Australian Dairy Industry Council Inc.

A Submission to

Senate Economics Committee

In response to

Inquiry into the Food Standards Amendment (Truth in Labelling Laws) Bill 2009

Prepared by

The Australian Dairy Industry Council (ADIC)

16 October 2009

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16 October 2009

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To the Senate Economics Reference Committee,

Inquiry into the Food Standards Amendment (Truth in Labelling Laws) Bill 2009

On behalf of the Australian Dairy Industry Council (ADIC) I welcome this opportunity to participate in the Inquiry into the Food Standards Amendment (Truth in Labelling Laws) Bill 2009.

As the national policy body of the Australian dairy industry, ADIC represents the interests of Australian dairy farm families and businesses, dairy manufacturers and traders across all states and territories.

We are pleased to provide a dairy industry perspective on the proposed Bill. We have outlined the reasons within the submission that we oppose the Bill and would welcome the opportunity to discuss these with you.

This submission was prepared with technical expertise from Dairy Australia and should be read as an adjunct to the NFF submission, outlining some of the specific issues, impacts and ramifications in the dairy industry.

We would welcome the opportunity to contribute further should the opportunity arise.

Yours sincerely,

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1. Dairy Industry position on the Proposed Amendment to *Food Standards* Australia New Zealand Act 1991(The Act)

The Australian Dairy Industry Council (ADIC) is the dairy industry's peak policy organisation that provides whole of industry policy. It represents both dairy farmers, through the Australian Dairy Farmers (ADF), and dairy companies, through the Australian Dairy Products Federation (ADPF). The ADIC is supported by Dairy Australia (DA), the dairy industry's owned service company.

ADIC welcomes the opportunity to provide comment to the Senate Inquiry into the *Food Standards Amendment (Truth in Labelling Laws) Bill 2009*.

The dairy industry does not support the proposed amendment to '*The Act*' as presented in the Bill. This position is based on:

- **Inconsistency with Australian policy developed for food regulation;**
- **Inconsistency with COAG guidelines for best practice regulation;**
- **Inconsistency with the process for Standard setting defined in 'The Act';**
- **Inconsistency with the Australian Competition Consumer Commission Guidelines for Country of Origin Labelling;**
- **Negative economic impact on the Australian dairy industry both from a trade and labour perspective;**
- **Negative impact on Australian dairy farmers;**
- **Potential for damage to trade and Australia's international reputation;**
- **Potential for the Australian dairy industry to become less competitive domestically and internationally;**
- **Potential for consumer confusion;**
- **Sets a dangerous precedent in parliamentary law by excluding integral objectives and review processes within an Act; and**
- **Difficulty in enforcement**

Imposing requirements that the use of the term "Australian" can only apply to 100% Australian content and 100% Australian production is more prescriptive than the current requirements described in the "Food and Beverage Industry – Country of Origin Guidelines to the Trade Practices Act" and Standard 1.2.11 –Country of Origin Requirements. The implications for the dairy industry are that only some white milks will be able to carry the Product of Australia label. It will effectively exclude all cheeses, natural/unflavoured yogurts and most dairy desserts that can currently make the claim. **This would mean that most dairy products containing milk produced in Australia by Australian dairy farmers and converted into Australian dairy products in Australian factories employing Australian workers would not be able to claim Australian origin.**

The proposed Truth in Labelling Amendment Bill would also be expected to have a negative impact on Made in Australia claims.

The dairy industry does not support the proposed Food Standards (Truth in Labelling Laws) Amendment Bill as it will add unnecessary costs to manufacturers and consumers. To introduce more prescriptive and discriminatory mandatory country of origin labelling beyond those specified in the *Trade Practices Act 1974* will damage the international trade reputation of the Australian dairy industry. It will also result in lack of recognition of Australian products in both national and international markets. Such a change will reduce the Australian dairy industry's competitiveness, which would result in loss of manufacturing capacity in Australia, increased inventory and auditing costs and ultimately loss of jobs and farmer incomes particularly in rural Australia. There would be a flow on effect into the distribution chain and also the research efforts and innovation in Australia.

2. Impact on the dairy industry

The dairy industry is one of Australia's major rural industries. Based on farm gate value of production, it is ranked third behind the beef and wheat industries. There are approximately 8,000 farmers producing over 9 billion litres of milk annually.

The dairy industry is the largest value added food industry contributing $11.5 billion at wholesale to the economy. It is estimated that more than 40,000 people are directly employed on farms, manufacturing, transport, distribution and research and development. As a major regional employer, the industry adds value through the processing of milk to produce drinking milk, cheese, butter, cream, yoghurts and a range of speciality products. The estimated value of farm production is $4 billion annually and total value added production (ex factory) is $12 billion.

The dairy industry is also one of Australia's leading agrifood industries in terms of adding value to Australia's primary produce. Much of this processing occurs in rural areas, thus generating significant employment and economic activity in country Australia.

The dairy industry exports approximately 45% of manufactured or further processed product, to over 100 countries and this makes Australia the third largest trader of dairy products on the world market, behind New Zealand and the European Union.

Our markets are concentrated in the Asia/East Asia regions, with Japan being our largest customer, followed by Singapore, Malaysia, Indonesia and China. In terms of our major export products, they are, cheese, milk powders (includes infant formula), butter, milk, and other dairy ingredients such as casein and whey products.

Under the status quo, Australian products are able to differentiate themselves from their international competitors on overseas shelves through use of the "Made in Australia" claim – the proposed Bill will remove this capability and therefore have negative marketing implications on Australian made goods on overseas shelves.

The dairy industry is one of the most effective and efficient agrifood sectors in value adding a primary commodity within Australia. It embraces and supports innovation. It

produces icon products using icon brands that are consumed both domestically and internationally including:

- Cheeses of all types
- Yogurts
- Long life milks
- Modified milks
- Flavoured milks
- Dairy desserts including custards, rice desserts
- Butter
- Milk powders, used as ingredients in a range of products including infant formulas

Conversion of milk into the variety of dairy products developed in Australia requires a wide range of ingredients, many of which are not produced in Australia either because the raw materials are not available or cannot be economically and sustainably manufactured here. These include

- Hydrocolloids and stabilisers (eg pectin, carrageenan, guar gum, locust bean gum, some modified starches)
- Flavours and colours
- Vitamins and minerals
- Animal and microbial rennets
- Cultures for fermented products such as yogurts and cheeses
- Enzymes
- Yeasts and moulds

A number of other raw ingredient materials are imported either because of seasonality, lack of suitable climatic conditions for agriculture in Australia or inability to provide continuity of supply. These usually undergo further processing in Australia prior to inclusion in the finished dairy products. Some common examples include

- Fruits and fruit juices that are processed into stabilised fruit preparations that are used as ingredients in yogurts, flavoured milks and dairy desserts
- Cocoa that is processed to chocolate
- Coffee beans that are processed to coffee powders

Should the proposed Food Standards (Truth in Labelling Laws) Amendment Bill be accepted, there is also the likelihood of an unrealistic time frame being required for labelling changes if the availability of minor local ingredient products is restricted and they need to be replaced with imported products, triggering a label change.

3. Impact on Consumers

One of the principles for best practice regulation adopted by COAG is that "Government action should be effective and proportional to the issue being addressed". There has not been regulatory failure in the marketplace indicating that consumers are being misled as to the true nature of country of origin of foods.

Consumers buying habits suggest that purchases are primarily influenced by price and quality. Evidence from the retail sector indicates that few consumers will pay premium price for Australian products over imported products given equivalence in quality.

The differences between “made in Australia” and “product of Australia” are not always well understood by many consumers. Although products that are made in Australia from local and imported products create jobs for Australians, frequently in rural areas, this is not always well understood.

Publicity campaigns that use the “Australian made” logo assist in clarifying consumer knowledge about these issues. Such logos are often controlled by agencies outside of the food regulatory jurisdictions. These campaigns would be undermined by introduction of a prescriptive regulatory environment that provides little if any benefits to consumers.

The dairy industry does not support the *Food Standards (Truth in Labelling Laws) Amendment Bill* as it will result in negative impacts on consumers. These will accrue from increased costs to industry that will inevitably be passed on to consumers, decrease in the amount of growing and manufacturing capability in Australia with a concomitant increase in not only imported ingredients but imported finished foods. It will result in confusion to consumers.

4. Policy Framework

The Council of Australian Governments (COAG) has developed a guide for best practice regulation over many years (see Appendix 1). It outlines the principles underlying “good regulatory practice and regulatory assessment requirements that apply to decisions of COAG, Ministerial Councils and intergovernmental standard setting bodies”. As outlined in this document there are a number of features common to good regulatory practice including accountability, performance based standards and compatibility with relevant international regulations or practices. In July 2009, COAG agreed to terms of reference for a general review of food labelling law and policy, to be chaired by an independent public policy expert appointed by the Ministerial Council.

Equally a number of Governments within Australia have initiated reviews of regulation within their jurisdictions to assess whether the regulations are efficient and effective and as necessary recommending changes that may improve the net benefit to stakeholders. Examples include the Australian Government Productivity Commission’s Annual Reviews of Regulatory Burdens on Business, March 2009, in which all of the Commission’s recommendations with respect to food regulation were accepted in principle or noted (see Appendix 2). Another example is the Victorian Government’s review of the Food Regulatory system in that State – Refer, Simplifying the Menu: Food regulation in Victoria, Final Report, September 2007.

The current *Food Standards Australia New Zealand Act 1991* defines clearly

- The object of ‘The Act’; and

- The establishment of the Authority, its powers and functions; and
- Food regulatory measures; and
- Objectives that must be met when setting Standards; and
- Processes for development of Standards; and
- Processes for achieving variations to Standards; and
- Processes for ratifying and reviewing developed Standards by the Australia and New Zealand Food Regulation Council.

Dairy Australia does not support the proposed *Food Standards Amendment (Truth in Labelling Laws) Bill* as it is inconsistent with COAG principles for best practice regulation, it is inconsistent with 'The Act' in that it bypasses the current Act which provides for policy development through the Food Regulation Ministerial Council. The intent appears to be the insertion of a clause into a parliamentary Act that is a default Standard. It provides direction to the Authority established in 'The Act' that is contrary to and inconsistent with other clauses in 'The Act' relating to processes for developing Standards whether by application or by proposal. Throughout the Standard setting process, there is provision for either approval or rejection of applications or approval or abandonment of proposals. Furthermore it introduces a precedent of exclusions to integral sections of 'The Act', including its primary objectives and the review by Ministerial Council. The wording of the drafting is confusing. On the one hand it requires the Authority "to develop and approve a Standard that prescribes" particular labelling regimes and in so doing that Standard is not subject to the s18 objectives of 'The Act' or the Ministerial Council reviews. On the other hand it provides for the Authority to revoke any Standard developed as described above, then "develop and approve a new standard or variation" that is subject to Ministerial review but by omission in the drafting of clause 4 of the proposed amendment not subject to s18 Objectives of 'The Act'.

5. Regulatory Framework

The Australia New Zealand Food Standards Code (ANZFSC) contains in Chapter 1.2.11 a Standard for Country of Origin Labelling that was developed over many years and after several rounds of consultation as required in 'The Act" and which is consistent with the *Trade Practices Act 1974.*

Dairy Australia on behalf of the dairy industry provided submissions during the development of the Standard. In development of this Standard, Food Standards Australia New Zealand (FSANZ) extensively examined and analysed options for labelling, the potential cost to industry and consumers. The Food Regulation Ministerial Council previously rejected highly prescriptive country of origin labelling based on lack of discernable benefit and potential increased costs to consumers. The current requirements are consistent with international trade requirements and with the *Codex Alimentarius* food standards.

The dairy industry acknowledges the significant work undertaken by FSANZ in preparing the User Guide to the Country of Origin Standard and the Advice for

Consumers. Both documents outline very clearly as does the Standard the need for manufacturers and retailers to comply with trade practices law.

The dairy industry recommends that until the completion of the general review of food labelling law and policy, the existing Country of Origin Standard stands.

The dairy industry does not support the proposed *Food Standards Amendment (Truth in Labelling Laws) Bill* as it proposes the introduction of an overly prescriptive and discriminatory approach to food labelling. It would also contribute to inconsistencies in the FSANZ processes for developing standards. Currently these have appropriate checks and balances throughout the entire process, which would be lost with the introduction of this Bill.

6. Consistency with the *Trade Practices Act 1974*

Sections 52, 53(a), 53(eb) and 55 of the *Trade Practices Act 1974* are the general provisions relating to country of origin claims. State and Territory fair trading acts generally reflect these provisions. The *Trade Practices Act 1974* has a number of defences set out in Part V, Division 1AA of the Act namely sections 65AA – 65AN that apply to sections 52, 53(a), 53(eb) and 55 as well as 75AZC(1)(a) and 75AZX(1)(i). (see Appendix 2)

This Act prevents false or misleading representations concerning the place of origin of goods. Under this Act, country of origin is a subset of place of origin.

Sections 65AA – 65AN describe in detail the requirements for making specific country of origin claims. (see Appendix 2).

Additionally the Australian Consumer Competition Commission has published a booklet entitled "Food and Beverage Industry – Country of Origin Guidelines to the Trade Practices Act" (see Appendix 3). This guideline plus the Act are very explicit about the defences and conditions around which both Product of Australia and Made in Australia claims may be made.

The dairy industry rejects the *Food Standards Amendment (Truth in Labelling Laws) Bill* as it is inconsistent with and more restrictive than both the *Trade Practices Act 1974* and the existing ANZ FSC Standard.

