

Evaluating benefits and costs of food regulation

A scoping study

Prepared for

Australia New Zealand Food Authority

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Glossary

AFGC	Australian Food and Grocery Council
AIHW	Australian Institute of Health and Welfare
ANZFA	Australia New Zealand Food Authority
BSE	Bovine Spongiform Encephalopathy
COAG	Council of Australian Government
DALY	Disability-adjusted life years
GM	genetically modified
НАССР	Hazard Analysis and Critical Control Point Program
MRL	Maximum residue limit
NIP	Nutrition Information Panel
PAF	population attributable fraction
QALY	Quality-adjusted life years
RIS	regulatory impact statement
SKU	stock keeping unit
TBT	Technical Barriers to Trade
WTO	World Trade Organization



Summary

- We have analysed the issues involved in assessing the impact of food regulation on the economy from improved health of the general population.
- Based on these issues and the Australia New Zealand Food Authority's (ANZFA) requirements we have recommended an analytical framework for ANZFA to use to quantify the economywide benefits of its portfolio of work.
- We recommend five components of analysis, which are combined sequentially into an integrated framework.
 - The first component is a scientific risk assessment that generates information on the reduction in morbidity and mortality likely to be achieved by the ANZFA project.
 - The second component calculates compliance and other costs associated with ANZFA regulation.
 - The third component combines the human capital and cost of illness approach to calculate the stream of benefits associated with the reduction in morbidity and mortality generated from the scientific assessment. These benefits are expressed in terms of the profile of change in labour earnings, the number of people of working age, labour productivity and medical expenses.
 - The fourth component combines these outcomes to calculate the effect of changing regulation on consumer health measured by present value of costs and benefits.
 - The final component uses an economywide model to add up the impact of the outputs from the human capital/cost of illness approach in component three and the compliance and other costs in component two to generate the economywide impact in terms of improving national income (GDP) and other macroeconomic and sectoral performance indicators.
- The series of linked components we propose will result in a manageable quantitative framework. Combining all elements into one model will not. It is important that the modelling framework be transparent.

Transparency would be lost in one overarching fully simultaneous system.

- We recommend that the economywide modelling component of the integrated framework make use of an existing economywide model. It would not be cost effective to construct a new model from scratch.
- Several existing economywide models could be readily adapted to fit into the integrated framework. The degree of theoretical modification needed would be minimal. The main problem is one of incorporating data at the very fine level of detail used by the work program of ANZFA with the sectoral detail in these models which is invariably much more aggregated. While disaggregation of some food sectors can be readily undertaken, to build a disaggregated framework down to the level of products which form the focus of ANZFA's work would be a monumental and time consuming task. Inevitably, trade offs on information detail will need to be made.



Objectives of the study

THE AUSTRALIA NEW ZEALAND FOOD AUTHORITY (ANZFA) requires advice on the feasibility of options to develop a model of the Australian and New Zealand economy that can demonstrate the impacts of food regulation.

ANZFA is the lead regulation body for food in Australia and New Zealand. In order to develop food standards under the *Australia New Zealand Food Authority Act 1991*, ANZFA must understand the costs and benefits of its regulations. This analysis must be conducted in a suitable framework that is accepted and transparent to stakeholders in industry, government and the community.

Section 11 of the Act sets out ANZFA's objectives. The objectives of the Authority in developing food regulatory measures and variations of food regulatory measures are:

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

In developing food regulatory measures and variations to food regulatory measures, the Authority must also have regard to:

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

These are supplemented by a range of implicit objectives and some broader government directives, such as:

- maintain consumer confidence in the food supply;
- provide scope for innovation of new products;
- move away from a prescriptive full regulation approach to a less rigid form of regulation where possible;
- provide a level playing field for industry and regulation through least cost compliance; and
- achieve harmonisation of regulatory approaches between the states, Australia and New Zealand and internationally.

From the Act and its other objectives it is clear that ANZFA is faced with assessing the costs and benefits of regulations that can potentially flow through to a broad range of outcomes. But, ANZFA is primarily concerned with regulation of food to minimise adverse public health outcomes. That is, regulation is designed to minimise morbidity and mortality in the general population. The second most important objective is the provision of consumer information to permit informed choices.

The next step is to outline ingredients of good modelling practice.

2

Principles of good economic modelling

WHEN CONSIDERING THE APPROACH to modelling a particular problem, it is important to focus on what matters. In this section we outline the principles and the ingredients of an effective model that captures the important components of the problem at hand but also is transparent to users and stakeholders.

A model is an abstraction from reality. Its purpose is to simplify the workings of a complex economic system so that it can be more easily understood. The art of good model building is to include in the model those factors — drivers, behavioural mechanisms, linkages — critical to shaping outcomes for the class of problems being analysed but to exclude those factors of low level or negligible importance.

Every part of the real economy is linked to every other part. But it does not make sense (nor is it possible) to include all links. To attempt to do so would be to defeat the whole purpose of modelling — which is abstraction to get down to a manageable and understandable unit.

No one modelling framework is suitable if the issues being addressed and the key economic pathways are too diverse. The required model is too large and complex to provide any meaningful insights to policy advisers. Models must never be used as 'black boxes'. Their value to users is in providing quantitative estimates of effects on key variables and in highlighting the key mechanisms behind them. Results need to be capable of being validated in terms of the underlying mechanisms in the model. Through this process of model interrogation much can be learned about the problem being studied.

This then leads to the possibility of an integrated approach — using a range of different models to analyse different classes of problems. To decide the correct approach we need to have an appreciation of:

- the various classes of problems ANZFA wishes to model
- the range of economic variables ANZFA requires projections for

the likely availability of data to drive the modelling work.

What are ANZFA's requirements?

ANZFA's recent work program has comprised two broad areas:

- harmonisation of existing food and food safety standards and labelling requirements; and
- modification of those standards and requirements to permit new foods, ingredients and additives.

Through addition of novel ingredients and foods, and changing labelling requirements, ANZFA is continually changing the Food Standards at the margin. For each change, a benefit cost analysis is conducted. This is currently comprised of two parts:

- a scientific risk assessment
- a qualitative assessment of benefits and costs to stakeholders.

The scientific risk assessment is required as part of the *Act* and identifies the risk of adverse public health outcomes and any 'at risk' groups in the general population. Box 2.1 outlines this process. The qualitative benefit cost analysis is conducted to satisfy the regulatory impact statement (RIS) requirement for any additional regulation under the Council of Australian Government's (COAG) agreement. The RIS identifies and qualifies the benefits and costs of regulation to all stakeholders for each option presented. The options for regulation involve degrees of prescription from full regulation down to self regulation.

How does ANZFA want to use the model?

There are several ways in which the modelling framework could be used as a decision tool within and outside of ANZFA. These include evaluation of the benefit and costs of:

- a proposal to change the food standards at the margin
- alternative options for implementing those changes in the standards
- food regulation generally (including ANZFA's activities).

2.1 Scientific risk assessment

The scientific risk assessment for substances that can be added to food or are found in food — including new food additive or ingredient — involves four stages.

The first stage primarily involves a toxicology study of the additive or ingredient identifying possible hazards for the chemical and what is known about acceptable levels of the hazard from overseas studies, etc.

The second stage characterises the hazard and sets limits (from a toxicology point of view) based on the acceptable daily intake analysis. This analysis often draws from animal studies. The third step is a dietary exposure assessment to see how actual intake through the diet matches up against the acceptable daily intake (includes identifying the foods in which the ingredient occurs).

The dietary exposure analysis is conducted based on diet surveys for Australia (1995) and New Zealand (1997). The Australian survey is based on a sample of 13 000 people. The risk analysis is based on consumption patterns at that point in time. The dietary analysis is therefore based on a snapshot of the population — in terms of dietary patterns — but can be applied to different population profiles as required to obtain an assessment for the population as a whole.

The final stage is comparing the dietary exposure estimates to reference health standards to characterise the extent of the risk.

The analysis does not factor in changing population structure or changes in dietary patterns, such as:

- ageing of the population so that more people move into the 'at risk' categories
- continuing shift in eating patterns to include eating out foods.

Benefit and costs of changes in the standards

The majority of the proposals put before ANZFA involve relatively small changes in the structure of the food standards. The calculation of the net benefits of each of these changes would permit ANZFA to rank each change in the code, in terms of net payoffs, that are on the proposal or application list. It would also permit ANZFA to evaluate, ex post, regulations already in the code.

