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Productivity Commission

Chemicals and Plastics Regulation

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The Productivity Commission

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Foreword

Chemicals and plastics play an essential role in our modern economy, but they can present risks for public health, workplace safety, the environment, and national security. Regulation is an important tool in managing these risks, to help ensure that the net benefits to the community of using chemicals and plastics are maximised. Yet chemicals and plastics regulation has long been criticised for its inconsistencies, particularly across jurisdictions, and the impacts these have on effectiveness and efficiency.

In 2006 the Council of Australian Governments (COAG) identified chemicals and plastics as a 'regulatory hotspot', and a Ministerial Taskforce was established to develop a streamlined and harmonised national system of chemicals and plastics regulation. COAG also agreed that the Productivity Commission would undertake a study to assist the work of the Taskforce. This report is the culmination of the Commission's study.

The Taskforce has already developed a range of 'early harvest' reforms — informed in part by the Commission's draft report — which have been endorsed by COAG. The Taskforce has indicated that it will draw on this final report to further develop its reform proposals.

In undertaking this study, the Commission consulted with a wide range of participants from industry, government and the community. It benefited greatly from the willingness of all parties to propose, debate and in the main agree on a series of reforms that will improve community wellbeing.

The study was overseen by Commissioner Mike Woods and Associate Commissioner Siobhan McKenna, with the involvement of Commissioner Angela MacRae in the early stages. The staff research team was headed by Paul Belin.

Gary Banks AO
Chairman

July 2008

Terms of reference

Productivity Commission Study
into Chemicals and Plastics Regulation

Preamble

The chemicals and plastics industry is a diverse sector comprising base and feedstock products, speciality and refined chemicals, intermediate goods and components as well as finished products. It plays an important role in manufacturing, with 70 per cent of its outputs used as essential inputs to other manufacturing and industrial sectors (e.g. automotive, building and construction, packaging, medical, agriculture and mineral processing).

Background

The Council of Australian Governments (COAG) decided at its meeting on 10 February 2006 that it would:

> … establish a ministerial taskforce, with each jurisdiction nominating one responsible Minister, to develop measures to achieve a streamlined and harmonised system of national chemicals and plastics regulation, and reporting progress to COAG by mid 2006 (*Decision 5.8, Attachment B, 10 February 2006 COAG communique*).

The purpose of this study is to inform the work of this Ministerial Taskforce.

Additionally, the Report of the Taskforce on Reducing Regulatory Burdens on Business, *Rethinking Regulation,* made six recommendations regarding the regulation of chemicals and plastics, which are complementary to the COAG decision. In particular, Recommendation 4.58 proposed that COAG establish a high-level taskforce to oversee an independent public review of chemicals and plastics regulation.

The study, the details of which are below, is to have regard to COAG's *Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard-Setting Bodies*, endorsed in April 1995 and amended in 1997 and 2004.

Research Task

The Productivity Commission is requested to undertake a research study examining the current arrangements for the regulation of chemicals and plastics in Australia. In the light of the COAG regulatory principles, the Commission is to assess the impact of current regulation on the productivity and competitiveness of the chemicals and plastics industry, Australian industry and the economy as a whole, together with the effectiveness of the regulations in addressing public health, environmental, and occupational health and safety issues, and substances of national security interest.

The Commission is to identify measures that could be introduced to achieve a streamlined and harmonised system of national chemicals and plastics regulation and any alternatives to regulation. In this work the Commission is to draw on the recommendations arising from the Report of the Taskforce on Reducing Regulatory Burdens on Business.

The Commission is to:

1. Investigate and document the current system of regulation of chemicals and plastics in Australia, including the interrelationships between the Australian, State and Territory government agencies, and local government layers of regulation, and the effect of these relationships on economic, public health and safety, occupational health and safety, and environmental outcomes. In examining these relationships, issues such as duplication and inconsistency both within and across jurisdictions should be identified. In particular, an assessment should be conducted of the impact of regulation on productivity and competitiveness.
2. Investigate the degree to which Australian regulations diverge from accepted standards (both international and those applying in similar jurisdictions overseas) and the costs and benefits of those variations. In doing so, the Commission should examine Australia's implementation of the United Nations' Globally Harmonised System of Classification and Labelling of Chemicals, and take into account the work underway to achieve mutual recognition and harmonisation with New Zealand in relation to industrial chemicals under the Trans-Tasman Mutual Recognition Arrangement.
3. Examine the efficiency of existing arrangements for security-sensitive ammonium nitrate, recognising that the requirement to achieve the Government's national security outcomes cannot be diminished, and having regard to the work being progressed by COAG's Review of Hazardous Materials.
4. Report on the efficiency and effectiveness of current institutional and regulatory frameworks for chemicals and plastics regulation in Australia in achieving economic, public health and safety, occupational health and safety, and environmental outcomes.
5. Make recommendations for reforms to regulations and regulatory arrangements and the establishment of a best practice governance framework including options to enhance national uniformity and consistency, to streamline data requirements and assessments processes to reduce unnecessary compliance burdens, and for alternatives to regulation.

In undertaking the study, the Commission is to prepare an issues paper, consult widely with all relevant stakeholders (including Australian Government agencies, State and Territory agencies, chemical supply and user industries, consumer and community groups) and prepare a draft report.

Timeframe

The Commission is to report within 12 months of commencing the study and its report is to be published.

Industry Definition

For the purposes of this study, the Chemicals and Plastics industry is considered to comprise ANZSIC 2006 Groups 18 and 19 (less 184 (Pharmaceutical and Medicinal Product Manufacturing)).

PETER COSTELLO
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Abbreviations

Abbreviations

AAT	Administrative Appeals Tribunal
AATSE	Australian Academy of Technological Sciences and Engineering
ABS	Australian Bureau of Statistics
ACA	Australian Consumers' Association
ACCA	Agricultural Chemical Control Area
ACCC	Australian Competition and Consumer Commission
ADG Code	Australian Code for the Transport of Dangerous Goods by Road & Rail (also known as Australian Dangerous Goods Code)
AEC	Australian Explosives Code
AEISG	Australian Explosives Industry and Safety Group
AERP	Adverse Experience Reporting Program
AFER	Australian Forum of Explosives Regulators
AFS	Anti-fouling Systems
AGVET	Agricultural and veterinary
AHMAC	Australian Health Ministers' Advisory Council
AHMC	Australian Health Ministers' Conference
AICS	Australian Inventory of Chemical Substances
ALGA	Australian Local Government Association
AMSA	Australian Maritime Safety Authority
ANAO	Australian National Audit Office
ANFO	Ammonium Nitrate-Fuel Oil

ANZECC	Australian and New Zealand Environment and Conservation Council
ANZFA	Australia New Zealand Food Authority (predecessor of FSANZ
ANZSIC	Australian and New Zealand Standard Industrial Classification
APVMA	Australian Pesticides and Veterinary Medicines Authority
AQIS	Australian Quarantine and Inspection Service
ARA	Australian Retailers Association
ASCC	Australian Safety and Compensation Council
ASIC	Australian Securities and Investments Commission
ASIO	Australian Security Intelligence Organisation
ATA	Australian Trucking Association
ATC	Australian Transport Council
CAP	Competent Authorities Panel
CASA	Civil Aviation Safety Authority
CCOs	Chemical Control Orders
COAG	Council of Australian Governments
CPAASG	Chemicals and Plastics Action Agenda Steering Group
CPLG	Chemicals and Plastics Leadership Group
CRP	Chemical Review Program
CSC	Chemicals of Security Concern
CSMF	Chemical Security Management Framework
CWG	Chemicals Working Group
DAFF	Australian Government Department of Agriculture, Fisheries and Forestry
DDT	Dichloro-Diphenyl-Trichloroethane
DEFRA	UK Department for Environment, Food and Rural Affairs
DEH	Australian Government Department of the Environment and Heritage
DEW	Australian Government Department of the Environment and Water Resources