7. Enforcement

On gazettal, food standards in Australia are taken up by reference into the various State and Territory Food Acts. As part of the criminal justice system, a prosecuting authority requires proof beyond reasonable doubt to prosecute successfully.

Misleading and deceptive conduct governed by the *Trade Practices Act (1984)* is a civil offence, thus requiring a lower level of proof.

The framework proposed in the *Food Standard (Truth in Labelling Laws) Amendment Bill* is unlikely to provide proof beyond reasonable doubt and could be resource

intensive. It will put prosecuting authorities at a distinct disadvantage and could be unenforceable. This is primarily because the method of substantiating claims on a label could be subjective and as such it will be reasonably simple to convince a magistrate that a reasonable doubt exists.

The dairy industry does not support the *Food Standards (Truth in Labelling Laws) Amendment Bill* on the grounds that it is likely to be unenforceable and will put the dairy and the wider food industry at a distinct disadvantage in the marketplace.

Appendices

1 COAG Best Practice Regulation – A Guide for Ministerial Councils and National Standards Setting Bodies
2 Australian Government Response to the Productivity Commission *Annual Review of Regulatory Burdens on Business: Manufacturing and Distributive Trades*
3 Food and Beverage Industry – Country of Origin Guidelines to the Trade Practices Act" (see Appendix 3).
4 Relevant Clauses *Trade Practices Act 1974*
5 *FSANZ Act 1991* – Section 18 Objectives

Appendix 1

COUNCIL OF AUSTRALIAN GOVERNMENTS

BEST PRACTICE REGULATION

A GUIDE FOR MINISTERIAL COUNCILS AND NATIONAL STANDARD SETTING BODIES

OCTOBER 2007

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INTRODUCTION

Over 40 Commonwealth-State Ministerial Councils and other inter-governmental decision making fora facilitate consultation and cooperation between the Commonwealth Government and state and territory and local governments in specific policy areas. The councils initiate, develop and monitor policy reform jointly in these areas, and take joint action in the resolution of issues that arise between governments. In particular, Ministerial Councils develop policy reforms for consideration by the Council of Australian Governments (COAG), and oversee the implementation of policy reforms agreed by COAG. Ministerial Council agreements are commonly translated into law and regulation, and it is important that all councils follow consistent principles in developing all proposals which have a regulatory impact.

This document provides guidance to Ministerial Councils and other standard setting bodies (hereafter referred to collectively as "Ministerial Councils") on best-practice regulation making and review by outlining:

- principles for best-practice regulation making agreed by COAG; and
- guidance for undertaking regulatory impact assessment and preparing a Regulation Impact Statement (RIS) including assistance on undertaking:-
  - risk analysis,
  - cost-benefit analysis,
  - assessments of compliance costs,
  - assessments of competition effects, and
  - consultation.

Importantly, the Guide reflects the commitment to establish and maintain effective arrangements to maximise the efficiency of new and amended regulation and avoid unnecessary compliance costs and restrictions on competition made by COAG at its 10 February 2006 meeting. COAG also agreed to apply these enhanced arrangements to Ministerial Councils. The Guide ensures that regulatory processes at the national level are consistent with principles of best practice regulatory process agreed by COAG.

Governments will establish and maintain effective arrangements at each level of government that maximise the efficiency of new and amended regulation and avoid unnecessary compliance costs and restrictions on competition by:

(a) establishing and maintaining "gate keeping mechanisms" as part of the decision-making process to ensure that the regulatory impact of proposed regulatory instruments are made fully transparent to decision makers in advance of decisions being made and to the public as soon as possible;

(b) improving the quality of regulation impact analysis through the use, where appropriate, of cost-benefit analysis;

(c) better measurement of compliance costs flowing from new and amended regulation, such as through the use of the Commonwealth Office of Small Business' costing model;

(d) broadening the scope of regulation impact analysis, where appropriate, to recognise the effect of regulation on individuals and the cumulative burden on business and, as part of the consideration of alternatives to new regulation, have regard to whether the existing regulatory regimes of other jurisdictions might offer a viable alternative; and

(e) applying these arrangements to Ministerial Councils.

COAG acknowledges that a large quantity of guidance material has also been developed on best practice regulation at the jurisdictional level that can assist Ministerial Councils to undertake regulatory impact assessment and make

sound regulatory decisions. In the case of Ministerial Councils, however, this Guide should act as the primary source of direction.

This Guide replaces the previous COAG document entitled *Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard-Setting Bodies*.

APPLICATION

Regulation refers to the broad range of legally enforceable instruments which impose mandatory requirements upon business and the community, as well as to those government voluntary codes and advisory instruments for which there is a reasonable expectation of widespread compliance.

The principles of good regulatory practice and regulatory assessment requirements outlined in this Guide apply to decisions of COAG, Ministerial Councils and intergovernmental standard-setting bodies, however they are constituted. This includes bodies established by statute, or administratively by government, to deal with national regulatory problems.

The principles and assessment requirements apply to agreements or decisions to be given effect, whether at the Commonwealth or State/Territory level, or both, through principal and delegated legislation, administrative directions or other measures which, when implemented, would encourage or force businesses or individuals to pursue their interests in ways they would not otherwise have done. This does not include purchasing policy or industry assistance schemes.

The principles and assessment requirements do not apply to agreements or decisions that result in regulation that is minor or machinery in nature and do not substantially alter existing arrangements. Nor do the principles apply to early "brainstorming" discussions of Ministerial Councils which are not supported by *written* submissions outlining regulatory options or recommendations regarding regulatory action.

Development of voluntary codes and other advisory instruments should take account of these principles and assessment requirements where there is a reasonable expectation that their promotion and dissemination by standard-setting bodies or by government could be interpreted as requiring compliance. For example, should non-compliance with provisions of a voluntary code be considered as evidence by a court or an administrative body when determining compliance with statutory obligations, such advisory documents are subject to the review process.

The Commonwealth Office of Best Practice Regulation (OBPR) will provide advice and assistance on regulation impact assessment, the preparation of RISs for Ministerial Councils and monitor and report on compliance with the requirements of this COAG Guide. Contact details for the OBPR are available at http://www.obpr.gov.au. Process requirements for the preparation of RIS are outlined in this document.

PRINCIPLES OF BEST PRACTICE REGULATION

Principles of Best Practice Regulation

COAG has agreed that all governments will ensure that regulatory processes in their jurisdiction are consistent with the following principles:

1. establishing a case for action before addressing a problem;
2. a range of feasible policy options must be considered, including self-regulatory, co-regulatory and non-regulatory approaches, and their benefits and costs assessed;
3. adopting the option that generates the greatest net benefit for the community;
4. in accordance with the Competition Principles Agreement, legislation should not restrict competition unless it can be demonstrated that:-
   a. the benefits of the restrictions to the community as a whole outweigh the costs, and
   b. the objectives of the regulation can only be achieved by restricting competition;
5. providing effective guidance to relevant regulators and regulated parties in order to ensure that the policy intent and expected compliance requirements of the regulation are clear;
6. ensuring that regulation remains relevant and effective over time;
7. consulting effectively with affected key stakeholders at all stages of the regulatory cycle; and
8. government action should be effective and proportional to the issue being addressed.

A discussion of the above principles, and some of the factors Ministerial Councils should consider in applying these principles to the regulation making process when assessing potential responses to policy problems, is included below.

Principle 1: Establishing a case for action before addressing a problem.

An important first step before considering any action is to examine closely whether there is a problem, and to make an initial decision on whether any action is required.

Principle 2: A range of feasible policy options must be considered, including self-regulatory, co-regulatory and non-regulatory approaches, and their benefits and costs considered.

Once the problem has been examined and a case for government intervention has been established, officers should identify the objectives for any intervention and consider all feasible options, of both a regulatory and non-regulatory nature, that could wholly or partly achieve these objectives. Working from an initial presumption against new or increased regulation, the overall goal is the effective and efficient achievement of the stated objectives. The 'status quo' and effectiveness of existing regulations should be considered as an option for meeting the objectives.

Principle 3: Adopting the option that generates the greatest net benefit for the community.

This requires a rigorous regulation impact assessment of all the feasible policy options available to address the identified problem. Decision makers should adopt the option which provides the greatest net benefit to the community. Decisions about whether regulatory action is in the public interest should be informed by an assessment of the effectiveness of the proposed action in meeting the identified objective, and the costs and benefits of the proposed action for the community as a whole.

Principle 4: In accordance with the Competition Principles Agreement, legislation should not restrict competition unless it can be demonstrated that:

- the benefits of the restrictions to the community as a whole outweigh the costs; and
- the objectives of the regulation can only be achieved by restricting competition.

Many existing and proposed regulations and requirements restrict competition, including by imposing barriers to entry, exit, or innovation, and can have the effect of restricting consumer choice, raising prices and reducing overall economic efficiency and productivity.

As far as possible, restrictions on competition should be avoided or minimised. Regulation should only restrict competition where this is necessary to achieve the objective, and the benefits of restricting competition outweigh the costs.

Principle 5: Providing effective guidance to relevant regulators and regulated parties in order to ensure that the policy intent and expected compliance requirements of the regulation are clear.

When making a decision to adopt a regulatory solution to a problem in order to deliver the greatest net benefit for the community, it is necessary to clearly articulate any decision and new regulations for the benefit of regulators administering the solution as well as regulated parties.

Regulation should have clearly identifiable outcomes and unless prescriptive requirements are unavoidable in order to ensure public safety in high-risk situations, performance-based requirements that specify outcomes rather than inputs or other prescriptive requirements should be used.

Good regulation should attempt to standardise the exercise of bureaucratic discretion, so as to reduce discrepancies between government regulators, reduce uncertainty and lower compliance costs. Regulatory measures should contain compliance strategies which ensure the greatest degree of compliance at the lowest cost to all parties.

Where possible, regulatory instruments should be drafted in ‘plain language’ to improve clarity and simplicity, reduce uncertainty and enable the public to understand better the implications of regulatory measures.

Appendix A sets out the key features of good regulation in more detail.

Principle 6: Ensuring that regulation remains relevant and effective over time.

To ensure regulation remains relevant and effective over time it is important that all regulation be reviewed periodically. All governments have committed to reviewing annually existing regulations with a view to

encouraging competition and efficiency, streamlining the regulatory environment, and reducing the regulatory burden on business arising from the stock of regulation.

Ensuring that regulation remains relevant and effective over time may be achieved through planning for monitoring and review of regulation as part of the development of new regulatory proposals, or by incorporating sunset provisions or review requirements in legislative instruments.

Principle 7: Consulting effectively with affected key stakeholders at all stages of the regulatory cycle.

There should be effective consultation with affected key stakeholders at all stages of the regulatory cycle. Public consultation is an important part of any regulatory development process. Consultation should occur when the options for regulatory action are being considered and a draft RIS (also known as the 'Consultation RIS') has been produced. This will give interested parties a range of options and also in some cases a firm proposal to consider.

Consultation on regulatory options can improve the quality of the solution adopted by:

- ensuring that both those affected by regulation, and the actioning agencies, have a good understanding of what the problem is;
- providing perspectives and suggestions, on alternative options to address the problem, from those parties that will be affected by the government action;
- helping regulators assess competing interests;
- providing a check on the regulator's assessment of costs (including compliance costs) and benefits and whether/how the proposed option will work in practice, thus reducing the risk of unintended consequences if a particular option is adopted;
- identifying interactions between different types of regulations; and
- possibly enhancing voluntary compliance through greater understanding and acceptance of a proposal, thereby reducing reliance on enforcement and sanctions.

Principle 8: Government action should be effective and proportional to the issue being addressed.

In all responses to identified problems, government action should be effective and proportional to the issue being addressed. Effectiveness should be judged solely in terms of meeting the specified objective. Consideration should be given to the effectiveness of implementation and administration and, as relevant, an assessment of likely compliance rates should be made taking into account matters such as incentive structures and costs to regulated parties.

Proportionality involves ensuring that government action does not 'overreach', or extend beyond addressing a specific problem or achieving the identified objective. The scope or nature of government action should be commensurate with the magnitude of a problem, its impacts, or the level of risk without action. The principle of proportionality applies equally to the implementation of regulation, including the development of frameworks for ensuring compliance.

PROCESS GUIDELINES FOR REGULATORY IMPACT ASSESSMENT

Regulation is an essential part of running a well functioning economy and society, but must be carefully designed so as not to have unintended or distortionary effects, such as imposing unnecessarily onerous costs on those affected by the regulations or restricting competition. Assessing the impact of regulation, including analysing the costs and benefits, is therefore important to ensure that it delivers the intended objective without unduly causing adverse effects.

If regulatory options are being considered (such as self-regulation where governments expect business to comply, quasi-regulation, co-regulation and 'black letter law') then Ministerial Councils must subject these options to a regulatory impact assessment process through the preparation of a draft and final RIS.

The purpose of a draft RIS for consultation is to canvass the regulatory options under consideration, in order to determine the relative costs and benefits of those options. The purpose of a final RIS for decision makers is to draw conclusions on whether regulation is necessary, and if so, on what the most efficient and effective regulatory approach might be, taking into account the outcomes of the consultation process. The basic feature of a RIS is the systematic examination of the advantages and disadvantages of possible methods of achieving the objective. A number of quantitative approaches exist to assist in evaluating options as part of the regulatory impact assessment including:

- risk analysis;
- cost-benefit analysis;
- measuring business compliance costs; and
- assessing effects on competition.

Detailed advice for Ministerial Councils on these quantitative approaches (risk analysis, measurement of business compliance costs and assessment of competition effects) is included in the appendices to this guide . The OBPR can also provide advice and assistance and is responsible for monitoring compliance with the requirements set out in this Guide.