However, applications or proposals for changes in the code are usually dealt with in the order they are received. Often neither costs or benefits are known until:

- the nature of the problem is investigated
- the feasible responses have been identified.

Therefore ranking of changes to the code, on the basis of net benefit would not be useful to ANZFA. ANZFA's key concern with changes to the code is that the benefit cost ratio be greater than one.

5

Where the framework would be useful is in providing assistance in ranking options for regulation. The scope for regulation from full regulation to self regulation involves a range of tradeoffs that impact on public health outcomes. There may be also many options available within any one type of approach. The cost of a less prescriptive approach may be poorer public health outcomes. The benefits may be less costs to industry and to regulators.

Benefit and costs of food regulation generally

One option would be to use the framework to evaluate the benefits and costs of food regulation for the economy as a whole. This would give policy makers a view of the total net contribution of food regulation.

The total contribution to the economy of food regulation or other aspects of ANZFA's could be measured in several ways through, for example:

- the addition to gross domestic product (national income)
- the reduction in total government outlays on health.

Results from this type of analysis would be useful to ANZFA in dealing with other government departments with regards to obtaining resources for its work. In principle this approach would be very difficult because we would need to attribute the changes in public health outcomes and the consequent benefits to national income and savings in government outlays between ANZFA (the lead regulator) and the relevant departments at all other levels of government (the implementers and monitors).

If we were to evaluate the benefit cost of ANZFA's activities alone, the correct counterfactual would be health outcomes without harmonisation of food regulations — that is — the fragmented regulations on a state by state basis.

How should benefits be assessed?

A key issue concerns how benefits (and costs) should be measured. There are a range of options. Since ANZFA is an Australian and New Zealand wide regulatory authority it seems appropriate that benefits should refer to the economy as a whole. The two most commonly used summary measures of economywide net benefits are:

- effects on national income GDP; and
- effects on aggregate consumer welfare (real aggregate household consumption expenditure).

The model would compute the extent to which these variables (perhaps expressed on a per person or per household basis) would be higher due to ANZFA's activities measured against their levels in a situation in which ANZFA was not operating.

Note that these summary measures of overall economic performance and welfare measure net benefits — after all costs of the measure have been properly accounted for. Any direct costs imposed on the food and other industries may need to be explicitly included in the model simulation.

3

Applying the principles

THIS CHAPTER IDENTIFIES what ANZFA must quantify. To do this we must understand the linkages between ANZFA's regulations, its outcomes and stakeholders.

ANZFA outcomes

The first step is to identify the direct outcomes of ANZFA. These are summarised in table 3.1. Each of these activities has an element of costs and benefits. The table also identifies stakeholder groups involved.

Compositional food standards(what is in food)

The core function of ANZFA is to protect public health and safety through regulation of the food supply. This involves two broad components. The standards involve the description and definition of foods, what is in those foods and any mandatory fortification. The standards also deal with:

- substances that can be added to foods;
- contaminants and residues (including maximum residue limits);
- foods requiring pre-market clearance (so-called novel foods and ingredients); and
- microbiological and processing requirements.

These activities are summarised in table 3.2. A large part of ANZFA's current workplan involves clearance of substances that can be added to food. This includes decisions to omit or to limit food additives that may have adverse public health outcomes generally or adverse outcomes to specific at risk groups. It is interesting to note that regulations also apply to additives that are not regarded as food themselves — such as processing aids — and to the processes by which food is manufactured.

Activity	Direct outcome	Stakeholders
Benefits		
Compositional standards	Improved public health and safety	General public At risk groups
Labelling requirements		
 Specific advice 	Improved public health and safety	At risk groups
 Nutritional Information 	More consumer information and choice	General public
Nutrient content claims	More consumer information and choice Improved public health	General public
Food safety	Improved public health and safety	General public
Maximum residue limits (MRL's)	Improved public health and safety	General public
Costs		
Compositional standards	Restriction of choice Restriction of product innovation	Consumers Food manufacturers
Labelling requirements		
 Specific advice 	Increased compliance costs	Food manufacturers
 Nutritional Information 	Increased compliance costs	Food manufacturers
Nutrient content claims	Increased compliance costs Increased costs of monitoring and surveillance	Food manufacturers Government
Food safety	Increased compliance costs Increased costs of monitoring and surveillance	Food retail and service Government
Maximum residue limits (MRL's)	Increased compliance costs	Primary food producers

3.1 Direct outcomes of ANZFA

3.2 Food and compositional standards activities

Apply to:	That are:
 New foods 	 Potentially toxic. Essential to be assessed as safe within proposed levels of use or consumption.
 Food additives 	 Potential health benefits. Still required to be assessed as safe within the proposed level of use or consumption.
 Ingredients 	 Not potentially toxic or might otherwise affect health.
 Processing aids 	
 Processes 	

The benefits of regulation may be both short and long term in nature in reducing adverse public health events. Substances added to food can have short and long term food safety implications through food borne illness. Other food additives can also cause longer term health problems through prolonged use and cumulative effects.

Food manufacturers may bear costs involved with these regulations by being restricted in the development of new products, or inclusion of new or lower cost ingredients. Regulation may not permit consumers access to new products.

Labelling regulation and nutrient content claims

Labelling regulation can be thought of as comprising two parts:

- specific advice to at risk groups on safe levels of consumption or to seek medical advice before consumption. A good example is the consumption of low fat milk products for infants. This labelling applies to foods that may be new or already being consumed by the population. This component includes a strong component of the food safety objective.
- more generic information like the Nutrition Information Panel (NIP) including percentage labelling. This is intended to move away from the prescriptive approach to regulation of inputs to the description of outputs. In this case the emphasis is on the provision of consumer information which provides benefits in terms of more choice and long term benefits from better diet.

There are also some elements of food safety. These are summarised in table 3.3. The nutrient content claims component of the food standards ensures that labelling is consistent with the product claims. Consumer information is the prime objective: proof of the claim and the prevention of fraud. Nutrient content and related claims refer to instances where food producers signal the amount of a nutrient to be found in a product or for product characteristics. These claims include low in fat and the like.

Again food manufacturers bear costs in complying with these regulations. The extent to which consumers value the information required by more stringent labelling requirements should be reflected by an increase in demand.

Applies to:	Ensures:
 Foods consumed by 'at risk' groups 	 Advisory statements, as a condition of a compositional standard. Assists in appropriate consumption by the general public, and particularly by 'at risk' groups. Warning statements would be an extreme sub-group in this category.
 All manufactured foods 	 Information to consumers generally (NIPs, Percentage Labelling, Nutrient Content Claims) that assists consumers choose food products.

3.3 Labelling activities

The costs of labelling regulation will be borne in the first instance by food manufacturers in terms of higher costs of compliance. Depending on demand conditions for the product some (perhaps nearly all) of these costs will be passed forward to consumers. Labelling regulation may also provide domestic manufacturers with marketing opportunities overseas.

Food safety

These regulations are described in volume 3 of the food standards. They include regulations for good practice in the preparation and sale of food by retail outlets and food service businesses. The regulations allow scope for alternative procedures providing they are efficient.

Food safety is focused on the reduction of food borne illness in the short and long term that benefits the general public. Costs of the regulation are born by food retailers and food service outlets in terms of higher operational costs. There are also possible increases in the cost of surveillance and monitoring by other government departments.

Maximum residue limits (MRL's)

The regulation of MRL's applies to all foods and applies to ingredients to additives that are potentially toxic. These are essential to be assessed as safe within proposed levels of use or consumption.

Key stakeholder groups

Consumers have the largest stake in the regulation of food safety and provision of more information and choice and maintenance of public confidence in the food supply. Within the general public, the regulations particularly focus on at risk groups that include:

- children
- the elderly
- consumers with special dietary requirements such as diabetes sufferers
- those that require complete foods such as babies on formula.

Stakeholders within industry include all segments of the food chain:

- primary food producers
- food manufacturers (domestic and export)

- food distribution and wholesale
- food retailers and food service business.

Industry associations like the Australian Food and Grocery Council (AFGC) represent food manufacturers and retailers and distributors. The AFGC represents larger companies in Australia but there are other industry bodies at all levels of the food value chain.