DEWHA	Australian Government Department of Environment, Water, Heritage and the Arts
DITR	Australian Government Department of Industry, Tourism and Resources
DITRDLG	Australian Government Department of Infrastructure, Transport, Regional Development and Local Government
DOFA	Australian Government Department of Finance and Administration
DOHA	Australian Government Department of Health and Ageing
DOTARS	Australian Government Department of Transport and Regional Services
DPMC	Australia Government Department of the Prime Minister and Cabinet
EC	European Commission
EHO	Environmental Health Officer
EPA	Environmental Protection Agency
EPHC	Environment Protection and Heritage Council
EPHCCWG	Environment Protection and Heritage Council Chemicals Working Group
EPHCNCT	Environment Protection and Heritage Council National Chemicals Taskforce
EPHSC	Environment Protection and Heritage Standing Committee
ERAs	Environmentally-relevant activities
ERMA	NZ Environmental Risk Management Authority
EU	European Union
FBIA	Food and Beverage Importers Association
FSANZ	Food Standards Australia New Zealand
GHS	Globally Harmonised System of Classification and Labelling of Chemicals
GMO	Genetically-modified organism
HSIS	Hazardous Substances Information System
HSRF	Hazardous Substances Regulatory Framework

HWSA	Hazardous Substances Information System
IAC	Industries Assistance Commission
ICAO	International Civil Aviation Organisation
IGA	Intergovernmental agreement
IGAE	Intergovernmental Agreement on the Environment
ITGS	International Trade in Goods and Services
IVA	Industry Value Added
LRCC	Low-regulatory-concern chemicals
MCCA	Ministerial Council on Consumer Affairs
MHF	Major hazard facility
MHF WG	Major Hazard Facilities Working Group
MOU	Memorandum of understanding
MRL	Maximum residue level
MSDS	Material Safety Data Sheet
MULO	Minor Use Liaison Office
NACTSO or NCTSO	National Counter Terrorism Security Office
NAP	National Action Plan for Addressing Dioxins in Australia
NCC	National Competition Council
NCCTG	National Coordinating Committee on Therapeutic Goods
NCHEM	National Chemicals Environmental Management
NCO	Notifiable Chemical Order
NDPSC	National Drugs and Poisons Schedule Committee
NEPC	National Environment Protection Council
NEPM	National Environment Protection Measure
NFF	National Farmers' Federation
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NOHSC	National Occupational Health and Safety Commission
NOPSA	National Offshore Petroleum Safety Authority

NRA	National Registration authority for Agricultural and Veterinary Chemicals (predecessor of APVMA)
NRS	National Registration Scheme for agricultural and veterinary chemicals
NRTC	National Road Transport Commission
NTC	National Transport Commission
OASCC	Office of the Australian Safety and Compensation Council
OBPR	Office of Best Practice Regulation
OCS	Office of Chemical Safety
OECD	Organisation for Economic Co-operation and Development
OGTR	Office of the Gene Technology Regulator
OHS	Occupational health and safety
PACIA	Plastics and Chemicals Industries Association
PC	Productivity Commission
PCBs	Polychlorinated biphenyls
PECs	Priority Existing Chemicals
PIHC	Primary Industries Health Committee
PIMC	Primary Industries Ministerial Council
PISC	Primary Industries Standing Committee
POPs	Persistent Organic Pollutants
PSIC	Product Safety and Integrity Committee
PVC	Polyvinyl chloride
QSAR	Quantitative Structure Activity Relationship
RIS	Regulation impact statement
SCCRHM	Steering Committee for the COAG Review of Hazardous Materials
SCOC	Standing Committee on Chemicals
SDS	Safety data sheet
SITC	Standard International Trade Classification
SSAN	Security sensitive ammonium nitrate
SUSDP	Standard for the Uniform Scheduling of Drugs and Poisons

SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons
TGA	Therapeutic Goods Administration
UHL	Unsupervised handling licence
UN	United Nations
VMDA	Veterinary Manufacturers and Distributors Association
WRMC	Workplace Relations Ministers' Council

Glossary

Article	Means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition (examples include furniture, electrical appliances or motor vehicles).
Allergy	A state of physical hypersensitivity to certain things, such as pollens, food, and fruits, which are normally harmless. Hayfever, asthma, and hives are common allergies.
Chemical	A substance produced by or used in a chemical process.
Corrosive	A substance or mixture that can eat away the surface of a solid, especially of metals, by chemical action.
Cosmetic	A substance or preparation intended for placement in contact with any external part of the human body with a view to cleaning the body, maintaining or protecting it, or altering the body's appearance.
Cost recovery	Fees and charges related to the provision of government goods and services (including regulation) to the private and other non-government sectors of the economy.
Explosive	A solid or liquid substance (or mixture of substances) which is capable by chemical reaction of producing gas at such a temperature, pressure and speed to cause damage to the surroundings.
Hazard	Anything (including work practices or procedures) that has the potential to harm the health or safety of a person.
HAZOP study	A hazard and operability study is used to identify process and operational hazards, evaluate safeguards and make recommendations for improving safety.

Label	Directions for the product's safe and effective use, which are attached to the product or its container.
Maximum residue limit (MRL)	The maximum concentration of a chemical residue allowed in or on a food, agricultural commodity, or animal feed, resulting from the registered use of an agricultural or veterinary chemical.
Oxidizing	An oxidizing substance or mixture is one that, while not necessarily combustible on its own, may cause or contribute to the combustion of other material.
Plastic	Any of a group of synthetic or natural organic materials which may be shaped when soft and then hardened, including many types of resins, resinoids, polymers, cellulose derivatives, casein materials, and proteins.
Poison	A non-pharmaceutical ingredient, compound, material or preparation which may cause death, illness or injury and includes any ingredient, compound, material or preparation referred to in a schedule to the current Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).
Polymer	A natural or man-made material formed by combining units, called monomers, into long chains. The word polymer means many parts. Examples include starch (which has many sugar units), polyethylene (which has many ethylene units) and polystyrene (which has many styrene units).
Precautionary principle	Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation (Principle 15 of the Rio Declaration, 1992 UN Conference on Environment and Development).
Preparation	Mixtures or solutions composed of two or more substances.
Risk	Risk is the likelihood that harm will occur as a result of exposure to a hazard.

OVERVIEW

Key points

- Chemicals and plastics contribute to our wellbeing, but some can pose substantial risks to health and the environment. Government intervention to manage risks is warranted where benefits materially exceed costs.
- Chemicals regulations are generally grafted onto (differing) state and territory Acts that deal with public health, workplace safety, transport safety, environment protection and national security.
- Current regimes are broadly effective in managing risks to health and safety, but are less effective in managing risks to the environment and national security. Efficiency can be improved through national uniformity in most areas.
- The Commission proposes building a governance framework that enhances national uniformity by addressing failures at four levels.
- *Level 1 — policy development and regime oversight.* A national function through ministerial councils supported by intergovernmental agreements:
  - chemicals policy coordination should be supported by an officer-level, cross-council standing committee on chemicals.
- *Level 2 — assessment of chemical hazards and risks.* An Australian Government science-based function undertaken under statutory independence:
  - the industrial chemicals agency should undertake assessments, not set risk management standards.
- *Level 3 — risk management standards setting.* A national function by expert-member agencies operating within the policy frameworks of the ministerial councils:
  - poisons scheduling should be separated from drugs
  - maximum residue levels for domestically produced foods that are set by APVMA should be automatically included in the food standards code, with right of change by FSANZ and the Australia and NZ Food Regulation Ministerial Council
  - while replacement of the workplace safety agency (ASCC) by an independent agency is supported, it should not be a tripartite representative body
  - the effectiveness of new model regulations for transport needs to be monitored
  - an environmental risk management standards body should be established
  - risk management of chemicals of security concern (including ammonium nitrate) should adopt the Commission's governance framework.
- *Level 4 — administration and enforcement.* Generally jurisdiction specific:
  - all standards should be adopted in a uniform or nationally consistent manner by administering agencies
  - control of use of agvet chemicals should be consolidated under the APVMA but delivered through service level agreements by the states and territories.
- Australia should defer adopting the Globally Harmonised System of Classification and Labelling of chemicals until the benefits from trade can be demonstrated.