The following steps for preparing RIS are provided to assist Ministerial Councils (including their secretariats or advisory committees) in determining appropriate courses of action and maximising the effectiveness and efficiency of new regulation taking into account the principles outlined above.

As a general rule the level of detail within the assessment should be commensurate with the impact of the proposed regulatory measures.

Steps for Policy Officers undertaking Regulatory Impact Assessment

Step one:

Consult early with the OBPR and seek advice about whether a RIS should be prepared.

Step two:

Send the draft RIS (also known as the 'consultation RIS') to the OBPR for advice as soon as practicable and before the draft RIS is made available for public comment. Where a trans-Tasman (such as Trans Tasman Mutual Recognition Arrangement (TTMRA)) issue is involved, the OBPR will refer it to the Regulation Impact Analysis Unit of the New Zealand Ministry of Economic Development for comment.

A Ministerial Council should continue to consult with the OBPR as the draft RIS is developed further.

It is expected that the level of analysis in a draft RIS would be lower than the level on analysis in the final RIS. This is because the impacts of options are sometimes unclear. The community consultation process is designed to allow

interested parties and stakeholders to identify help such impacts. In such cases the OBPR may focus its assessment primarily on the first three parts of the draft RIS, the problem, objectives and options section of the RIS.

Step three:

The Ministerial Council should await the comments of the OBPR prior to public release of the draft RIS for the purpose of consultation. The draft RIS approved by OBPR should be publicly released as part of the mandatory community consultation process.

Step four:

Consult with affected stakeholders by placing advertisements in all jurisdictions to give notice of the intention to adopt regulatory measures, to advise that the RIS is available on request and invite submissions.

Step five:

The RIS should be developed further following its public release, taking into account outcomes from the consultation process and incorporating a list of stakeholders consulted and a summary of their views.

Step six:

The final RIS for decision makers should be forwarded to the OBPR prior to a decision being made by a Ministerial Council. The OBPR will assess the RIS within two weeks of receipt. The assessment will focus on whether the RIS meets the requirements set out in this document, including:

- whether the RIS Guidelines have been followed;
- whether the type and level of analysis are adequate and commensurate with the potential economic and social impacts of the proposal; and
- whether the RIS demonstrates that the preferred option results in a clear net benefit to the community.

Where the preferred option restricts competition, the benefits to the community of the restriction should outweigh the costs and it should be demonstrated that the objectives of the regulation can only be achieved by restricting competition.

The OBPR will advise the Ministerial Council or standard setting body of its assessment, incorporating any comments from New Zealand relating to a trans-Tasman issue.

The Ministerial Council will determine whether or not to adopt the OBPR's advice.

Step seven:

Following a decision by the Ministerial Council to proceed with a regulatory course of action, the decision making body should respond to any issues that have not been dealt with in the way recommended by the OBPR.

Step eight:

Both OBPR comments and any responses made by Ministerial Councils should be available to Commonwealth, State and Territory Cabinets.

Step nine:

The OBPR is to advise Senior Officials through the COAG Secretariat in the Department of the Prime Minister and Cabinet if, in its opinion, decisions of Ministerial Councils are inconsistent with COAG Guidelines.

After a decision is taken, the final RIS, which should be of a standard suitable for publication, will generally be made public.

RIS Guidelines

What needs to be included in a RIS?

This section outlines the process for preparing a RIS and the key questions for consideration at each stage in the process. The basic feature of a RIS is the systematic examination of the advantages and disadvantages of possible methods of achieving an agreed objective.

As a general rule, the level of analysis included in the final RIS provided to the decision maker should be higher than that included in the draft RIS which is prepared for the purpose of consultation.

As outlined below there are seven key elements that should be contained in a RIS. The detail and depth of analysis in a RIS should be commensurate with the magnitude of the problem and with the size of the potential impacts of the proposal. More detailed discussion of the seven elements of a RIS can be found in the OBPR's *Best Practice Regulation Handbook*, which can be downloaded from http://www.obpr.gov.au/bestpractice/index.html

Element 1 Statement of the Problem

The RIS should clearly identify the fundamental problem(s) that need to be addressed. This part of the analysis must:

- present evidence on the magnitude (scale and scope) of the problem;
- document relevant existing regulation at all levels of government, and demonstrate that it is not adequately addressing the problem;
- if the problem involves risk, identify the relevant risks and estimate the probability of an adverse outcome, including where no new or amended regulations are made and where government action would reduce the risk; and
- present a clear case for considering that additional government action may be warranted, taking account of existing regulation and any risk issues.

The statement of the problem should establish a case for action (Best Practice Regulation Principle 1). In particular, officers should consider the following questions:

- what is the problem being addressed?
- how significant is it?
- what are the costs, risks or benefits of maintaining the status quo?
- why is government action needed to correct the problem?
- is there relevant regulation already in place?
- if regulation is in place, why is additional action needed?

Information should be obtained on the nature and magnitude of the problem as well as identifying what government actions (if any) have been taken in the past to address the problem. In some cases government intervention in a market may be justified on the basis of 'market failure', which can arise where there is:

- imperfect competition;
- externalities;
- public goods; or
- imperfect or costly information.

The term market failure is sometimes misunderstood to indicate a failure of markets to deliver a desirable social or equity goal. Any underlying market failure, regulatory failure (for example, unintended consequences or failure of existing regulation) or risks should be clearly identified.

Element 2 Objectives

The RIS should clearly articulate the objectives, intended outcomes, goals or targets of government action. The objectives should not pre-justify a preferred solution. Nor should government regulation be considered to be an objective of government action (that is, regulation is a means to an end, not an end in itself). The objectives should be specified broadly enough to allow consideration of all relevant alternative solutions, but without being so broad that the range of options becomes too large to assess, or the extent to which objectives have been met becomes too hard to establish.

Element 3 Statement of Options

The RIS should identify a range of viable options including, as appropriate, non-regulatory, self-regulatory and co-regulatory options. If only one option (apart from the status quo) is considered feasible, the RIS should provide sound justification for considering only two options.

The Statement of Options of a RIS should address Principle 2 by demonstrating that officers have considered a range of policy options and the benefits and costs of these options.

Regulatory measures and instruments should be the minimum required to achieve the pre-determined and desirable outcomes. Where a decision is made to consider regulatory options additional factors that should be explored include:

- consistency with Australia's international obligations and relevant international accepted standards and practices;
- potential incentive effects and secondary effects;
- minimisation of regulation and administrative burdens as much as possible;
- the potential regulatory burden of alternative measures on the community; and
- compliance and enforcement issues.

Alternatives to regulatory options might include education campaigns.

Element 4 Impact Analysis (Costs and Benefits)

The RIS should provide an adequate analysis of the costs and benefits of the feasible options and should:

- identify the groups in the community likely to be affected by each option and specify significant economic, social and environmental impacts on them;
- assess the costs and benefits of all the options supported by an acceptable level of evidence, where appropriate through a formal cost-benefit analysis (see Appendix C);
- assess the impacts on business, particularly small business, and quantify the effect of each option on business compliance costs (using a tool such as the Business Cost Calculator) (see Appendix D);
- quantify other significant costs and benefits where appropriate, taking into account the significance of the proposal, its impact on stakeholders;
- if an objective of regulation is to reduce risk, analyse the extent to which each option would reduce the relevant risk, and the costs and benefits involved (see Appendix B);
- recognise the effect of the options on individuals and the cumulative burden on business;

- document any relevant international standards, and if the proposed regulation differs from them, identify the implications and justify the variations;
- if the proposed regulation would maintain or establish restrictions on competition, demonstrate that government objectives can be achieved only by restricting competition (see Appendix E); and
- provide evidence in support of key assumptions and clearly identify any gaps in data.

Where a proposed regulation would maintain or establish restrictions on competition, an assessment against the Competition Principles Agreement guiding principle should be undertaken (see Appendix E). The extent of this assessment should be commensurate with an initial assessment of the extent of the anti-competitive impact. It should involve the evaluation of the impact (for primary and relevant related markets) of the regulatory proposal on the following:

- incumbent businesses;
- entry of new businesses;
- prices and production;
- quality and variety of goods and services;
- innovation;
- market growth; and
- related markets.

The results of this assessment should be compared with assessments of feasible alternative policy options that would equally achieve the policy goal but be less anti-competitive. If there are no available alternatives, the proposal should be assessed from the perspective of economic well being or net benefit to the community.

Regulation impact analysis of the feasible policy options, should also include an assessment of whether a regulatory model is already in place in a participating jurisdiction that would efficiently address the issue in question and whether a uniform, harmonised or jurisdiction-specific model would achieve the least burdensome outcome (or generate the greatest net benefit for the community). A regulation impact assessment should also have regard to whether the issue is state-specific or national, and whether there are substantial differences that may require jurisdiction-specific responses.

The impact analysis in a RIS should include an assessment of Principle 3, that is, adopting the option that generates the greatest net benefit to the community.

There are a number of different approaches to quantitative analysis to help establish the most efficient form that any regulation might take. The techniques set out below are to be employed to determine the option with the greatest net benefit for the community (a particular technique may be omitted if circumstances render it irrelevant).

Risk analysis

This methodology is of use in addressing the threshold issue of whether or not to regulate. Risk analysis should be used in conjunction with other quantitative assessment techniques. Detailed guidance for Ministerial Councils on undertaking risk analysis is included at Appendix B.

Cost-benefit analysis

This technique requires that all the major costs and benefits of a proposal be quantified in monetary terms. In this way, the outcomes of a range of options are translated into comparable terms in order to facilitate evaluation and decision-making. Cost-benefit analysis is most effective in instances where there is sound information on which to base the analysis. However, it should also be noted that cost-benefit analysis should involve consideration of the

distribution of benefits and costs, as well as taking account of impacts which are unable to be valued quantitatively. Detailed guidance for Ministerial Councils on undertaking cost-benefit analysis is included at Appendix C.

Business compliance costs

Consideration should also be given to the compliance burden imposed on business. These are the additional (incremental) costs incurred by businesses when complying with regulations.

One option for making initial assessments of the likelihood a proposal will involve compliance costs for business is through the use of the Business Cost Calculator's *Quickscan* function. This tool is located on the OBPR website at www.obpr.gov.au/businesscostcalculator/index.html

If this indicates there are compliance costs for business, then the Business Cost Calculator can be used to complete a detailed assessment of these costs.

As part of a regulatory impact assessment, a practical approach for considering the impacts on business compliance costs potentially flowing from regulatory proposals is through a set of threshold questions. A compliance cost checklist is included at Appendix D.

Competition effects

Ministerial Councils will also need to have regard to the competition effects of any policy options. This is discussed in the next section.

Each RIS should outline the results of this analysis and come to a conclusion on which of the options being considered provides the greatest net benefit for the community for the benefit of the ultimate decision making body.

The impact analysis in a RIS should also include an assessment of Principle 4, that legislation should not restrict competition unless it can be demonstrated that the benefits of the restrictions to the community as a whole outweigh the costs; and that the objectives of the regulation can only be achieved by restricting competition adopting the option that generates the greatest net benefit to the community.

A preliminary analysis of whether a proposal may restrict competition can be conducted by working through the questions in the competition checklist included at Appendix E.

Element 5 Consultation

The final RIS should:

- outline the consultation objective;
- describe how consultation was conducted (including the stages of the policy development process at which consultation was undertaken, the timeframes given, and the methods of consultation);
- articulate the views of those consulted, including substantial disagreements;
- outline how those views were taken into consideration; and
- if full consultation was not undertaken, provide a reasonable explanation.

The consultation statement in a RIS should address Principle 7 by setting out the consultation undertaken with affected key stakeholders.

Consultation should occur as widely as possible but, at the least, should include those most likely to be affected by regulatory action (for example, consumer and business organisations) which might provide valuable feedback on the costs and benefits of regulation and on the impact assessment analysis generally. Consultation will also provide feedback on the level of support for the proposed regulation.

A statement of the consultation undertaken is a key component of the RIS process.

The OBPR has developed seven principles for best practice consultation and these are detailed in Appendix F.

Element 6 Evaluation and Conclusion

The RIS should provide a clear statement as to which is the preferred option and why.

The RIS should demonstrate that:

- the benefits of the proposal to the community outweigh the costs; and
- the preferred option has the greatest net benefit for the community, taking into account all the impacts.

Element 7 Implementation and Review

The RIS should provide information on how the preferred option would be implemented, monitored and reviewed. Interactions between the preferred option and existing regulation of the sector should be clearly identified.

The implementation and review section of a RIS should address Principle 6, ensuring that regulation remains relevant and effective over time. Specified outcomes of standards and regulatory measures should be capable of revision to enable them to be adjusted and updated as circumstances change. However, it is important to ensure that amendments to regulatory measures and instruments do not result in undue uncertainty in business operations and in so doing, impose excessive costs on that sector.

Strategies for reviewing new regulations should be identified in the RIS when considering the policy option.

Frequently Asked Questions

What if there is not time to prepare a RIS?

A Ministerial Council may decide that a situation requiring a regulatory response is an emergency. In these cases, a RIS need not be prepared before the regulation comes into effect. However, the Chair of the Ministerial Council must write to the Prime Minister before making the regulation:

- seeking agreement to waive the need for a RIS; and
- explaining why the situation was an emergency and why no transitional measures were available.

If the situation was an emergency, the Ministerial Council would be expected to prepare a RIS within 12 months of making the regulation. Alternatively, in emergency cases the briefing material prepared for a Ministerial Council can be provided to the OBPR, which will advise whether the key elements of a RIS are addressed in such material. If so, the OBPR can "post assess" the material as complying with the COAG Guidelines.

At what point is a RIS required?