Governments in Australia and New Zealand play a significant role in improving public health outcomes through all means available including:

- enforcement:
- surveillance and monitoring of compliance with food standards;
- delivery of public health care services within and outside of the hos-pital system; and
- public health education.

The government also has an obligation that any regulation satisfies and is consistent with domestic agreements and international treaties such as the:

- Codex Alimentarius, the Codex Guidelines;
- principles laid out in the COAG agreement; and
- Technical Barriers to Trade (TBT) agreements under the World Trade Organization (WTO).

Commodity detail

After identifying the stakeholders and the linkages by which they are affected by food regulation, the next important dimension is the level of commodity detail to which ANZFA's activities apply. This has important implications for choice of framework just as has correctly classifying outcomes and stakeholders of ANZFA.

Appendix A lists the proposals and current and finalised projects of ANZFA. Each project has been classified according to:

- the number of foods covered by the additional legislation; and
- how important these foods are likely to be in total household consumption.

The commodity detail of ANZFA's regulation varies from extremely specific individual products to changes in legislation that apply to all foods.

From table A.1, the majority of the current workplan involves changes to the existing food standards at the margin — and so applies to very narrowly defined products or ingredients. These products are usually small in terms of total diet exposure and total expenditure by households but legislation is required because of potential growth and to give consumers and industry access to new products. Take, for example, sports foods. Potential for strong market growth in specialist sport foods and possible misuse by non target consumers lead to a case for setting upper limits for some key ingredients.

Tightening of food labelling to deal with emerging trends towards organic and genetically modified (GM) foods is an example where the change in the legislation potentially applies to a broad range of commodities — particularly for fresh fruit and vegetables — but which currently represents a small but growing proportion of household expenditure.

At the other end of the spectrum, projects such as the expanded NIP and nutrient claims review apply to most foods that represent the majority of consumers' food expenditure.

Mapping of direct outcomes to benefits and costs

Table 3.4 takes the effects of food regulation one step further by allocating likely indicators to the benefits and costs identified in table 3.1. The table also suggests whether the effects are primarily short term or long term in nature and how they may be directly quantifiable.

The key message from table 3.4 is that the major source of direct benefits from ANZFA's activities is a reduction in morbidity and mortality over the longer term. This has an obvious benefit to individuals. There are also indirect or economywide benefits through a higher potential labour supply available to generate additional national income and living standards. In addition, there will be reduced health costs —most likely evident as reduced pressure on growth in health costs.

Public health and safety

Table 3.4 shows that as the result of food regulation, we can expect a reduction in:

- diet related disease (primarily in the long term)
- food borne illness (primarily in the short term).

Outcome	Indicators	Period	Directly quantifiable?
Benefits			
Improved public health	 Reduction in diet related disease 	 Primarily long term Drimarily chart 	 Yes, reduction in morbidity and mortality
	 Reduction in food borne illness 	term	
Improved food safety	 Reduction in food borne illness 	 Primarily short term but some long term component 	 Yes, reduction in morbidity and mortality
More consumer information	 Increased willingness to pay by consumers 	 Long term 	 Very difficult
	 Reduction in diet related disease 	 Long term 	 Yes, reduction in morbidity and mortality
Confidence in food supply	 Increased willingness to pay by consumers 	 Both long and short term effects 	 Very difficult
Industry sustainability	 Increase in industry profitability 	 Primarily short term 	 Yes, but contentious
Costs			
Restriction of choice	 Reduction in product range 	 Both long and short term effects 	 Very difficult
Restriction in product innovation	 Loss of market share or reduction in profitability 	 Both long and short term effects 	 Very difficult
Increased compliance costs	 Increased costs of production by industry 	 Primarily short term 	 Yes, but contentious
Increased costs of monitoring and surveillance	 More government resources 	 Short and long term 	 Very difficult

3.4 How direct outcomes could map to quantifiable benefits or costs

These can be quantified, in principle, by looking at the changes in the risk of morbidity and mortality in the general population. That is, if this regulation was introduced the attributable risk of illness in the population would drop from x per cent to y per cent.

The scientific risk assessment would be the logical starting point to evaluate the potential reduction in deaths and illness than would otherwise be the case.

Increased willingness to pay

An assured food supply, more consumer information and greater choice provides substantial benefits to consumers in both the short and long term. However, evaluation of the size of these benefits for all food regulation and for food regulation at the margin is very difficult. The typical approach to these types of benefits is to evaluate the consumer's willingness to pay. That is, what would consumers be willing to pay, in addition to what they pay otherwise, to have better product information and a more assured food supply? This would then translate to an increase in demand for food — and higher prices paid for food.

A recent example is the labelling legislation for GM foods — although the scientific risk assessment revealed no public health issue, the public demanded additional information be presented on labels.

The willingness to pay approach is now more sophisticated than it has in the past where measuring these types of benefits would have been subject to heavy bias. This is because consumers overstate the value of benefits because they do not really have to pay for them. Typically this meant that the sum of willingness to pay was found to be greater than the capacity to pay. The latest techniques for eliciting the value of these benefits address these problems through better 'framing' of the question — choice modelling. That is, instead of directly asking the value of public health benefit, the respondent is confronted with a series of tradeoffs. In public health, these involve choosing between dollar amounts and relative health risks. The big advantage of this approach is that it is not open ended. There are two disadvantages:

- Cost: the requirement for larger survey size and face-to-face interviews of complex questionnaires indicates that for a lot of applications cost would be prohibitive.
- It is very difficult to compare the results between different surveys because of the way in which they are framed.

That said, choice modelling is becoming more popular in the US health sector but restricted to very large health issues due to its cost. ANZFA may consider choice modelling only for very significant issue.

Industry profitability and sustainability

One of the perceived benefits of food regulation is the prevention of food safety events that may result in firm closure and a reduction in industry profitability generally. While this is true, it is worthwhile noting that:

 while these events can have a devastating impact at the firm level, the impacts on the broader industry are much milder and short term in value;

- consumers may switch to foods that are perceived to be safe but total food consumed is likely to remain unchanged as people satisfy their daily nutritional requirements; and
- measurement of both of these effects and abstracting away from other factors is very difficult.

The way in which 'food scare' outcomes are typically handled is as follows. A food scare is normally observed as a fall in demand over a short period followed by a recovery which may or may not get back to the previous level of consumption. For example, the outbreak of Bovine Spongiform Encephalopathy (BSE) in Europe during 1999 resulted in a fall in beef consumption of 30 per cent over a 3 to 4 month period translating to an 8 per cent fall on an annual basis. Demand for beef recovered fully in the UK (where BSE has ceased to be evident). But in continental Europe, demand for beef did not fully recover over following years as consumers switched preferences to competing meats (pig and poultry meats) and to as new outbreaks of BSE were reported.

Increased compliance costs and restriction in innovation

Redesign of labelling and provision of more information imposes costs on food manufacturers. However, the extent of these costs depend on the timeframe give to manufacturers to adjust. There is little doubt that the impact on manufacturers would be smaller over the medium term than if they had to comply immediately. This is mainly due to the fact that there is a natural evolution in food product lines and changes in packaging as manufacturers develop new products to target trends in the market.

Quantifying the costs of lost marketing opportunities to industry is also very difficult. One way would be to estimate the number of product lines that are restricted from the market as a result of food regulation. However, the true opportunity cost of the restriction is difficult to assess because the inability to market a new product or incorporate a new ingredient may force the manufacturer to modify the product or bring forward other products that were planned for development.

The size of these costs is contentious —it will be in the interests of manufacturers to overstate these costs.

Increased costs of surveillance

The costs of all food regulation or changes to regulation, taking a whole of government view, is very difficult to determine. The government system in

place to protect public health is broad, complex and involves some duplication at all levels of government.

One method of quantifying these effects would be to establish labour cost and other cost increases required to implement and monitor changes in food regulation. In reality, government departments would shift resources between areas on an as needs basis -making this aspect very difficult to quantify.



4

Quantifying the direct and indirect effects

WE HAVE IDENTIFIED that of the direct outcomes from ANZFA's activities the most fruitful areas for quantification in terms of significance and feasibility are:

- improvements in public health
- increased compliance costs on industry.

