



**Australian Government**  
**Productivity Commission**

# Annual Review of Regulatory Burdens on Business:

Manufacturing and Distributive Trades

Productivity Commission  
Research Report

August 2008

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# Foreword

The reduction of unnecessary regulatory burdens has become an increasingly important part of the economic reforms to improve the competitiveness of business and the overall performance of the Australian economy. The Commission has been asked to conduct annual reviews of the burdens on business arising from the stock of Australian Government regulation, over a five year cycle. This study of the manufacturing and distributive trades is the second in that series.

In undertaking this review, the Commission has focused on identifying those regulatory burdens placed on businesses in the manufacturing and distributive trades sectors which are unnecessary within the current policy settings. It has put forward proposals for reducing these burdens, as well as for the better design of future regulatory frameworks affecting these sectors.

The study was overseen by Commissioners Matthew Butlin and Mike Woods, with a staff research team led by Les Andrews.

The Commission has been greatly assisted by many discussions with participants and by the 77 submissions they have provided. Thanks are extended to all those who have contributed.

Gary Banks AO  
Chairman

August 2008

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## Terms of reference

### ANNUAL REVIEW OF REGULATORY BURDENS ON BUSINESS

#### Productivity Commission Act 1998

The Productivity Commission is asked to conduct ongoing annual reviews of the burdens on business arising from the stock of Government regulation. Following consultation with business, government agencies and community groups, the Commission is to report on those areas in which the regulatory burden on business should be removed or significantly reduced as a matter of priority and options for doing so. The Commission is to report by the end of October 2007, and the end of August each following year.

The Commission is to review all Australian Government regulation cyclically every five years. The cycle will commence with a review of regulatory burdens on businesses in Australia's primary sector. In subsequent years, the Commission is to report sequentially on the manufacturing sector and distributive trades, social and economic infrastructure services, and business and consumer services. The fifth year is to be reserved for a review of economy-wide generic regulation, and regulation that has not been picked up earlier in the cycle. The Commission's programme and priorities may be altered in response to unanticipated public policy priorities as directed by the Treasurer.

#### *Background*

As part of the Australian Government's initiative to alleviate the burden on business from Australian Government regulation, on 12 October 2005, the Government announced the appointment of a Taskforce on Reducing Regulatory Burdens on Business and its intention to introduce an annual red tape reduction agenda. This agenda incorporates a systematic review of the cumulative stock of Australian Government regulation. The Government approved this review process to ensure that the current stock of regulation is efficient and effective and to identify priority areas where regulation needs to be improved, consolidated or removed.

Furthermore, the regulatory reform stream of the Council of Australian Governments (COAG) National Reform Agenda focuses on reducing the regulatory burden imposed by the three levels of government. On 10 February 2006, COAG agreed that all Australian governments would undertake targeted public annual reviews of existing regulation to identify priority areas where regulatory reform would provide significant net benefits to business and the community. COAG also

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agreed that these reviews should identify reforms that will enhance regulatory consistency across jurisdictions or reduce duplication and overlap in regulation and in the role of regulatory bodies.

*Scope of the annual review*

In undertaking the annual reviews, the Commission should:

1. identify specific areas of Australian Government regulation that:
  - a) are unnecessarily burdensome, complex or redundant; or
  - b) duplicate regulations or the role of regulatory bodies, including in other jurisdictions;
2. develop a short list of priority areas for removing or reducing regulatory burdens which impact mainly on the sector under review and have the potential to deliver the greatest productivity gains to the economy;
3. for this short list, identify regulatory and non-regulatory options, or provide recommendations where appropriate to alleviate the regulatory burden in those priority areas, including for small business; and
4. for this short list, identify reforms that will enhance regulatory consistency across jurisdictions, or reduce duplication and overlap in regulation or in the role of regulatory bodies in relation to the sector under review.

In proposing a focused annual agenda and providing options and recommendations to reduce regulatory burdens, the Commission is to:

- seek public submissions at the beginning of April in 2007, and at the beginning of February in each following year, and consult with business, government agencies and other interested parties;
- have regard to any other current or recent reviews commissioned by Australian governments affecting the regulatory burden faced by businesses in the nominated industry sectors, including the Australian Government's response to the report of the Taskforce on Reducing Regulatory Burdens on Business;
- report on the considerations that inform the Commission's annual review of priorities and reform options and recommendations; and

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- have regard to the underlying policy intent of government regulation when proposing options and recommendations to reduce regulatory burdens on business.

The Commission's report will be published and the Government's response announced as soon as possible.

PETER COSTELLO

[received 28 February 2007]

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# Abbreviations

ACCC	Australian Competition and Consumer Commission
ABCB	Australian Building Codes Board
AGO	Australian Greenhouse Office
AHA	Animal Health Alliance
ANZFRMC	Australia New Zealand Food Regulation Ministerial Council
ANZSIC	Australia New Zealand Standards Industrial Classification
ANZTPA	Australia New Zealand Therapeutic Products Authority
APVMA	Australian Pesticides and Veterinary Medicines Authority
AQIS	Australian Quarantine Inspection Service
ARTG	Australian Register of Therapeutic Goods
BCA	Building Code of Australia
CDL	Container Deposit Legislation
COAG	Coalition of Australian Governments
CoOL	Country of Origin Labelling
CSO	Community Service Obligation
DEAL	Device Electronic Application Lodgement System
DEWHA	Department of Environment, Water, Heritage and the Arts
DIISR	Department of Innovation, Industry, Science and Research
DOHA	Department of Health and Ageing
E3 Committee	Equipment Energy Efficiency Committee
EC	European Community
EU	European Union
FDA	Food and Drug Administration (US)
FRSC	Food Regulation Standing Committee
FSANZ	Food Standards Australia New Zealand

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GMP	Good Manufacturing Practice
HCFC	Hydrochlorofluorocarbon
HFC	Hydrofluorocarbon
HTA	Health Technology Assessment
JAS-ANZ	Joint Accreditation System of Australia and New Zealand
MDIAA	Medical Devices Industry Action Agenda
MEPS	Minimum Energy Performance Standards
MRA	Mutual Recognition Agreement
MSAC	Medical Services Advisory Committee
MWh	Megawatts per hour
MTAA	Medical Technology Association of Australia
NATA	National Association of Testing Authorities
NEPM	National Environmental Protection Measure
NHMRC	National Health and Medical Research Council
NPC	National Packaging Covenant
NPI	National Pollutant Inventory
OBPR	Office of Best Practice Regulation
PBAC	Pharmaceutical Benefits Advisory Committee
PBPA	Pharmaceutical Benefits Pricing Authority
PBS	Pharmaceutical Benefits Scheme
PBS	Performance Based Standards
PC	Productivity Commission
PDC	Prostheses and Devices Committee
PIC/S	Pharmaceutical Inspection Cooperation Scheme
R&D	Research and Development
RIS	Regulatory Impact Statement
TGA	Therapeutic Goods Administration
VCEC	Victorian Competition and Efficiency Council
WAMTC	Weighted Average Monthly Treatment Cost
WELS	Water Efficiency Labelling and Standards



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# OVERVIEW

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## Key points

- Regulation of the manufacturing and distributive trades sectors is complex and diverse, involving all tiers of government. This study proposes the reduction of specific Australian Government regulations which are unnecessarily burdensome for businesses in these sectors. These initiatives build on the significant amount of reform currently underway, including the expanded COAG regulation reform agenda.
- Many of the concerns raised by businesses related to jurisdictional differences in the implementation and enforcement of regulations. While governments are pursuing greater uniformity, this process is ongoing but incomplete, leading to a level of frustration by businesses.
- A common concern of businesses was poor communication with regulators. The information provided by regulators could be difficult to access, inconsistently communicated or costly to understand. Poor communication can also be a barrier to small businesses entering markets as they may be less able either to employ or to contract expert assistance to understand the regulations affecting them.
- Concerns which were the subject of other reviews (such as chemicals and plastics) have been referred to the relevant agency. This review has identified and addressed three main areas.
- Food regulation can be made less burdensome by
  - increasing national consistency of regulation
  - improving timeliness and transparency of decision making by the Australia New Zealand Food Regulation Ministerial Council
  - ensuring public health issues are considered by the Health Ministers' Conference before referring any food regulation-related issues to the Australia New Zealand Food Regulation Ministerial Council.
- The frameworks for approving and registering new medicines and medical devices can be streamlined by
  - reducing the time and cost, and improving the transparency, of assessment processes by the Therapeutic Goods Administration (TGA)
  - improving coordination between regulators where regulatory processes overlap
  - removing the TGA's monopoly on conformity assessment for Australian manufacturers of medical devices by allowing manufacturers to choose a certification body approved by the TGA
  - a comprehensive review of health technology assessment processes.
- Compliance and enforcement of environmental regulations can be improved to ensure the policy objectives are being achieved and that complying businesses are not disadvantaged. These regulations include
  - the Water Efficiency Labelling and Standards Scheme
  - energy labelling and minimum energy performance standards.

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# Overview

In February 2007, the Commission was asked to review, over a five-year period, the burdens on business arising from Commonwealth Government regulation. The review process will be repeated at the end of each five-year period.

This is part of a broader range of measures set in train by the Commonwealth Government and the Council of Australian Governments (COAG) to consider the extent to which the regulatory burden on businesses can be reduced or removed. In February 2006, as part of the National Reform Agenda, COAG agreed that:

- all Australian governments would review, annually and publicly, existing regulation to identify priority areas where reform would provide significant net benefits to business and the community
- these reviews should identify reforms that will enhance regulatory consistency across jurisdictions or reduce duplication and overlap in regulation and regulatory bodies.

The objective of the review is to ensure that the current stock of regulation is efficient and effective and to identify priority areas where regulation needs to be improved, consolidated or removed in order to raise productivity. The Commission's task is to identify improvements to regulation that will lower costs for industry without compromising the underlying policy objectives.

The regulations to be assessed each year are determined according to the sector on which they have their main impact. For 2008, the task is to examine regulations that affect the manufacturing and distributive trades (wholesale and retail) sectors. This work is being done in a context of significantly increased attention by the Australian Government and COAG since December 2007 to reducing regulatory burdens, including a significant increase in the number of identified regulatory hotspots and associated review and reform activity. These concurrent activities include, among other things, major reviews of automobiles; textiles, clothing and footwear; chemicals and plastics; and innovation and a large amount of review and reform within Australian Government agencies.

The range of regulations that apply to manufacturing and distributive trades sectors is broad, with some applying generally and several applying only to parts of these sectors. The Commission is mindful of the amount of related review activity and, to

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reduce duplication and costs to participants, has focused attention on those regulatory issues for the sectors that are not being addressed by other activities.

Taking these considerations into account, this report identifies a range of improvements to regulations that primarily affect food manufacturing and distribution, medical devices, medicines and veterinary chemicals and some environmental regulations. A range of other issues was assessed as being of a lower priority.

Whilst the resurgence in governments' attention to reducing red tape was welcomed by participants, it was also clear there were risks of review overload and review fatigue. Many participants — especially those involved in small business — are finding it challenging to participate in all of the reviews relevant to their industry or business. Credibility will be diminished if they see no evidence of real and significant reduction in their regulatory burdens.

## Conduct of the review

The terms of reference for the review are set out on pages IV–VI. The review draws on the concerns expressed by industry bodies, individual businesses and government agencies at meetings and in written submissions. These issues were tested against the terms of reference and with the relevant policy makers and regulators regarding their substance and capacity to be addressed and whether there were reforms or policy reviews afoot. Where no concerns were raised, the review generally accepted this as *prima facie* evidence that there were no perceived problems of excess burden.

The nature of this process can impart an issues- or complaints-based perspective, that does not give due credit for the progress in reform that has been made. Some of these reforms have been substantial and there are some notable examples of careful attention to engaging industry and businesses in the effective design of regulations to minimise the unnecessary compliance costs. Wherever possible, the Commission has sought to acknowledge the reforms that have been made to date and to build further on them.

'Regulatory burdens' have been broadly defined to include:

- the time and financial costs directly involved in complying with regulations, such as form filling, mandatory returns and so on
- changing the ways by which goods and services would otherwise be produced by businesses



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- changing or restricting the goods and services that would otherwise be produced by businesses
  - the costs of foregone or reduced opportunities resulting from constraints on the capacity of a business to innovate or respond to changing technology, market demand or other factors.

To be examined in this year's review, 'regulatory burdens', affecting mainly the manufacturing and distributive trades sectors, needed to satisfy the following criteria:

- there are compliance cost(s) imposed by the nature of the regulation or the actions of the regulator that appear to be unnecessary in order to achieve the regulation's objectives
- they are the consequence of regulation by the Australian Government, which includes areas where state and territory government regulations overlap with Australian Government regulation or involve Australian Government policy participation.

## **Industries and regulation under reference**

The manufacturing and the distributive trades sectors represent a large share of the economy. Manufacturing accounts for 10 per cent of Australia's GDP (\$107 billion) and employment (employing around one million persons). It is a significant exporting industry accounting for \$85 billion in exports in 2006-07. The distributive trades contribute roughly the same level of output (\$105 billion) as manufacturing but are much more labour intensive — employing almost two million persons or 20 per cent of total employment in Australia.

The manufacturing and distributive trades sectors both have an above average share (relative to the economy as a whole) of small businesses in their respective populations. Small businesses find accessing information regarding the compliance requirements for regulations a major challenge.

## **Assessment of concerns raised**

The Commission received 77 submissions from participants, with 56 submissions coming from businesses — 44 from manufacturing and 12 from distributive trades — 12 from regulators and government departments and another nine submissions from other stakeholders and individuals affected by or involved with regulations covering the sectors. Appendix A lists the submissions. Four roundtable discussions

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were held after the release of the draft report, attended by representatives from regulators, other government agencies, individual companies and industry bodies.

The terms of reference for this review set boundaries on the scope of the concerns considered by the Commission. The review was required to accept the policy intent of the regulations, which meant that some concerns were out of scope as they were the intrinsic consequence of regulation rather than being an avoidable impost due to the way regulations were designed or administered.

Some other concerns fell outside the terms of reference because they addressed regulation that did not involve the Australian Government in any way. Where concerns fell within the terms of reference of other ongoing reviews (such as chemicals and plastics and automobiles), they were referred on and were not considered by this review (see appendix B).

The Commission has generally taken the position that where there has been a recent and adequate review, and where ameliorating reforms have been taken, sufficient time should be given to test the effectiveness of the changes. There were also a number of concerns raised about generic regulations. These will be more fully addressed in the final year of review.

## **Regulatory issues facing the manufacturing and distributive trades sectors**

The manufacturing and distributive trades sectors are subject to both Australian Government and state/territory government regulations. The Australian Government has no constitutional powers that relate exclusively, or largely, to the manufacturing and distributive trades sectors alone. The pattern of Australian Government regulations in these sectors arises from:

- broad powers in the Constitution including to regulate corporations, set taxes, regulate interstate trade, regulate international trade and be a party to international treaties. Some of these powers have been used as the means for implementing generic policies including in relation to the environment
- the capacity of the Australian Government to establish and fund specific policies, including in areas such as health, industry policy, innovation and education. For manufacturing in particular, this element of regulation is relatively more important than for wholesale and retail trades
- the Australian Government taking, by agreement with the state and territory governments, a co-ordinating role to harmonise regulations across Australia,

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including through model legislation and referred powers. Examples of this include food and building regulation and land transport.

The state and territory governments have constitutional authority over much of the regulatory landscape for these sectors, including in relation to transport, land use and the sale of goods. Many of the licences and permits specific to these sectors are issued at the state/territory and, in some instances, local government level. Local government is also often responsible for the local administration of aspects of state regulation, such as inspecting food preparation premises for compliance with hygiene and food safety standards.

There is relatively more Australian Government regulation that impacts on the manufacturing sector than on the wholesale and retail trade sector. There are a number of Australian Government programs that focus on particular parts of the manufacturing sector, including food, automobiles, textiles, clothing and footwear and on activities, such as research and development, that are relatively more common in manufacturing than in the distributive trades.

While participants acknowledged the high standards of some regulators, such as the Therapeutic Goods Administration (TGA), that had oversight of their industry they, nevertheless, highlighted specific aspects of performance that needed to improve including in relation to the TGA. There were concerns raised by participants regarding the capacity of some regulators to develop and administer regulations in an efficient, transparent and timely manner. They cited administrative processes and practices that did not match the intent of the policy makers and produced apparently unintended excess burdens.

Business concerns about the administration of regulation included:

- *excessive time to gain approval/registration* for goods to be supplied to the Australian market, such as the amendment of food standards which reduces innovation and delays entry of new products and technologies of benefit to Australian users. The lengthy approval process regarding therapeutic goods reduced the time available for owners of the intellectual property rights to receive a return on their development costs
- *inconsistent and/or untimely advice* from regulators. There were reported difficulties in businesses accessing the correct information on websites and receiving inconsistent advice across a range of regulatory regimes
- *poor communication* between regulators and businesses. Businesses frequently spoke of having to employ experts (including external consultants) in fields such as law, accounting and engineering to interpret regulations. Poor communication can be a barrier to small businesses entering markets as they may be less able

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either to employ or to contract such expert assistance. This can thereby undermine an important dynamic aspect of competitive markets. In addition, poor communication imposes a disproportionate burden on small businesses in understanding and complying with regulations. Some agencies, including the Australian Taxation Office, were identified by participants as having taken action to improve communication

- *ineffective/ad hoc enforcement* of some regulations. Businesses provided examples where compliance was patchy, giving non-compliant businesses an advantage over compliant businesses and raising some questions over the effectiveness of the protections or benefits to consumers that regulations were intended to achieve. For example, enforcement of some food regulations, such as country of origin labelling, varies between jurisdictions.

A major theme was inconsistency among jurisdictions in developing and administering regulations. This was particularly a concern for participants whose businesses operate in more than one jurisdiction. Inconsistent regulations can impose unproductive variation in the way goods and services are produced or delivered and they may require costly modifications in the goods and services themselves. They can also give competitive advantage to single-state businesses that do not need to ensure that they comply with the full gamut of regulatory variations.

The multiplicity of jurisdictional agencies, compounded by differing approaches, increases the demand for resources and regulatory and enforcement skills when such skills are already in short supply.

Inconsistency is recognised as an impediment to encouraging national markets and to exploiting economies of scale. Reforms have included the development of intergovernmental agreements or arrangements and nationally uniform codes in such areas as food regulation, building regulation and road transport. These approaches to harmonisation reflect the balance between centralisation and diversity that can be provided through a cooperative federalist structure.

The Commission supports these initiatives but this review process has shown that the full range of potential benefits from uniformity, or at least harmonisation, so far remain unrealised. Some state/territory governments have not fully adopted model codes or have implemented them differently, such as in regard to the Model Food Bill. This is an area where a stronger approach to harmonisation and consistency is highly appropriate if national markets for foods are to be better defined. Jurisdictions have introduced variations to meet specific local considerations, including in road transport.

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This review identified a priority list of participants' concerns. Ideally, priorities should be determined by the size of the unnecessary burden and potential gains in productivity to the whole economy. In practice, the cost of the unnecessary burden is often difficult to estimate given the lack of data, differences in business processes and attribution problems. Moreover, participants often found it difficult to cost separately the unnecessary parts of a regulatory burden from the total cost of compliance. This is to be expected as business accounting systems are not set up to measure the incremental costs imposed by specific regulations or to benchmark them against best practice.




Due to the difficulties in quantifying regulatory burdens, a largely qualitative approach has been taken in determining whether a given regulation is imposing excessive burdens on businesses. One means of doing this is by applying best practice principles within a chain of regulation. Principles for the development of good quality regulation have been developed by a number of bodies including COAG and the Australian Government's Office of Best Practice Regulation. These principles can also inform the most efficient and responsive regulatory practice.

The chain of regulation comprises four stages (see table 1):

- *justification/regulation making stage*. This stage refers to the justification for the regulation and to the quality of the process for making regulations. Issues may arise because the justification for a regulation is based on a premise that has not been sufficiently tested in relation to other possible regulatory interventions
- *regulation design*. This stage refers to the quality and appropriateness of the design of the regulation, including the quality of consultation and attention to practical matters, such as implementation in the design stage
- *implementation/administration*. This stage refers to the process of implementing the regulation and the ongoing processes of administration
- *reviewing/amending regulations*. This covers processes for reviewing regulations periodically to test their effectiveness and efficiency or in response to changing circumstances.

Some of the main concerns raised by participants are set out in table 1 and are categorised in the regulation chain according to the stage where they arise. The full list of concerns is contained within the body of the report.

**Table 1 Stage of regulatory process and examples of issues warranting action**

<i>Regulation Stage</i>	<i>Concerns raised by participants</i>
<p><b>Justification and Regulation Making Process</b></p> 	<p><b>Food regulation</b></p> <ul style="list-style-type: none"> <li>• Pursuing national health objectives through regulatory responses without prior consideration of alternative approaches</li> </ul>
<p><b>Design of Regulation</b></p> 	<p><b>Food regulation</b></p> <ul style="list-style-type: none"> <li>• Implementing country of origin labelling on fresh food despite the regulation failing the Regulatory Impact Statement process</li> </ul> <p><b>Therapeutic goods regulation</b></p> <ul style="list-style-type: none"> <li>• Aspects of reference pricing methodology in Pharmaceutical Benefits Scheme (PBS) may impose excessive compliance costs</li> </ul>
<p><b>Implementation and Administration of Regulation</b></p> 	<p><b>Food regulation</b></p> <ul style="list-style-type: none"> <li>• Inconsistency in implementation and enforcement of the Model Food Bill across the states and territories</li> </ul> <p><b>Therapeutic goods regulation</b></p> <ul style="list-style-type: none"> <li>• Delays in achieving PBS listing of medicines due to overlapping processes</li> <li>• Therapeutic Goods Administration (TGA) monopoly on conformity assessment for Australian medical device manufacturers</li> <li>• Timeliness, lack of transparency, inefficiencies and cost of TGA assessment processes</li> </ul> <p><b>Environmental regulation</b></p> <ul style="list-style-type: none"> <li>• Delays in registration of products under the Water Efficiency Labelling and Standards (WELS) Scheme</li> <li>• Overlap between the WELS Scheme and the WaterMark certification scheme</li> <li>• Poor compliance and enforcement of the WELS scheme and requirements for energy labelling and minimum energy performance standards</li> <li>• Uncertain timing of the development and implementation of requirements for energy labelling and minimum energy performance standards</li> <li>• Administrative cost of paying quarterly ozone protection fees of 1c or less on low volume imports</li> </ul> <p><b>Customs and excise administration</b></p> <ul style="list-style-type: none"> <li>• The involvement of two agencies in the administration of customs and excise duties, leading to duplication for industry</li> <li>• Excessive compliance burdens due to weekly reporting requirements for customs and excise duties</li> </ul>
<p><b>Reviewing and Amending Regulations</b></p>	<p><b>Food regulation</b></p> <ul style="list-style-type: none"> <li>• Delays in developing and amending food standards</li> </ul>

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## **Approach to reducing regulation burdens**

The review identified opportunities to reduce the regulatory burden in the following areas (being areas that are not addressed by policy reviews identified in appendix B):

- food manufacturing and distribution regulation
- therapeutic goods regulation
- chemicals and veterinary medicines regulation
- environmental regulation
- selected issues in the distributive trades.

These five areas are addressed in chapters 3 to 7. Chapter 8 addresses other issues including several generic issues that span the economy as a whole. The responses proposed in this review, if acted upon, should go some way to reducing the regulatory burden on businesses. Also, by seeking to streamline and focus regulatory processes, they will produce a more integrated regulatory structure which is responsive to business concerns while fulfilling the policy intent of the governing regulation.

## **Overview of case-by-case assessments**

The responses to the concerns, based on an assessment of what further action was required, can be broadly categorised as follows:

### ***Unnecessary burdens which can be removed without delay***

#### **Food regulation**

Reduce the unnecessary costs and time delays to business by

- implementing the Model Food Bill on a consistent basis across all jurisdictions
- making enforcement of food regulation with national requirements the responsibility of the Australian Government
- incorporating the COAG guidelines for the development of regulation into the Food Regulation Agreement
- amending the Food Regulation Agreement to improve the decision-making processes and transparency of the work of the Australia New Zealand Food Regulation Ministerial Council (ANZFRMC)

- 
- ensuring public health issues are considered initially by Health Ministers meeting in their capacity as members of the Health Ministers' Conference before any related food regulation issues are considered by the ANZFRMC.

#### Therapeutic goods

- reduce time and cost, and improve transparency, of assessment processes by the Therapeutic Goods Administration (TGA)
- allow the Pharmaceutical Benefits Advisory Committee to conduct its assessment of a medicine for listing on the Pharmaceutical Benefits Scheme in parallel with the TGA's assessment of the application to register the medicine, when requested by a company
- remove TGA's monopoly on conformity assessment for Australian manufacturers of medical devices by allowing manufacturers to choose a certification body approved by the TGA.

#### Veterinary medicines

- ensure that the assessment requirements of the Australian Pesticides and Veterinary Medicines Authority consider compliance and other costs and are commensurate with risk.

#### Environmental regulations

- introduce tight legislative or administrative time limits into the process for registering products under the Water Efficiency Labelling and Standards (WELS) Scheme
- reduce the time involved in transmitting tax invoices for payment of registration fees under the WELS Scheme
- update and publicly announce specific timeframes for the development and implementation of energy labelling and minimum energy performance standards requirements.

#### Customs duty

- allow monthly reporting and payment of customs and excise duties for all businesses.

### ***Some time should pass before assessing recent changes***

#### Environmental regulations

- evaluate the recently developed compliance and enforcement program of the Department of Environment, Water, Heritage and the Arts in achieving the objectives of the WELS Scheme.



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## Food regulation

- evaluate the amendments made to the *Food Standards Australia New Zealand Act 1991* to improve the timeliness of the process for the development and amendment of food standards.

## *Examine the impacts of, or case for, making changes*

### Therapeutic goods

- amend the Weighted Average Monthly Treatment Cost methodology of reference pricing in the Pharmaceutical Benefits Scheme with a view to reducing compliance costs for business
- implement the Australia New Zealand Therapeutic Products Authority-related reforms which streamline and clarify advertising rules for medicines and the associated complaints system
- more widely accept prior overseas assessments for medicines and medical devices.

### Environmental regulations

- introduce amendments to make compliance with the WaterMark certification scheme a prerequisite for registration under the WELS Scheme
- benchmark 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
- change the *Ozone Protection and Synthetic Greenhouse Management Act 1989* to allow low volume importers to report annually rather than quarterly.

### Building regulations

- have the Australian Building Codes Board determine whether compliance programs for standards on structural plywood are currently effective.

### Customs duty

- delegate authority for the administration of customs duty on excise equivalent goods to the Australian Taxation Office.

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***Conduct a fundamental policy review***

Therapeutic goods

- undertake a comprehensive and independent public review of Health Technology Assessment processes for medical devices/technologies, with the aim of cutting time and costs in:
  - assessing the safety and performance of devices
  - assessing the suitability of the devices and associated medical procedures for public funding and for reimbursement by private health insurers.

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# Responses

*Following are the Commission's responses to the material concerns raised by participants.*

## **Food manufacturing regulation**

*Concern: Inconsistency in food regulation.*

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 Australia New Zealand Food Regulation Ministerial Council as to each jurisdiction's compliance with the agreed to guidelines and strategies.*

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*Concern: Delays in implementing and amending food standards.*

RESPONSE 3.2

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

*Concern: Improving the operations of the Australia New Zealand Food Regulation Ministerial Council.*

RESPONSE 3.3

***The Australia New Zealand Food Regulation Ministerial Council (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 Food Standards Australia New Zealand.***

***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.***

*Concern: Problems in the regulation making process.*

RESPONSE 3.4

***The Australia New Zealand Food Regulation Ministerial Council (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.***

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*Concern: Food regulation and public health.*

RESPONSE 3.5

***The Australia New Zealand Food Regulation Ministerial Council (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.***

## **Therapeutic goods regulation**

### **Medicines regulation**

*Concern: Timeliness and cost of Therapeutic Goods Administration manufacturing audits/Good Manufacturing Practice assessment process, including insufficient recognition of overseas assessments.*

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***
- ***wider recognition of international processes and acceptance of GMP certificates where conducted by bodies assessed as suitably competent.***

*Concern: PBS reference pricing methods impose excessive compliance costs.*

RESPONSE 4.2

***The Department of Health and Ageing should examine ways to reduce compliance costs for business associated with the Weighted Average Monthly Treatment Cost 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.***

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*Concern: Delays in achieving PBS listing due to overlapping TGA and PBAC processes.*

RESPONSE 4.3

***The Pharmaceutical Benefits Advisory Committee 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.***

*Concern: Confusing and inconsistent advertising restrictions and associated complaints mechanism for pharmaceuticals.*

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.***

## **Medical devices**

*Concern: TGA monopoly on conformity assessment for Australian manufacturers.*

RESPONSE 4.5

***The Department of Health and Ageing 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 Therapeutic Goods Administration), based in Australia or overseas, to verify and certify their conformity assessment procedures.***

*Concern: Timeliness, transparency and consistency of assessments/approvals.*

RESPONSE 4.6

***The Therapeutic Goods Administration (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.***

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*Concern: Insufficient recognition of overseas regulatory approval processes and assessments.*

RESPONSE 4.7

***The Therapeutic Goods Administration (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.***

*Concern: Multiple and overlapping processes.*

RESPONSE 4.8

***The Australian Government should commission a comprehensive and independent public review of the overall Health Technology Assessment (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***
- improving the operations of the Medical Services Advisory Committee.***

## **Chemicals and veterinary medicines**

### **Veterinary chemicals/medicines**

*Concern Non-acceptance of overseas Good Manufacturing Practice certificates by APVMA.*

RESPONSE 5.1

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

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

## **Environmental regulation**

### **Water Efficiency Labelling and Standards Scheme**

*Concern: Delays in registration.*

RESPONSE 6.1

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

*Concern: Poor compliance and enforcement.*

RESPONSE 6.2

*The Department of the Environment, Water, Heritage and the Arts should commission an independent evaluation in 2010 of the effectiveness of its compliance and enforcement program in achieving the objectives of the Water Efficiency Labelling and Standards Scheme. The results of the evaluation should be made public.*

*Concern: Overlap with the WaterMark certification scheme.*

RESPONSE 6.3

*The Department of the Environment, Water, Heritage and the Arts should introduce legislative amendments to make compliance with the WaterMark certification scheme a prerequisite for registration under the Water Efficiency Labelling and Standards Scheme, provided there is satisfactory evidence of overlap between the two schemes.*



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## Energy labelling and minimum energy performance standards

*Concern: Uncertainty about the timing of implementation.*

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.***

*Concern: Poor compliance and enforcement.*

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.***

## Ozone protection: pre-charged equipment

*Concern: The burden associated with small but frequent imports of hydrochlorofluorocarbons (HCFCs) and hydrofluorocarbons (HFCs).*

RESPONSE 6.6

***The Department of the Environment, Water, Heritage and the Arts 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 HCFCs and HFCs below an agreed threshold should be allowed to report annually rather than quarterly.***

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## Other concerns

### Customs and excise administration

*Concern: The involvement of both the Australian Customs Service and the Australian Taxation Office in the administration of customs and excise duties leads to duplication and complexity for the affected industries.*

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 Australian Taxation Office. The Australian Customs Service should retain its current border management role in relation to excise equivalent goods.*

*Concern: Weekly reporting requirements for customs and excise duties create excessive burdens.*

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.*

### Building products regulation

*Concern: Compliance with structural plywood standards.*

RESPONSE 8.3

*The Australian Building Codes Board 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.*

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# 1 About the review

Governments have introduced regulations as one means of producing beneficial economic, social and environmental outcomes, or reducing undesirable outcomes, which would not otherwise occur if left to markets to deliver. Examples include the regulation of the emission of pollutants, occupational health and safety matters, food safety and the provision of product information to consumers.

Regulations also impose costs, some of which may be unnecessary. Regulations can, in such cases, be made more efficient, thus reducing costs and producing greater net benefits.

The Council of Australian Governments (COAG) has recognised that there is a growing burden of regulation — both within and between jurisdictions — and has set out to examine the extent to which the burden on businesses could be removed or reduced. Such reforms have the potential to increase community living standards by improving the efficiency, productivity and competitiveness of the Australian economy.

## 1.1 What the Commission has been asked to do

The Commission has been asked to undertake a review of the burdens placed on businesses from Australian Government regulation. The review is being conducted as a series of five annual exercises, each focussing on different sectors of the economy.

The review aims to identify areas where regulation can be improved, consolidated or simplified to achieve its policy objectives more efficiently. The Commission has been asked to identify regulatory and non-regulatory options that will lower costs for industry without compromising the underlying policy objectives.

The terms of reference specify the following focus areas for each of the five annual reviews:

- primary industries in 2007 (completed)
- manufacturing and distributive trades in 2008
- social and economic infrastructure services in 2009

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- business and consumer services in 2010
  - economy-wide generic regulation and any regulation missed in earlier reviews in 2011.

This year the Commission will report on regulations which mainly affect the manufacturing and the distributive (that is, wholesale and retail) trades sectors.

**Box 1.1 Industries included in the 2008 review**

The business activities that are considered to be within the scope of this year's review are based on divisions C, F and G of the Australian and New Zealand Standard Industrial Classification (ANZSIC). This includes:

**Division C: Manufacturing**

- Food product manufacturing
- Beverage and tobacco product manufacturing
- Textile, leather, clothing and footwear manufacturing
- Wood product manufacturing
- Pulp, paper and converted paper product manufacturing
- Printing (including the reproduction of recorded media)
- Petroleum and coal product manufacturing
- Basic chemical and chemical product manufacturing
- Polymer product and rubber product manufacturing
- Non-metallic mineral product manufacturing
- Primary metal and metal product manufacturing
- Fabricated metal product manufacturing
- Transport equipment manufacturing
- Machinery and equipment manufacturing
- Furniture and other manufacturing

**Division F: Wholesale Trade**

- Basic material wholesaling
- Machinery and equipment wholesaling
- Motor vehicle and motor vehicle parts wholesaling
- Grocery, liquor and tobacco product wholesaling

(continued on next page)

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**Box 1.1** (continued)

- Other goods wholesaling
- Commission-based wholesaling

**Division G: Retail Trade**

- Motor vehicle and motor vehicle parts retailing
- Fuel retailing
- Food retailing
- Other store-based retailing
- Non-store retailing and retail commission based buying and/or selling

*Source:* ABS Australian and New Zealand Standard Industrial Classification 2006, catalogue no. 1292.0.

The full terms of reference are set out on pages IV–VI.

## **1.2 The regulatory reform context**

The Taskforce on Reducing Regulatory Burdens on Business was appointed by the Australian Government in October 2005 to broadly examine regulatory burdens in the Australian economy and to identify practical options for alleviating the compliance burden on business.

As with this study, the Taskforce was directed to focus on Australian Government regulation, with a remit to also identify burdens arising from the overlap of Australian Government regulations with those of other jurisdictions.

The Government accepted many of the report's recommendations in 2006. As a consequence, some regulatory reforms have been undertaken and further reviews have been announced or set in train. The report of the Taskforce forms the foundation of these five ensuing annual reviews.

### **COAG's National Reform Agenda**

During 2006–2007, regulatory reform was further advanced when COAG developed and agreed to a National Reform Agenda, which aims to increase Australia's productivity and workforce participation. This long-term agenda is comprised of three streams: human capital, competition and regulatory reform.

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COAG members also agreed to conduct targeted annual reviews of existing regulation to identify areas where reform would provide significant benefits to business and the community.

In 2006, COAG agreed to take action to reduce the regulatory burden in ten ‘hot spots’ where cross-jurisdictional overlap and/or unnecessarily burdensome regulatory regimes are impeding economic activity. The initial ten ‘hot spots’ were reaffirmed and have been broadened — to include 27 areas — by the Australian Government at COAG meetings in December 2007 and March 2008. The areas targeted for reform range from rail safety and trade measurement to building regulation and product safety.

### **Previous and current reviews concerning regulatory reform**

Some industry specific reviews relating to the manufacturing and distributive trades sectors fall within the scope of this review.

The ACCC has reviewed the Horticulture Code of Conduct as part of a wider review of grocery prices, and there are independent reviews of the quarantine system, the textile, clothing and footwear industry, the automotive industry and the national innovation system. The Productivity Commission has recently completed a review of chemicals and plastics regulation. In addition, COAG has established the Business Regulation and Competition Working Group to accelerate and broaden the regulatory reduction agenda, and to improve the processes for regulation creation and review.

The Commission is currently benchmarking regulatory compliance burdens across all jurisdictions in Australia. The initial area of review is the compliance cost involved in establishing and running a businesses. The progressive development of the benchmarks will occur in parallel with this review and will extend across all jurisdictions and a wide range of sectors of the economy.

### **State and territory government reviews**

In line with their COAG commitments, state and territory governments are actively undertaking reviews of existing regulation to reduce business compliance costs.

The Victorian Government has recently undertaken a stocktake of regulation as part of its strategy to reduce the burden and complexity of business regulation in that State (VCEC 2007). In New South Wales, the Independent Pricing and Regulatory Tribunal has undertaken a review to identify areas of significant and unnecessary regulatory burdens on business and provide recommendations to reduce such

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burdens. Following from this was a review by the NSW Better Regulation Office of shop trading hours which has led to simplification of this regulation. The Queensland Government Department of Tourism, Regional Development and Industry conducts an annual red tape reduction stocktake.

Food regulation has been subject to a number of reviews such as that by the Victorian Competition and Efficiency Commission (2007), and the New South Wales manufacturing sector was recently reviewed by the Small Business Regulation Review Taskforce (2006). Other focussed areas of review include small business regulation in New South Wales, tourism, retail and manufacturing in Queensland, and building construction, heavy vehicle road transport, cafes and restaurants, motor vehicle retailing and servicing, wine production and metal manufacturing in South Australia.

Further detail on the regulation review activity by jurisdiction is contained in appendix B.

### **1.3 The approach and rationale of this review**

A more complete discussion of the approach taken to defining regulation, the costs associated with poor regulation and the limitations of these annual reviews can be found in the report on the first of this series, Annual Review of Regulatory Burdens on Business: Primary Sector (PC 2007a).

#### **Defining regulation**

‘Regulation’ can be broadly defined to include laws or other government-influenced ‘rules’ that affect or control the way people and businesses behave. It is not limited to legislation and formal regulations, but also includes quasi-regulation and co-regulation.

As the terms of reference for this review refer to Australian Government regulation, the Commission is not examining regulation that is solely the responsibility of state, territory or local governments. Nevertheless, any duplication or overlap of regulatory responsibilities between the Australian Government and other jurisdictions does fall within the terms of reference. This includes circumstances where national agreements exist to coordinate matters that are the responsibility of the states and territories, and matters where Australian Government regulation is inconsistent with international agreements, conventions or standards.

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## **The cost of poorly designed and implemented regulation**

In most cases, a regulation inevitably imposes some costs on the businesses affected by it. An unnecessary burden arises when a given policy objective could be achieved at a lower total cost to those involved. The unnecessary cost can usually be attributed to poorly designed and/or implemented regulation, and can arise from excessive coverage, overlap or inconsistency, overly complex approval and licensing processes, exceedingly prescriptive measures and burdensome reporting.

The costs imposed on businesses may include unnecessary operational costs, delays to production and marketing, changes to the way things are produced and additional uncertainty which affects investment decisions. Importantly, regulations may impose unnecessary delays and restrictions that inhibit innovation, resulting in dynamic costs to affected businesses and ultimately to consumers.

### **A focus on business impact**

The terms of reference of this review focus on the regulatory burden on businesses, the characteristics of which can vary widely in terms of legal form, size, industry and market orientation. Some regulation that does not directly target the manufacturing sector or the distributive trades sector can also affect businesses in those industries. For example, regulations concerning occupational health and safety, transport, and the environment affect businesses within the scope of this review.

The focus on business impact has highlighted issues relating to the cumulative impact of regulation, a point that may be lost when considering the impact of a single regulation in isolation. A business is subject to regulation at a number of stages throughout its establishment, production, marketing and expansion. Each regulation builds on other surrounding regulations. Even where the individual impact is small, the combined burden can be significant.

### **Limitations of the review process**

The scope of this review and its findings are determined by the terms of reference. Boundaries have been set out which may, in some instances, restrict or limit the scope of the review.

By focussing only on the manufacturing sector and the distributive trades sector, the potential exists to miss important interactions with other parts of the economy. For example, labour mobility between states is limited by recognition of training



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qualifications and this has ramifications for manufacturing and retail businesses and can impede the internal mobility of their staff. To overcome this, the review has extended its focus to Australian Government regulations which apply to the parts of the economy that have a major impact on the manufacturing sector and distributive trades sectors.

The Commission is required to have regard to the underlying policy intent of regulation when proposing options to remove unnecessary burdens on business. This is interpreted to mean that the concern of this review is on the translation of objectives into regulation, not with the objectives themselves. Accordingly, while some comment might be made on objectives when the Commission considers them to be demonstrably inadequate, the Commission is reporting only on the unnecessary costs of regulations required to meet the set policy objectives.

### **Identifying the significant issues**

The allocation to review years and the development of the list of the most significant issues raised by participants is a matter for analysis and judgment. Having conducted a similar review of the primary industries in 2007, the Commission found that defining the scope of the review was vital to the final list of priority areas for regulatory improvement.

The approach used by the Commission was as follows:

- A concern or complaint was ruled out of scope if it did not relate to existing regulation which impacts on business and cannot be related to Australian Government regulation or to a national agreement or arrangement. Generally, a matter was also ruled out of scope if it clearly related to the *objectives* of regulation rather than its business impact.
- Where concerns and complaints were recently reviewed this was taken into account. In situations where other reviews were conducted in industries covered by this review, judgement had to be made about the adequacy of the terms of reference, the independence and make-up of the review body, transparency, consultation and timeliness.
- Where interested parties did not raise any concerns in relation to an area of Australian Government regulation, it was generally taken as *prima facie* evidence that there was no perceived problems of excess burden.
- On occasion, the Commission has chosen to view narrowly expressed concerns with relatively low impact in a wider context.

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## **Quantifying impacts, including unnecessary burdens**

Ideally, the relative importance of each concern raised would be determined by estimating the magnitude of unnecessary costs and potential productivity gains from improvements. The Commission, in its issues paper, asked participants to provide as much information as possible about the costs associated with unnecessary burdens.

There were significant challenges associated with quantitative approaches to measuring and assessing whether the regulatory burden on businesses was ‘excessive’. Among the key challenges was obtaining relevant data from businesses, ensuring the data were not compromised unduly by selection bias and other measurement errors, and identifying the appropriate benchmark against which the measured burden was assessed. Furthermore, where information about the overall regulatory cost was available it was often impossible to determine the component of costs which were unnecessary in meeting the objectives of the underlying policy.

## **Qualitative indicators of excessive regulatory burdens**

Due to the substantial difficulties in quantifying regulatory burdens, a largely qualitative approach, supplemented by relevant case studies where available, was taken in determining whether a given regulation was imposing excessive burdens on businesses.

Regulations that were developed in line with best practice principles were considered less likely to impose undue burdens on the economy. Factors indicating the quality of regulation that were considered include adequate assessment at the proposal stage, clarity and consistency with other business requirements, and best practice administration (including information availability, guidance to businesses, reporting requirements, approvals processes, and coordination within and between agencies).

## **Detailed consideration of priority areas**

All relevant concerns raised by participants were examined by the Commission. The first step was to examine and clarify the relevant regulatory objectives in terms of the underlying economic, social and/or environmental objectives. Where possible, consideration was given to possible alternative regulatory means of meeting those objectives, including analysis of the associated benefits and costs.

The responses to the concerns — based on an assessment of what further action was required — are broadly categorised as follows:

- 
- unnecessary burden, which can be removed without delay
  - some time should pass before assessing recent changes
  - examine the impacts of, or case for, making changes
  - conduct a fundamental policy review.

## **1.4 Conduct of the study**

The Commission received the terms of reference for the five annual reviews in February 2007 and completed the first review in November 2007. A circular announcing the commencement of the second annual review was released on 15 January 2008 and advertisements were placed in major newspapers as well as on the Commission's website. An issues paper was released in early February to assist those preparing submissions, which were due by 20 March 2008. A draft report was publically released on 27 June 2008 and submissions on the draft were due by 31 July 2008.

The Commission has held informal consultations with government agencies and peak industry groups representing the manufacturing and distributive trades sectors throughout the review. Furthermore, direct consultation was conducted with businesses in a broad cross-section of industries involved in the manufacturing and the distributive trades sectors. The Commission had the benefit of 41 submissions from businesses, industry groups, individuals and government agencies prior to the release of the draft report and a further 36 submissions were received after the draft report was released. Several roundtable discussions were held after the release of the draft report. These were attended by representatives from government agencies and industry. The Commission would like to thank all those who have provided valuable input into this review.

## **1.5 Structure of the report**

The following chapter provides a snapshot of the characteristics of the manufacturing and distributive trades sectors. Chapters 3 to 8 address the concerns raised during consultation with stakeholders, including in submissions. Most of the issues raised concern more than one industry and are presented under broad thematic headings relating to the major areas of concern. The appendices contain information regarding the consultation with government agencies, industry and representative bodies undertaken as part of this review, and other recent reviews relevant to the manufacturing and the distributive trades sectors.



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## 2 Industry characteristics

Manufacturing and the distributive trades — wholesale trade and retail trade — make an important contribution to the Australian economy. Manufacturing accounts for 10 per cent of Australian output and employment and is a significant exporting industry. The distributive trades contribute roughly the same level of output as manufacturing but are much more labour intensive — employing almost two million people or nearly 20 per cent of total employment in Australia.

This chapter presents a statistical overview of the manufacturing and distributive trades sectors and presents value chains to illustrate the extent of government regulatory requirements placed on businesses in these parts of the economy.

### 2.1 Industry size and characteristics

Manufacturing involves the transformation of materials or components into new products through a broad range of production techniques ranging from computer assisted robots to hand crafting. Industries within the sector are highly diverse, with activities including the manufacture of fibres, clothes, shoes, paper, books, computer disks, toys, petroleum, plastics, chemicals, pharmaceuticals, structural and sheet metal products, motor vehicles, prefabricated buildings and furniture. A list of Australia and New Zealand Standard Industrial Classification (ANZSIC) manufacturing divisions are detailed in chapter 1, box 1.1.

The distributive trades form part of the services sector. Wholesalers collate, store and disburse new or used products to businesses for resale and to institutions including government. Retailers specialise in providing new or used goods to final consumers for personal or household consumption. Businesses in retail trade include department stores and other shops, motor vehicle retailers and service outlets, stalls, mail order houses (including internet shops), door-to-door sellers, milk vendors, vending machine operators and consumer cooperatives.

Throughout Australia, over 105 000 businesses operate in the manufacturing sector and almost 305 000 businesses are in the distributive trades (table 2.1).

## Output and exports

In 2006-07, the manufacturing sector contributed 10 per cent of GDP or \$107 billion in gross value added to the Australian economy. The distributive trades sector added a similar value — 10 per cent of GDP or \$105 billion in gross value added. Within the distributive trades sector, retail trade (5.5 per cent) contributed a little more to GDP than wholesale trade (4.5 per cent) (table 2.1).

Table 2.1 **Summary statistics, manufacturing and the distributive trades**  
2006-07

	<i>Manufacturing</i>	<i>Wholesale trade</i>	<i>Retail trade</i>	<i>Distributive trades (combined)</i>
<b>Gross value added</b>				
\$ million	107 497	47 800	57 313	105 113
Contribution to GDP (per cent)	10.3	4.5	5.5	10.1
<b>Exports by classification of good</b>				
ABS estimate (\$ million)	85 383	-	-	-
DFAT estimate (\$ million)	44 011			
<b>Imports by classification of good</b>				
ABS estimate (\$ million)	164 353	-	-	-
DFAT estimate (\$ million)	141 782			
<b>Employment</b>				
Number of persons ('000)	1 087	466	1 485	1 951
Contribution to total (per cent)	10.4	4.5	14.2	18.7
<b>Businesses</b>				
Number operating at end of financial year	106 565	85 398	219 308	304 706
Contribution to total (per cent)	5.3	4.2	10.9	15.2

<sup>a</sup> Merchandise exports exclude service sector exports.

Sources: Gross value added data from ABS, *Australian National Accounts*, Cat. no. 5204.0. Export and import data from ABS, *Manufacturing Indicators, Australia*, Cat. no. 8229.0, ABS, *International Trade in Goods and Services*, Cat. no. 5368.0 and DFAT, *Composition of Trade Australia, 2006-07*. Employment data from ABS, *Australian Labour Market Statistics*, Cat. no. 6105.0, June quarter values. Business data from ABS, *Counts of Australian businesses including entries and exits*, Cat. no. 8165.0.

Estimates of the value of manufacturing exports vary considerably because of differences in the methodology used to classify exports by sector. In 2006-07, the ABS valued exports of manufactured goods at \$85 billion, half the total value of Australia's merchandise exports. In the same year, more conservative estimates produced by the Department of Foreign Affairs and Trade (which include only goods that have undergone a significant amount of manufacturing processing such as sheet metal products and motor vehicles) placed a value of \$44 billion on Australia's manufacturing exports, or 26 per cent of Australia's total merchandise

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exports.<sup>1</sup> Despite differences in measurement, all estimates demonstrate that manufacturing is a significant contributor to Australia's export earnings.

Overall, Australia is a net importer of manufactured goods. In 2006-07, the ABS valued imports of manufactured goods at \$164 billion, almost twice the value of manufactured exports in that year (table 2.1).

The distribution sector does not produce goods for export and therefore does not figure in industry of origin or commodity based or export statistics.<sup>2</sup>

### **Labour market and average business size**

Over one million people are employed in manufacturing, representing 10 per cent of the total number of people employed. Nearly twice as many (two million people) or 19 per cent of the total number of people employed are working in distributive trades. The majority employed in the distributive trades, almost 1.5 million workers, are employed in retail trade. More significantly, retail trade is the largest employer by industry in Australia, employing over 14 per cent of the working population (table 2.1).

There are marked differences in the predominant type of employment between manufacturing and the distributive trades. Retail trade has one of the lowest rates of full time employment. In 2006-07, 53 per cent of employment in retail trade was on a full time basis. Food retailing in particular has a low rate of full time employment, with less than 40 per cent of workers employed full time. In contrast, manufacturing (87 per cent) and wholesale trade (83 per cent) have a high prevalence of full time employment when compared with the total working population (71 per cent).

Around half the number of businesses in manufacturing (47 per cent), wholesale trade (49 per cent) and retail trade (50 per cent) employ staff. These shares are significantly higher than that of the all industry average — about 30 per cent of all businesses employ staff.

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<sup>1</sup> ABS classifies manufacturing exports according to ANZSIC. This can be misleading – some goods are attributed to manufacturing even if the manufacturing process involved is trivial relative to the value of the good. Commodity-based estimates such as the Department of Foreign Affairs and Trade Export Classification include only products that have undergone 'significant' manufacturing. Commodity estimates are generally appropriate for estimating the contribution of manufacturing relative to other sectors in the economy. However, they are not compatible with firm based industry classified statistics such as value added, employment, investment and wages (PC 2003).

<sup>2</sup> Wholesale and retail trade play a role in the distribution and exchange of goods from producers to consumers located overseas. The ABS estimated that, in 2006-07, over 16 000 businesses in the distribution sector exported goods valued at \$31 billion (ABS 5368.0.55.006).

Manufacturing and the distributive trades have an above average proportion of small businesses. Compared to an all industry average where 30 per cent of businesses employ between 1-19 people, in manufacturing the rate is over 40 per cent and for the distributive trades it is over 45 per cent. Manufacturing also has a significantly larger proportion of medium sized businesses (employing between 20 to 200 people) — over 5 per cent — compared with the all industry average of just over 1 per cent.

Few businesses (0.1 per cent of businesses) employ 200 or more people. However, manufacturing and the distributive trades have a relatively high share of large businesses (table 2.2).

**Table 2.2 Business size<sup>a, b</sup>**  
Number of businesses (percentage of total), 2005-06

	<i>Manufacturing</i>	<i>Wholesale trade</i>	<i>Retail trade</i>	<i>All industries</i>
Small employers	54 557 (40.9)	44 412 (45.7)	120 175 (47.6)	944 753 (29.4)
Medium employers	7 103 (5.3)	2 782 (2.9)	5 220 (2.1)	42 996 (1.3)
Large employers	638 (0.5)	256 (0.3)	263 (0.1)	3 620 (0.1)
Non employers	71 138 (53.3)	49 727 (51.2)	126 942 (50.3)	2 218 999 (69.1)
<b>Total</b>	<b>133 436 (100)</b>	<b>97 177 (100)</b>	<b>252 600 (100)</b>	<b>3 210 368 (100)</b>

<sup>a</sup> These data do not correspond to the number of businesses in table 2.1. These data are for 2005-06 the latest available at the time of printing and do not take into account businesses which may have ceased operation during the financial year. <sup>b</sup> Large businesses employ 200 or more people, medium businesses employ between 20 and 200 people and small businesses employ less than 20 people.

Source: ABS, *Australian Industry*, Cat. no. 8155.0.

## State and territory sectoral contributions

Within Australia, New South Wales contributes the most to GDP in manufacturing and the distributive trades — around 30 per cent of each sector or \$34 billion in manufacturing, \$17 billion in wholesale trade and \$18 billion in retail trade. Victoria and Queensland also contribute significantly to GDP in these sectors. The largest employers by state in manufacturing and the distributive trades are again New South Wales, Victoria and Queensland, the most populous states. In 2006-07, Victoria employed the largest number of workers in manufacturing (almost 348 000 people) and New South Wales employed the largest number of workers in wholesale trade (165 000 people) and retail trade (451 000 people) (table 2.3).