A final RIS is required at the point a decision is taken. For multi-staged decision-making processes, where a RIS is prepared in accordance with these Guidelines, a RIS will not generally be required for follow-up or subsequent regulation which implements the original decision, unless significant additional regulation is contemplated.

What is the role of the OBPR?

The OBPR does not have any power over decisions made by Ministerial Councils and its role is advisory. COAG has directed the OBPR to provide independent advice on the adequacy of RIS prepared for both public consultation and decision by Ministerial Councils. In fulfilling this role the OBPR does not support any particular regulatory approach or jurisdiction. The OBPR can assist and advise as to whether a RIS is consistent with the principles and Guidelines in this document. However, the attention of COAG can be drawn to any regulatory proposals for which the RIS is seriously inadequate through the Productivity Commission's annual regulatory report.

REQUESTING A REVIEW OF A REGULATION IMPACT STATEMENT

If, prior to the introduction of a regulation, there is some dissatisfaction with the process or adequacy of the analysis by which conclusions were reached, two or more jurisdictions may request an independent review of the proposed regulation. The Ministerial Council must then defer its consideration of the regulation and commission a review.

The process of independent review would be triggered if two Heads of Government write to the Chair of the Ministerial Council requesting an independent review of the assessment process. Upon completion, the review body will report back to the relevant Ministerial Council.

The Ministerial Council is to nominate an independent body to conduct the review (the review body). This might include a regulatory review body in any jurisdiction, an appropriate specialist body or a consultant. Jurisdictions that request the review will meet the review's cost and agree to make resources available for the conduct of the review if the Ministerial Council decides to use State or Territory government regulatory review units to conduct the review.

The review body's task is to reassess the RIS and report on whether it can be demonstrated that the assessment process has been carried out according with the Guidelines in this document. It is not intended that the independent review should necessarily repeat the quantitative analysis. The review body may also comment on any aspect of the proposed regulation and will have access to public submissions made in the course of the assessment process.

The report of the review body would become a public document and would be considered by the Ministerial Council in its discussion of the adoption of the proposed regulatory measures. Once the report has been considered, the Ministerial Council's consideration of whether or not the regulation should be adopted by member governments can proceed.

The initial regulatory impact assessment and any review of that assessment are designed to provide the best possible information for decision making by the Ministerial Council. The impact assessment will not bind them or the participating governments since most Ministerial Councils are not formally established and do not have formal and binding voting arrangements. Their purpose is to develop a national consensus in relation to the matters which they consider.

If, upon the advice of the review body, a State or Commonwealth regulatory review body, or other advice, the impact assessment is found to have been faulty, the Ministerial Council retains discretion in its use of the impact assessment to inform its decision making.

If a Ministerial Council fails to act on the recommendations of the review, the matter may be further examined by Heads of Government.

APPENDIX A: FEATURES OF GOOD REGULATION

In formulating national standards and regulatory measures according to the above principles and guidelines, Ministerial Councils should also take into account the following practical features of good regulation.

Accountability

As set out in the protocols for the operation of Ministerial Councils, it is the responsibility of Ministers to ensure that they are in a position to represent appropriately their Government at Council meetings. Therefore, to the greatest extent possible, Ministers should obtain full government agreement on matters which may involve regulatory action before they are considered at Ministerial Council level.

Where a Minister is dissatisfied with the outcome of the impact assessment process, the Minister may seek the agreement of his/her Head of Government to request an independent review of the assessment process.

Compliance strategies and enforcement

Regulatory measures should contain compliance strategies which ensure the greatest degree of compliance at the lowest cost to all parties. Incentive effects should be made explicit in any regulatory proposals. Measures to encourage compliance may include regulatory clarity, brevity, public education and consultation and the choice of alternative regulatory approaches with compliance in mind.

The special characteristics of process regulation need to be considered. For example, the number of licences, certifications, approvals, authorities et cetera. should be kept to the minimum necessary to achieve the regulatory objectives.

The regulatory burden can be reduced if the public is required to undertake a minimum level of interaction with government to, for example, renew permits/ licences or file information. This can be achieved through measures such as 'one stop shops'; mutual recognition of approval processes within government as well as between governments; better forms and process design.

Having taken these steps to facilitate compliance, regulators also need to consider the feasibility of enforcing regulatory requirements through the detection of non-compliance.

Mandatory regulatory instruments should contain appropriate sanctions to enforce compliance and penalise non-compliance. However, enforcement options should differentiate between the good corporate citizen and the renegade, to ensure that 'last resort' penalties are used most effectively (rarely) but model behaviour is encouraged. Enforcement measures should not have the effect of encouraging otherwise good corporate citizens to subvert compliance measures.

Inclusion of standards in appendices

Standards should be referenced as current editions in appendices to regulatory instruments rather than embodied in such instruments themselves. It may be appropriate in some circumstances for regulations to reference a specific standard (eg AS 1234).

A disadvantage of only referencing the title of a standard (eg AS1234) is that impact assessment is carried out only on the initial instrument and referenced standard. The standard, however, may be subsequently changed or updated. This may result in significant changes to the costs or benefits of regulation, with no opportunity to review the implications of such a change. This can have the effect of transferring regulatory power from governments to standard setters. To prevent this, it may be appropriate in some circumstances for regulatory instruments to reference a specific version of a standard by referring to its date (for example, AS 1234, 1993). If an amended version of a standard is to be adopted any changes to this standard would then require amendment of the regulatory instrument and hence further impact assessment.

An advantage of only referencing the title is that changes to the standards do not render the regulations null and void.

In determining whether to include a standard, consideration should also be given to the costs of obtaining the standard in order to comply with it.

Performance-based regulations

Regulatory instruments should be performance-based, that is, they should focus on outcomes rather than inputs. 'Deemed to comply' provisions may be used in instances where certainty is needed. In such cases, regulations might reference a standard or a number of standards deemed to comply with the regulation. There should be no restrictions on the use of other standards as long as the objectives of the regulation are met.

Plain language drafting

Where possible, regulatory instruments should be drafted in 'plain language' to improve clarity and simplicity, reduce uncertainty and enable the public to understand better the implications of regulatory measures.

Date of effect

The dates of commencement of proposed standards and regulatory measures should be carefully planned to avoid or mitigate unintended or unnecessary market consequences, such as the necessity to discard non-complying stock and to allow transition to compliance with new regulatory requirements.

Advertising the introduction of standards and regulations

Public consultation usually only involves interested parties. Therefore, once produced, new regulatory measures should be advertised to bring them to the attention of the wider community.

International standards and practices

Wherever possible, regulatory measures or standards should be compatible with relevant international or internationally accepted standards or practices in order to minimise the impediments to trade. Compatibility in this context does not necessarily imply uniformity, however.

National regulations or mandatory standards should be consistent with Australia's international obligations. Australia has obligations under the GATT Technical Barriers to Trade Agreement (Standards Code) and the World Trade Organisation's Sanitary and Phytosanitary Measures (SPS) Code. Regulators may refer to the Standards Code relating to the International Standards Organisation's Code of Good Practice for the Preparation, Adoption and Application of Standards.

APPENDIX B: RISK ANALYSIS

What is risk?

Risk is the probability of an undesirable event occurring. Much regulatory activity, for example in the areas of health and safety, is concerned with the risk of persons being harmed by engaging in a particular activity (for example, by consuming a product or by working in a factory). The notion of harm encompasses fatality, injury or illness.

Risks can be viewed in several ways. It is possible to look at societal risk or individual risk. The former averages out individual risk and measures the risk to society as a whole or to a large group of people. Individual risk, on the other hand, varies from person to person. In addition, voluntary risk can be distinguished from involuntary risk. Voluntary risk occurs where an individual can choose to undertake or avoid the risk-causing activity and is fully aware of the consequences.

Conversely, involuntary risk occurs where there is no choice or inadequate information about the consequences. Incomplete information is one of the main forms of market failure. An analysis should also make a distinction between perceived risks and actual risks. Perceived risks occur where individuals overstate the importance of relatively improbable events or discount the importance of highly probable events.

An important distinction to make when conducting risk analysis is that between risk and uncertainty. Risk involves a situation where the probabilities of the various outcomes are reasonably well known. In statistical terms, a probability distribution can be attached to the cost or benefit in question. Uncertainty involves a situation where, while the values the costs or benefits may take may be known, the probabilities of the outcomes are not known.

What is risk analysis?

Risk assessment is a means of analysing the risk of an undesirable event occurring and the consequences that are liable to arise if does occur. An integral part of the assessment process, following on from these first two steps, is determining what action may be necessary to reduce or eliminate the risk and/or its consequences.

Risk analysis is commonly used by policy analysts as a means of assessing individual and societal risks and proposing possible regulatory and non-regulatory solutions to an identified problem. It is most commonly used to analyse regulatory interventions in the health and safety field. However it can also be applied in other public policy fields.

Risk analysis

Risk analysis can serve a number of functions. By comparing the risk associated with the status quo with that after government intervention, it can be used to determine more accurately whether intervention is appropriate and/or worthwhile. Risk analysis can also be used as an input into other assessment techniques like cost-benefit analysis.

Risk analysis, in its most basic form, involves quantitative assessment of the magnitudes of the risk affected by the proposal. The contents of a risk analysis can easily be extended by the assessment of additional information, such as benefits or associated risks.

Risk analysis is a valuable tool in further addressing the threshold issue of whether or not to regulate. Furthermore, risk analysis is of use in answering two important questions. First, whether the risks that regulation is intended to address are of significant magnitude compared with other risks. Second, the extent to which regulation reduces the initial risk problem.

Content of a risk analysis

The following issues can be addressed in the risk assessment of regulation:

- an appraisal of the current level of risk to the exposed population from an identifiable source;
- the reduction in risk which will result from the introduction of the proposed measures;
- consideration of whether the proposed measures are the most effective available to deal with the risk; and
- whether there is an alternative use of available resources which will result in greater overall benefit to the community.

Limitations of risk analysis

There are a number of ways of assessing risk and the impact it is liable to have. They tend to be relatively arbitrary and non-empirical, so that a set of results can be easily interpreted by different persons in different ways. Risk assessment does not normally involve an assessment of the costs likely to be incurred by the affected parties if the undesirable event does happen. Nor does it take into account the costs and benefits associated with the measures proposed to reduce or eliminate the risk and/or its consequences. Risk analysis should therefore not be used as the sole basis for deciding whether to take action to correct an undesirable situation or for determining the type of action to be taken.

The risk analysis process

Risk analysis involves three distinct but inter-linked steps:

- defining the risk;
- selecting the appropriate response; and
- monitoring the situation and reviewing the effectiveness of the response that was selected and implemented.

Defining the risk

The following questions should be answered to ensure that the risk is defined as accurately as possible:

1. What is the hazard? It is necessary to define exactly what the hazard is;

2. What is the risk? It is important to distinguish between commercial risks and physical risks. Commercial risks can, and probably should, be borne by the company or industry involved and resolved at that level. On the other hand, a physical risk (and this ranges from a direct personal threat to life to environmental pollution) is a problem that is likely to affect individuals and society as a whole and therefore is best addressed at the appropriate government level;

3. How widespread is the risk? Is the risk local only, is it state-wide, national or international ? Obviously, the extent of measures to be considered to combat the risk will depend on this assessment, and may include the need for international co-operation;

4. Is the risk transmittable? In the case of medical risks, for example (such as a contagious disease), the transmitability of the risk is crucial to this assessment, as is the means of transmission and its avoidability. This will also involve identification of the source of the risk and whether transmission occurs across boundaries, for example, from plants to insects to animals to humans, or between different geographical locations;

5. In what circumstances will the risk arise? Is the risk continuous, or will it arise only in particular circumstances (for example, if a product is used only in a specific way; or only if a particular chemical is used);

6. Who or what is most at risk? Identification of the at-risk groups is crucial. It is necessary to determine for instance whether children of certain ages are most at risk, whether it is the population as a whole, whether the risk is confined to a particular group (for example, only plants, or male children below the age of 10, or women over 45); and

7. Is harm or injury liable to occur? Having gone through the above steps, it is important to determine whether any actual harm (for example, to the environment) or injury is liable to occur. This necessarily involves assessing not only the immediate effects but also the longer term effects. If no actual harm or injury is liable to occur, then any question of intervention probably becomes almost superfluous.

Selecting the response

This step is dependent on the accuracy and completeness of having defined the hazard. The first question to be asked is whether there is any realistic, viable action that the government can take to correct or ameliorate the situation. If the answer is no, or if the costs of any action are likely to outweigh the benefits, then serious consideration should be given to not taking any action at all. An explanation must be given as to what actions were considered, why they are impractical and the consequence (if any) of no action being taken.

Monitor the situation and review the effectiveness of the response

Whether the selected response is no action, introduction of a tax or subsidy, or a voluntary code of practice or a mandatory regulation, it is essential that both the situation and the effectiveness of the response be closely monitored. Monitoring will determine whether:

- the risk was under- or over-estimated and the response is adequate in the circumstances;

- the risk has changed and the response no longer applies to new circumstances; and
- those at which the action was directed are responding.

The monitoring and assessment process requires determination of:

- whether the risk has been eliminated. In which case, can the response be removed altogether or should it be retained in place to prevent a recurrence of the risk?
- whether the risk has been reduced but not eliminated. It may be unrealistic to expect complete elimination of the risk to occur. In that case, what level of reduction in the risk leaves a situation which, while not necessarily ideal, is acceptable? and
- how much longer the response should be left in place. If any reduction in the level of risk is not sufficient to justify considering the situation to be acceptable, how much longer should the response stay in place to reach an acceptable level of reduction?