These changes affect the economy through a variety of mechanisms such as changes in labour supply and medical costs and the like to influence overall economic performance and living standards.

Benefit–cost analysis and risk assessments are commonly used in support of public health and environmental policy decision-making. When used to evaluate alternative policies, risk assessments provide estimates of the incidence of an adverse effect. From table 3.4 we concluded that the reduction in incidence of adverse events in public health through a reduction in food borne illness and diet related disease provides the bulk of the benefits from food regulation.

Benefit-cost analysis can then be used to value the benefits associated with the reduction in the adverse effects in relation to the cost of implementing the policy. This process involves attaching a dollar value to human longevity, which is potentially increased by reducing the risk of an adverse health event. While risk assessment can be performed without benefit–cost analysis, benefit–cost analysis cannot be conducted without risk assessment.

Reduction in death and illness

The first step in the process of quantifying the benefits of food regulation would be to formally quantify the numbers of deaths and illnesses prevented by changing food regulation. To do this we need to develop aetiologic or population attributable fractions (PAF's) as part of the scientific risk assessment (box 4.1). Explicit estimates of the potential reduction in morbidity and mortality as a result in the change of regulation are the mandatory first step in calculation of the benefits and costs.

This step would then naturally feed into the later steps involving an economic evaluation. For example, information on aetiologic fractions is used as an input to compute the change in the value of a person's life as a result of a change in disease status.

Dynamics are important

Any benefit cost approach relies on comparing the outcomes in the absence of regulation with that which would happen with regulation. A fundamental characteristic of public health risks is that they are heavily time dependent. That is, the incidence of adverse public health events will naturally change over time with population dynamics and as health trends develop.

Chart 4.2 provides a stylised illustration of public health dynamics. The baseline scenario of adverse public health outcomes should take into account:

- the dynamics of the population that the elderly, a major at risk group, will become a larger part of our population;
- that existing patterns of diet and nutrition will change; and
- the profile of disease and more specifically diet related disease is likely to change dramatically especially with technological breakthroughs such as a cure for diabetes.

In the case, as illustrated in chart 4.2, a medical breakthrough could potentially reduce the number of adverse events in the future. Without such a breakthrough the number of adverse events will increase steadily into the future. For instance, the incidence of deaths, as a ratio of the population, from cardiovascular disease in the US has halved since the 1970's, whereas the incidence of cancer has increased modestly. The drivers for the reduction in heart disease included elements of improvement in diet (lower fats and salts), but also elements of public education and the discovery of other risk factors such as smoking. In principle, these types of changes should underlie the baseline scenario against which changes in health outcomes — as the result of regulation — are evaluated.

4.1 Aetiologic or population attributable fractions (PAF's)

People get sick and die for a variety of reasons. In practice, the cause of a particular death or disease and the ultimate cause may be different from the proximate cause. For example, the underlying cause of many cancers is very difficult to determine.

Aetiologic fractions are the fundamental epidemiological statistic necessary to quantify the relationship between a risk factor and disease or illness. The fraction is defined as the proportion of total illness or ill health events in the population that could be prevented if a particular risk factor was reduced or eliminated.

Crowley et al. (1992) derived population attributable fractions for diet related diseases in Australia for a broad range of health conditions. This type of work would have to be extended to incorporate the impact of food regulation. Appendix B outlines the calculation of these fractions and draws on experience from studies that evaluate the benefits and costs of alcohol consumption.



4.2 Time profile of adverse public health events

The way in which the scientific risk assessment is currently conducted assumes a static view of population and dietary behaviour based on current and available data and sometimes makes qualitative assessment of how regulation should cater for future trends. Scientists are somewhat reluctant to factor in views about underlying public health drivers to establish the baseline.

The other component of the dynamic problem is how the reduction in risk, from regulation, would alter outcomes from the baseline. This is also shown in figure 4.2. The shaded area provides the benefit, in terms of reduction in adverse outcomes, from the regulation. In figure 4.2, the gap

closes between the baseline and with regulation because of the potential for a medical breakthrough. Equally without this breakthrough, the gap would widen so that the pay offs from changes to regulation would be greater.

Food regulation will have impacts on public health outcomes in the short and long term. Generally, changes in regulation that affect diet related disease will have long term effects — 20 years or more into the future. The evidence suggests food borne illness has short term and even long term impacts. It is also accepted that the majority of benefits of improved diets — as a result of public education and more nutrition information — will be realised well down the track.

The dynamics of the public health problem are likely to have significant implications for the payoffs to changes in food standards and in food safety. Although creating a baseline of the 'business as usual' outcomes for public health without the regulation(s) being evaluated is time consuming, it is nevertheless an important task.

Economic benefits of better public health

The next step is to estimate the economic value of the reduction in death and illness. Improvements in human health in the form of avoiding adverse health outcomes constitute the majority of benefits from a range of government based regulation that includes:

- food regulation and food safety
- policies to target reduction in alcohol and tobacco consumption
- policies to target reduction in substance abuse
- occupational health and safety programs
- medical research.

The economic literature in this field is extensive. Cost benefit has been the traditional vehicle for evaluating payoffs to changes in regulations and programs that have public health outcomes. But there are a variety of approaches to estimating the values of these benefits.

Valuing a human life is an extensive and controversial subject within economic analysis. There are three broad alternatives:

- willingness to pay approach
- the human capital approach
- the cost of illness approach.

These approaches also give an insight how the direct effects flow on to the rest of the economy to give a broader perspective of how the benefits and costs stack up.

Willingness to pay approach

An ideal approach would be to estimate the value of these improvements to health to everyone in the community affected by death, illness or disability to avoid death, illness or disability. The willingness to pay approach estimates the value of life in terms of how much individuals are prepared to pay to reduce risks in their lives and this approach uses revealed preference to value a life.

Table 4.3 summarises the direct and indirect benefits that could be incorporated into a willingness to pay approach to value the reduction of morbidity and mortality (lives saved and sickness avoided) in the general population.

Although this approach is in principle very appealing, it is problematic in its application. The outcomes of such an approach very much depend on how the questions are asked and the checks made for consistency of answers. The main area of bias comes about because the respondent faces no real budget constraint — which leads to overstatement of willingness to pay. This approach also gives rise to ethical and equity issues. What does the willingness to pay for an individual mean given the existence of a public health system or insufficient income to pay for health care insurance?

Human capital approach

The human capital approach treats people as a source of labour inputs to the production process. Under this approach the value of a person's life is equal to the discounted present value of that persons future earnings

4.3	Elements of	willingness	to	рау	approach
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Direct costs avoided	Indirect costs avoided
 Medical and related expenses paid directly by patient 	 Foregone labour earnings (paid and unpaid work) in the case of death or disability
 Medical and related expenses paid indirectly through the public health system 	 Loss of labour productivity (through paid sick leave) due to illness
	 Pain and suffering (by patient and carers)
	 Lost leisure time (by patient and carers)

stream — adjustments have to be paid for the value of unpaid work. This can be taken as an indicator of personal welfare (see stage 4 of chart 5.1). This approach implies that younger people have a higher value than older people and that the retired have a very small value.

Cost of illness approach

The cost of illness approach focuses on medical costs rather than the value of a person's life. It provides an estimate of the incremental direct medical costs associated with medical diagnosis, treatment and follow-up care which in turn results from adverse public health events.

The Environmental Protection Agency in the United States have constructed a comprehensive handbook on the calculation of the costs of various classes of illnesses based on estimates of US medical costs (EPA 2001). This handbook provides a comprehensive methodology and approach that would need to be followed to calculate the present value of labour earnings foregone and medical costs incurred.

Combining the human capital and cost of illness approaches

It makes good economic sense to combine the human capital and cost of illness approaches. This is sometimes done. An example is the work of Crowley et al. (1992) which estimated the economic cost of diet related disease in Australia for coronary heart disease, hypertension, stroke, cancer and other conditions. The estimates include direct and indirect costs. The direct costs included health care costs attributable to diet in 1989-90 involving:

- cost of hospitals, medical and pharmaceutical expenses
- cost of allied health professional services
- cost of nursing homes.

The indirect costs measured included costs due to sick leave and the net present value of earnings foregone due to premature death.