Overview

This study examines Australia's system of regulating chemicals and plastics. In particular, it:

- examines the four main areas of public policy concern that relate to the hazardous nature of some chemicals — public health; workplace (including agricultural and veterinary (agvet) and transport) safety; environment protection; and national security
- assesses the efficiency and effectiveness of current institutional and regulatory frameworks
- proposes a redesigned regulatory structure, including options to enhance national uniformity and consistency.

The Commission finds that the current institutional and regulatory arrangements are broadly *effective* in managing the risks to health and safety, but are less effective in managing risks to the environment and national security. *Efficiency* could be enhanced by: national uniformity in some regulatory areas; by reducing costs and delays in obtaining regulatory approvals; and by attaining economies of scale in regulatory administration.

Chemicals regulation is not a strong unifying theme in its own right, as it is one of many issues in the broader areas of health, safety, environment and national security. Some parts of the regulatory framework are functioning well, and under the Commission's proposals would serve as foundation blocks for building a more coherent and efficient approach. The Commission has proposed a suite of inter-related reforms for the less well-functioning parts of the framework. These reforms would also serve to reduce and simplify the regulatory burden on businesses.

More substantial and timely reform will require firm commitment by government leaders, incentives to governments to undertake the changes, and arrangements that enable them to collectively achieve greater national efficiency, while responding to their own electoral accountabilities.

Background

In 2005-06, the chemicals and plastics industry accounted for about 9 per cent of manufacturing value added in Australia and about 1 per cent of gross domestic product (ABS 2007a, 2007b). About one third of the industry's economic activity was attributable to basic chemicals, and a similar proportion to plastic products. In 2001-02, nearly three quarters of its output was used as an input in other sectors (ABS 2006b). The products range from basic industrial chemicals to agricultural pesticides, household cleaners and cosmetics. This study does not cover petroleum and coal products (including the refining and manufacture of fuels), or medicinal and pharmaceutical products.

There are several grounds for government policy intervention in this industry. There are significant externalities and information asymmetries concerning the risks associated with the hazardous (toxic, flammable, corrosive or explosive) nature of some of the chemicals or products which contain them. There is also a public good argument that protection of public health, the environment and national security is underprovided by the private sector.

The policy settings for government regulation of the chemicals industry are mostly determined by ministerial councils. The Commonwealth undertakes most hazard and risk assessment, implements international agreements and regulates international trade. The states and territories typically focus on control of use. Their regulatory regimes cover: public health; occupational health and safety; the transport and storage of dangerous goods; the use of agvet chemicals; disposal; and environment protection. Local government involvement varies considerably, but is usually limited to planning and waste disposal issues. Under various initiatives, some aspects of the management of chemical risk are self-regulated or coregulated by industry.

The regulation of chemicals and plastics has long been the subject of concerns about inconsistencies, complexity and fragmentation (box 1). As a result, it became one of COAG's top ten national 'hotspots' in the National Reform Agenda, a Ministerial Taskforce on Chemicals and Plastics Regulation was formed, and the Commission was asked to undertake this study. The taskforce has already developed a range of 'early harvest' reforms — informed in part by the Commission's draft report — which have been endorsed by COAG. The taskforce will be using this final report to further develop its reform proposals.

Effectiveness and efficiency

The terms of reference for this study request the Commission to document and investigate the current system of regulation of chemicals and plastics in Australia and its divergence from accepted international standards, and report on its effectiveness and efficiency.

Box 1 **Participants views**

Duplication and inconsistencies in the regulatory framework were sources of concern for many industry participants:

> One of the greatest impediments to Australia efficiently maintaining the health and dynamism of its chemical and plastic industries is the existence of multiple regulatory authorities. This existing system, which can at best be described as duplicative, often gives rise to inequalities between businesses across State borders, and adds to business processes and costs where businesses operate in multiple States. (Chamber of Commerce and Industry of Western Australia, sub. 23, p. 2)
>
> There is substantial duplication of legislation and other requirements across not only state and federal government, but also within states. There is also difficulty with consistency between states. (Australian Vinyls Corporation, sub. 6, p. 1)
>
> Essentially the chemical regulators exist in silos. There appears to be very little cross-utilisation of skills, resources, opinions and views or mechanisms and facilities … [and] … little action to improve consistency between and within different legislators. (3M Australia, sub. 34, p. 5)
>
> There is significant scope at the national level for the regulation of pesticides to become more streamlined through the vertical integration of Commonwealth and state and territory regulatory regimes. (Croplife, sub. 35, p. 16)
>
> … often variations in State and Territory Regulation may result from an attempt to convert an **inappropriate national product** like the COAG Principles on SSAN or an ASCC National Standard into regulation … if we are to eliminate variation in state and territory regulation, then we need to change our national development processes, so we prepare national legislation that can either be adopted by template by the states, or simply have the states administer the national legislation. (PACIA, sub. 33, p. 5)

Other stakeholders have raised concerns about gaps in the regulatory framework:

> The major concern I have about Australia's regulatory system for chemicals and plastics is the lack of attention to human health impacts and the resultant disregard that is displayed. (Australian Chemical Trauma Alliance, sub. 9, p. 1)
>
> … there is currently no statutory mechanism to require the States and Territories to implement a NICNAS environmental risk assessment recommendation, or to implement it consistently across jurisdictions. (EPHSC sub. 20, attachment 2, p. 1)
>
> … it is generally acknowledged that many of the perceived gaps in Australian environmental regulation of chemicals will be resolved through better inter and intra-governmental information sharing and collaboration involving NICNAS, federal and state OH&S agencies and federal and state environment agencies. (ACCORD Australasia, sub. 42, p. 13)

The Commission has identified only a limited number of direct assessments of the effectiveness of the chemicals regime in achieving the required health, safety, environment and national security outcomes. Indirectly, inferences can be drawn from an array of available statistics on public health outcomes and reported work safety incidents. Environmental outcome measures are generally restricted to location-specific research, although 'state of the environment' reporting is progressively improving. There is little publicly available data on national security outcomes, and little inference can be drawn as to the contribution made by the regulation of security sensitive ammonium nitrate.

The efficiency of current regulations is assessed by considering the potential for alternatives — including reliance on generic regulations — to achieve greater community wellbeing. Overall, there is a paucity of comprehensive and accurate data on administration and compliance costs, and much of the evidence on opportunity costs for firms from delays, impediments to innovation and barriers to entry is anecdotal. There are some claims that new and safer products are not entering Australia due to the high regulatory costs, thus denying consumers and the environment the benefits that would result. The current arrangements are also claimed to reduce competition between suppliers.

The paucity of hard evidence is not unexpected. In the main, firms do not set up their accounts to record the incremental costs imposed by specific regulations, or to net out the costs of activities they would have undertaken irrespective of the regulatory requirements. Similarly, it is difficult to calculate the excess burden of inefficient regulation because there is no clear benchmark of best practice for comparison.

National and international uniformity

The study was required to identify 'options to enhance national uniformity and consistency' and investigate the costs and benefits of diverging from international standards. This presumption in favour of a national system carries through to the terms of reference of the COAG Ministerial Taskforce on Chemicals and Plastics Regulation, which has been requested to develop measures to achieve a streamlined and harmonised system of national chemicals and plastics regulation.