Within each state and territory, the economic contribution of manufacturing and the distributive trades varies. In Western Australia, Queensland and the Northern Territory, manufacturing has a less significant role than in other states because of the significance of mining and agriculture in these economies. Manufacturing is most significant in Tasmania (15 per cent of output) and South Australia



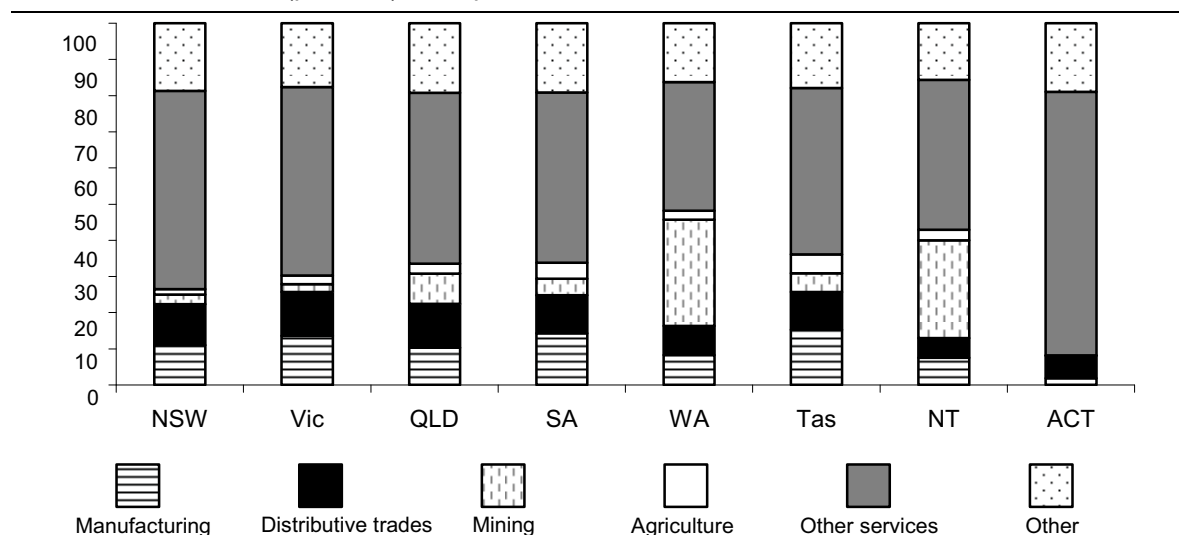
(14 per cent of output). Distributive trades are particularly significant in Queensland and Victoria (12 per cent of output). In the ACT, manufacturing and the distributive trades play a negligible role as the territory is dominated by other services (in particular government administration and defence, which accounts for over 40 per cent of service sector gross value added) (figure 2.1).

**Table 2.3 Value added and employment by state/territory 2006-07**

	Value added \$ million (% total)			Employment '000 persons (% total)		
	Manufacturing	Wholesale trade	Retail trade	Manufacturing	Wholesale trade	Retail trade
NSW	34 368 (32.0)	16 887 (35.3)	18 101 (31.6)	324.2 (29.8)	164.7 (35.4)	451.0 (30.4)
Vic	30 535 (28.4)	13 946 (29.2)	13 224 (23.1)	347.5 (32.0)	133.6 (28.7)	365.1 (24.6)
Qld	18 498 (17.2)	8 509 (17.8)	13 295 (23.2)	197.8 (18.2)	80.3 (17.3)	328.7 (22.1)
SA	8 873 (8.3)	2 656 (5.6)	3 854 (6.7)	88.4 (8.1)	28.1 (6.0)	114.7 (7.8)
WA	11 012 (10.2)	4 568 (9.6)	6 133 (10.7)	97.8 (9.0)	45.8 (9.8)	158.9 (10.7)
Tas	2 809 (2.6)	624 (1.3)	1 297 (2.3)	22.2 (2.0)	7.2 (1.5)	34.4 (2.3)
NT	1 036 (1.0)	279 (0.6)	473 (0.8)	3.9 ( 0.4)	3.2 (0.7)	11.3 (0.8)
ACT	366 (0.3)	330 (0.7)	936 (1.6)	4.8 (0.4)	2.8 (0.6)	21.4 (1.4)
<b>Total</b>	<b>107 497 (100)</b>	<b>47 800 (100)</b>	<b>57 313 (100)</b>	<b>1 086.7 (100)</b>	<b>465.6 (100)</b>	<b>1 485.4 (100)</b>

Sources: Value added data from ABS, *Australian National Accounts, State Accounts 2006-07*, Cat. no. 5220.0. Employment data from ABS, *Australian Labour Market Statistics*, Cat. no. 6105.0, June quarter values.

**Figure 2.1 Sectoral contribution of manufacturing and distributive trades to state and territory economic activity, 2006-07<sup>a, b</sup>**  
Share (per cent) of output



<sup>a</sup> The services sector is defined as all industries other than those producing goods. It includes wholesale trade, retail trade, accommodation, cafes and restaurants, transport and storage, communication services, finance and insurance, property and business services, government administration and defence, education, health and community services, cultural and recreational services and personal and other services. Other services excludes distributive trades. <sup>b</sup> Other includes construction, electricity, gas and water and ownership of dwellings, so the output measures are equal to the national accounts gross value added at basic prices.

Data source: ABS, *Australian National Accounts, State Accounts 2006-07*, Cat. no. 5220.0.

## The composition of manufacturing and distributive trades

Machinery and equipment manufacturing is the largest subsector within manufacturing, accounting for over 20 per cent of production and employment. Food, beverages and tobacco and metal product manufacturing are also significant manufacturing subsectors (table 2.4).

Within wholesale trade, the machinery and motor vehicle sector is the largest contributor to industry value added while the largest employer is the personal and household goods sector. Similarly, personal and household goods is the largest sector in retail trade accounting for just under half of total production and employment (table 2.4).

Table 2.4 **Gross value added and employment**  
Manufacturing and the distributive trades

	<i>Industry value added 2005-06<sup>a</sup></i>		<i>Employment<sup>b</sup> June 2007</i>	
	\$ million	% total	'000 persons	% total
<b>Manufacturing</b>				
Food, beverages & tobacco	18 602	18.5	206.1	20.2
Textile, clothing, footwear & leather	2 676	2.7	54.9	5.4
Wood & paper product	6 445	6.4	71.8	7.0
Printing, publishing & recorded media	10 491	10.4	113.5	11.1
Petroleum, coal, chemical & assoc prod	14 000	13.9	92.8	9.1
Non-metallic mineral product	4 793	4.8	37.2	3.6
Metal product manufacturing	19 223	19.1	154.5	15.1
Machinery & equipment	20 040	19.9	234.6	23.0
Other	4 343	4.3	55.6	5.4
<b>Total</b>	<b>100 613</b>	<b>100.0</b>	<b>1 021.0</b>	<b>100.0</b>
<b>Wholesale trade</b>				
Basic material wholesaling	11 482	23.0	112.9	25.7
Machinery & motor vehicle	20 539	41.2	144.9	33.0
Personal & household goods	17 810	35.7	181.7	41.3
<b>Total</b>	<b>49 831</b>	<b>100.0</b>	<b>439.5</b>	<b>100.0</b>
<b>Retail trade</b>				
Food	17 871	31.1	543.8	37.3
Personal & household goods	27 099	47.2	664.0	45.5
Motor vehicles & services	12 418	21.6	250.4	17.2
<b>Total</b>	<b>57 388</b>	<b>100.0</b>	<b>1 458.2</b>	<b>100.0</b>




<sup>a</sup> 2005-06 was the latest available data at time of printing — data do not correspond to the 2006-07 data in tables 2.1 and 2.3. <sup>b</sup> Employment does not sum to industry total (in tables 2.1 and 2.3) as some employment is uncategorised.

Sources: Employment data from ABS, *Australian Labour Market Statistics*, Cat. no. 6105.0, June quarter values. Industry Value Added from ABS, *Australian Industry*, Cat. no. 8155.0.

## 2.2 Value chains and the impact of regulation

In an attempt to illustrate the myriad of Australian and state and territory government regulatory requirements placed on business the Commission has constructed value chains for manufacturing (table 2.5) and the distributive trades (table 2.6). These value chains indicate the key regulatory requirements that businesses can face at each stage of their activity. For example, the manufacturing value chain commences with the regulatory compliance surrounding the acquisition of the site for the business's plant, then to the operation of the plant outlet, distribution of the production and cessation of activities if the business needs to relocate or exit the industry.




Table 2.5 **Manufacturing value chain and the impact of regulations**

<i>Key Australian Government involvement/regulation</i>	<i>Key stages of cycle</i>	<i>Key state/territory government involvement/regulation</i>
<ul style="list-style-type: none"> <li>• environmental protection and biodiversity conservation</li> <li>• financial sector (access to finance)</li> </ul>	<p><b>Acquisition of site and manufacturing plant</b></p> 	<ul style="list-style-type: none"> <li>• land use and planning</li> <li>• building code</li> <li>• environmental protection</li> </ul>
<ul style="list-style-type: none"> <li>• industrial relations</li> <li>• national pollutant inventory</li> <li>• immigration</li> <li>• water access</li> <li>• superannuation</li> <li>• industrial and agricultural and veterinary chemicals</li> </ul>	<p><b>Operation of plant</b></p> 	<ul style="list-style-type: none"> <li>• Occupational Health &amp; Safety (OHS)</li> <li>• food safety</li> <li>• machinery operations</li> <li>• local government rates and charges</li> </ul>
<ul style="list-style-type: none"> <li>• export certificates</li> <li>• national land transport regulatory frameworks</li> <li>• shipping and maritime safety laws</li> <li>• international maritime codes and conventions</li> <li>• trade practices</li> <li>• product regulation (labelling etc)</li> </ul>	<p><b>Distribution of output</b></p> 	<ul style="list-style-type: none"> <li>• transport</li> <li>• food safety</li> <li>• OHS</li> <li>• land use and planning</li> <li>• building code</li> <li>• local government rates and charges</li> <li>• hazardous goods handling and transport</li> <li>• product safety</li> <li>• consumer protection</li> </ul>
<ul style="list-style-type: none"> <li>• corporation law</li> <li>• redundancy provisions</li> </ul>	<p><b>Cessation of operations</b></p>	<ul style="list-style-type: none"> <li>• contaminated sites</li> <li>• land use and planning</li> </ul>

Generic regulation, such as taxation, occupational health & safety (OHS), corporations and industrial relations legislation are included in the value chain because they are a potential source of burden to business. However, they do not have a particular or discriminatory impact on the manufacturing and/or distribution sectors. The Commission, generally, will not provide responses on generic regulation in this year's review. Providing responses on such generic regulations based on only the considerations pertaining to the manufacturing and the distributive trades sectors risks creating unintended adverse consequences for industries outside the scope of this year's review. Concerns with generic regulation will be addressed in the final year of the review cycle.

There are also certain regulations, such as those relating to chemicals, foreign labour and research and development expenditure, that are being considered in other reviews. Where appropriate, the Commission has ascertained whether this review can complement these other reviews. For example, other reviews may focus on high level strategy and policy, rather than practical improvements in response to specific concerns, which is the focus of this review.

**Table 2.6 Distributive trades value chain and the impact of regulations**

<i>Key Australian Government involvement/regulation</i>	<i>Key stages of cycle</i>	<i>Key state/territory government involvement/regulation</i>
<ul style="list-style-type: none"> <li>• financial sector (access to finance)</li> <li>• franchising code</li> </ul>	<p><b>Acquisition of premises</b></p> 	<ul style="list-style-type: none"> <li>• land use and planning</li> <li>• building code</li> <li>• retail tenancy</li> </ul>
<ul style="list-style-type: none"> <li>• national land transport regulatory frameworks</li> <li>• trade practices</li> <li>• product regulation (labelling etc)</li> </ul>	<p><b>Distribution (larger multi-branch retailers)</b></p> 	<ul style="list-style-type: none"> <li>• transport</li> <li>• food safety</li> <li>• OHS</li> <li>• land use and planning</li> <li>• local government rates and charges</li> <li>• hazardous goods handling and transport</li> <li>• product safety</li> </ul>
<ul style="list-style-type: none"> <li>• trade practices</li> <li>• taxation compliance</li> <li>• industrial relations</li> <li>• superannuation</li> <li>• horticulture code of conduct</li> </ul>	<p><b>Operation</b></p> 	<ul style="list-style-type: none"> <li>• consumer protection</li> <li>• trading hours</li> <li>• OHS</li> <li>• industrial relations</li> <li>• food safety</li> </ul>
<ul style="list-style-type: none"> <li>• corporation law</li> <li>• redundancy provisions</li> </ul>	<p><b>Cessation of operations</b></p>	<ul style="list-style-type: none"> <li>• land use and planning</li> </ul>

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## 3 Food Regulation

Food produced and imported into Australia is highly regulated in terms of safety standards, reflecting high community expectations in regard to public health and safety. This regulation also plays a role in meeting consumer demand for information concerning food products and as an international marketing tool signifying the quality of Australia's food. Importantly, such regulation balances food safety and the protection of public health with the commercial needs of industry to innovate and bring new food products to the market in a timely manner.

Food regulation has been subject to considerable scrutiny in the past decade. There have been a number of reviews, including the Blair Review (1998), the Report of the Regulation Taskforce (2006) and the Victorian Competition and Efficiency Commission review of food regulation in Victoria (2007) which have highlighted ongoing regulatory problems facing the industry. These problems broadly relate to the inconsistency in regulation and enforcement across jurisdictions, lengthy delays and difficulties in implementing new food standards and amending existing standards as well as problems with the regulation making process and surrounding governance arrangements.

Governments have taken actions to address these issues. An Intergovernmental Agreement (the Agreement) has delivered a Model Food Bill to provide consistency across jurisdictions and changes have been recently introduced to speed up the amendment and adoption of food standards. COAG has also added food regulation to its regulation work program. However, there are still considerable concerns in these areas and in relation to the regulation-making process and surrounding governance arrangements.

### **Background**

Australia's food regulation system is a cooperative arrangement between the states, territories and the New Zealand and Australian governments. The initial step was taken in 1991 with the establishment of the National Food Authority to develop national food standards and further progressed with the agreement to develop a joint Australia New Zealand Food Code and the creation of the Australia New Zealand Food Authority in the mid-1990s. The current arrangements were established following the Blair Review (1998) which found that the regulatory framework

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surrounding food was complex and fragmented. In response, a reform package was developed which included an intergovernmental agreement to regulate food standards signed by COAG. New Zealand subsequently joined the system via a treaty. The Australia and New Zealand Food Regulation Ministerial Council (ANZFRMC) was established, responsible for developing food policy and Food Standards Australia New Zealand (FSANZ) was established with the responsibility for developing food standards (box 3.1). A Food Regulation Standing Committee, reflecting the membership of the Ministerial Council and made up of senior officials, was also established to coordinate policy advice to the Ministerial Council and ensure a nationally consistent approach to the implementation and enforcement of food standards.

However, in Australia, the enforcement of food standards is the responsibility of the state and territory governments. The Australian Government has no explicit constitutional power to regulate food produced or sold in Australia.

**Box 3.1 Food Standards Australia New Zealand legislation**

The object of the *Food Standards Australia New Zealand Act 1991* is to ensure a high standard of public health protection throughout Australia and New Zealand by establishing FSANZ to achieve the following:

- a high degree of consumer confidence in the quality and safety of food produced, processed, sold or exported from Australia and New Zealand
- an effective, transparent and accountable regulatory framework within which the food industry can work efficiently
- the provision of adequate information relating to food to enable consumers to make informed choices
- the establishment of common rules for both countries and the promotion of consistency between domestic and international food regulatory measures without reducing the safeguards applying to public health and consumer protection.

*Source: Food Standards Australia New Zealand Act 1991, Section 3.*

### 3.1 Inconsistency

Inconsistency is an ongoing issue in food regulation. As with previous reviews — including the Commission’s 2007 (PC 2007a) review of regulatory burdens on business which focused on the primary sector — inconsistency was raised by a number of participants. The Australian Food and Grocery Council (AFGC) noted that the jurisdictions:

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- have different expectations and priorities for the food regulatory system and how it should operate;
  - do not agree on priorities for food regulation resulting in different levels of agency resource allocation and technical competencies between jurisdictions including in enforcement;
  - have adopted the Model Food Bill to differing degrees resulting in a lack of national uniformity. (sub. 10, p. 8)

It went on to say:

Food safety is a given and the AFGC supports all regulations that permit the supply of safe food to consumers. It is the price of entry to the market place. However, the development of separate food hygiene regulations by individual states and territories has resulted in differing application of those rules. These cause efficiency losses in requiring differing policies and procedures and food safety training programs. (sub. 10, p. 16)

Woolworths were critical of the inconsistency of enforcement of the regulation across jurisdictions:

Although the Food Standards Code has been adopted by all States and Territories, responsibility for enforcement generally lies with the States and Local Government, meaning that there are hundreds of agencies involved in the enforcement and administration of the Food Standards Code. (sub. 25, p. 7)

And considered that this provided a competitive advantage to those firms operating within a single jurisdiction.

Some jurisdictions are not enforcing the country of origin labelling requirements. Non-enforcement creates difficulties for Woolworths because considerable time, effort and costs have been incurred in all supermarkets to ensure national standards compliance, however, other smaller fresh food businesses or independently owned supermarkets often do not comply, which gives these businesses an unfair competitive advantage. (sub. 25, p. 7)

The Confectionery Manufacturers of Australasia (CMA) commented:

The CMA can cite many examples where uniform interpretation of regulations has been inadequate, making it difficult for companies to do business intra and interstate as companies are denied the option whilst their competitors are given the go ahead. (sub. 32, p. 6)

Choice also pointed out inconsistencies in enforcement across jurisdictions:

There are inconsistencies in the way food regulation is enforced across jurisdictions, particularly in relation to food labels. For example, one state government might be interested in policing country of origin labelling while another may see health claims as an enforcement priority. (sub. DR61, p. 12)

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Coles Group pointed to the continued use of prescriptive state based regulation despite the agreement to implement nationally consistent food standards:

... the Primary Production Standard for Eggs & Egg Production (Proposal P301) is being developed for inclusion into the Food Standards Code, however, Safe Food Queensland (SFQ) has just released an extremely prescriptive (31 page) guideline for egg production within that state. The Egg Food Safety Workbook Guide to Food Safety and Quality has also been developed for Queensland commercial egg suppliers and may be used by regulators within Queensland as a minimum requirement for egg production. This guideline is outside the intent of modern 'outcome based' Australian legislation and may, by its prescriptive and state-based nature, introduce greater complexity for national retailers which could lead to an increase in the price of eggs and egg products for consumers. (sub. 17, p. 2)

The Department of Agriculture, Fishing and Forestry (DAFF) noted that, while some improvements had been made, inconsistencies remained:

DAFF recognizes that although Australia's food regulatory system has improved since changes were incorporated in 2002, inefficient and inconsistent regulation continue to frustrate industry and government stakeholders. (sub. DR72, p. 2)

Australian Dairy Industry were concerned that:

... national Food Standard System objectives will not be achieved because regulations are duplicated and guidelines are over-prescriptive. (sub. 26, p. 4)

The AFGC, in summing up, was of the view that:

... the problems with Australia's food policy and regulatory system are so extensive and profound that only a complete overhaul of the regulatory system will provide sufficient change, and relief of regulatory burden, for the food industry to ensuring its competitiveness into the future. (sub. 10, p. 3)

## **Assessment**

An important element of the reform package flowing from the Blair Review (1998) was the development of an integrated and coordinated regulatory regime through the introduction of a Model Food Bill to underpin the Food Acts in each jurisdiction and provide national consistency. This was to be a key to meeting a specific objective of the Agreement to provide, 'a consistent regulatory approach across Australia through nationally agreed policy, standards and enforcement procedures' (COAG 2002). However, this is yet to be achieved.

The Regulation Taskforce (2006) found that while there had been improvements as a result of these changes, a number of issues remained. It commented that some jurisdictions had adopted only the core provisions of the Model Food Bill and retained their own laws, resulting in overlaps with national laws. Consequently,



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there were significant inconsistencies in implementing and enforcing food regulation across the states and territories.

The Model Food Bill contains two parts. Annex A contains the ‘core provisions’ which each jurisdiction agreed to implement in the same terms in their respective food acts. Annex B contains the ‘non core’ provisions which provided for flexibility and enabled each jurisdiction to adopt those provisions that best suited their needs. It included provisions for inspection and seizure powers, improvement notices, taking and analysis of samples, notification and registration of food premises and procedural and evidentiary provisions.

It appears that, for the most part, the core provisions in Annex A have been adopted as agreed. However, the non core provisions of Annex B, where they have been adopted, have been adopted inconsistently resulting in the development of a range of food safety management systems across the jurisdictions (Theobald 2007). This means that significant differences, and resulting excess burdens for businesses, remain.

The Regulation Taskforce (2006) recommended that the Australian Government commission an independent public review to implement the outstanding recommendations from the Blair Review on the consistent application of food laws, align levels of enforcement and penalties across jurisdictions and examine the role of the Australian Government in the food regulatory system, including a greater involvement in enforcing standards.

In its response, the Australian Government agreed to implement a review and in January 2007 commissioned an independent review, the Bethwaite Review of Food Regulation, to identify means to streamline and provide national consistency to the food regulatory framework. However, this review has not been completed. Although submissions were taken and consultations held there has been no publicly available information as to its status or any reporting date. Coles Group (DR47) said:

Coles submitted a detailed paper on the Bethwaite Review of Food Regulation in February 2007 and is extremely disappointed that 18 months have past since the Review and the Australian Government has still not publicly released any information to industry about what food regulatory reforms will be implemented. (sub. DR47, p. 1)

In its review of regulatory burdens on the primary sector (PC 2007a), the Commission concluded that the Bethwaite Review was the most appropriate means to address these issues. The Commission in its draft report considered that the Australian Government, through the relevant agencies, should publicly announce the proposed responses to the submissions to the Bethwaite Review, including any proposed reforms and their timing.

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The status of the Bethwaite Review remains unclear and there is a pressing need for accelerated reforms to reduce regulatory burdens. Accordingly, the Commission has proposed a number of reforms to improve national consistency of food regulation. They include changes to the legislative framework, adjustments to the enforcement arrangements and strengthening of the implementation processes.

### *Changes to the legislative framework*

The starting point to improve consistency in regulation across jurisdictions would be to determine which food regulations contained in the Model Food Bill should be applied nationally and which should be applied at a state and territory or local level. Such an approach would involve determining which of the ‘non-core’ provisions currently contained in Annex B of the Model Food Bill relate to national requirements and those that are required to reflect unique regional or local needs. All those provisions that are able to be applied on a nationally consistent basis would be placed in Annex A to be implemented consistently in each jurisdiction and those relating to local and regional requirements would remain in Annex B. The default position would be that all the provisions of the Model Food Bill are considered as ‘core’ provisions unless there are demonstrable regional or local requirements that could only be met by varying the provisions at the jurisdictional level. Regulatory consistency should also be encouraged in Annex B where similar regional or local requirements occur within jurisdictions.

A stronger approach to greater consistency would be to move from the use of a model bill to template legislation. Under this arrangement, the core provisions of the existing Model Food Bill and those provisions of Annex B that are not required to meet regional or local requirements would be contained in the template legislation. This would involve the necessary template legislation being enacted in one state or territory and then being applied in the other states and territories

The arguments for using template legislation in this context is that it minimises differences in style, interpretation and content in the drafting of legislation by individual jurisdictions. As such, this approach would go beyond regulatory consistency and more towards regulatory uniformity across jurisdictions.

### *Adjusting enforcement arrangements*

The present arrangements for enforcing national food regulation, such as food labelling and standards, have not resulted in a consistently regulated market place.

The states and territories are the appropriate level of government to undertake the enforcement of national regulations, because of their involvement in enforcing their

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own food regulations. The key requirement is that each jurisdiction enforces national regulations consistently, having agreed to national consistency in food regulation in the first instance.

To that end, the Commission considers that 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 regulation. Moreover, these arrangements should be periodically reviewed and audited from time-to-time to ensure the contracted enforcement outcomes are being met. The Commission considers an agency such as DOHA might have the administrative role of supervising the contractual agency arrangement on behalf of all jurisdictions.

### *Strengthening the implementation processes*

Greater consistency in food regulation and its enforcement would also be assisted by strengthening the implementation process of national regulations. At present, the Implementation Sub-Committee (ISC), a sub-committee of the Food Regulation Standing Committee, seeks to develop and oversee a consistent approach to the implementation and enforcement of food regulation through the development of appropriate guidelines. The objectives of these guidelines are to minimise cost to industry and meet the broader objective of minimum effective regulation (DOHA 2008c).

DAFF (sub. DR72) pointed to proposed changes developed by the ISC that could improve consistency in the implementation of standards. This would involve the Ministerial Council receiving the draft standard, an implementation plan and the related Regulatory Impact Statement (RIS) as a single package rather than receiving the draft standard in isolation. These changes are to be piloted and evaluated by the Ministerial Council.

The Commission considers that having the ISC operate as a high level forum for regulators responsible for food regulation from each jurisdiction would strengthen the implementation process. The ISC should be the forum through which regulatory agencies are able to develop strategies and guidelines for the consistent implementation, interpretation and enforcement of food regulation including new food standards. This would involve jurisdictions being represented on the ISC by heads of food regulation agencies or senior officials responsible for the implementation and enforcement of food regulation within their jurisdictions. To ensure transparency and accountability, the ISC should also report to the Ministerial Council, through the Food Regulation Standing Committee, on a regular basis as to each jurisdiction's compliance with the agreed to guidelines and strategies.

*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 Australia New Zealand Food Regulation Ministerial Council as to each jurisdiction's compliance with the agreed to guidelines and strategies.*

### **3.2 Delays and difficulties in implementing and amending food standards**

The introduction of new foods or modified or improved formulations for existing foods often requires variation of national food standards contained in the Australia New Zealand Food Standards Code (the Food Code) (box 3.2). This usually involves an application from a manufacturer or industry body to FSANZ for an amendment or addition to the Food Code.

The Food Code can also be amended via a Ministerial Council request to FSANZ to review an existing standard and develop a proposal in accordance with a policy guideline developed by the Ministerial Council and FSANZ can prepare proposals for changes to the Food Code on its own initiative.

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Several participants noted lengthy delays in having existing food standards amended and new standards implemented. The Commission was told that food standards can take up to four years to be amended following application. Not surprisingly, these delays attracted considerable criticism from participants.

**Box 3.2 The Australia New Zealand Food Standards Code**

The Food Code sets out the compositional requirements for food and mandates compliance with the use of ingredients, additives, food colouring, processing aids and residues. It also sets out standards for advertising, marketing and product labelling as well as food hygiene and standards for the processing of certain primary products. The Food Code is divided into four chapters:

- chapter 1 – standards applying to all foods in regard to ingredients, additives as well as labelling
- chapter 2 – standards applying to particular types of foods (for example, dairy, meat and oils)
- chapter 3 – food hygiene
- chapter 4 – standards dealing with primary production in Australia.

Chapters 3 and 4 and the section of chapter 1 dealing with country of origin labelling do not apply to New Zealand.

Applications to amend the Food Code currently being considered by FSANZ include an application by the Australian Beverages Council to permit the voluntary addition of fluoride to packaged water as a nutrient, to a maximum claimable amount of 1.5 milligrams per litre.

The Confectionery Manufacturers of Australasia (CMA) have applied to amend the Food Code to increase the existing maximum level for cadmium in peanuts from 0.1 to 0.5 milligrams per kilogram. This would increase flexibility to source peanuts from a variety of countries — most countries do not have maximum cadmium levels for peanuts — to meet demand that may result from crop seasonality and product quality.

*Sources: VCEC (2007).*

Australian Dairy Industry said:

... it is a real concern that a FSANZ draft guideline (written by regulator officers), has taken a year to evolve. (sub. 26, p. 9)

The Confectionery Manufacturers of Australasia (CMA) commented:

In November 2004, the CMA made an application to FSANZ to review the maximum level of cadmium in peanuts in the Code. ... A552 was subsequently released for Initial Assessment in October 2006 (the CMA notes two years later). (sub. 32, p. 5)

The AFGC noted:

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... amendments to change the FSC [Food Standards Code] are very slow, with the great majority of applications from industry taking over 12 months before completion. (sub. 10, p. 11)

## Assessment

For food manufacturers, timeliness in having any necessary amendments made to the Food Code is crucial in allowing them to innovate and bring these innovations to the market ahead of their competitors.

In recognition of the concerns of industry, in 2004 the Ministerial Council commissioned an internal review by officials of the Food Regulation Standing Committee of the process for amending the Food Code. The main weakness identified with the existing system was the 'one size fits all' approach in the legislation for the development and amendment of food standards regardless of the nature, complexity or scope of the amendment or addition to the food standards. This review also recommended improved engagement with stakeholders in the development of food standards.

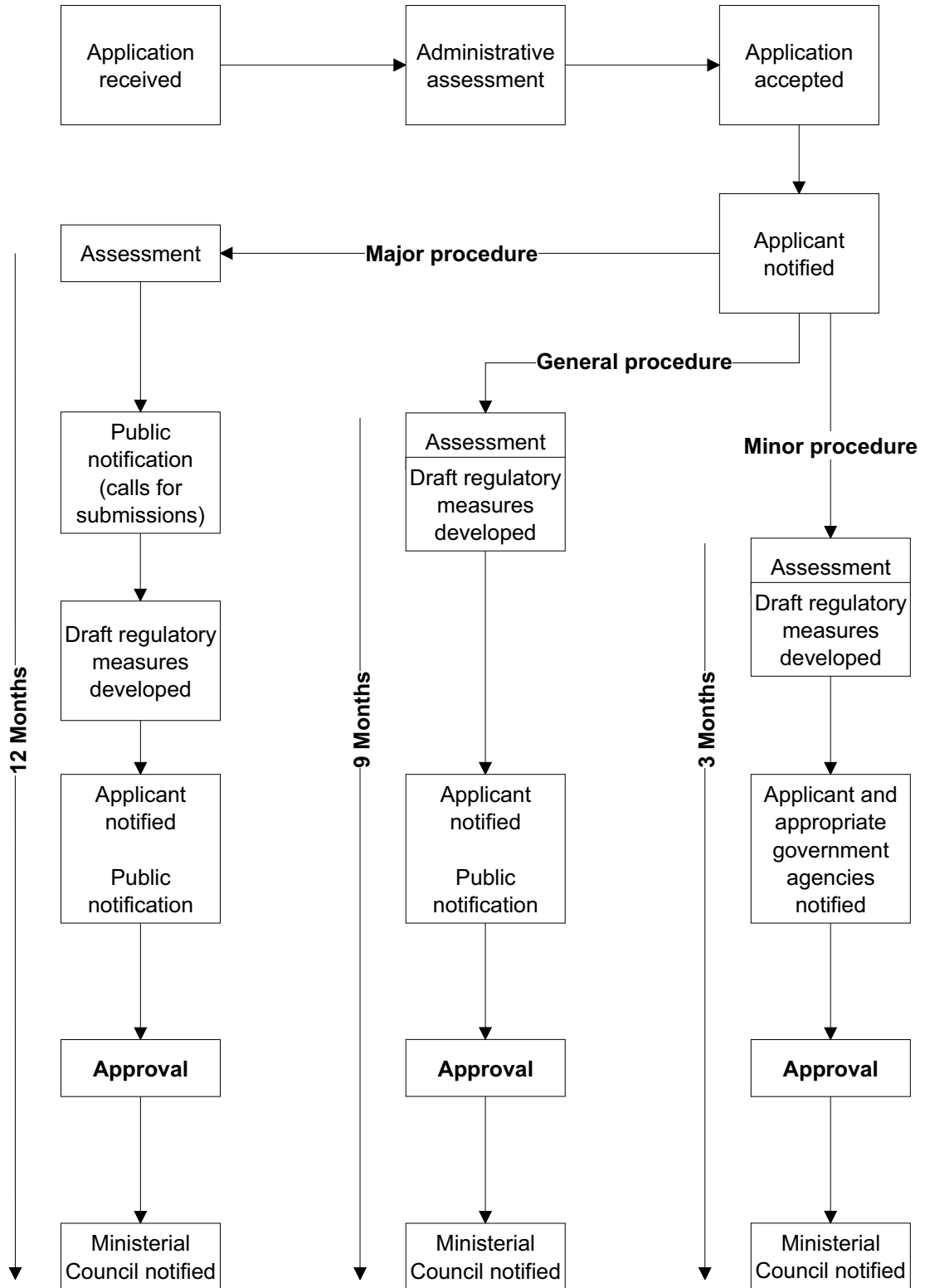
Following this review, amendments were made to the *Food Standards Australia New Zealand Act 1991* to improve the process. These amendments came into effect in October 2007 and provide three different streams of assessment depending on the complexity of the application:

- a truncated process for minor variations to the Food Code
- a more extended process for a new food standard or a major variation to an existing standard
- a general procedure for all other changes (Parliament of Australia 2007).

Time for public consultation in each process is included in each assessment stream. These amendments were aimed at reducing assessment times. Minor changes are expected to take 3 months, major changes and the development of new standards up to 12 months with most changes taking around 9 months (Mason 2007). Figure 3.1 provides further details.

The revised assessment procedures make use of application guidelines that ensure that all applicants have included all the required data and information in their applications prior to submission. This will reduce the need for FSANZ to delay the assessment of the application while it seeks further information from the applicant. The increased consultation between FSANZ staff and applicants prior to submission is also likely to assist in this area.

Figure 3.1 **FSANZ assessment procedures for applications to amend the Australia New Zealand Food Standards Code**



Source: FSANZ website, 'Information for Applicants', (2007).

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The amendments made to the *Food Standards Australia New Zealand Act 1991* to improve timeliness of the standards process came into effect in October 2007. It is too early to assess their impact on the timeliness of the development and amendment of food standards. However, achieving the stated timelines would represent a material improvement. To assess their effectiveness, these amendments should be independently reviewed after they have been in operation for two years.

RESPONSE 3.2

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

Any improvement in timeliness from the recently implemented changes may be lost, however, due to further reviews being requested by the Ministerial Council, as set out below.

### **3.3 Improving the operations of the Australia New Zealand Food Regulation Ministerial Council**

Under the current arrangements as set out in the Food Regulation Agreement (the Agreement), the Ministerial Council has the capacity to adopt, amend or reject the standards developed by FSANZ. It can also request FSANZ to review a draft standard if any single jurisdiction believes that the draft standard:

- is not consistent with existing policy guidelines set by the Ministerial Council
- is not consistent with the objectives of the legislation which establishes FSANZ
- does not protect public health and safety
- does not promote consistency between domestic and international food standards where these are at variance
- does not provide adequate information to enable informed choice
- is difficult to enforce or comply with in both practical or resource terms and / or
- places an unreasonable cost burden on industry or consumers (COAG 2002).

Concerns have been put to this review that the governance arrangements of the Ministerial Council, which enable an individual jurisdiction to request a review, can unreasonably delay improvements and innovations to the Food Code. There have also been concerns that these ‘voting arrangements’ work against the interests of the food producing states (VCEC 2007).



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Australian Beverages Council said:

States and territories with small populations and with only small food & beverages manufacturing sectors can frustrate the needs of the larger states i.e. Victoria and NSW where our food and beverages manufacturing industries are primarily based. ...

A single jurisdiction can seek a review — this usually delays the finalization of a regulation by at least 90 days. After that a majority of small states and territories can reject a regulation by outvoting the combined support for such a regulation by the Commonwealth, New Zealand, Victoria and NSW. (sub. 33, pp. 7–8)

It went on to say that the current arrangements stymied innovation:

Australia is a single market and the food and beverages sector is on the one hand encouraged to be innovative and export orientated and on the other hand is stymied by a system that not only has in-built delays but is also open to artificially generated delays where philosophy contradicts with the business community's needs for innovation and progressive market developments both locally and overseas. (sub. 33, p. 8)

The AFGC commented:

It is also a concern to the AFGC that the Ministerial Council frequently requests FSANZ to conduct reviews of food standards. This indicates a lack of confidence in jurisdictions regarding FSANZ capabilities to develop standards and/or tensions regarding the priorities and directions of standard setting by FSANZ. (sub. 10, p. 11)

Australian Dairy Industry supported:

...[the] need for further improvements in the governance arrangements for ANZFRMC including the transparency and timeliness of decision making, particularly to stimulate food industry innovation. (sub. 26, p. 13)

On the other hand, Choice supported the current arrangements:

We feel that in requesting these reviews Ministers are in fact looking after the interests of their constituents when they feel consumer public health interests have not been adequately addressed by FSANZ. Limiting the capacity of Ministers to request a review would limit their ability to protect the interests of consumers. (sub. DR61, p. 15)

The Obesity Policy Coalition supported this view.

The capacity of a single jurisdiction to request a review of national food standards is important for allowing Ministers to ensure that the interest of consumers in their States are protected. (sub. DR66, p. 1)

As a result of these concerns, there have been suggestions to change the decision-making arrangements of the Ministerial Council to improve the timeliness of the decision-making process. The AFGC (sub. 10, p. 18) proposed that the Australian and New Zealand Governments each have a single vote and the state and territory governments have a single collective vote to reflect their population and the

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importance of the food industries to their economies. Australian Beverages Council (sub. 33, p. 9) recommended that the powers of the Ministerial Council be limited to rejecting a proposed standard and referring a proposed standard for reconsideration once only and then either approve or reject the standard.

The VCEC (2007) report also made a number of recommendations in this area. To improve timeliness in the decision-making process, it recommended that the basis for requesting a review through the Ministerial Council be changed to require two or more jurisdictions to request a review of a FSANZ decision on a draft amendment to the Food Code. (The Victorian Government did not accept this recommendation.) To improve the transparency of the process, it recommended that when jurisdictions request a review they be required to publicly state their reasons for such a review and to meet the full cost of the review. The AFGC (sub. DR58) and Fonterra (sub. DR57), in responding to the draft report, supported this arrangement.

## **Assessment**

The two major issues for the food industry arising from Ministerial Council initiated reviews are timeliness and transparency. To improve transparency, the Ministerial Council in October 2007 agreed that it would publish the grounds for requesting a review and a summary of the Statement of Reasons provided by the jurisdiction(s) (Victorian Government 2008). More recent changes to the Food Regulation Agreement require members of the Ministerial Council requesting a review of a draft standard to specify which of the criteria in the Agreement apply in requesting the review and the grounds on which they are applicable (DOHA 2007b).

Nevertheless, concerns were raised by some participants, such as the AFGC (sub. DR58) and the Confectionery Manufacturers of Australasia (CMA) (sub. DR65), that recent Ministerial Council requests for reviews were inadequate in specifying why the review was required.

It is appropriate that the Ministerial Council, as a representative body of the Australian and state and territory governments and the New Zealand Government, is able to request that draft amendments be subject to review by FSANZ as these amendments will become legally binding in their jurisdictions once included in the Food Code. Indeed, such arrangements ensure that the technical processes of developing and implementing food standards are oversights by representative government.

However, although numerically small, between 10 and 33 per cent of the finalised applications to amend the Food Standards Code notified to the Ministerial Council by FSANZ were subject to a 'first' review in each of the past four years. Second

reviews — the Ministerial Council is no longer able to request a second review following the recent amendments to the Act — were rarely used in this period (table 3.1).

**Table 3.1 Reviews requested by the Ministerial Council of applications to amend the Australia New Zealand Food Standards Code**

	2003-04	2004-05	2005-06	2006-07	2007-08 <sup>a</sup>
Applications finalised by FSANZ for Ministerial Council approval	20	24	23	14	13
Requests for 'first' review	2 (10%)	8 (33%)	5 (22%)	2 (14%)	2 (15%)
Requests for 'second' review	0	1	3	0	0

<sup>a</sup> The 2007-08 data covers the period 1 July 2007 to 9 April 2008.

Source: Information provided by FSANZ.

The timeliness of the process could be improved by requiring widespread support across the Ministerial Council to request a review and that those requesting a review of the draft standard be called on to provide sufficient evidence to justify the need for the review. Enabling a single jurisdiction to request a review is at odds with this approach.

Indeed, other resolutions of the Ministerial Council require a majority vote. The decision-making processes 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 are based on at least a majority vote of the members, with a number of processes requiring higher levels of agreement such as a two-thirds majority and others requiring unanimity.

Suggestions such as changing the voting on the Ministerial Council to have the state and territory governments have a single collective vote or requiring the vote of two or more jurisdictions to initiate a review would create a significant difference with the operations of other ministerial councils. It would also diminish the ability of the Ministerial Council to adequately represent constituent governments in accordance with the agreed to COAG protocols and guidelines for the operation of ministerial councils.

In the interests of improving the timeliness of the process, the Food Regulation Agreement should be amended to require a majority vote of the Ministerial Council to initiate a review of a draft food standard. This would also reflect the decision-making processes of other ministerial councils established to oversight, coordinate and integrate policy.

Also, it is not clear that on all occasions the criteria in the Food Regulation Agreement under which a review can be requested have been met or that adequate

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evidence has been provided to support the request for a review. This process should be improved by ensuring that a request for a review of a draft standard prepared by FSANZ by the Ministerial Council is supported by sufficient evidence to meet the required criteria as set out in the Food Regulation Agreement and that the grounds for the review are published.

RESPONSE 3.3

*The Australia New Zealand Food Regulation Ministerial Council (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 Food Standards Australia New Zealand.*

*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.*

### **3.4 Problems in the regulation-making process**

There have been ongoing concerns from sectors of the food industry that the best practice regulatory principles and guidelines agreed to by COAG have not been adhered to in the development of food standards. These concerns involve the adoption of standards in the Food Code, despite these proposals in their draft form failing to meet a cost-benefit analysis and/or consideration of alternative policy options and their relative cost effectiveness. This is most widely raised in regard to mandatory fortification of bread-making flour with folic acid and mandatory country of origin labelling (CoOL) for unpackaged foods.

In relation to the mandatory fortification of bread-making flour with folic acid, the Flour Millers Council of Australia said:

The flawed nature of the FSANZ standards setting process is certainly reflected in the whole manner of introduction of this standard for mandatory fortification of bread-making flour. However, it may well be an example of a systemic problem in FSANZ whereby FSANZ appears to have become reticent about undertaking rigorous scientific assessments. ... A flawed process in the introduction of the standard certainly has exacerbated the risk of an imminent loss of confidence by Australian consumers in the national food safety assessment processes. (sub. 12, p. 7)

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Qrtsa — The Retailers Association said:

FSANZ has proposed the addition of folate to bread at the bakery/retail level as a means of overcoming low levels of folate intake by some pregnant women – even though a large proportion of these women do not eat bread and, in any case, a more effective means of dosing with folate would be at the milling or master batching stage. (sub. 1, p. 13)

In regard to CoOL, the AFGC said:

Two cost benefit analyses commissioned by FSANZ showed costs outweighed benefits in terms of consumer utility, but FSANZ persisted with its approach to mandate country of origin labelling, sending their final assessment to the Ministerial Council in October of that year. (sub. 10, p. 12)

Woolworths commented:

In reviewing this proposal [CoOL], the legitimate concerns of the industry regarding the size of the font were given little weight by FSANZ, meaning that an application to amend the provisions of the Food Standards Code to reduce the required font size was necessary. Now there are two different font sizes for unpackaged food — 9 mm for fresh produce and nuts and 5 mm for unpackaged food sold from a refrigerated display case which represents an unnecessary burden on business. (sub. 25, p. 7)

## **Assessment**

These concerns are not new. The VCEC (2007) report provided a number of examples of the failure to adhere to the agreed best practice regulatory principles. For example, the Ministerial Council requested that FSANZ develop a mandatory standard for the fortification of bread with folic acid to address concerns regarding neural tube defects in infants. It did so without first considering alternative policy options and the relative cost effectiveness of these alternatives. Indeed, a study commissioned by FSANZ (Segal et. al. 2007) concluded that the alternative approaches to reducing the number of neural tube defects were more cost effective than mandatory fortification.

The introduction of mandatory CoOL for unpackaged food is another clear example of apparent failure to adhere to agreed regulatory practices. Previously, only packaged food was required to display CoOL. Since 2006, unpackaged fresh food and unpackaged processed food has required to be labelled at the point of sale with information as to its country of origin. This involves providing a label with the display of unpackaged food.

In the development of this standard, the Ministerial Council requested that FSANZ develop a mandated standard for CoOL to be applied to unpackaged food. The Regulation Taskforce (2006) noted that although the RIS indicated that there were

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substantial costs which outweighed the consumer benefit, the standard was introduced. In its response, the Office of Regulation Review, now the Office of Best Practice Regulation, commented that the RIS had failed COAG's requirements which included the requirement to demonstrate that the benefits of introducing the standard would outweigh the costs. Indeed, the cost-benefit analysis undertaken for FSANZ pointed to additional costs without commensurate benefits (box 3.3). Moreover New Zealand, given its treaty status in the regulatory arrangements, opted not to implement the standard.

The Office of Best Practice Regulation (sub. DR44) commented that its role was only advisory and it was a decision of the Ministerial Council as to whether or not to proceed with the standard for CoOL despite the inadequacy of the RIS. It pointed out that this was in contrast to the best practice requirements used by the Australian Government which had decided that no regulatory proposal should go to Cabinet or other decision maker unless it had complied with the RIS. The Cabinet Secretariat provided a gate-keeping role to prevent such proposals proceeding without an adequate RIS or compliance costs assessment or unless the Prime Minister deemed that exceptional circumstances applied.

The Regulation Taskforce (2006) recommended that the Australian Government undertake an independent public review of CoOL requirements, including a full cost-benefit analysis, two to three years after these changes came into force. The Government in its response to the Taskforce agreed to conduct such a review within three years (Australian Government 2006).

The situations discussed above highlight the tension between political and other imperatives and good regulatory practices in regard to food regulation. In these instances governments appear to have set aside the agreed regulatory processes.

VCEC (2007) raised a number of options to improve adherence to agreed practice. These included having the COAG best practice regulatory guidelines incorporated into the Food Regulation Agreement and having the Ministerial Council publish a regular report of its actions in relation to regulation and how these actions reflect the COAG guidelines.

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### Box 3.3      **Mandatory country of origin food labelling**

The rationales for mandatory country of origin food labelling are that consumers prefer domestic food products to imported food products, it provides health and safety benefits to the food system and enables consumers to identify where the food is from. However, all the recent cost-benefit analysis suggests that mandatory country of origin labelling imposes significant costs and only provides limited benefits.

Analysis undertaken for the United States Department of Agriculture (USDA) (Krissoff et. al 2004) following the introduction of the US Farm Bill 2002 found that the net benefits flowing from country of origin labelling were nebulous and probably minimal whereas the costs were likely to be extensive.

Much of this work undertaken for the USDA focused on dispelling the beliefs of domestic producers that mandatory labelling would increase consumption of domestically produced food. It found that food suppliers had generally not emphasised or advertised food as originating in the USA, as such labelling would attract little consumer interest. Accordingly, there was little evidence of market failure as suppliers would use such labelling if there was sufficient consumer interest. Even where consumers in the United States preferred domestic products, they were generally unwilling to pay the additional costs to cover the labelling costs (Krissoff et. al 2004).

The study commissioned by FSANZ found that there were additional costs to changing the standards without commensurate benefits (NZIER 2005). For example:

- there were no additional health benefits from country of origin labelling as there were existing regulatory structures already in place to deal with health issues
- country of origin labelling would not improve product recall and tracking systems as there were existing systems in place
- mandatory labelling would not improve consumer trust in the food system from the additional information as, if there was an appreciable benefit from country of origin labelling, suppliers would do so on a voluntary basis
- there appeared to be limited social value in the 'consumers right to know' from country of origin labelling as retailers and producers in both New Zealand and Australia reported that there was no large latent demand for such information.

Source: NZIER (2005), Krissoff et. al (2004).

The Commission agrees with both of these proposed changes and further suggests more positive reporting may be possible by having the Chair of the Ministerial Council manage the business of the Ministerial Council so as to comply with the regulatory guidelines. This should also extend to ensuring that all regulatory proposals comply with an adequate RIS unless exceptional circumstances apply. Such an approach would improve consistency and transparency of decision making and bring the guidelines into the regulatory framework relating to food. It would also strengthen a key objective of the *Food Standards Australia New Zealand Food*

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*Act 1991*, which is to provide ‘an effective, transparent and accountable regulatory framework within which the food industry can work efficiently’.

RESPONSE 3.4

***The Australia New Zealand Food Regulation Ministerial Council (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.***

### **3.5 Food regulation and public health**

There is a broader question surrounding food regulation and public health. That is, what role should food regulation play in meeting national health objectives? One view is that food regulation should be used to address a range of diet-related national health issues such as obesity, excessive alcohol consumption, heart disease and type 2 diabetes. For example, Choice (sub. DR 61) said that public health and safety should address more than just food-borne illness and as obesity is one of Australia’s major health problems, obesity prevention should underpin all food regulation.

Others, such as Qrtsa – The Retailers Association (sub. 1), were of the view that food regulation should address food safety and that using food standards to require specific ingredients be added to food for public health reasons was akin to mass medication. Some, such as Australian Beverages Council (sub. 33), were critical of elements of food regulation that took a ‘good food/bad food’ approach rather than supporting a healthy balanced diet approach.

VCEC (2007) drew attention to what it described as the ‘fuzzy dividing line’ between food safety and public health issues. For example, the consumption of small amounts of food high in saturated fats may pose little or no health risk for most people, whereas consuming large amounts of these types of foods over a period of time is likely to lead to less benign health outcomes in relation to heart disease, obesity and type 2 diabetes which are of increasing concern in Australia.

Food regulation may not be the only, or most efficacious, means of meeting national health objectives. Before reaching such a conclusion it would be appropriate for the full range of options for addressing public health issues to be examined in a broad



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context prior to any consideration by the Australia New Zealand Food Regulation Ministerial Council. Otherwise, given the remit of the Ministerial Council, any public health issues considered by that forum are constrained to be dealt with as matters of food regulation alone when better options beyond food regulation may exist.

The Commission concurs with VCEC (2007) that these public health issues are national issues and should be addressed at the national level and that policy makers need to be clear about the underlying problems to be addressed and the required policy outcomes. It notes there are three Ministerial Councils (Health, Community and Disability Services; Food Regulation; and Drug Strategy) the membership of which consists largely or solely of health ministers. In the Commission's view, it would be appropriate that all national health policy issues be first dealt with by Health Ministers meeting in their capacity as members of the Australian Health Ministers' Conference, with any policy matters relating to food regulation being subsequently referred to and considered by the Australia New Zealand Food Regulation Ministerial Council.

This approach would be underpinned by the Australian Health Ministers' Advisory Council, or a specialist body on its behalf, examining a wider range of, and possibly lower cost, policy options (other than food regulation alone) to address public health issues. This would ensure that national health objectives are initially addressed outside the food regulation framework. It would also better separate food safety issues from public health issues and ensure that the focus of the Australia New Zealand Food Regulation Ministerial Council remained on developing safe food controls. Given the overlap in membership of the Health Ministers' Conference and the Australia New Zealand Food Regulation Ministerial Council there is clearly scope to develop a coordinated approach to ensure appropriate and effective policy responses, including the use of food regulation, are developed.

RESPONSE 3.5

***The Australia New Zealand Food Regulation Ministerial Council (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.***

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## 3.6 Nutrition, health and related food claims

There were a number of concerns surrounding the proposed regulation of nutrition, health and related food claims, particularly those indicating the food was free of a certain ingredient.

The Confectionery Manufacturers of Australasia (sub. 32) was concerned that the proposed food standard in relation to nutrition, health and related claims would make it difficult for the industry to make health claims. It advocated that all foods should be permitted to carry health claims provided they were accurate and could be scientifically substantiated.

In particular, it was concerned that under the proposed draft standard (P293) to the Food Code the claim of food being ‘sugar free’ would not be prescribed in the standard, but be regulated through consumer protection legislation dealing with misleading and deceptive conduct. At present, the Food Code does not prescribe ‘free’ claims, but under the existing voluntary Code of Practice on Nutrient Content Claims (CoPoNC) the claim of ‘sugar free’ means no more than 0.2g of sugar(s) per 100g of food. CMA said:

Omission of *sugarfree* terminology from food law is also inconsistent with international food law practice, where the US, European Union and Codex allow food containing nutritionally insignificant amounts of sugar(s) to be labelled as *sugarfree* with up to 0.5% sugar(s). This practical view recognises the limitations of technology, while at the same time keeps a reasonable perspective under on what is physiologically insignificant. (sub. 32, p. 2)

CMA’s view (sub. 32) was that if ‘sugar free’ claims were regulated by the consumer protection provisions of the *Trade Practices Act 1974* (TPA), the Australian Competition and Consumer Commission (ACCC) was likely to move to a zero tolerance stance and ‘sugar free’ would then become a no detectable sugar claim rather than the current qualified amount of insignificant sugar. The CMA concluded by calling for the current qualified ‘sugar free’ claim of no more than 0.2g of sugar per 100g of food to be included in the draft standard to be considered by the Ministerial Council. This would provide greater consistency between domestic and international standards and greater certainty for industry and protection for consumers.

In its submission on the draft report, the CMA (sub. DR65) again called for the draft standard to use the threshold of sugar free of 0.2g of sugar per 100g of food. It said that introducing sugar free claims as zero sugar would have a negative impact on the confectionery industry including inconsistency with international food standards and local producers having to meet higher standard in competing with imports if border controls were not enforced. It also said that there had been no consumer

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complaints to date and that industry compliance with the existing voluntary standards was reasonable.

The CMA (sub. DR65) pointed to a number of costs if the proposed standard was implemented including the costs of relabelling, the uncertainty surrounding testing as technology increases sensitivity levels, stifling of innovation, withdrawal of importers from the market and the risk of future litigation.