This combined approach is more simple and transparent to implement than the willingness to pay approach. In addition, it is likely to result in more accurate estimates of the components of total willingness to pay that it attempts to measure. Most notably, it omits several components of total willingness to pay especially that of the patient and of others to avoid pain and suffering.

Compliance costs

The extent of compliance costs depends heavily on the ranges of the regulation options. Previous studies on the benefit and costs of NIPs and percentage labelling — see ACG (2001) — focused on the size of these costs and how they may change.

The costs of compliance to industry can be summarised in two parts:

- transitional or implementation costs that require changes in investment in new machinery or processes, training, product testing and redesign of packages; and
- ongoing costs which depended on the level of compliance required.

There appears to be no one universal systematic approach to estimating the extent of compliance costs. A common approach is to estimate the number of product lines or stock keeping units (SKUs) that will be affected by the change in regulation. This approach has a very short term focus. Again, we note that it is likely that costs on producers will be higher the shorter the period of compliance required. A long transitional period will minimise costs as industries change product lines in the normal course of business.

Linkages with the rest of the economy

The human capital and cost of illness approaches measure the impacts of food regulation on the health of the population. The summary measures used calculate the direct impacts in terms of improvement in lifetime earnings and savings on medical treatment costs. But there are also indirect or flow on effects as changes in these measures impact on overall economic performance (GDP) and the monetary value of community living standards (change in aggregate household consumption expenditure). An economywide modelling framework is needed to take the results from the human capital and cost of illness approaches and compute their flow on effects on the economy as a whole. The economywide model needs to treat as exogenous the outcomes from the human capital and cost of illness approaches. It also needs to be able to accept exogenous changes at the sector level in industry production costs — to incorporate the impact of any additional compliance costs on the performance of food supplying industries. If there were no benefits on the demand side from regulation, higher compliance costs would reduce the economy's overall productivity and living standards.

There is little doubt that there are economywide impacts of changes in morbidity and mortality. There are well designated pathways through which these changes affect overall economic performance. These include the effects on labour supply and productivity, the effects of lower medical costs to households and government and the effects of additional costs on industries through compliance.

Labour supply and productivity

In the short term, illness reduces labour productivity and in the long term disability and death reduces the number of people of working age in the economy. This would mean that the results of the analysis described above would have to differentiate at least between groups of working age and others that include children and the retired.

The effects of increased labour productivity in the short and long term would be relatively easy to identify. In the short term fewer days on sick leave would lower real labour costs to employers. In the longer term, the impact of a reduction in disease means more people available for entry into the workforce. How an increase in employment would flow through to benefits to industry and the rest of the economy (through lower real wages) would depend on the incidence of a particular illness for people of working age.

Population dependency ratio

Changes in public health also affect the population dependency ratio. The population dependency ratio is the relationship between workers and nonworkers in the population. Those not working include people not of working age and those of working age with disabilities. With the ageing of the population, the number of dependants per worker is steadily rising. Other things equal this means reduced per person incomes. Any improvement in public health may offset this trend.

Lower medical costs

Lower medical costs would impact on both households and government. Lower direct medical costs and insurance premiums would free up expenditure by households to be spent on other goods and services which is likely to have a significant impact on non health sectors of the economy.

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Approximately 60 per of medical costs in Australia are paid for by the public hospital system. Small changes in morbidity and mortality can impact significantly on the cost of provision of public health, especially if these changes apply to high cost care areas such as treatment of cancer, heart disease and stroke. The impact of such a change is likely to differ between the short and long run. In the short run, the case load (and related expenditures) of the hospital system will be unlikely to change. Reassessment of treatment priority on the basis of need should see reduced waiting lists.

The hospital system currently uses demographic information to plan probable patient demands. In the long term, the hospital system could actually reduce costs below that which would otherwise be the case.

Compliance costs

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In reality, compliance costs from additional regulation are likely to be shared between food manufacturers and consumers and between each stage of the processing chain. Regulations that target what is in food and how it is labelled do not discriminate between domestic and imported food products and so do not put local producers at a disadvantage.

In the short term, there will be adjustment issues for industry but in the long term the regulations will not particularly discriminate between one set of producers in the industry over another.

5 What framework and inputs are needed?

WE SUGGEST A POSSIBLE CONCEPTUAL FRAMEWORK but focus on the input requirements to a model, particularly issues around identifying and quantifying the health benefits associated with food regulation.

Structure of the framework

No one econometric or structural model can address the issues and requirements stated in the terms of reference. The suggested integrated modelling framework below is driven by the overall imperative of quantifying the benefits of improvements in public health that are likely to flow from food standards and food safety regulation. These benefits are likely to dominate all other costs and benefits from changes in regulation. The integrated framework will permit evaluation of the effect of changes in regulation on both welfare and GDP in dollar terms.

Suggested approach

In our approach we draw on experience and techniques from existing models. We would not suggest the construction and implementation of a new model from scratch. Rather, the preferred approach is modification of existing frameworks to suit the requirements of the task.

The proposed steps required to develop such a framework are outlined in chart 5.1.



5.1 **Components in integrated approach**

The first component in the framework is to quantify the reduction in morbidity and mortality that may result from a change in food regulation. To do that we need to attribute deaths and illness to a particular cause and then explain how the risk of that event will change as a result of a change in food regulation. This step will draw heavily on the scientific assessment already conducted by ANZFA and also include work on aetiologic fractions. The output of this step would be changes in morbidity and mortality due to the existence of, or changes in regulation. There may some resistance to this stage of the process because projecting the health benefits is inherently full of unknowns and requires a series of judgements. What is required is that assumptions are made explicit and transparent to permit the remaining stages of the analysis.

The second component is the estimation of the stream of compliance costs that may result from changes in regulation. There appears to be no one systematic methodology that can be applied across issues that industry face when dealing with changes in food regulation. This type of information will usually be drawn from the consultation process. The drivers from this component would be changes in unit costs of industries (and imported products) in response to a change in regulation.

The third broad component involves identifying and calculating the stream of benefits associated with the reduction in morbidity and mortality. We have already flagged that an appropriate framework would be similar to that used in Crowley et al. (1992) which combines a human capital and cost of illness approach. Combined with information from the second component, this step would permit the calculation of the effect of the change in regulation on consumer health (direct consumer welfare) (component 4) measured by the present value of costs and benefits. The drivers of this component would be changes in:

- labour productivity
- the supply of labour
- medical expenses (private and public).

As identified in chapter 4, many of the benefits from reducing diet related illness would accrue up to 40 years into the future. The time period over which the net present value would be calculated would be at least 25 years.

The final component would be to translate the shocks from components 2 and 3 via a general equilibrium framework to obtain an estimate of the economywide impact on GDP and living standards. This overall approach parallels that used by Golan et al. (2000) — see box 5.2.

Economywide framework

Ideally, the economywide model to be used in the integrated framework would be a fully dynamic general equilibrium model of both the Australian and New Zealand economies that is capable of handling intertemporal maximising behaviour. This type of framework would be capable of projecting out the length of time that would match the anticipated flow of benefits from public health. However, with this class of model, there are currently substantial tradeoffs between intertemporal behaviour and sectoral detail. The fully dynamic versions of general equilibrium models have considerably less sector detail than the comparative static versions or versions where the dynamics is not driven by intertemporal maximising behaviour. The level of detail incorporated in the latter class of models is shown in table 5.3. Even this looks much too aggregated when compared with the detail that ANZFA works with (appendix A).

5.2 Economywide effects of benefits of HACCP

Golan et al. (2000) used a two stage approach in the evaluation of economywide costs and benefits of Hazard Analysis and Critical Control Point Program (HACCP) for the meat and poultry sector in the United States. The analysis accounted for the benefits of reducing food borne illness and the costs of implementing the HACCP.

Estimates of the present value of 20 years of HACCP program benefits were obtained from a cost of illness approach. The starting point was calculation of the cost of illness from 4 pathogens across all sources of contamination. These estimates were then adjusted down to account for the contribution by meat and poultry to the total effect and the contribution of HACCP to reducing food borne illness. The 20 year present value of costs estimates were taken from a cost benefit study of HACCP for industry.

The next step was to construct a social account matrix (based on an input-output table) that:

- highlighted sectors of the economy most directly impacted meat and poultry production and distribution sector, the health care and health insurance sectors
- identified at risk group through three types of households households with children, households without children and the elderly.

