intent of Act is clear - to encourage & document immunisation, notify cases, and to exclude them. Ongoing effort is required by public health unit staff to educate those affected by this process. There has been greatly improved disease notification sensitivity *but* diminished specificity and probably improved immunisation uptake.

The exclusion provisions have proved confusing and possibly discriminatory.

Example 3: Regulation of colonic irrigation

This is a newly identified ‘health’ procedure, made fashionable by Princess Diana. It is not regulated under usual health acts ie professional registration or the *Public Health Act*. There is a risk that poor hygiene will lead to the transmission of serious infections (enteric, blood borne). There has also been an investigation of an acute hep C case, which has implicated colonic irrigation. The operators of this procedure have inadequate public health knowledge and the Act provides no powers to regulate or impose conditions on operators’ behaviour. The Skin penetration regulations were changed as a result.

Workshop Discussion

For the last part of this session, the Workshop broke into 4 groups in order to consider and then report back on the following questions (set out below).¹⁷ The following is a dot point summary of the issues raised by the groups for each question.

Question 1 How can risk management principles be incorporated into public health policy making

- Traditionally public health has always taken a risk management focus. (B)
- Risk assessment processes are important in public health policy making and they do not necessarily have to be required in legislation. (B)
- The emphasis on *public health* is important. (B)
- The process of risk management helps to determine options for action, such as legislation, community education. (B)

¹⁷ The 4 groups were "colour coded" as follows - blue (B); green (G); red (R) and yellow (Y).

- Guidelines for risk management are important for establishing consistency in risk assessment. (B)
- An assessment done properly nationally, or at a State level, can provide a model that can be used at the local level. (B)
- "de-jargonised" information is necessary so as to train EHOs and others in risk assessment. (B)
- It is important to take account of community concern. (B)
- Public health administrators need to know *how* to explain *risks* and the *cost benefits* of strategies. They also need to understand the political process. (B)
- Consultation needs to be skilled and sensitive to the culture of the affected communities, as do the strategies to deal with risks. (B)
- Being clear about the context at the beginning is important - for example the priorities that the affected community might have. (B)
- Often resources are lacking to assess risks properly, especially in the case of benefits which are beyond the scope of the normal public health process (eg where employment opportunities will be affected by the proposal). (B)
- Policy should be tied into the RIS process. It should be built into the culture of the organisation and linked to the objects of the legislation. (B)
- Administrative processes must be able to detect and take account of emerging issues of public health concern - eg the horizontal transmission of HIV (patient to patient transmission) - it was felt that the New Zealand model will be structured in a way that allows this. (R)
- Public health administrations need the power and capacity to require information for public health surveillance and action. (R)
- There should be a requirement to notify the presence of a public health hazard (R)
- There needs to be clear guidelines that allow public health administrators to work through what amounts to a *risk to public health*. (R)
- Policy (perhaps through legislation that supports it) must make operators of processes that can adversely affect health and which are of interest to the public health process:
 - carry the burden of proof;
 - impose reporting requirements;
 - recognise a hierarchy of controls, where certain approaches are take priority over others. (R)
- Overall, it is possible to incorporate risk management principles into public health policy making. (R)
- Involve the community not just the public health policy makers. (Y)
- Making the consultation process more "consumer friendly". (Y)

Question 2 How do you translate concepts of risk management principles into everyday practice and/or guidelines for decision makers?

- The process articulated by ANZFA is a good one - it is linear and iterative. (G)
- There is a need to define risk as it is applied and relevant to public health. (G)
- Building up a constituency is important. (Y)
- Identifying the champion or expert for the "cause." (Y)
- It is important to have examples where risk management has been successful - it is good to get publicity for successful initiatives. (Y)

Question 3 What do you see as the challenges to incorporating risk management principles into public health legislation?

- The need to balance competing interests. (R)
- Communication of risks to the public - but how effective can that be in shaping and influencing its views? (R)
- Some ongoing processes are promising - eg Municipal Health Plans - where there are ongoing links with the local community. (R)
- Health Departments are reluctant regulators - they don't see it as part of their "core business". (R)
- The perception of uncertainty and how to deal with it. (Y)
- The political cycle - political needs may flow separately from public health needs. (Y)
- Risk Management principles are very useful but there are issues of the competency and the technical expertise of those who are involved in them. (Y)
- It is always difficult to quantify the public outrage in any particular incident (eg Legionella outbreaks). (Y)

Question 4 How would you incorporate risk assessment /risk management into your Public Health Act?

- Objects are important, it was felt that ANZFA's objects were straightforward, simple and unqualified - to protect public health and safety. (G)
- A public health advisory committee - though not necessarily established by legislation - it needs to have credibility and be seen as independent. (G)
- Risk friendly legislation - would this help to encourage performance based outcomes? (G)
- Regulations should be objective and functional. They should focus on outcomes and output measures. (G)
- Statutory consultation and methodology for risk assessment should not be written into statute - rather they can be provided for administratively. (G)
- The precautionary principle allows for different interpretations about its content and requirements. There needs to be a definition about what's it is and how it will be applied

if it is to be put in legislation. It may not be required as a stand alone provision if there are well defined objects. (G)

- Organisational structures in jurisdictions influence the type of legislation - eg the relationship between the State and local government, the involvement of other agencies and community participation. (G)
- Risk management plans imposed on the regulatory community can be very important - they place the onus on operators to ensure that their processes do not pose a risk to health. (R)
- The municipal health plans are supported. (R)
- The defence of due diligence - which places an onus on the operator if prosecuted to demonstrate that he/she actively took steps to safeguard health as part of the ongoing process of operation. (R)
- A range of appropriate enforcement tools are necessary (infringement notices, 3rd party certification etc.) (R)
- Health issues must be integrated into the Impact Assessment process, and public health specialists must be involved from the initial meetings, to ensure that these issues are properly integrated. This involves changing legislation other than public health. (R)