A similar situation arises in the use of ‘gluten free’ claims. The Coeliac Society of Australia (DR46) noted that the definition of the term ‘gluten free’ varies throughout the world and was concerned that the proposed standard would define ‘gluten free’ as requiring no detectable gluten. It called for ‘gluten free’ to be less than 20 ppm in line with overseas standards and said:

The testing methods for gluten have improved over the past ten years and the limit of detection is now 5 ppm. So for a product to be labelled gluten free in Australia it must contain less than 5 ppm. Accordingly products labelled gluten free in Europe may not necessarily be gluten free in Australia. (sub. DR46, p. 1)

The Coeliac Society also noted that it will become increasingly difficult to ensure products are completely free of an ingredient as testing procedures became more sensitive. It said:

Of more concern is the fact that as analytical testing becomes more sensitive, the level of detection may decrease to 1 ppm and it may be difficult, because of cross contact, for any product to be labelled gluten free. (sub. DR46, p. 1)

The AFGC were concerned that the ‘gluten free’ claims would have adverse impacts on food producers:

The small size of the Australian domestic market limits the opportunity for manufacturers to produce a range of products specifically designed to comply with Australian legislation. The range and variety of gluten-free foods in Australia is therefore relatively small due to the substantially tighter restrictions under the Food Standards Code on the requirements for gluten-free foods compared to Europe and the United States. While this limits choice for the consumer, it also reduces competition within the food industry. (sub. DR58, p. 16)

Fonterra was concerned that ‘fat free’ and ‘no fat’ claims would continue to be regulated and enforced through the misleading and deceptive conduct provisions of the TPA. It said:

Food legislation in the USA, European Union and *Codex alimentarius* allows for labels of “sugar free” and “fat free” when the level is under that which is physiologically insignificant. (sub. DR57, p. 9)

The AFGC (sub. DR58) were highly critical of the proposed standard in general including that it:

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- is very long and extremely complex running to almost 50 pages which makes it the longest standard yet developed by FSANZ;
  - is highly prescriptive for the process for determining claims which might be made, and subsequently how to make them;
  - is highly restrictive limiting the conditions for making claims;
  - increases regulatory burden threatening to prohibit claims which are currently made on food labels, without demonstrating that they are currently misleading consumers or threatening public health and safety;
  - lacks a scientific basis through the introduction of a Nutrient Profiling Scoring Criteria (NPSC) scheme and substantiation approaches to determine if claims can be on food packages; and
  - is likely to result in a *de facto* prohibition on claims for many companies not able to afford the resources required to determine whether food products may be able to make claims. In doing so it is anti-competitive. (sub. DR58, p. 13)

There were also more general concerns raised with the Commission during consultations that the regulations surrounding health claims on food and beverages were stifling the introduction of new products on to the market and the competitive position of manufacturers and suppliers. For example, Fonterra (sub. DR57) expressed concerns that innovation and new product development in ‘no fat’ and ‘low fat’ dairy products would be stifled by the proposed regulation in contrast to overseas markets where these claims allowed for physiologically insignificant amounts of these ingredients.

In contrast, Choice was highly critical of the use of health claims:

For many years CHOICE has opposed the use of health claims on food labels. We believe that they are little more than marketing messages encouraging consumption of processed foods because of their potential health benefits. In reality, it is unlikely that an individual product will deliver a health benefit. Yet, the food industry and regulators have previously defended health claims on food labels suggesting that they would assist consumers to make healthy choices thus improving public health. (sub. DR61, p. 7)

## Assessment

At present, the Food Code prohibits the use of most health claims in regard to food, but allows nutrition related claims (eg this food is high in fibre). Voluntary codes of practice such as the CoPoNC, provide further guidance to manufacturers. All claims relating to food, including ‘free claims’ are subject to consumer protection legislation.

To remove ambiguity and uncertainty, the Ministerial Council released policy guidelines on nutrition, health and related claims in December 2003. In response,

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FSANZ has developed a draft standard (P293) following extensive public consultations, the use of advisory groups, stakeholder forums and the publishing of a preliminary report outlining the draft standard. A final assessment report was released in April 2008 and after being considered by the Ministerial Council was returned to FSANZ for review in June 2008. The grounds for review included that the standard was inconsistent with existing policy guidelines, does not protect public health and safety, places unreasonable costs on industry and consumers, is difficult to enforce and comply with and is inconsistent with the objectives of the legislation establishing FSANZ (ANZFRMC 2008).

The proposed standard will identify three types of claim:

- Nutritional content claims — describing what is in a food product, such as the presence of a certain nutrient or substance (eg this food is high in calcium).
- General level health claims — describing the function of the food, nutrient or other substance in relation to a health effect (eg helps keep you regular as part of a high fibre diet). These claims do not refer to a serious disease or biomarker of a serious disease.
- High level health claims — describing the function of the food, nutrient or other substance in relation to a serious disease (eg this food is low in sodium. Diets low in sodium may reduce the risk of elevated blood pressure).

All claims are required to be substantiated. For general level health claims, suppliers are required to hold the necessary records to support such claims for possible review by enforcement agencies. High level health claims must be pre-approved by FSANZ and based on a substantiated food-disease relationship.

In regard to ‘free claims’, FSANZ (2008a) recommended that apart from certain fatty acids, gluten, lactose and cholesterol — due to limitations on analytical testing methods — the draft standard should not provide conditions or tolerances for free claims.

As part of the draft standard, FSANZ has developed conditions for ‘low in gluten’ claims of 20 mg of gluten per 100g of food. This was based on international agreement by the medical profession during the development of the draft standard that this amount of gluten was tolerated by most people with coeliac disease. These conditions would also enable manufacturers and producers to make a gluten claim where it cannot be guaranteed that the food meets the ‘free’ claim. Further information would also be provided to consumers through average quantity of gluten being contained in the nutrition information panel. FSANZ acknowledged that there were potential difficulties associated with the ‘no detectable’ criteria for ‘gluten free’ claims, but specifying a threshold level of gluten to be permitted in

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‘gluten free’ foods would be contrary to consumer protection legislation requiring that information is not false, misleading or deceptive (FSANZ 2008a).

The FSANZ rationale was that all ‘free’ claims should continue to be regulated and enforced through the misleading and deceptive conduct provisions of the Trade Practices Act. This would avoid inconsistency between the Food Code and the Trade Practices Act. It noted that the ACCC’s and the New Zealand Commerce Commission’s interpretation of *free* is that *free* means ‘zero’. As such, it would be misleading under consumer protection/fair trading legislation to include a free claim on a product containing a detectable quantity of a specified substance. (FSANZ 2008a).

However, the proposed draft standard (P293) enables food manufacturers to use alternative claims to ‘free’ such as ‘99.5 per cent fat free’ or ‘contains less than 1 per cent fat’ as well as ‘low in fat’ and ‘reduced fat’ and ‘low in gluten’ setting out the specific conditions attached to such claims. Similar conditions are set out in relation to claims concerning sugar such as ‘low sugar’, ‘reduced sugar’ and ‘no added sugar’ (FSANZ 2008a). Consequently, these conditions surrounding health and nutrition related claims will provide greater certainty for food manufacturers and suppliers in complying with consumer protection legislation.

Nevertheless, in dealing with the proposed draft standard, regulators will need to be aware that as sensitivity in testing improves, maintaining ‘zero’ and ‘no detectable’ quantities of certain ingredients in food due to cross contamination will become increasingly difficult for food manufacturers. Under such a scenario, tolerance levels for free claims may have to be specified and included in the TPA, as well as the Food Code, to ensure that such claims are consistent with the relevant provisions of the TPA.

Finally, the Commission notes that these regulations are only proposed and are currently being reviewed by FSANZ at the request of the Ministerial Council. As such, it is unclear as to what the final standard will contain when implemented and its actual impact on producers and consumers.

### **3.7 Labelling requirements impacting on pick ‘n’ mix confectionery**

The CMA (sub. 32) was concerned that there would be costs imposed on confectionery manufacturers from the proposal (P272) to the Food Code being developed by FSANZ relating to the labelling requirements for food for catering purposes and retail sale which, would include pick ‘n’ mix confectionery. This

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proposal would require that labelling requirements be included on small packaged items including pick ‘n’ mix confectionery items such as chocolates served in restaurants with coffee and in hotel bed ‘turndowns’.

The CMA commented that such labelling was impractical as pick ‘n’ mix confectionery wrapper and formats had limited surface area on which to print the information. It also noted that implementing this labelling would be costly to manufacturers and said:

The affected products range in size from 10-50 cm<sup>2</sup> in surface area and weigh between 5-15g. In order to comply, companies will need to re-originate packaging, incur capital investment for new technology and there would also be ongoing costs associated with the loss of production efficiency.

The re-origination of new labelling is estimated to cost from \$4000 per item and amount to a sum of \$150,000 to \$200,00 for some companies. (sub. 32, p. 4)

It went on to say that the approach of the majority of businesses in the industry has been not to label in accordance with the requirements of a small package well before the new Food Code came into operation in 2000 (sub. 32).

The CMA (sub. 32) concluded that wrapped pick ‘n’ mix confectionery should be treated in the same manner as its unwrapped counterpart and be exempt from labelling requirements. To this end, the CMA has placed an application with FSANZ to amend the proposed standard.

## **Assessment**

The proposal developed by FSANZ (P272) in regard to labelling requirements for food for catering purposes and retail sale was to provide improved clarity and certainty to the Food Code without additional labelling requirements (FSANZ 2007). The proposal was put to the Ministerial Council in July 2007. The Council then requested that FSANZ conduct a first review of the proposal on the grounds that it placed unreasonable cost burdens on industry and consumers, was difficult to enforce or comply with in practical and resource terms and did not provide adequate information.

The review was completed in December 2007 and FSANZ reaffirmed its original proposal. It responded that the proposal retained the status quo for the labelling of small packages and would therefore not add to costs as there were no additional regulatory requirements.

It said:

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Following best practice regulation FSANZ has undertaken a comprehensive assessment of the impacts of the regulatory options on business, government and individuals and found that the preferred regulatory option has only negligible impacts and compliance costs. This indicates that even where there are proposed changes to the Code because of Proposal P272, these are predominantly technical in nature and generally require little or no change to current requirements, resulting in little or no additional cost to those currently complying with the Code. In the case where there may be some minor costs associated with the proposed amendments these are commensurate with the risk that is being managed. The Office of Best Practice Regulation reviewed the Final Assessment Report and the impact analysis and supports FSANZ's view. (FSANZ 2007, p. 15)

In regard to confectionery, FSANZ commented that such items could not be considered in isolation as other small packaged food portions such as cheese and spreads were subject to similar requirements (FSANZ 2007).

It concluded that the labelling requirements for small packages have been in place for many years and the proposal would not change the current situation in respect to compliance and enforcement of the Food Code. However, it did note that amending the application of these generic labelling requirements in regard to small packages, such as pick 'n' mix confectionery, should be dealt with separately.

As such, the industry concerns surrounding the labelling of small packages should be addressed by seeking to amend these generic requirements through an application to FSANZ. Indeed, the CMA (sub. 32) indicated that it has an application underway to amend the Food Code.

## **3.8 Other issues**

### **New Zealand**

There were concerns that New Zealand was provided with a competitive advantage in respect to food manufacturing due to the Trans-Tasman Mutual Recognition Arrangements (TTMRA). For example, the CMA said:

... New Zealand food producers operate with an advantage over their Australian counterparts as New Zealand dietary supplements are permitted to be sold in Australia, whereas Australian producers are not permitted to do the same. (sub. 32, p. 6)

Cadbury Schweppes (2007) commented that:

Certain formulated beverages and energy beverages can legally be manufactured in New Zealand but not in Australia. Under the Treaty [TTMRA], a product that may be legally sold in one country may be sold in the other. For example, a product that complies with the New Zealand dietary supplements regulations can be imported into



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New Zealand and once it has cleared customs, it can be trans-shipped to Australia. Some imported beverages are being sold in Australia as a result of this loophole. (p. 3)

These ‘loopholes’ and exemptions are to be examined by the Commission’s review of the Trans-Tasman Mutual Recognition Arrangement.

A further issue is that there are parts of the Food Code not followed by New Zealand such as CoOL, discussed above, and primary production standards. This could present problems for firms operating in both Australia and New Zealand.

However, this reflects the agreement between Australia and New Zealand for the establishment of joint food standards which provides for New Zealand to vary food standards adopted across Australia. As noted in the agreement, there may be specific geographical, environmental, trade and cultural circumstances that require variation or non-adoption of the standards. In others, non-adoption would appear to be at odds with the objective to develop joint Australia New Zealand food standards and an option unavailable to other jurisdictions subject to the standards.

### **Measurement in the filling of packaged food**

The use of average quantity system (AQS) as opposed to the current minimum quantity system (MQS) in the filling of packaged food products was also raised as an issue.

The CMA (sub. 32) noted that moving to AQS would result in a significant reduction in overfill of products and savings for manufacturers. Cadbury Schweppes (2007) commented that the adoption of the AQS would bring Australia into line with its major trading partners, including Japan, the United States, the European Union and New Zealand. It would also result in a significant reduction in the overfill of products and subsequent cost savings for Australian food manufacturers. Inconsistencies in this area also impede market access and impose costs on Australian manufacturers producing for export markets. VCEC (2007) noted that the use of MQS was at odds with Australia’s international treaty obligations under the International Convention on Legal Metrology, under which there are obligations to adopt AQS for international trade in prepacked goods.

There is progress in this area. In 2007, COAG endorsed the development of a national trade measurement system. The proposal to introduce the AQS has been referred to the Australian Government for inclusion in the proposed national trade measurement system (Victorian Government 2008). The legislation to create this system, which will be administered by the Australian Government, is due for passage in 2008 and implementation from July 2010 (BRCWG 2008). In

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responding to the draft report, the CMA (sub. DR65, p. 2) was, ‘keen to ensure that the processes are complete that enable industry adoption by 1 July 2010, or earlier, as there has already been a long standing commitment to adopting AQS’.

## **Export Orders and Primary Production Processing Standards**

Australian Dairy Industry (sub. 26) was concerned that the incorporation of Primary Production Processing Standards (PPPS) for dairy products into the Food Code would create separate regulatory systems for domestic and export markets. The PPPS for dairy products is being implemented over a two year period with full compliance required from October 2008. The Export Control (Milk and Milk Products) Orders regulate dairy exports.

In the draft report, the Commission noted that the Australian Quarantine and Inspection Service (AQIS) had commenced incorporating the PPPS for dairy products into the Export Control (Milk and Milk Products) Orders to harmonise domestic and export requirements for dairy products and to simplify the system. This was to be achieved by way of reference to the PPPS in the Orders. The amended Orders were to come into effect in October 2008.

In response to the draft report, Australian Dairy Industry (sub. DR50) called for the proposed Dairy PPPS to be the single standard for both domestic and export dairy product manufacturing.

Although AQIS has indicated it will incorporate the Dairy PPPS into the Milk Orders, this will not itself lead to regulatory streamlining. ...

With full implementation of the Dairy PPPS on 5 October 2008, the Dairy PPPS should be the single and only Australian standard for dairy product manufacturing for domestic and export (the model recommended by the *Export Assurance Report 2000*). (sub. DR50, p. 7)

AQIS has put on hold any further work on integrating the Dairy PPPS into the Export Control Orders at the request of industry and state regulatory authorities. AQIS said:

At the meeting of the Dairy Export Consultative Committee in April 2008, the industry and State Regulatory Authorities put on hold the process to integrate the Standard 4.4.2 [Dairy PPPS] into the orders. (sub. DR73, p. 1)

Governments of importing countries often impose requirements different or additional to the Australian standards. As AQIS noted:

... governments in countries importing Australian dairy products have a right to impose requirements that are different from Australian standards and are more prescriptive than Australian standards. Australian government authorities continuously negotiate the

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acceptance of Australian standards as equivalent with importing country requirements, but are not always successful. (sub. DR73, p. 1)

It went on to say:

At this stage the PPPS, Standard 4.2.4. is not acceptable to overseas markets as the single and only Australian standard for dairy product manufacturing for export. (sub. DR73, p. 3)

Although a single standard for domestic and export production would be desirable for industry, there is likely to be a need to meet any additional requirements specified by the importing country — a situation recognised by the National Competition Policy review of the *Export Control Act 1982* (Frawley *et al.* 1999).

For these reasons, the review of the *Export Control Act 1982* recommended the adoption of an integrated three tier export assurance system consisting of a first tier of Australian Standards harmonised with international standards, a second tier of importing country requirements/conditions not covered by Australian Standards and a third tier of emergency or special requirements. These recommendations were subsequently endorsed by the Australian Government (DAFF 2001).

### **Compliance guidelines for Primary Production Processing Standards**

Australian Dairy Industry also expressed concern that that the guidelines for the Dairy PPPS, which will come into effect in October 2008, were overly prescriptive and called for minimum risk-based effective regulation in this area. It said:

Dairy argues that industries under productivity and competitiveness pressures (and their regulators) need to work to develop basic Compliance Guidelines associated with Standards. The regulatory system needs to identify that these are base Guidelines only – not prescriptions or requirements. Guides should not stand in the way of innovation.

Applying views on ‘best practice’ is a commercial decision not for regulation regimes. Guidelines are often referred to in Standards or other instruments and are regulatory. (sub. DR50, p. 5)

The guidelines contained in the Guide to Primary Production and Processing Standards for Dairy (FSANZ 2008b) are not legally binding and the examples provided are only to illustrate how a certain standard might apply. Nevertheless, regulators need to be mindful that such guidelines do not ‘evolve’ into quasi-regulations. Indeed, where guidelines are treated as prescriptions or requirements there is not only unintended regulatory coverage, but also the risk of over-compliance on the part of those being regulated and a possible check on innovation and ‘best practice’ on the part of industry in meeting the standards.

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However, it is unclear how these guidelines will be interpreted as the Dairy PPPS are not yet operational.

### **Quarantine regulations**

Woolworths (sub. 25) were concerned that quarantine regulations created significant regulatory burdens in regard to the importation of certain foods and products. It said:

... Commonwealth food quarantine regulations should be reviewed to ensure that restrictions are only imposed where the burden is justified by the level of risk the regulation is seeking to address. (sub. 25, p. 6)

The Australian Government has commissioned an independent panel (the Beale Review) to review Australia's biosecurity and quarantine systems. The Review is to provide recommendations on the appropriateness, effectiveness and efficiency of these systems and is to report to the Minister for Agriculture, Fishing and Forestry by the end of September 2008 (Burke 2008).

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## 4 Therapeutic goods regulation

### 4.1 Overview of regulation

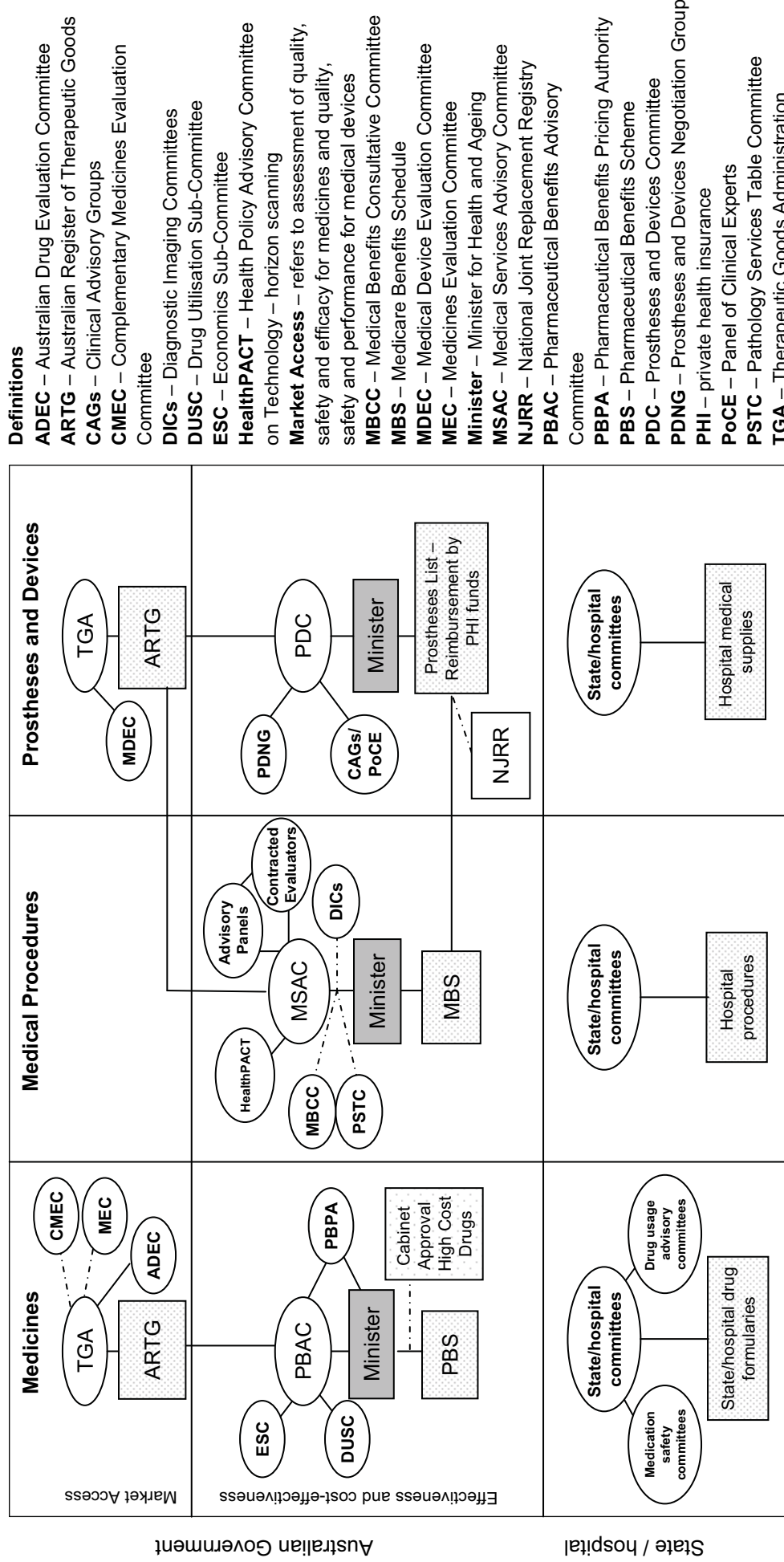
Regulatory control of the standard of therapeutic goods (medicines and medical devices) is provided by the *Therapeutic Goods Act 1989* (the Act) and associated regulations, orders and standards. The regulatory framework — which applies nationally, with provisions adopted into state and territory legislation as relevant — seeks to safeguard the community from substandard, unsafe or ineffective therapeutic goods.

Responsibility for the regulatory system, and administration of the Act and associated regulations and orders, lies with the Therapeutic Goods Administration (TGA), a unit within the Department of Health and Ageing (DOHA). Various other regulatory agencies and advisory bodies form part of the overall regulatory framework (see discussion below and figure 4.1). In the overview of the regulatory framework for medicines (below) and for medical devices in section 4.3, the Commission has described the roles of selected bodies only, focussing mainly on those considered most relevant to the specific concerns that have been raised.

A ‘therapeutic good’ is broadly defined in the Act as a good which is represented in any way to be, or is likely to be taken to be, for therapeutic use. Therapeutic use means use in or in connection with: preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury; influencing inhibiting or modifying a physiological process; testing the susceptibility of persons to a disease or ailment; influencing, controlling or preventing conception; testing for pregnancy; or replacement or modification of parts of the anatomy. A snapshot of the Australian therapeutic goods industry is provided in box 4.1.

The TGA carries out a range of assessment and monitoring activities to ensure therapeutic goods available in Australia are of an acceptable standard. TGA is concerned with ensuring the quality, safety and efficacy of therapeutic goods (but not cost effectiveness). It charges, on a full cost recovery basis, for services provided to industry, such as processing of applications for inclusion on the Australian Register of Therapeutic Goods (ARTG), good manufacturing practice audits and annual licensing.

Figure 4.1 Current Health Technology Assessment Processes in Australia, Simplified



Adapted from Productivity Commission Research Report 2005, *Impacts of Advances in Medical Technology in Australia*, Overview, page XLVII.

Note: for clarity, the HTA conducted by private hospitals, private health insurers, and for special access schemes have been excluded from this figure. Also excluded are the interactions between public and private hospitals. Note that the Departments of Veterans Affairs and Health & Ageing administer services specifically for veterans which also may involve HTA.

Source: Department of Innovation, Industry, Science and Research.

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## Box 4.1 Australian therapeutic goods industry

### Medicines

The Australian medicines industry spans a range of activity from human-use prescription medicines through to the production of generic over the counter medicines and complementary medicines — which includes herbal medicines; vitamin, mineral and other nutritional supplements; traditional and homoeopathic medicines. It includes Australian-owned companies and international companies with headquarters overseas.

The Australian pharmaceutical medicines industry:

- comprises approximately 1 per cent of the world market, with turnover of \$18 billion
- employs 40 000 people across at least 300 firms and institutions, including manufacturing, research and wholesaling — approximately 14 000 employed directly in the pharmaceutical manufacturing industry
- supplies 80-90 per cent of its output via the Pharmaceutical Benefits Scheme (PBS) to individuals, but there is also a large supply via hospitals
- is concentrated, with the top 20 companies (primarily large multinational corporations) accounting for more than 85 per cent of PBS sales
- exports were approximately \$3.9 billion in the 12 months to December 2007, making pharmaceuticals Australia's second largest manufactured export (DIISR 2008)
- spent around \$752 million on research and development in 2005-06 (DIISR 2008) — medicines typically have a long investment recovery period.

Reliable statistics on the complementary medicines industry are hard to find because of definitional difficulties and no comprehensive survey has been carried out. However, a handful of large companies dominate product manufacture and supply, with the remainder of the industry comprising a large number of very small companies. Total retail sales are in excess of \$1 billion.

### Medical devices/technology

The medical technology industry in Australia has an annual turnover of \$4.75 billion and earns an export income of \$1.75 billion (in 2006-07). The industry comprises a small number of global multinational companies (approximately 20 per cent of the industry) and a large number of small and medium sized enterprises (80 per cent of the industry). The Australian market is small — less than two per cent of the global market for medical technologies (MTAA, sub. 23, p. 2). The industry has at least 10 000 employees in about 1100 companies. Australia exports most of the medical devices produced, yet imports most of the medical devices consumed. Medical devices typically have a short investment recovery period.

*Sources* Medicines Australia, sub. 35, pers. comm., 5 February 2008 and (<http://www.medicinesaustralia.com.au/pages/page4.asp>, accessed 5/2/08); Medical Technology Association of Australia, sub. 23, DIISR 2006, DIISR 2008, DIISR, pers. comm., 8 August 2008, DITR 2006.

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The TGA also aims to ensure that the Australian community has access, within a reasonable time, to therapeutic advances and that unnecessary business compliance costs are avoided.

The regulatory framework is based on a risk management approach designed to ensure public health and safety, while at the same time freeing industry from any unnecessary regulatory burden. (DOHA 2008a)

It is evident from submissions that industry participants clearly recognise that any initiatives aimed at reducing regulatory burden must not compromise the need to maintain appropriately high standards of public health and safety.

Therapeutic goods are broadly divided into medicines and devices. In 2002, new regulatory arrangements for devices were introduced which differed in significant ways from the arrangements that continued to operate for medicines. The rest of this section outlines regulatory arrangements for medicines. Devices regulation is covered in section 4.3.

## **Medicines regulation**

Australian manufacturers of medicines must hold a licence that is issued by the TGA. To obtain a licence the manufacturer must demonstrate adherence with internationally recognised manufacturing principles in the Australian Code of Good Manufacturing Practice (GMP).<sup>1</sup> The principles cover how medicines should be made, the standards that should be adhered to and the processes in place to provide assurance that each batch of a therapeutic good is safe and reliable and of consistent high quality. Before a licence is granted, Australian manufacturers are subjected to an audit by the TGA and, once licensed, are regularly audited to ensure that necessary standards are maintained. Overseas manufacturers of medicines imported into Australia are required to operate to standards equivalent to those expected of Australian manufacturers. They are either subject to similar licensing requirements in their own country (and the TGA makes an assessment of specific documentation) or they are audited by TGA inspectors where necessary.

Under the approval process, all medicines are required to be included in the ARTG before they can be supplied in Australia.<sup>2</sup>

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<sup>1</sup>The Australian Code is based entirely on the international standard published by the Pharmaceutical Inspection Co-operation Scheme (PIC/S) which is harmonised with the EU Guide to Good Manufacturing Practice for Medicinal Products and its Annexes.

<sup>2</sup> The ARTG is a computer database of information about therapeutic goods for human use approved for supply in, or exported from, Australia. Some goods captured by the Act are classified as 'exempt goods' and are not entered on the ARTG.



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The Register has two parts: one for ‘registered goods’ and the other for ‘listed goods’. In general, medicines are:

- ‘registered’ if assessed as having a higher level of risk (prescription medicines and some non-prescription medicines), requiring rigorous and detailed examination of quality, safety and efficacy by the TGA before market entry<sup>3</sup> or
- ‘listed’ if they are lower risk medicines (consumer medicines purchased over the counter such as complementary medicines, including herbal, vitamin and mineral products) — requiring an assessment of quality and safety by TGA.<sup>4</sup>

The Act, regulations and orders set out the requirements for inclusion of medicines in the ARTG, including advertising, labelling, product appearance and appeal guidelines. Products are issued with a certification of registration or listing prior to supply.

An independent statutory body — the Australian Drug Evaluation Committee — provides advice to the Minister and the Secretary of DOHA, through the TGA, on the suitability for marketing of prescription medicines in Australia, including:

- the quality, risk-benefit, effectiveness and access within a reasonable time of any medicine referred to it for evaluation
- medical and scientific evaluations of applications for registration of prescription medicines (for example, new chemical entities, new forms of previously registered medicines and therapeutic variations to registered medicines).

Post marketing monitoring and surveillance by TGA concentrates on checking safety and efficacy of products already on the Australian market through systems of adverse drug reactions and problem reporting, laboratory testing, and surveillance of product advertising. There are a variety of mechanisms for this task including the Adverse Drug Reaction Committee.

Some regulatory provisions, such as the scheduling of substances and the safe storage of therapeutic goods, are covered by the relevant state or territory legislation.

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<sup>3</sup> This requires manufacturers or importers to provide comprehensive scientific data to the TGA, which carries out independent assessments of the data. The main considerations are pharmaceutical chemistry and toxicological studies undertaken prior to the conduct of clinical trials and assessment of data from clinical trials.

<sup>4</sup> In assessing the level of risk, factors such as the strength of a product, side effects, potential harm through prolonged use, toxicity and the seriousness of the medical condition for which the product is intended to be used, are all taken into account.

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## *Pharmaceutical Benefits Scheme*

Most prescription medicines in Australia are supplied through the Pharmaceutical Benefits Scheme (PBS). The Government subsidises PBS medicines so as to allow Australian patients access for a low standardised patient co-payment. Medicines have to be registered before they can be considered for inclusion on the PBS.

The Pharmaceutical Benefits Advisory Committee (PBAC) makes recommendations to the Minister about which medicines, medicinal preparations and vaccines should be listed on the PBS. The PBAC is an independent expert body established under the *National Health Act 1953* and its membership includes medical practitioners, pharmacists, consumers and health economists. It is supported by two sub-committees:

- the Drug Utilisation Sub-Committee, which primarily advises the PBAC on use and financial forecasts for major medicine submissions
- the Economics Sub-Committee, which primarily advises the PBAC on cost effectiveness aspects of major medicine submissions.

In submissions to the PBAC companies are required to do a full evaluation, providing evidence of the efficacy and safety of a new patented medicine as well as a cost-effectiveness analysis demonstrating that having the medicine on the PBS represents value for money for the taxpayer.<sup>5</sup> The PBAC's assessment is based on the submission of the company and an evaluation by an external academic group.

If the PBAC recommends the product for listing on the PBS, then the information is sent to the Pharmaceutical Benefits Pricing Authority (PBPA) which makes recommendations to the Minister on the price and conditions of supply under the PBS. Companies have to make submissions to the PBPA and engage in pricing negotiations.

Within the PBS there are specifically defined therapeutic groups of medicines which have similar safety and health outcomes. Within these groups, the medicines can be interchanged at the patient level. If the PBAC's analysis merely establishes equal effectiveness, then consistent with the objective of minimising costs, a newly listed medicine's initial reimbursement price is linked to the lowest in the relevant price reference group. The difference in price between the lowest priced medicine and higher priced medicines within the group is called a therapeutic group premium, this is paid by the patient. There is always at least one drug within each group of

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<sup>5</sup> Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee (Version 4.2, December 2007) (DOHA 2007a).

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medicines available without a premium. The PBPA reviews the PBS price of every listed medicine at least once a year based on their therapeutic group.

Marketing of medicines is heavily regulated, including how medicines can or cannot be marketed to the community and health professionals. There is a ban on the advertising of prescription medicines direct to consumers.

## 4.2 Concerns about regulation of medicines

Numerous specific concerns were raised about the regulation of medicines by a small number of participants. Taken as a whole, the issues suggest the need for significant reforms to improve the timeliness, transparency and consistency of assessment and approval processes, in particular the time taken from registration of medicines to eventual PBS listing. More efficient and timely processes have the potential to:

- reduce compliance burdens and lost marketing opportunities for business
- reduce administration costs for regulatory agencies, resulting from current overlap and other inefficiencies
- provide quicker public access to innovative medicines with potentially significant health benefits and savings in public health costs.

Many of the concerns have been recognised by previous reviews and in some cases the Government had agreed to the need for changes. However, progress in implementing reforms to address these unnecessary burdens has been slow.

In addition to the specific concerns raised, Pfizer (sub. 31) Australia emphasised the need for better compliance by the various regulators that govern its activities with regulatory best practice principles more generally, including:

- fairness
- transparency
- consistency in decision making and advice
- accountability
- a focus on outcomes
- creating certainty for all stakeholders
- decisions about the quality, safety, efficacy and cost-effectiveness of medicines should be based on objective scientific evidence and on rigorous statistical methods

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- duplication should be minimised and, where possible, eliminated.

### **Requirement for multiple ethics approvals**

Pharmaceutical companies that undertake clinical trials in multiple states/territories in Australia need to obtain ethics clearance from the respective human research ethics committees in each jurisdiction.

Medicines Australia claimed that this ‘adds unnecessary burden on the industry in having to navigate its way through the different regulatory and approval processes as the applications for clinical trials need to be tailored for each jurisdiction’ (sub. 35, p. 5).

#### *Assessment*

Scientific and ethical reviews of research proposals are important steps in the approval of research involving humans in Australia.

Research on humans is approved by human research ethics committees before being allowed to commence. Where approvals from multiple ethics committees are required the process can impose significant unnecessary compliance costs for companies. It can also cause delays that slow access to new treatments and, in extreme cases, can lead to the abandonment of research.

The National Health and Medical Research Council (NHMRC) — an independent statutory agency, which provides advice on ethical behaviour in health care and in the conduct of health and medical research, including research involving humans (clinical trials) — has been working on a number of initiatives to make the research approvals process more efficient and effective.<sup>6</sup> In particular, the Australian Health Ministers Advisory Council agreed in October 2006 that the NHMRC should establish a process for the harmonisation of multi-centre ethical review.

The NHMRC is not involved in the operational aspects of conducting reviews, but has been charged with developing a framework for the harmonisation of reviews involving multiple research centres. NHMRC’s work is informed by a reference group which includes Medicines Australia. The 2007 Federal Budget made \$5.6 million available to the NHMRC to establish a coordinated *national* system to

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<sup>6</sup> The NHMRC Australian Health Ethics Committee advises the NHMRC on ethical issues relating to health and develops guidelines to ensure that research is conducted in a professional and ethical manner. More broadly, the NHMRC is Australia’s principal agency for funding health and medical research and for developing health advice for the Australian community, health professionals and governments.

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streamline ethics reviews of cross-jurisdictional and multi-centre human research (NHMRC 2007).

A number of jurisdictions already have or are moving to establish human research ethics committees that are able to provide appropriate ethical and scientific review on behalf of all participating institutions *within* their jurisdictions. NSW was the first State to introduce a streamlined, multi-centre ethical approval process and there has been some evidence that ethical approval times have improved. Whilst such state initiatives are welcome, a coordinated nationally harmonised system is likely to maximise efficiency gains.

A consultant was commissioned by NHMRC to help develop an implementation plan and a report was presented to NHMRC in July 2007. The Pittman Report confirmed the importance of reform in this area:

A change to improve the process of approval for multi-centre research is critical, with Australia lagging behind other developed economies. In the UK, for example, multi-centre research ethics committees were formally established in 1997. (Pittman 2007, p. 4)

In its submission in response to the Commission's draft report, Medicines Australia acknowledged the work of the NHMRC and offered its ongoing support, but expressed concern about the lack of tangible progress since the release of the Pittman Report.

... there is a real need to urgently push forward with a national streamlined approach to multi-centre clinical trial approval as soon as possible. Medicines Australia calls for a clear work-plan and timeline for implementation to be set so that the new system should be ready to commence early in 2009. It is disappointing that the harmonisation work has not been completed, particularly given that NHRMC was explicitly given funding by the Federal Government in 2007 to complete this work. (Medicines Australia, sub. DR64, p. 6)

The NHMRC (sub. DR 63) provided an update on the status of the harmonisation project, including information on timelines and key commitments, including a commitment to full implementation by 2009-10. Currently NHMRC is conducting focus groups in all states and territories to determine stakeholder views on the critical elements of a harmonised system. Some of the issues being considered, include:

- recognition/accreditation of ethics committees
- insurance and indemnity
- costs and fees.

NHMRC has also committed to providing updates on the project on its website.

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A more centralised ethics approval process will reduce red tape and other compliance costs and facilitate faster access to new medicines. The Commission notes the current work of the NHMRC and encourages all governments to achieve full implementation of a national system by no later than the 2009-10 timeframe commitments set out by the NHMRC.

### **Timeliness and cost of manufacturing audits/GMP assessments**

Various concerns were raised relating to TGA processes for assessing manufacturers' compliance with Good Manufacturing Practice (GMP), including:

- the cost and time taken to conduct audits or desktop assessments can be excessive and uncertain:

Companies are frequently left waiting for months for such assessments ... Often the current GMP clearance has expired. Finally when clearances are received, they have short expiry times requiring companies to make new applications within a short time-frame. This is time and labour intensive as well as a costly regulatory burden. (Medicines Australia, sub. 35, p. 4)

The ability to recoup the application fee (many thousands of dollars including additional resources to prepare an application) as well as overall uncertainty of approval timeframes discourages new ingredient applications ... Although an extraordinary example ..., CHC submitted, on behalf of a number of members ... an application for a new ingredient (widely used as a traditional medicine overseas) for use in listed medicines in June 2003. The ingredient was gazetted for use on 31 July 2008; i.e. 5 years later. (Complementary Healthcare Council of Australia, sub. DR68, p. 3)

- insufficient recognition of overseas GMP audits/assessments — audits are repeated throughout many global regulatory authorities, but information is rarely shared and TGA is duplicating inspections conducted by overseas authorities (Medicines Australia, sub. 35).

For Pfizer, as a major international manufacturer, all of these additional requirements create significant duplication of effort. Plants now spend a great deal of time preparing for and participating in GMP audits. Currently, plants may be inspected by a European Union authority and a USA authority — and now the TGA can insist on inspecting the same site for exactly the same processes.

Our core concern — beyond the cost and inconvenience and uncertainty of multiple inspections — is that the principle of inspection has been lost. We have a duplication of effort and an increase in uncertainty for no increase in outcome (that is, safety and quality). (Pfizer, sub. 31, pp. 7–8)

There is concern that the recently revised ... Guidelines ... will lead to a significant increase in the number of actual overseas audit visits by MAB [Manufacturing Assessment Branch, now known as the Office of Manufacturing Quality]. This will add

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a considerable cost, time and regulatory burden to industry. (Medicines Australia, sub. 35, p. 4)

- uncertainty around expiry date for GMP clearances — there has been a recent change by TGA from expiry 3 years from last inspection to expiry based on a risk matrix which they do not make available to industry (Pfizer, sub. 31).
- difficulties obtaining documentary evidence of a standard acceptable to the TGA for desk-top audits of overseas manufacturing plants — including problems obtaining Establishment Inspection Reports (EIR), scope and confidentiality issues (reports are often edited and the TGA will not accept an edited EIR) (Pfizer, sub. 31, pp. 6–7).

In comments on the draft report, Johnson and Johnson Family of Companies (sub. DR70) stated that it generally shared the above concerns and also raised the following additional concerns:

- inconsistencies in the risk minimisation approach adopted by the Office of Manufacturing Quality:

... due to the TGA's inability to efficiently process large volumes of desktop audits applications, they have been granting, on a case-by-case basis, extensions of expired Clearances. Similarly, due to the shortage of auditors available to perform overseas manufacturer inspections, the TGA have been issuing GMP Pre-Clearances without prior inspection. Such practices, are inconsistent with the risk minimisation approach that the TGA is striving to adopt. Additionally, we feel that the TGA should not be implementing requirements that they do not have the adequate resources to cope with. (sub. DR70, p. 10)

- short response timeframes when random TGA inspections are announced (a similar concern was also raised by Pfizer in its comments on the Draft Report (sub. DR53)):

... when Janssen-Cilag [part of the Johnson & Johnson Group] was informed of a random inspection initiated by the TGA, we were given a very short timeframe (5 working days) in which to respond. This is of concern given that the typical cost of audits may range in the tens of thousands of dollars and sometimes into the hundreds of thousands, depending on the duration of the inspection as well as the number of TGA representatives performing the inspection. Decisions involving such large sums cannot easily be made, particularly in the case of multinational companies where input may be required from Head Office. (sub. DR70, p. 10)

### *Assessment*

The TGA audits Australian manufacturers before a licence is granted, to ensure their production procedures comply with internationally recognised GMP principles

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and then regularly inspects licensed manufacturers to ensure that necessary standards are maintained.

Overseas manufacturers of medicines imported into Australia are required to operate to standards equivalent to those expected of a licensed Australian manufacturer. A Sponsor<sup>7</sup> applying to the TGA for registration or listing of therapeutic goods manufactured outside Australia, in the absence of a TGA audit, must provide documentary evidence to show that the manufacture of the goods is of an acceptable standard. Sponsors of therapeutic goods manufactured outside Australia must obtain GMP Clearance for the overseas manufacturer(s) before the goods are entered on the ARTG.

Documentary evidence is assessed by the TGA through a 'desktop audit' process. If acceptable documentary GMP evidence cannot be provided, the TGA will undertake on-site audits in the same manner as that conducted for the Australian manufacturers.<sup>8</sup>

Australia participates in several international arrangements including Mutual Recognition Agreements (MRAs), the Pharmaceutical Inspection Cooperation Scheme (PIC/S) and other arrangements that provide for the exchange of regulatory information. The countries of the regulators who are recognised participants in an MRA (or equivalent) with Australia include the EC and EFTA Countries,<sup>9</sup> Canada, Singapore, and Switzerland (arrangements generally equivalent to an MRA).

The TGA has an agreement with the US Food and Drug Administration (US FDA) that provides for the exchange of information in relation to manufacturers for regulatory purposes.

The TGA recently revised its Guidance for Sponsors and manufacturers on the GMP clearance of overseas medicine manufacturers.<sup>10</sup> Medicines Australia and Pfizer both expressed concern that changes in the latest edition of the Guidance document will significantly increase the number of duplicative inspections and consequent unnecessary compliance costs for business and administration costs for the TGA.

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<sup>7</sup> 'Sponsor' is the person, business or company that has the prime responsibility for the supply of the product in Australia. The Sponsor may also be the manufacturer of the good.

<sup>8</sup> The term 'audit' is generally used in Australia, whereas overseas regulatory agencies may use the term 'inspection'.

<sup>9</sup> Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden.

<sup>10</sup> Guidance on the GMP clearance of overseas medicine manufacturers, 16<sup>th</sup> edition, March 2008, (DOHA 2008b, available at <http://www.tga.gov.au/manuf/gmpsom.htm>).



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A number of the changes to GMP clearance of overseas medicine manufacturers initiated in recent years by the TGA have been in part a response to the Performance Audit Report of the Australian National Audit Office into *Regulation of Non-prescription Medicinal Products* (ANAO 2004). The Audit raised significant concerns about the standard and timeliness of assessments of overseas manufacturers. Notwithstanding that the report did not deal directly with regulation of prescription medicines, many of the findings and recommendations of the Review were equally of relevance to these medicines. The Audit found:

The TGA has a structured framework for the regulation of risk ... However, more rigour around systems, procedures and resource management within the framework is required to provide assurance that non-prescription medicines are appropriately and cost-effectively regulated. (ANAO 2004, p. 19)

And recommended:

... that the Department of Health and Ageing review and improve the TGA's quality assurance program to improve the quality, consistency and reliability of its GMP audits. (Recommendation No. 25) (ANAO 2004, p. 28)

The recently revised GMP clearance guidance document provides the following information in relation to acceptable documentary evidence:

- the TGA will accept Certificates of GMP Compliance, issued under the provisions of an MRA (for types of products covered by the MRA), where the manufacturer is located in the same country as a Regulator that is a recognised participant in the MRA
- the scope of an MRA does not include audits conducted in countries outside the country of an MRA Regulator

Audits and GMP Certification, from MRA Regulators, for manufacturers in third countries will no longer be automatically accepted. This is because audits in these countries may not include all aspects of the manufacture of medicines for supply to Australia (DOHA 2008b)

- GMP Certification from PIC/S member countries are not automatically accepted; the only exceptions to this is where the Regulator in the PIC/S member country is also a Regulator who participates in an MRA with Australia, and the certificate is issued under the provisions of the MRA
- GMP Clearance is not automatically granted to Sponsors of US manufacturers inspected by the US FDA or New Zealand Medsafe.<sup>11</sup>

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<sup>11</sup> Under the Trans Tasman Mutual Recognition Arrangement, generally goods that can lawfully be sold in New Zealand can also be sold in Australia. However, therapeutic goods are one of six sectors covered by a special exemptions. The Commission is currently undertaking a review of the mutual recognition schemes.

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Where documentary evidence is submitted under the provisions of an MRA, a brief assessment is typically undertaken. In all other cases a desktop audit of the documentary evidence is conducted.

Whereas some overseas regulatory authorities (for example the US FDA) are required to conduct their own inspections for all overseas plants supplying to their domestic market, the TGA endeavours to minimise the number of overseas inspections and will not conduct its own inspection where suitable evidence to demonstrate acceptable GMP compliance is received. Given the TGA's full cost recovery arrangements, this policy substantially reduces regulatory compliance costs for sponsors in Australia, since the direct cost of desk-top audits are generally only a small fraction (less than one tenth) of the cost of a full on-site GMP inspection. Further, indirect costs to businesses of preparing and participating in an audit inspection (including staff time costs) are substantial.

The TGA has an obligation to ensure that documentary evidence provided by sponsors is of sufficient quality to provide the necessary assurance of an overseas manufacturer's compliance with GMP. One aspect of assessing the quality of the evidence is ensuring that it is relevant in its scope. One reason that the TGA will not automatically issue GMP clearances for sites inspected by the US FDA is that the FDA generally limits the scope of its inspections to products and processes which impact on medicines approved and marketed in the US. The TGA has a statutory obligation to ensure there is evidence that the relevant factories (buildings) on the site that are manufacturing products for Australia were inspected and cleared by FDA inspectors.

The medicines industry did not argue that the TGA's evidentiary requirements are unreasonable and in roundtable discussions acknowledged that evidence submitted by industry to the TGA was on occasions of a poor standard. Many of the concerns raised by industry about problems obtaining the required evidence are generally beyond the control of the TGA. The TGA should continue to work with companies to try to improve the quality of reports from overseas subcontracting plants and facilitate access to inspection reports. As a further initiative, the Commission sees merit in the TGA preparing an advisory document listing common deficiencies in applications for desk top audits, as suggested by Medicines Australia (sub. DR64) so as to reduce the incidence of delays or rejections, due to unacceptable evidence, that could have been anticipated by the sponsor.

While the Commission acknowledges that outside the MRA countries, a case by case assessment may generally be appropriate when assessing the evidentiary or audit requirements for GMP Clearance, there would be significant cost savings for many pharmaceutical companies if the TGA were to more widely recognise prior certification processes conducted overseas by bodies assessed as suitably

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competent. The TGA Office of Manufacturing Quality (formerly the Manufacturing Assessment Branch) has a current initiative to identify where manufacturing audit results may be shared between global regulatory authorities and to improve communication of audits and this may lead to some greater recognition and acceptance of overseas GMP assessments. DOHA has advised:

The TGA is initiating improvements in international regulation of GMP. The TGA's 'Smart GMP Regulation' initiative is in the vanguard of international work to enhance inter-regulator communication and information exchange, actively addressing unnecessary duplication of inspections of medicine manufacturers. Other international regulators are working with the TGA to adopt our GMP regulatory approaches to collectively ensure that regulators do not unnecessarily duplicate inspections of medicine manufacturers in any specific part of the world. (pers. comm., 5 June 2008)

The TGA has also recently joined with the US FDA and the European Medicines Agency (EMA) in a pilot project designed to facilitate collaboration on inspections of active pharmaceutical ingredients manufacturers in third countries. The pilot project provides for sharing of information on inspections between the TGA, US FDA and the EMA and rationalisation of international GMP inspection activities. DOHA stated that 'should the pilot project demonstrate that it is an effective mechanism for improving the efficiency of GMP inspections, further international collaborative inspection programs are likely to be developed' (DOHA, sub. DR71, p. 4).

In relation to complementary medicines, the Commission notes that any move to recognise more widely prior overseas inspections/assessments may not significantly reduce compliance costs for manufacturers in Australia. This is because many overseas regulatory agencies (including the US FDA) do not audit complementary medicine manufacturers supplying their market, since these products are not regulated as 'medicines'. As one option for reducing costs and improving timeliness of access to complementary medicines, the TGA should examine the feasibility of using competent overseas-based third party accredited auditors as an alternative to sending TGA auditors. Any examination would need to establish the scope for such a change to result in significant cost savings that could be passed on to businesses. This was suggested by the Complementary Healthcare Council of Australia (sub. DR68), but might have wider application to prescription medicines, possibly after a trial implementation period for complementary medicines.

### *Timeliness*

In relation to concerns about the time taken to conduct audits, the Commission understands that Australian inspections are given the highest priority and according to the TGA are 'always conducted on time' (TGA, pers. comm., 1 August 2008).

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Overseas inspections of manufacturers of medicines are prioritised taking into account available resources. The TGA acknowledges that ‘from time to time inspections ... that have no impact on national supply can be delayed’ (TGA, pers. comm., 1 August 2008).

The Commission accepts that there may be times when it is appropriate for the regulator to insist on an inspection on short notice. But where the regulator is open to the alternative of a desk-top assessment based on suitable documentary evidence, companies should be allowed sufficient advance notice in order to investigate the feasibility of opting for that less costly alternative.

The Office of Manufacturing Quality within the TGA is working to reduce waiting periods for processing of desktop audits. It is currently conducting an internal review of processes and recruiting additional staff, including GMP inspectors. While this should go some way to addressing delays, the Commission is concerned that the TGA has not committed to specific GMP Clearance timeframes — with the exception of MRA certification where the Guidance document gives a rather loose commitment that ‘the processing of the application will generally be completed within fifteen (15) working days’ (DOHA 2008b, p. 16). Where non-MRA certification and supporting documentation is submitted as evidence the assessment (desktop audit) and decision process ‘will be completed as soon as possible’ (DOHA 2008b, p. 16). In advice to the Commission, DOHA stated:

‘Desktop audits’ are not constrained by legislated timeframes as significant additional costs would be borne by industry for additional resources (GMP inspectors) to meet these timeframes. (pers. comm., 5 June 2008)

While acknowledging that faster processing may imply some additional charges for industry, these must be balanced against the substantial benefits associated with being able to get products into the marketplace quicker.

The time taken to conduct assessments should, at a minimum, be constrained by a strong written commitment by TGA to specific timeframes, negotiated with industry and with any cost trade-offs made transparent. There would need to be some flexibility to deal with special circumstances and ‘stop the clock’ provisions to make allowance for delays in the provision of evidence that are beyond the control of the TGA.

### *Uncertainty of expiry dates*

In relation to specific concerns about *uncertainty* of expiry dates for GMP clearances, the Commission notes that the TGA’s policy is as follows:

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- for GMP clearances issued on the basis of an MRA Certificate of GMP Compliance, the GMP Clearance remains current until the date of expiry on the MRA Certificate, unless the TGA has documentary evidence to vary the expiry date
  - for other GMP Clearances, the expiry depends on the type of product manufactured and the outcome of the desktop assessment process. The period of GMP Clearance is determined using a risk-based criteria similar to that used by the TGA to determine the re-audit period for any manufacturer (domestic or overseas) audited by the TGA, so as to be ‘consistent with the TGA’s “level playing field” approach to GMP regulation’ (DOHA 2008b, p. 10).

Previously, a GMP Clearance for an active pharmaceutical ingredient or finished product would expire three years from the date of the last audit. Pfizer’s concern is that under the new risk-based approach, expiry dates will be reduced. This would generate additional compliance costs associated with more frequent applications, and the number of TGA audits will increase. More fundamentally, Pfizer has concerns about the uncertainty created by the new approach:

Now the TGA has indicated that it will calculate expiry dates using a risk matrix. However, the TGA will not make this risk matrix available to industry, and manufacturers like Pfizer Australia have no way of determining what length of clearance they will receive for subcontracted plants overseas. (sub. 31, p. 7)

Once the re-inspection period is determined using the risk matrix, GMP clearance is issued for that period of time, plus six months, to allow for the TGA inspection to be scheduled and conducted.

Consistent application of risk criteria to Australian and overseas manufacturers supplying the Australian market does establish a ‘level playing field’, in one sense. But greater consideration also needs to be given to the requirements Australia is placing on its domestic manufacturers and overseas plants supplying the Australian market relative to requirements imposed by other developed countries that seek to maintain similarly high standards of safety for medicines supplied to their domestic market, for example the US and EC countries. According to Pfizer (sub. 31, p. 8) and Johnson and Johnson Family of Companies (sub. DR70, p. 10) Australian sponsors have a harder time registering overseas plants than pharmaceutical manufacturers anywhere else in the world. In a similar vein, the Complementary Healthcare Council of Australia noted that complementary medicines are typically not regulated as ‘medicines’ internationally (and current MRA’s do not apply to complementary medicines), but the Commission notes that this reflects a difference in policy and so is outside the scope of this study.