APPENDIX C: COST-BENEFIT ANALYSIS

What is cost-benefit analysis; and how and where can it be used?

Cost-benefit analysis (CBA) is an analytical tool that can be used to measure the economic and social impact of government action by reference to the 'net social benefits' that action might produce. As such, it can be a valuable aid to decision making. Its power as an analytical tool rests in two main features:

- costs and benefits are each as far as possible and appropriate expressed in money terms and hence are directly comparable with one another; and
- costs and benefits are valued in terms of the economy and society as a whole, so the perspective is 'global'. This contrasts with, for example, a financial evaluation, which is conducted from the vantage point of an individual, a firm, an organisation or group.

Cost-benefit analysis can be employed to decide:

- whether a regulatory proposal should be undertaken;
- if an existing regulation should be maintained; or
- between alternative regulatory proposals (usually aimed at similar objectives).

Decisions about the overall effectiveness of regulatory action should not be made on the basis only of its effect on particular groups in society. Public policy makers are expected to make judgments based on what is best for the community as a whole. By measuring 'social', as opposed to only private, market-based costs and benefits, CBA is a valuable tool when developing good policy responses to economic and social problems. When undertaking CBA as part of the evaluation of the regulatory action being considered, TTMRA Principles should be adequately considered.

The term 'net social benefits' refers to the difference between social benefits and social costs. According to the cost-benefit rule, government action is only justified where, subject to budget constraints, there are positive net social benefits expected to be gained from intervention, such as imposing regulations on the community. Benefits and costs are 'social' rather than private or individual, in the sense that they are measured irrespective of the people to whom they accrue and are not confined to formal market transactions. If there are non-market implications from regulatory activities or market prices are distorted, CBA proceeds as if the correct market prices existed. These are referred to as shadow prices.

Inevitably, some costs and benefits resist the assignment of dollar values. Known as 'intangibles', these are separately presented to decision-makers for assessment in conjunction with those that can be quantified.

A major advantage of CBA is that costs and benefits occurring at different points in time can be explicitly compared. The 'factoring down' of benefits and costs that will occur in the future into present values is known as 'discounting'. Since a dollar in the future is usually worth less than a dollar today, future costs and benefits need to be discounted to their equivalent 'present value'. Conversely, in a retrospective analysis, past costs and benefits are compounded forward to their present value.

Under the net present value rule, a regulatory activity should only be undertaken if its net present value (that is, benefits minus costs) is positive. Accordingly, CBA is a valuable tool for decision makers when assessing the issue of whether a particular proposal is appropriate. If comparing a number of options, the alternative with the highest positive net present value would be preferred.

CBA can provide guidance on the implications of regulatory activity, where there are grounds for mistrusting the signals provided by market prices or where no markets exist. CBA is also helpful where regulations impose 'spillover' costs or benefits on third parties. Often these do not receive due recognition because no formal market transactions take place. Through the use of shadow prices, values can be placed on non-market 'spillover' effects (for example, pollution, safety) and compared with market transactions.

Examples where the signals that market prices normally provide are either absent or fail to reflect the true costs of regulatory action arise when valuing:

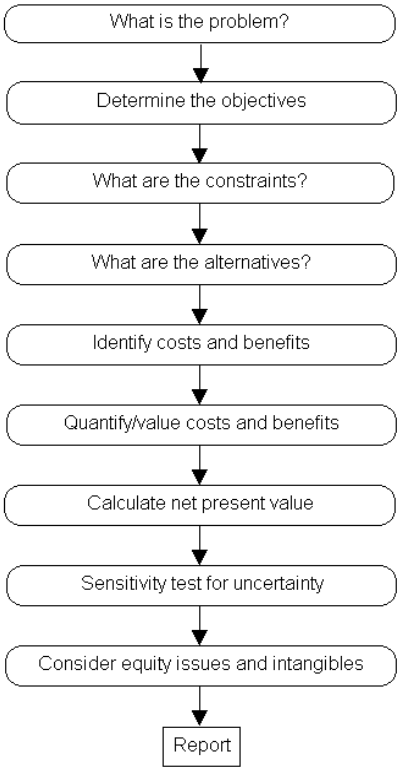
- intermediate goods - such as savings in travel time resulting from transport regulations;
- 'externalities' - or unmarketed positive or negative spillover effects such as arise from pollution, vaccination programs or banning a dangerous product;
- goods affected by taxes and subsidies; and
- labour in the presence of unemployment.

The main practical constraint to using CBA is the feasibility and appropriateness of assigning money values to the costs and benefits generated by government action. In circumstances where these constraints are overwhelming, cost-effectiveness analysis is frequently a viable alternative approach.

The key steps in the CBA process

There is a logical sequence of steps to take when undertaking a cost-benefit analysis prior to deciding on a standard or regulation. A diagram of the steps outlined below is shown in Figure 1.

Figure 1: Key steps in the cost-benefit process



1. *What is the problem?*

The first step entails an investigation and assessment of the problem, its context and its background. A proposal to intervene with regulation or standard will be based on an assessment that the status quo is undesirable. That assessment needs to be described to define the problem. This is an opportunity to place the proposal for intervention in its broader context, before narrowing the focus to its specific details.

2. *What are the objectives?*

This step includes a definition of the objectives to be achieved and who the intended beneficiaries are.

3. *What are the constraints?*

Public policy makers face various constraints on government action. Examples of such constraints are:

- financial - for example, budgetary limitations and price ceilings;
- distributional - for example, a perverse distribution of benefits among individuals or groups (for example, from the less well off to the wealthy);
- managerial - for example, limits on the staff;

- environmental - for example, compliance with environmental protection requirements; and
- policy - for example, is the proposal consistent with broad government policy?

Before options are identified for further consideration, any practical constraints on the feasibility of such alternative options should be examined and documented in the RIS. In some cases the nature and extent of these constraints may be unclear or difficult to measure. In which case, any uncertainties and risks should also be acknowledged and documented in the RIS.

When analysing all alternatives consideration should be given to the principles contained in the Competition Principles Agreement of 11 April 1995, in particular clause 1 (3), which includes reference to consideration of the environmental, social and economic aspects.

4. *What are the alternatives?*

While each alternative to the proposal for intervention that is identified will require a considerable amount of subsequent analysis if it is to be fully incorporated into a CBA, the number of alternatives generated should be sufficient to provide the decision-makers with real scope for exercising choice. To facilitate this, alternatives should be clearly distinguished.

Furthermore, a 'do nothing' alternative should always be identified, implicitly if not explicitly. This will be the base case against which alternatives can be compared. Then costs and benefits would be incremental to what would have happened in the absence of regulatory action.

5. *What are the benefits?*

A list of the benefits that are expected to flow from the proposals should be drawn up. To identify benefits (and costs), a clear account of the chain of causation from the proposal is needed. This should be available from the policy analysis undertaken in formulating the proposal. The list of benefits might include such items as:

- an increase in the value of economic output as a result of a particular action;
- avoided costs - costs which would have been incurred in the 'do nothing' situation;
- productivity savings – that is, producing more with less; and
- health, environmental and other social benefits, which are often not marketed or are characterised by prices which reflect less than the full value of the benefits.

6. *What are the costs?*

Similarly, for each alternative a list of costs should be drawn up. Examples of costs are:

- increases in expenditure by governments to establish and/or maintain regulation and enforcement regimes;
- increased costs on business and the broader community from higher input costs and regulatory compliance costs. A RIS should provide quantitative data on regulatory compliance costs, including information about the number and type of businesses or individuals affected, and the likely financial (and other) impacts on those affected. Compliance costs can include additional paper burden costs,

additional staffing, licence fees or charges, external advice, transport and/or restrictions on competition. RIS should also give full consideration to ways of minimising such costs. Where quantitative data about such costs are unavailable, a qualitative assessment should be provided;

- increased costs on consumers from higher prices for goods and services; and
- externalities or spillover effects on other parties, both positive and negative. For example, environmental costs such as air, water and noise pollution.

Particular attention should be given to the likely impacts on small business, especially where regulatory compliance costs could have a disproportionate impact on small business.

7. *How can costs and benefits be quantified?*

Cost-benefit analysis compares costs and benefits using a common measure, usually dollars. Therefore, dollar values must be assigned to as many of the costs and benefits as possible. Market prices, where they exist, provide a great deal of information concerning the magnitude of costs and benefits. However, actual prices sometimes have to be adjusted to convert private costs and benefits into social ones, that is, costs and benefits which reflect gains and losses to the economy as a whole, rather than to individuals or groups.

8. *How should net present value be assessed?*

The values assigned to costs and benefits should be based on an explicit assumption about price inflation; normally, costs and benefits will be valued in real terms with the base being that of the current year. Total costs in each year of the project's life are subtracted from total benefits in that year to yield net benefits in each year. Annual net benefits are then discounted back to today's dollars. The stream of discounted net benefits is then summed to yield the net present value.

Subject to a consideration of budget constraints, intangibles and distributional issues, a CBA will support a proposal if the net present value is equal to or greater than zero. Similarly, if there are a number of ways of achieving the desired outcome, a CBA will support the alternative with the highest net present value, where that is equal to or greater than zero.

9. *How should uncertainty be dealt with?*

The values included in a CBA are the 'most likely' or 'best' estimates. Sensitivity analysis is a simple procedure for providing the decision-maker with information about the impact of estimation errors on the viability of the proposal. The first step in a sensitivity analysis is to substitute the most pessimistic estimates for each variable simultaneously, and see how much the net present value is affected. If the result is still greater or equal to zero, then we are able to say that even under worst case assumptions, the CBA supports the proposal.

The second step is to try to assess how risky the proposal is, that is, which variables significantly affect the net present value and which do not. This can be established by varying each variable one at a time, holding all other variables unchanged.

10. *How should the report be structured?*

The final step in the cost-benefit process is the writing-up of the analysis, which includes the recommendation to the decision-maker. The report should include:

- a summary of the results of the analysis;
- an introduction describing the considerations which led to the decision to undertake a CBA;
- a statement of the 'problem' the proposal is designed to redress;
- the objectives of the regulatory proposal;
- a description of the alternatives considered;
- the constraints considered in conducting the analysis and the alternatives selected;
- the time profiles of costs, benefits and net benefits, together with information on the sensitivity of those profiles to alternative assumptions;
- information on intangible costs and benefits;
- a list of assumptions made in performing the analysis, and information on how benefits and costs were estimated;
- a description of distributional effects;
- a conclusion discussing the results of the analysis; and
- an outline of an evaluation mechanism.

To what level or depth should the analysis be conducted?

The steps outlined are recommended for every CBA. However, obtaining and analysing information also incurs costs. Hence, there are important choices to make regarding the level or depth to which the analysis is conducted. The more significant a proposal and the greater the likely economic and social implications, the more expenditure on a CBA can be justified. The viability of smaller proposals can be threatened by investing too much in analysis. This possibility should set obvious limits on the level and depth of the analysis required.

The likely benefits of obtaining and analysing additional information should always exceed the costs of so doing. Better information often reduces the uncertainty surrounding estimates, however, if a proposal is already known to be clearly viable or unviable, the pay-off from obtaining extra information may be negligible. Detail and complexity are not the same as rigour - which is ultimately more important. An elaborate and detailed analysis of a problem that has been wrongly conceptualised may well be worthless. But a 'back of the envelope' analysis of a problem that has been thought through correctly will, at the very least, be a helpful first step.

Letting decision-makers decide

Distributional implications can be obscured by the aggregating character of the cost-benefit process. Analyses should include all the information available to ensure that decision-makers are aware both of the identity of the groups likely to gain and to lose as a result of government action, and of the nature and size of the gains and losses. This information should be carefully presented, most usefully in the form of a distributional incidence chart or matrix.

Distributional judgements are properly made at the political level. In the interests of avoiding subjective bias, analysts should, by and large, refrain from attaching distributional weights to cost and benefit streams. Exceptions might be where there are unambiguous government policy objectives to assist specific groups in the community, and where the justification for special assistance to these groups relative to other groups is clearly established. However, for reasons of transparency, decision-makers and the public should be made fully aware of the costs of government action aimed at benefiting particular individuals or groups in the community.

APPENDIX D: BUSINESS COMPLIANCE COSTS

Consideration should be given to the compliance burden imposed on business. These are the additional (incremental) costs incurred by businesses when complying with the regulations.

One option for making initial assessments of the likelihood a proposal will involve compliance costs for business is through the use of the Business Cost Calculator's *Quickscan* function. This tool is located on the OBPR website at www.obpr.gov.au/businesscostcalculator/index.html

As part of a regulatory impact assessment, a practical approach for considering the impacts on business compliance costs potentially flowing from regulatory proposals is through consideration of the set of threshold questions in the checklist below.

Business Compliance Cost Checklist

As part of a regulatory impact assessment, a practical approach for considering the impacts on business compliance costs potentially flowing from regulatory proposals is through a set of threshold questions (a compliance cost checklist).

Would the regulatory proposal involve one of the following compliance tasks?

Notification

Will businesses incur costs when they are required to report certain events?

- For example, businesses may be required to notify a public authority before they are permitted to sell food.

Education

Will costs be incurred by business in keeping abreast of regulatory requirements?

- For example, businesses may be required to obtain the details of new legislation and communicate the new requirements to staff.

Permission

Are costs incurred in seeking permission to conduct an activity?

- For example, businesses may be required to conduct a police check before legally being able to employ staff.

Purchase cost

Are businesses required to purchase materials or equipment?

- For example, businesses may be required to have a fire extinguisher on site.

Record keeping

Business Compliance Cost Checklist

Are businesses required to keep records up-to-date?