A case can be made for national uniformity in setting broad policies, undertaking hazard and risk assessments and setting risk management standards and codes.

- A single policy framework recognises the reality of our single national economy: inter-jurisdictional businesses, workers, training bodies and government

authorities avoid the costs associated with multiple regimes, and compliance can be enhanced.

- A uniform national system can be more easily integrated into emerging international arrangements — such as the United Nations' Globally Harmonised System of Classification and Labelling of Chemicals (GHS) — and facilitate international trade.
- There is little need for technical standards to vary across the jurisdictions — chemical hazards and assessment methodologies are universal and, although risks can vary by location and use, appropriate flexibility can be incorporated into a national regime.
- Interstate trade is more efficient when there is a uniform approach to the transport, labelling and control of use of chemicals and products.
- Given the specialised nature of the skills needed for formulating policy, undertaking chemical assessments and setting standards, national agencies can harness economies of scale and scope.
- Without uniformity, national security could be compromised by inadequacies of regulation or administration in one or more of the jurisdictions.

Importantly, the states have constitutional sovereignty over much of this regulatory landscape, and a national system requires their support. States and territories attach importance to their ability to respond quickly to local incidents and to manage risks in accordance with local exposure pathways and environmental conditions. These features work in favour of them administering regulation. Further, specific chemical regulations may need to vary, given that they are grafted on to the differing, generic legislative rootstocks of the individual states and territories.

The reform program must recognise that there are costs in developing and adopting nationally agreed standards, and that uniformity may not always have a net benefit, let alone be achievable. But in this area of regulation it should be the default option, with a robust case needed to explain why variations, other than those necessary to accommodate institutional differences, are required.

Assessing the regulatory framework

This study assesses the effectiveness and efficiency of the current arrangements, and the extent of national uniformity from the perspective of the four main functions of: policy formulation; chemical assessment; standards setting; and standards administration. A summary of the Commission's approach is set out in box 2.

Strategic policy and system oversight

While COAG has established the ministerial taskforce to give focus and momentum to the reform of chemicals regulation, ongoing policy and oversighting activities will continue to be the responsibility of specific ministerial councils. These councils vary in their governance and their use of template and model legislation as means for developing national frameworks. The effectiveness and efficiency of these councils varies considerably.

Box 2 **The Commission's proposed institutional and regulatory approach**

- *Formulation of strategic policy and oversight of the institutional and regulatory arrangements* — a national function, to be undertaken by ministerial councils underpinned by intergovernmental agreements.
- *Assessment of the hazards and risks of chemicals* — a national, science-based function to be undertaken under statutory independence.
- *Risk-management standard setting* — a national function to be undertaken by independent statutory agencies within the policy frameworks of the ministerial councils.
- *Administration of agreed standards and monitoring of their impact* — jurisdiction-specific functions to be undertaken by their own agencies or delegated to other bodies such as national regulators.

The Australian Transport Council is one of the more effective of the councils. It oversights a jointly-funded independent statutory authority, there is a well developed intergovernmental agreement and all members are committed to implementing nationally uniform codes. This includes the Australian Dangerous Goods Code (ADG Code) — which itself is aligned with a United Nations code. Given that the ADG Code is mainly administered by work safety authorities, transport policy makers liaise with their workplace relations counterparts through a number of forums.

The Workplace Relations Ministers' Council (WRMC) — supported by the Australian Safety Compensation Council (ASCC) — has extensive responsibilities in chemicals regulation, including workplace-related chemicals policy, hazardous substances, the storage and handling of dangerous goods and explosives. The Commission notes COAG's commitment to replace the ASCC with an independent statutory body, underpinned by a strong intergovernmental agreement, and to achieve national uniformity in OHS regulation generally. This bodes well for the future development and application of workplace standards — including those

relating to chemicals — but the retention of tripartite representation on the new body and its influence on policy is still a concern.

Under the Primary Industries Ministerial Council, the 'conferral' of some powers to the Commonwealth by the states and territories has resulted in an effective single national regulator and a uniform approach to the management of agvet chemicals (the Agvet Code), up to the point of retail sale.

The impact of chemicals on the environment has been identified by an intergovernmental working party as a significant gap in the regulatory framework. Under the direction of the ministerial Environment Protection and Heritage Council (EPHC), the National Chemical Environmental Management framework (NChEM) has been developed, and the Council has signed off on a set of principles.

Australian governments are developing a framework for considering whether additional regulations are needed for chemicals of security concern. The recommendations arising from this study will be an input into their considerations.

At a broader level, there is a need for ongoing consideration of chemicals and plastics regulation that cuts across all of the specific areas of responsibility of the individual ministerial councils. To this end, the Commission is proposing the creation of a Standing Committee on Chemicals that would support the coordination of chemicals policy across the different regulatory silos and make recommendations to appropriate ministerial councils (table 1). The Department of Innovation, Industry, Science and Research is well placed to provide secretariat functions, but committee membership would be drawn from the standing committees of all relevant Ministerial Councils.

Hazard and risk assessment

Industrial chemicals are assessed by the National Industrial Chemical Notification and Assessment Scheme (NICNAS). It also provides (mainly) non-binding risk management recommendations regarding public health, workplace safety, and environment matters that feed into the work of national standard-setting bodies — such as the National Drugs and Poisons Schedule Committee — and to the states and territories. Adoption is voluntary, often inconsistent and tardy, and there is little by way of feedback to NICNAS. This reduces both effectiveness and efficiency and creates uncertainty for industry. The Commission is recommending that all relevant standard setting bodies be required to respond to specific NICNAS recommendations within specified time frames, and further that NICNAS be required to maintain a public schedule of these responses.

Table 1 **The Commission's preferred institutional arrangements for key chemicals regulation frameworks[a,b]**

Issue	*Poisons scheduling*	*Workplace safety*	*Transport of dangerous goods*	*Agricultural and veterinary products*	*Chemicals in the environment*	*Chemicals of security concern (CSC)*
Policy oversight	Australian Health Ministers' Conference	Workplace Relations Ministers' Council	Australian Transport Council	Primary Industries Ministerial Council	Environment Protection and Heritage Council	Attorney General and nominated state and territory ministers
	NNTGC	ASCC (to be replaced)	NTC	PSIC	EPHCSC and NEPC	As needed
	Intergovernmental Agreement (IGA) required	Review effectiveness and efficiency of new body, including effect of tripartite structure, within six years	Review effectiveness of new model regulations	Negotiate national approach to control of use New IGA and conferral of powers required	IGA required — include formal voting	IGA required — include formal voting SSAN to be re-evaluated under new CSC framework
	Standing Committee on Chemicals (supports coordinated policy development and makes recommendations to policy oversight bodies)					
Hazard and risk assessment	NICNAS and OCS	Employers must do own risk assessment. Some reference to NICNAS/APVMA.	UN modified by NTC consultation and CAP decisions	APVMA (with OCS and DEWHA)	NICNAS and APVMA (with OCS and DEWHA)	Assessment in conjunction with security agencies
Standard setting and risk management	Establish separate poisons scheduling committee	Nationally uniform OHS regulations for chemicals	National Transport Commission retains administration of ADG7 for now	Add control-of-use standard setting to APVMA's roles	Establish independent standard-setting body	Risk-based measures to be developed for individual chemicals of security concern
Administration and enforcement	S&Ts to reference all scheduling decisions and regulations	S&Ts adopt model codes and standards in uniform or nationally consistent manner	No change to current arrangements	S&Ts administer and enforce control-of-use regs. through service level agreements	S&Ts would adopt national standards and enforce them	S&Ts uniformly adopt any agreed controls & use AusCheck for security checks

a Other ministerial councils and policy frameworks not shown include those for food safety, therapeutic goods, drug strategy and consumer products. **b** Acronyms in this table are defined in the list of abbreviations at the front of the report.