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Further, the risk-based criteria used to determine expiry dates should be more transparent, ideally via publication on the TGA's website, such that Sponsors are able to reasonably anticipate the expiry dates that are likely to be determined for their GMP Certificates and plan accordingly. In comments submitted on the Commission's draft report, DOHA agreed:

... increased transparency could be achieved through publishing some details of the risk-based approach used by the TGA in its GMP processes, on the TGA website. The TGA will undertake to publish such information. (sub. DR71, p. 3)

In principle, the design of TGA's processes for assessing manufacturers' compliance with GMP have a high degree of consistency with best practice principles. They are based on a risk-management approach and a desire to minimise unnecessary business compliance costs and administration costs. Nevertheless, in practice, there is scope to improve the transparency, timeliness and consistency of application of audit processes, particularly the times and costs associated with overseas audits or desk-top assessments.

#### 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***
- ***wider recognition of international processes and acceptance of GMP certificates where conducted by bodies assessed as suitably competent.***

## **TGA transparency and communication**

Various concerns were raised regarding TGA's transparency and communication with stakeholders, including:

- a general lack of transparency (and certainty) in TGA processes — '...we are not certain how or why the TGA makes decisions.' (Pfizer, sub. 31, p. 8)
- frequent changes to Guidance, and the imposition of new requirements without sufficient consultation with industry

This document [Guidance on the GMP Clearance of Overseas Medicine Manufacturers] has been updated 4 times in the last 2 years and only with the latest edition, i.e. the 16<sup>th</sup> edition, was industry given a small window of opportunity to comment. We believe that the TGA needs to take a true consultative approach in

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adopting new/revised Guidelines by giving companies the opportunity and sufficient time to comment on changes and new requirements. In addition the TGA should allow for a transition period for new requirements to be operational. This would provide multinational pharmaceutical companies with sufficient time to familiarise their Head Office functions with the new requirements and to allow generation of new information to meet these additional requirements. (Johnson & Johnson Family of Companies, sub. DR70, p. 11)

- the system for registration requires hard copy submissions to the TGA.

The preparation of these hard copy submissions causes a burden on industry in the time taken to print, the cost of materials, the work in collating volumes of paperwork, as well as the transport and printing costs in providing this material to TGA. Having to review paper copies also increases the time taken for TGA to review submissions. Complex submissions to TGA often run to many volumes of paperwork. (Medicines Australia, sub. 35, p. 5)

### *Assessment*

Although highlighting specific aspects of TGA's performance that need to improve, participants were keen to acknowledge the high standard of the TGA's work:

... the TGA's assessment of the medicines' quality, safety and efficacy is of the highest standard. The advice that our Australian manufacturing staff receive from the TGA following audits is also excellent. The TGA's policy work has been very good. (Pfizer, sub. DR53, p. 1)

And Medicines Australia noted that 'TGA has a very good international reputation' (Medicines Australia, sub. 35, p. 2).

Transparency of processes for making, changing, reviewing, communicating and then administering regulations is vital for ensuring regulatory efficiency and the control of business compliance costs. Affected businesses should be consulted and have adequate opportunity to contribute to the development and design of the regulation and associated administrative processes. Regulations and administrative decision making by the TGA must be clear, consistent and accessible.

The TGA publishes all requirements and guidelines and is required by legislation to meet prescribed timelines and provide reasons to applicants for decisions. The TGA's website has substantial, readily accessible information about regulatory requirements and administrative processes. As well as providing links to relevant legislation and regulation, Guidance documents are available covering various aspects of the Regulatory Framework that provide more detail on process and information requirements.

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The TGA consults with industry on individual proposals and through standing arrangements, especially the Industry Consultative Committee. Consultative processes were improved following a review in 2003-04 (Evans, A. 2004). The Industry Consultative Committee provides a forum to exchange information on industry trends and regulatory expectations, to discuss the development of the TGA's corporate plan, annual business plans and budget. The TGA reviews its fees and charges each year and consults with stakeholders on proposed changes through the Industry Consultative Committee. Bilateral discussions are also conducted with industry associations on sector specific changes to fees and charges (pers. comm., 5 June 2008).

The TGA also conducts seminars and workshops for industry to facilitate better understanding of current regulatory requirements and proposed reforms. For example, in late July and early August 2008, the TGA held workshops for each of the four major therapeutic goods sectors on proposed regulatory reforms. These workshops have been welcomed by Medicines Australia, which stated that the consultations 'point to a renewed commitment on the part of the TGA to implement the workflow practices reforms' (sub. DR64, p. 2), but it also emphasised that the 'priority is now to ensure that the reforms are finalised and implemented in a timely manner and in partnership with the industry' (ibid).

For prescription medicines the TGA has a process for establishing or amending guidelines, which was negotiated with industry associations — copies of the proposed guidelines are sent to the three key industry associations in the prescription medicines sector, who are asked to respond in a one to two month period. The associations then collate comments from their members and forward these to the TGA (pers. comm., 5 June 2008).

The TGA has recognised that there is the potential for efficiency gains through improved information technology capability and has initiated a project to enhance its IT capability. This includes facilitating electronic lodgement of submissions. The TGA informed the Commission that it expects to issue a tender for the IT support for the review of electronic submissions for prescription medicines before the end of this calendar year.

Overall, with respect to the transparency of TGA's regulation of *medicines*, the Commission did not receive conclusive evidence to confirm that there are widespread or systemic problems. Moreover, the Commission has identified a number of positive aspects of the TGA's communication and consultative processes. Nevertheless, the concerns that have been raised suggest there is scope to do better and this has been acknowledged by the TGA. The TGA should use the current internal process review being conducted by the Office of Manufacturing Quality to identify, in consultation with industry, further measures to improve the



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regulator's transparency and communication with stakeholders. Outcomes should include ensuring that the reasons for decisions are always clearly communicated and that there are adequate opportunities for affected businesses to provide feedback on proposed reforms to regulation and associated administrative processes.

## **Concerns about PBS listing and pricing processes**

The following specific concerns were raised in relation to PBS listing and pricing processes:

- lack of fairness and transparency in PBAC processes
  - ‘mismatch of early advice on our PBAC submissions and the PBAC’s final recommendations’ — advice given by the PBAC secretariat within DOHA is often not adequately reflected in the independent evaluation on which the listing decision is based or in the PBAC’s final recommendations to the Minister. (Pfizer, sub. 31, p. 8)
  - companies are allowed only ten minutes to address PBAC in relation to their submissions and following receipt of commentary from external academic groups, which is not commensurate with the complexity of submissions and the time involved in their preparation (Pfizer, sub. 31, p. 10)
  - under PBAC Guidelines manufacturers are allowed only five days to respond to evaluator’s comments (which are often more than 50 pages and highly technical), which ‘is quite disproportionate to the months that are spent preparing and evaluating submissions’ (Pfizer, sub. 31, p. 10) and currently PBAC posts commentaries by mail, reducing the already limited time to respond
- lack of accountability of PBAC evaluations — manufacturers have limited opportunities to address errors of fact or major omissions
  - ... an increasing number of elements in evaluations are simply wrong or contain major omissions, and consequently the PBAC is being given guidance that may lead to them incorrectly reject[ing] our medicines. Pharmaceutical manufacturers currently have only limited opportunities to address errors of fact or major omissions. While there is a review process, this can only assess the PBAC’s own processes, not the evaluation itself. (Pfizer, sub. 31, pp. 9–10)
- generally there is insufficient transparency around the PBAC evaluation process
  - ... there are important parts of the evaluation system that are unclear to us: how many evaluators there are; what their workload is; how many submissions they typically evaluate for each sitting of the PBAC; how often they are replaced or rotated (if at all); what sort of feedback they receive from the PBAC and Pharmaceutical Benefits Branch; and how feedback is institutionalised amongst the body of evaluators. We also do not know how the responses we provide to the PBAC and its subcommittees are

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actually handled by those groups and, most importantly, have no opportunity to interact with the evaluators during the evaluation process. It would certainly help us to know how the PBAC views those responses which point out errors in evaluations, and what formal processes it has for dealing with them. (Pfizer, sub. DR53, p. 3)

- PBAC is not allowing evaluators sufficient time to undertake complex evaluations (Pfizer, sub. 31, p. 10)
- the application of the Weighted Average Monthly Treatment Cost (WAMTC) method for reference pricing purposes generates substantial financial and administrative costs to both the Government and industry

A WAMTC review can take between 10 to 14 weeks. During this time, considerable resources are allocated by both Government and companies to collecting, collating and analysing data, followed by verification of the accuracy of the WAMTC calculation. The cost of purchasing data alone is prohibitive. For example, the costs of purchasing necessary data range from \$8000 and \$16000 for an ad-hoc WAMTC query. The total average cost thus amounts to between \$110 000-120 000 per annum for each company. Considering there are around seven WAMTC reviews each year, and any one review will have a number of companies involved — each required to collect and submit their own data — the compliance cost to the industry as a whole ... will be much higher. (Medicines Australia, sub. 35, p. 7)

In commenting on the Commission's draft report, Medicines Australia (sub. DR64), Pfizer (sub. DR53) and Johnson & Johnson (sub. DR70) also questioned the continuing need for the WAMTC policy in light of recent PBS reforms. Medicines Australia, for example stated:

The rationale of the PBS reforms is to encourage savings to the taxpayer by facilitating differential pricing for medicines with multiple brands where there is competition. WAMTC, by definition, is designed to equalise the price of different medicines – it is inconsistent with the policy direction of the PBS. It is likely to be increasingly untenable in a competitive pricing environment with different prices for multiple brand medicines driven by PBS reform. This inconsistency and increasing irrelevance, coupled with the regulatory cost of WAMTC on companies, suggests that WAMTC should be abandoned as a methodology altogether. (Medicines Australia, sub. DR64, p. 5)

### *Assessment*

In applying to have a medicine listed on the PBS, a company must submit to PBAC detailed clinical evidence (including safety — toxicity, adverse reactions, etc) as well as an analysis of the cost-effectiveness of the medicine relative to alternatives. The submissions are complex and becoming more complex over time. According to Pfizer (sub. 31), the main reasons for this are that medicines are becoming more specialised with smaller patient populations. This means the trial data are more complex to evaluate and more sophisticated analytical methods are required. The

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complexity and detail makes submissions costly and time consuming for companies to develop (submissions can take many months to prepare) and they also impose significant resource and expertise demands on evaluators. Submissions to PBAC and PBPA:

... can impose a significant regulatory burden on ... companies ... particularly for complex submissions, such as where there is a request for further information or clarification is required, or where a medicine has been rejected previously and requires multiple resubmissions in order to achieve a positive recommendation from PBAC. ... [it] can be quite a resource intensive process. (Medicines Australia, sub. 35, p. 6)

PBAC and PBPA must have sufficient resources and time to evaluate submissions so as to avoid errors or omissions that can be very costly both to companies and potentially in terms of health outcomes for the community. The volume of submissions to PBAC has been growing in recent years and this together with the increasing complexity of submissions would have significantly increased the workload of PBAC.

In 2000, each PBAC meeting made around 15-25 recommendations to list medicines on the PBS; in November 2007, they recommended 53 medicines for listing. Despite this increase, the PBAC has not advertised any increase in the time devoted to evaluations, or in specialist subcommittees or in PBAC meetings. (Pfizer, sub. 31, p. 11)

To address this, provision has been made in the legislation to increase the membership of the PBAC from 12 to 18 members and the length of the scheduled PBAC meetings has recently been increased to three days (from one to three days previously). However, the number of meetings per year has been reduced from four to three. The PBAC also holds separate one-day extraordinary meetings to deal with other matters, but these meetings have typically dealt with a very small number of assessments.

Companies must also be given sufficient time to respond to feedback/commentaries on their submissions. In this regard, some aspects of PBAC procedures and processes do *prima facie* seem unnecessarily burdensome. This is particularly evident with respect to the extremely short time (five days) that companies are given to respond to evaluators' comments, especially in light of PBAC's insistence that the comments be sent to the company by post.

DOHA have informed the Commission that commentaries are sent in hard copy so that commercial-in-confidence material can be appropriately blacked out (pers. comm., 5 June 2008). The Commission considers that commentaries should be transmitted electronically consistent with the requirement imposed on manufacturers to make submissions in a useable electronic format. The PBAC Secretariat should explore technical options that would enable electronic transmission while ensuring confidential material cannot be accessed in electronic

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files. At a minimum ‘portable document file’ (PDF) files (with blacking out) could be sent rather than hard copies in the mail.

Based on DOHA’s description of current processes it would appear that there are opportunities for sponsors to address errors of fact or omissions, including in the reports of the contracted evaluators:

If the sponsor has correctly identified in its pre-sub-committee response that errors of fact or omissions exist in the evaluation report, the errors are documented and tabled at the sub-committee meeting. The errors are then formally acknowledged and specifically brought to the attention of the PBAC, and the sponsor, as part of the minutes of the meetings. The evaluators receive the comments from the sponsors to the evaluation reports. The groups also receive general feedback on their performance as part of usual contract management between the Pharmaceutical Evaluation Branch and the academic evaluation groups.

The sponsor is provided with a copy of the [Economics Sub Committee] Advice to the PBAC and has a further opportunity to comment in a pre-PBAC response.

The sponsor of a major submission can also request a hearing at the PBAC meeting. The scope and duration of the hearing before the PBAC have been extensively discussed and jointly agreed upon by the Department of Health and Ageing and the pharmaceutical industry, represented by Medicines Australia, as part of the implementation of the Australia United States Free Trade Agreement. (DOHA, pers. comm., 5 June 2008)

However, the concerns raised by Pfizer (including further elaboration in a supplementary submission, DR53) suggest the need for a further examination of the adequacy of current review opportunities and the process of ensuring that any significant errors, including in evaluators reports, are corrected. There appears to be a case for allowing companies additional time to present at PBAC hearings. As a first step, however, there is a need for DOHA to more clearly communicate review opportunities that exist within current processes and, more generally, to enhance the transparency of the whole PBAC evaluation processes.

Typically, before a manufacturer lodges a major PBAC submission it holds preliminary discussions with officers from the Pharmaceutical Benefits Branch (PBB) of the DOHA, which provides secretariat and technical support to the PBAC. The initial meetings with the PBB can help to ensure that the time consuming process of preparing the submission is as focused and efficient for the company as possible. Pfizer stated in their submission that such meetings are an opportunity for both sides to ‘discuss issues with clinical evidence, determine the comparator, and discuss approaches to the PBAC if there is a rejection’ (Pfizer, sub. 31, p. 9). DOHA told the Commission that meetings are used to:

... discuss aspects of data collection, submission preparation, PBAC considerations and pricing matters, and other related issues. These meetings aim to assist in the listing

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process, and encourage cooperative working arrangements with pharmaceutical companies. (pers. comm., 5 June 2008)

The advice of PBB is non-binding on evaluators and PBAC so it is possible for submissions to be rejected or deferred, notwithstanding that early advice provided by PBB has been followed.

Judgements must be made on the basis of the totality of available clinical and economic evidence, by PBAC after an independent assessment by evaluators and consideration by PBAC sub-committees. A system that sought to make preliminary advice of the Department binding would appear unworkable, in effect making the Department the decision maker, rather than PBAC. Even something less than binding is likely to make the Department reluctant to provide any early advice. This would overall be to the detriment of companies that benefit from early consultation and feedback on their proposed submissions. This position was accepted by Pfizer in its comments on the draft report (sub. DR53).

The Commission considers that the preliminary meetings with the PBB serve a useful function, particularly in relation to ensuring procedural and information requirements are clearly understood. The costs of avoidable re-lodgements can be very high for companies so there is an onus on DOHA to ensure that any preliminary advice given in relation to the evaluation method, data requirements or other process matters is well considered and as accurate as possible.

Pfizer suggested that an agreed record of the advice given by PBB with respect to the evaluation method the sponsor should use should be included with the submission so that the evaluator is aware of that advice. Therefore any decision by the evaluator to select a different evaluation method would not be one taken lightly. This suggestion has some merit and may serve to enhance transparency and accountability. However, any consideration of whether to make this a requirement would need to take into account additional administrative costs for PBB and the potential either to constrain their advice or to place pressure on the independent evaluators to select a method consistent with the PBB advice.

Several participants raised concerns about aspects of the Weighted Average Monthly Treatment Cost (WAMTC) methodology. For medicines that have been assessed as being of equivalent safety and efficacy for a common clinical indication, a 'Reference Pricing Policy' is adopted and the WAMTC is a method of calculating a benchmark or reference price for groups of related medicines, using clinician prescribing data. There are currently six WAMTC groups which are each composed of medicines that provide the same or similar health outcomes.

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Regular reviews of the cost-effectiveness of medicines are necessary to ensure that the Government and taxpayers get the best value from the PBS. Medicine prices may need to be changed, for example, if actual patterns of use differ from that predicted or if post-marketing evidence shows that a medicine has worked better or worse than it had in the original clinical trials. DOHA stated that WAMTC reviews result in price decreases where there is strong statistical evidence that medicine sponsors have been paid at levels greater than justified by demonstrated health outcomes. Reviews have yielded \$500 million in savings to PBS expenses (DOHA, sub. DR71).

Keeping medicine prices low for users and containing the cost to taxpayers is the major focus of reforms to the PBS being implemented progressively from August 2007 (Abbott 2006). The Commission notes the views put forward by some participants that these reforms render WAMTC measures unnecessary. Questions about the continuing justification for WAMTC would need to be addressed by a separate policy review and are beyond the scope of this study.

Notwithstanding DOHA advice that ‘individual sponsors are able to quickly assess their situation using a WAMTC calculator and submit a suitable price response ...’ (DOHA, sub. DR71, p. 4), the costs of participating in WAMTC reviews claimed by pharmaceutical companies are substantial. While not all sponsors are obliged to obtain specific prescribing data additional to what is already subscribed for, or otherwise purchased, the cost of purchasing data is a particular concern.

According to Pfizer (sub. DR53), in order to establish prices under WAMTC for medicines where the price is above the PBS co-payment level, manufacturers have to purchase data on prescription volumes from Medicare Australia. In such cases Medicare Australia’s cost recovery fees form a large component of WAMTC compliance costs for firms. Given the rationale for the WAMTC policy and the Government’s broader health policy objectives, it may be appropriate to review whether charging for this data is consistent with the Australian Government’s Cost Recovery Guidelines. Consideration should also be given to whether there might be efficiencies if DOHA were to access the required data from Medicare Australia directly.

Consideration needs to be given either to modifications to the WAMTC reference pricing methodology or to adoption of an alternative methodology that would reduce the compliance burden on business and administration costs for PBPA, while not compromising the achievement of the Government’s objectives. Within the existing WAMTC methodology, options to consider might include reducing the frequency of reviews for any group of medicines, and accepting alternative data sets that are less costly to collect and analyse.

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*The Department of Health and Ageing should examine ways to reduce compliance costs for business associated with the Weighted Average Monthly Treatment Cost 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.*

### **Delays in achieving PBS listing due to overlapping processes**

Medicines Australia (sub. 35), Johnson and Johnson Family of Companies (sub. DR70) and Pfizer (sub. 31) all raised concerns about the time taken from initial application to register a medicine with the TGA through to listing of the medicine on the PBS.

... we routinely spend around two years before a product is listed on the PBS and, in some cases, we may lose half the patent protected-period waiting for listing. (Pfizer, sub. 31, p. 4)

The average time it takes now from drug submission to when it comes on the PBS is between 24 and 30 months (Chairman Medicines Australia quoted in *Age* Newspaper, p. 3, 29 April, 2008)

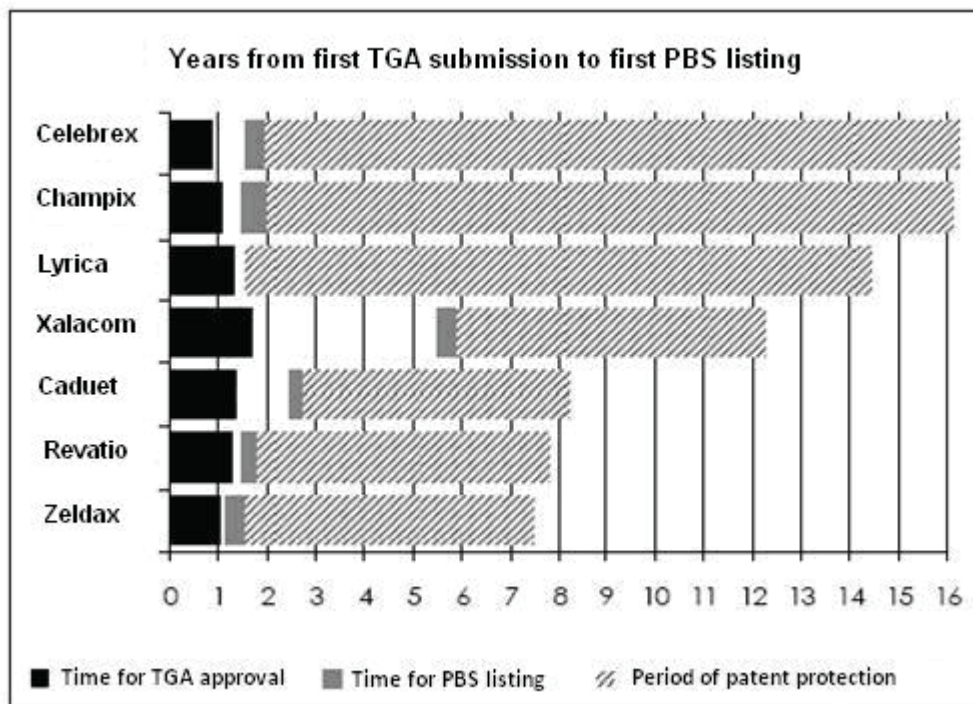
Figure 4.2 illustrates approval and assessment timeframes for a selection of Pfizer's recently-listed products.

Delays in getting medicines listed on the PBS have been attributed to overlap and duplication in some aspects of the TGA registration and PBAC/PBS listing processes and the lack of alignment or synchronisation of these processes.

Currently you put an application to the TGA and you wait between a year and a year and a half and then towards the end of the process you apply for PBS listing. (Chairman Medicines Australia quoted in *Age* Newspaper, p. 3, 29 April, 2008)

... the PBAC and TGA assessment periods are not synchronised at the moment, so efficiencies are fortunate rather than planned. For example, the date we receive approval from the TGA may be just after the cutoff for PBAC submissions (meaning we have to wait several months if we miss the cut-off date), and the TGA process itself may be delayed. (Pfizer, sub. 31, pp. 4–5)

Figure 4.2 Delays in achieving registration/PBS listing



Note: Lyrica was not listed on the PBS (although the PBAC recommended the product for listing the price was not commercially viable).

Data source: Pfizer (sub. 31, p. 4).

### Assessment

As noted in section 4.1 above, currently the TGA assesses the quality, safety and efficacy of medicines in determining whether a medicine can be included on the ARTG and legally sold in Australia. TGA’s assessment does not consider the cost-effectiveness of medicines.

All pharmaceuticals must have TGA approval before they can be listed on the PBS. However, PBAC accepts submissions to have medicines listed before finalisation of ARTG approval, provided that the TGA delegate has recommended the medicine for registration in their overview. In practice, current processes allow PBAC to commence its assessment of a medicine when it is around two-thirds of the way through the TGA process. There is further flexibility in particular cases, allowing ‘assessments to commence earlier in the TGA process when a new medicine provides a real advance in the treatment or prevention of disease’. (DOHA, sub. DR71, p. 5)



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The PBAC assessment is essentially about questions of cost-effectiveness and value for money for the tax payer. The PBAC accepts that products included on the ARTG have established adequate safety and efficacy to allow marketing in Australia. However, as noted by Medicines Australia, ‘companies are required to provide evidence of efficacy and safety as well as cost-effectiveness’ in their submissions to PBAC (sub. 35, p. 6) — thus overlapping to some extent with the information submitted to TGA.

The pharmaceutical medicines industry has called for manufacturers to be able to make synchronised/parallel applications to the TGA and the PBAC. It has been suggested that this could reduce the total time to PBS listing by some six months.

Each organisation is concerned with different assessment questions — the TGA with effectiveness and safety; the PBAC with cost effectiveness — so at a level of principle, there is little to impede the two evaluations happening in parallel. (Pfizer, sub. 31, p. 4)

These issues are currently being examined by the joint Medicines Australia/DOHA Access to Medicines Working Group (AMWG), established as a result of reforms to the PBS announced in November 2006.

The AMWG has been considering the capacity for better streamlining and coordination of TGA/PBAC processes with a view to achieving improved efficiency and more timely processes. Under its terms of reference, the AMWG is charged with exploring the capacity to further streamline and coordinate regulatory approval, reimbursement and pricing processes to reduce the time it takes to list a medicine on the PBS. AMWG met with representatives of the PBAC, the TGA, consumers and the generic medicines industry to discuss these issues. The AMWG recently delivered its Interim Report to Government and it is under consideration.

There is also currently an investigation of ways to streamline medicine safety evaluation of applications for registration and reduce time to registration and subsequent PBS listing being undertaken by TGA internally.

While there would appear to be considerable merit in greater streamlining of assessments by TGA and PBAC, in principle there may also be some potential for inefficiencies or unnecessary effort, including some risk of wasteful diversion of scarce medicine assessment resources, in a system of parallel assessments. DOHA submitted that the most significant risk is that the subsidy recommendation by PBAC is not aligned with the TGA approved uses of the product:

Further streamlining current TGA and PBAC processes is not without risk. ... As medicines cannot be subsidised for non-approved uses, PBAC may need to reassess its recommendations which would result in significant delays in achieving PBS listing and additional costs to both Government and industry. (DOHA, sub. DR71, p. 5)

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Medicines Australia (sub. DR64), Johnson and Johnson Family of Companies (sub. DR70) and Pfizer (sub. DR53) expressed the view that significant additional costs to Government were unlikely. Medicines Australia stated:

... most submissions to TGA are approved and there is no major reason why any changes to indication as a result of TGA evaluation (which are not common) could not be incorporated into an already-commenced PBAC evaluation. (sub. DR64, p. 3)

Consideration might be given to a system whereby companies are given the option to request parallel processing, rather than it being the default. The Commission acknowledges that the existing costs associated with seeking PBS listing already provide an incentive for firms to avoid the pursuit of unlikely listings. With cost recovery for PBAC services announced in the May 2008 Budget industry would have a further incentive to ensure requests for parallel processing would only be made when there was a high level of confidence that it would not result in significant inefficiencies, or unnecessary effort and cost.

RESPONSE 4.3

*The Pharmaceutical Benefits Advisory Committee 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.*

One other issue that impacts on timeframes for PBS listing relates to the requirement for higher cost medicines to be approved by Cabinet before they can be listed. Since 2002, medicines expected to cost more than \$10 million a year in any of the first four years must be considered by Cabinet. The Commission understands that this requirement can add up to four months to the process compared to medicines that do not require Cabinet approval. The \$10 million threshold has not been indexed and will be triggered more often as the cost of medicines increases. The Government should consider the merits of increasing the threshold to account for price changes over the past six years and implementing an automatic annual indexation adjustment.

## **Concerns about marketing and advertising rules**

In relation to the area of marketing and advertising restrictions, participants raised the following specific concerns:

- regulations governing the advertising of medicines are confusing and the majority of pharmacists and the public are not aware of how the associated advertising complaints system, which differs across jurisdictions, works. (Pharmacy Guild, sub. 15, p. 8)

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- requirements, imposed by the Australian Competition Tribunal, on Medicines Australia member companies to disclose details of all educational meetings and symposia — this ‘reporting and disclosure process imposes considerable administrative and financial burden upon companies with the cost of compliance for the industry in the millions of dollars’ (Medicines Australia, sub. 35, pp. 8-9). Further, because the requirements imposed under the Code apply only to Medicines Australia members, they place an excess compliance burden on members over and above other (non member) suppliers of prescription medicines (Medicines Australia, sub. DR64, and similar concerns were raised by Johnson & Johnson Family of Companies, sub. DR70).
  - the Fourth Community Pharmacy Agreement imposes obligations and offers incentives (to wholesalers) which disadvantage manufacturers that wish to distribute products directly to pharmacies.

### *Assessment*

Concerns about regulations governing the advertising of medicines and the associated complaints system were raised with the Regulation Taskforce (2006), which recognised the need for reform:

The Australian Government should simplify the regulatory system for advertising therapeutic products to provide greater clarity and awareness of pharmacies’ obligations. (recommendation 4.16)

The Government agreed to this recommendation and a new regulatory model for advertising therapeutic products was being developed in preparation for the proposed Australia New Zealand Therapeutic Products Authority (ANZTPA). Draft regulatory instruments had been prepared and extensive stakeholder consultation undertaken.<sup>12</sup>

In July 2007, the New Zealand Government announced that New Zealand would not be ‘proceeding at this stage with legislation that would have enabled the establishment of a joint agency with Australia to regulate therapeutic products.’<sup>13</sup>

In the draft report the Commission suggested that the Australian Government should implement the proposed ANZTPA reforms to streamline and clarify advertising rules in an Australian-only context. In commenting on the draft report, the Complementary Healthcare Council of Australia opposed this, submitting:

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<sup>12</sup> Such as the Australia New Zealand Therapeutic Products Regulatory Scheme (Advertising) Rule 2006.

<sup>13</sup> ANZTPA website, <http://www.anztpa.org> accessed April 2008.

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... the ANZTPA model can no longer be regarded a suitable model as considerable time has elapsed (4-5 years) since it was developed and there was also considerable industry concern expressed about the proposed model at the time. (sub. DR68, p. 4)

In light of such outstanding concerns, further consideration should be given as to how best to streamline and clarify advertising rules, including the most appropriate requirements for complementary medicines. The Commission understands that the TGA is consulting with stakeholders on the proposed ANZTPA reforms so that they can move forward in an Australia-only context. This includes possible changes to the advertising regulatory arrangements which would streamline requirements and simplify the complaints system. Specific consideration is being given to implementing a centralised mailbox for all complaints about therapeutic goods advertisements (DOHA, sub. DR71).

It is important that this consultation process takes account of the concerns of industry groups such as the Complementary Healthcare Council of Australia and that alternative models are actively considered.

#### 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.***

Regarding information disclosure requirements, all Medicines Australia members are required to make public disclosure every six months of all educational meetings and symposia held or sponsored by the company.

The Australian Competition Tribunal (the Tribunal) imposed these requirements as a condition of its authorisation, in June 2007, of the 15th Edition of the Medicines Australia Code of Conduct. Authorisation exempts Medicines Australia members from anti-competitive conduct provisions of the Trade Practices Act which might otherwise be breached by implementation of the Code.<sup>14</sup>

Failure to comply with the reporting requirements will constitute a breach of the Medicines Australia Code, resulting in probable adverse findings from the Code Committee followed by sanctions.

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<sup>14</sup> The Australian Competition and Consumer Commission (ACCC) had granted conditional authorisation of the Code of Conduct in July 2006, but Medicines Australia subsequently sought a review of this decision by the Tribunal.

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Information that member companies must report includes details of venue, duration, attendees, nature and total cost of hospitality provided and total cost of the function. Medicines Australia is required to publish the information on its website and to conduct reviews of the information.

These requirements are intended to minimise the possibility of non-arms length relationships between pharmaceutical companies and health care professionals (and the receipt of direct benefits from companies) influencing prescribing practices, such that patient care might be compromised.

Although the Code seeks to impose some control, the Tribunal considered it to be insufficient and that public disclosure and the associated public scrutiny would provide a stronger incentive for appropriate self-imposed restraint by companies. The Tribunal, in its decision, considered that the disclosure conditions:

... increase the likelihood that the public benefit claimed for the Code is realised in respect of the provisions dealing with the conferral of such benefits on doctors. (Application by Medicines Australia Inc [2007] ACompT4, paragraph 8, as quoted in ACCC, sub. DR55, p. 2)

The Tribunal did give some consideration to the likely compliance costs associated with the disclosure requirements, but did ‘not consider that such burdens are unreasonable having regard to the benefit likely to be derived from the condition’ (Application by Medicines Australia Inc [2007] ACompT4, paragraph 363, as quoted in ACCC, sub. DR55, p. 2).

While the objectives for these quasi-regulatory disclosure requirements are clear enough, it is apparent from the concerns of participants that the compliance costs are substantial and may be greater than was anticipated by the Tribunal.

The ACCC advised (sub. DR 55) that because the current authorisation of Medicines Australia’s Code has been granted by the Tribunal, it is not able to vary or amend the authorisation (and its disclosure conditions). It would be up to Medicines Australia to seek authorisation for its Code once the current Tribunal authorisation expires, or for any new or amended Code, if it wishes to retain the protection provided by authorisation. At such time there would need to be careful consideration of any disclosure requirements to ensure that the specific details that must be disclosed, reporting formats and frequency of reporting, impose the minimum compliance burden consistent with achieving the public scrutiny objectives of the requirements.

The Commission does not support the suggestion made by Medicines Australia (DR64) and Johnson & Johnson Family of Companies (DR70) that the disclosure requirements and other provisions of the Medicines Australia Code should apply to

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non-member companies as well and be a condition of marketing approval. The Commission notes that:

- the disclosure requirements were only imposed by the Tribunal as a condition of authorisation of the Code, which otherwise may have been in breach of provisions of the Trade Practices Act
- membership of Medicines Australia is purely voluntary and as with any such industry association a decision to apply for membership or to maintain membership is based on an implicit weighing up of the benefits (advantages) of membership against any costs (disadvantages).

In the Fourth Community Pharmacy Agreement, the margins that wholesalers may charge for PBS products in sales to pharmacies was reduced and a Community Service Obligation (CSO) was introduced. The CSO imposed certain key restrictions and service delivery expectations on suppliers to ensure universal patient access, including:

- a requirement to supply all medicines on the PBS within 24 hours of a pharmacy placing an order in most areas of Australia
- being able to supply the full range of PBS products, with set criteria on lower volume products.

In return, eligible wholesalers are entitled to claim a government subsidy. Claims are submitted on a monthly basis and are based on sales volume and composition. Currently only wholesalers may claim the subsidy.

Pfizer's concern is that the CSO incentive scheme provides a competitive advantage for eligible wholesalers (receipt of government funding can allow them to sell to pharmacies at lower prices) and creates disincentives for pharmaceutical companies to supply direct to pharmacies. Pfizer claim that the subsidy scheme prevents competition and contributes to over-servicing and other distribution inefficiencies. They have suggested that a parallel scheme should be available to manufacturers supplying direct to pharmacies under the same CSO 'with the single distinction that they are only obliged to stock all of their own medicines (not the full PBS list)' (Pfizer, sub. 31, p. 12).

The intention of the CSO incentive scheme is to ensure universal patient access to PBS products. The government funds paid to wholesalers are the *quid pro quo* for cost inefficiencies that the suppliers bear in order to meet restrictions imposed, for example having to hold more stock, including low volume products, and to have in place more costly distribution arrangements that guarantee prompt supply.

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The concerns raised by Pfizer and the merits of its proposal to broaden the Community Service Obligation incentive scheme fall outside the terms of reference for this review because they relate to the policy underpinning the scheme.

### **Concerns regarding supply of PBS medicines**

The Pharmacy Guild of Australia raised the following concerns in relation to the supply of PBS medicines:

- the ‘Safety Net 20 day rule’ is considered to be ‘unworkable and impractical for pharmacists and unfair and potentially a health risk for patients’ (Pharmacy Guild, sub. 15, p. 5).
- problems with PBS supply arrangements in the context of aged care residential facilities and private hospitals — such as dealing with a prescription for less than one month’s supply of medication when an aged care facility may require the pharmacy to provide one or even two month’s supply. The pharmacist ‘is forced to “bend the rules” and supply medication on an “owing script” basis’ and then bear the burden of following up with the doctor to obtain a written prescription so that the resident can receive medicines at the subsidised PBS price. These problems are causing ‘enormous frustration and time wastage by ... nurse[s], doctors and pharmacists – involved in the administrative process of supplying medicines ...’ (Pharmacy Guild, sub. 15, pp. 6–7).

Neither is a new concern, both having been raised with the Regulation Taskforce.

### *Assessment*

Under the PBS Safety Net, once heavy users of medicines reach a certain safety net threshold in a calendar year, they can apply for a PBS Safety Net Concession (CN) card, which enables them to access PBS medicines free or at a much reduced cost for the remainder of the calendar year.

These Safety Net entitlements can act as an incentive for repeat prescriptions to be used to obtain medicines earlier than they are needed. The Safety Net ‘20 day rule’ was introduced to discourage hoarding and wastage of medicines by requiring a 20 day gap between separate dispensing of certain specified PBS medicine. A resupply within 20 days falls outside Safety Net benefits and any patient contribution does not count towards the Safety Net threshold. If the Safety Net threshold has been reached, the usual patient co-payment applies, rather than the free or reduced Safety Net amount.

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Repeats may be necessary within the 20 day period, ‘where, for example, the doctor requires the medicine to be taken more frequently than normal, where the patient loses the prescription, or where the patient is travelling and has left their medicine behind’ (Pharmacy Guild, submission to Regulation Taskforce, quoted in sub. 15, p. 5). The Pharmacy Guild has also highlighted particular difficulties implementing the 20 day rule in nursing homes (especially with respect to maintenance of supply and packing more than one month supply in a dose administration aid) and in rural and remote locations (a patient may only be able to access pharmacies on infrequent visits to town).

The Commission notes that the ‘Safety Net 20 day rule’ applies to only certain PBS medicines prescribed for long-term therapy. Importantly:

- it does not apply to any medicines for acute conditions or short-term use
- if an additional or early supply of a medicine to which the rule applies is genuinely needed, a PBS-subsidised supply can still be obtained.

DOHA provided the following comments:

It is reasonable that extra supplies are charged at a person’s usual co-payment, as this amount already takes into account the person’s ability to pay. As many PBS medicines are expensive, the benefit of being able to access an early PBS-subsidised supply at the usual co-payment rate outweighs the Safety Net effects. (pers. comm., 5 June 2008)

The Regulation Taskforce (2006) recommended that ‘The Australian Government, in consultation with pharmacies, should review the impact of changes to the 20 day rule, to address negative impacts on pharmacies and consumers’ (recommendation 4.13).

In its response, the Australian Government did not agree to this recommendation:

The Australian Government introduced the 20 day rule as a budget measure which is expected to save \$70.1 million over four years. The rule supports good practice in the safe use of medicines by discouraging patients from obtaining additional, or early, supplies of medicines. The Australian Government has worked with the pharmacy sector to provide explanatory materials to ensure that the new arrangements are implemented in an efficient manner and are understood by patients and pharmacists. The Australian Government will continue to work with the sector to ensure that policies aimed at quality use of medicines are implemented effectively. (Australian Government 2006, p. 7)

It is clear, therefore, that the change to the 20 day rule was a deliberate policy decision designed to reduce the budgetary cost of the PBS and also to address safety concerns associated with hoarding of medicines. Therefore the issue falls outside this review’s terms of reference. DOHA’s present view is that the policy objectives are being met:



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While there were some initial concerns raised regarding the introduction of the Safety Net 20 day rule in January 2006, no compelling arguments have been identified that suggest the need to change, or review, the application of the rule. This policy appears to have been effective in helping to contain PBS outlays, while at the same time supporting good practices for safe use of medicines in the community. (pers. comm., 5 June 2008)

Notwithstanding this view, now that the revised arrangements have been in operation for more than two years, the operation of the 20 day rule could be evaluated to verify the actual savings that have been achieved compared with any costs imposed on consumers, pharmacists or others.

With respect to concerns about the supply of PBS medicines in aged care residences and private hospitals, the Regulation Taskforce (2006) recommended that:

The Australian Government should review the supply of PBS medicines in residential aged care facilities, including what may constitute a prescription in this setting, and safe and effective packaging issues' (recommendation 4.15)

The Australian Government agreed in principle to the recommendation:

The intent of this recommendation is consistent with and addresses Part 6, Section 38.1 of the Fourth Community Pharmacy Agreement, which commenced on 1 December 2005. This states that "the parties agree to undertake a review of the existing PBS supply arrangements in the context of aged care residential facilities and private hospitals". The precise scope of this review is currently being considered. The review will be completed by 30 November 2006. (Australian Government 2006, p. 7)

The Commission notes that this review has only recently commenced. The commencement of the Review was delayed at the request of the Pharmacy Guild of Australia pending finalisation of the PBS Reforms negotiations.

The Review is being overseen by the Pharmacy Guild and DOHA, as the parties to the Fourth Community Pharmacy Agreement, and facilitated by an independent consultant, Healthcare Management Advisors. The Review is to consider changes to relevant legislation that would improve the efficiency and effectiveness of PBS supply (including through community pharmacies) to aged care residential facilities and private hospitals and possible alternative models of PBS supply to such facilities. The Review is expected to conclude in late 2008 (DOHA, pers. comm., 12 June 2008).

## **Other concerns**

Various concerns were raised by Medicines Australia and Pfizer in relation to aspects of Australia's intellectual property (IP) regime, in particular issues

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surrounding the enforcement of patent rights and inadequate data exclusivity periods. In relation to patent rights, a specific concern related to changes introduced during the passage of legislation to implement the Australia-United States free trade agreement in 2004, which introduced patent certification requirements that Pfizer (sub. 31) described as ‘unworkable’ (p. 3) and ‘administratively burdensome’ (p. 13).

These amendments [the so called ‘Latham amendments’] facilitate early market entry by generics before patent expiry without prior notice to the patent holder, and actively deter patent holders from defending their patents ... (Medicines Australia, sub. 35, p. 9)

The Commission acknowledges that the operation of these amendments could create a significant burden for patent holders, particularly through:

... increased patent litigation costs for the originator pharmaceutical industry. Companies are increasingly forced to defend more valid patents against infringements than in the past ...

... [A]n increase in unnecessary litigation ... increases red tape and cost of doing business in Australia. Moreover, due to a lack of sufficient notification to innovator companies of ... an impending entry of a generic competitor brand, originator companies are compelled to spend considerable time, money, and resources to keep track of whether generic companies are intending to seek marketing approval for patented medicines. (Medicines Australia, sub. DR 64, p. 5)

However, the Commission considers that these burdens are intrinsically tied to the pursuit of the policy objective, namely to facilitate early market entry for generic medicines. As such, in accordance with the terms of reference for this review, these intellectual property issues have not been assessed by the Commission as part of this report. They should be considered in the context of the Review of the National Innovation System, currently being conducted by an expert panel, chaired by Dr. Terry Cutler, which has as part of its terms of reference to ‘identify regulatory barriers to innovation and recommend ways to minimise these’. The Commission notes that both Medicines Australia and Pfizer have made a separate submission to that Review raising the concerns identified above and other issues relating to the protection of intellectual property.

In conducting the Review, the Panel is to have regard to relevant reports and studies, including the Productivity Commission’s Report on Public Support for Science and Innovation (PC 2007c). A ‘Green Paper’ detailing policy options is to be provided to the Government by the end of August 2008 and will be used as the basis for the development of a Government ‘White Paper’ to be delivered by the end of the year.

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## 4.3 Overview of medical devices regulation

Medical devices are products used in the diagnosis, prevention, treatment and management of disease and disability. They range from more basic or everyday items such as medical gloves, bandages, syringes, condoms and disinfectants through to high technology items such as in vitro diagnostic devices, X-ray equipment, surgical lasers, orthopaedic implants, cardiac defibrillators and pacemakers, and dialysis equipment.<sup>15</sup>

Medical devices are regulated under the Therapeutic Goods Act. The Act was amended in 2002 to introduce a new system for medical device regulation incorporating the principles of the international regulatory model developed by the Global Harmonization Task Force (GHTF).<sup>16</sup>

### Assessing safety and performance and approval for sale

The TGA conducts three key assessment processes for medical devices:

- conformity assessment procedures that assess requirements imposed on manufacturers
- assessment of applications for inclusion of devices on the ARTG<sup>17</sup>
- post-market monitoring, surveillance and review of medical devices.

Medical devices cannot be marketed in Australia unless they are approved by the TGA for inclusion on the ARTG or are specifically exempt in the legislation. The TGA uses a risk-based approach to assess the safety and performance of devices, against essential principles defined in the Act. The essential principles set out the requirements relating to the safety and performance characteristics of medical

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<sup>15</sup> The term ‘medical technologies’ is sometimes used as an alternative to or interchangeably with ‘medical devices’. Whilst not a clearly defined term, the Commission considers that ‘technologies’ is a broader term than devices. Generally in this section the term devices is used when discussing the regulatory framework since this term is defined in Section 41BD of the Therapeutic Goods Act and this determines the scope (product coverage) of the Act.

<sup>16</sup> Australia’s regulatory model is aligned with the GHTF model rather than the European model. Although the GHTF has its origins in the European process, there are some important differences between the European and GHTF models. With recent reviews of the relevant Directives in Europe, technical requirements are now more closely aligned, but differences in implementation remain.

<sup>17</sup> A small number of applications are also assessed by the Medical Devices Evaluation Committee (MDEC), comprising expert clinicians. The MDEC provides advice to the Minister for Health and Ageing and the TGA on safety, quality, performance and timely availability of medical devices.

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devices. The principles may define results to be achieved, performance levels, hazards to be addressed or issues to be considered, but do not necessarily specify how they must be satisfied or complied with. Thus, compliance with applicable medical device standards is not required, but is one way to establish compliance with the essential principles. This provides greater flexibility for manufacturers and scope to adapt more readily to technological advances or changes in the application of medical devices.

Medical devices are classified to one of five categories according to classification rules based on the risk presented to the patient, the user and the environment (see table 4.1).

Conformity assessment must be performed before a device can be included in the ARTG. Conformity assessment is the manufacturer's responsibility, and requires the manufacturer to certify that the medical device conforms to the essential principles of safety and performance and that an appropriate conformity assessment procedure has been applied. Supporting technical documentation is required. For low risk (Class I devices — eg non-sterile gloves and gowns, elasticised bandages, etc) manufacturers self certify and there is no pre-market audit.

The TGA, or an overseas 'Notified Body', issues certification after confirming the Conformity Assessment procedures applied by the manufacturer are appropriate. Assessment by the TGA is required for Australian manufacturers of medical devices intended for supply in Australia. The decision to issue a conformity assessment certificate depends on several factors, including: the application of quality management systems; certification of compliance with the essential principles; and that the applicant and relevant other people within the manufacturer's organisation are fit and proper persons within the meaning of the regulatory framework.

Lower risk category devices are usually included in the ARTG automatically once a proper application is made, together with the appropriate certification. Applications may be selected by TGA for an Application Audit which involves checking some or all aspects of the application and certification. Applications for inclusion of medical devices onto the ARTG can be submitted electronically using the Device Electronic Application Lodgement (DEAL) System. Applications for both registration and listing on the ARTG for certain other therapeutic goods, but not pharmaceutical medicines, can also be lodged through DEAL.

Overseas manufacturers can either arrange for the TGA to undertake the necessary assessments or present evidence of acceptable assessment to the appropriate European Medical Devices Directive, and supplement this with the preparation and signing of a Declaration of Conformity to Australian requirements.

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For over 97 per cent of medical devices, that evidence is provided in the form of either an EC Certificate issued by one of the 78 Notified Bodies operating in Europe, or an MRA Certificate issued by one of the 18 Conformity Assessment Bodies approved for the purposes of the Australia-European Mutual Recognition Agreement. (TGA pers. comm., 11 August 2008)

Transitional arrangements for the implementation of the new regulatory system included a two year transition period (until October 2004) for all devices that met the definition of a medical device, but were previously exempt from entry on the ARTG or were excluded under the Therapeutic Goods (Excluded Goods) Order of 1998. A five year transition period was allowed for medical devices registered or listed in the ARTG prior to October 2002 to be included in the ARTG under the new system.

### **Assessment for funding/reimbursement**

The Medical Services Advisory Committee (MSAC) makes recommendations to the Minister about public funding of *professional services* involving medical technologies and procedures, most commonly via the Medicare Benefits Schedule. MSAC assesses the safety, clinical effectiveness and cost effectiveness of medical technologies and procedures in response to submissions from the industry or references from government.

MSAC funds and organises assessments, but the majority are undertaken by contracted evaluators, overseen by an expert advisory panel chaired by a member of MSAC. MSAC members are appointed by the Minister and include: specialist practitioners; general practitioners; health economists; a health consumer representative; health planning and administration experts and epidemiologists.

The Prostheses and Devices Committee (PDC) makes recommendations to the Minister on the listing and benefit levels of new prostheses on the Prostheses List<sup>18</sup> which, under the *Private Health Insurance Act 2007*, determines those items that private health insurers are required to reimburse. The PDC does not consider, or make recommendations about, public funding.

Private health insurers are required to pay benefits for a range of prostheses that are provided as part of an episode of hospital treatment or hospital substitute treatment where the patient is covered for the treatment. The legislation does not define

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<sup>18</sup> Prostheses on the List include cardiac pacemakers and defibrillators, cardiac stents, hip and knee replacements and intraocular lenses, as well as human tissues such as human heart valves, corneas, bones (part and whole) and muscle tissue. The list does not include external legs, external breast prostheses, wigs and other such devices.

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‘prosthesis’, however, the Minister has endorsed a set of criteria for listing products on the Prostheses List.

The PDC considers the safety and clinical effectiveness of prostheses. It does not formally consider cost effectiveness, but does provide advice on appropriate benefits that have been negotiated between the Prostheses and Devices Negotiating Group and the sponsors. PDC members include: clinicians; insurers; private hospital nominees and representatives of consumer groups and the medical technology industry.

All medical devices to which the TGA legislation applies must be included on the ARTG before an application can be made for assessment by the Medical Services Advisory Committee or Prostheses and Devices Committee (if appropriate).

#### **4.4 Concerns about medical devices regulation**

Concerns were raised about various aspects of the regulatory arrangements for medical devices. These are discussed under the following headings:

- TGA monopoly on conformity assessment for Australian manufacturers
- timeliness, transparency and consistency of assessments/approvals
- definition of the central circulatory system
- problems associated with access to funding and reimbursement
- multiple and overlapping processes.

Most of the concerns are not new and have been raised in submissions to various reviews, including: a DOHA administrative review of the Medical Services Advisory Committee (2004-5); the Commission’s Research Study on Impacts of Advances in Medical Technology (PC 2005b); the Regulation Taskforce (2006); during the development of the Medical Devices Industry Action Agenda (DITR 2006); and the recent Doyle Review of Prostheses Listing (2007).

The Medical Technology Association of Australia (MTAA) are concerned about slow progress, submitting that the industry ‘has seen little progress in structural reform to processes ... [if] anything MTAA has seen additional impositions on industry ... as a result of failures to restructure and address the inconsistencies and inequities in access to medical technologies’ (sub. 23, pp. 5–6).

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## **TGA monopoly on conformity assessment for Australian manufacturers**

Under the Therapeutic Goods Act, the TGA is required to examine and certify the conformity assessment procedures undertaken by Australian manufacturers. While the Act permits the TGA to accept CE certification for medical devices manufactured overseas, it mandates inspections by the TGA for Australian manufacturers of equivalent devices.

The MTAA (sub. 23) claim that this disadvantages Australian manufacturers relative to their direct competitors overseas in terms of the costs of the domestic inspections and time delays. In its submission to the Regulation Taskforce, the Medical Industry Association of Australia (MIAA, as the MTAA was named at that time) provided an indication of the magnitude of the regulatory cost disadvantage faced by Australian manufacturers of medical devices:

... it is 36 times more difficult for this company to recover regulatory costs from sales in Australia than in Europe. This situation is created by compulsory TGA inspections, the associated fees and the small size of the market.

Initial costs for these inspections typically range from approximately \$20 000 to \$200 000 (if the device contains an unapproved medicinal component) with costs of \$6 000 for regular surveillance audits every 12 to 20 months. (MIAA 2005, p. 7)

### *Assessment*

In addition to being considered by the Regulation Taskforce, the TGA's monopoly was discussed in the Productivity Commission's Research Study on Impacts of Advances in Medical Technology (PC 2005b) and the Medical Devices Industry Action Agenda (DITR 2006).

The Regulation Taskforce (2006) recommended:

The Australian Government should consider allowing Australian manufacturers to choose a certification body (acceptable to the Therapeutic Goods Administration), based in Australia or overseas, to verify and certify their conformity assessment procedures (having regard to the recommendations of the Medical Devices Industry Action Agenda). (recommendation 4.19)

The Government agreed to this recommendation and stated in its response that the issue, and best practice regulation for devices more generally, would be considered as part of the implementation phase for the Medical Device Industry Action Agenda (Australian Government 2006). However, the Government has concluded the Action Agenda process and the issue remains unresolved, so an alternative process

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is needed for considering best practice regulation for devices and for introducing third-party conformity assessment.

The ability of Australian manufacturers to use a certification body other than the TGA, was also raised as part of the stakeholder consultations during the development process for the Australia New Zealand Therapeutic Products Authority (ANZTPA). This and other issues identified during that process are now being discussed with the industry with a view to bringing these elements in to the Australian regulatory framework. DOHA submitted:

The TGA has conducted initial consultations with stakeholders on a possible model to enable the use of external assessment bodies in conformity assessment. Further consultations will be required acknowledging changing international experience. (DOHA, sub. DR71, p. 6)

Notwithstanding these recent developments, this issue has taken too long to resolve. The Regulation Taskforce recommendation to allow third party conformity assessment for Australian manufacturers should be implemented as soon as possible. A high priority should be given to resolving implementation details following the completion of the current consultation process.