The final step was to calculate the indirect economywide effects of HACCP through multipliers calculated from the social accounting matrix.

The analysis showed that for every dollar of income saved through prevention of death from food borne illness there was an economywide gain of \$1.92. Likewise, multipliers were calculated for household expenditure on medical expenses and the increased costs to beef and poultry production due to HACCP implementation.

Compared with using an economywide behavioural model, the multiplier approach has some major drawbacks as it assumes that prices are fixed and infinite supply elasticities of industries and factors of production.

Agriculture	Food processing	Related industries
Sheep	Meat and meat products	Wholesale trade (distribution)
Grains	Dairy products	Retail trade (food service)
Beef cattle	Fruit and vegetable products	Accommodation, cafes and restaurants (food service)
Dairy cattle	Oils and fats	Road transport (transport)
Poultry	Flour mill and cereal products	Insurance (health insurance)
Other agriculture	Bakery products	Government administration (regulators)
	Confectionary	Health services (hospital system)
	Other food products	Community services (health support)
	Soft drinks, cordials and syrups	
	Beer and malt	
	Wine and spirits	
	Tobacco products	

5.3 Commodity and industry detail of economywide models

Therefore it is suggested that a variant of the latter class of models be used to capture the indirect effects of food regulation — through the drivers that we have outlined above. Examples of such models are the various versions of the ORANI model, in particular the Monash model. Like the work by Golan et al. (2000) the model detail would focus on food, health and regulatory sectors in as much detail as the data permits. Unlike Golan et al. (2000), this class of model would include explicit economic theory that:

- describes profit maximising behaviour by producers and consumers;
- permits prices to adjust through market clearance; and
- recognises imperfect substitution in household consumption and between domestically produced and imported goods and services.

The constraint of such an approach is the comparative static nature of such a model. The first significant problem is translating changes in labour supply and the like that would occur, say in 25 years time, to a model that looks like the current economy. To handle the dynamics successfully in a comparative static framework, the shock would be required to be correctly 'calibrated'. For example, the possible increase in labour supply of x persons in 2025 would represent y per cent of the workforce in that year — this would be the shock to the CGE model.

In comparative statics, the model is also unclear about timing of adjustment to a particular shock to the economy. That is, how many years does a particular shock takes to fully work its way through the economy? Typically we would assume a long run closure where the benefits take between 5 and 10 years to flow through the economy.

Given these constraints, the comparative static framework would still be very valuable in identifying both the direct and indirect effects of food regulation in the economy. That is, the value of the model is in its completeness accounting for all impacts on industry and household activity.

GDP or GNP?

One question is whether you use GDP or GNP as the measure of benefit from the economywide analysis. The difference between GDP and GNP in practice is how income is distributed according to ownership of assets between residents and foreigners. It would be very difficult to model changes foreign ownership in the context of food regulation. Other key variables of interest may also be aggregate government revenue and expenditure.

Results from economywide framework

In the majority of cases that ANZFA would analyse in the course of its work program, the bottom line results of the economywide model — percentage change in GDP — would be negligible. In these cases, a partial approach (stopping at step 4 above) would be preferable to a complete analysis with the economywide framework. Indeed, the economywide framework should be used when large changes are involved rather than on a marginal or case-by-case basis.

Combining data inputs from Australia and New Zealand

The objective of the integrated framework is to assess the impact of food regulation on the people of Australia and New Zealand. Quantifying these impacts will require data from both countries. This raises the issue of data inconsistency, where some data is held in one country but not the other, or where each country defines statistical aggregates differently.

There are three possible approaches:

- aggregating of Australia and New Zealand
- identifying each region identified separately
- make assumptions concerning key structural relationships.

The regional approach to modelling has the advantage of allowing regional differences to be taken into account, such as differences in expenditure patterns or industry structure. Identifying each region separately or as an aggregate will inevitably lead to a number of problems regarding data collection and methodology. These problems will most likely apply more to public health rather than input-output accounting data components of the framework. The long term solution would the harmonisation of data standards and conventions, especially in health related data, between Australia and New Zealand.

Another way to address this issue is on a case-by-case basis. Where data is unavailable in one country or there are significant differences in statistical definitions, it may be reasonable to extrapolate the impacts from one country to the other as long as the methodology and assumptions are made transparent.

Indications of costs

Detailed costing for each of the stages of the suggested framework would be a complex assignment. However, in this section we will indicate the relative costs involved in terms of once off costs and ongoing costs that depend on the case-by-case basis.

Scientific risk assessment extension

This stage will comprise both up front and ongoing costs. The up front costs will involve two parts:

- an education and training component for ANZFA staff; and
- working with Australian Institute of Health and Welfare (AIHW) to collate existing information on incidence and prevalence of diet related disease.

A series of workshops to familiarise staff will be required to explain why the existing scientific risk assessment and qualitative benefit cost is being extended and what is expected and why — in terms of inputs to the later stages of the framework. In addition, the current work programs at AIHW will have to be accessed to extract any relative information especially from their current databases and their burden of disease work. Some work would have to be done on how this pool of information can be adapted and modified for ANZFA's uses.

In terms of ongoing costs, this stage will probably be the most costly for ANZFA in terms of additional time spent by staff on top of their existing case load. But extending the scientific analysis represents a logical next step. Some judgement would be necessary on a case-by-case basis as to whether the additional analysis would be required. If a potential change is likely to have little or no health impact or are regulated elsewhere — like the addition of a processing aid or an MRL issue — the additional analysis would not be necessary.

Human capital/cost of illness analysis and economywide model

These steps would involve primarily an up front investment but should require little in terms of ongoing costs. As identified earlier the methodology and applications for the human capital/cost of illness approach has been well established for some time. It is a matter of building on existing studies. Once the *base case* has been established it is then a matter of reapplying different 'shocks' from each case that ANZFA examines.

In ball park terms, the cost of this component depends on the overall approach. If a framework were to be developed from scratch, a budget would be required to fund 3 to 4 months full time work — in the order of \$120 000. In terms of new skills within ANZFA, it would be desirable to recruit personnel with a specialised health economics background but not necessary. The economics behind this approach is straightforward and not onerous but is very data intensive. The primary skills required for this task would be liaising with AIHW staff to make the most of existing work and understanding the existing literature base. An option could even be contracting out or joint funding work with AIHW to extend their existing work in this area (see appendix B).

In the case of the economywide model the up front costs are likely to be considerably less as ANZFA would be able to access one of the number of frameworks available in Australia at marginal cost. In short, \$30 000 per year would secure access to an economywide model for Australia to identify the direct and indirect effects of some of the larger issues that ANZFA requires to be evaluated.

A stylised example

In this section we illustrate the inputs required to drive the quantitative framework using a recent application as an example — Application no. A424: *Addition of calcium to fruit and vegetable juices, fruit and vegetable drinks, fruit based cordial, soups and crispbread/cracker type biscuits.* The addition of calcium is currently not permitted in the food standards and the application is considered in the preliminary assessment report.

The potential benefits

Manufacturers would like to add calcium to a range of proposed foods to provide consumers with alternative food sources of calcium. The beneficial role of calcium in the diet is well established in terms of protection of calcium in bones (prevention of osteoporosis), regulation of muscle contraction and maintenance of blood pressure. There are also other indirect or anecdotal claims of the benefits of calcium.

Estimating costs and benefits

The steps required for each stage of the integrated framework for the stylised example are set out in table 5.4. The first step in the calculation of the costs and benefits of such a proposal is to extend the scientific risk

assessment that has already been conducted to incorporate estimates of reduction in illness and the reduction in death (if any). The assessment compares the recommended dietary intake and the mean actual intakes of calcium by sex and age groups for Australia and New Zealand. A preliminary dietary intake assessment has been performed to determine the potential impact of the fortification of the specified products on the intake of the population as a whole and the various at risk groups — including middle age women. This dietary modelling required the following assumptions:

- all manufacturers take up the fortification of all proposed foods to a given level;
- all consumers take up the new foods; and
- that 100 per cent of the additional calcium is useable in the diet.

The results of the preliminary assessment in this example were significant. The increase in calcium in the diet was 25 per cent for the total population in Australia, and 21 per cent for the principal at risk group comprised of females 45 years and over.