- For example, businesses may be required to keep records of accidents that occur at the workplace.

Enforcement

Will businesses incur costs when cooperating with audits or inspections?

- For example, businesses may have to bear the costs of supervising government inspectors on site during checks of compliance with non-smoking laws.

Publication and documentation

Will businesses incur costs when producing documents for third parties?

- For example, businesses may be required to display warning signs around dangerous equipment or to display a sign at the entrance to home-based business premises.

Procedural

Will businesses incur costs that are of a non-administrative nature?

- For example, businesses may be required to conduct a fire safety drill several times a year.

Other

Are there any other business compliance costs associated with the regulatory proposal?

APPENDIX E:COMPETITION EFFECTS

When considering regulatory options Ministerial Councils will need to consider what the impact is of the proposed regulatory measure on competition, including the introduction of new processes and techniques.

A preliminary analysis of where a proposal may restrict competition can be conducted by working through the questions in the competition checklist below. Where this preliminary analysis indicates there will be an impact on competition, then a competition assessment should be undertaken as part of the RIS.

Competition Assessment Checklist

As part of a regulatory impact assessment, a practical approach for considering the impacts on business and individuals and on competition potentially flowing from regulatory proposals is through a set of threshold questions (a competition checklist) followed by, where appropriate, a competition assessment.

The competition assessment checklist is made up of the following threshold questions. (Some examples are provided.)

Would the regulatory proposal affect the number and range of suppliers?

- Grant exclusive rights for a supplier to provide a good or service?
- Establish a licence, permit or authorisation process as a requirement of operation?
- Affect the ability of some types of firms to participate in public procurement?
- Significantly alter costs of entry or exit to a supplier?
- Create a geographic barrier to the ability of businesses to supply goods or services, invest capital or supply labour?

Would the regulatory proposal change the ability of suppliers to compete?

- Control or substantially influence the price at which a good or service is sold?
- Alter the ability of suppliers to advertise or market their products?
- Set standards for product/service quality that are significantly different from current practice?
- Significantly alter costs of some suppliers relative to others?

Would the regulatory proposal alter suppliers' incentives to compete vigorously?

- Create a self-regulatory or co-regulatory regime?
- Impact on the mobility of customers between suppliers?
- Require/encourage the publishing of information on company outputs/price, sales/cost?
- Exempt an activity from general competition law?

Competition Assessment Checklist
If the answer to any of these questions is 'yes', then further analysis may be required and you should contact the OBPR. (There may be other impacts on business and individuals which are not covered in the checklist. In such cases you should consult with the OBPR.)

APPENDIX F:CONSULTATION GUIDELINES

Consistent with the principle for good regulatory process that effective consultation with affected key stakeholders should occur at all stages of the regulatory cycle, In February 2006, COAG committed to improving mechanisms for consultation with business and supporting appropriate consultation with all relevant stakeholders.

Consultation ensures that both the regulator and the regulated have a good understanding of the problem, alternative options to address it, possible administrative and compliance mechanisms and associated benefits, costs and risks.

Lack of consultation can lead to regulation that is inappropriate to the circumstances, costly to comply with and poorly adhered to.

Seven principles for best practice consultation are outlined below:

Continuity — Consultation should be a continuous process that starts early in the policy development process.

Targeting — Consultation should be widely based to ensure it captures the diversity of stakeholders affected by the proposed changes. This includes Commonwealth, State, Territory and local governments, as appropriate.

Appropriate timeliness — Consultation should start when policy objectives and options are being identified. Throughout the consultation process stakeholders should be given sufficient time to provide considered responses.

Accessibility — Stakeholder groups should be informed of proposed consultation, and be provided with information about proposals, via a range of means appropriate to those groups.

Transparency — Ministerial Councils need to explain clearly the objectives of the consultation process, the regulation policy framework within which consultations will take place and provide feedback on how they have taken consultation responses into consideration.

Consistency and flexibility — Consistent consultation procedures can make it easier for stakeholders to participate. However, this must be balanced with the need for consultation arrangements to be designed to suit the circumstances of the particular proposal under consideration.

Evaluation and review — Policy agencies should evaluate consultation processes and continue to examine ways of making them more effective.

Various consultation mechanisms can be used that are consistent with these principles such as annual regulatory plans, business consultation portals and the use of policy 'green papers' and exposure drafts for matters of major significance.

These consultation Guidelines are to be applied to all major initiatives and cover all aspects of developing regulation: from the policy proposals/'ideas' stage through to post-implementation reviews. The nature

and extent of consultation should be commensurate with the potential magnitude of the problem and impact of proposed regulatory and non-regulatory solutions.

Appendix 2

Australian Government

Australian Government Response to the Productivity Commission *Annual Review of Regulatory Burdens on Business: Manufacturing and Distributive Trades*

March 2009

Executive Summary

Since 2007, the Productivity Commission (PC) has been undertaking a series of annual reviews of the burdens on business from the stock of Commonwealth regulation in the following areas:

- primary sector (completed);
- manufacturing sector and distributive trades (completed);
- social and economic infrastructure services (current);
- business and consumer services; and
- economy-wide generic regulation and regulation not addressed earlier in the cycle.

2. The reviews are designed to ensure that all Commonwealth Government regulations are efficient and effective, by recommending reforms which could offer net benefits to business and the community, without compromising underlying policy goals.

3. The PC released its report on the *Annual Review of Regulatory Burdens on Business: Manufacturing and Distributive Trades* (Manufacturing Report) on 16 September 2008.

4. In undertaking its review, the PC sought submissions from, and consulted with, a wide range of stakeholders, including industry associations, state and territory governments, Commonwealth Government departments and agencies, as well as companies directly involved in manufacturing, retailing and wholesaling.

5. The Manufacturing Report presents 23 PC responses, covering issues including regulation of food manufacturing, therapeutic goods, chemicals and veterinary medicines, environmental and selected issues in the distributive trades (customs and excise administration and building products regulation).

6. The Government is supportive of a majority of the PC responses, the Government accepts or accepts in principle 19, notes two and has not accepted two responses.

7. The proposed Government Response indicates that considerable action has already taken place: four responses have been completed or are

substantially completed, 12 have reforms or reviews underway and three are subject to future action.

8. Four responses, which require national cooperation, are being addressed through the Council of Australian Governments (COAG). The issues being addressed through COAG include matters relating to national consistency of food regulation, voting arrangements for the Australia and New Zealand Food Regulation Ministerial Council (ANZFRMC) and the cost of chemical assessments.

9. The Commonwealth has already agreed with the states and territories, through COAG, to progress food regulation reforms with COAG to:

- consider in early 2009 options to reform the voting arrangements of the ANZFRMC;
- improve national consistency in the monitoring and enforcement of food standards; and
- improve food labelling law and policy.

10. To drive improvements in health technology assessment (HTA) regulation, a review was announced by the Minister for Health and Ageing and the Minister for Finance and Deregulation on 18 December 2008. The HTA Review will take public submissions and consider processes for the regulation of therapeutic goods, the approval of Medical Benefits Schedule funding and the listing of prostheses and devices for private health insurance coverage.

11. The Australian Taxation Office (ATO) and the Australian Customs and Border Protection Service (Customs) will jointly develop and report on options to further reduce the duplication of revenue administration for excise and excise equivalent goods in order to reduce the regulatory costs associated with the collection of these revenues.

12. The Government does not support the following two responses raised in the report:

- The PC proposal that the Australian Building Codes Board (ABCB) determines whether compliance programs on structural plywood are currently effective. As compliance is a state and territory responsibility, the Chair of the ABCB will write to relevant authorities in the state and territory jurisdictions informing them of industry concerns on this matter.

- The PC proposal to allow all businesses to report and pay excise and excise equivalent customs duties on a monthly basis. However, the Government has already announced that it will reduce small business

compliance costs by introducing measures allowing small businesses to report and pay excise and duties monthly rather than weekly.

13. The Commonwealth Government's formal response to the Manufacturing Report is set out below.

Given the large number of abbreviations used in the response, a quick reference list is provided at the conclusion of the document.

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Inconsistency

PC Response 3.1

Changes to the legislative framework, the enforcement arrangements and the implementation processes are required to improve national consistency of food regulation.

- All jurisdictions should implement the provisions of the Model Food Bill on a consistent basis unless there are demonstrable regional or local requirements. The provisions relating to national requirements would remain in Annex A of the Model Food Bill, or be adopted as template legislation, and those relating to regional or local requirements would be contained in Annex B.
- The Australian Government, on behalf of and with the agreement of the states and territories, should establish identical contractual agency arrangements with each jurisdiction with respect to the enforcement of national food regulations.
- The Implementation Sub-Committee of the Food Regulation Standing Committee should become a high level forum for food regulators. It should comprise the heads of food regulation agencies or senior officials responsible for the implementation and enforcement of food regulation within each jurisdiction. The Sub-Committee would be tasked with developing strategies and guidelines for the consistent implementation, interpretation and enforcement of food regulation, including new food standards. The Sub-Committee should report regularly, through the Food Regulation Standing Committee, to the ANZFRMC as to each jurisdiction's compliance with the agreed to guidelines and strategies.

Accepted in principle

The Government agrees that change is required. At its 29 November 2008 meeting, COAG agreed to examine reforms to the voting arrangements of the ANZFRMC. COAG also agreed to consider options to improve national consistency in the monitoring and enforcement of food standards and options to improve food labelling law and policy in early 2009. This will be done in consultation with the ANZFRMC.

Delays and difficulties in implementing and amending food standards

PC Response 3.2

The Department of Health and Ageing (DOHA) should ensure that the changes made to the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), to improve the timeliness and stakeholder consultation in the amendment and development of food standards, are independently reviewed two years after their implementation.

Accepted in principle

Amendments to the FSANZ Act took effect from 10 October 2007. Applications and proposals received by Food Standards Australia New Zealand (FSANZ) since the date of effect have been assessed using the new process. Sufficient assessments need to be completed to ensure that any reviews are meaningful. Following the agreement by the ANZFRMC, monitoring the effectiveness of the changes to the FSANZ Act has commenced and an independent review of these results will be conducted within five years of the date of effect.

Improving the operations of the Australian New Zealand Food Regulation Ministerial Council

PC Response 3.3

The ANZFRMC should amend the Food Regulation Agreement to reflect the practices for decision making by a number of other ministerial councils established to oversight, coordinate and integrate policy, such as the Australian Transport Council, the Gene Technology Ministerial Council and the Ministerial Council on Energy. In particular, the Ministerial Council should require a majority vote to initiate a review of a draft amendment of the Australia New Zealand Food Standards Code prepared by FSANZ.

The ANZFRMC should incorporate, in managing its business, an explicit process step of ensuring that all requests from members of the Ministerial Council to initiate a review provide a comprehensive justification in terms of the criteria that are specified in Part III of the Food Regulation Agreement. The justification for any review should be published.

Accepted in principle

At its 29 November 2008 meeting, COAG agreed to examine reforms to the voting arrangements of the ANZFRMC. Also see PC Response 3.1.

The ANZFRMC requires that all regulatory proposals comply with the Government regulatory impact analysis requirements. Also see PC Response 3.4.

Problems in the regulation-making process

PC Response 3.4

The ANZFRMC should ensure that the COAG guidelines for the development of regulation are incorporated into the Food Regulation Agreement. The ANZFRMC should publish a regular report of its regulatory actions against the COAG regulatory guidelines. Compliance could be further improved by having the Chair of the Ministerial Council manage the regulatory business of the Ministerial Council so as to comply with these guidelines. This should also include ensuring that all regulatory proposals comply with an adequate Regulatory Impact Statement.

Noted

The ANZFRMC ensures that all regulatory proposals comply with a Regulatory Impact Statement that is assessed as suitable by the Office of Best Practice Regulation (OBPR). The OBPR is obliged to report annually on regulatory compliance by Ministerial Councils. In all its reports covering the period April 2005 to March 2008, the OBPR found that the ANZFRMC had complied with COAG's Regulatory Impact Statement requirements. Also see PC Response 3.1 and 3.3.

Food regulation and public health

PC Response 3.5

The ANZFRMC should not consider making decisions on matters of public health through food regulation until such time as the Australian Health Ministers' Conference has considered all policy responses and has referred the relevant matters to the ANZFRMC for a food regulation response.

Accepted in principle

The Government agrees that further clarity between decisions on matters of public health policy and decisions of regulation would assist the operation of the ANZFRMC. An administrative process of information sharing has been established by the ANZFRMC.

THERAPEUTIC GOODS REGULATION

Concerns about regulation of medicines

PC Response 4.1

The current reviews by the Therapeutic Goods Administration (TGA) need to achieve the following outcomes:

- a stronger commitment by TGA to timely audits/clearance processes, including by incorporating explicit timeframes into publicly available guidelines;
- improved transparency and consistent application of the risk-based criteria used to determine expiry dates for Good Manufacturing Practice (GMP) certificates; and
- wider recognition of international processes and acceptance of GMP certificates where conducted by bodies assessed as suitably competent.

Noted

The Government has established targets for audits and overseas manufacturing clearances. Targets for manufacturing audits are set out in the TGA's Business Plan 2008-09, while the target time for processing overseas clearances is included in the TGA's *Guidance on the GMP Clearance of Overseas Medicines Manufacturers, 16th Edition*. Both documents are available on the TGA's website.

The TGA publishes information on its website about its current regulatory practices and guidelines. The TGA acknowledges the benefits of increasing transparency of its regulatory approach and will publish further details on its website of the risk-based approach used in planning and conducting audits once necessary legislative change has been passed by parliament. These legislative changes are expected to be passed in the Autumn 2009 sitting.