The Australian Pesticides and Veterinary Medicines Authority (APVMA) assesses agvet chemical products and decides on their subsequent registration. It covers risks to health, environment and trade, and reviews product efficacy. APVMA differs from NICNAS in that it combines risk assessment with risk management and standard setting. The effectiveness of the agvet arrangements is enhanced by state and territory implementation — via the template Agvet Code — and their commitment to the National Registration Scheme. However, less desirably, the states and territories can also have their own, differing, control-of-use regulations.

Firms incur significant costs in having chemicals assessed, whether by NICNAS or APVMA. The costs include the expensive data requirements (which often duplicate international assessments), delays and the risk averse approach adopted by the assessment agencies. The small size of the Australian market restricts the ability of firms to recoup these costs. Accordingly, some firms claim that they are deterred from introducing new chemicals that may be more beneficial to users and the environment than the chemicals currently used.

The delays and data costs of assessments could be reduced through the greater recognition of appropriate overseas schemes, and more extensive utilisation of international data and modelling tools. Neither NICNAS nor APVMA is currently explicitly required by their legislation to manage risk within a cost–benefit framework. The Commission is recommending such a requirement to help ensure assessment costs, including data requirements imposed on applicants, are commensurate with the risks.

The effectiveness of the industrial chemicals and agvet schemes is limited given that all existing chemicals were grandfathered, without modern assessment, at the inception of the schemes. These constitute the vast majority of chemicals 'approved' for use in Australia. NICNAS and APVMA have programs for assessing existing chemicals, with review priorities determined on the basis of perceived health and environmental risks. So far only a tiny fraction of existing chemicals have been assessed. Initiatives to greatly accelerate the pace of review under both programs are warranted. In particular, NICNAS should improve its engagement with international existing chemical review programs, and make greater use of modelling tools.

The procedures for assessing and registering low regulatory concern chemicals are inefficient. They are time consuming and demanding and, as a result, industrial and agvet sectors are reluctant to introduce some chemicals, despite their potential benefits. However, both agencies recognise this. Much needed reform of the agvet system that will expedite the assessment process for agvet chemicals of low regulatory concern is underway. And NICNAS is scheduled to review the

effectiveness and efficiency of its own program. This is welcomed but must involve adequate stakeholder consultation if it is to address industry's concerns.

The processes for assessing chemicals in consumer articles are ineffective. The ACCC and NICNAS should enter into a formal arrangement and establish a program to actively assess consumer articles of concern.

Under the Commission's proposed approach (box 2), chemical assessment (essentially a science-based function) should be a statutorily independent process conducted at the national level, which utilises (rather than reproduces) high-integrity international data whenever possible. This raises the issue of whether the industrial (NICNAS) and agvet (APVMA) chemical assessment functions should be amalgamated. While this would achieve some economies of scale and scope, efficiencies can also be achieved through greater use of contracting out and competitive tendering. The immediate priority should be to strengthen NICNAS's capabilities, and rationalise agvet control-of-use regulation under the APVMA. In the longer term, the creation of a single chemical assessment agency that would meet the needs of all standard setting bodies, including the APVMA, should be considered.

Risk management standards

A range of approaches is used when translating policy and assessments into risk management standards, with some of the standards being more effective and efficient than others, and some falling well short of national uniformity.

The National Transport Commission (NTC) is responsible for developing legislation and technical regulations for the transport of dangerous goods, drawing on a United Nations code. The Commonwealth previously enacted template legislation that was referenced by some jurisdictions or used as a model by others. The individual jurisdictions then administer the regulatory package — mainly through their workplace safety agencies. Between major regulatory revisions, a Competent Authorities Panel of jurisdictional (mainly workplace safety) regulators helps maintain national uniformity.

However, with the seventh edition of the ADG Code coming into effect in 2008, the Commonwealth is no longer maintaining the supporting template legislation. Instead, it has issued model legislation developed by the NTC to guide jurisdictions in developing their own legislation. Industry has expressed concern about the potential for this to result in less legislative consistency than under the template approach. The Commission's preferred approach is for the continued adoption of a single code, and consistency of legislation to the extent possible. While COAG has

announced its commitment to implement the ADG package consistently, the effectiveness of the 'model' approach should be closely monitored.

National workplace safety model standards are developed by the tripartite Australian Safety and Compensation Council (ASCC), which, as noted, is soon to be replaced by a statutorily independent body. The states and territories have consistently implemented some standards (such as for labelling), but not others (such as the storage and handling of workplace dangerous goods). The disparate implementation is inefficient, all the more so given the significant bureaucratic and industry resources employed in developing the common standards.

The ASCC is currently developing a single set of standards to regulate all workplace chemicals. If implemented uniformly, this would simplify regulatory compliance for employers undertaking risk assessments for chemicals that are currently classified as both hazardous substances and dangerous goods. Elements of the proposed system would be based on the GHS.

So far, no country has fully implemented the GHS, although New Zealand is the most advanced. Of Australia's other major trading partners, the EU is planning to begin implementing a GHS-based system this year. Under current conditions, implementing the GHS in Australia would impose significant costs on industry without offsetting trade benefits. As other countries implement the system, it is likely that the costs of implementation will fall and the trade benefits increase. Australia's implementation of the GHS should be delayed until it can be demonstrated that the system would deliver a net benefit.

A case has been put to the Commission to transfer responsibility for the regulatory package governing the transport of dangerous goods to the ASCC. While there may be some institutional benefits, this would involve moving from the very effective transport framework, and the potential loss of transport expertise and profile within the standard-setting agency. On balance, retention within the transport purview is favoured at this stage, until the new independent workplace agency has demonstrated its effectiveness.

When NICNAS or APVMA assess a chemical to be a poison, it is referred to the National Drugs and Poisons Schedule Committee for a decision. Although there is no obligation on state and territory governments to follow the recommendations of the Committee, or to be accountable for their variations, poisons regulation is broadly consistent across jurisdictions. Efficiency would be improved by not only having scheduling decisions adopted by reference — as is currently being considered by the Australian Health Ministers' Conference — but the associated regulatory controls as well. The Commission supports the proposed separation of the scheduling of poisons from drugs (medicines), but has some concerns about

scheduling decisions being made by the Secretary of the Department of Health and Ageing.

The APVMA sets maximum chemical residue limits (MRLs) in food (taking into account dietary impacts) as a way of monitoring good agricultural practice. It also makes a recommendation to Food Standards Australia New Zealand (FSANZ), which undertakes its own processes before incorporating a MRL in the Food Standards Code (for health reasons). This has been taking a year or more to occur, leaving farmers faced with the dilemma of being able to use the agvet chemical concerned, but not being legally able to sell the relevant produce during this time. A more efficient solution would be for the agvet MRL (for domestic produce) to be automatically adopted in the Food Standards Code. Any decision to the contrary by FSANZ and the Australia and New Zealand Food Regulation Ministerial Council should be based on a transparent cost–benefit analysis. Based on the Commission's draft report, COAG has agreed to adopt this reform.

Some participants have argued for additional regulation to address concerns about the environmental consequences of chemicals not used, stored or disposed of properly, and EPHC has referred this issue to the Ministerial Taskforce, which this study will inform. The case for amending legislation to require the states and territories to implement NICNAS's environmental recommendations is not supported. The proposal lacks the appropriate governance and regulatory checks needed in a national system of regulation, and would inappropriately extend NICNAS's role into risk management, when it should be focusing on risk assessment. The Commission recommends instead that a new environmental standard-setting body be created that would report to the EPHC.

Risk management administration

The administration of risk management is primarily a state/territory function. Governance models within jurisdictions vary considerably.