RESPONSE 4.5

*The Department of Health and Ageing 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 Therapeutic Goods Administration), based in Australia or overseas, to verify and certify their conformity assessment procedures.*

### **Timeliness, transparency and consistency of assessments/approvals**

Concerns were raised about excessive timeframes for the processing of applications for registration of *higher risk* devices. MTAA, for example, stated:

Timeframes have extended for the processing of applications for registration of higher risk devices as a result of the backlog of applications ... arising from the surge of products transitioning to meet the cut-off date under the regulatory changes introduced in 2002 ... As a result there is a significant backlog in products awaiting conformity assessment (both new products caught up in the backlog) and transitioning products ... (MTAA, sub. 23, pp. 2–3)

Johnson & Johnson Family of Companies (sub. DR70) claimed that changes at the TGA aimed at clearing the backlog of re-registration applications are having a negative impact on evaluation times for new and innovative products while Medtronic (sub. DR62) submitted that generally timeframes for registration of



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*lower risk* devices have become longer since the October 2007 transition cut-off date.

Medtronic (sub. DR62) also considers that the TGA is reporting inaccurately on its efficiency in meeting assessment timeframes, by ‘starting the clock’ from the date an officer is assigned, rather than when payment is received.

Several participants consider that there is insufficient recognition of overseas regulatory approval processes and assessments. For example:

Australia is in an excellent position to take greater advantage of regulatory approval processes undertaken by its international regulatory partners so that the emphasis of the regulatory resources in Australia can be changed to one of a structured post-market review process. (MTAA, sub. 23, p. 5)

In a market where over 90% of medical devices are imported and Australia represents less than 2% of the global medical device market it would be most effective for the TGA to focus on working with reputable overseas regulatory authorities and Notified Bodies to develop a common understanding of, and confidence in each other’s processes and decision making. (Johnson and Johnson Family of Companies, sub. DR70, p. 14)

[Medtronic has a concern] regarding ... [TGA] ... approval of medical devices containing components of animal origin or that contain substances classed as medicines. These applications are expensive and lengthy (approximately 18 months) and delay the entry of medical technology that may have already been assessed and approved by international notified bodies. (sub. 62, p. 3)

Medtronic (sub. DR62) and Johnson & Johnson Family of Companies (sub. DR70) also raised various concerns regarding transparency, communication and consistency in their dealings with TGA, including:

- a lack of transparency in conveying policy decisions and new application rules to industry
- a lack of accessibility of TGA officers
- inconsistency in decision making and advice
- a lack of clarity with regard to the reasons or justification for certain decisions.

### *Assessment*

The life cycle of an average medical device is about 18 months. Medical devices are therefore less likely to benefit from extended patent protection and regulatory delays in getting products to the market place can be particularly costly.

Medical technology development has been characterised as a continuous, iterative process. This iterative and ongoing development process, characterised by constant

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product changes made in response to user needs and preferences distinguishes medical technology innovation from other therapeutic products. ... systems which support speed to market are as critical to the survival and success of the industry as they are to the capacity to make new technologies available to patients who need them. (MTAA, sub. 23, p. 2)

The TGA reports publicly on its performance in meeting target timeframes for application processing.<sup>19</sup> An analysis of information provided by the TGA for the latest available two quarters (July to December 2007) reveals that:

- for processing of DEAL applications, TGA's performance ranged from 98% completed within the target time of 15 days<sup>20</sup> for 'Manufacturing Evidence of Conformity Assessment' (where an overseas notified body has already issued certification) through to only 46% completed within the target time of 60 days for a 'Level 2 application audit' for an individual new device<sup>21</sup>
- for conformity assessment applications (where the TGA is required to issue certification, for example for Australian manufacturers), 76% of 'Schedule 3 Part 1' assessments were completed within the 90 day target time,<sup>22</sup> 53% of 'Schedule 3 Part 1.6 Design Examination' assessments were completed within the 120 day target time<sup>23</sup> and all assessments were completed within the statutory time limit of 255 days.

The TGA received an extremely large number of applications for conformity assessment and inclusion onto the ARTG, for medical devices in the last year of the five year transition period to the new regulatory framework for medical devices, ending in October 2007.

The Therapeutic Goods Act has been amended to ensure that registered and listed medical devices transitioning to the new framework, for which an effective application was received before 4 October 2007, can continue to be supplied until their new application for inclusion is processed. New administrative processes have allowed the transitioning applications to be quarantined.

The TGA's priority is the processing of applications for new products and it has been focusing on meeting agreed industry/TGA timeframes for these applications. In relation to Medtronic's claims about inaccurate reporting by TGA on its timeliness, the Commission notes that the TGA's practice is to 'start the processing

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<sup>19</sup> See <http://www.tga.gov.au/about/tgabp0809.htm>.

<sup>20</sup> With an average completion time of 8 days and a range of 1 to 71 days.

<sup>21</sup> With an average completion time of 73 days and a range of 1 to 269 days.

<sup>22</sup> With an average completion time of 49 days and a range of 3 to 182 days.

<sup>23</sup> With an average completion time of 49 days and a range of 10 to 236 days.

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clock' when the application becomes effective, that is when the application fee is received. The clock is stopped when the TGA is waiting for requested further information from the applicant or when further fees remain unpaid.

The processing of the transitioning applications is being managed separately and TGA is engaging the industry in a risk-based approach to prioritising the assessment of these applications and will report regularly on progress in clearing the backlog. The task of separating transitioning applications and prioritisation has been made difficult because not all sponsors clearly identified their applications as new or transitioning, and some applications include both types of product. The TGA has flagged that it is in the process of engaging additional resources to manage current workloads and the peak in applications received. (TGA, pers. comm., 28 April and 11 August 2008)

A review of business processes in the TGA, Office of Devices, Blood and Tissue was initiated in 2007. Consultation with industry has commenced on the Medical Device Business Improvement Program. The Business Improvement Program has a number of objectives, including to improve: efficiency in pre-market processing; transparency in decision making; industry understanding of the legislative framework; accuracy in the applications submitted; and more effective post-market monitoring of product safety.

Timeliness of approval processes is specifically being addressed as part of the Program. One significant measure will be the move to 'auto-inclusion' of all Class I medical devices onto the ARTG. The TGA is also working with the industry to address problems with the quality and completeness of the applications it receives, which has also contributed to delays in processing.

Also, as part of the Business Improvement Program, the TGA has recently implemented some initiatives which aim to provide stakeholders with more effective service, and these are likely to contribute to some improvement in transparency and consistency. This includes specific initiatives relating to written correspondence, telephone and email enquiries and website enhancements (including answers to 'frequently asked questions'). The TGA is also currently considering, across all program areas, ways in which the agency's decision-making processes can be made more transparent, including the publication of decisions (TGA pers. comm., 11 August 2008).

***The Therapeutic Goods Administration (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.***

*Acceptance of overseas assessments*

With respect to acceptance of overseas registrations/certifications, table 4.1 provides a summary of the assessment process for the different categories of devices. For lower risk devices the TGA currently accepts prior overseas registrations as part of its decision-making processes. Greater than 90 per cent of medical devices are entered on the Register without further assessment by the TGA — based on declarations by the manufacturer that the product is in compliance and where appropriate, supported by certifications issued demonstrating compliance with a regulatory framework similar to Australia. For higher risk devices, the application audit process is designed to ensure that devices have undergone the appropriate level of scrutiny, commensurate with the risks posed by their use.

Since adopting the principles of the Global Harmonisation Taskforce for the Australian regulatory framework for medical devices, the TGA has very similar data requirements to Europe and Canada. This makes preparation of the audit dossier simpler for the approximately eight per cent of applications which undergo the application audit process and are required to provide documentation to support an existing overseas certification.

Nevertheless, participants have concerns about the unnecessary cost and delays associated with what they perceive to be a duplicative process. Johnson and Johnson Family of Companies submitted:

In most cases, overseas manufacturers undertake the appropriate conformity assessment procedures for Class III devices by having Quality Management System certification issued by a Notified Body (NB) together with the preparation of a Design Dossier comprising technical product specific documentation for evaluation by the NB. ...

Rather than the audit process being a check that the appropriate conformity assessment process has been applied, the Level 2 Application Audit process is a duplicative evaluation process where much of the same documentation that was assessed by the NB in the Design Dossier review is re-evaluated by the TGA.

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The overall cycle time for TGA approval for new products (not re-registrations) at present is approximately 6 months.

Since the TGA evaluation can only commence once the Design Dossier review has been completed and the Design Examination Certificate issued, the sequential nature of these two processes means that products are launched in Australia 6 – 9 months later than they are available in Europe. With the average lifecycle of a medical device being 18 months, the duplicated process conducted in Australia means that, not only are new technologies not available to Australian patients until much later than European patients but one third of the investment recovery period is lost. (sub. DR70, pp. 14-15)

The Australia-EU Mutual Recognition Agreement does provides a rapid path to TGA approval for Class III devices where the manufacturer is located in the EU and the device is substantially manufactured within the EU. Class III devices that have been reviewed and CE marked by a Notified Body can have a Mutual Recognition Agreement (MRA) Certificate issued, which is lodged with TGA and the product approved without any additional evaluation within two weeks. Johnson and Johnson Family of Companies called for an equivalent MRA process to be established with the US:

Class III devices from US manufacturers go through the identical process of Design Dossier review by a NB [Notified Body] however are then required to go through an additional costly 6 months review process by TGA in order to be included in the Australian Register of Therapeutic Goods (ARTG). (sub. DR70, p. 16)

The TGA has informed the Commission that it has commenced discussions with the US Food and Drug Administration in relation to mutual acceptance of device assessments (TGA, pers. comm., 11 August 2008).

More generally, Johnson and Johnson Family of Companies queried the need for TGA to conduct expensive overseas audits of manufacturers in non-EU member countries, where the facilities ‘are regularly audited by a reputable ... [Notified Body of the EU] ... with their audit reports and recommendations available for review by TGA ...’ (sub. DR70, p. 16).

There would appear to be scope for wider recognition by the TGA of prior overseas assessments for devices. A policy of generally accepting assessments from competent bodies that have demonstrated suitably rigorous assessment processes could potentially:

- reduce regulatory burdens for business
- reduce TGA administration costs and free up regulatory resources to focus on post-market monitoring and on pre market assessments for the highest risk devices
- facilitate quicker market access to new devices with consequent health benefits.

**Table 4.1 Assessment procedures by category of device**

<i>Class of device</i>	<i>Proportion of medical device entries on ARTG<sup>a</sup></i>	<i>Assessment procedure</i>
Class I (low risk)	58	Not required to be assessed, either by an EU Notified Body for EU market entry or by the TGA for Australian market entry, but are entered on the Australian Register of Therapeutic Goods (ARTG) on the basis of the manufacturer drawing up an appropriate Declaration of Conformity certifying the products are in compliance with the regulatory framework.
Class IIa (low to moderate risk)	22	Class IIa (and all but four types of Class IIb) medical devices are entered on the ARTG supported only by evidence provided by the manufacturer that they, and the devices as appropriate, have been assessed and found in compliance with the EU regulatory framework for medical devices. It is expected the manufacturer will have drawn up and signed the appropriate Declaration of Conformity to support placing the device(s) on the Australian market, but this declaration is not required to be presented to the TGA.
Class IIb (moderate to higher risk — includes most implantable devices)	15	With the exception of four types of Class IIb devices, procedure is as for IIa. For the other four see procedure for higher risk devices.
Class III (high risk)	4	Of the remaining (approximately 10% of total entries on ARTG).
Class AIMD (high risk — implantable devices equipped with an energy source)	1	<ul style="list-style-type: none"> <li>• 2 % of total entries are those devices required, by the Act, to have their conformity assessment processes reviewed by the TGA. This category includes devices from Australian manufacturers.</li> <li>• 8 %, which represent the highest risk devices, undergo an application audit — a desktop review process where certification(s) demonstrating compliance with a regulatory framework similar to Australia and documentation prepared by the manufacturer, or the assessment body, as part of the process to achieve that certification, is reviewed by the TGA.</li> </ul>

<sup>a</sup> Devices available on the Australian market today, as represented by entries on the ARTG.

Source: Based on information provided by the TGA (per. comm., 11 August 2008).

However, for such a policy to ensure continuing high standards of devices available in Australia and deliver net benefits for the community, the TGA must have a high

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level of assurance as to the quality of the assessments by the overseas bodies. The Commission notes the advice of the TGA (pers. comm., 11 August 2008) that its experience over recent years, including in reviewing documentation supplied as part of the application audit process, has revealed:

- some variability in the competence of Notified Bodies of the EU to assess high risk devices and variability in the standard of clinical evidence collection and evaluation
- evidence of different manufacturing standards being applied to a product sourced from the same overseas manufacturer, depending on the ultimate destination market.

Similar concerns have been identified by European authorities. The EU is currently considering a complete restructure of the Medical Device Directives, including a ‘drawing back’ of assessment of high risk devices to a centralised assessment body, akin to the European Medicines Evaluation Agency, and away from the various Notified Bodies.<sup>24</sup>

RESPONSE 4.7

***The Therapeutic Goods Administration (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.***

### **Definition of the central circulatory system**

Johnson & Johnson Family of Companies (sub. DR70) submitted that differences between the Australian and European definition of the central circulatory system results in classification of some devices to the higher risk Class III in Australia compared to Class IIb in Europe, with corresponding increases in compliance costs. In order to complete the appropriate conformity assessment procedure as a Class III device specifically for Australia, the manufacturer is required to undertake ‘a great deal of additional work to prepare a Design Dossier for the product and submit it to the NB [Notified Body] for evaluation in order to have a Design Examination Certificate and Summary Technical Report issued’ (Johnson & Johnson, sub. DR70, p. 17).

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<sup>24</sup> See *Public Consultation on a Recast of the Medical Devices Directives* available at ([http://ec.europa.eu/enterprise/medical\\_devices/consult\\_recast\\_2008\\_en.htm](http://ec.europa.eu/enterprise/medical_devices/consult_recast_2008_en.htm)), accessed 14 August 2008.

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## *Assessment*

Concerns about inconsistencies in the definition of the central circulatory system were raised with the Regulation Taskforce (2006), which recommended the Australian Government should apply an internationally agreed definition of the central circulatory system to all applicable medical devices. (Recommendation 4.20)

The Government agreed to this recommendation and has worked closely over recent years with its international counterparts to harmonise with an internationally-accepted definition of the central circulatory system. However, around the world there are differing views on the most appropriate definition. Australia although not aligned with the European definition, is aligned with the internationally accepted definition as set out by the Global Harmonisation Taskforce (GHTF). The Commission notes that member economies of the Association of South East Asian Nations (ASEAN) and the Asian Harmonisation Working Party (AHWP) are working to introduce the GHTF regulatory framework and hence their definitions will also align with the principles of the GHTF.

In the longer term, achieving alignment between the GHTF and European Medical Devices Directives should be the goal for regulators internationally. This would facilitate trade and earlier access to devices and reduce business compliance costs. In the short term, notwithstanding existing definitions, the TGA should give consideration to whether, for certain devices that are classified to a higher risk class in Australia than in Europe, some additional flexibility or abbreviated assessment/documentary evidence requirements may be appropriate. Any decision or ruling to facilitate more rapid approval would, however, need to be transparent and consistently applied across equivalent devices.

## **Problems associated with access to funding and reimbursement**

Several concerns were raised about Government funding and reimbursement for medical devices. An overarching concern related to the fragmentation and overlap in these processes, including the need for streamlining the whole process of registration through to reimbursement (discussed separately below). Other concerns included:

- assessment of new medical procedures involving medical devices by the Medical Services Advisory Committee (MSAC) ‘continues to lack transparency and a sense of urgency’ (MTAA, sub. 23, p. 3) — ‘in Medtronic’s experience it is not uncommon for a review to take over 2 years’ (sub. DR62, p. 3).



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- the requirement to re-submit a completely new application in the event that the Minister endorses a negative MSAC recommendation:

It would be more efficient if there was a re-submission process setup that did not require a new application and the subsequent time frame associated but rather an application process linking to the review conducted by MSAC previously. This will negate the requirement to commence an application and review from the beginning and minimise the duplication in the process. (Medtronic, sub. DR62, p. 3)

- the Prostheses List has not kept pace with innovation and this is distorting treatment decisions — there are some technologies on the List that many would not consider to be prostheses, and many other technologies that should be considered for reimbursement that are not reimbursed because they are not ‘prostheses’. ‘As a result treatment decisions are being driven by whether or not a particular therapy is reimbursed, rather than by a decision based on the most appropriate procedure’ (MTAA, sub. 23, p. 4). Johnson and Johnson Family of Companies had a particular concern that there ‘is currently no reimbursement mechanism that permits high cost, single use devices to be covered by health funds’ (sub. DR70, p. 21).
- inconsistencies in access to funding arrangements for a range of ‘essential care’ items — some items receive reimbursement or subsidy from the Australian Government, some from state governments and some none at all.<sup>25</sup>
- inequity in access between privately insured and uninsured (public) patients to preferred technologies:

The current operation of the Prostheses List is widening that inequity by creating increasing numbers of gapped items for insured patients who may need to access a preferred technology recommended by their clinician. (Medtronic, DR62, p. 2)

### *Assessment*

Regarding the MSAC processes, the Commission notes that current concerns are not new. Submissions to an internal review of MSAC conducted by DOHA in 2004-5 identified five major areas for improvement:

- clear reasons for decisions
- consistent use of evidence
- timely decisions
- including others in the process
- information and communication.

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<sup>25</sup> Essential care items are those necessary for the care, well-being or, in some cases, survival, of patients.

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The MSAC identified and agreed to 37 action items relating to these areas (DOHA 2006) and a number of reforms have been implemented that have gone some way toward addressing concerns, but overall MTAA are of the view that ‘[i]mprovements that might have resulted from MSAC’s review of itself have not eventuated’ (sub. 23, p. 3).

The MSAC should commit to clear timeframes for its assessments and identify further measures to improve efficiency and enhance transparency of its processes. MSAC processes would, however, benefit from independent external review.

The Doyle Review of Prostheses Listing Arrangements reported to the Minister in October 2007 and made recommendations that would result in a streamlined listing process (discussed below) and reduced administrative burden and red tape (Doyle 2007). The Report was generally supported by industry, but there has been no formal Government response and ‘reimbursement processes have not improved’ (MTAA, sub. 23, p. 3). DOHA advised that it is implementing a process of continuous improvement for the prostheses arrangements.

Expert clinicians are completing grouping work – sorting similar prostheses into groups to inform benefit negotiations. The outcome will be a comprehensive framework that ensures similar benefits for products with the same clinical outcomes, and a less burdensome application and assessment process for manufacturers. (pers. comm., 12 June 2008)

MTAA (sub. 23) proposed the establishment of an ‘Essential Care List’ that would operate in a similar manner to the PBS scheme for pharmaceuticals for a range of products that come within acceptable parameters of essential care. Johnson and Johnson Family of Companies also supported this type of list and claimed this ‘would allow for consistency in a reimbursement process that is defined by a set of criteria based on improved health outcomes, and not by whether a device is a ‘prosthesis’...’ (sub. DR70, p. 21).

The Commission recognises a need to achieve greater consistency and transparency in funding/reimbursement arrangements across Australia. However, there are a number of competing policy objectives in this area, including ensuring clinical effectiveness and promoting cost effective use of technologies. The Commission sees a particular need for a more holistic view to be taken when making assessments of devices/health technologies, including the need to take into account a broad range of societal costs and benefits — for example, longer term health benefits and reductions in costs to the health system overall. However, the design of an appropriate scheme requires detailed consideration and extensive consultation and is beyond the scope of this review.

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Consideration of the Essential Care List proposal, prostheses listing arrangements and the operation of MSAC require further independent review. This would be best undertaken in the context of a broader review of Health Technology Assessment processes for devices (see below).

### **Multiple and overlapping processes**

Participants raised concerns about the overall complexity of the Health Technology Assessment (HTA)<sup>26</sup> System in Australia. The complexity is apparent from figure 1. Even this somewhat simplified diagram gives a clear indication of the number of bodies involved and the difficulty interpreting their respective roles and responsibilities.

Johnson and Johnson Family of Companies submitted:

Whereas other countries with larger healthcare sectors have only one HTA body, Australia has four (five, if the Pharmaceutical Benefits Advisory Committee is included) government funded HTA groups. With the overlapping objectives of the TGA, MSAC, PDC and ASERNIP-S, and their responsibilities unclear, it is essential that regulations relating to funding and reimbursement decisions are streamlined to reduce inefficiencies and excessive delays in access to new technology avoided due to duplicated assessment processes. (sub. DR70, p. 20)

Similarly, Medtronic saw a need for a streamlined, transparent and accountable process for the registration, assessment and reimbursement of new medical technologies and advocated ‘the parallel review of medical devices for regulatory approval by the TGA, review by MSAC for the service associated with a medical device and review of the medical device for listing on to the Prostheses List’ (sub. DR62, p. 4).

The MTAA (sub. 23) continues to have concerns about the overall Health Technology Assessment (HTA) and the fragmented and duplicative nature of aspects of the current processes for registration and assessment for funding and reimbursement. Specific concerns raised with this review, include:

- products must undergo multiple assessments for regulatory and reimbursement purposes — ‘There continues to be a lengthy, sequential pathway to bring medical technology to the patient through mandatory regulatory requirements, procedural review by MSAC, and reimbursement examination for the Prostheses List’ (sub. 23. p. 3)

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<sup>26</sup> Health Technology Assessment (HTA) refers to the process and mechanisms designed to ensure safety, efficacy, effectiveness and cost effectiveness in health service delivery (PC 2005b, p. 178).

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- it is necessary to provide similar conformity clinical trial and investigation information to different government agencies due to a lack of coordination and understanding
  - processes take insufficient account of differences in complexities of medical technologies.

### *Assessment*

These concerns have been raised with other reviews, including the Commission's Review of the Impacts of Advances in Medical Technology (PC 2005b) and the Regulation Taskforce.

The Commission's 2005 study found that health technology assessment processes were highly fragmented, leading to inefficient duplication and unnecessary costs and delays and that procedural transparency needed to be improved. The Commission also found that many of the states and territories have instigated their own bodies to advise on the use of medical technologies in hospital settings and the roles of these bodies (for example, the Victorian Policy Advisory Committee on Technology) partially overlap with various bodies at the Australian Government level, including MSAC and its advisory bodies and also duplicate assessments conducted by the PDC.

The Regulation Taskforce also recognised the need to improve regulatory arrangements for medical devices and endorsed a recommendation in the earlier Commission study for a major review of Health Technology Assessment. The Taskforce (2006) recommended that:

The Australian Government should undertake a system-wide, independent and public review of health technology assessment, with the objective of reducing fragmentation, duplication and unnecessary complexity, which can delay the introduction of beneficial new medical technologies. Health technology assessment processes and decisions should also be made more transparent, in line with good regulatory practice. (recommendation 4.22)

The Government accepted the Taskforce's recommendation (Australian Government 2006, p. 11), but the review has not commenced.

The Medical Devices Industry Action Agenda (DITR 2006) also highlighted the need for more coordinated and systematic health technology assessment, including the need for better synchronisation between the TGA and the PDC (box 4.2).

More recently, the Doyle Review of Prostheses Listing (Doyle 2007) recommended streamlining processes by allowing concurrent applications for TGA registration and inclusion on the Prostheses List. The review noted that the Prostheses and

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Devices Committee should not require evidence of the safety and performance of devices as assessment of this information is the responsibility of the TGA.

MSAC also assesses procedures and technologies in relation to safety and effectiveness, potentially overlapping with prior assessments of safety and performance by the TGA.

**Box 4.2 Impact of inefficiencies in HTA on timely access to devices**

The Medical Devices Industry Action Agenda stated:

The assessment and negotiation processes managed by the Prostheses and Devices Committee generally take four and a half months from the time applications for listing close to when the new List is released. However, if listing on the ARTG occurs after a cut-off date for an application cycle, then listing on the Prostheses List can take up to eleven months. Product reimbursement is limited during this time as consumers and hospitals will be reluctant to purchase a device if it is not reimbursed by private health insurance. If approval by the Medical Services Advisory Committee is also required, that approval process can take up to 21 months in exceptional circumstances, although these times are expected to decrease as the recommendations of the recent review of this committee are implemented.

The best-case timeframe for a product to reach market is 18 months, if it is required to pass through the TGA, Medical Services Advisory Committee and Prostheses and Devices Committee processes in sequence; the worst-case timeframe is 40 months.

*Source:* DITR (2006, pp. 26-27).

Within the existing framework there is significant scope to streamline application processes across the different HTA bodies. Currently businesses are required to supply the same information in different formats to separate agencies. Consideration needs to be given to standardising information requests and, if possible, allowing businesses to submit the information once, to the TGA, which would then make the information available for use by MSAC, the PDC or other bodies.

Some general framework reforms were being drafted as part of the development of the proposed joint Australia New Zealand Therapeutic Products Authority. With the indefinite suspension of negotiations on the establishment of ANZTPA, the Commission understands that the Government has been considering the most appropriate process for addressing concerns about the regulatory and reimbursement systems. DOHA provided the following information on recent developments:

The Department is putting advice to the Minister for Health and Ageing on options for a review of Health Technology Assessment in the broader context of strategic health reform, incorporating ideas from the 2020 Summit and the National Health and Hospital Reform Commission's agenda.

At the same time, work to reform HTA processes outside of a public review framework has continued. The objective of the reforms is to improve the timeliness of patient

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access to beneficial technologies without comprising patient safety or value for money. These reforms are consistent with the medical device industry's urging for shortened assessment timeframes and reduction in 'red tape', through the introduction of better risk management and information sharing strategies. (pers. comm., 5 June 2008)

RESPONSE 4. 8

*The Australian Government should commission a comprehensive and independent public review of the overall Health Technology Assessment (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*
- *improving the operations of the Medical Services Advisory Committee.*

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# 5 Chemicals and veterinary medicines

## 5.1 Background

Chemicals and plastics manufacturing — and importing — in Australia is subject to a wide range of regulations, administered by several agencies at all levels of government. These regulations seek to balance the protection of human health and the environment with the benefits gained from the use of the chemicals themselves. Within the Australian Government, the main regulators are the National Industrial Chemicals Notification and Assessment Scheme (NICNAS); the Australian Pesticides and Veterinary Medicines Authority (APVMA); and the Therapeutic Goods Administration (TGA – see chapter 4). Other agencies, such as the Australian Quarantine and Inspection Service (AQIS) and Food Standards Australia New Zealand (FSANZ), can also impact on the manufacturing and importation of chemicals, where the use of such chemicals falls within their regulatory domain — for example, the use of imported vaccines in the animal health industry or chemical additives in food products.

### The Regulation Taskforce

Several submissions to the Regulation Taskforce raised issues with chemicals and plastics regulation, relating to duplication, delays and lack of consistency with international standards. Overall:

There was a sense of urgency in submissions around the need for a national chemicals policy. The overriding concern is that achieving national uniformity (or even national consistency) is essential to the competitiveness of the industry. This is still far from being realised, despite numerous recent reviews and reforms in the sector. (2006, p. 63)

In examining the issue, the Regulation Taskforce recommended that COAG establish:

... a high-level taskforce to develop an integrated, national chemicals policy. The taskforce should commission and oversee an independent public review of regulation in the chemicals and plastic sector. (2006, recommendation 4.58, p. 67)

In response, COAG established a ministerial taskforce to help streamline chemicals and plastics regulation. Additionally, the Australian Government initiated a

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Productivity Commission review of chemicals and plastics regulation, with that review to inform the considerations of the ministerial taskforce. The review commenced on 27 July 2007, and released its final report on 7 August 2008 (PC 2008a).

## **5.2 Concerns about the regulatory framework for chemicals**

Several participants in the current review believe that aspects of chemicals and plastics regulation create an unnecessary burden on their industry, with some focus on the role of NICNAS:

While the subject of comparative regulatory burden is multifaceted and complex, there is no doubt that the NICNAS 100% cost recovery model, coupled with the wide net of substances under the NICNAS framework, is inconsistent with most other OECD economies. (PACIA, sub. 11, attachment p. 48)

The set up of NICNAS tends to favour the large multi-national who has much greater resources. It undeniably stifles innovation and entrepreneurial activities. (Endeavour Chemicals and Plastics, sub. 3, p. 1)

Participants also raised specific issues such as Material Safety Data Sheet (MSDS) requirements (Science Industry Australia, sub. 13), inconsistency in interstate regulations (Croplife Australia, sub. 18) and duplication in chemical and plastics regulation, both among local regulators, and between Australian and international requirements:

There would be advantage in streamlining and co-ordinating the activities of the different regulatory agencies, especially in terms of determining which agency is actually responsible for any given product or situation. (ACCORD Australasia, sub. 27, p. 6)

With business supply chains becoming more global, issues of unjustified unique Australian regulatory requirements need to be addressed. These act against the integration of Australian businesses into these global supply chains and have negative implications for Australian export manufacturers as well as importers of new technologies that could be of use to Australian business and manufacturing. (ACCORD Australasia, sub. 27, p. 11).

It is clear that these concerns important to the industry, and warrant detailed scrutiny. As such, these concerns — in relation to duplication and inconsistency in the chemicals and plastics regulatory framework, the role of NICNAS, MSDS requirements and unique Australian requirements — have been drawn to the attention of, and were dealt with by, the Commission's chemicals and plastics regulation research study. Accordingly, these matters will not be addressed in this review.



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Some participants (particularly the Animal Health Alliance (Australia), sub. 4) raised a number of concerns relating to AQIS and the APVMA. These are dealt with in the following sections.

### **5.3 Regulation of veterinary chemicals and medicines**

Veterinary products require approval from the APVMA — a statutory authority within the portfolio of the Minister for Agriculture, Fisheries and Forestry — before they can be supplied to the Australian market. The APVMA’s powers and functions are set out in the *Agricultural and Veterinary Chemicals (Administration) Act 1992*.

Under the National Registration Scheme for Agricultural and Veterinary Chemicals, the APVMA is responsible for registering and regulating the manufacture and supply of all pesticides and veterinary medicines used in Australia, up to the point of retail sale. Before being registered for sale, products go through a risk assessment process. Companies must provide the APVMA with information about the product to allow independent evaluators to decide whether it is effective and safe for people, animals and the environment, and not a trade risk. The APVMA also assesses the ongoing quality of products following registration and monitors compliance with regulations on the importation, manufacture, supply and advertising of pesticides and veterinary medicines, up to the point of retail sale.

The APVMA operates on cost-recovery principles and is principally funded by a levy imposed on sales of registered agvet products and by application and annual registration fees. The APVMA also collects licensing fees from manufacturers of veterinary medicines.

State and territory governments are responsible for controlling the use of registered pesticides and veterinary medicines after retail sale. All jurisdictions have adopted the template Agricultural and Veterinary Code and the conditions of use specified by the APVMA during product registration form part of the state and territory control-of-use regimes.

Imported biologically derived animal health products, such as veterinary vaccines, must also satisfy certain regulatory requirements administered by AQIS. Vaccines are classified under the Quarantine Proclamation 1998 as a prohibited biological material and a permit is required for their importation. In issuing an import permit, AQIS evaluates data submitted by the applicant to determine whether import of the product would pose a pest or disease quarantine risk.

The Commission’s draft report on chemicals and plastics regulation has assessed the role of the APVMA in relation to the regulation of pesticides, but not veterinary

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medicines. However, some of the draft report's findings and recommendations (PC 2008a) are relevant to this review. A number of concerns were also raised in relation to the APVMA and AQIS in the Commission's report in 2007 on regulatory burdens affecting the primary sector (PC 2007a).

## **5.4 Concerns about the Australian Pesticides and Veterinary Medicines Authority**

The Animal Health Alliance (Australia) (AHA) raised three main concerns about the APVMA:

- it does not recognise/accept overseas Good Manufacturing Practice (GMP) certificates issued by other recognized OECD country authorities
- excessive time frames for the processing of some applications
- duplication/overlap/inconsistency between APVMA and other agencies.

### **Non-acceptance of overseas Good Manufacturing Practice certificates**

The AHA is concerned that, with the exception of European authorities recognised under the Mutual Recognition Agreement with the European Union (EU) on Conformity Assessment, the APVMA does not automatically recognise/accept overseas GMP certificates issued by other competent authorities from OECD countries.

All the relevant information APVMA requires is on the GMP certificate issued by other OECD countries but it is not in the specific EU-MRA (Mutual Recognition Agreement) format that APVMA will accept. Also, it is necessary to maintain a document database of each issued EU-MRA formatted GMP certificate, as these are valid for 3 years only from the date of last inspection of the relevant facility. (sub. 4, p. 5)

It is claimed that Australian veterinary chemical product registrants incur costs negotiating with overseas subsidiaries and/or government agencies to convert an overseas issued GMP certificate to the EU MRA format acceptable to the APVMA.

#### *Assessment*

The APVMA responded to this issue in its submission (sub. 42) to the Commission's review of regulatory burdens on the primary sector. The following discussion draws on that submission and more recent advice from the APVMA (pers. comm., 21 April 2008 and 13 June 2008).

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The *Agricultural and Veterinary Chemicals Code Act 1994* (and regulations) requires the APVMA to be satisfied of a number of matters with respect to the manufacture of chemical products (including the keeping of records) and GMP certificates are necessary for the APVMA to fulfil its legislative obligations.

The APVMA is currently conducting a review of the overseas GMP scheme, which will determine if any change to the scheme is necessary, and if the scheme is meeting its original objectives, namely:

- to ensure safety of veterinary chemical products registered for use in Australia, irrespective of the site of manufacture
- to ensure compliance of veterinary chemical products with Australian legislative requirements
- to improve/maintain stakeholder confidence in imported products by applying requirements that are comparable to those that domestic manufacturers must comply with (APVMA 2007, pp. 1–2).

The Commission notes that while the review is examining the effectiveness of the overseas GMP scheme against these objectives, the acceptance of overseas GMP certificates is not a key focus for it.

For the APVMA to accept a GMP certificate from a foreign country it must be satisfied that the GMP standards that are required in that jurisdiction are appropriate, and have confidence in the authority and assessment system which underpins the issue of that certificate.

The APVMA has a mutual recognition agreement (MRA) with the EU and with EFTA and both have a sectoral annex for GMP inspection. Australia, therefore accepts GMP certificates from competent authorities identified in the original MRA.

The APVMA makes a case-by-case assessment of GMP certificates it receives from jurisdictions not covered by the MRAs. It accepts GMP certificates from various counterpart authorities to reduce duplication and continues to work (through the Department of Foreign Affairs and Trade) to extend international harmonisation. Of the non-EU OECD countries, the USA is a significant veterinary drug producing country and the APVMA generally accepts GMP certificates from the US Department of Agriculture and the US Food and Drug Administration. The APVMA also accepts certificates issued by the Food Safety Authority in New Zealand in accordance with a Memorandum of Understanding between the two agencies.

The Commission understands that the APVMA frequently accepts GMP certificates from a number of other authorities where the GMP certification process is known to

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be of a comparable standard. The APVMA has advised that in most cases acceptable evidence of compliance can be obtained from either the counterpart regulatory authority or a third-party regulator recognised as equivalent by the APVMA. An APVMA audit of an overseas manufacturing facility may only be required where these avenues are exhausted (APVMA, pers. comm., 13 June 2008).

The APVMA does not require GMP certificates from non-EU countries to be in the EU format. However, the APVMA does require GMP certificates from non-EU countries to contain the same type of information which is contained in EU MRA format certificates. The APVMA has stated that most manufacturers are able to provide acceptable evidence of GMP compliance. However, the Authority acknowledges that some manufacturers may, on occasion, have problems obtaining acceptable evidence of compliance from some foreign regulatory authorities.

To undertake appropriate audits of all foreign manufacturing sites would be very costly for the APVMA, so a policy of selective case-by-case acceptance of overseas GMP certificates is appropriate. In practice, this policy has resulted in the APVMA already accepting GMP certificates from various counterpart authorities beyond those covered by MRAs.

Wider acceptance of overseas GMP certificates could result in savings in both business compliance costs and ongoing government administration costs. The Commission acknowledges, however, that such reductions in costs must be weighed against any increase in risks that may be associated with a policy of wider acceptance. While the Commission is not well placed to comment on whether the APVMA's current approach strikes the appropriate balance, it is important that assessments about whether to accept prior overseas Good Manufacturing Practice certificates have regard to compliance and other costs.

As stated in the final report on chemicals and plastics regulation (PC 2008a), the Commission considers that a statutory obligation should be placed on the APVMA to conduct its assessments in a manner that has regard to the costs of assessments (including the data requirements placed on applicants) relative to the likely benefits from reducing the risks posed by the chemical/medicine concerned.

RESPONSE 5.1

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

- ***business compliance and other costs are considered when making assessments about whether to accept prior overseas Good Manufacturing Practice certificates***

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- *the costs are commensurate with the risks posed by the chemical/medicine concerned.*

## **Timeliness of the Australian Pesticides and Veterinary Medicines Authority assessments**

AHA also raised concerns about excessive time frames for the APVMA's processing, in particular for applications to "over sticker" approved product labels with amended product shelf life information. It claimed that the time taken is 'commercially unrealistic'.

... the time-line to test retention product, obtain an extension of shelf life and over-sticker the product is not far off the 12 months shelf life extension that is approved. A company may as well do nothing and save their APVMA application fees, stability testing costs and write-off the product. (sub. 4, p. 7)

As a further indication of the regulatory cost burden, the AHA stated:

Stock valued at less than \$50,000 would not be extended due to the regulatory difficulties. Across the industry millions of dollars would be lost in value of product lost sales and waste disposal cost of expired products. (sub. 4, p. 7)

### *Assessment*

Requests for extension of shelf life for a particular product batch are made via a permit application. In order to approve the extension of shelf-life, the APVMA must be satisfied that the batch of product will continue to meet specifications and be safe and effective for the approved period.

This often necessitates the submission and assessment of data to demonstrate that the extension proposal will be acceptable. The APVMA has advised (pers. comm., 21 April 2008) that the requirements and timeframes for such applications<sup>1</sup> state that, where an assessment of data is necessary, the legislated assessment timeframe may be five months. Where no data assessment is necessary, the legislated timeframe may be as short as two months.

Timeframes for assessments by the APVMA that are considered by industry to be excessive can potentially be the result of:

- legislative timeframes that are too long, thus providing insufficient incentive for the APVMA to process applications most efficiently

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<sup>1</sup> These are set out in Volume 2 of the APVMA's Manual of Requirements and specific guidelines for such applications (Guideline 48 — detailed in section 2.4).

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- non-compliance by the APVMA with legislated timeframes — this can have many causes, including poor commitment, inadequate resources/lack of expertise or inefficient processes and practices
  - defective or inconclusive supporting information provided by applicants, and the time taken to provide the additional information to remedy this.

In relation to the first point, the Commission considers that all the APVMA-legislated timeframes should be subjected to periodic review to ensure that they remain appropriate.

With respect to the second point, the APVMA acknowledges the importance of timely assessments and has committed, in the formal guidelines, to endeavouring to process all permit applications to extend shelf life of a particular batch of product well within the legislated timeframe.<sup>2</sup>

The Commission's draft report on chemicals and plastics regulation (PC 2008a) includes a more general discussion of the timeliness of the APVMA assessments. A number of industry groups participating in that study claimed that timeliness of assessments is a problem. The following findings are relevant.

- An audit by the Australian National Audit Office (ANAO 2006) found that between 2001 and 2005-06 the number of evaluations finalised within statutory timeframes increased from 94 to 98 per cent for veterinary medicines, while for agricultural chemical products (covered by the Commission's chemicals and plastics study), it declined from 95 to 87 per cent. The ANAO report also found that the greatest contributor to the delays in the overall application process was the time taken by applicants to remedy the various defects in their applications while the statutory clock was paused — on average, the APVMA processing time was around one third of total elapsed time from application to registration.
- A report undertaken by Business Decisions Limited (BDL 2007) for AHA, suggests that mandatory local assessment of non-controversial animal health products by the APVMA typically requires less time than assessments in Canada and Japan.<sup>3</sup> Nevertheless, industry survey results presented in the report indicate that assessment times have increased over the last five years — possible reasons listed include the introduction of additional requirements, but also gaps in expertise or insufficient resources within the APVMA.

The APVMA is currently implementing the recommendations of the ANAO report and this should improve timeliness. More broadly, the APVMA has been

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<sup>2</sup> This commitment is set out in a note at the bottom of section 2.4 of Guideline 48.

<sup>3</sup> The study findings were based on the views of experts within a number of the largest animal health companies in Australia, Canada and Japan.

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conducting a program of process reform to improve efficiency and reduce elapsed times for applications.

Given that the ANAO report found that defects in applications were the greatest contributor to delays in the overall application process, a particular focus of the APVMA has been on identifying process improvements that might reduce the incidence of defective applications. A ‘recording proforma’ is being developed to identify the type and nature of defects in applications so improvement initiatives can be well targeted. Other current initiatives aimed at improving the quality and completeness of applications include: pre-application meetings; routine updating of the Manual of Requirements and Guidelines (and access via the web); an electronic application and registration system (this can reduce some types of administrative errors); pre-submission data assessments; and registration seminars.

While in some cases it may be appropriate to commence the assessment of an application prior to receipt of all required information, in many other cases there may be efficiencies for applicants and for the APVMA in ensuring all critical information has been received before ‘starting of the clock’ for the purposes of measuring performance against legislated timeframes.

### **Duplication/overlap/inconsistency between the Australian Pesticides and Veterinary Medicines Authority and other agencies**

AHA highlighted various examples of duplication, overlap or a lack of coordination between the APVMA and AQIS and between the APVMA and the Department of Health and Ageing (DOHA).

- Duplication of certain auditing activities — veterinary chemical product registrants have to pay the cost of AQIS auditors (between \$4000 to \$10 000 depending on who does the audit)<sup>4</sup> to audit product manufacturing facilities that have already been audited by the APVMA. This includes doubling up on agency audit fees and travel and living allowances for the auditors, costs of organizing facilities and downtime as a result of reduced manufacturing activity during the audit. AHA also expressed dissatisfaction with the quality of AQIS audits and the expertise of their auditors, which they say is impacting on industry’s confidence in the process.
- Overlap/duplication of effort between the APVMA, AQIS and TGA (the relevant function has transferred to the Office of Chemical Safety (OCS), within DOHA) in relation to the issuing of import permits, particularly for dealings

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<sup>4</sup> Audits can be conducted either by AQIS biologicals unit staff from Australia or the Australian Government Veterinary Counsellor in the country of concern.

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with antimicrobial products. AHA suggested that the lack of alignment and coordination in the systems and requirements of the regulators resulted in unnecessary costs, including: duplication of effort on the part of regulatory personnel and doubling up on paperwork and files containing much of the same information. Direct company costs to industry include money, time and human resources in dealing with duplicate requests. Indirect company costs include the AQIS fees for processing permits.<sup>5</sup>

- The APVMA and TGA (now OCS) both require information on import and export of active ingredients used in production (OCS only for antimicrobial) but in different formats and at different times of the year. As a guide to the likely cost of such duplication/lack of alignment, AHA stated:

On average, a veterinary chemical product registrant needs to allocate 5 working days of a semi-skilled employee to deal with this issue each time it occurs. The employee cost is \$100.00 per hour for 8 hours per day for 5 days which equates to \$4,000 per data generation activity. (sub. 4, p. 5)

### *Assessment*

AQIS and the APVMA both may audit manufacturing premises, but the purpose of the audits is different and the premises may have different functions.

With respect to audits of Australian manufacturing premises AQIS may conduct an inspection if the premises will use imported products which are of quarantine concern, and if a condition of the AQIS import permit is that the products must be stored in a Quarantine Approved Premises (QAP). AQIS audits QAPs annually to ensure they continue to comply with the QAP conditions. The APVMA audits Australian manufacturing premises to ensure that they comply with the Australian Code of Good Manufacturing Practice for Veterinary Chemical Products. After an initial satisfactory audit, the APVMA issues a manufacturing licence. Ongoing audits are conducted at approximately 18 month intervals.

The Veterinary Manufacturers and Distributors Association (VMDA) has undertaken a study in cooperation with AQIS and the APVMA, to identify areas of overlap between the APVMA GMP audits and AQIS QAP audits, with a view to a single agency audit of both matters. This report on the reduction of duplication for vaccine assessment also examines the degree of overlap between AQIS evaluation of imported animal vaccines for quarantine safety purposes and the APVMA evaluation of imported vaccines for animal safety purposes. At the time of the Commission's draft report, the APVMA advised that the APVMA and AQIS have discussed an early draft of the VMDA report, and will further discuss this matter

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<sup>5</sup> No fees are involved for TGA permits.



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after the VMDA releases the final report. The Commission understands that, immediately prior to the finalisation of this review, AQIS and the APVMA received the report on the reduction of duplication. The report's two main proposals related to harmonisation of data requirements between AQIS and the APVMA, and coordination of audits between AQIS, the APVMA and the Office of the Gene Technology Regulator. The APVMA advised that both they and AQIS were considering the proposals.

AQIS also inspects overseas manufacturers which seek to export biological products to Australia, for example abattoirs (meat products), pet food manufacturers and vaccine manufacturers.<sup>6</sup> APVMA advised that for overseas premises, AQIS and the APVMA have different interests and there is no overlap between the APVMA GMP requirements and AQIS quarantine requirements (pers. comm., 21 April 2008).

On the issue of overlap relating to import permits, the permits issued by the APVMA, AQIS and OCS are for different purposes and share very little common data. The APVMA's Consent to Import Unregistered Products or active constituents is commonly linked to an application for a research permit to use an unregistered product or active constituent. This is nearly always for the purpose of conducting field trials to develop data in support of an application for registration of a new product in Australia. The APVMA issues a 'Consent to Import' via a simple administrative process which requires no technical data and for which there is no fee. Customs will not release imported unregistered product unless they see that the APVMA has issued a 'Consent to Import'.

AQIS issues a permit to import biological materials if satisfied that the product does not represent a quarantine risk to Australia. An applicant must submit to AQIS technical data related to the quarantine policy which is relevant to the product. AQIS will accept data in any format provided that it addresses all relevant issues outlined in the relevant quarantine policy.

DOHA has responsibility under regulation 5A of the Customs (Prohibited Imports) Regulations 1956 for issuing permissions to import antibiotic substances into Australia. The requirement for an import permit applies to all therapeutic substances that are antibiotic substances, including those destined for both human and animal use. The import permitting function was previously administered from within the TGA. It is currently undertaken by the OCS. The OCS also administers an import/export licensing regime for narcotics, psychotropic substances and precursor

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<sup>6</sup> If there is an overseas-based Veterinary Counsellor in the Australian Embassy, he/she will often do the audit on behalf of AQIS to reduce costs; otherwise, an Australia-based AQIS officer must travel to the overseas country to audit the premises.

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chemicals in accordance with United Nations convention requirements. The import controls placed on antibiotics are a response to concerns about the development of antimicrobial resistance. DOHA advised:

Importers who are granted import permissions by the OCS are required to report at the end of each financial year on the actual quantity of each antibiotic substance imported during the life of the permit and its intended end use (eg veterinary, human therapy). The submitted data are collated into a report to reflect total imports, by substance type and end use. The report is provided to the Expert Advisory Group on Antimicrobial Resistance as part of the information that they require to consider antibiotic resistance issues in Australia. (pers. comm., 5 June 2008)

Information provided by DOHA would suggest that the OCS requirements are unlikely to impose significant compliance costs for business:

- the target timeframe for issuing permits for antibiotic imports is ten working days
- there are no fees associated with the issuance of a permit
- the majority of permits for antibiotic imports are issued as ‘continuing authorities’ which are valid for up to 12 months and expire at the end of the financial year. A continuing authority permit authorises the holder to import nominated antibiotics throughout the life of the permit. There is no limit on the number of antibiotic substances that can be specified on a permit and multiple consignments can be imported during the life of the permit. (DOHA, pers. comm., 5 June 2008)

APVMA told the Commission that it knows of no scenario in which an importer is required to seek a permit from all three regulatory agencies. One of the few scenarios where a permit from more than one agency is required is where an importer wishes to undertake field trials with a new antibiotic — a permit is required from both the APVMA and the OCS. These are administrative permits which contain some similar information (for example, name and address of the importer), but the overlap in regulatory burden is very slight, and therefore any unnecessary component would be very small.

DOHA also noted that a sub-set of the antibiotics for which the OCS issues import permits would also be subject to the need for import authorisation from AQIS.

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## 5.5 Concerns about the Australian Quarantine and Inspection Service

A number of issues were raised in relation to effectiveness and efficiency of AQIS<sup>7</sup> including:

- timeliness of assessments
- frequency of import permit review/renewal requirements
- requirements for import permits for certain lower risk products are unjustified.

Each of these concerns is discussed in turn below, but an overall assessment is left to the end of the section.

In addition, concerns were raised about some duplication and overlap in requirements between the APVMA and other regulatory agencies, including AQIS. These are discussed above in relation to the assessment of concerns about the APVMA.

### **Australian Quarantine and Inspection Service assessments take too long**

AHA is of the opinion that AQIS assessment timelines are unacceptably long and has concerns regarding the unpredictability of processing times, which makes planning difficult.

Industry confidence in AQIS complying with its own guidelines/standards when assessing industry product applications is lacking. Industry confidence that AQIS will even make a decision on any particular product application is lacking. Time-lines for assessment in excess of 3 years have been seen by industry. Uncertainty also exists in time-lines for renewal of existing applications. (sub. 4, p. 4)

Delays can result in lost market share, especially for seasonal products:

In the case of a product with sales potential of \$1 million per year, one years delay to market results in at least \$1 million lost sales. Costs over the past 5 years to industry are estimated to be in the range of \$20 - \$50 million. (sub. 4, p. 4)

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<sup>7</sup> AQIS and Biosecurity Australia have differing, but complementary roles. AQIS manages quarantine controls at Australia's borders to minimise the risk of exotic pests and diseases entering the country. AQIS also provides import and export inspection and certification to help retain Australia's highly favourable animal, plant and human health status and wide access to overseas export markets. Biosecurity Australia provides science based quarantine assessments and policy advice that protects Australia's favourable pest and disease status and enhances Australia's access to international animal and plant related markets.

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Other potential costs associated with delays in having product applications approved, highlighted by AHA, were:

- significant costs to the agricultural industry as a consequence of not having access to vaccines available to treat various diseases, including suffering by livestock inflicted by diseases that could be prevented by vaccines
- the cost of additional resources needed by industry to deal with the AQIS issues.

To reduce assessment timelines and introduce greater certainty, AHA called for:

- statutory time-frame commitments
- AQIS to agree on a service charter with industry
- greater sharing of information between regulators
- more of a risk-management approach to reviews ‘rather than what often appears to be a “nil risk” approach’ (sub. 4, p. 4).

The *Quarantine Act 1908*, under which AQIS operates, does not impose any statutory timeframes within which AQIS must undertake evaluations for any biological product. This is in contrast to the APVMA — the regulations to its governing legislation (the Agricultural and Veterinary Chemicals Code Act) stipulate timeframes within which the APVMA must finalise an application for registration of an agricultural or veterinary chemical product (see above).

AQIS is reliant on industry to provide relevant data to demonstrate compliance with quarantine requirements. In some cases delays in the assessment of applications can be partly or largely attributable to a failure by applicants to provide all of the required data.

Therefore, should calendar timeframes for evaluations be instituted, some provision to ‘stop the clock’ may be required to make allowance for time periods where extra information is being sought from the applicant, or advice is being sought from Biosecurity Australia. AQIS advised that the intervals over which such advice is delivered can often be many months depending on the vaccine or quarantine issue in question. (pers. comm., 23 April 2008).

With respect to assessments by the APVMA and the relevant statutory timeframes, the clock stops while applicants respond to the APVMA’s requests to remedy defects in their applications (PC 2008a). However, as was suggested above in relation to addressing concerns about the timeliness of the APVMA assessments, AQIS should consider additional measures directed to reducing the incidence of incomplete or otherwise defective applications. Then, providing all requirements of applicants have been clearly specified, there are likely to be efficiencies if the ‘clock’ generally only starts when all critical information has been received.

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## **Import permits are required to be renewed too frequently**

AQIS requires holders of import permits to seek their review/renewal every two years even when there has been no apparent change to the material/product or the risks it poses. AHA (sub. 4) and Science Industry Australia (sub. 13) are of the view that a two year validity period is generally too short, arguing that five years would be more appropriate as the norm. AHA suggested that more frequent reviews should only be required where there is a clear scientific justification and is concerned that presently there ‘appears to be no credible risk management processes used by AQIS in dealing with these permits being reissued’ (sub. 4, p. 7).

The process of applying for import permit renewals imposes significant compliance costs on industry. AHA submitted that ‘[t]he total cost can amount to tens of thousands of dollars per company per year’ (sub. 4, p. 7). Costs include direct costs associated with preparation of the renewal application and AQIS charges to process permits. For veterinary vaccines, an updated ‘full dossier’ is usually also required to support the application for renewal. Industry typically incurs significant costs associated with liaison with overseas subsidiaries, necessary to provide these dossiers.

AHA also pointed to potentially substantial additional indirect costs associated with interruption to imports during the review/renewal process. This can include costs of holding products/ingredients on wharves and associated manufacturing delays and loss of product sales.

... the permit holder is required to await the permit being re-issued before they can legally continue importing the product/ingredient. As all applications are placed in a queue, there can be delays of some months before an application is evaluated. (sub. 4, p. 7)

AQIS considers that the two year limit for import permits is appropriate as it ensures a regular reassessment of the quarantine risks associated with biological product. For a given product, risks may change, for example, due to alterations in manufacturing procedures or the origin of ingredients. A reassessment can also take into account changes to quarantine policy applicable to the product.

The reassessment is undertaken against product-specific quarantine policy. Where necessary AQIS may apply new permit conditions to a product previously imported to ensure the product continues to meet Australia’s accepted level of quarantine protection.

AQIS advised the Commission that where there is no change to quarantine policy or the nature of the risks associated with the product, re-assessments can progress relatively quickly. In contrast, re-assessments can be protracted where quarantine

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policy or production methodologies have changed, or where information/advice needs to be generated either from the applicant or from Biosecurity Australia.