The TGA has already developed and implemented a risk-based approach to guide the planning, conduct and follow-up action to provide assurance of the standard of manufacturing quality, both within Australia and overseas. These risk methodologies, together with the applicable manufacturing standards (which themselves are based on international codes of GMP), are documented in the TGA's Standard Operating Procedures to promote consistency of practice and treatment of risks.

The TGA has mutual recognition agreements and information exchange arrangements in place with many overseas authorities to facilitate low-burden regulatory oversight of materials and products manufactured in those countries.

The TGA is expanding its efforts to conduct collaborative audits and share audit reports with many overseas authorities (such as the US Food and Drug Administration and the European Medicines Agency) to harness international regulatory capability and reduce the regulatory burden on Australian product sponsors using overseas manufacturers.

Concerns about Pharmaceutical Benefits Scheme listing and pricing processes

PC Response 4.2

DOHA should examine ways to reduce compliance costs for business associated with the Weighted Average Monthly Treatment Cost (WAMTC) methodology for reference pricing, including by making better use of extant Medicare data, consistent with ensuring tax payers continue to get the best value from Pharmaceutical Benefits Scheme listed medicines.

Accepted

The current process for WAMTC reviews has been designed to minimise costs to companies in complying with the methodology. Dispensing data from Medicare Australia and the Drugs Utilisation Sub Committee of the Pharmaceutical Benefits Advisory Committee is provided free of charge. However, DOHA will work with industry representatives to see whether there is scope to streamline other data requests with a view to reducing the cost of purchasing additional data.

Delays in achieving Pharmaceutical Benefits Scheme listing due to overlapping processes

PC Response 4.3

The Pharmaceutical Benefits Advisory Committee (PBAC) should be allowed, when requested by applicants, to conduct its assessment of a medicine for Pharmaceutical Benefits Scheme listing in parallel with the Therapeutic Goods Administration's assessment of the application to register the medicine.

Accepted in principle

The current TGA and PBAC processes allow PBAC to commence its assessment of a medicine when it is around two-thirds of the way through the TGA process and DOHA provides some flexibility to the current PBAC process to enable PBAC assessments to commence earlier in the TGA process.

The Access to Medicines Working Group (AMWG), a joint DOHA and Medicines Australia working group, is consulting with relevant organisations with a view to further streamlining TGA and PBAC processes including parallel processing of applications.

Concerns about marketing and advertising rules

PC Response 4.4

After further consideration of the most appropriate model, the Australian Government should streamline and clarify advertising rules and work with state and territory governments to ensure reforms also address the need for a simplified system for complaints about national advertising.

Accepted in principle

PC Response 4.4 relates to regulation covering the advertising of therapeutic goods. The Government will consider changes to the advertising regulatory arrangements to streamline requirements and reduce regulatory burdens. Consultation with interested parties on the proposed revised arrangements will occur in 2009. In advance of further consultation the Government has established a centralised mailbox for all complaints about therapeutic goods advertisements.

TGA monopoly on conformity assessment for Australian manufacturers

PC Response 4.5

DOHA should introduce amendments to the *Therapeutic Goods Act 1989*, and regulations as necessary, to allow Australian manufacturers to choose a certification body (acceptable to the TGA), based in Australia or overseas, to verify and certify their conformity assessment procedures.

Accepted in principle

This issue was canvassed in the now postponed negotiations to create the Australia New Zealand Therapeutic Products Authority. Subsequently, the Government has agreed that the TGA consult with stakeholders in order to progress Australian reforms in the absence of participation by New Zealand. The TGA has conducted initial consultations with stakeholders on a possible model to enable the use of external assessment bodies in conformity assessment. The TGA released a consultation paper regarding third party conformity assessment in late December 2008 and will engage in further direct consultation with stakeholders in February 2009, with a view to a final options paper being released by the end of June 2009. The final options paper will detail a preferred model and implementation arrangements for any revised conformity assessment arrangements.

Timeliness, transparency and consistency of approvals

PC Response 4.6

The TGA should ensure that the outcomes of its current Medical Devices Business Improvement Program include the implementation of measures to ensure improved transparency, consistency and timeliness in decision making, including provision of clear advice regarding the reasons for all decisions. The TGA should publish specific commitments and timelines for the Improvement Program.

Accepted in principle

The TGA is working closely with the medical devices industry on the development and implementation of measures under the Medical Devices Business Improvement Program, which is delivering consistent, timely and transparent decision making processes. In line with the current collaborative approach, the TGA continues to provide industry with detailed information relating to measures and timelines contained in the Business Improvement Program. The TGA is working to introduce measures that will improve transparency of decision making across all TGA programs. As discussed in PC Response 4.1, the TGA expects legislative changes will be passed in Autumn 2009 to allow this to occur.

Timeliness, transparency and consistency of assessments

PC Response 4.7

The TGA should examine the scope to make greater use of acceptable prior overseas assessments. This should include identifying competent inspection bodies overseas. In general, where a device has been approved by such bodies there should be no requirement for a further assessment by the TGA.

Accepted in principle

The TGA currently provides considerable scope for the consideration of prior overseas assessments. For instance, the TGA currently accepts evidence of prior overseas assessments as part of its decision making processes, supplemented by a Declaration of Conformity to Australian Regulations for lower risk devices.

Further, a Mutual Recognition Agreement (MRA) has been in place with Europe since 1998 on conformity assessment and the TGA is in the final stages of establishing a Memorandum of Understanding (MOU) with Canada in relation to

assessment of manufacturing Quality Management Systems (QMS) for medical devices. Manufacturers availing themselves of these agreements are able to introduce their product into the Australian market either without any further assessment in the case of the European MRA, or with assessment of only the technical file, and not the QMS, in the case of the Canadian MOU.

Additionally, for manufacturers of high risk devices who do not utilise the provisions of either of these agreements, an abridged assessment by the TGA is conducted of the assessment undertaken by a recognised overseas assessment body rather than of the manufacturer and their product(s). This is supplemented by a Declaration of Conformity from the manufacturer that the product has undergone an appropriate conformity assessment process, and is in compliance with the requirements of the Regulations. There are only four categories, of the highest risk devices, where the TGA is required to undertake a full conformity assessment, and even within these categories the process is often abridged in part, by taking into account assessments of some of the regulatory requirements by a recognised overseas assessment body.

Multiple and overlapping processes

PC Response 4.8

The Australian Government should commission a comprehensive and independent public review of the overall HTA System for medical devices/technologies as soon as possible. The review should examine regulatory and policy frameworks and processes impacting on access to, and use of, devices and technologies.
Outcomes should include options to improve the efficiency, transparency and timeliness of processes for assessing safety and performance, and suitability for public funding and reimbursement by private health funds, including:

- streamlining the overall HTA framework to remove duplication and overlap;
- addressing inconsistencies in prostheses listing arrangements, which can impede the introduction of new technologies and distort treatment decisions; and
- improving the operations of the Medical Services Advisory Committee.

Accepted

A review of HTA arrangements has commenced. On 18 December 2008, the Minister for Health and Ageing and the Minister for Finance and Deregulation

jointly announced that the HTA Review will be conducted as a Better Regulation Ministerial Partnership. The HTA Review will report in late 2009 and will recommend ways to improve the timeliness of patient access to beneficial technologies without compromising patient safety or value for money.

CHEMICALS AND VETERINARY MEDICINES

Non-acceptance of overseas Good Manufacturing Practice certificates

PC Response 5.1

The Australian Government should impose a statutory obligation on the Australian Pesticides and Veterinary Medicines Authority (APVMA) to ensure that:

- business compliance and other costs are considered when making assessments about whether to accept prior overseas Good Manufacturing Practice certificates; and
- the costs are commensurate with the risks posed by the chemical/medicine concerned.

Accepted in principle

THE PC'S RESPONSE IS SIMILAR IN THE PC RESEARCH REPORT ***CHEMICALS AND PLASTICS REGULATION***, RECOMMENDATION 8.1, WHICH IS BEING ADDRESSED BY THE COAG MINISTERIAL TASKFORCE ON CHEMICALS AND PLASTICS REGULATION REFORM. AT ITS MEETING ON 29 NOVEMBER 2008, COAG AGREED TO THE PC RECOMMENDATION RELATING TO THE IMPOSITION OF A STATUTORY OBLIGATION ON THE APVMA TO ENSURE THAT THE COSTS OF CHEMICAL ASSESSMENTS ARE COMMENSURATE WITH THE RISKS POSED BY THE CHEMICALS CONCERNED. THE COMMONWEALTH WILL EXPLORE THE POTENTIAL FOR EMBEDDING GUIDING VALUES IN LEGISLATION CONSISTENT WITH THE PRINCIPLES UNDERPINNING THE COMMONWEALTH'S BEST PRACTICE REGULATION REQUIREMENTS.

AS THE NATIONAL REGISTRATION SCHEME FOR AGRICULTURAL AND VETERINARY CHEMICALS IS A PARTNERSHIP BETWEEN THE COMMONWEALTH AND THE STATES AND TERRITORIES, CHANGES TO THE LEGISLATION MUST BE ENDORSED BY THE SIGNATORIES TO THE AGREEMENT ESTABLISHING THAT FRAMEWORK. IT IS THEREFORE APPROPRIATE FOR THIS RECOMMENDATION TO BE ADDRESSED BY COAG.

ENVIRONMENTAL REGULATION

Delays in registration

PC Response 6.1

The Department of the Environment, Water, Heritage and the Arts (DEWHA) should introduce tight legislative or administrative time limits into the process for registering products under the Water Efficiency Labelling and Standards (WELS) Scheme. It should also expedite the transmission of tax invoices to businesses upon request once adequately completed applications are submitted.

Accepted in principle

DEWHA has established an administrative benchmark of seven working days for finalisation of approvals and seven working days for gazettal, where complete information is submitted. A new online registration database is now in place and this will assist a more efficient registration process. Mechanisms are currently being explored for the more expeditious transmission of tax invoices to businesses.

Poor compliance and enforcement

PC Response 6.2

DEWHA should commission an independent evaluation in 2010 of the effectiveness of its compliance and enforcement program in achieving the objectives of the WELS Scheme. The results of the evaluation should be made public.

Accepted

An independent evaluation of the effectiveness of the compliance and enforcement program in achieving the objectives of the WELS Scheme will be commissioned in 2010 and the results will be made public.

Overlap with the WaterMark certification scheme

PC Response 6.3

DEWHA should introduce legislative amendments to make compliance with the WaterMark certification scheme a prerequisite for registration under the WELS Scheme, provided there is satisfactory evidence of overlap between the two schemes.

Accepted in principle

The Commonwealth Government has considered this issue in the context of its response to the House of Representatives Standing Committee on Environment and Heritage report *Managing the Flow: Regulating Plumbing Product Quality*. The Government response to this report was tabled in Parliament on 5 February 2009. An appropriate and open legal approach to addressing this issue is to amend the *Water Efficiency Labelling and Standards Act 2005* (WELS Act) to allow the Minister for the Environment, Heritage and the Arts, via a Determination, to require third party certification (such as attainment of WaterMark) as a prerequisite for registration of WELS products. DEWHA will address, in consultation with relevant agencies, any further regulatory impact assessment requirements before determining whether to finally support the proposed amendment to the WELS Act.

Uncertainty about the timing of implementation of minimum energy performance standards

PC Response 6.4

The Equipment Energy Efficiency Committee should update and make public specific timeframes for the implementation of requirements for energy labelling and minimum energy performance standards.

Accepted in principle

The Equipment Energy Efficiency Committee, established under the National Framework on Energy Efficiency (NFEE), has provided in principle agreement to update and make public specific timeframes for the implementation of requirements for energy labelling and minimum energy performance standards. To progress this issue the Commonwealth must obtain the formal agreement from all state and territory governments as well as the New Zealand Government. This approval will be obtained through the NFEE which is comprised of the Australian, state and territory governments as well as the New Zealand Government.

Poor compliance and enforcement

PC Response 6.5

The Equipment Energy Efficiency Committee should seek independent and publicly available benchmarking of the compliance and enforcement activities of state and territory agencies and of the Australian Government's check testing program in relation to requirements for energy labelling and minimum energy performance standards. The benchmarking should include the extent to which agencies undertake a risk management approach to compliance and enforcement.

Accepted

The Government will benchmark by 2010 the compliance and enforcement activities of state and territory agencies and the Commonwealth Government's check testing program in relation to requirements for energy labelling and minimum energy performance standards. This will be undertaken by the Equipment Energy Efficiency Committee, established under the NFEE, and will be conducted independently and results will be publicly available. The benchmarking will consider the extent to which agencies undertake a risk management approach to compliance and enforcement.

The burden associated with small but frequent imports of hydrochlorofluorocarbons and hydrofluorocarbons

PC Response 6.6

DEWHA should conduct an assessment of the benefits and costs of changing the *Ozone Protection and Synthetic Greenhouse Management Act 1989* to allow low-volume importers to report annually rather than quarterly. If there is a net benefit to be gained from amending the legislation, importers of volumes of hydrochlorofluorocarbons and hydrofluorocarbons below an agreed threshold should be allowed to report annually rather than quarterly.

Accepted in principle

The Government has already undertaken some actions to minimise the impact of the legislative system on low-volume importers, such as providing for prospective reporting and waiving reporting requirements for inactive licensees. DEWHA will develop options for streamlined licence application, reporting and levy requirements for low-volume importers and, subject to stakeholder consultation,

recommend legislative amendments at the next opportunity. Any further changes will need to take into account both broader climate change policy and relevant legislation.