In Victoria, many chemical regulatory functions including OHS, transport and major hazard facilities are brought together under WorkSafe Victoria, which also has a memorandum of understanding with the Environment Protection Agency to coordinate some inspection and enforcement activity. By contrast, multiple agencies have responsibility for administering these regulations in Queensland. New South Wales regulates the control of use of agvet products through its environment portfolio, whereas Victoria administers their use under its Department of Primary Industries. In Western Australia, a pesticides advisory committee coordinates policy across agencies.

In terms of public health, the assessment, control-of-use and product safety regimes all appear to be generally effective in achieving a high standard of protection of people from the toxic characteristics of chemicals. However, regulatory inconsistencies between jurisdictions in this area can also limit overall effectiveness. As noted earlier, effectiveness could be enhanced by poisons scheduling decisions being automatically adopted by reference by the states and territories. Nationally uniform storage and supply controls for illicit drug precursors would enhance efficiency.

Australian workplace safety standards are generally high. The hazardous substances regulations developed by the ASCC are adopted reasonably consistently by the states and territories (less so for dangerous goods), and the transport code is essentially nationally uniform and consistent with UN practice.

A national framework for managing the environmental risks of chemicals has the potential to result in significant improvements in administrative effectiveness and some efficiency gains.

States and territories currently adopt their own control-of-use regimes for agvet chemicals. This is proving ineffective and inefficient. Control of use should be consolidated under the APVMA, but delivered through service level agreements by the states and territories.

Despite national agreement in 2004 to a common set of principles for regulating security sensitive ammonium nitrate, there is an inconsistent patchwork of regulation across the nation. The impact this has had on effectiveness is ambiguous. However, it has led to some inefficiencies. The Commission supports moves towards mutual recognition of licences across jurisdictions. A single national system for background checking, a national database containing security clearance information, and agreement on the criteria for determining eligibility for access would facilitate this. When the new Chemicals of Security Concern framework has been developed, SSAN regulations should be reassessed, with a view to establishing a uniform, risk-based approach.

Most jurisdictions have adopted or are introducing legislation to regulate major hazard facilities. But despite drawing on a national standard, regulatory requirements differ. For example, in its regulations, New South Wales has introduced security arrangements different from the national standard. As a result of the variation, the compliance costs faced by operators vary, depending on where their plant is located. A separate review of the regulation of major hazard facilities is underway and should address these issues.

Box 3 **Reforming regulation to deliver community benefits**

This study has made a range of recommendations aimed at improving the effectiveness and efficiency with which chemicals and plastics are regulated in Australia. Implementing these recommendations should generate net benefits for the community in a number of ways.

More effective regulation

Reforms that should improve regulatory outcomes in cost-effective ways include:

- accelerating NICNAS assessment of existing chemicals and establishing a risk-based approach to prioritising chemical assessments by both NICNAS and APVMA to help identify chemicals of concern
- establishing time limits within which national standard setting bodies are required to respond to NICNAS recommendations and reporting on those responses to improve timeliness and transparency
- bringing control of use of agvet chemicals under APVMA control to achieve closer adherence to permitted use of those chemicals
- developing closer cooperation between the ACCC and NICNAS regarding chemicals in consumer articles to help address public concerns proactively
- making standards such as the ADG Code available at avoidable cost (including being free on the internet) to improve compliance
- implementing a nationally uniform approach to security checks for access to SSAN to remove gaps and reduce 'forum shopping'.

National approaches will help effectiveness and efficiency

Further commitment to national frameworks for developing and implementing consistent regulatory policy would improve efficiency and effectiveness. Examples include:

- direct referencing by state and territory governments of poisons scheduling decisions and uniform adoption of associated regulatory controls
- development of illicit drug precursor regulations by the Ministerial Council on Drug Strategy for adoption by reference by the states and territories
- transferring responsibility for control of use of agvet chemicals from jurisdictional authorities to the APVMA
- establishing an independent national standard-setting body as part of the management of the environmental impacts of chemicals
- greater harmonisation of the existing disparate state and territory SSAN regulations and the subsequent review of these regulations within the proposed Chemicals of Security Concern framework.

(Continued next page)

Box 3 (continued)

Lower compliance costs

Many of the Commission's proposed reforms would lower compliance costs for firms without compromising effectiveness. Costs would be reduced by the wider and more consistent adoption by the states and territories of technical standards produced by national standard setting bodies, such as the ASCC and the NTC.

Other cost-reduction measures include:

- statutory requirements for NICNAS and APVMA to ensure that the costs of chemical assessments (including data requirements) are commensurate with the risks
- wider recognition of approved foreign schemes to reduce assessment costs
- statutory time limits on technical screening of applications by NICNAS to expedite decision making
- removing overlaps between poisons and workplace substances regulations to reduce costs
- reviewing the regulation of major hazard facilities to achieve greater national consistency to assist firms operating in multiple jurisdictions.

But some further reviews will be required

As part of best-practice regulation, further reviews will be necessary in the future to verify the effectiveness and efficiency of reforms currently being implemented. These include:

- assessing whether to implement GHS-based systems of regulating workplace chemicals once key trading partners have commenced implementation
- examining the effectiveness and efficiency of the proposed new national body for developing OHS regulation, including the impact of its tripartite structure
- reviewing whether agvet chemical labels approved by APVMA for products that are also workplace hazardous chemicals are sufficient for workplace purposes
- assessing the proposed governance arrangements for poisons scheduling two years after their commencement
- reviewing, in an independent public manner, the level of consistency with which jurisdictions have adopted the ADG7 transport package in its 'model' form
- undertaking an integrated review of explosives legislation, regulations and the Australian Explosives Code to deliver national consistency.

Undertaking reform

The Commission notes, and in the main supports, the ongoing series of reforms being pursued by agencies, and collectively by jurisdictions, to remove unnecessary burdens, reduce delays in regulatory approvals, and undertake other efficiency enhancing reforms. However, many of these reforms are taking too long to implement, the *par exemplar* being the long recognised need to separate poisons scheduling from drugs scheduling.

Each of the reforms proposed in this report should produce a net benefit and also contribute to a more integrated regulatory structure (box 3). It is recognised that chemicals and plastics regulation is not a strong unifying theme in its own right, but is one of many concerns in the broader areas of: public health; workplace (including agvet and transport) safety; environment protection; and national security. While chemicals regulations will often be grafted onto underlying, and differing, legislative rootstocks, the Commission strongly supports the adoption of uniform operational codes in each of those areas. National uniformity of the regulations themselves should also be possible, and is supported, in many instances. The agreement of all states and territories, and the support of other stakeholders, is essential to achieving these reforms. In this respect, COAG's recent strong commitment to national uniformity in many aspects of chemicals and plastics regulation is a welcome development.

There are many implementation issues to be addressed, including how reforms in one component of the overall framework affect the need for, and timing of, reforms in others. By way of example, the timing of Australia's adoption of the GHS will influence when to merge hazardous substances and dangerous goods regulations. There are transition costs involved in undertaking the reforms, and these may need to be recognised so as to facilitate adjustment, drawing down a dividend from the greater national effectiveness and efficiency where that occurs.

Finally, as part of good regulatory practice, reviews of current and proposed reforms will be needed in the future. In some cases, the Commission has endorsed reforms in progress that are less than ideal, but which, nevertheless, are either an improvement over current arrangements and/or have only been achievable with the considerable good will of all parties involved. Suggesting that these should be modified would be counterproductive at this stage, but they should be reviewed as soon as is practicable after implementation, with a view to aligning them with the Commission's governance and operational principles.