Potential costs associated with interruptions to the importation of product/ingredients can be avoided if the importer submits an application for a new permit sufficiently prior to the expiry of an existing import permit.

A shift to longer duration import permits potentially exposes Australia to undetected risks from imported biological product. Although AQIS has the power under the *Quarantine Act 1908* to revoke permits or amend import conditions for existing permits at any time where significant changes in the level of quarantine risk arise, many such changes in risk may not be identified by the regulator outside routine import permit renewal examinations.

The Commission acknowledges that the *initial* two year time limit for the renewal of import permits may be appropriate to allow reassessment of the quarantine risks of a given product after it has been used in Australian conditions. Following this initial review, continuation of a two year cycle for all products would inevitably lead to unnecessary burdens for some businesses, especially in cases of low risk products for which conditions are unlikely to change. Where unnecessary regulatory activity is reduced, this approach would also allow for more efficient use of agency resources.

At a minimum there would appear to be a strong case for improved communication between AQIS and Biosecurity Australia and applicants about the reasons for re-assessments and in particular to make any relevant changes to quarantine policy transparent.

### **Import permits required for low risk products**

AHA consider that AQIS is imposing an unnecessary requirement for full import permits, with associated requirement for renewal every two years, for certain highly processed products that pose little risk. For example, certain ‘products of fermentation’ for use in veterinary chemical product manufacturing (for example, ivermectin and the stearate chemicals) are highly processed and pure and do not carry the risks associated with plant or animal materials.

Further, according to AHA, multiple companies import these chemicals, usually from the same overseas manufacturing sources and a separate import permit application is required in every case.

This has been a relatively recent imposition on industry and appears to have no scientific rationale ... [it] costs companies financial and human resources in generating

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the information to support the permit application, the costs for processing the permit application and lost time awaiting the permit being issued. (sub. 4, p. 6)

Direct costs for business associated with this permit requirement were estimated by AHA to be ‘\$4000 per incident’ (sub. 4, p. 6), not including AQIS processing fees. AHA suggested that, as an alternative, companies could be permitted to provide an annual declaration to AQIS regarding such products, or revert to the system AQIS previously had in place whereby permits were not required unless the import material is coming from an unknown manufacturer or one with a suspicious history.

AQIS advised (pers. comm., 23 April 2008) that ‘Microbial fermentation products’ (other than alcohols, vitamins and amino acids) are classified under Part 4 of the Quarantine Proclamation Act 1998 as a prohibited biological material and as such a permit has been required for their importation for over 10 years. In issuing an import permit for these products, AQIS evaluates data submitted by the applicant against scientifically-based quarantine policy advice from Biosecurity Australia, and any other relevant information, to determine whether import of the product would pose a pest or disease quarantine risk.

## **Assessment**

The Commission appreciates that determining quarantine measures involves a delicate balance. Imports can involve the likelihood that pests or diseases are brought into Australia with potentially devastating consequences. But excessive restrictions or inefficient delays in assessing imports can reduce choice and access to beneficial new products, impose unnecessary burdens on business and increase prices for consumers.

It is important, therefore, that measures are supported by scientifically-sound quarantine risk analysis and, moreover, that the process in which the analysis is undertaken is as cost-effective as possible, with burdens imposed on those who participate kept to a minimum. This includes ensuring:

- processes and information requirements are commensurate with the objective evidence of risks and there is appropriate flexibility to impose lesser requirements where risks are demonstrated to be low
- the avoidance of unnecessary replication of relevant international data and information.

In principle, the Commission sees merit in introducing explicit statutory timeframes (with reasonable flexibility, including ‘stop the clock’ provisions) similar to the approach adopted in legislation governing the APVMA’s regulatory functions. A

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service charter would also be consistent with best practice administration of regulation and potentially serve to provide greater certainty and clarity for industry in what it can expect in its dealings with AQIS.

However, these and the other specific issues raised are best examined in the context of the broad ranging review of Australia's quarantine and biosecurity arrangements currently being conducted by an independent panel, chaired by Roger Beale. This review's terms of reference specifically ask the panel to examine the appropriateness, effectiveness and efficiency of current arrangements, including resourcing levels and systems, and, where appropriate, to benchmark Australia's arrangements in an international quarantine context. The panel is to provide a final report to the Minister for Agriculture, Fisheries and Forestry by 30 September 2008. The specific concerns raised by AHA in relation to timeliness of assessments and renewal of import permit requirements have also been submitted to the Beale review.



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## 6 Environmental regulation

Most environmental regulation in Australia is beyond the scope of the Commission's annual reviews of regulatory burdens on businesses as regulatory responsibility for environmental matters largely resides with the state and territory governments.<sup>1</sup>

However, the Australian Government's role in relation to environmental matters has grown since the mid-1970s. This trend coincides with growing community concerns about environmental problems characterised as national or international in scope (such as water usage in the Murray Darling basin and climate change).

There has thus been an emergence of intergovernmental agreements and programs (such as the Intergovernmental Agreement on the Environment 1992, the Climate Change Strategy 2004 and the National Framework for Energy Efficiency 2004) and national bodies (such as the National Environment Protection Council) to deal with environmental matters in which the Government participates.

In addition to, or as part of, these various actions, the Government has enacted legislation in relation to environmental matters using its constitutional powers to make laws over external affairs, corporations, taxation and the like. This covers such legislation as the *Environment Protection Biodiversity Conservation Act 1999*, the *Renewable Energy (Electricity) Act 2000* and the *Water Efficiency Labelling and Standards Act 2005*. It is anticipated that the Government will use its constitutional powers to enact legislation to support the proposed Australian emissions trading scheme (currently referred to by the Government as the carbon pollution reduction scheme).

Several areas of environmental regulation in which the Australian Government has a role have attracted the concerns of participants to this review, particularly from the manufacturing sector. This chapter considers these concerns.

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<sup>1</sup> This reflects the division of powers in the Constitution under which the Australian Government has no direct or exclusive power to make laws in relation to environmental matters (ss. 51 and 52).

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## 6.1 Water Efficiency Labelling and Standards Scheme

Participants expressed several concerns about the Water Efficiency Labelling and Standards (WELS) Scheme, focussing on the slow development of Australian Standards and poor regulatory compliance and enforcement. These and other concerns were also raised at a ‘stakeholder forum’ held by the Department of Environment, Water, Heritage and the Arts (DEWHA) in March 2008 (DEWHA 2008c) and with the House of Representatives Standing Committee on Environment and Heritage in its 2007 inquiry into the regulation of plumbing quality in Australia (HRSCEH 2007).

The WELS Scheme is a national scheme established by the Australian Government *Water Efficiency Labelling and Standards Act 2005* (the WELS Act) and complementary state and territory legislation. It is administered by the WELS Regulator (the Secretary of DEWHA) on behalf of all Australian governments.

The objectives of the scheme are to:

- conserve water supplies by reducing water consumption
- provide information for purchasers of water-use and water-saving products
- promote the adoption of efficient and effective water-use and water-saving technologies.

The scheme requires certain products that are manufactured or imported into Australia to be registered and labelled in accordance with standards set under the Act before they can be sold. Applications for registration must be made online and be accompanied by test reports showing compliance with standards, a sample label and the payment of a fee. A product is not registered unless it is gazetted.

The products that are covered by the scheme are showers, tap equipment, flow controllers,<sup>2</sup> lavatory equipment, urinal equipment, clothes washing machines and dishwashers.

The standards setting out the criteria for rating water efficiency and/or performance of each product covered by the scheme are contained in the Australian and New Zealand Standard ‘Water efficient products — rating and labelling’ (AS/NZS 6400:2005), which are developed by Standards Australia. The standards are available for purchase from SAI Global under an exclusive publishing and distribution agreement with Standards Australia.

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<sup>2</sup> Flow controllers can be voluntarily registered under the scheme.

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The WELS ‘water rating’ label provides water efficiency information for the products covered by the scheme. It shows: a zero to six star rating — the more stars on the label, the more water efficient is the product — and a figure showing the water consumption flow of the product based on laboratory tests.

At the stakeholders’ forum, DEWHA advised it was undertaking a range of actions in relation to the WELS Scheme including:

- a review of the WELS Act
- preparing the Government’s response to the House of Representatives Standing Committee report
- work to expand the WELS Scheme to include new products, introduce new minimum water efficiency standards for some products and to raise minimum water efficiency standards for toilets (DEWHA 2008c).

### **Delays in registration**

The Commission was made aware of concerns about delays in the registration of WELS products (for example, Australian Industry Group, subs. DR42 and DR48).

There are few specified time limits on the deciding of applications for registration. The WELS Act provides that if the applicant has not been notified, or there has been no gazettal of registration, within three months after the date of the application being made, the WELS Regulator is taken to have refused the application. According to DEWHA, ‘correct and complete’ registration applications are currently finalised in three to four weeks (sub. DR56, p. 1).

Key factors affecting the timing of registration include whether the applications are adequately completed, whether businesses require a tax invoice before paying the application fee, and the time in which gazettal takes place.

- Delays occur when applicants ‘do not supply correct information, do not complete all required fields in the application, or do not pay the fee promptly’ (DEWHA, sub. DR56, p. 1).
- A business requiring a tax invoice before making a payment — a common practice — could expect it to take a week to receive the invoice (DEWHA 2008d).
- Even though a product may be approved for registration, the product is not registered until it is gazetted — the timing of gazettal is the responsibility of the agency and notices for gazettal can occur from as little as 24 hours (Special Gazette) to up to a week (Periodic Gazette) of lodgement with the Attorney-General’s Department.

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DEWHA advised that it will commence a new online registration system in September 2008 (sub. DR56, p. 1). It will consider requests on how the system could be improved and give applicants the opportunity to trial the system prior to its implementation (DEWHA 2008c).

### *Assessment*

Unnecessary delays in registration can adversely affect the capacity of manufacturers or importers to plan the production and marketing of products in Australia.

In the draft report, the Commission noted that there appeared to be little rationale for any delays. The WELS Regulator is required to ensure that the application is adequately complete and verifiable. There are no other matters it need consider. The Commission's draft response stated that DEWHA should introduce tight legislative or administrative time limits into the process for registering products under the WELS Scheme. The Commission suggested that DEWHA consider an overt time limit of two or three weeks for approving adequately completed registration applications.

In its submission on the draft report, DEWHA considered that its new online registration system 'will prevent many of the application errors that are the key factor in delays and facilitate timely processing of applications' (sub. DR56, p. 1). It noted that the new system and departmental practices will be reviewed after six months to determine whether there is a need to formalise administrative time limits. It also noted that applicants are now able to pay registration fees over the phone by credit card and 'this has improved efficiency for applicants although this still involves a two step process'. However, a credit card payment procedure that would allow payment as part of the online registration process (as for airline bookings and payments) is not being pursued.

The Australian Industry Group noted that it was 'not clear' how the new registration system would address the complaints to date (sub. DR42, p.1). It said there appeared to be little time for trialling the system to confirm that it addressed reported problems prior to implementation.

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It also said that time limits for registration should be introduced:

While there is conjecture on an appropriate timeframe we suggest that many of the delays related to incomplete applications and the resource drain on WELS administrative resources could be minimised by the development of a more sophisticated on-line registration system (perhaps similar to that used for MEPS and Energy Labelling programs) that places the responsibility on the applicant to input data and does not allow an application to proceed unless all essential information is provided. (sub. DR48, p. 3)

The Australian Industry Group suggested also that alternative models for payment by applicants be developed so that application for registration can be done in one seamless series of steps at one sitting (sub. DR48, p. 3).

The Commission considers that, although there are recent and prospective changes to the registration system that can help deal with any delays, there is still scope for introducing tighter time limits. Once applicants pass the hurdle of submitting online an adequately completed application, DEWHA should then comply with tight legislative or administrative time limits for approval and registration. These time limits would increase certainty amongst businesses about the timing of registration and, thus, help them to more effectively plan the release of their product. They would also increase the incentive of DEWHA to manage the entire registration process more expeditiously. Time limits of one week for DEWHA to approve adequately completed applications and of one week for gazettal appear to be reasonable.

Any delays associated with the provision of tax invoices by the DEWHA to businesses who require them for paying fees should also be addressed. Delays may arise because the departmental area providing the invoice is different to that which is responsible for approving the applications. If the volume of applications is sufficiently large, DEWHA could consider decentralising the issuing of tax invoices for the payment of fees through the appointment of a finance delegate or collector of public monies within the departmental area responsible for applications approvals.

RESPONSE 6.1

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

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## Poor compliance and enforcement

Participants (for example, Australian Industry Group, sub. DR42; Fisher and Paykel, sub. DR45) have raised concerns about non-compliance with and poor enforcement of the WELS Scheme, particularly in relation to imported products, and the impact this has on the competitiveness of those businesses who comply with the scheme. Fisher and Paykel said about the competitive disadvantage that:

... the deleterious impact is significant because various states offer a \$150 or \$200 rebate for washing machines with a certain WELS rating. Also many domestic and commercial building projects specify a minimum WELS rating for the plumbing products. Therefore the commercial pressure to claim a good water efficiency rating is extremely high. If there is not effective enforcement then an optimistic water efficiency rating can be claimed without any adverse commercial consequences. (sub. DR45, p. 1)

At the Commission's roundtable on environmental regulation, held after the release of the draft report, some participants noted that poor compliance and enforcement is a problem across all products. But this is particularly so for low value high volume products such as tap equipment and showers. Some also considered that poor compliance and enforcement could arise if the Australian Standard itself is poorly drafted or the testing method is not proven.

Compliance monitoring and enforcement activities under the scheme is undertaken by DEWHA. The WELS Act provides the WELS Regulator with the power to:

- appoint inspectors to monitor compliance and/or investigate alleged breaches of the scheme
- impose significant fines and penalties for breaches of the scheme
- compel the withdrawal of a product from the market
- deregister a product
- advertise convictions.

The WELS Regulator can also use administrative actions and education, as an alternative to legal action, to assist businesses to comply with the scheme.

Guidelines and information have been issued by DEWHA (DEWR 2007a, b, c, d) in which the approach to compliance under the WELS Act is set out. Key features of this approach are that it:

- is undertaken on a case-by-case basis
- reflects an 'adaptive hierarchy' of actions (from education and awareness activities to administrative actions such as warning letters to enforcement-related legal action).

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There is also scope for members of the public and the industry to report breaches of the WELS Act to DEWHA, which are then investigated. DEWHA encourages such allegations to be substantiated with as much detail as possible. Allegations may be treated confidentially.

DEWHA advised that the WELS Scheme became mandatory for all WELS products at the end of December 2007 (sub. DR 56, p. 2). It said that, to date, compliance activities have been focussed on education and awareness and targeted at both suppliers and consumers. Procedures, letters and infringement notices have been developed and stronger action to fine offenders is now possible. A compliance database to track complaints through to resolution has been developed and is currently being trialled. The upgraded procedures will be in place by mid-August 2008. DEWHA also noted that a check testing program to independently test WELS-labelled products against manufacturer's or supplier's claims is expected to be in operation by the end of 2008. It said that consultation with stakeholders will occur on the design, scope and scale of the program prior to implementation.

The Australian Competition and Consumer Commission (ACCC) also has a role in investigating complaints about the WELS label in relation to potential breaches under the *Trade Practices Act 1974* and, in particular, in relation to provisions governing misleading or deceptive conduct (s. 52), and false or misleading representations (s. 53) (ACCC 2008). The ACCC accepts referrals about matters of potential breaches of the Trade Practices Act from DEWHA, consumers and businesses (ACCC, pers. comm., 17 June 2008).

In its 2007 report, the House of Representatives Standing Committee on the Environment and Heritage responded to concerns about compliance with, and enforcement of, the scheme by recommending that DEWHA examine its current enforcement practices (HRSCEH 2007, recommendation 3 and pp. 23–6). This recommendation was made subsequent to the issuing by DEWHA of its guidelines and information.

Various suggestions have been made to improve compliance with and enforcement of the WELS Scheme. Some participants to this review suggested that compliance of imported products with the WELS Scheme be enforced at the border by the Australian Customs Service (Customs). In addition, participants at the stakeholders' forum requested that consideration be given by DEWHA to producing a scorecard on compliance efforts, providing feedback to the person making an allegation, ensuring compliance through the whole supply chain in addition to the point of sale and increasing inspection capacity in the field, including by enlisting state inspectors.

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## *Assessment*

Where compliance with and enforcement of the scheme is deficient, the regulatory burden placed on compliant businesses could be exacerbated. Not only do they face the burden of complying with the scheme's requirements, but they may also experience other costs. Compliant businesses may experience a competitive disadvantage in relation to non-compliant businesses. The extent of this deleterious impact, however, will depend on the behaviour of consumers of the products covered by the scheme and, in particular, the extent their purchasing decisions are influenced by the WELS water rating label.

DEWHA's approach to compliance and enforcement is only recently developed. It just predates the House of Representatives Standing Committee inquiry and, thus, may not have been fully reflected in the Standing Committee's findings.

In the draft report, the Commission considered that there should be independent evaluation of the effectiveness of DEWHA's current compliance and enforcement activities in achieving the objectives of the WELS Scheme. It said that this evaluation, however, should occur once DEWHA's new approach has had a reasonable period of time to yield assessable outcomes and nominated 2009 as the review year.

In its submission on the draft report, DEWHA said it was prepared to conduct an independent review of the effectiveness of its compliance and enforcement program in 2010 and considered that the 2009 timing would 'not provide a sufficient window for the upgraded compliance procedures ... to take effect and to have a measurable impact' (sub. DR56, p. 2).

Fisher and Paykel supported an independent evaluation, but that this had to be publicly available (sub. DR 45).

The Australian Industry Group supported an independent evaluation whose results are made public. It recommended that the review commence with the introduction of any new initiatives arising from the current review of the WELS Act and operate in parallel with the implementation of new requirements. It said this would 'minimise the impact of further delays in responding to industry's call for improvements and enable continual fine-tuning of the system as it continues to develop'. It considered that a 'scorecard' of activities of the WELS Regulator would help stimulate additional feedback and ideas for improvement as the compliance and enforcement system is developed (sub. DR 48, p. 3).



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The Australian Industry Group also observed that before any assessment of the effectiveness of the enforcement can be made the base case or extent of the problem of non-compliance needs to be understood (sub. DR48, pp. 3–4).

The Commission accepts the need for the results of the evaluation to be made public and to be delayed until 2010 so that there is sufficient time for new changes implemented by DEWHA to yield assessable outcomes. It does not consider that holding the evaluation at the start of, or in parallel to, the implementation of new changes — as suggested by one participant — would provide meaningful results. Such an approach may compound any uncertainty by businesses as to DEWHA’s approach to compliance and enforcement.

RESPONSE 6.2

***The Department of the Environment, Water, Heritage and the Arts should commission an independent evaluation in 2010 of the effectiveness of its compliance and enforcement program in achieving the objectives of the Water Efficiency Labelling and Standards Scheme. The results of the evaluation should be made public.***

In the meantime, DEWHA should further consider options to improve its compliance and enforcement approach.

One option that has merit is the production of a scorecard by DEWHA, which could involve the naming of those businesses who breach the WELS Act. This could facilitate transparency and increase the incentive of businesses (who are concerned about their market reputation) to improve their compliance.

Another option worth considering is for the Australian Government to enter into agreements with relevant state and territory agencies to undertake enforcement activities (including inspections) on its behalf. There is currently scope under the WELS Act for the WELS Regulator to appoint inspectors who are officers or employees of a state or territory agency pursuant to an agreement with the state or territory.<sup>3</sup> An advantage of using these agencies is that enforcement activities could be more efficiently consolidated.

A further option that has merit in relation to the enforcement and compliance of imported products under the WELS Scheme is to require importers to sign a statutory declaration attesting that the product complies with the WELS Act. Should the product be later found to be in breach, the importer would be liable to additional penalties under the Act.

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<sup>3</sup> WELS Act s. 45.

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However, there are several options that have been suggested at the stakeholders' forum that may neither be legally possible nor practical. The suggestion that officials provide feedback about the progress of investigations to those who make allegations of breaches could breach privacy laws or complicate any potential criminal proceedings. DEWHA's current practice is to confirm the receipt of the allegation in writing. It notes that those making allegations:

... should not necessarily expect any further correspondence or to be informed directly of the results of any action on the matter ... Investigations are confidential. Nevertheless, if an investigation leads to prosecution, this may be the subject of some public and official reporting. (DEWR 2007d, p. 5)

The suggestion that compliance of imported products with the WELS Act be enforced at the border by Customs draws on such examples as the *Ozone Protection and Synthetic Greenhouse Gas Management Act 1989*. That said, this suggestion is confronted by several legal and practical difficulties. As the WELS Act applies at the point of sale, enforcement at the border may not be legally possible.<sup>4</sup> Even if the WELS Act were amended to allow for enforcement at the border, resources would need to be allocated to Customs in order for it to adequately check the registration of the products and to organise or undertake inspections (for example, as to whether the product in fact performs as the label states).

## **Overlap with the WaterMark certification scheme**

Concerns have been raised before the House of Representative Standing Committee on Environment and Heritage about the overlapping relationship of the WELS Scheme and the WaterMark certification scheme leading to anomalies and, thus, confusion among businesses and consumers (HRSCEH 2007, pp. 15–19). One anomaly is where a certified plumber may have to refuse to install a product with the WELS label if it is not also WaterMark certified. As DEWHA said:

... it is possible to legally buy some plumbing products (including some WELS registered products) but under state legislation, not legal to install them. This becomes an issue for consumers who buy a product on the basis of its WEL's endorsement only to find they cannot install it as it is not also WaterMarked. (sub. DR56, p. 2)

The WaterMark certification scheme, which is set out in the Plumbing Code of Australia (NPRF 2004), is administered by Standards Australia on behalf of the

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<sup>4</sup> For example, the Ozone Protection and Synthetic Greenhouse Gas Management Act is imposed at the point of manufacture, importation, exportation or distribution. A person cannot manufacture, import, export or distribute the substances (HCFC, synthetic GHG and so on) or pre-charged equipment without holding a licence.

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National Plumbing Regulators Forum.<sup>5</sup> The scheme applies to water supply, sewerage, plumbing and drainage goods, whether manufactured in Australia or imported. The objective of the scheme is to help Australian consumers be confident about the quality and safety of the products to which the WaterMark is applied. The scheme is mandatory only to the extent that state and territory legislation refers to it (whether by referring to the Plumbing Code of Australia or otherwise).

There are two levels of certification under the WaterMark certification scheme, which are determined by the level of risk of particular plumbing products to the plumbing and drainage system. WaterMark Level 1 (full product certification) applies to higher risk products and involves periodic testing, assessment and surveillance of a ‘quality system’ involved for compliance with relevant standards and specifications. WaterMark Level 2 (type test certification) applies to lower risk products and involves testing product samples for compliance (Standards Australia 2008a).

Australian Standards relevant to the WaterMark certification scheme are primarily set out in AS 5200:2005 ‘Technical specification for plumbing and drainage products — procedures for certification of plumbing and drainage products’.

Changes to the administration of the WaterMark certification scheme are in prospect. Standards Australia has advised the National Plumbing Regulators Forum that it wishes to divest itself of the responsibility for administering the scheme (Standards Australia 2007).

There are fundamental differences about the WELS Scheme and the WaterMark certification scheme.

- Each scheme is given legislative effect differently: the former is based on an Australian Government Act that refers to Australian Standards; the latter scheme is embodied in an industry code that incorporates Australian Standards and is variously referenced in state and territory legislation.
- Each scheme has different objectives: the WELS Scheme focuses on water efficiency whereas the WaterMark certification scheme not only deals with water efficiency but public health and safety. Indeed, although both schemes refer to the same Australian Standards for relevant products, the WELS Scheme utilises only the water consumption testing requirements, whereas the

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<sup>5</sup> Standards Australia owns the WaterMark certification trademark. It does not grant licences for the use of the WaterMark directly to users (including manufacturers). It, instead, enters into agreements with approved certifiers and grants them the right to enter into licence agreements with approved users. Both approved certifiers and approved users must comply with the rules approved by the ACCC in March 2005.

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WaterMark certification scheme utilises both the safety and water consumption testing requirements.

WaterMark certification can already be used by applicants for WELS registration to confirm that the product has been tested against the relevant water efficiency performance criteria. As DEWHA noted, applicants can supply WaterMark certificates ‘in place’ of test reports against particular requirements (sub. DR 56, p. 2).

In its 2007 report, the House of Representatives Standing Committee on Environment and Heritage considered that greater integration of the two schemes was not only:

... desirable, but very necessary, to address industry and community confusion and frustration, to maintain industry and community confidence in the schemes and (sic) ensure the quality of the plumbing products in the Australian marketplace and homes. (HRSCEH 2007, p. 19)

The Standing Committee thus recommended that the Australian Government act to make the necessary legislative changes to establish WaterMark certification as a prerequisite for compliance with the WELS Scheme (HRSCEH 2007, recommendation 2).

### *Assessment*

The concurrent operation of the WELS Scheme and the WaterMark certification scheme has led to anomalies with the potential to impose unnecessary burdens on businesses. This is particularly the case where products registered in the WELS Scheme do not satisfy WaterMark certification scheme requirements for water efficiency and resources are expended by businesses having to respond to any ensuing consumer confusion.

Confusion appears to be focused on a small percentage of plumbing and drainage products. Information from DEWHA indicates that, of the products registered under the WELS Scheme, around 85 per cent referred to the WaterMark certification scheme. DEWHA claimed that 10 per cent of products registered under the WELS Scheme that did not refer to the WaterMark certification scheme would not meet the requirements of that scheme. It also claimed that the quality of the remaining 5 per cent of products was unknown (HRSCEH 2007, p. 17).

The Commission notes that the House of Representatives Standing Committee’s recommendation to mandate compliance with the WaterMark certification scheme as a prerequisite for compliance with the WELS Scheme is likely to add to the burden of producing a small percentage of products, possibly at most 15 per cent of

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those products registered under the WELS Scheme. It does this by imposing on the businesses producing these products, a wider range of standards beyond that needed to determine water-efficiency.

The added compliance cost of the Standing Committee's recommendation may be matched by an offsetting benefit of reduced consumer confusion. There may also be an added benefit in that the water efficiency and public health and safety of some WELS products are raised.

A further benefit is that it would force consistency among state and territory governments in so far as their legislation refers to the WaterMark certification scheme. This could facilitate a nationally consistent and integrated approach to government regulation directed at the water efficiency and labelling of certain plumbing and drainage products.

The Commission's draft response to the issue of potential confusion arising from the two schemes was for DEWHA to identify areas of overlap and, where there is overlap, to make compliance with the WaterMark certification scheme as a prerequisite under the WELS Scheme.

In its submission on the draft report, DEWHA advised that it was already reviewing the extent of overlap between the two schemes and possible options:

The Department is undertaking research to determine the scale and scope of this problem as to date only anecdotal evidence is available. It should also be noted that requiring WaterMark certification as a prerequisite for WELS registration would not solve this problem for every plumbing product (i.e. taps for over-bath which require WaterMark but are not WELS regulated).

Nevertheless, the Department is investigating options for addressing the [House of Representatives Standing Committee on Environment and Heritage's] recommendation in relation to WaterMark. One option is legislative change that would bring within the scope of the Act, requirements for third party product certification, such as WaterMark. The WaterMark is a certification trademark owned by Standards Australia. It is not considered appropriate for the Department to take over the administration or ownership of the WaterMark scheme. (sub. DR 56, p. 3)

The Australian Industry Group urged for an 'appropriate method of meshing' the two schemes (sub. DR 48, p. 4). It considered that it is 'obvious' that WaterMark certification be a prerequisite for WELS registration since consumer health and safety is 'paramount'. It acknowledged jurisdictional issues associated with resolving the overlap of the two schemes and endorsed moves to have the National Plumbing Regulator's Forum take responsibility for the WaterMark certification scheme. However, it noted that the Forum lacked a national focus and that there was a need for a suitably empowered national body to take responsibility for energy and water efficiency.

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Rheem Australia considered that a ‘strong’ WaterMark certification scheme was essential for the ongoing safety and efficiency of the local plumbing industry (sub. DR 52, p. 1). It believed that the most appropriate regulator to manage the scheme should be a national body involved with building and plumbing regulations, such as the Australian Building Codes Board. It considered that ownership of the WaterMark be transferred from Standards Australia to the body running the scheme.

The Commission notes DEWHA’s current approach to examining the relationship of the two schemes as well as options. It considers that there is need for DEWHA to satisfactorily substantiate its policy response with evidence of the scale and scope of the problem. Only if there is satisfactory evidence of a problem, should WaterMark certification become a prerequisite to registration under the WELS Scheme. The Commission agrees that it would not be necessary nor appropriate for DEWHA to administer the scheme. Administration of the WaterMark certification scheme is a matter for Standards Australia and the National Plumbing Regulators Forum to resolve.

RESPONSE 6.3

*The Department of the Environment, Water, Heritage and the Arts should introduce legislative amendments to make compliance with the WaterMark certification scheme a prerequisite for registration under the Water Efficiency Labelling and Standards Scheme, provided there is satisfactory evidence of overlap between the two schemes.*

### **Costs in accessing standards**

A general concern has been raised with the House of Representatives Standing Committee on Environment and Heritage about the costs of accessing Australian Standards relating to plumbing products in Australia, including standards under the WELS Scheme (HRSCEH 2007).

The Commission previously considered the costs of accessing standards as part of its review of standard setting and laboratory accreditation (PC 2006a, pp. 122–30). In relation to mandatory standards it recommended that:

... [m]indful of the fundamental principle of transparency and accessibility of legal requirements, the Australian Government and other governments (through their agencies) should fund free or low-cost access to Australian Standards made mandatory by way of regulation. (recommendation 7.3)

There has as yet been no public Australian Government response to the Commission’s report.

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In a memorandum of understanding between the Australian Government (represented by the Department of Innovation, Industry, Science and Research) and Standards Australia signed on 30 May 2008, there is limited provision for Australian Government funding of mandatory Australian Standards. The Australian Government:

... may, through a grant-in-aid, provide financial assistance in relation to activities contributing in net terms to the welfare and wellbeing of the Australian community as a whole that would not occur if left entirely to the private market. (para. 6.1)

### *Assessment*

There are two key reasons for free or low cost access. First, businesses are required to access Australian Standards to meet their legal obligations under the WELS Scheme. Free or low cost access is fundamental to legislative transparency. Second, the scheme (and the standards) seeks to address environmental benefits — benefits that accrue to the community at large — rather than private (business or industry-focussed) benefits.

However, there are costs associated with developing, publishing and distributing the standards that must be recovered by Standards Australia and SAI Global. Normally, these costs would be recovered through membership subscriptions and user charges. However, as they are referenced in legislation, the Australian Government and state and territory governments should, in principle, ensure the standards are readily available.

That said, the actual costs to businesses of accessing the standards under the scheme are not excessive and, indeed, appear already to be ‘low-cost’. The standards are available for purchase from SAI Global International with prices for electronic copies ranging from around \$130 for Standards Australia members to around \$155 for non-members.

The Commission reiterates its recommendation in its review of standard setting and laboratory accreditation. Where Australian Standards are made mandatory by way of regulation, the Australian Government and other governments should fund free or low cost access to them.

### **Slow development of standards**

Participants raised concerns with the Commission about the slow development of standards by Standards Australia under the WELS Scheme. The concerns are also relevant to minimum energy performance standards and are, thus, dealt with in section 6.3.

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## 6.2 Climate change policies and programs

There are numerous Australian Government and state and territory policies and programs intended to address climate change arising from greenhouse gas emissions. Participants have expressed concerns about:

- the multiplicity of policies and programs
- mandatory energy labelling and minimum energy performance standards – these concerns are dealt with in section 6.3
- the renewable energy certificates scheme
- the National Greenhouse and Energy Reporting Act and regulations
- the proposed Australian emissions trading scheme (currently referred to by the Australian Government as the carbon pollution reduction scheme).

### Multiplicity of policies and programs

Several participants (for example, Rheem Australia, subs. 14 and DR52; Queensland Resources Council, sub. 34; the Plastics and Chemicals Industries Association, sub. 11, attachment; the Australian Industry Group, sub. DR48; the Australian Food and Grocery Council, sub. DR58) raised concerns about the multiplicity of Australian Government and state and territory government climate change policies and programs and, in particular, about the potential overlap and conflict with the proposed Australian emissions trading scheme. Concerns about the multiplicity of climate change policies and programs were also raised during the Commission's primary sector review in 2007 (PC 2007a).

Rheem Australia provided the Commission with detailed examples of different and overlapping climate change policies and programs affecting the water heater industry (subs. 14 and DR52). It observed:

The most pressing regulatory matters with which we deal are those that literally have the potential to threaten the ongoing viability of the Australian water heater industry. All Australian governments are rapidly developing and implementing a range of regulations that are attempting to address climate change concerns. Government mandated regulations to address climate change are absolutely necessary. However, these changes are currently uncoordinated in terms of policy alignment not just between jurisdictions, but also between different departments within the same jurisdiction. Worse still, we see examples of a policy change in one area resulting in a perverse outcome in another area eg water and energy. (sub. 14, p. 2)

The Australian Food and Grocery Council expressed 'serious' concerns about multiple government programs intended to improve energy, water and/or waste



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efficiency of Australian businesses (such as the Australian Government’s Energy Efficiency Opportunities Program, the New South Wales Energy Savings Action Plan Program, the Victorian WaterMAP Program and the Queensland Water Efficiency Management Plan Program). It said:

.... there are now multiple teams within various levels of government duplicating the tasks required to implement these programs such as stakeholder consultation, legislation development, preparing program guideline documents, facilitating public information sessions and reviewing company reports and submissions.

This approach subsequently requires hundreds of businesses across Australia to review extensive and complicated documentation, so as to understand the different regulatory requirements associated with various programs that are all designed to achieve very similar objectives. The unfortunate consequence is that many companies are now spending substantial resources working on the compliance components of these programs, rather than concentrating on the implementation of projects that will actually improve national resource efficiency. (sub. DR58, p. 19)

It suggested that all governments work together to identify the most effective components of the programs and to roll them into a single national program addressing energy, water and waste efficiency (sub. DR58).

The Australian Industry Group noted that businesses currently face a range of mandatory energy efficiency measures originating at the Australian Government and state and territory government level. It said at ‘the very least, any such measures should have clear sunset clauses aligned to the full operation of the [carbon pollution reduction scheme]’ (sub. DR48, p. 3).

At its meeting in December 2007, COAG established a Working Group on Climate Change and Water to undertake work within a specified timetable to ensure an ‘effective national response to climate change’ encompassing:

- a single national emissions trading scheme, incorporating state schemes
- a nationally-consistent set of climate change measures to support the emissions trading scheme
- a nationally cooperative approach to long-term adaptation to climate change.

This work is to specifically include the development of national expanded Mandatory Renewable Energy Target by 2009 and the development of options to accelerate the uptake of energy efficiency measures (COAG 2007b).

A strategic review of the Australian Government’s climate change policies was commissioned in February 2008 (Wong and Tanner 2008). The review, to be led by Roger Wilkins, is to develop a set of principles to assist the Government’s assessment of whether existing programs are complementary or redundant to an emissions trading scheme. The review was due to report in July 2008. However, the

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terms of reference for the review have not been made public. Nor is there any indication from Government whether the outcomes of the review will be made public.

At its subsequent meeting in March 2008, COAG confirmed its commitment to cooperative concerted action to address climate change and agreed to finalise a comprehensive framework for addressing climate change at its October 2008 meeting (COAG 2008a). In particular, it expressed support for a national emissions trading scheme and complementary policies and measures that achieve emissions reductions at least cost.

At its July 2008 meeting, COAG noted that all jurisdictions were assessing the complementarity of their existing climate change measures to the proposed emissions trading scheme (COAG 2008b).

### *Assessment*

The current approach to dealing with climate change concerns in Australia is fragmented across sectors and jurisdictions. This is out of step with the nature of the problem to be addressed, which is the emission of greenhouse gases regardless of how or where it occurs. The approach has resulted in a patchwork of programs and bans in various industry sectors and jurisdictions, but no consistent economy-wide signal of the social cost of greenhouse gas emissions. The outcome is that the average cost of reducing greenhouse gas emissions is higher than need be and many low-cost abatement options are not pursued.

With the introduction of an effective emission trading scheme much of the current patchwork of climate change policies and programs would be expected to become redundant. An effective scheme — one in which the market is harnessed to achieve emissions abatement at least cost to the community — would shoulder much of the abatement effort. Other policies and programs would be needed only to fill any gaps beyond the scheme's reach or satisfy other rationales not achieved through the scheme (PC 2008b).

Were climate change policies and programs to continue in the presence of an emissions trading scheme, there is a risk of further costs being placed on the community, including burdens on businesses, for no additional gain in emissions reductions.

All existing and prospective policies and programs therefore need to be assessed comprehensively according to principles of good regulatory process. Essentially, this means that the policies and programs should target clearly expressed and sound objectives in a manner that maximises net community benefit. Sound objectives

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include demonstrated market failures. The policies and programs should also satisfy an additional hurdle — namely, whether their underlying objective is already met by the emissions trading scheme. For a number of policies and programs — such as the Mandatory Renewable Energy Target, which is part of the renewable energy certificates scheme, and mandatory minimum energy performance standards (MEPS); there are serious doubts this hurdle would be met.

The various actions announced by COAG and the Australian Government to develop a national comprehensive approach to addressing climate change have the potential to resolve many of the concerns raised by participants to this review. This is particularly the case were the outcomes of the Wilkins review made public and were there an independent and transparent review of the compatibility of state and territory government climate change policies and programs to the proposed emissions trading scheme.

### **Complexity of the renewable energy certificates scheme**

Rheem Australia raised concerns about the renewable energy certificates scheme stating that undue complexity was leading to substantial administrative costs for participating businesses as well as uncertainty about the tax treatment of the certificates.

It is a complex scheme with different climate zones, with different levels of credit, and is hard for stakeholders to understand. There are substantial administrative costs associated with [renewable energy certificates] for organisations that must deal with them. We have 4 or 5 people full time on that.

...

There are questions of how tax and GST get treated in that. It turns out that GST does apply – it is a very complex process, selling to a middle man, and needing a serial number off a unit at installation. This complexity is baggage due to the [renewable energy certificates] regulation, that has nothing to do with the industry itself. (sub. 40, p. 1)

The renewable energy certificate scheme is established under the Australian Government *Renewable Energy (Electricity) Act 2000*. The Act is supported by the *Renewable Energy (Electricity) (Charge) Act 2000* and the Renewable Energy (Electricity) Regulations 2001.

Three broad objectives of the legislation are to:

- encourage the additional generation of electricity from renewable energy sources
- reduce greenhouse gas emissions
- ensure energy sources are ecologically sustainable.

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Two inter-related features of the legislation are:

- the establishment of a mandatory renewable energy target — 9.5 million megawatt hour (MWh) by 2010 — as well as interim targets
- the creation of a market for renewable energy certificates.

The legislation imposes a legal liability on parties making ‘relevant acquisitions of electricity’ — typically large buyers of electricity who do not generate electricity themselves such as electricity retailers and wholesalers — to source increasing proportions of their electricity from renewable energy sources until the collective amount reaches the relevant target for the year. These so-called ‘liable entities’ are required to discharge their liability by obtaining and surrendering renewable energy certificates to the Office of the Renewable Energy Regulator or pay a shortfall charge of \$40 per MWh.

Renewable energy certificates under the legislation can only be created by ‘eligible accredited renewable energy generators’, which include power stations that generate renewable energy, small generators of renewable energy and solar water heaters. Each certificate is equivalent to one MWh of renewable energy.

Through this legally created market, liable entities can then trade directly or indirectly with certificate suppliers to acquire certificates to meet their liability.

A review of the operation of the renewable energy legislation was conducted, including of the mandatory renewable energy target, and a report was released in 2004 (Tambling *et al.* 2004).

As noted earlier, the COAG Working Group on Climate Change and Water is working on an expanded national renewable energy target scheme (COAG 2007b). The new scheme is intended to bring together the Australian Government’s mandatory renewable energy target and existing and proposed state and territory government targets. The scheme is to reflect the Australian Government’s commitment to ensuring that 20 per cent (or 60 million MWh) of Australia’s electricity supply is generated from renewable sources by 2020. The Working Group released in July 2008 a consultation paper on the design of the new scheme (Wong 2008c). The consultation paper noted that the scheme is intended to be a transitional measure, phasing out between 2020 and 2030, until the Australia emissions trading scheme ‘matures’. The Working Group is to report to COAG by September 2008 with a final mandatory renewable energy target design (COAG 2007b).

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## Assessment

Rheem Australia is a voluntary participant in the renewable energy certificates scheme and, although it incurs a compliance burden in participating, it receives private benefits from the generation of renewable energy certificates. That said, its participation may be effectively mandatory if it is to maintain its competitiveness against rivals who do participate in the scheme.

Even though the concerns of Rheem Australia are within scope of this year's review, the Commission intends to delay consideration of them until 2009, when the Commission's annual review of regulatory burdens will consider social and economic infrastructure services. Most of the businesses affected by the scheme are electricity retailers and wholesalers as well as power stations that generate renewable energy. Also, the requirements on generators of renewable energy certificates are intrinsically linked to that applying to liable entities and are, thus, best considered together.

## Concerns about the National Greenhouse and Energy Reporting Act

Several concerns by participants have been raised about the *National Greenhouse and Energy Reporting Act 2007*, which establishes a single national reporting framework from 1 July 2008.

For example, Boral drew the Commission's attention to a submission it made to Government (Boral 2008) in which it expressed concerns about:

- the feasibility of being able to put systems in place to collect data to the level of detail being proposed by 1 July 2008 — the designated starting date for collecting information under the Act
- the proposed breakdown of data by Australian and New Zealand Standard Industrial Classification and by site level (as opposed to product or operations level)
- materiality thresholds being too low<sup>6</sup>
- public disclosure of data that are commercial in confidence

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<sup>6</sup> The Government's regulations policy paper (Department of Climate Change 2008a) proposed that a corporation is not required to report on a facility that, for a given reporting year: comprises less than 2 per cent of the corporate group's inventory; and emits less than 3 kilotonnes of carbon dioxide equivalent greenhouse gases; and produces/consumes 12 terajoules of energy and the aggregated total of all facilities excluded on the basis of material could not be estimated to make up more than 5 per cent of the corporation's total emissions or energy production/consumption.

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- being at a competitive disadvantage compared with companies who are not required to report.

The National Greenhouse and Energy Reporting Act flows from an agreement between all levels of Australian government (see COAG Communiqués of 14 July 2006 and 13 April 2007). Its object is to introduce a single national reporting framework (known as the National Greenhouse and Energy Reporting System) for the reporting and dissemination of information related to greenhouse gas emissions, greenhouse gas projects, energy consumption and energy production of corporations to:

- underpin an emissions trading scheme in the future
- inform government policy formulation and the Australian public
- meet Australia's international reporting obligations
- assist government programs and activities
- avoid duplication of similar reporting requirements in the states and territories (s. 3).

The Act sets out among other things:

- provisions for the mandatory registration of corporations that exceed specified reporting thresholds<sup>7</sup>
- requirements for registered corporations to keep records and provide reports
- administration arrangements (including the establishment of a Greenhouse and Energy Data Officer)
- enforcement arrangements.

The Department of Climate Change under the Act has developed the National Greenhouse and Energy Reporting Regulations and the National Greenhouse and Energy Reporting (Measurement) Determination 2008<sup>8</sup> and is developing the External Audit Legislative Instrument.

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<sup>7</sup> The specified reporting thresholds at the corporations level for the first financial year of operation of the Act (starting 1 July 2008) are 125 kilotonnes of greenhouse gases (carbon dioxide equivalent), or 500 terajoules of energy produced or consumed. These thresholds are to phase down over time to 50 kilotonnes of greenhouse gases, or 200 terajoules of energy produced or consumed. The facility level threshold is 25 kilotonnes of greenhouse gases (carbon dioxide equivalent) or 100 terajoules of energy produced or consumed.

<sup>8</sup> The Determination is made under s. 10(3) of the Act, which provides for the Minister to determine methods, or criteria for methods, for the measurement of greenhouse gas emissions, the production of energy and the consumption of energy.

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Although corporations who meet reporting thresholds should begin data collection from 1 July 2008, they have until 31 August 2009 to apply to register and until 31 October 2009 to submit their first report under the scheme.

Regulations governing the mandatory Australian Government's Energy Efficiency Opportunities program<sup>9</sup> will be amended from 1 July 2008 to enable companies to which the program applies to streamline energy use reporting with requirements under the new national greenhouse and energy reporting framework (Wong and Ferguson 2008).

### *Assessment*

The Commission notes that the National Greenhouse and Energy Reporting Act's core objective is to harmonise the multiplicity of reporting arrangements that exist in all jurisdictions. Presently, there are at least 20 Australian Government and state and territory government greenhouse gas and energy programs through which businesses report greenhouse gas emissions and/or energy data (PC 2007a, p. 211).

The substance of the Commission's assessment and response to concerns raised in its primary sector review (PC 2007a, pp. 209–13, response 4.13) continues to be relevant here.

Existing reporting arrangements should be phased out as quickly as circumstances permit. Proposed streamlined reporting changes to the Australian Government's Energy Efficiency Opportunities program are thus a positive step.

### **Concerns about the future design of the emissions trading scheme**

Several participants (for example, Australian Dairy Industry, sub. 26; Queensland Resources Council, sub. 34; the Plastics and Chemicals Industry Association sub. 11, attachment) expressed concerns about the proposed Australian emissions trading scheme and the interaction of the scheme with other climate change policies and programs. Similar concerns were also raised during the Commission's primary sector review (PC 2007a).

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<sup>9</sup> The Energy Efficiency Opportunities program seeks to encourage large energy-using companies to improve their energy efficiency. It does this by requiring companies using more than 0.5 petajoules of energy a year to undertake energy efficiency opportunity assessments and report publicly on the results of those assessments and measures planned to reduce energy use.

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The Australian Government is currently undertaking work to establish the scheme, which is to be part of an ‘effective framework for meeting the climate change challenge’ (Department of Climate Change 2008b).

The Government has outlined five tests for the scheme to be effective, namely that it must:

- be a ‘cap and trade’ scheme to be internationally consistent
- effectively reduce emissions
- be ‘economically responsible’
- be ‘fair’
- recognise ‘the need to act now’ (Department of Climate Change 2008b).

The Australian emissions trading scheme is to commence no later than 2010 (Wong 2008a). The timetable for the scheme’s introduction includes the public release of the Carbon Pollution Reduction Scheme Green Paper in July 2008, the proposed public release of draft exposure legislation in December 2008 and the proposed entry into force of legislation and the establishment of a regulator by the third quarter 2009.

A concurrent process that will feed into the Government’s work is the Garnaut climate change review, commissioned by state and territory governments in April 2008. The Prime Minister has subsequently confirmed the Australian Government’s participation in that review. The review is to examine the impacts of climate change on the Australian economy and recommend medium to long-term policies and policy frameworks to ‘improve the prospects for sustainable prosperity’ (Garnaut 2008). An interim report was released in February 2008, a draft report was released in June 2008, and a final report is to be released by 30 September 2008.

As already noted, COAG has expressed support for a national emissions trading scheme and complementary policies and measures that achieve emissions reductions at least cost.

### *Assessment*

The substance of the Commission’s assessment and response to concerns raised in its primary sector review (PC 2007a, response 4.15) as well as in its submission to the Garnaut review (PC 2008b) continues to be relevant here.

The development of the Australian emissions trading scheme has the capacity to address red tape and reduce unnecessary burdens provided that best practice policy design is applied. The new scheme should establish ways to facilitate market



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transactions so that abatement of greenhouse gases emissions occurs at the lowest overall cost and any exemptions from the scheme are fully justified. Ongoing monitoring and evaluation of progress of the scheme is important.

As noted earlier, with an effective emissions trading scheme, much of the current patchwork of climate change policies and programs will become redundant. Retaining existing, or introducing new, policies and programs would need to offer other benefits. All supplementary policies and programs must be subject to rigorous evidence-based analysis to determine if their rationales are sound and, if so, whether intervention would deliver a net community benefit after consideration of the costs of action.

### **6.3 Energy labelling and minimum energy performance standards**

Participants expressed several concerns about mandatory requirements governing energy labelling and MEPS. Although some participants (for example, the Australian Industry Group, sub. DR48) have questioned the ongoing rationale for these requirements, particularly given the proposed emissions trading scheme, the focus of this section is on concerns about the regulatory burden arising from the requirements, particularly about the timing of implementation of requirements, the development of Australian Standards as well as compliance and enforcement.

Mandatory energy labelling and MEPS requirements apply to a range of domestic and commercial appliances under the National Equipment Energy Efficiency Program<sup>10</sup>, which is part of the overarching National Framework on Energy Efficiency developed by the Ministerial Council on Energy (box 6.1).

The National Equipment Energy Efficiency Program is managed within the Ministerial Council on Energy by the Equipment Energy Efficiency (E3) Committee, which comprises officials from the Australian Government and state and territory governments. DEWHA chairs and supports the E3 Committee. The objective of the Program — and that of energy labelling and MEPS requirements — is to improve energy efficiency and reduce greenhouse gas emissions from household appliances and equipment as well as from commercial and industrial equipment.

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<sup>10</sup> Formerly called the National Appliance and Equipment Energy Efficiency Program.

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### Box 6.1 **National Framework for Energy Efficiency**

This national framework, developed by the Ministerial Council on Energy, seeks to enhance Australia's energy efficiency performance, by reducing energy demand and lowering greenhouse gas emissions. It encompasses a range of policy measures including expanding the application of energy standards, improving the capacity to identify and deliver energy savings, and raising consumer awareness of energy efficiency issues.

In August 2004, the Ministerial Council agreed to a package of policy measures comprising Stage One of the national framework. This package covers residential buildings, commercial buildings, commercial/industrial energy efficiency, government energy efficiency, appliance and equipment energy efficiency, trade and professional training and accreditation, commercial/industrial sector capacity building, general consumer awareness and financial sector awareness.

The Ministerial Council later agreed in December 2004 to eight implementation plans for Stage One for the period 2005 to 2007.

The implementation plan for appliance and equipment seeks to 'drive on-going improvements to the energy efficiency of major energy using appliances and equipment' and contains the following key elements:

- expanded electrical appliance and equipment program, through regulating new products for MEPS and/or labelling, and increasing the stringency of regulations for existing products
- inclusion of gas appliances and equipment in the National Equipment Energy Efficiency Program
- increased focus on industrial products.

In December 2007, the Ministerial Council agreed to Stage 2 of the National Framework for Energy Efficiency, which is to comprise the continuation of some existing measures, along with the introduction of five new measures:

- expanding and enhancing the MEPS program
- a heating, ventilation and air conditioning high efficiency systems strategy
- phase out of incandescent lighting
- government leadership through 'green leases'
- development of measures for a national hot water strategy.

The Stage 2 measures are scheduled to commence from 1 July 2008.

*Sources:* E2 Working Group (2007); Ministerial Council on Energy (2004, 2007, 2008).

Energy labelling and MEPS requirements are made mandatory by state and territory legislation, which refers to the relevant Australian Standards published by Standards Australia.

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- The state and territory legislation, administered by state and territory energy regulators, sets out the general requirements for energy labelling and MEPS for products, including offences and penalties for non-compliance. The legislation is based on nationally-endorsed model legislation.
  - Australian Standards set out the technical requirements for energy labelling and MEPS. There are two parts to the Australian Standards: part 1 contains requirements relating to test procedures and ambient conditions such as the test method, performance measures and test materials; part 2 contains detailed technical requirements for energy labelling and MEPS, where applicable.

Administrative Guidelines set out how the National Equipment Energy Efficiency Program is administered by the relevant state and territory agencies and provide guidance for uniform and consistent practice among the agencies (Ministerial Council on Energy 2005).

As noted earlier, the COAG Working Group on Climate Change and Water is developing options to accelerate uptake of energy efficiency measures.

The Australian Government announced additional funding under the Federal Budget 2008-09 of \$14 million over four years to improve the energy efficiency of appliances (Energy Efficiency Fast-Track Program) (Garrett 2008). This will involve:

- revising the current 6-star energy rating label to 10 stars
- complementing MEPS with combined ‘greenhouse and energy minimum standards’ (GEMS)
- expanding the number of products required to meet GEMS
- accelerating the introduction of standards for a range of previously unregulated products such as set top boxes, computers and home entertainment equipment
- reviewing standards every three years for all major appliances
- accelerating the introduction of the one watt standard for standby across all consumer electrical appliances
- enhancing the testing and compliance regime for regulated products.

These measures will require the introduction of new Australian Government legislation that will complement the current energy labelling and MEPS requirements under the National Equipment Energy Efficiency Program.

The Commission considered energy labelling and MEPS requirements as part of its inquiry into the private cost effectiveness of improving energy efficiency (PC

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2005a, chapter 9). The focus of its examination was largely on the benefits and costs of the requirements, rather than on the regulatory burden on businesses.

- It found that appliance energy performance labels have some influence on consumers after they have short-listed products on the basis of characteristics such as price, performance capacity and style. While the benefits of labelling may have been overstated in regulation impact assessments, it is likely to have produced net benefits for consumers (finding 9.1).
- It recommended that future regulation impact assessments of appliance MEPS should include a more comprehensive analysis of:
  - whether MEPS reduce competition and how this affects prices and service quality
  - why individuals — with guidance from an energy performance label — are not best placed to judge what is in their best interests
  - whether a disendorsement label and/or voluntary standard would be a more cost-effective policy
  - the distributional impacts, including the extent to which MEPS are regressive and prevent consumers from buying products that are more cost-effective for them.

The extent to which individuals are forced to forgo product features they value more highly than energy efficiency should also be reported in regulation impact assessments if MEPS are to continue to be promoted as privately cost effective (recommendation 9.1).

## **Uncertainty about the timing of implementation of MEPS**

Several participants expressed concerns about the timing of implementation of MEPS. They claimed that uncertainty about timing adversely affects business production and marketing decisions for the products covered by MEPS.