The next step required, to calculate the costs and benefits of the change in regulation, is largely left as an open question in the preliminary assessment. That is, how will this change in the diet of the population translate into reduction in illness? The work by Crowley et al. (1992) did not address the link between diet and the most noticeable outcome of calcium deficiency — osteoporosis. Would a 20 per cent increase in calcium intake in the principal at risk group decrease osteoporosis related illness by 20 per cent. If not, then what would be the likely change?

The next section is the identification of changes in compliance costs. For the industries advocating these changes, the compliance costs will be zero, they would willingly incur the additional costs for the new product. The preliminary assessment indicates that there will be possible displacement of dairy based substitutes and calcium additives. While this is true, consumers currently have the option of fortification of calcium in the diet through a number of means which are not current by being used in sufficient levels. The proposed change in the regulation represents a marketing opportunity for industry advocates and a potential cost to its competitors that would not readily occur if the original legislation did not exist.

The next step is the calculation of the benefits and costs through the human capital/cost of illness approach. There are two broad areas that have been identified as readily quantifiable. The first is the calculation of the impact of

the change in regulation on medical expenses. Information about days in hospital and medical expenses should be available from the Australian Institute of Health and Welfare (AIHW). The primary evidence of insufficient dietary calcium could be prevalence of bone fractures and the like. But because of the nature of osteoporosis, much of the related medical costs may also be due to surveillance and screening programs for the at risk groups. The methodology for the cost of illness approach is set out in EPA (2001).

5.4	Steps	involved	in	evaluation of	calcium	fortification
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Steps in framework	Data requirements	Outputs		
Scientific risk assessment	 Extent of the increase in calcium in the diet for population and at risk groups 	Estimate the reduction in illness and reduction in death if any, for the:		
	 Aetiologic fractions between 	 population generally 		
	calcium deficiency and various related diseases	 at risk groups particularly middle age women 		
Compliance and other	 Zero for advocating industries 			
COSIS	 Possible costs for the dairy industry 	 Very difficult to measure this impact 		
Human capital / cost of	 Per person treatment costs of calcium deficient disease 	 Present value of medical costs saved 		
		 Present value of wages foregone 		
	 Lost working time or reduction in those of working age 	 Reduction in the workforce 		
Welfare analysis	 From steps 1 to 3, discounting identified costs and benefits 	 Present value of costs and benefits 		
Economywide model	From steps 1 to3, change in labour supply, medical expenses etc.	 Impact on Australian GDP 		

Inferences about the impact on labour productivity and supply should be able to be made on the basis of the likely impacts on people of working age. Labour productivity is affected in the case of short term illness and a reduction in the number of employed if the disease leads to long term disability. The extent of this impact would depend on the pattern of workforce participation of the affected groups.

Steps 4 and 5 of chart 5.1 provide ways of summarising and bringing together the data collected in steps 1 to 3. However, the analysis above would clearly omit the potential benefits of a reduction in pain and suffering. Diseases like osteoporosis are largely untreatable and with onset, suffers generally have to endure a lower quality of life. The benefits estimated within this framework would represent the lower bounds available.

ANZFA's requirements with the integrated framework

Box 5.5 comments on how ANZFA's modelling requirements are addressed in the modelling framework we have proposed.

5.5 Specification of model — addressing the requi	urements
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Requirement	Comment
Food industry detail, identifying products and classes of producers in as much detail as possible, including sub-sectors of the production chain (for example retail, wholesale and transporters);	The economywide model distinguishes the key components of the value added chain for food processing including food distribution and retail. The disadvantage is very broad sectoral detail — expansion to finer detail is very data intensive and time consuming
Government detail, with emphasis on food regulation enforcement, and health and welfare services	Economywide model identifies very broad sectors that include Health and Community Services. Identifying and separating food regulation and enforcement would be very difficult.
Consumers in general, and if possible also to distinguish various 'at risk' groups which will consume a different basket of goods	At risk groups would be accounted for primarily in the risk assessment and value of human life and cost of illness components. Very difficult to obtain and incorporate entire consumption profile for these groups in economywide model.
Capable of comparing different scenarios and sensitivity to assumptions used in framework	Integrated framework addresses this requirement directly. Both morbidity and mortality outcomes and economic parameters can be varied.
Show short term as well as long term adjustments	Integrated framework addresses this requirement directly through the dynamics of risk assessment component and through model closure that determines length of run.
Include historic data to derive trends and compare scenarios	Possible to compare morbidity and mortality profiles from scientific risk assessment back to historical series. Very difficult to verify economic outcomes.
Capable of estimating short term effects of food borne illness and long term effect of diet related disease	Integrated framework addresses this requirement directly through the risk assessment component.
Capable of estimates of benefits of food regulation on private and public sectors	Integrated framework addresses this requirement directly through industry, government and household detail.
Capable of estimating average and marginal costs of industry	Economywide model industry behaviour based on constant return to scale technology where a change in marginal costs equals changes in average costs.
Capture the effect of replacement of assets and equipment	This implies a long run closure of an economywide model where capital stocks are endogenous.
Capable of extension to New Zealand	Framework is capable of extension to New Zealand by replicating Australian model. No benefits from having countries linked through trade.

Appendixes

A

ANZFA food standard workplan

Project	Description	Number of foods covered	Significance in household consumption
Group 1			
P230	lodine fortification	Potentially broad range	Potentially large
P233	Expanded NIP	All foods	Large
P234	Nutrient claims review	All foods	Large
P235	Dietary supplements review	Very specific	Small but growing
P236	Sports foods	Very specific	Small but growing
P237	Country of origin labelling of food	All foods	Large
P239	Listeria	Broad range	Potentially large
P240	Advisory statements for condensed milk	Very specific	Small
P242	Foods for special medical purposes	Very specific	Small at risk groups
P244	Folate pilot revisions to list of approved products	Quite specific	Potentially large
P248	Stock in trade, Volume 2 of the Food Standards	All foods	Large
P250	Health and related claims about foods	Broad range	Large
P251	Uncooked comminuted fermented meat products	Very specific	Relatively small
Group 2			
A343	Organic labelling	Broad range	Potentially large
A360	Use of hemp	Very specific	Small
A380	DBT418 - GM corn	Very specific	Potentially large
A388	BA tolerant canola	Very specific	Potentially large
A416	GMF Roundup ready corn	Very specific	Potentially large
A417	Tall oil phytoesterols	Very specific	Small
A418	Labelling duty free spirits	Very specific	Potentially large
A424	Addition of calcium to juices, drinks, soups and biscuits	Broad range	Potentially large

A.1 Applications or proposals in ANZFA's food standards workplan^a

(Continued on next page)

Project	Description	Number of foods covered	Significance in household consumption
Group 2 (co	ontinued)		
A427	Caffeine in sports drinks	Very specific	Potentially large
A429	Hydrogen peroxide — anti microbial	Broad range	Small
A430	Carotene (Vitamins A and C) in sweet biscuits	Very specific	Potentially large
A432	MSG labelling	Broad range	Large
A433	Phytosterols in bread, breakfast bars and salad dressing	Broad range	Potentially large
A434	Dairy phytosterols in low fat milk and yoghurt	Quite specific	Potentially large
A438	Gamma cyclodextrin	Broad range	
Proposals			
P152	Labelling of peanut ingredients	Very specific	Small, for at risk groups
P154	Labelling of royal jelly	Very specific	Small, for at risk groups
P93	Review of infant formula	Very specific	Potentially large
Group 3			
A428	Marine Micro-algae	Novel food	Small
A435	Triacylglycerol lipase	Processing aid	Small
A436	Ingard II cotton	Very specific	Potentially large
A443	Irradiation of tropical fruit	Very specific	Potentially large
A446	Insect glufosinate resistent corn	Very specific	Potentially large
A449	Phytosterol enriched Multibene	Very specific	Small
Finalised p	rojects		
A437	AHA and DRA in infant formula	Very specific	Significant
A394	Formulated caffeinated beverages	Very specific	Large
A396	Erthrosine in preserved cherries	Very specific	Small
A400	Citrus fruit coatings	Quite specific	Large
A413	Irradiation of herbs and spices	Quite specific	Large
P232	Compositional standards	All foods	Large
P238	Bovine Spongiform Encephalopathy	Quite specific	Large
A445	MRL ethylene oxide	Very specific	Small
P228	Amendments to food additives	All foods	Large
P229	Enzymes (Chyosin)	Broad range	Small

A.1 Applications or proposals in ANZFA's food standards workplan^a (Continued)

(Continued on next page)

EVALUATING BENEFITS AND COSTS OF FOOD REGULATION

A.1 Applications or proposals in ANZFA's food standards workplan^a (Continued)

Project	Description	Number of foods covered	Significance in household consumption	
Finalised projects (continued)				
P243	Chloropropanols in soy and oyster sauces	Very specific	Relatively small	
P247	Definition of carbohydrates in Standards	Broad range	Significant	
P249	Stock in trade provisions for GM labelling	Broad range	Small but growing	
A372,5,8	Glufosinate ammonium tolerant canola, corn and sugar	Very specific	Potentially large	
A379	Bromoxynil. tolerant cotton	Very specific	Small	
A411	Pasteurisation of orange juice	Very specific	Significant	
A419	Use of sorbic acid and sorbates in edible casings	Very specific	Small	

^a As at October 25 2001.