Recommendations

3. National policy formulation and system governance

RECOMMENDATION 3.1

Subsequent to the COAG Ministerial Taskforce on Chemicals and Plastics Regulation Reform having completed its reference, the Commonwealth, states and territories should establish a Standing Committee on Chemicals comprising representatives of all ministerial councils that have responsibility for chemicals regulation. It would:

- ***provide an ongoing forum for assessing:***
  - ***the consistency of chemicals-specific policy settings across the various areas of concern, including public health, workplace and on-farm safety, transport safety, environment protection and national security***
  - ***the effectiveness and efficiency of the overall chemicals-specific regulatory system***
- ***oversee the consistent application of chemical hazard and risk-assessment methodologies and international standards such as the Globally Harmonised System of Classification and Labelling of Chemicals***
- ***support the coordinated development of regulatory proposals that have cross-portfolio implications, including the conduct of regulatory impact assessments***
- ***make recommendations for specific actions by relevant ministerial councils***
- ***be supported by a secretariat in the Department of Innovation, Industry, Science and Research.***

4. National hazard and risk assessment

RECOMMENDATION 4.1

The Australian Government should impose a statutory obligation on NICNAS to ensure that:

- ***the costs of chemical assessments are commensurate with the risks posed by the chemicals concerned***
- ***its assessment priorities are directed to the most efficient management of the aggregate risk of all industrial chemicals.***

RECOMMENDATION 4.2

The Australian Government should establish a technical advisory committee within NICNAS, as a statutory requirement.

RECOMMENDATION 4.3

The Australian Government should generally limit the role of NICNAS to the scientific assessment of the hazards and risks of industrial chemicals. The power to annotate the Australian Inventory of Chemical Substances to ban or phase out chemicals, and the responsibilities for administering the Cosmetics Standard 2007, and for implementing the Rotterdam Convention, should be removed from NICNAS.

RECOMMENDATION 4.4

All relevant national standard setting bodies should be required to respond to NICNAS recommendations within defined time limits. NICNAS should maintain a public schedule of all responses.

RECOMMENDATION 4.5

The Australian Government should introduce a statutory timeframe for the technical screening of applications by NICNAS.

RECOMMENDATION 4.6

NICNAS should implement a program to greatly accelerate the assessment of existing chemicals that:

- ***screens all existing chemicals to develop a list of high-priority chemicals for assessment***
- ***makes greater use of simulation techniques based on the hazards of chemical analogues***

- ***reviews the scope for recognising the existing chemical assessment schemes of a range of other countries as 'approved foreign schemes'. Priorities should be the schemes operated by Canada, the European Union and the United States.***

The Australian Government should meet the cost of screening all existing chemicals from budget funding. NICNAS should continue to recover the costs of subsequent assessment of chemicals of concern.

5. Public health

RECOMMENDATION 5.1

The Australian Health Ministers' Conference should:

- ***proceed as soon as feasible with implementing its proposed reforms to separate poisons and medicines scheduling processes, including that poisons scheduling decisions be made by the Secretary of the Department of Health and Ageing, upon advice from a Chemicals Scheduling Committee***
- ***undertake a review of the Australian Health Ministers' Advisory Council model for poisons two years after commencement, including:***
  - ***an analysis of the consistency between the recommendations of the Chemicals Scheduling Committee and the decisions of the Secretary of the Department of Health and Ageing***
  - ***an analysis of the impact of the model on national uniformity of poisons regulations.***

RECOMMENDATION 5.2

State and territory governments should:

- ***adopt poisons scheduling decisions made by the Department of Health and Ageing directly by reference, as published in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)***
- ***uniformly adopt regulatory controls for poisons through either a template or model approach, as published in the SUSMP***
- ***continue to report any variations to nationally-agreed poisons scheduling or regulatory decisions at the state and territory level to the Australian Health Ministers' Conference, and include a statement of reasons for the variations.***

RECOMMENDATION 5.3

Where a poison is adequately covered under workplace substances regulations and there is demonstrated compliance with those regulations, state and territory governments should exempt workplace users from poisons controls.

RECOMMENDATION 5.4

The ACCC and NICNAS should negotiate formal arrangements for cooperation on issues regarding chemicals in consumer articles. These arrangements should include the establishment of a more systematic research program to identify and deal with the risks of chemicals in consumer articles.

RECOMMENDATION 5.5

The Australian Government should transfer responsibility for the administration and enforcement of the Cosmetics Standard 2007 (Cwlth) from NICNAS to the ACCC.

RECOMMENDATION 5.6

The Ministerial Council on Drug Strategy should develop illicit drug precursor regulations for adoption by reference by all jurisdictions. The associated risk-based schedule of chemicals and apparatus, which are to be subject to the regulations, should be maintained by a committee of experts overseen by the Ministerial Council, and also be adopted by reference in each jurisdiction.

6. Occupational health and safety

RECOMMENDATION 6.1

As part of its review of the National Standard and Code of Practice for the Control of Major Hazard Facilities, the Australian Safety and Compensation Council should:

- ***determine whether there is a case for regulation of Major Hazard Facilities beyond existing generic regulation in areas such as occupational health and safety, environmental protection, and planning, based on cost–benefit analysis***
- ***if such a case exists, identify strategies and opportunities for achieving greater consistency in the adoption and application of the Standard across jurisdictions, than has been achieved to date.***

RECOMMENDATION 6.2

The Workplace Relations Ministers' Council should implement the Globally Harmonised System of Classification and Labelling of Chemicals in the workplace sector in Australia only when it can be shown that adoption of the new regime would produce net benefits.

The Australian Safety and Compensation Council should undertake a further regulatory impact assessment when some of Australia's key trading partners, such as China and the United States of America, have commenced implementation of systems of regulation for workplace chemicals that are based on the Globally Harmonised System of Classification and Labelling of Chemicals.

RECOMMENDATION 6.3

The Australian Safety and Compensation Council should conduct a regulatory impact assessment of the proposal to require agricultural and veterinary chemical products that are also workplace hazardous chemicals to carry workplace hazardous chemicals labels. The assessment should identify alternatives and the costs and benefits of the options. The Workplace Relations Ministers' Council should only adopt the proposal if it can be demonstrated that it would deliver a greater net benefit to the community than any alternative.

Until the regulatory impact assessment has been completed, recognition of agricultural and veterinary chemical product labels for occupational health and safety purposes should continue to apply.

RECOMMENDATION 6.4

The review of the operation of the body that replaces the Australian Safety and Compensation Council that is planned to commence within six years of its creation should assess its effectiveness and efficiency, including the impact of the tripartite structure of the body on the quality and nature of advice that it provides to the Workplace Relations Ministers' Council. The review should also consider the case for replacing the new body with a smaller, statutorily independent body comprised of experts in standard setting, rather than representatives of particular constituencies.

7. Transport Safety

RECOMMENDATION 7.1

The Australian Transport Council should commission an independent public assessment of the consistency with which the Australian Dangerous Goods Code is adopted by jurisdictions, and of the regulatory outcomes produced by their implementation of the associated legislation and regulations. The review should commence not later than twelve months after the reforms have been implemented by all jurisdictions.

RECOMMENDATION 7.2

Responsibility for policy development and monitoring should remain with the National Transport Commission, reporting to the Australian Transport Council.

Once proposed revised governance arrangements have become operational in the transport and workplace relations arenas, the Australian Transport Council should undertake a public review, involving consultation with all stakeholders and including consideration of necessary funding, to determine the most appropriate forum for developing and implementing future national dangerous goods transport policy.

RECOMMENDATION 7.3

The current review of the Australian Explosives Code by the Australian Forum of Explosives Regulators (AFER) should be completed as expeditiously as possible to produce uniform regulations that are adopted and consistently applied by all jurisdictions.

The AFER should then immediately undertake a review of jurisdictional legislation and regulations for explosives transport, with the aim of achieving nationally consistent legislation and regulations to complement the uniformly adopted technical code. Any technical code issues not adequately resolved in the current review of the Australian Explosives Code (AEC3), should also be considered.

RECOMMENDATION 7.4

The National Transport Commission should price all modes of provision of the Australian Dangerous Goods Code at avoidable cost, including free provision on the internet. The resultant revenue loss for the National Transport Commission, together with any compensation payable to the Code distributor, should be offset by increased jurisdictional contributions. Pricing of the Australian Explosives Code should also follow these principles.