For example, Rheem Australia said it was a ‘strong supporter of legally mandated lead times for the application of new regulations’ (sub. DR52, p. 2). Furthermore, it called on the following:

- Any regulation and regulatory impact statement (RIS) should only be developed based on published, rather than unfinished, standards.
- During the RIS process, industry should be heavily consulted to determine an appropriate timeframe for ceasing manufacture of non-compliant products. At least 18 months would be the minimum required to implement minor changes.

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- Once a MEPS requirement has been introduced, industry should have time to recoup its investment in R&D and capital made to meet the new regulations, time to adapt work practices to the new products, and time to educate the market on the advantages of newer and usually more costly product upgrades.

Fisher and Paykel noted that the US *National Appliance Energy Conservation Act 1987* (section m) requires a minimum of three years before new regulations can be implemented (sub. DR45).

Timeframes for the development and implementation of new and revised energy labelling and MEPS requirements to 2008 have been set out in such documents as the:

- National Framework for Energy Efficiency Stage One for the period 2005 to 2007 (Appliance and Equipment Energy Efficiency Implementation Plan)
- 2005 Administrative Guidelines for the Appliance and Equipment Energy Efficiency Program of Mandatory Labelling and Minimum Energy Performance Standards
- Summary of Products Regulated for Energy Efficiency in Australia: Schedule of Changes and Updates, 1 May 2007.

The Commission understands that the timeframes contained in these documents have been superseded and will be updated later in 2008 ( DEWHA, pers. comm.. 26 August 2008).

### *Assessment*

Two factors contributing to the uncertain timing of implementation of energy labelling and MEPS requirements are delays in the finalisation of RISs and the slow development of Australian Standards. Both these factors, which have attracted participants' concerns, are considered in the following subsections.

Another significant factor is current Australian Government and COAG-initiated review processes associated with the proposed emissions trading scheme (now referred to as the carbon pollution reduction scheme), in particular, the Wilkins review.

The Commission notes that timeframes announced for the development and implementation of energy labelling and MEPS requirements have not been formally updated since May 2007. It considers that priority be given by the E3 Committee to updating the timeframes and making them public to enable businesses to plan their

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production and marketing activities with greater certainty. This is likely to be feasible once the Government has developed its response to the Wilkins review.

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.*

### **Delays in the finalisation of regulatory impact statements**

Participants were concerned about the delays in the finalisation of RISs associated with regulatory proposals relating to energy labelling and MEPS (particularly in relation to the proposed gas MEPS). It is claimed that the delays are adding to uncertainties about the timing of regulations and, in turn, adversely affecting business production and marketing decisions for the products that are affected.

Rheem Australia expressed a particular concern about delays in the RIS governing the proposed MEPS for gas water heaters:<sup>11</sup>

... in June 2007 the Australian Greenhouse Office (AGO) announced a proposal that MEPS ... would be applied to gas water heaters from 2008. Two levels of MEPS have previously been applied to Electric Water Heaters. Under the new Gas MEPS proposal, the AGO proposed the ban of 3 star gas products (still the main form of gas storage water heaters) from 2008. Rheem have responded to this with an alternative proposal to first allow a 4 star rating in 2009 until the new standard is redefined with a view of moving towards 5 star in a second round of MEPS. The AGO is now proposing 3 alternatives for Gas MEPS. A Regulatory Impact Statement was due to have been released for comment in October 2007 but this has been delayed and is expected shortly. None of the options to be proposed by the AGO will allow a continuance of 3 star product. In the absence of clarity we have been forced to embark parallel and redundant research and development activity. (sub. 14, pp. 2–3)

Regulatory proposals for energy labelling and MEPS by the Ministerial Council on Energy are required to comply with COAG guidelines (COAG 2004). The COAG guidelines require the preparation of RISs, which involve an examination of the need or rationale for regulation as well as of the benefits and costs of regulation and its alternatives. The Office of Best Practice Regulation (OBPR) reviews RISs against the COAG guidelines at two stages:

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<sup>11</sup> The E3 Committee proposed to introduce a MEPS for gas water heaters from October 2008 with the practical effect of excluding gas water heaters with an energy rating of less than 5 stars. It issued an initial cost–benefit analysis of the proposal in June 2007 for public comment (E3 Gas Committee 2007). A consultation RIS on a revised proposal was subsequently issued in August 2008, with stakeholder comments due by October 2008 (E3 Gas Committee 2008).

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- before the RIS is made public for consultation (the consultation RIS)
  - before a decision on the regulation is made by the ministerial council or national standard setting body (the decision RIS).

The COAG guidelines provide for the OBPR to assess a RIS within two weeks.

In 2006, the E3 Committee proposed providing a cost-benefit analysis (a pre-consultation' RIS) to the OBPR to 'allow feedback to be provided before the first draft of the consultation RIS was submitted' (OBPR, sub. DR44, p. 3). The OBPR agreed to providing comment on any pre-consultation RISs submitted.

The Australian Industry Group (sub. DR42) observed that the delays in the finalisation of a RIS may have arisen from attempts by the E3 Committee to trial the publication of a cost-benefit analysis prior to clearance by the OBPR.

The aim of the [cost-benefit analysis] was to allow industry to respond to potential OBPR issues, meaning that successive discussion and decision RISs would be expedited. However, this theory did not match practice as OBPR questioned similar issues at both CBA and RIS stages, and as a result delayed implementation as timelines lapsed. (sub. DR42, p. 2)

The E3 Committee has since agreed in January 2008 to drop the formal policy of undertaking cost-benefit analyses prior to a RIS (sub. DR42). The Australian Industry Group considered that although a cost-benefit analysis may be developed occasionally on a case-by-case basis, 'it is not clear how this will be decided and how/if industry will have input to the decision' (sub. DR42).

### *Assessment*

RISs play an important role in ensuring that regulatory proposals are adequately assessed and, thus, that the quality of any ensuing regulation is satisfactory.

In its submission on the draft report the OBPR noted that agencies with responsibility for preparing a RIS also have responsibility for managing timelines in the policy development process, including allowing time to address any OBPR feedback on draft RISs (sub. DR44).

However, it acknowledged the need for improvements to the RIS process such as through more face-to-face meetings with agencies to discuss its feedback on draft RISs, the provision of training on best practice regulation requirements and the encouragement of secondments of staff from other agencies (sub. DR44). In relation to energy labelling and MEPS RISs, the OBPR noted it has agreed to engaged in more face-to-face meetings with DEWHA at key points in the process and that DEWHA has offered to second an officer to the OBPR (sub. DR44).

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DEWHA noted that all government agencies are committed to improving the certainty of regulatory assessment processes addressing the concerns expressed by industry to the Commission (sub. DR56). It said that this commitment is expected to lower the risk to business of undue delay, which causes difficulties to industry in taking binding investment and related business decisions. It proposed that the Commission recommend that:

The Office of Best Practice Regulation and the Department of the Environment, Water, Heritage and the Arts should seek to improve the clarity surrounding nationally consistent regulation-making by agreeing [to] reasonable timelines under which all parties must complete these assessments. (sub. DR56, p. 3)

The Commission considers that it is important that the finalisation of RISs are not undermined by poor management and communication practices of either the E3 Committee or the OBPR. It supports discussions held between the DEWHA and the OBPR about how they could better resolve the finalisation of RISs such that their public release is not unduly delayed.

That said, the Commission notes that the current development of the carbon pollution reduction scheme and the current Wilkins review of climate-change related policies and programs by the Australian Government have the potential to affect this area of regulation. There may be thus reasonable justification for delaying RISs, at least, until the Australian Government has responded to outcomes from the Wilkins review.

### **Slow development of standards by Standards Australia**

Participants raised concerns about the slow development of standards by Standards Australia, particularly those to do with MEPS. They argued that delays in standards development adversely affect industry production processes and marketing as well as place pressures on DEWHA, which does not necessarily have the expertise to develop the standards itself. Similar concerns were raised about the development of Australian Standards under the WELS Scheme.

The general approach that Standards Australia takes to the development of standards involves a number of phases including initial research on the need for a standard, the formation of a technical committee to draft the standard, the release of a draft standard for public comment and the publication of the final standard.

Factors identified by participants as contributing to the slow development of standards include membership of the technical committee responsible for developing the standard, the way in which the technical committee project manages



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standards development, and the consensus voting model applied by the technical committee.

The Commission examined general concerns about the development of standards by Standards Australia in its 2006 review of standard setting and laboratory accreditation (PC 2006a). It noted Standards Australia's efforts at the time in improving its approach to standards development. It recommended that Standards Australia should continue to improve the efficiency and timeliness of standards development including by:

- making greater use of independent experts to prepare early drafts of Australian Standards
- reducing face-to-face meetings, including through better use of technology
- increasing use of partnering arrangements
- improving project management (recommendation 8.6).

Government funding has been given to Standards Australia to assist it in the development of standards relating to the energy efficiency of products. Since 2003, DEWHA, acting on behalf of the then National Appliance and Equipment Energy Efficiency Committee (now known as the E3 Committee), has a Memorandum of Understanding with Standards Australia under which it provides a financial contribution for consultancy services in the energy efficiency area (Standards Australia 2008b).

State and territory energy regulators have also indicated they wish to expedite standards development through increasing the public sector resources committed to writing and publishing specific efficiency standards (Standards Australia 2008b).

In recognition of the increased demand for standards governing the energy efficiency of products, Standards Australia developed a discussion paper on Different Models of Standards Development for Energy Efficiency of Specific Products in April 2008 in which it explored a number of models.

Following stakeholder comment, Standards Australia prepared a position paper in July 2008 in which it supported a co-resourced development option — this would involve increasing the degree of government funding of standards development by Standards Australia. The E3 Committee agreed to recommend that future standards development proceed to use this option in future. The E3 Committee and Standards Australia intends to negotiate a new memorandum of understanding to cover such issues as management of the standards development process. A review of the

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effectiveness and efficiency of the new arrangements is proposed for 2010. These developments are subject to confirmation by the Ministerial Council on Energy.<sup>12</sup>

### *Assessment*

The development of well-drafted standards by Standards Australia necessarily takes time. It involves undertaking the necessary research, achieving consensus within the technical committee and public consultation. Rushing the process can result in unsatisfactory standards and a need for revision.

That said, unnecessary delays in the development of standards can impose unavoidable costs on industry, particularly if the standards are referenced in legislation and thus become mandatory, such as in the case of standards applying to energy labelling and MEPS as well as standards under the WELS Scheme. Such costs arise if the timing of the release of the standard fails to take account of industry production and marketing time-frames, thus imposing costs on businesses who must then withdraw or otherwise deal with products produced before the standard was released to ensure compliance.

In its submission on the draft report, DEWHA considered that explicitly recognising the need for all parties to provide adequate staff and related resources to ‘important energy efficiency dialogues’ within Standards Australia’s committee system will lead to the production of more ‘robust and accurate’ testing and performance standards (sub. DR56, p. 3). It proposed that the Commission recommend that:

Standards Australia and the Department of the Environment, Water, Heritage and the Arts, together with industry, should seek to share the costs of adequately resourcing these tasks into the future. (sub. DR 56, p. 3)

The Australian Industry Group, noted a ‘high level of dissatisfaction’ with current standards development processes:

... to deliver standards at the rate required to support new and amended regulations, particularly in the area of energy efficiency. ... We do however, have some concern with the emphasis on speed over quality of outcome inherent in the options. (sub. DR48, pp. 4–5)

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<sup>12</sup> As a backdrop to these developments is Standards Australia’s ‘new business model’, which it released in April 2008, and the memorandum of understanding it has with the Australian Government (represented by the Department of Innovation, Industry, Science and Research), signed on 30 May 2008. The business model (Standards Australia 2008c, p. 1) addresses various standards development issues, such as the inclusion of a net benefit assessment, for each standards project proposal. The memorandum of understanding contains undertakings addressing the efficiency and timeliness of standards development by Standards Australia and the provision of resources for standards development by the Australian Government (paragraphs 5.10, 6.1 and 6.2).

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Fisher and Paykel considered that further improvement is required in the timeliness and efficiency with which standards are developed (sub. DR45). It said that, while a number of steps have been undertaken by Standards Australia to structure its organisation, the changes ‘will not be effective’ (sub. DR45, p. 2). It suggested that there should be an independent and public evaluation in 2009 of the timeliness and efficiency with which standards are developed.

Fisher and Paykel also considered that insufficient time and money was spent on proving a newly proposed test method.

Often this will require round robin testing in a number of laboratories to confirm repeatability and reproducibility. Unfortunately this time and cost is often not factored into policy launch schedules. This can result in the policy being launched without the possibility of effective enforcement because the test method has not been proven. (sub. DR45, p. 2)

The Commission supports Standards Australia’s preferred option for standards development. The option recognises that sufficient resourcing is required if Australian Standards are mandated under energy labelling and MEPS legislation. It reinforces the Commission’s recommendation in its report on standard setting and laboratory accreditation (PC 2006a) to improve the timeliness and efficiency with which standards are developed.

## **Poor compliance and enforcement**

Participants raised concerns about poor compliance with, and enforcement of, energy labelling and MEPS requirements (for example, Australian Industry Group, sub. DR42; Fisher and Paykel, sub. DR45). The concerns are similar to those raised about the WELS Scheme.

Enforcement of energy labelling and MEPS requirements is primarily the responsibility of state and territory energy agencies. The Australian Government has no direct enforcement responsibility.

The E3 Committee conducts a national ‘check testing’ program to provide information to the community on compliance by suppliers. Appliances are purchased from retail outlets or obtained anonymously and tested in National Association of Testing Authorities-accredited independent laboratories to verify the claims associated with the energy label and MEPS where applicable. Units are not randomly selected for check testing, rather selection criteria and market intelligence are used to target testing towards units more likely to fail. However, as noted later, there are participant concerns that this is not in fact the case. The outcomes of check testing are published in a compliance newsletter.

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Misleading or deceptive conduct as well as false or misleading representations by a supplier of a product's performance or energy efficiency may also constitute breaches of the Trade Practices Act. The ACCC accepts referrals on Trade Practices Act matters from DEWHA, consumers and businesses (ACCC, pers. comm., 17 June 2008). An example is ACCC's investigation in 2006 into the accuracy of energy efficiency values claimed on labels on a number of LG Electronics Australia airconditioner models, which led to the company making court enforceable undertakings to the ACCC (ACCC 2006).

The ACCC conducted a review in 2000 of the legal and administrative enforcement mechanisms in relation to the national energy equipment efficiency program (ACCC 2000). The paper outlined a range of sanctions or regulatory tools available to the ACCC to assist it in seeking 'fast effective consumer-friendly outcomes' (ACCC, pers. comm., 17 June 2008). The ACCC made a number of recommendations or suggestions for change including:

- a transparent system of public reporting of enforcement outcomes
- the introduction of Australian Government legislation to complement and reinforce the current State-based regime
- the introduction of a wider range of sanctions to allow timely and appropriate actions by regulators
- improvements to the Administrative Guidelines for the Appliance and Equipment Energy Efficiency Program of Mandatory Labelling and Minimum Energy Performance Standards including the establishment of an organisation with responsibility for administering and monitoring the Administrative Guidelines to promote consistency between the various state and territory regulatory enforcement agencies (ACCC 2000, pp. 21–2).

### *Assessment*

As noted in relation to the WELS Scheme, poor compliance with, and enforcement of, energy labelling and MEPS requirements can exacerbate the regulatory burden for compliant businesses.

In its draft report and response, the Commission considered that, although the E3 Committee's compliance check testing program usefully addresses concerns in this area, DEWHA should, through its representation on the Committee, seek an independent and public review of compliance with and enforcement of energy labelling and MEPS requirements. This review should examine activities of the state and territory energy regulators. The review should cover options for improvement.

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DEWHA agreed with the Commission's draft response to seek agreement from state and territory agencies to independently benchmark their enforcement activities (sub. DR56, p. 4).

The Australian Industry Group also supported benchmarking of the enforcement activities by state regulations of the MEPS and labelling programs. It said that, in addition, 'a clear analysis of the complementarity of these programs must be provided to industry within the framework of the Wilkins Review' (sub. DR 48, p. 4)

Fisher and Paykel considered that independent benchmarking needs to be made available to the public. It also expressed reservations about the E3 Committee's check testing program. As noted earlier, the E3 Committee's program is apparently targeted at products that are likely to fail. However, Fisher and Paykel indicated that this was not the case:

... the selection of units for check testing should be more specifically targeted at product that is likely to fail. Currently DEWHA has an arrangement with a leading consumer organisation to check test appliances that they already tested for their consumer magazine. This is not target testing units more likely to fail, but rather testing popular units that are of interest to this particular consumer organisation.

There is a real concern that the current selection method will ignore suppliers who provide appliances into the market for only a short period. This is often described as event marketing. Suppliers know that if the product is only in the market for six months then they will not be picked up by the current enforcement regime. Even if they are detected the current penalties are not adequate as it is possible to liquidate the entity and consumers are left with no apparent opportunity to achieve compensation. (sub. DR45, pp. 2-3)

Rheem Australia was of the opinion that 'adequate funds should be set aside to undertake compliance auditing of manufacturing claims relating to compliance with schemes such as MEPS and WELS' (sub. DR52, p. 1). It also suggested that

Whilst acknowledging the importance of ongoing monitoring of all suppliers within the market, we would support the view that the majority of compliance funding should be focussed on targeting those operators within the market that are known to pose a higher potential risk. Audit programmes and audit frequency should therefore focus on those operators with a poor track record. (sub. DR52, p.1)

The Commission considers that DEWHA should, through its representation on the Committee, seek an independent and public review of compliance and enforcement of energy labelling and MEPS requirements. This should examine activities of the state and territory energy regulators as well as the E3 Committee's check testing program against appropriate benchmarks. The review should cover options for improvement, including the need for adequate funds to be allocated through the E3

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Committee to ensure effective compliance with and enforcement of energy labelling and MEPS requirements.

Benchmarks should relate to such matters as the:

- policy versus the practice of an agency's approach to enforcement
- limitations on the extent of enforcement by an agency — for example, resource limitations and limited statutory powers
- priority areas for enforcement and the criteria used to determine priority area
- the approach to identifying breaches — for example, the extent of an agency's efforts or resources expended in following up complaints relative to undertaking inspections and the types of inspections undertaken (whether random or systematic, risk-based or non-risk based, or geographically-targeted versus general purpose)
- the measures used in rectifying specific breaches — for example, providing education or advice, using adverse publicity, imposing fines, or undertaking prosecutions
- whether a hierarchy of measures (or an enforcement pyramid) is used.

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.*

## 6.4 National Pollutant Inventory

Participants such as the Australian Dairy Industry (sub. 26), the Plastics and Chemicals Industry Association (sub. 11) and the Red Meat Industry (sub. 24) raised various concerns about the National Pollutant Inventory (NPI) requirements, in particular, about:

- the benefits of the NPI
- the inclusion of greenhouse gases emissions
- the inclusion of transfers
- the inappropriate use and quality of data.

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The NPI is a database established through a National Environment Protection Measure (NEPM), agreed to by the Australian Government and state and territory governments in 1998. It is to contain information:

- about emissions and transfers of specified substances, on a geographical basis, including those of a hazardous nature or involving significant impact
- that enhances and facilitates policy formulation and decision making for environmental planning and management
- about waste minimisation and cleaner production programmes in industry, government and the community and promotes and facilitates their implementation
- that is available and accessible to the public (clause 7).

The NEPM is implemented through state and territory legislation under the auspices of the Environment Protection and Heritage Council (which incorporates the National Environment Protection Council).

Under the NEPM, unless it is exempt,<sup>13</sup> a business is required to report within a reporting period if it has a facility that:

- used specified amounts or more of particular categories of substances
- burned 400 tonnes or more of fuel or waste (or burned one tonne or more in any one hour) or consumed 60 000 MW or more of electric power
- emitted 15 tonnes or more of total nitrogen or three tonnes or more of total phosphorous to water and/or sewer (DEWHA 2008a).

The NEPM was last reviewed in 2005 to examine the NPI's effectiveness and whether it was delivering benefits to the community, industry and governments (Environment Link 2005).

Largely in response to that review, the NEPM was varied in June 2007 to include transfers, include greenhouse gas reporting, change publication requirements and to change substance and threshold requirements (NEPC 2007). The variation to include greenhouse gas reporting in the NPI was an interim measure pending the establishment of the national greenhouse gas and energy reporting framework (section 1.2). Following the introduction of the National Greenhouse and Energy

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<sup>13</sup> Facilities that do not have to report to the NPI are: a mobile emission source (for example, an aircraft in flight) operating outside the boundaries of a facility; a petroleum retailing facility engaged in the retail sale of fuels; a dry cleaning facility employing less than 20 persons; a scrap metal handling facility trading in metal that is not engaged in the reprocessing of batteries or the smelting of metal; and a facility or those parts of a facility solely engaged in agricultural production including the growing of trees, aquaculture, horticulture or livestock raising unless it is engaged in the processing of agricultural produce or intensive livestock production (for example, a piggery or a cattle feedlot).

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Reporting Act, the National Environment Protection Council commenced a statutory process in April 2008 to make a minor variation to the NEPM to repeal the greenhouse gas reporting provision.

### *Assessment*

In its draft report, the Commission drew attention to its responses to several concerns expressed about the NPI in its primary sector review, considering them to still be of relevance to this review (PC 2007a).

- The Environment Protection and Heritage Council should review the reporting thresholds for all NPI substances by 2009 (PC 2007a, p. 62, response 3.8).
- The Environment Protection and Heritage Council should review whether facility-based data collected under the NPI could be aggregated to geographic regions before being made available to the public without unduly reducing the value of the information or the incentive for businesses to reduce their emissions (PC 2007a, p. 63, response 3.9).
- Progress has been made by DEWHA to improve public awareness of the NPI, through the development of a communication and awareness plan, and to improve the quality of data reported to the NPI. DEWHA should, after a reasonable period of time, evaluate the effectiveness of these actions (PC 2007a, p. 206, response 4.10).
- The adequacy of funding for the administration of the NPI by DEWHA should be reviewed. There should not be any further expansion of the NPI until this has been done (PC 2007a, p. 207, response 4.11).

In its submission on the draft report, DEWHA (sub. DR56, pp. 4–5) noted:

- that, as required under the NEPM, the NPI will be comprehensively reviewed as determined by the Council at least every five years. The review will consider the need to amend the NEPM to add or delete substances and change thresholds from the reporting list. The next review is scheduled for 2012
- that, following its evaluation of the facility-based approach to reporting NPI data the NPI Implementation Working Group has agreed to maintain public disclosure at the facility level
- that a full evaluation of its communication and awareness plan will be undertaken in 2009-10
- the Commission's response on inadequate resourcing of the NPI.

The Commission notes DEWHA's comments about proposed reviews of substances and reporting thresholds under the NPI, maintaining public disclosure at the facility



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level, and a proposed evaluation of the Department's communication and awareness plan in 2009-10. It considers, that all future reviews and evaluations should be independently undertaken and publicly reported.

## **6.5 National Packaging Covenant**

The National Packaging Covenant (NPC) is a voluntary product stewardship measure whereby producers assume part of the responsibility for their product and its packaging throughout its lifecycle — from production through to disposal. The NPC aims to reduce environmental damage caused by waste disposal and to conserve resources. This can be achieved by reducing the amount of packaging used, increasing the amount of packaging that is reused and/or by increasing the amount of packaging that is recovered for recycling (National Packaging Covenant, sub. DR49). The NPC attempts to achieve its goals by improving packaging design, and encouraging recycling and reuse of used packaging material.

The NPC is supported by an Environmental Code of Practice for Packaging, which sets out general principles for packaging manufacturers and those who use packaging to deliver products to consumers, and suggests ways to achieve them. Signatories to the NPC commit to implement, incorporate and work towards the Covenant's goals, adopt the Environmental Code, make annual financial contributions, prepare annual reports and prepare action plans every three to five years.

The NPC is supported by the National Environment Protection (Used Packaging Materials) Measure. State and territory governments have created legislation giving force to the NEPM. As such, all brand owners<sup>14</sup> with revenue exceeding \$5 million are legally obliged to comply with stringent regulations if they are not voluntarily committed to comparable processes, such as the NPC.

In effect, the NEPM creates an incentive for product stewardship by large companies who are not signatories to the NPC thereby preventing these companies from 'free riding' on the environmental efforts of covenant signatories.

As a co-regulatory measure, regulatory responsibility for the NPC lies with a council composed of representatives from government, industry associations and

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<sup>14</sup> A brand owner is defined in the NPC as the owner or licensee of a trade mark under which a product is sold or distributed in Australia, a franchisee of a business in Australia, the first person to sell an imported good in Australia, suppliers of packaging to stores which package their own goods, and importers, manufacturers or suppliers of plastic bags provided to consumers at the point of sale.

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the community. As such, the Australian Government is not the regulator of the NPC, but it can exert a degree of influence as a member of the NPC Council.

An independent mid-term review of the NPC is currently underway with reporting to occur late 2008. The current covenant expires on 30 June 2010. If a new or revised covenant is to be implemented after this date it will have to be preceded by a RIS based on sound scientific and economic evidence in line with OBPR guidelines.

The Commission reported on waste generation and resource efficiency in 2006 and recommended that:

The terms of reference for the scheduled 2008 review of the National Packaging Covenant should be expanded by the Australia Government beyond an assessment of effectiveness. An independent review should consider all relevant evidence about whether the Covenant (and supporting regulation) delivers a net benefit to the community. (PC 2006b, p. 294)

The Australian Government supported this recommendation and indicated that it would either broaden the terms of reference for the 2008 mid term review or conduct a more comprehensive review in 2010 at the expiry of the current NPC. The terms of reference for the mid-term review focus on the effectiveness of the NPC, and have been broadened beyond the initially planned scope to include consideration of the burden of reporting requirements on businesses.

### **The burden of reporting requirements**

Membership of the NPC requires signatories to provide data on the volume and composition of all packaging used to deliver products to the customer. This data is required to be included in annual reports.

The Commission is aware of concerns that the time required to collect data for annual reports was excessively burdensome. Further burdens were placed on businesses when changes were made to packaging design — whether they were to reduce packaging material use, improve ease of handling or change the appearance of the product — as they must re-calculate the volumes of different types of materials used. This has the effect of delaying some changes in packaging design.

#### *Assessment*

There is a burden on businesses from NPC reporting requirements. Total costs to business from reporting requirements were estimated in the 2001 RIS at \$1-4 million per annum (Nolan-ITU 2005).

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Any simplification of reporting requirements would have to balance the cost saving to business against the possible loss of data precision and quality. It would need to ensure that only the unnecessary component of the burden is removed. As it appears that the data collected under the NPC are frequently approximated, any loss to data precision and quality from simplification is likely to be minimal.

The mid-term review of the NPC is currently underway and will include some assessment of the effectiveness of data gathered from businesses as well as the burden on businesses from reporting.

It is recognised that improvements to the current data collection requirements may be required to reduce the reporting burden on signatories and improve the quality of data collected. (DEWHA, sub. DR56, p.5)

One component of the mid-term review includes interviewing participants to gauge the weight of the burden. Furthermore, the NPC has commissioned a number of independent analyses addressing the efficiency and effectiveness of data collection. The Commission considers these valuable exercises and thorough evaluation of the necessity of information required of participants is needed.

### **Poor compliance and enforcement**

A concern was raised that low levels of monitoring, auditing and enforcement by the NPC Council were increasing the likelihood that companies would approximate data. The specific concern brought to the attention of the Commission related to the quality of information included in annual reports, particularly that the high level of detail and large volume of data required increases the propensity of companies to approximate. This inherently compromises the quality of data and can occur undetected without effective auditing procedures.

Further, concerns were raised about enforcement of the NEPM on non-covenant signatories.

Member concerns with the implementation, measurement and enforcement of the program stem mainly from the fact that many organisations still remain outside the voluntary scheme and do not have to comply with its targets. Although such organisations are technically subject to stricter targets under the NEPM, industry evidence indicates that poor enforcement and compliance means that ‘free-riders’ is an issue with the scheme at the moment. (Australian Industry Group, sub. DR48, p. 5)

Detection of brand owners with annual turnover exceeding \$5 million who are not signatories to the NPC occurs in two ways. An annual brand owner survey is conducted in all states, this helps detect companies that have turnover above the threshold for coverage under the NEPM but who are not signatories to the NPC.

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Furthermore, non-signatories are detected through direct referral, most frequently by competitors. The effectiveness of these measures are being evaluated as part of the current mid-term review.

Most companies prefer to participate in the NPC rather than the state NEPM legislation. Compliance of companies who have elected to comply with NEPM requirements is a matter for state and territory governments and is outside the scope of this review.

### *Assessment*

The current arrangement is that 10 per cent of all signatories are independently audited each year and non-compliant organisations are sent letters in response to breaches. Four letters are sent and non-compliers are listed on the NPC website before the issue is referred to the relevant state or territory government and action can be taken for non-compliance with the NEPM legislation. Infrequent audits and modest penalties on companies reduce a participant's incentive to put the required time into collecting precise data. This also diminishes the goodwill of companies as they are uncertain of whether their competitors are expending comparable effort in collecting precise data.

Without reliable information about the effectiveness of compliance procedures, it is difficult to say whether or not the current program is effective, or what the ideal rate of audit frequency is.

The effectiveness of the NPC in its present state is currently under review. The Commission considers that, if poor compliance is confirmed in the review, the NPC Council should respond with options to address this concern, including variations of the current NPC and alternative options for achieving waste reduction.

However, the NPC's compliance procedures were updated in November 2007 to improve enforcement. The Covenant Council are also looking at updating their auditing processes. The Mid Term review of the National Packaging Covenant will look into the effectiveness and workability of monitoring and enforcement policies and procedures, including through stakeholder consultation. (DEWHA, sub. DR56, p.6)

### **Inappropriateness of targets**

Concerns were raised that as the amount of packaging material used per item is reduced, damage to products can become more prevalent. This creates a problem for businesses as they must demonstrate continual improvement in their management of packaging to contribute to the objectives of the NPC.

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This is a point reiterated by the Plastics and Chemicals Industries Association (sub. 11) who stressed the importance of differentiating aspirational goals and achievable targets, as the former can result in perverse outcomes if taken literally.

Targets for reduction of the disposal of packaging material were set by EPHC Ministers and included in the NPC without estimating the benefits and costs of different target levels.

The Covenant targets are overarching and apply only to the Covenant as a whole and not to individual businesses. Signatories are asked to show how their actions can contribute towards the Covenant achieving its overarching targets, not to report progress against them individually. (sub. DR49, p.1)

Access Economics (2005) noted in its review of the RIS that without linking targets to how they will be achieved, it is unlikely that the best target levels will be chosen.

Assessment of the optimal target level has not been conducted due to a lack of available data. The value of data for this purpose and the required information should be considered during assessment of data requirements prior to the expiration of the current NPC. The information collected under the current and previous NPC should be used to inform any decision about the future of the covenant beyond its expiration in 2010. This is to be examined in the current mid-term review.

## **6.6 Ozone protection: pre-charged equipment**

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

Eppendorf South Pacific raised a concern about frequent reporting of small volumes of ozone depleting substances (Science Industry Australia, sub. 13, p. 7). As a manufacturer and distributor of scientific equipment, it imports a small number of centrifuges containing a small amount of ozone depleting gasses.

Under the *Ozone Protection and Synthetic Greenhouse Gas Management Act 1989*, companies importing any pre-charged equipment must acquire a licence (valid for two years) and report quarterly on the volumes of hydrochlorofluorocarbons (HCFCs) and hydrofluorocarbons (HFCs) then pay a fee based on the volume of these gases.

Eppendorf South Pacific said that there are numerous occasions where it has no HCFCs or HFCs to report. On the occasions where it does report, the volumes are so small that fees around one cent are payable. The company stated that the time

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and administrative burdens of reporting are far greater than the fee. It suggested that businesses with a history of importing only small volumes of HCFCs and HFCs should be allowed to report annually.

### *Assessment*

The current legislation governing the system does not include scope for low volume exemptions, and so the suggested change would require an amendment to the legislation. Recent changes to simplify compliance included encouraging pre-payment of fees, developing systems for online reporting and issuing email reminders prior to reporting deadlines.

Any examination of options to create a low volume exemption would have to weigh up the cost of amending legislation against the benefits to importers of low volumes.

DEWHA informed the Commission that it has estimated reporting requirements for businesses and has information on the number of importing businesses (DEWHA, pers. comm., 3 April 2008). It should, thus, be possible for DEWHA to estimate potential cost savings to businesses from reducing the required reporting frequency for low volume importers. If the benefits of changing the legislation outweigh the costs of doing so, this should occur. If changes are being made to the legislation on other matters, the insertion of a low volume exemption should be included. In this situation there is likely to be a net benefit from making changes.

RESPONSE 6.6

***The Department of the Environment, Water, Heritage and the Arts 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 HCFCs and HFCs below an agreed threshold should be allowed to report annually rather than quarterly.***

## **6.7 Container deposit legislation**

A number of participants raised concerns about the possible expansion of container deposit legislation (CDL) to all state and territory governments. The scheme currently operates in South Australia covering most soft drink, beer and water containers, and some juice and flavoured milk containers. CDL aims to reduce beverage container litter and encourage recycling.

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CDL is a form of deposit-refund scheme whereby consumers pay a deposit on containers when they purchase an item included in the scheme. This amount is returned when the container is deposited at a specified collection or treatment facility.

Previous research by the Commission indicated that CDL is not likely to be the most efficient means of reducing container waste, except in circumstances where the cost of illegal disposal is very high, such as toxic waste products. It was found that kerbside recycling and general anti-litter programs are likely to be more efficient methods of reducing packaging waste (PC 2006b).

At the April 2008 meeting of Australian environment ministers, a national CDL scheme was discussed and an agreement was made to investigate options for reducing container wastes.

At the Environment Protection and Heritage Council (EPHC) meeting of 17 April 2008, Federal, state and territory environment ministers agreed to establish a Beverage Container Working Group (BCWG) to examine options for national reduction in packaging wastes, particularly beverage containers. Container deposits are one of the options to be examined. The BCWG is establishing a stakeholder reference group consisting of all levels of government, industry, community groups and environmental NGOs which will input into the analysis.

The BCWG will report to the EPHC on its findings on the viability of a National container deposit scheme and alternatives in 2009. These findings will include examination of the costs of the varying options. (DEWHA, sub. DR56, p. 7)

There is currently a Senate Inquiry into the Management of Australia's Waste Streams being conducted, which will consider the *Drink Container Recycling Bill 2008* amongst other waste policy issues. The report of this inquiry is to be presented to Parliament by 28 August 2008.

### **Cost of container deposit legislation**

Imposition of CDL imposes costs on businesses through levy collection, changed administrative practices and product relabelling. Coca-Cola Amatil informed the Commission that the recent levy increase from 5 cents to 10 cents in South Australia will cost the company approximately \$2 million for labelling changes when implemented.

Furthermore the costs to government of container collection and administration are likely to be substantial. Coca-Cola Amatil estimates that a national CDL scheme would cost \$400 million each year to operate, based on the current South Australian system. However, the Commission acknowledges that the South Australian system

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of hand sorting containers by material and brand is not the most efficient system possible (PC 2006b).

When assessing the merits of different options to reduce container waste, it is essential that the Environment Protection and Heritage Council requires a rigorous cost-benefit analysis to be completed and that processes are consistent with COAG's principles of good quality regulation (COAG 2007a).

### **Uniformity of container deposit legislation**

A concern was raised in reference to consistency between states and territories if CDL was to be implemented in other jurisdictions. Unnecessary costs would be avoided if new regulations are uniformly applied and interpreted from the beginning of any new scheme.

The CDL is currently being considered in a national context by the EPHC and under the *Drink container Recycling Bill 2008*. These approaches ensure that uniform legislation is applied to all participating jurisdictions. It is possible that states and territory governments would have slightly differing interpretations of the same legislation, in a similar fashion to the interpretation of food standards, and this should be resolved through coordination and communication between the responsible state and territory governments.

Conversely, if the Australian Government chooses not to implement a national CDL scheme, it is possible that individual states could design their own schemes. State based schemes could be designed to apply harmoniously with the schemes of other states. Analysis of potential regulation in jurisdictions other than the Australian Government is outside the scope of this review.



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## 7 Regulatory issues in the distributive trades

The distributive trades comprise both the wholesale and retail trades divisions of the *Australian and New Zealand Standard Industrial Classification* (ANZSIC). The wholesale trade division includes businesses engaged in the purchase and onselling of goods without significant transformation to other businesses, usually retailers. Business premises are usually warehouses or offices. Business activity is characterised by high value and/or bulk transactions. Retail trades businesses are also engaged in the purchase and on-selling of products without significant transformation, but to the general public. These businesses usually operate from premises designed to attract a high volume of customers.

It became clear during the consultation phase including through submissions that because many of the distributive trades businesses operated across multiple jurisdictions their concerns focused on the lack of regulatory consistency between jurisdictions both in the distribution of goods and at the point of sale. Many of the concerns raised by businesses in this sector related to state and territory government regulation as many of the licences and permits specific to activities in these sectors are issued at the state and territory and, in some instances, local government level. A number of other matters raised by the distributive trades were also raised by manufacturers, including country of origin labelling.

One common theme raised by small businesses in this area was not so much the burden of regulation, but the lack of adequate information provided by governments to enable businesses to comply with the regulation. Other concerns, such as the Goods and Service Tax (GST), were of a more generic nature and are discussed in the following chapter.

The remainder of this chapter discusses specific regulatory burdens raised by participants on the distributive trades.

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## 7.1 Tobacco retailing

There were concerns that the different state and territory regulation surrounding the sale, promotion and supply of tobacco products increased the regulatory compliance burdens for national retailers. Coles Group said:

The problem with these inconsistencies is that they require national tobacco retailers to develop and implement specific processes, procedures and training material for each jurisdiction, which makes compliance unnecessarily more difficult and costly. It also means that national tobacco retailers have to frequently redesign or purchase new tobacco displays to accommodate the different display size restrictions in each state and territory.

Coles' view is that inconsistencies that exist in current jurisdiction-based legislation should be addressed as a matter of urgency in order to reduce the regulatory compliance burden on national retailers. (sub. 17, p. 2)

To address inconsistencies, Coles Group (sub. 17) proposed that a nationally consistent approach to the regulation of tobacco sales be developed through the Ministerial Council on Drug Strategy.

Qrtsa – The Retailers Association (sub. 1) noted that there were also costs imposed on retailers associated with the ongoing regulatory changes covering the sale of tobacco.

### *Assessment*

A nationally consistent approach to the regulation of tobacco sale, promotion and supply would clearly reduce the compliance burden for national retailers in relation to tobacco sales. However, as the regulation of tobacco sales is a state and territory responsibility, the introduction of a nationally consistent approach in this area is a matter for the states and territories and could be addressed through their membership of the Ministerial Council on Drug Strategy.

## 7.2 Anti Monetary Laundering and Counter Terrorism Financing Act 2006

The Australian Newsagents Federation (ANF) (sub. 8) raised concerns surrounding the compliance costs involved in meeting the provisions of the *Anti Monetary Laundering and Counter Terrorism Financing Act 2006* (AML/CTF) Act for newsagents undertaking money remittance services. As agents accepting and making payments through the Western Union network, individual newsagents are registered providers of remittance services and subject to the regulatory provisions

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of the legislation, which involves staff checks, training of staff and implementation of certain procedures.

The ANF noted that although these services are only a small part of a newsagent's business the burden of compliance, for what are mainly small businesses, outweighed any benefits derived by the newsagent from providing these services and many newsagents had ceased providing money remittance services (sub. 8).

It said:

The ANF and Western Union do provide compliance support to assist ANF agents in complying with the AML/CTF Act, but complications arise through the identification and reporting of specific exemptions within the network.

Further, there are a number of specific compliance obligations which require ANF agent level measures to be enacted by the responsible authority within each business. These measures include but are not limited to: employee due diligence, such as background reports and checks on all staff; implementation of specific policies and procedures; independent review of policies and procedures; comprehensive risk assessment programs and risk training for all employees. (sub. 8. p. 3)

### *Assessment*

The objective of the legislation is to reduce the risk of money laundering in Australia and the threat to national security caused by the financing of terrorism. This legislation aims to bring Australia's AML/CTF regulation in line with the agreed international standards and meet Australia's international obligations in this area (Attorney-General's Department 2008).

Following industry concerns about its complexity, this legislation is being introduced on a staggered basis over a two year period. The legislation will be fully implemented by December 2008.

The Australian Transaction Reports and Analysis Centre (AUSTRAC), as Australia's anti-money laundering and counter-terrorism financing regulator, is involved in industry consultation regarding the implementation of the legislation. As noted by the ANF (sub. 8), there are processes in place to allow the ongoing review and potential amendment of the package to address practical considerations. To this end, the ANF (sub. 8) has provided a submission to AUSTRAC seeking permission to adjust the compliance reporting arrangements.

The AML/CTF legislation and related rules are not fully implemented and there is ongoing consultation surrounding their application to address practical considerations. As such, minimising compliance burdens while meeting the objectives of the legislation is a matter for the ANF, Western Union and

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AUSTRAC. However, to further good regulatory process, the effectiveness and efficiency of the legislation should be independently reviewed in an appropriate timeframe following its implementation.

### **7.3 Motor vehicle and motor vehicle parts wholesaling and retailing**

The Motor Trades Association of Australia (MTAA) was concerned with the poor linkages and inconsistencies between the National Exchange of Vehicle and Driver Information System (NEVDIS) and the Register of Encumbered Vehicles (REVS). It said:

Problems arise, however, when the NEVDIS database and state based REVS are not aligned, as dealers are not able to obtain, with confidence, accurate and timely information regarding the history of the motor vehicle proposed to be bought or sold. This in turn creates an additional burden and impediment to the productive operation of the retail motor traders business. Licensed retail motor traders are obliged to guarantee 'clear title' of vehicles they sell. An inability to get accurate and timely information on title can have a significant impact on dealers. (sub. 6, p. 4)

#### *Assessment*

The Australian Government does not operate these data bases. NEVDIS was established to link the various state and territory transport department/roads and traffic authority data bases to enable automatic exchange of vehicle and driver information. The REVS data base is operated by the relevant state or territory fair trading and/or consumer affairs department and holds information about motor vehicles and boats that have been used as security for a loan from a bank, finance company, credit union or other credit provider.

The problem for the motor vehicle retailer is not with any specific regulation, but with the ability to access timely and accurate information from these various state and territory operated data bases. As such, improvement in this area is likely to require improved coordination between the various fair trading departments within the states and territories as well as between them. The Australian Transport Council would appear to be an appropriate forum to progress inter-jurisdictional cooperation — it is the Ministerial forum for the coordination and integration of all transport and road policy issues at a national level through which the NEVDIS was implemented. Intra-jurisdictional cooperation is a matter for individual states and territories.

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The MTAA (sub. 6) also raised the issue of the different motor vehicle registration fees and stamp duty regimes across each state and territory. This disadvantages those motor vehicle dealers operating in jurisdictions with relatively high registration fees and stamp duty in selling vehicles to buyers in other jurisdictions or in attempting to secure large fleet sales. However, the level of motor vehicle registration fees and stamp duty is a matter for each state and territory and outside the scope of this review.

## 7.4 Food premises and assistance animals

Woolworths (sub. 25) were concerned that the definition of ‘assistance animal’ was unclear and that there was the potential for people to bring pets into stores and falsely claim that the animal was an assistance animal which would put Woolworths in breach of the Food Code. Woolworths were concerned that if they were to refuse admittance to a person with an ‘assistance animal’ they ran the risk of breaching the *Disability and Discrimination Act 1992* (DAA). It said:

The definition of “assistance animal” needs to be clear and consistent between the Food Standards Code and *Disability and Discrimination Act 1992* so that businesses can comply with their obligations — for example, the animal must be trained, certified and controlled in a harness and solid grip handle rather than a lead. (sub. 25, p. 7)

In its submission on the Draft Report, Woolworths said:

In the past 5 to 7 years there have been many claims by customers that animals they wish to bring into Supermarkets are assistance animals. In that time, there has been two specific cases whereby customers have been denied entry into Woolworths Supermarkets because it was determined the animals they claimed as assistance animals were clearly not Guide or Hearing Assistance Dogs. A grievance was claimed with the Human Rights and Equal Opportunity Commission [HREOC]. [HREOC] required Woolworths to provide an explanation in defence that no discrimination had occurred. Both cases have been ongoing for several years and has cost Woolworths in excess of \$80,000 in legal fees (both in-house and external). These complaints have been protracted because there is no clear definition in either the Food Standards Code nor the Disability & Discrimination Act defining an ‘Assistance Animal’. (sub. DR51, p. 1)

Division 6 of the Food Standards Code states that a food business is only to permit an assistance animal in the dining and drinking areas and other areas used by customers. It refers to section 9 of the DDA to determine what is meant by an assistance animal. There is an editorial note in the Code that sets out the definition of an assistance animal from the DDA which refers to ‘a guide dog, a dog trained to assist a person in activities where hearing is required or any other animal trained to assist a person to alleviate the effect of a disability’.

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Similar concerns have been raised by other retailers, local governments, guide dog organisations and public transport operators that the DDA does not provide an adequate definition of assistance animals. A decision of the Federal Magistrates Court in 2002 further highlighted concerns in regard to the DDA providing recognition for assistance animals other than a trained guide or hearing dog (see *Sheehan V Tin Can Bay Country Club*, FMCA, 9 May, 2002). In response, the Human Rights and Equal Opportunity Commission (HREOC) (2003) undertook a review to provide a clearer regime for determining which assistance animals should be recognised for the purposes of the DDA. It recommended that amendments be made to section 9 of the DDA to refer to assistance dogs, rather than animals, but with provision for other assistance animals to be added by regulation. These amendments would also specify that companionship or reassurance in social interactions provided by an animal is not itself assistance and that it is not discrimination to require:

- the animal to be under direct physical control by its user
- a person accompanied by an assistance animal to provide evidence that the animal provides assistance to the person's disability and the nature of that assistance
- that the animal has been trained to comply with the standards required of guide dogs
- or to refuse access to an animal which it is reasonable in the circumstances to regard as an inappropriate breed or temperament for use as an assistance dog.

The Australian Government is considering amending the DDA in light of these recommendations.

## **7.5 Regulatory restrictions on the sale of certain food in government facilities**

The Australian Beverages Council (sub. 33) raised concerns over the current and/or proposed initiatives by the New South Wales, Queensland, South Australian and Western Australian Governments to restrict food sold through vending machines or food service outlets in government facilities such as hospitals and correctional facilities. This imposed costs on food manufacturers in having to develop different products for different jurisdictions and impacted on the rights of consumers to purchase food and beverages which if not sold on these facilities would be freely available to them.

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However, with most facilities the owner or operator is able to specify or restrict the sale of certain food products and beverages on their facilities. As such, the decision on the type of food and beverages to be sold in state government facilities is a matter for those state governments.





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## 8 Other concerns

Specific concerns raised by participants, which did not fall within the broad areas covered in the previous chapters are addressed in this chapter.

### 8.1 Skills shortage, labour mobility issues and skilled migration

Many participants raised concerns about shortages of labour and skills, barriers to the movement of workers within Australia and regulatory barriers associated with employing skilled workers from overseas. These were similar to concerns raised in last year's review of regulatory burdens on the primary sector.

These problems are being experienced in most sectors of the economy and concerns about the burden associated with regulations in this area are mainly of a generic nature. That is, the regulations are not having a particular or discriminatory impact on the manufacturing and distributive trades sectors.

Some specific concerns raised are briefly outlined below. A more detailed examination in this year's review is not appropriate given the generic nature of the issues and the substantial concurrent review activity that is occurring relevant to these areas (appendix B).

#### **Regulatory burdens in accessing overseas labour**

Several submissions made reference to difficulties associated with the employment of migrants to address labour and skill shortages and in particular aspects of the Temporary Business (Long Stay) Visa (Subclass 457).

The 457 visa scheme allows businesses to recruit skilled labour from overseas for temporary entry to Australia for between three months and four years.

In consultations, several participants raised concerns about the time taken to process applications and the lack of certainty regarding timeframes (for example, Mrs Mac's and Business SA).

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The Queensland Resources Council, while generally acknowledging that the Federal Government's skilled migration program 'represents an important (and timely) response to the acute shortage of skilled employees facing industry in Queensland', called for 'fast tracking' of applications to be made available for pre-qualified companies (sub. 34, p. 2).

The Red Meat Industry (sub. 24) was concerned that the current rules surrounding the access to the 457 visa and its focus on importing skilled workers was placing a burden on meat processors and their ability to access semi-skilled labour. In particular, it pointed to problems related to the classification of meat industry workers in the Australian Standard Classification of Occupations (ASCO) codes used to specify minimum skill levels for the 457 visa program. For example,

ASCO listing Boners and Slicers at level 9 rather than equal to slaughter persons at level 4, making these roles basically ineligible under 457 rules. The [Red Meat Industry] considers the ASCO classification of meat Cert. III Boners and Slicers has been confused with fish industry roles described similarly but not aligned. The [Red Meat Industry] has faced difficulty trying to discuss this. (sub. 24, p. 14)

### *Assessment*

The Commission's report on regulatory burdens on the primary sector (PC 2007a) noted that there had been several reviews in relation to 457 visas and skilled migration policies. More recently there has been further review activity.

In February 2008, the Government appointed an External Reference Group, made up of industry representatives, to improve the efficiency and flexibility of the temporary skilled migration program (457 visas). In its final report to the Minister (in April 2008), the External Reference Group made various recommendations, many of which have been accepted by the Australian Government and are likely to contribute to a reduction in costs for business. Amongst the accepted recommendations are measures to clear the backlog of applications, assist industry in preparing applications and streamline the application and approval process.

Of particular note, the External Reference Group recommended a process of accreditation, which would 'fast track' applications received from accredited employers who display a set of 'low risk' characteristics. This recommendation has been accepted by the Australian Government (Evans, C. 2008a).

In response to the final report of the External Reference Group, the Minister for Immigration and Citizenship has proposed to increase minimum salary levels for workers to qualify for 457 visas, expand the range of penalties available for unscrupulous employers to protect employees, eliminate duplicative steps, implement a comprehensive information strategy and review employer training

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obligations (Evans, C. 2008c). This is part of a broader reform package designed to strengthen the integrity of working visa arrangements, which includes the establishment of a departmental working group to develop a long term reform package (Australian Government 2008b). A discussion paper detailing proposed changes to skilled migration legislation has recently been released for comment by stakeholders and it is expected that changes to the legislation will be presented to Parliament in September 2008 (Department of Immigration and Citizenship 2008).

In April 2008, the Government announced a further review of the temporary skilled migration program. This review is broader than and complementary to that of the External Reference Group. It is headed by Australian Industrial Relations Commissioner Barbara Deegan and is examining the integrity of the program; including minimum wage and salary levels and English language requirements. The review will report periodically to the Minister and the Deputy Prime Minister with a final report to be presented by 1 October 2008 (Evans, C. 2008b). Adjacent to the Deegan Review, a Skilled Migration Consultative Panel has been established to provide advice on issues referred to it by Barbara Deegan and the Minister for Immigration and Citizenship, and to provide informed feedback on reform proposals (Evans, C. 2008d).

With respect to the specific concerns of the Red Meat Industry, similar classification issues were raised in last year's review of burdens on primary sector businesses. The Commission reiterates its finding from that review that the extent to which employers are unable to access workers through the 457 visa program due to the classification of skills is a matter for immigration policy and consultation between the Department of Immigration and Citizenship and the relevant employers (PC 2007a).

### **Jurisdictional inconsistencies in the recognition of skills and training**

Two major national retailers, Coles Group and Woolworths, raised concerns about inconsistencies across jurisdictions in training competency requirements for staff working with and selling liquor. Each jurisdiction has different requirements for Responsible Service of Alcohol (RSA) training and, with the exception of Western Australia, will not recognise RSA training that is completed in another jurisdiction. This imposes a barrier to the transferability of staff between stores in different states since staff must be retrained to work in another jurisdiction. This was a particular concern in relation to stores located near state and territory borders. Coles Group said:

Team members who work in stores near state borders for example Albury and Wodonga, are required to complete RSA training in both NSW and Victoria. (sub.17, p.4)

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The Motor Trades Association of Australia (MTAA) also had concerns about recognition of skills and competencies across jurisdictions. Currently motor mechanics/repairers are only required to be licensed in New South Wales and Western Australia. The lack of a consistent national approach is restricting the movement of trained and competent unlicensed tradespeople to those jurisdictions with a formal licence requirement.

Should a motor vehicle mechanic from another state wish to move to New South Wales or Western Australia they may experience significant difficulty having their qualifications recognised. (sub. 6, p. 4)

### *Assessment*

COAG has been implementing a National Action Plan for addressing skills shortages through a consistent approach to apprenticeships, training and skills recognition. This was agreed to in February 2006. It has included working towards the effective implementation of full mutual recognition of skills/qualifications across Australia.

New arrangements for the recognition of occupational licences for *priority* skills shortage trades, including motor mechanics, came into effect in February 2007. Additional options for reform were presented to COAG in July 2008 and a new national system for trade licensing for all vocationally trained occupations where licences are required will be signed off by COAG in December 2008. However, as noted above, only two states currently require mechanics to be licensed and the MTAA's concern relates to difficulties unlicensed tradespeople experience in having their competencies recognised when they move to a state that has a licensing requirement.

The Commission notes that the COAG National Action Plan also covered initiatives directed towards improving the quality, flexibility and portability of skills and training, which included a nationally consistent Statement of Attainment that clearly sets out competencies and skills achieved. Full implementation of this initiative should reduce the barriers to skills mobility.

COAG has also requested the Commission to undertake a further review of the coverage, efficiency and effectiveness of the Mutual Recognition Agreement and Trans-Tasman Mutual Recognition Arrangement.

Similar issues were raised in the Commission's review of regulatory burdens on the primary sector (PC 2007a). In that review, the Commission found that while reforms were being implemented or considered, progress was slow and a

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commitment to accelerated implementation was needed. This continues to be the case.