 $Source: \ http://www.anzfa.gov.au/foodstandards/standardsworkplan/index.cfm.$

B

Aetiologic fractions

IF THE PROCESS OF CALCULATING BENEFITS and costs of ANZFA regulation were to wait until fully acceptable and precise estimates of reduction in mortality and morbidity were available, there would be an indefinite delay because of the difficulties in proving causality. It is very difficult to:

- prove causality between components of the diet and disease;
- assess the exact proportion of disease incidence that is attributable to diet; and
- attribute changes in the structure of food regulation with improvements in public health.

The fundamental problem is that the association between diet and many of the diseases are the combination of and interaction between multiple risk factors such as:

- environmental
- behavioural
- biological
- social.

Ideally, the linkages and attribution could be determined through life time trials on humans. This is, of course, not feasible. Policy development needs to be based on the best information available including judgements from relevant experts on the field. These judgements must be made on the basis of evidence from a number of sources, such as:

- clinical observation
- animal experiments
- epidemiological studies
- any experimental studies on humans
- intervention studies.

Quantifying the relationship

For the combined value of life and cost of illness approaches, the fundamental epidemiological statistic that is necessary to quantify the direct relationship between a risk factor and disease is the aetiologic or PAF. It has been defined as the proportion of total adverse events in a population that could be prevented if a particular risk factor could be eliminated or reduced (Crowley, 1992, p. 7).

The first step would be to estimate the proportion of disease directly attributable to diet. Where only one category of exposure is present:

PAF = [p (RR-1)] / [p (RR-1)+1], where

- p = prevalence of exposure in age group
- RR = relative risk = (Ie)/(Io)
- Ie = the incidence of the condition among those exposed to the risk factor
- Io = the incidence among those not exposed.

The formula can be extended to deal with multiple category exposure. The PAF can be presented as a fraction or percentage. Thus a PAF of 0.3 means that 30 per cent of the incidence of the disease could be eliminated by the removal of the risk factor or conversely that the risk factor contributes to 30 per cent of the incidence of the disease.

With diet related disease calculation of PAF's are more complex than for alcohol and substance abuse because the causality is not clear. Certain food components have harmful effects and others protective effects. Also, some food components can be both protective and harmful depending on the level in the diet — unlike alcohol, smoking and substance abuse — the exposure to risk factor is not as simple as either being present or absent. For example, coronary heart disease can result from the combination of risk factors that are:

- diet related
- genetic
- behavioural
- tobacco and alcohol related.

Disability-adjusted life years (DALY's) and Quality-adjusted life years (QALY's) are also widely used in the quantification of the links between reduction in disease and benefits to the public. These concepts are

described in box B.1. These concepts are used to measure the incidence, prevalence and duration of disease and injury.

Australian results

In the absence of reliable estimates, Crowley used sensitivity analysis to provide a range of estimates based on different assumptions that contribute to PAF's. Table B.2 shows the estimates of fractions produced for Australia. The rationale for the fractions, for each disease, are set out in Crowley et al. (1992).

B.1 DALY's and QALY's

DALY's for a disease or health condition is calculated as the sum of years of life lost due to premature mortality in the population (YLL) and the years lived with disability (YLD). YLD is calculated as the number of incidences or cases by the average duration by a disability weight. The most difficult step in estimating YLD's is matching existing population data to disease or disability categories.

Quality-adjusted life years (QALY's) are calculated by multiplying the number of life years added by an intervention by a standardised weight reflecting health-related quality of life during the added years. A weight of 0 typically represents death, and 1 represents perfect health. Weights of less than 1 are possible for health states considered worse than death. Weights are obtained by asking relevant individuals which health states they prefer, and by how much.

Disease	High	Middle	Low
	%	%	%
Coronary heart disease	60	40	20
Atherosclerosis	75	50	25
Stroke	60	40	20
Diabetes mellitus (non insulin			
dependant)	75	50	25
Concerc			
Cancers			
Overall	35		
Stomach		50	15
Colon		35	15
Rectum		35	15
Breast		30	10
Endometrium		25	10
Diverticular disease	75	50	25
Haemorrhoids	75	50	25
Dental caries	75	50	25
Gallbladder disease	75	50	25
Constipation	75	50	25
Iron deficiency anaemia	75	50	25

B.2 Proportion of disease onset attributable to diet, 1989

Source: Crowley et al. (1992).

Two features of the estimates of fractions for diet related disease stand out:

- the broad ranges involved in the sensitivity analysis
- the similar estimates across quite different disease categories.

This indicates that not a lot is known about the causality between diet and disease with a great deal of certainty. Certainly, these estimates would be outdated now due to shifts in population composition and shifts in the incidence of disease. To look at the effect of food regulation — estimates like those provided in table B.2, would have to be broken down further.

Burden of disease studies

The AIHW and the Victorian Department of Human Services collaborated during 1998 and 1999 in undertaking two Australian studies of the burden of disease, injury and risk factors: a national study and a Victorian study for 1996. The Australian Burden of Disease and Injury Study has produced comprehensive estimates of incidence, prevalence and average duration for a large number of diseases and injuries and their disabling effects on Australians for 1996. These studies used the DALY as the key measure.

The information behind the calculation of the DALY's in this study would serve as important inputs to the calculation of diet related PAF's as the AIHW already holds information on the incidence of death, disease and injury in Australia and the duration of disability involved.

Deriving fractions for alcohol consumption

Much of the work in deriving PAF's has occurred for cost of illness studies in areas such as:

- alcohol and tobacco consumption
- substance abuse
- occupational health and safety

Unlike the case of food regulation and food safety, the causality between these actions and adverse outcomes is far more direct and obvious. There is already a substantial body of work that calculates the potential costs of particular alcohol consumption choices for Australia. For these studies, there are essentially three methods that have been used to calculate PAFs for alcohol. The first is to attribute all deaths of particular proximate causes to alcohol. For example, it is safe to assume that all the deaths from cirrhosis of the liver are due to alcohol consumption, so the PAF is equal to one. The second approach is to use clinical case studies to assist in the derivation of the fractions. For example, studies provide information about the association between drowning and alcohol by examination of blood alcohol level of drowning victims. The third approach is to use statistical research — which takes the form of analysis of a number of other studies — to derive the relative risk of different levels of alcohol consumption.

The relative risks of alcohol is generally calculated by identification of PAFs for groups that may display substantial differences in consumption behaviour and observed outcomes. In the case of alcohol, Australian studies such as English et al. (1995) and Ridolfo and Stevenson (2001) identify different PAFs for:

- males and females
- low, medium and high levels of consumption.

For example, low consumption refers to up to 4 standard drinks per day for males and 2 standard drinks for females. These groups are identified because alcohol at low levels can have a protective effect — especially for females — and have different adverse outcomes at high levels for males and females.

The relative risks are expressed relative to abstinence — which may not be realistic. Most of the relative risk numbers in these studies refer to the risk of an adverse medical condition — the exception is suicide and self inflicted injury — which refers to a behavioural condition.

In some cases the relative risk is less than one — in these cases a drinker has a lower chance of dying from a particular cause than a non-drinker because of the protective effect of alcohol. The PAF can then be calculated from the relative risk and information on the prevalence of alcohol consumption — which is derived from special purpose studies and publicly available statistics.

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