Other Concerns

Customs and excise administration – dual administration

PC Response 8.1

The Australian Government should, subject to appropriate consideration and assessment, delegate authority for administering customs duty in relation to excise equivalent goods to the ATO. Customs should retain its current border management role in relation to excise equivalent goods.

Accepted in principle

The Government will request the ATO and Customs jointly develop options to minimise duplication of revenue administration and compliance costs for excise and excise equivalent goods. These options should be presented within six months for joint consideration by the Assistant Treasurer and Minister for Competition and Consumer Affairs and the Minister for Home Affairs. This should include an option considering ATO officers administering, under delegation, the customs legislation applying to imported excise equivalent goods.

Customs and excise administration – weekly reporting

PC Response 8.2

The Government's proposal to allow small businesses to report and pay customs and excise duty on a monthly basis should be extended to all businesses.

Not accepted

On 13 May 2008 the Government announced that it would allow small business to defer the settlement of excise and excise equivalent customs duties to a monthly cycle, rather than the existing weekly cycle. At the time of this announcement the Government noted that legislation was not expected to be introduced before 2009. The Government's announced measure is intended to reduce the compliance burden of the excise system (and excise equivalent customs duty system) for eligible small businesses by allowing them to better manage their interactions with the ATO and Customs. The Government does not intend to extend the scope of the measure beyond that which was originally

announced as the risks to the revenue at this time outweigh the potential benefits of the proposal.

Lack of compliance with building regulations – structural plywood

PC Response 8.3

The ABCB should determine whether compliance programs for standards on structural plywood are currently effective. If not, it should consider the costs and benefits of restricting acceptable forms of evidence of suitability against other options for inducing higher rates of compliance.

Not accepted

The ABCB is responsible for the development and maintenance of the Building Code of Australia (BCA). The ABCB is not, however, responsible for the administration and enforcement of the BCA.

The use of non-compliant products in a building is an enforcement issue and is the responsibility of the relevant state and territory authorities. However, the Commonwealth Government recognises that this is an issue that needs to be addressed. As such, the Chair of the ABCB will write to the state and territory governments alerting them to the potential risk of unsafe structural building products and recommending they investigate the matter for possible follow up action.

Abbreviations

Access to Medicines Working Group (AMWG)
Australia and New Zealand Food Regulation Ministerial Council (ANZFRMC)
Australian Building Codes Board (ABCB)
Australian Pesticides and Veterinary Medicines Authority (APVMA)
Australian Customs and Border Protection Service (Customs)
Australian Taxation Office (ATO)
Building Code of Australia (BCA)
Council of Australian Governments (COAG)
Department of the Environment, Water, Heritage and the Arts (DEWHA)
Department of Health and Ageing (DOHA)
Food Standards Australia New Zealand (FSANZ)
Food Standards Australia New Zealand Act 1991 (FSANZ Act)
Good Manufacturing Practice (GMP)
Health Technology Assessment (HTA)
Memorandum of Understanding (MOU)
Mutual Recognition Agreement (MRA)
National Framework on Energy Efficiency (NFEE)
Office of Best Practice Regulation (OBPR)
Pharmaceutical Benefits Advisory Committee (PBAC)
Productivity Commission (PC)
Quality Management Systems (QMS)
Therapeutic Goods Administration (TGA)
Water Efficiency Labelling and Standards (WELS)
Water Efficiency Labelling and Standards Act 2005 (WELS Act)
Weighted Average Monthly Treatment Cost (WAMTC)

Appendix 3

Relevant Clauses from *Trade Practices Act 1974* Relating to Country of Origin Labelling

Misleading or deceptive conduct

(1) A corporation shall not, in trade or commerce, engage in conduct that is misleading or deceptive or is likely to mislead or deceive.

(2) Nothing in the succeeding provisions of this Division shall be taken as limiting by implication the generality of subsection (1).

Note: For rules relating to representations as to the country of origin of goods, see Division 1AA (sections 65AA to 65AN).

53 False or misleading representations

A corporation shall not, in trade or commerce, in connexion with the supply or possible supply of goods or services or in connexion with the promotion by any means of the supply or use of goods or services:

(a) falsely represent that goods are of a particular standard, quality, value, grade, composition, style or model or have had a particular history or particular previous use;

(aa) falsely represent that services are of a particular standard, quality, value or grade;

(b) falsely represent that goods are new;

(bb) falsely represent that a particular person has agreed to acquire goods or services;

(c) represent that goods or services have sponsorship, approval, performance characteristics, accessories, uses or benefits they do not have;

(d) represent that the corporation has a sponsorship, approval or affiliation it does not have;

(e) make a false or misleading representation with respect to the price of goods or services;

(ea) make a false or misleading representation concerning the availability of facilities for the repair of goods or of spare parts for goods;

(eb) make a false or misleading representation concerning the place of origin of goods;

(f) make a false or misleading representation concerning the need for any goods or services; or

(g) make a false or misleading representation concerning the existence, exclusion or effect of any condition, warranty, guarantee, right or remedy.

Note: For rules relating to representations as to the country of origin of goods, see Division 1AA (sections 65AA to 65AN55 Misleading conduct to which Industrial Property Convention applies

A person shall not, in trade or commerce, engage in conduct that is liable to mislead the public as to the nature, the manufacturing process, the characteristics, the suitability for their purpose or the quantity of any goods.

65AA Overview

This Division provides that certain country of origin representations made about goods do not contravene section 52 (which deals with misleading or deceptive conduct), paragraph 53(a) or (eb) or paragraph 75AZC(1)(a) or (i) (which all deal with false or misleading representations).

65AB General test for country of origin representations

If:

(a) a corporation makes a representation as to the country of origin of goods; and

(b) the goods have been substantially transformed in that country; and

(c) 50% or more of the cost of producing or manufacturing the goods (as the case may be) is attributable to production or manufacturing processes that occurred in that country; and

(d) the representation is not a representation to which section 65AC (product of/produce of representations) or section 65AD (prescribed logo representations) applies;

the corporation does not contravene section 52, paragraph 53(a) or (eb) or paragraph 75AZC(1)(a) or (i) by reason only of making the representation.

65AC Test for representations that goods are product of/produce of a country

If:

(a) a corporation makes a representation that goods are the produce of a particular country (whether the representation uses the words “product of”, “produce of” or any other grammatical variation of the word “produce”); and

(b) the country was the country of origin of each significant ingredient or significant component of the goods; and

(c) all, or virtually all, processes involved in the production or manufacture happened in that country;

the corporation does not contravene section 52, paragraph 53(a) or (eb) or paragraph 75AZC(1)(a) or (i) by reason only of making the representation.

65AD Test for representations made by means of prescribed logo

(1) If:

(a) a corporation makes a representation as to the country of origin of goods by means of a logo specified in regulations made under subsection (2); and

(b) the goods have been substantially transformed in the country represented by the logo as the country of origin of the goods; and

(c) the prescribed percentage of the cost of producing or manufacturing the goods (as the case may be) is attributable to production or manufacturing processes that occurred in that country;

the corporation does not contravene section 52, paragraph 53(a) or (eb) or paragraph 75AZC(1)(a) or (i) by reason only of making the representation.

(2) The regulations may, in relation to a specified logo, prescribe a percentage in the range of 51% to 100% as the percentage applicable to goods for the purposes of paragraph (1)(c).

65AE Substantial transformation of goods

(1) For the purposes of this Division, goods are ***substantially transformed*** in a country if they undergo a fundamental change in that country in form, appearance or nature such that the goods existing after the change are new and different goods from those existing before the change.

(2) Without limiting subsection (1), the regulations may prescribe changes (whether in relation to particular classes of goods or otherwise) that are not fundamental changes for the purposes of subsection (1), and may include examples (in relation to particular classes of goods or otherwise) of changes which are fundamental changes for the purposes of subsection (1).

65AF Method of working out costs of production or manufacture

For the purposes of this Division, the cost of producing or manufacturing goods is to be worked out under Subdivision B.

Subdivision B—Cost of production or manufacture of goods

65AG Definitions

In this Subdivision:

inner container includes any container into which goods are packed, other than a shipping or airline container, pallet or other similar article.

materials, in relation to goods, means:

(a) if the goods are unmanufactured raw products—those products; and

(b) if the goods are manufactured goods—all matter or substances used or consumed in the manufacture of the goods (other than matter or substances that are treated as overheads); and

(c) in either case—the inner containers in which the goods are packed.

65AH Cost of producing or manufacturing goods

The cost of producing or manufacturing goods means the sum of:

(a) the expenditure on materials in respect of the goods, worked out under section 65AJ; and

(b) the expenditure on labour in respect of the goods, worked out under section 65AK; and

(c) the expenditure on overheads in respect of the goods, worked out under section 65AL.

65AJ Expenditure on materials

Calculation of expenditure on materials

(1) Expenditure on materials in respect of goods means the cost of materials:

(a) incurred by the producer or manufacturer of the goods (as the case may be); and

(b) that are used in the production or manufacture of the goods; and

(c) that has not been prescribed under paragraph (2)(a).

Regulations may prescribe materials that are not allowable

(2) The regulations may prescribe, for the purposes of subsection (1):

(a) the cost of a particular material, or a part of such a cost, that is not allowable in respect of goods, or classes of goods; and

(b) the manner of working out the cost of a material, or part of the cost.

65AK Expenditure on labour

Calculation of expenditure on labour

(1) Expenditure on labour in respect of goods means the sum of each labour cost:

(a) that is incurred by the producer or manufacturer of the goods (as the case may be); and

(b) that relates to the production or manufacture of the goods; and

(c) that can reasonably be allocated to the production or manufacture of the goods; and

(d) that has not been prescribed under paragraph (2)(a).

Regulations may prescribe labour costs that are not allowable

(2) The regulations may prescribe, for the purposes of subsection (1):
  (a) a particular labour cost, or a part of a labour cost, that is not allowable in respect of goods, or classes of goods; and
  (b) the manner of working out a labour cost, or part of the cost.

65AL Expenditure on overheads

Calculation of expenditure on overheads

(1) Expenditure on overheads in respect of goods means the sum of each overhead cost:
  (a) that is incurred by the producer or manufacturer of the goods (as the case may be); and
  (b) that relates to the production or manufacture of the goods; and
  (c) that can reasonably be allocated to the production or manufacture of the goods; and
  (d) that has not been prescribed under paragraph (2)(a).

Regulations may prescribe overhead costs that are not allowable

(2) The regulations may prescribe, for the purposes of subsection (1):
  (a) a particular overhead cost, or a part of an overhead cost, that is not allowable in respect of goods, or classes of goods; and
  (b) the manner of working out an overhead cost, or part of the cost.

65AM Regulations may prescribe rules for determining the local percentage costs of production or manufacture

(1) Subject to subsection (2), the regulations may prescribe rules for determining the percentage of the total cost of production or manufacture of goods attributable to production or manufacturing processes that occurred in a particular country.

Note: Section 65AH deals with the cost of production or manufacture of goods.

(2) Rules prescribed under subsection (1) must not discriminate (whether favourably or unfavourably) between countries or classes of countries.

Subdivision C—Evidentiary matters

65AN Proceedings relating to false, misleading or deceptive conduct or representations

(1) If:
  (a) proceedings are brought against a person in respect of section 52, paragraph 53(a) or (eb) or paragraph 75AZC(1)(a) or (i); and

(b) the person seeks to rely on a provision of this Division, or of a regulation made under this Division, in the proceedings;

the person bears an evidential burden in relation to the matters set out in the provision on which the person seeks to rely.

(2) In this section:

evidential burden, in relation to a matter, means the burden of adducing or pointing to evidence that suggests a reasonable possibility that the matter exists or does not exist.

Appendix 4

Section 18 Guidelines of *FSANZ Act 1991*

Objectives of the Authority in developing or reviewing food regulatory measures and variations of food regulatory measures

(1) The objectives (in descending priority order) of the Authority in developing or reviewing food regulatory measures and variations of food regulatory measures are:

(a) the protection of public health and safety; and

(b) the provision of adequate information relating to food to enable consumers to make informed choices; and

(c) the prevention of misleading or deceptive conduct.

(2) In developing or reviewing food regulatory measures and variations of food regulatory measures, the Authority must also have regard to the following:

(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;

(e) any written policy guidelines formulated by the Council for the purposes of this paragraph and notified to the Authority.

(3) If any policy guidelines formulated by the Council for the purposes of paragraph (2)(e) are notified to the Authority, the Authority must publish the guidelines on the Authority's Internet site.

(3A) Policy guidelines formulated by the Council for the purposes of paragraph (2)(e) must not be inconsistent with the objectives set out in subsection (1).

(4) Where the Authority considers that the best available scientific evidence referred to in paragraph (2)(a) is insufficient, the Authority may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent scientific information. In such cases, the Authority must take all reasonable steps to obtain the information necessary for a more objective risk analysis and a review of the sanitary or phytosanitary measures, to be undertaken within a reasonable period of time.

(5) For the purposes of this section, a ***sanitary or phytosanitary measure*** means any measure applied:

(a) to protect animal or plant life or health from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms; or

(b) to protect human or animal life or health from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs; or

(c) to protect human life or health from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or

(d) to prevent or limit other damage from the entry, establishment or spread of pests;

and includes:

(e) any relevant law, decree, regulation, requirement or procedure, including end product criteria; and

(f) processes and production methods; and

(g) testing, inspection, certification and approval procedures; and

(h) quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; and

(i) provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and

(j) packaging and labelling requirements directly related to food safety.

(6) A policy guideline formulated by the Council for the purposes of paragraph (2)(e) is not a legislative instrument.

Appendix 5

Food and Beverage Industry – Country of Origin Guidelines to the Trade Practices Act

(attached in separate document)