## **8.2 Occupational, health and safety and workers' compensation**

Occupational health and safety (OHS) and workers' compensation are primarily the responsibility of state and territory governments.

### **Inconsistencies in occupational health and safety across jurisdictions**

There are eight separate state and territory OHS arrangements as well as Australian Government arrangements applying largely to public sector agencies and seafarers. The general objective of these arrangements is to prevent workplace injury, illness and death.

Many participants, from both the manufacturing sector and distributive trade sectors, raised concerns about inconsistencies in state and territory OHS requirements (for example, MTAA, sub. 6; Plastics and Chemicals Industry Association, sub. 11; the Red Meat Industry, sub. 25; Metcash, sub. 5; Woolworths, sub. 25; Coles Group, sub. 17; ACCORD Australasia, sub. 27).

Illustrative of these concerns is the following comment by ACCORD Australasia:

Despite ongoing recognition of the need for national uniformity in this important area, manufacturers still encounter significant differences in state-based approaches. This not only imposes an additional compliance burden on businesses, especially those operating sites in a number of states, but presents a barrier to clear understanding of requirements, thereby running counter to the overarching policy goal of strengthening compliance to make Australian workplaces safer. (sub. 27, p. 9)

Some participants have called for a national uniform OHS (and workers' compensation) scheme. For example, the Coles Group said:

Ultimately, the most appropriate manner to achieve efficiencies is to have a national approach and uniformity must be a primary aim. In practical terms a national Regulator is seen as a potential solution. The current situation of differing state legislation and regulation in OH&S and WC is at odds with the process applied in areas of immigration, customs, work place relations, family law and the Corporations Act.

There are many benefits associated with a national uniform approach to OH&S and workers' compensation. One safety regime ensures that accountabilities and work practices do not change irrespective of where employees work within Australia and one set of workers' compensation obligations allows for ease of understanding, equity and

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consistency of benefits i.e. one definition of “employee” and “injury/disease”. (sub. 17, p. 7)

Similar concerns were raised in the Commission’s review of regulatory burdens on the primary sector (PC 2007a).

### *Assessment*

In 2007, COAG placed OHS on a list of cross-jurisdictional regulatory hot spots and the National OHS Strategy 2002–2012 was agreed to by the Australian Government, state and territory governments, the Australian Chamber of Commerce and Industry, and the Australian Council of Trade Unions.

At its meeting in March 2008, COAG agreed that national harmonisation of OHS laws was a top priority and that its commitment to harmonisation would be reflected in an intergovernmental agreement by May 2008 (COAG 2008a, attachment B). Model legislation would be developed and submitted to the Workplace Relations Ministers Council by September 2009. COAG further agreed that governments should aspire to reduce the five year implementation timeframe for OHS and that it would consider the scope for a reduced implementation timetable at its meeting in July 2008.

Subsequent to the COAG meeting in March 2008, and to help contribute to the development of model legislation, the Australian Government announced a national OHS review to be chaired by Robin Stewart-Crompton (Gillard 2008). The review panel is to examine OHS legislation in each jurisdiction for the purpose of making recommendations on the ‘optimal structure and content’ of a model OHS Act that is capable of being adopted in all jurisdictions. It is to issue its final report by 30 January 2009.

At its meeting in July 2008, COAG signed an intergovernmental agreement for OHS reform that formalises the commitment of all governments to adopting model OHS laws (COAG 2008b). A key feature of the intergovernmental agreement is that it specified that OHS harmonisation meant national uniformity of the OHS legislative framework (comprising a model OHS Act supported by model OHS regulations and model codes of practice) complemented by a nationally consistent approach to compliance and enforcement. COAG also brought forward the implementation timetable for national uniformity by one year to 2011.

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## **Inconsistencies in workers' compensation across jurisdictions**

There are eight state and territory workers' compensation schemes, one Australian Government scheme (the Comcare scheme, a self-insurance scheme primarily applying to employees of existing and former Australian Government public sector agencies and of the ACT Government). There are also a small number of industry-specific schemes (for example, the Australian Government schemes applying to military personnel and seafarers and the New South Wales coal industry scheme).

Workers' compensation schemes generally operate as a compulsory, no-fault insurance arrangement. Employers are obliged to pay premiums to a public or private insurer, or otherwise self-insure, to cover their liability for all work-related fatality, injury or illness. Premiums are used to compensate and/or rehabilitate workers with work-related injuries or illnesses, or their dependants in the case of fatalities. Employers can self-insure if they meet certain requirements (for example, in relation to prudential matters, employment size, claims management and OHS).

Several participants (for example, Woolworths, sub. 25; Coles Group, sub. 17; Metcash, sub. 5) raised concerns about inconsistencies in workers' compensation schemes, in particular about:

- such matters as employee definition, return to work requirements, different benefit requirements and different reporting requirements
- problematic aspects of the National Self Insurance Audit Tool, such as its inconsistent interpretation amongst jurisdictions.

Illustrative of the concerns is the following comment by Woolworths:

Numerous inconsistencies exist across State, Territory and Commonwealth Workers Compensation Legislation. Woolworths, as a national operator, must comply with each of the regulations in the States and Territories in which it operates, which is costly and time consuming. (sub. 25, p. 5)

Some participants have called for a national workers' compensation scheme or for greater access to the Comcare scheme (for example, Coles Group, sub. 17; Woolworths, sub. 25).

### *Assessment*

As the concerns raised apply to all sectors of the economy, the Commission considers that they are best dealt with in 2011 when it reviews economy-wide generic legislation.

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That said, it notes that there is a review of the Comcare scheme as well as a moratorium on new corporations joining the scheme pending the outcomes of that review (Gillard 2007 and 2008). The review is to consider such matters as:

- whether the Comcare scheme provides appropriate OHS and workers' compensation coverage for workers employed by self-insurers
- why private companies seek self-insurance with Comcare and whether there are alternatives available to address the costs and red tape for employers with operations across jurisdictions having to deal with multiple OHS and workers' compensation systems.

The review is due to be completed on 31 July 2008.

Some of the concerns raised by participants are thus likely to be relevant to the review of the Comcare scheme.

### **8.3 Equal opportunity reporting requirements**

The *Equal Opportunity for Women in the Workplace Act 1999* seeks to promote merit-based employment for women, eliminate discrimination and promote equal employment opportunity for women, and foster workplace consultation between employers and employees about equal employment opportunity for women (s. 2A).

The Act requires all non-government organisations with 100 or more employees to develop and implement a workplace program applying to women entering and advancing in their organisation. These organisations must report each year to the Equal Opportunity for Women in the Workplace Agency on the outcomes of their workplace program. In reporting, organisations must:

- set out a workplace profile
- describe the analysis undertaken to identify any issues for women within the workplace
- describe the actions taken to address priority issues
- evaluate the effectiveness of the actions taken
- describe the actions the organisation plans to take in the next reporting period to address issues for women in the workplace.

Organisations that have been assessed as compliant with the Act for at least three consecutive years and which can prove they are taking all reasonable and practical actions to progress equal opportunity for women in the workplace may be eligible to be exempt from reporting for a period of up to three years.



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## **The burden of annual reporting requirements**

Metcash expressed concerns about the requirement for reporting under the Act. It noted that the:

... penalty for failure to report is to be named in Parliament and excluded from participation in tendering for Government contracts. There is no apparent evidence of any benefit from this requirement. Cost to the company: Approximately \$10 000. (sub. 5, p. 1)

Metcash recommended that the outcomes of equal employment opportunity reporting be measured and either the need for these reports re-evaluated in the light of the results or actions taken to ensure meaningful benefits ensue from the reporting process (sub. 5).

The Regulation Taskforce (2006) considered concerns about the Act and said that the requirements were no longer justified. It recommended that:

The Australian Government should replace mandatory reporting under the Equal Opportunity for Women in the Workplace Act with voluntary reporting that focuses more broadly on workplace diversity, rather than just the participation of women in the workplace. (recommendation 4.43)

In its response to the report, although the Australian Government did not agree to the recommendation, it recognised that there was scope to reduce the regulatory burden and compliance associated with reporting to the Equal Opportunity for Women in the Workplace Act. The Australian Government decided to change the reporting requirements of Act to reporting every two years rather than annually:

This change will assist in further reducing the compliance burden upon business in line with the purpose of the Taskforce. It will require amendment to the Equal Opportunity for Women in the Workplace Act 1999. (Australian Government 2006, p. 23)

The proposed changes, however, have not as yet come into effect.

### *Assessment*

The Commission notes actions by the Equal Opportunity for Women in the Workplace Agency to lessen the regulatory burden for organisations reporting under the Act. For example, the Agency has introduced step-by-step online packages to assist businesses to complete reports or to apply for waivers. Research undertaken for the Agency has also found that 73 per cent of organisations believed that the Agency was effective in minimising effort involved in reporting each year (EOWWA, pers. comm., 2 June 2008).

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In the draft report, the Commission considered that reducing the frequency of reporting to the Agency from annually to biennially, as decided by the previous Australian Government, would further ease the compliance burden of businesses subject to the Act. The Commission's draft response stated that the Australian Government should introduce amendments to the Act to enable biennial reporting as soon as possible.

Several participants (Ms Willis, sub. DR74; Dr Charlesworth, sub. DR75; Prof. Gaze, sub. DR76) opposed the Commission's draft response. For example, Ms Willis noted several reasons for retaining annual reporting including the following:

- Biennial reporting is incompatible with the aims of the Equal Opportunity for Women in the Workplace Act, particularly, the aim of fostering workplace consultation between employers and employees on equal opportunity for women in relation to employment. Annual reporting 'maintains the momentum' for that consultation to take place in the workplace.
- Businesses already have the option of having their reporting deadline waived on the basis of 'good compliance' under the Act.
- The Equal Opportunity for Women in the Workplace Agency provides 'excellent' website and telephone advice, reporting forms, workshops, site visits and an annual publications with best practice examples.

After employers establish a template in the first year of reporting, it should be a simple matter to update figures and report new initiatives. It is difficult to see how the reporting of measures relating to equal opportunity for women in the workplace would be a separate "burden" on business, rather than part of the general human resource policy framework and overall strategic planning of the organisation. (sub. DR74, p. 7)

- The goal of reducing regulatory burdens on businesses needs to be considered against the backdrop of such complementary Australian Government legislation as the *Sex Discrimination Act 1984* and relevant international obligations such as the UN Declaration on the Elimination of All Forms of Discrimination against Women.

The Commission will re-assess the burden created by reporting requirements under the Equal Opportunity for Women in the Workplace Act in 2011, when it reviews economy-wide generic legislation. This will enable the Commission to examine whether the proposed changes to the Act have come into effect and what impact those changes have had.

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## 8.4 Customs and excise administration

In Australia, excise duty is payable on locally manufactured petroleum, tobacco and alcohol products (excluding wine, which is subject to the Wine Equalisation Tax). The collection of duties on domestic production is administered by the Australian Taxation Office (ATO).

Where excise equivalent goods are not manufactured in Australia, but instead imported, they are subject to customs duty at the same rate as the excise,<sup>1</sup> to ensure that all relevant goods pay the same amount of tax, regardless of their place of manufacture. Customs duty is administered by the Australian Customs Service (Customs). As such, where their product range includes both imported and locally manufactured products, sellers of excise equivalent products may have to deal with both the ATO and Customs. The processes relating to excise equivalent goods under Customs' control, and their interaction with the ATO are discussed in box 8.1.

Both customs and excise duties are paid on a *volumetric* basis, that is, the amount payable is calculated based on the quantity (rather than price) of the good in question – for example, per litre of petrol, per kilogram of tobacco or per litre of pure alcohol. As such, it is important that the volume of dutiable goods that is the basis for each manufacturer or wholesaler's tax liability is monitored. In order to maintain revenue security, both the ATO and Customs issue licences for secure premises, and require reporting and payment of duties on a weekly basis.<sup>2</sup>

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<sup>1</sup> Some excise equivalent goods are also subject to an ad valorem customs duty, in addition to the excise equivalent amount. As such, some excise equivalent goods may be liable for different total amounts of tax than others.

<sup>2</sup> Reporting and payment are required for every movement of excise equivalent goods away from licensed premises, however, for practical purposes companies operate on 'periodic settlement provisions', which allow them to submit aggregated payments on a weekly basis.

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### Box 8.1 Customs processes for excise equivalent goods

Customs described the processes relating to imported excise equivalent goods as:

Customs [maintains] control over imported goods for excise manufacture until they are used for that purpose. It is at the time of first use in a process of excise manufacture that the goods become subject to the excise legislation and control transfers to the ATO.

There are several circumstances under which Customs deals with the different forms of excise-equivalent goods (EEG):

- *imported in the form in which they will be sold at retail level* — Customs control continues until any border risks are assessed, relevant Customs duty and GST is paid and the goods are delivered into home consumption in accordance with an authority to deal given under the Customs Act 1901; or
- *imported in bulk and warehoused<sup>3</sup> prior to being mixed, blended and/or repackaged and entered for home consumption or export* — Customs control continues from the point of importation until relevant Customs duty and GST is paid and the goods are delivered into home consumption in accordance with an authority to deal given under the Customs Act 1901, or they are exported; or
- *imported for use in domestic excise manufacture* — Customs control continues until the goods are transferred to the excise regime (ie when they are used in the manufacture of excisable goods). The owner of the imported goods 'enters' them under Customs duty concession arrangements at the time they leave Customs control for use in excise manufacture.

Importers of EEG:

- *must declare the importation of imported product to Customs; and*
- *report and acquit the transfer of product to the excise system.*

There is a requirement to maintain records and acquit duty liability for each product (imported or locally produced) separately.

Customs compliance activity relates to imported goods until they leave Customs control and does not relate to excise manufacture or the payment of excise duties. Similarly, the ATO's compliance activities do not apply to imported EEG until they become subject to the excise regime (ie are used in the manufacture of excisable goods).

*Source:* Australian Customs Service (sub. DR69, p. 2).

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<sup>3</sup> Imported goods *other than* EEG are also warehoused under the Customs warehouse licensing system in order for the owners to defer payment of customs duty until the time goods are delivered into home consumption.

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## Dual administration

The affected industries regard dual administration of customs and excise duty as an administrative burden. For example, the Distilled Spirits Industry Council of Australia (DSICA) has commented that:

DSICA members are currently covered by the weekly settlement provisions of the customs and excise law, which require weekly accounting and payment for actual sales made each week of all excisable and excise equivalent imported goods.

... Government requirements imposed on this industry sector result in unnecessary duplication of systems and communications with both Customs and the ATO for clearance of goods. ... This complexity can only be compounded by having two agencies from which to seek that certainty. (2008, pp. 73–4)

Participants in this study also commented on the regulatory burden that arises under the current system. Metcash submitted that the dual administration ‘... has led to inconsistencies in the treatment of dutiable liquor products and duplicated audit requirements’ (sub. 5, p. 1).

### *Assessment*

As noted above, the affected industries believe that the involvement of two agencies in the collection of duties causes duplication, and as such they have called for the consolidation of administrative responsibility within a single agency. For example, DSICA stated that:

... spirits companies would prefer to deal with a single agency for all revenue acquittal and administrative issues.

The creation of a single entry point for licensing, permissions, reporting, payment and other compliance matters will provide greater efficiency and eliminate the duplication the [excise equivalent goods] industry currently encounters for compliance. (2008, p. 73)

There was disagreement as to which agency should take sole responsibility, as Metcash (sub. 5, p. 1) suggested that Customs should be responsible, while both DSICA (2008) and British American Tobacco Australia (BATA) (sub. 7, p. 2) believed that the ATO was the appropriate agency. However, they both noted that while the ATO should have responsibility for the collection and administration of revenue, Customs should retain responsibility for border management — that is, risk assessment and inspections of cargo in order to identify and intercept any illegal activity — of imported excise equivalent goods. As BATA noted:

... there is another important facet to control of tobacco products in Australia, being the securing of our border from illicit and counterfeit imports which rob BATA of volume and profit and the Australian Government of revenue. This is the area in which our

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Customs Service excels and we firmly believe that this should be their appropriate area of focus. (sub. 7, p. 2)

The Commission acknowledges the efforts of both Customs and the ATO in working to minimise the compliance burdens on business:

Customs is working with the [ATO] to identify potential options for harmonising reporting and licensing aspects of the EEG and Excise systems, where practicable, while ensuring that Customs is able to maintain control over, and risk assessment of, all imported goods before they are cleared for release into home consumption or into a process of excise manufacture. (Australian Customs Service, sub. DR69, p. 1)

Nonetheless, the Commission considers that consolidation of the responsibility for the collection and administration of revenue within a single agency would further reduce regulatory burdens on the affected industries. Given that the core activity of the ATO is the administration and collection of tax, and that excise is by far the larger source of revenue, accounting for 91 per cent of non-GST revenue on excise equivalent goods in 2006-07 (Australian Government 2008a), the ATO could also be responsible for collecting customs duty on EEGs. For business, such a move would reduce duplication in account keeping, reporting and communication with government. It would also lead to savings to the Australian Government, as the processing for one company's receipts would now be handled by one agency, rather than two. Industry bodies have estimated that this change would save the Australian Government \$3.1 million (DSICA 2008, p. 73).

As such, the Commission proposes that, subject to appropriate consideration and assessment of the costs and benefits of such a move by Government, the authority for administering customs duty in relation to EEGs should be delegated to the ATO. This should include the collection of revenue, the responsibility for amendments, rulings, licences, permissions and fees relating to the administration of EEGs. Such a change would ensure that the administration resides in one agency — reducing compliance costs from businesses having to deal with two sets of rules, without compromising revenue security. Given the commercial scale of most imports of excise equivalent goods, current collection mechanisms (such as the use of licensed warehouses) could be administered by the ATO. However, if issues arise following the general transfer of authority for administration of customs duty for excise equivalent goods, the precise role of both ATO and Customs could be refined by amendments to the existing inter-agency agreement between the agencies.

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

### **Weekly reporting**

Participants considered that the regulatory burden of dual administration is exacerbated by weekly reporting requirements. BATA noted that, in addition to dealing with two sets of regulation, it is compelled to make payments to two separate bodies on a weekly basis (sub. 7, p. 1).

### *Assessment*

In light of the concerns stated above regarding the burden arising from weekly reporting of customs and excise duty, the Commission notes that provision was made in the 2007-08 federal budget for small businesses to be allowed to submit customs and excise duty on a monthly basis (Australian Government 2007b). The current Government has announced it intends to enact this change, but the legislation is not expected to be introduced to Parliament before 2009 (Swan and Bowen 2008).

The Commission acknowledges that a move from weekly to monthly reporting would entail lost revenue to the Government, in the form of foregone interest on the later receipt of payments. In the case of customs and excise duty — which are indexed every six months — a move to monthly payments also expands the ability of companies to shift products (and thus excise liability) to the month before excise rates are indexed, possibly reducing overall revenue. As Customs noted:

... any increase to the period for settlement of duties for all parties who deal in excisable goods and EEG could introduce a significant new risk to Commonwealth debt management that would require an appropriate compliance response. (sub. DR69, p. 3)

However, a similar situation arises with the payment of the Goods and Services Tax (GST),<sup>4</sup> which is levied on a monthly basis for large businesses, with small

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<sup>4</sup> In 2006-07, the GST constituted 15 per cent of taxation revenue, compared to 9 per cent in the case of customs and excise (Australian Government 2008a).

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businesses able to report on their Business Activity Statements (BAS) on a quarterly basis. Although immediate payment of GST receipts would net the government additional revenue, such reporting arrangements were introduced with an aim to curb excessive compliance costs.

The Commission considers that if the proposed changes to reporting time frames for small businesses were extended to all businesses, the reduced compliance burden — as well as administrative costs for government — should outweigh revenue considerations, particularly if revenue administration is consolidated within the ATO. As with other areas of taxation, compliance with monthly reporting requirements could be sufficiently monitored through audit processes.

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.***

The Commission notes existing calls for further consolidation of customs and excise payments, namely as part of the BAS:

DSICA sees opportunities for these benefits [tax collection via the BAS] to flow to the collection of customs and excise duties, either under the BAS or under a separate arrangement. In particular ... there is an opportunity to reduce business compliance costs if duty payments were able to be made on an estimated basis, with periodic reconciliation and acquittal. (DSICA 2008, p. 74)

While the Commission agrees that further consolidation may be of benefit beyond the responses above — especially if collection of duties using the BAS assists the implementation of a deferral scheme as noted above — the existing complexities and compliance issues with the BAS and GST in general are not insignificant. As such, after monthly payments have been in operation for some time, there should be an examination of the costs and benefits of including excise payments on the BAS, alongside GST payments.

## **8.5 Goods and Services Tax**

The GST is a value added tax levied at 10 per cent of the price of most goods and services within Australia. Businesses collect GST on sales, and pay it to the ATO through their BAS which is submitted on a quarterly basis for small businesses (with a turnover less than \$20 million), or a monthly basis for larger businesses.



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## Compliance costs, complexities and other concerns

Participants in this review noted the general compliance costs arising from the collection, payment and administration of GST. For example, Qrtsa — The Retailers Association listed among its regulatory concerns ‘[t]he high cost to business of managing the GST legislation’ (sub. 1, p. 11). Further to this, the MTAA noted the effect of the GST on small businesses:

With the introduction of the GST, small businesses have effectively become taxation collection agents for the Australian Government. This has caused a further burden on small business people as they must take time away from their businesses to complete the required forms and procedures to transfer the GST collected to the Australian Taxation Office. While this has now been accepted by Government as the preferred method of collection of taxation, small business people would prefer it if there was more assistance from Government agencies in the completion of their collection and reporting requirements. One method of doing this would be simplifying the forms and reducing the amount of ‘red tape’ that surrounds taxation reporting requirements. (sub. 6, p. 7)

In addition to the general compliance burden, Woolworths raised concerns about the complexities with the GST system:

The complexities of GST legislation have led to inconsistent interpretation (and hence application) of those laws by the ATO, creating uncertainty and additional costs of compliance. The GST legislation is extremely complex and because it was designed for a paper based transaction environment, it imposes additional costs of compliance on business. In addition, the legislation creates conflict as businesses move to an electronic transaction environment. (sub. 25, p. 6)

Others participants pointed to specific issues arising from exemptions within the GST system. For example, the Pharmacy Guild of Australia believed that the current model of administration for GST-free products led to:

... unnecessary regulatory burden for pharmacy. ... this has been exacerbated by the model which has been applied to collect GST on scheduled products sold in pharmacy which are all GST-free to the public and which comprise approximately 85% of all products distributed through pharmacies. The problem for pharmacy is that these products only become GST-free at the point of retail sale rather than being tax-free all the way through the supply chain.

This means that the pharmacy has to pay the GST on these goods and then claim the tax back as an input credit, which in many cases is a quite substantial sum, from the Tax Office.

Therefore, unlike other small businesses, pharmacies are always in a negative cash-flow situation and this in turn creates a need to lodge monthly Business Activity Statements in order to retrieve the money paid out as soon as possible. (sub. 15, p. 9)

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## Assessment

It is clear that the burden from GST compliance is an important issue to the sectors under review, especially for small business. However, there has been significant reform and review activity covering GST compliance issues. The ATO itself regularly reviews the compliance requirements under the GST, as part of overall tax compliance, with the objective of making interactions with the ATO ‘easier, cheaper and more personalised’ (ATO 2008, p. 1). Some participants acknowledged such positive steps by the ATO. For example, the National Independent Retailers Association noted that:

... the Australian Taxation Office is taking practical steps to improve their interaction with, and understanding of, small business. ... [The ATO] offers excellent support to small business. ... [It] has started work, in partnership with COSBOA, on developing better ways of communicating and engaging small business ... (sub. 37, p. 6).

Additionally, the Board of Taxation is currently conducting a review of the legal framework for the administration of the GST, with a focus on:

- streamlining and improving the operation of the GST;
- reducing compliance costs; and
- removing anomalies. (Bowen 2008, p. 1)

The Board is also undertaking a scoping study of tax compliance costs facing the small business sector (Board of Taxation 2008). These reviews will provide an opportunity to address GST compliance issues in an economy-wide context. Accordingly, these matters will not be considered as part of this review.

## 8.6 Transport regulation

### Inconsistencies between jurisdictions

Concerns regarding a lack of consistent transport rules across jurisdictions were raised in last year’s primary sector review (PC2007a). Similar concerns were raised again by participants this year.

The Red Meat Industry reiterated views expressed in a submission to last year’s review raising the following three issues:

- Achieving functioning national uniformity in road transport rules including weights.
- Driving time limits and other duties of care, and
- Chain of responsibility laws. (sub. 24, p. 18)

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Similarly, Woolworths listed goods transportation and load limit regulations as examples of where inconsistent legislation operates across jurisdictions. Woolworths commented that:

Inconsistencies in regulations between the jurisdictions result in additional compliance burdens and costs for national operators such as Woolworths. These costs are consequently passed on to consumers in the form of higher prices. (sub. 25, p. 3)

### *Assessment*

In last year's review, the Commission reported that unjustified differences in road transport regulations between jurisdictions are being addressed by the National Transport Commission's (NTC's) ongoing development of Performance Based Standards (PBS).

In regard to the costs imposed on businesses by chain of responsibility and fatigue management rules, the Commission reported that these appear to be unavoidable if health and safety objectives are to be served.

The NTC submitted the following regarding the development of PBS:

Performance Based Standards have been developed as a national alternative to the current system of heavy vehicle regulation. Rather than a 'one size fits all' approach, PBS will allow industry additional scope to innovate, resulting in fewer vehicles, safer performance and the least possible effects on roads and bridges. Performance Based Standards provides an improved regulatory system that encourages innovation and provides a better match between vehicles and roads, also setting minimum safety standards for heavy vehicle performance such as rollover risk, braking and the ability to turn in traffic within a defined safe 'envelope'. (sub. 21, p. 1)

Further, the NTC (sub. 21) advised that PBS is currently operating as an administrative arrangement and draft model legislation is expected late in 2008. However, jurisdictions have been slow to map the PBS network.

PBS includes the mapping of a four-level national road network that will determine the access rights of various vehicles, subject to any local operating constraints. The characteristics of vehicles will determine whether they will have a high or low level of network access. The NTC reported:

To date benefits of the PBS network have not been fully realised due to the slow take-up rate among jurisdictions, with most failing to publish PBS networks by the COAG deadline at the end of 2007. As Commonwealth funding levers are not tied to regulatory reform, the lack of anything more than persuasive power and industry pressure limits the effectiveness of the NTC in ensuring this occurs. The role of local government is seen as critical in developing PBS given the national implications for the Scheme and the subsequent positive effects of doing business. (sub. 21, p. 4)

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Issues in transport regulation will be examined in more detail as part of the third year in this process, covering social and economic infrastructure services.

## 8.7 Australian Design Rules

Australian Design Rules (ADRs) are a set of national standards with the objective of:

... to achieve uniform national vehicle standards that apply to new vehicles when they begin to be used in transport in Australia. The ADRs cover vehicle safety, emissions and anti-theft. (DOTARS 2007, p. 7)

They are administered by the Australian Government Department of Infrastructure, Transport, Regional Development and Local Government (the Department) under the *Motor Vehicle Standards Act 1989*. Both locally manufactured and imported vehicles must comply with the ADRs when they are supplied to the Australian market. Beyond the point of supply, state and territory governments regulate the use of the vehicles through, for example, vehicle registration requirements.

### Undue compliance costs

Concerns have been raised with the Commission about the compliance with ADRs in relation to the manufacture of buses in Australia. For buses, there is a two stage manufacturing process. The chassis of the bus is manufactured first, typically by an overseas firm. The chassis is then imported into Australia and the body of the bus is constructed on top of it by a separate — usually Australian — manufacturer (the ‘body builder’). As such, the exact construction, and detailed information about the chassis, may be outside of the control of the body builder. Given these circumstances, Express Coach Builders were concerned that:

... the body builder (being the ADR Compliance Plate holder for the completed vehicle) is responsible for the ADR Compliance of the entire vehicle. This includes the Bus Chassis (which DoTARS deemed is now a Sub-Assembly of the complete vehicle). This responsibility now requires the body builder to continually monitor and review chassis ADR approval status ... and to sort-out all chassis compliance concerns with the chassis manufacturer.

The body builder (typically) has no commercial interest, selection or control over the chassis manufacturer’s product. Yet body builders have experienced situations whereby body builders have expressed concerns on chassis non-compliance issues to the chassis manufacturers, only to be disregarded. (sub. 36, p. 1)

Express Coach Builders also submitted that the degree of this compliance burden (and legal responsibility) for the entire vehicle is compounded when an ADR

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applicable to the chassis of the vehicle changes after the imported chassis arrives in Australia, but before the completed vehicle is supplied to the Australian market:

When chassis ADR updates now occur, the chassis must either be upgraded or otherwise disposed of as it is no longer suitable for new vehicle construction.

The bus industry (and including bus operators) must now be certain that the bus chassis will in fact meet all current chassis ADR's at the time of completion of body build (when the vehicle is plated with its Date of Manufacture). The bus body builder has this prime responsibility. (sub. 36, p. 1)

This situation can lead to significant time and labour costs in acquiring and reporting the relevant information, especially in the case where the local body builder must themselves acquire information from the overseas chassis supplier. In addition to such costs, the potential to have to dispose of already imported chassis can hinder the industry's 'longer term scheduling and planning of upcoming work' (sub. 36, p. 1).

### *Assessment*

In order to obtain compliance plate approval to certify that their vehicles meet the relevant ADRs, manufacturers must nominate themselves as 'licensees' on the Department's online 'Road Vehicle Certification System' (RVCS). In doing so, they assume final responsibility for ensuring that all the relevant ADRs for their vehicle are met at the 'date of manufacture' of the finished vehicle (when it is ready for supply to the Australian market).

Licensees do not necessarily bear the entire compliance burden. In submitting evidence of compliance for ADRs that are specific to the chassis only, they may rely on information in the Bus Chassis Sub-Assembly Registration Number (BC-SARN). The BC-SARN is a plate affixed to the chassis by the supplier that ensures that the body builder is aware of which ADRs the chassis has complied with at the time it is delivered to them. The body builder is then responsible for compliance with the remaining ADRs for the completed vehicle.

In most cases, the BC-SARN will be all the evidence the Department requires for chassis-specific ADRs. However, there are some circumstances that would require the body builder to submit further information beyond the BC-SARN. First, if in completing the vehicle the body builder makes substantial changes to the chassis such that its specification or design has changed, then the BC-SARN is no longer accurate in regard to the changes and is essentially voided for the affected ADRs. In this situation, the body builder must establish compliance with the affected ADRs at the date of manufacture themselves (DOTARS 2006). Given that the body builder is

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responsible for making these changes, it is appropriate that they are also responsible for ensuring compliance with the associated ADRs.

Another situation where further information may be required regarding the chassis is in relation to ‘whole of vehicle standards’ (as opposed to those standards that apply to solely the chassis or solely the body build). Standards relating to vehicle noise are an example of whole of vehicle standards because, although the engine is part of the chassis, how the body is built over that chassis — including for example the positioning of vehicle exhausts — affects noise levels for the completed vehicle. As the objective of the ADRs is to test vehicles at the final point of manufacture, it is appropriate that completed vehicles are tested at this point, rather than relying on information relating to each component at a stage before they are combined.

The Commission acknowledges that the responsibility for compliance with such standards imposes a burden on body builders. However, it appears that such an arrangement is necessary in order to effectively enforce the ADRs. Without such a clear assignment of legal responsibility, areas of overlap between producers could create confusion or gaps in responsibility.

A final situation where information on the chassis beyond that in the BC-SARN may be required is if there has been a change in the relevant ADRs in between the time the chassis was imported and when the vehicle has reached the point of final manufacture — that is, where the BC-SARN assesses the chassis against subsequently outdated ADRs. While change in regulations is unavoidable, the resulting transition costs can be ameliorated by effective communication from governments — providing notification of changes to industry and allowing adequate time between the notification and the actual application of the new regulations. The current time between notification and application of ADRs is 18 months for new bus models, and 24 months for existing models (DOTARS 2007, p. 16).

The Commission notes that the Department has made significant efforts to communicate past changes to ADRs to industry through, among other things:

- consultation with industry as part of the Regulatory Impact Statement process.
- ongoing consultation with peak industry bodies and an industry working group
- publication on the Federal Register of Legislative Instruments
- notification through the ‘What’s New’ link on the RVCS website.<sup>5</sup>

Given that the Department already has access to licensees’ details through the database, one option for communication of regulatory changes would be through emails providing notification of a new standard, a link to the standard, and the date

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<sup>5</sup> <http://rvcs.dotars.gov.au>

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of application. While this would incur little additional cost to the Department, it would further ensure that the industry is aware of any changes to standards, allowing them to better plan their inventory and production, minimising any burdens from changes to regulation.

## **8.8 Regulation of building products**

A concern was raised regarding compliance with building products regulation, as implemented through the Building Code of Australia (BCA). The BCA sets out technical requirements for the design and construction of buildings and other structures; it aims to achieve nationally consistent minimum standards for health, safety, amenity and sustainability in buildings. Generally, the BCA only specifies minimum performance requirements, however, where there are health, safety and environmental implications more stringent requirements may be set.

As the regulation of building and construction is the responsibility of state and territory governments, the BCA itself is not legally binding until state and territory governments enact legislation bringing it into force. Currently all states and territories refer to all or most of the BCA.

The Australian Building Codes Board (ABCB) produces and maintains the BCA under an inter-governmental agreement. The ABCB consists of representatives from the Australian Government, state and territory governments, local government and industry.

### **Lack of compliance with building regulations – structural plywood**

While no major concern was raised about the practical requirements of building regulations, the Building Products Innovation Council raised a concern about their enforcement, in particular with respect to the use of structural plywood. Without adequate enforcement of regulation, compliance levels can fall and this can reduce the effectiveness of the regulation. This can potentially impose unnecessary cost on those who comply by reducing their competitiveness in the marketplace relative to those that do not comply.

Regulations on structural plywood used in buildings include references to a number of Australian Standards. These standards require structural plywood to have attained certain grades for the strength of the wood's structure and its bonding, amongst other requirements. The plywood must be branded in a prescribed format to reflect strength grades, the Australian Standards which have been met, and the manufacturer's name or registered mark. Without meeting minimum grades and

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displaying these markings the plywood cannot be used in the structure of a building, but it can be used for other purposes.

While the BCA does not prescribe enforcement programs, it does state the types of evidence of compliance that are acceptable. Methods for testing compliance of structural plywood are established in Australian Standards, which are referenced in the BCA.

The use of building materials and their compliance with standards is regulated in a number of ways. Firstly, if the product does not meet the grades specified in the branding on it, the supplier, importer or manufacturer may be in breach of the misleading and deceptive conduct provisions of the *Trade Practices Act 1974*. This is administered and enforced by the Australian Competition and Consumer Commission (ACCC).

Second, state and territory governments typically delegate part of their building regulation responsibility to local governments, particularly approvals and inspection of construction.

Additional assurance can be provided to buyers of structural plywood that it meets the required Australian Standards through certification under the Joint Accreditation System of Australia and New Zealand (JAS-ANZ) (box 8.2).

**Box 8.2 JAS-ANZ certification and accreditation**

It is important to note that the terms certification and accreditation refer to different and specific functions and associated organisations.

- Certification is verification provided by an independent third party regarding processes, products, systems or persons. Certification can be provided to assure customers that a product meets all the requirements of a given Australian or international standard, often where the properties are not directly observable by the consumer.
- Accreditation is an endorsement of a third party conformity assessment body's competence, credibility, independence and integrity in awarding certification.

JAS-ANZ is the government appointed accreditation body for Australia and New Zealand. It is the organisation which provides accreditation to the conformity assessment bodies which can then certify producers of building materials.

*Source:* JAS-ANZ (2007).

Producers of certified structural plywood are entitled to display the JAS-ANZ symbol in association with the conformance assessment body's mark and a statement that certain Australian standards have been met. This additional layer of



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assurance is valuable as the structural and bonding strength of plywood are not easily observed.

JAS-ANZ monitors the use of its symbol by accredited conformance assessment bodies. Accredited conformance assessment bodies — those who are accredited to certify producers and products — are assessed every six months when they first become accredited and this can be relaxed to up to two years for organisations with a good record. Furthermore, JAS-ANZ staff members observe accredited conformance assessment bodies as they certify manufacturers, importers and suppliers two to five times each year.

The JAS-ANZ symbol is a registered trademark and therefore may not be replicated by parties who are not accredited and registered with JAS-ANZ. Misuse of the symbol is a breach of intellectual property laws. However, JAS-ANZ does not routinely monitor non-registered organisations due to the large resource requirements. JAS-ANZ relies on their accredited conformance assessment bodies to highlight any misuse of the JAS-ANZ symbol.

The complaint brought to the attention of the Commission involved the use of non-branded plywood in structural formwork and potential for misleading claims to go unnoticed. The Engineered Wood Products Association of Australasia made the following comments through the submission by the Building Products Innovation Council:

JAS-ANZ has done a tremendous job as there is no doubt that Australian manufactured materials are amongst the most reliable however, there has been no mandatory requirement that products carry independent accredited product certification ... this is very unlike our major trading partners.

This has created a situation where due to the lack of mandatory certification, low cost inferior products with misleading claims of compliance appear to have equal access to the Australian market as Australian products which carry the additional costs of maintaining credible certification. (sub. 38, p. 2)

It has been suggested by one participant that JAS-ANZ approved certification (or approved overseas equivalent) be compulsory for all building products where non-conformities can have serious consequences. However, as noted by the Building Products Innovation Council, this would be excessive for many building products:

While BPIC recognises the particular issue for structural plywood, it does not believe that compulsory Certification is an appropriate response for all building products. The is one of context and each case should be considered on its own merits. (sub. DR59 p. 1)

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## Assessment

The regulatory framework for ensuring compliance with BCA requirements for the use of structural plywood exists and can be enforced at up to three points in the life of the product:

1. **Manufacturer** — through truth in branding and ACCC enforcement
2. **Marketing** — correct use of JAS-ANZ intellectual property (voluntary product certification)
3. **Installation** — through use of compliant product and local government inspections.

If it is established more broadly in the industry that compliance with structural plywood regulation is a problem (that is, that this is not an isolated case) then stronger action needs to take place. This could be in the form of increased penalties for inaccurate product claims, increased inspection rates to increase the chances of detection, or more rigorous inspections at the installation stage to ensure that the products used in structural formwork conform to mandated standards.

The suggestion by the Building Products Innovation Council to mandate JAS-ANZ certification for structural plywood where it is currently voluntary effectively reduces the number of options for evidence of suitability, from the five currently specified in the BCA to one. Onus would remain on the builder or end user to ensure that product claims are legitimate and that only certified products are used in the structure of the building. Claims would become easier to verify as a central register of JAS-ANZ accredited bodies, processes and personnel exists, however this is a more rigid and restrictive option and could increase business costs.

Initially, it needs to be determined whether or not compliance needs to be improved. If so, then the ABCB can consider options for inducing higher levels of compliance which should include consideration of the three points where enforcement can occur; manufacturing, marketing and installation.

RESPONSE 8.3

***The Australian Building Codes Board 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.***

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# APPENDICES



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# A Consultation

## A.1 Introduction

Following receipt of the terms of reference, the Commission placed advertisements in national and metropolitan newspapers inviting public participation in the study. An initial circular was distributed in January 2008 and an issues paper was released in February 2008.

The Commission has held informal consultations with governments, peak industry groups in the manufacturing and distributive trade sectors, as well as with a number of companies and individuals. Roundtables were held in Canberra after release of the draft report in July 2008. A list of meetings and discussions undertaken is provided below.

The Commission received 77 submissions. A list of these is provided below. All public submissions are available on the Commission's website.

The Commission would like to thank all those who contributed to the study.

## A.2 Submissions

Table A.1 **Submissions received**

<i>Participant</i>	<i>Date received 2008</i>	<i>Submission no.</i>
ACCORD Australasia	10 April	27
Air Con Serve Pty Ltd	19 March	19
Animal Health Alliance (Australia)	19 March 17 July	4 DR43
Australian Association of Leather Industries	17 June	41
Australian Beverages Council	23 April 1 August	33 DR67
Australian Competition and Consumer Commission	31 July	DR55
Australian Customs Service	5 August	DR69
Australian Dairy Industry (joint submission)	4 April 31 July	26 DR50

(Continued next page)

**Table A.1 (continued)**

<i>Participant</i>	<i>Date received 2008</i>	<i>Submission no.</i>
Australian Food and Grocery Council	20 March 31 July	10 DR58
Australian Industry Group	26 June 30 July	DR42 DR48
Australian Newsagents' Federation	25 March	8
Australian Quarantine and Inspection Service	15 August	DR73
British American Tobacco Australia	20 March	7
Building Products Innovation Council	22 May 31 July	38 DR59
Caterpillar	17 April	30
Dr Sara Charlesworth, Vic	21 August	DR75
Choice	31 July	DR61
Coeliac Society of Australia	28 July	DR46
Coles Group Ltd	25 March 28 July	17 DR47
Complementary Healthcare Council of Australia	5 August	DR68
Confectionery Manufacturers of Australasia	22 April 1 August	32 DR65
Council of Small Business Organisations of Australia	28 May	39
CropLife Australia Ltd	28 March	18
David Gray & Co Pty Ltd	18 March	20
Department of Agriculture, Fisheries & Forestry	8 August	DR72
Department of Finance and Deregulation — Office of Best Practice Regulation	21 July	DR44
Department of Health and Ageing	8 August	DR71
Department of the Environment, Water, Heritage and the Arts	31 July	DR56
Endeavour Chemicals & Plastics Pty Ltd	3 March	3
Ewe Beaut Products Pty Ltd	24 March	9
Express Coach Builders Pty Ltd	28 April	36
Fisher & Paykel Australia Pty Ltd	25 July	DR45
Flour Millers Council of Australia	20 March 31 July	12 DR54
Fonterra Australia Pty Ltd	31 July	DR57
Prof Beth Gaze, Vic	21 August	DR76
Johnson & Johnson Family of Companies	5 August	DR70
Medical Technology Association of Australia	26 March 31 July	23 DR60

(Continued next page)

**Table A.1 (continued)**

Participant	<i>Date received 2008</i>	<i>Submission no.</i>
Medicines Australia	29 April	35
	1 August	DR64
Medtronic Australasia Pty Ltd	31 July	DR62
Metcash Ltd	20 March	5
Motor Trades Association of Australia	20 March	6
National Health and Medical Research Council	1 August	DR63
National Independent Retailers Association	20 May	37
National Packaging Covenant	30 July	DR49
National Transport Commission	26 March	21
NSW Business Chamber	28 March	22
Obesity Policy Coalition	31 July	DR66
Ms Carol O'Donnell, NSW	29 February	2
Pfizer Australia Pty Ltd	22 April	31
	31 July	DR53
Pharmacy Guild of Australia	20 March	15
Plastics and Chemicals Industries Association	18 March	11
Qrtsa — The Retailers Association	27 February	1
Queensland Resources Council	24 April	34
Red Meat Industry (joint submission)	31 March	24
Rheem Australia Pty Ltd	27 March	14
	6 June	40
	31 July	DR52
Robert Bosch Australia Pty Ltd	11 April	28
Science Industry Australia	20 March	13
Standards Australia Ltd	26 March	16
	11 April	29
Prof Margaret Thornton, ACT	26 August	DR77
Ms Judith S Willis, Vic	18 August	DR74
Woolworths Ltd	4 April	25
	30 July	DR51

### **A.3 Consultations with organisations and individuals**

Akubra Hats Pty Ltd

Australian Electrical and Electronic Manufacturers Association (now Australian Industry Group)

Australasian Compliance Institute

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Australian Beverages Council  
Australian Chamber of Commerce and Industry  
Australian Government  
    Department of Agriculture, Fisheries and Forestry  
    Department of Environment, Water, Heritage and the Arts  
    Department of Health and Ageing  
    Department of Health and Ageing — Therapeutic Goods Administration  
    Department of Innovation, Industry, Science and Research  
Australian Industry Group  
Australian Retailers Association  
Boral Ltd  
Building Products Innovation Council  
Business Council of Australia  
Business SA  
Chamber of Commerce and Industry Western Australia  
Coca-Cola Amatil Ltd  
Coles Group Ltd  
Commerce Queensland  
Ewe Beaut Products Pty Ltd  
Express Coach Builders Pty Ltd  
Federal Chamber of Automotive Industries  
Federation of Automotive Parts Manufacturers  
Fisher & Paykel Australia Pty Ltd  
Food Standards Australia New Zealand  
Medical Technology Association of Australia  
Medicines Australia  
Mrs Mac's Pty Ltd  
National Independent Retailers Association  
New South Wales Business Chamber  
New South Wales Business Chamber — Mid North Coast  
New South Wales Government  
    Department of Premier and Cabinet  
    Department of State and Regional Development



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New South Wales Food Authority  
New South Wales Treasury  
New South Wales Manufacturing Council  
Nutricia Australia Pty Ltd  
Queensland Government  
    Department of Premier and Cabinet  
    Department of Tourism, Regional Development and Industry  
    Treasury Office — Queensland Office of Regulatory Efficiency  
Qrtsa — The Retailers Association  
Remote Control Technologies Pty Ltd  
Retail Confectionary and Mixed Business Association  
Rheem Australia Pty Ltd  
Robert Bosch Australia Pty Ltd  
Science Industry Australia  
Smiths Alternative Bookshop  
South Australian Government  
    Department of Health  
    Department of Premier and Cabinet  
    Department of Treasury and Finance  
Standards Australia Ltd  
Thermal Electric Elements Pty Ltd  
Victorian Competition and Efficiency Commission  
Victorian Government  
    Department of Innovation, Industry and Regional Development  
    Department of Premier and Cabinet  
    Department of Treasury and Finance  
Western Australian Government  
    Department of Premier and Cabinet  
    Department of Treasury and Finance  
    Small Business Development Corporation  
Woolworths Ltd

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## List of roundtable attendees

### *Food regulation*

Australian Food and Grocery Council  
Australian Beverages Council  
Confectionery Manufacturers of Australasia  
Dairy Australia (also representing Australian Dairy Products Federation and Australian Dairy Farmers)  
Department of Agriculture, Fisheries and Forestry  
Department of Finance and Deregulation  
Department of Health and Ageing  
Fonterra Australia Pty Ltd  
Woolworths Ltd

### *Medicines*

Amgen Australia Pty Ltd  
Department of Health and Ageing  
Medicines Australia  
Pfizer Australia Pty Ltd  
The Pharmacy Guild of Australia  
Roche Products Pty Ltd

### *Medical devices*

Cochlear Ltd  
Cook Medical  
Department of Health and Ageing  
Device Technologies Australia Pty Ltd  
Johnson & Johnson Medical Pty Ltd  
Medical Technology Association of Australia

### *Environmental regulation*

Australian Industry Group  
Australian Competition and Consumer Commission

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Department of Environment, Water, Heritage and the Arts  
Department of Finance and Deregulation — Office of Best Practice Regulation  
Fisher & Paykel Australia Pty Ltd  
Plastics and Chemicals Industries Association  
Rheem Australia Ltd  
Standards Australia Ltd



# B Reviews of regulation

Table B.1 A selection of reviews of regulation in manufacturing and the distributive trades sectors<sup>a</sup>

Sector/Industry	COAG commitments	Productivity Commission work	Australian Government reviews	State government reviews
<b>Manufacturing</b> Food, beverages and tobacco	The BRCWG of COAG is developing reforms for reducing the regulatory burden on businesses and non-profit organisations with respect to food regulation, including consistency in legislation, governance arrangements, uniformity in enforcement, and setting or modifying food standards. Alignment of wine labelling requirements for domestic and export markets expected to be implemented late 2008.	Performance benchmarking of Australian business regulation (2010).	Beale review of quarantine and biosecurity (current). Bethwaite review of food regulation (incomplete). ACCC review of grocery prices and horticulture code of conduct (2008). Australian National Audit Office audit of export certification by AQIS (2006).	Victoria: VCEC Review of Food Regulation (2007).
Textiles, leather, clothing and footwear		Review of textile, clothing and footwear assistance (2003).	Review of Australia's textile, clothing and footwear industry (current).	
Wood, paper and printing	Ensuring best practice regulation making and review processes for the Building Code of Australia and removal of unnecessary state-based variations to the Code.	Performance benchmarking of Australian business regulation – land development assessment (2010). Commissioned study into building regulation reform (2004).		

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Table B.1 (continued)

Sector/Industry	COAG commitments	Productivity Commission work	Australian Government reviews	State government reviews
Petroleum, coal, minerals and metal	A national mine safety framework is being developed with agreement on the new framework expected March 2009.	Commissioned study of regulation of upstream petroleum (oil and gas) (2009).		NSW: report of the Small Business Regulation Review Taskforce into the Manufacturing Sector (2007).
Chemicals, plastics and rubber	Ministerial taskforce established to develop a national system of chemicals and plastics regulation.	Commissioned study into chemicals and plastics regulation to inform the work of the ministerial taskforce (2008). Commissioned study into the impacts of advances in medical technology (2005).	<p>Review of the APVMA's Veterinary post-registration overseas good manufacturing practice compliance scheme (current).</p> <p>Review of PBS supply arrangements in the context of aged care facilities (current).</p> <p>Doyle review of prosthesis listing (2007).</p> <p>Australian National Audit Office audit of pesticides and veterinary medicines regulation (2006).</p> <p>Development of a Medical devices industry action agenda commissioned by Department of Industry, Tourism and Resources (2005).</p> <p>Australian National Audit Office audit of regulation of non-prescription medicinal products (2004).</p> <p>Review of TGA's Consultative arrangements (2004).</p>	

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Table B.1 (continued)

Sector/Industry	COAG commitments	Productivity Commission work	Australian Government reviews	State government reviews
Transport and machinery	Implementation of national rail safety legislation and a nationally consistent rail safety regulatory framework is underway. Model legislation will be in place in all states, except Tasmania, by the end of 2008. Tasmania will follow in 2009.		Bracks review of the automotive industry (2008). Australian National Audit Office audit of the administration of the Automotive Competitiveness and Investment Scheme (2008). House of Representatives Standing Committee on Environment and Heritage inquiry into the regulation of plumbing product quality (2007). Beale review of quarantine and biosecurity (current). House of Representatives Standing Committee inquiry into coastal shipping (current). ACCC review of grocery prices (2008). ACCC review of petrol prices (2008).	
<b>Distributive trades</b>	Legislation for a nationally consistent trade measurement system administered by the Australian Government will be introduced into parliament by September 2008.		NSW: Better Regulation Office review of shop trading hours (2007).	
<b>Generic issues</b>	COAG signed an IGA to commit to adopt a nationally consistent model OHS laws. Full implementation is proposed to occur by 2011.	Performance benchmarking of Australian business regulation – occupational health and safety (2009).	National review of occupational health and safety laws (current).	

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Table B.1 (continued)

Sector/Industry	COAG commitments	Productivity Commission work	Australian Government reviews	State government reviews
Environmental regulation	<p>Bilateral agreements between each state government and the Australian Government for environmental assessment and approval processes to be complete by 31 August 2008. Further opportunities for streamlining to be presented to COAG in October 2008.</p> <p>A plan for achieving the national mandatory renewable energy target is due by 2009.</p>	<p>Performance benchmarking of Australian business regulation (2010).</p> <p>Submission to the Garnaut Climate Change Review (2008).</p> <p>Inquiry into waste management (2006).</p> <p>Inquiry into improving the private cost effectiveness of energy efficiency (2005).</p> <p>Commissioned study into mutual recognition arrangements (2009).</p>	<p>Garnaut climate change review involves State, Territory and Australian Governments (current).</p> <p>Wilkins review of climate change policies (2008).</p> <p>Senate Inquiry into the management of Australia's waste streams (2008).</p> <p>Review of the National Pollution Inventory (2005).</p>	
Mutual recognition	<p>COAG has agreed to a national system of trade licensing with an inter governmental agreement to be endorsed in December 2008.</p>			
Business regulation and taxation	<p>Harmonisation of payroll tax administration. Implementation began in July 2008.</p> <p>All Australian governments agreed to a national system of registration for Australian Business Numbers and business names, an implementation strategy will be presented to COAG in October 2008.</p> <p>Standardisation of reporting requirements – a multi-agency program of standard business reporting is due for implementation in 2010.</p>	<p>Performance benchmarking of Australian business regulation – payroll tax administration (2009).</p> <p>Performance benchmarking of Australian business regulation (2008).</p>	<p>Henry review of Australia's tax system (current).</p> <p>Board of Taxation (Treasury) review of legal framework for GST administration (current).</p> <p>Board of Taxation study of small business tax compliance costs (2007).</p> <p>Australian National Audit Office audit of the administration of ABN registrations (2003 and follow up audit in 2007).</p> <p>Report of the Taskforce on Reducing Regulatory Burdens on Business (2006).</p> <p>Australian National Audit Office audit of the administration of petroleum and tobacco excise collections (2001 and 2006).</p>	<p>NSW: IPART Investigation into the burden of regulation in NSW and improving regulatory efficiency (2006).</p> <p>NSW: IPART review of state taxation (current).</p>

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Table B.1 (continued)

Sector/Industry	COAG commitments	Productivity Commission work	Australian Government reviews	State government reviews
Other		<p>Commissioned study into public support for science and innovation (2007).</p> <p>Commissioned study into standards setting and laboratory accreditation (2006).</p>	<p>Review of the national innovation system conducted by a panel of experts (current).</p> <p>Reviews of patentable subject matter and post-grant patent enforcement strategies (current).</p> <p>Review of the Comcare scheme (current).</p> <p>Deegan review of 457 visa program integrity (current).</p> <p>External reference group report on efficiency and flexibility of 457 visa program (2008).</p> <p>Australian National Audit Office audit of the Australia Research Council's management of research grants (2006).</p>	

**a** This is not an exhaustive list of reviews undertaken by Australian governments and associated agencies, it contains a selection of current, recent and announced reviews relevant to the manufacturing and distributive trades sectors.



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