8. Agricultural and veterinary chemical products

RECOMMENDATION 8.1

The Australian Government, in consultation with the states and territories, should impose a statutory obligation on the Australian Pesticides and Veterinary Medicines Authority to ensure that:

- ***the costs of chemical assessments are commensurate with the risks posed by the chemicals concerned***
- ***its assessment priorities are directed to the most efficient management of the aggregate risk of all agvet chemicals.***

RECOMMENDATION 8.2

The Australian Pesticides and Veterinary Medicines Authority (APVMA) should regulate the use of agricultural and veterinary chemical products after the point of retail sale through amendments to the Agvet Code:

- ***The scope of the new control-of-use regime should be negotiated through the Primary Industries Ministerial Council, and should include, at a minimum, uniform approaches to enforcing conditions of use on product labels and to the licensing and training of users.***
- ***The Commonwealth, state and territory governments should renegotiate the intergovernmental agreement to confer the necessary powers on the Commonwealth, and develop service level agreements for the regime to be delivered by the states and territories.***
- ***The APVMA should recover additional costs through a mix of charges and levies.***

9. Environment protection

RECOMMENDATION 9.1

The Environment Protection and Heritage Council should examine the costs and benefits of mandatory environmental labelling of chemicals. Mandatory environmental labelling should only be introduced if there is a demonstrated net benefit to the community.

RECOMMENDATION 9.2

The Commonwealth, state and territory governments should negotiate an intergovernmental agreement to create an independent standard-setting body to manage the impact of chemicals on the environment. This body should:

- ***report to the Environment Protection and Heritage Council (EPHC)***
- ***develop standards for the environmental risk management of chemicals and undertake regulatory impact assessment where appropriate***
- ***comprise members who are experts in standard setting, and have the ability to appoint advisory bodies as necessary***
- ***assess and respond to the NICNAS recommendations on the environment, with any other work to be agreed specifically by the EPHC***
- ***meet only as required and be funded by jurisdictions.***

The standards developed by this body should be submitted to the EPHC for consideration and approval, and adopted uniformly and automatically by the states and territories by reference. Once adopted, any variation by a jurisdiction should, at a minimum, be reported to the EPHC and include a statement of reasons for the variation.

A sunset clause should apply to the new body, which would require that it be dissolved unless a review of its effectiveness and efficiency showed an ongoing need.

RECOMMENDATION 9.3

Commonwealth, state and territory governments should develop a performance measurement framework for monitoring the impact of chemicals on the environment that identifies national environmental monitoring and reporting objectives, and includes performance indicators for measuring outcomes against these objectives.

- ***The data needed to construct these performance indicators should be compared to what is already collected (using the Department of Environment, Water, Heritage and the Arts database) to determine if any gaps exist.***
- ***The case for further monitoring should be based on cost–benefit analysis and consider options for reallocating monitoring resources on a budget neutral basis.***

10. National security

RECOMMENDATION 10.1

Commonwealth, state and territory governments should implement a nationally uniform approach to conducting security checks for access to security sensitive ammonium nitrate, irrespective of other harmonisation measures. The

background checking process should be managed by a single agency such as AusCheck. A database that reports current, refused or revoked security clearances should be established, and the information shared across jurisdictions.

RECOMMENDATION 10.2

State and territory governments should consider the following improvements for achieving greater national harmonisation of the security sensitive ammonium nitrate (SSAN) regulations:

- ***removing major inconsistencies in reporting requirements***
- ***basing storage requirements on agreed physical properties of SSAN, provided adequate security controls are met***
- ***ensuring that a single security plan can be lodged for transporting SSAN nationally***
- ***making licence durations nationally consistent***
- ***requiring regulatory agencies to commit to, and report on, timeframes for assessing licence applications.***

RECOMMENDATION 10.3

State and territory governments should not add any additional security sensitive chemicals to the current security sensitive ammonium nitrate regulations.

RECOMMENDATION 10.4

Commonwealth, state and territory governments should establish an agreed framework for assessing the security risks and appropriate control measures associated with chemicals of security concern. This framework should incorporate strong governance arrangements, underpinned by an intergovernmental agreement, that ensure control measures are implemented consistently across jurisdictions. Once established, this framework should be used to re-examine the controls on ammonium nitrate.

Recommendations from draft report adopted in whole or part by COAG at its 3 July 2008 meeting

DRAFT RECOMMENDATION 5.9

Maximum residue limits set by the Australian Pesticides and Veterinary Medicines Authority, which take account of dietary impacts using methods agreed

with Food Standards Australia New Zealand (FSANZ) and the Australian Government Department of Health and Ageing, should be automatically incorporated into the Australia New Zealand Food Standards Code. Any decision to the contrary by FSANZ and the Australia and New Zealand Food Regulation Ministerial Council should be based on a cost–benefit analysis and be reported publicly.

DRAFT RECOMMENDATION 7.1

Jurisdictions should consistently adopt the Model Transport of Dangerous Goods Act and Regulations and should uniformly reference the Australian Dangerous Goods (ADG) Code.

In light of the risks of greater inconsistency in moving from template to model legislation for implementing the ADG7 package, the National Transport Commission should undertake a transparent public review of the consistency with which the new legislation, regulations and the ADG Code are adopted by jurisdictions.

DRAFT RECOMMENDATION 7.4

The Australian Dangerous Goods Code should be available free on the internet and at avoidable cost for hard copies. The resultant revenue loss for the National Transport Commission should be offset by increased jurisdictional contributions. Pricing of the Australian Explosives Code should also follow these principles.

Additional actionable proposals

The following is a compilation of actions proposed by the Commission throughout the body of the report. They are secondary to the main recommendations, but nonetheless, in the Commission's view, would contribute to the more effective and efficient regulation of chemicals and plastics in Australia.

4. National hazard and risk assessment

NICNAS should improve its guidance to applicants for confidential listing of chemicals on the Australian Inventory of Chemical Substances.

NICNAS should consider industry concerns with the operation of its self-assessment provisions and its research and development exemption provisions as part of the general review of the low regulatory concern chemical reforms.

NICNAS should investigate opportunities for greater utilisation of quantitative structure activity relationship modelling in its assessments.

NICNAS should investigate opportunities for further integration with international assessment regimes including through wider recognition of overseas schemes as 'approved foreign schemes'.

5. Public Health

Poisons scheduling and regulation

A RIS should be undertaken for any amendments, undertaken by the National Coordinating Committee on Therapeutic Goods, to the overall design of the Poisons Standard where they are not minor or machinery in nature. As well, the proposed Chemicals Scheduling Committee should be charged with responsibility to determine whether a RIS should be undertaken for significant scheduling decisions.

Where scheduling decisions need to be made quickly in an emergency, the Secretary of DOHA should be empowered to make those decisions out of session,

with limited or no consultation. The decision should be reviewed, following the normal advisory and consultation processes, as soon as practicable.

Labelling requirements for consumer products

If, after the completion of the EU cosmetic regulation reforms, stakeholders identify problems due to inconsistent requirements in Australia, the ACCC should review the Information Standard for cosmetics and the scope for implementing deemed-to-comply arrangements for cosmetic products.

6. Occupational health and safety

Updating the Hazardous Substances Information System

It should be mandatory for the Australian Safety and Compensation Council to update the Hazardous Substances Information System whenever a new National Exposure Standard is declared under the Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment.

Generic material safety data sheets

The Commission supports the approach of Worksafe Victoria and the Western Australian Commission for Occupational Safety and Health of warning users of 'generic' material safety data sheets that they may not be meeting their obligations under occupational health and safety regulations if they use these documents.

7. Transport safety

National Transport Commission funding for the development of dangerous goods transport regulations

The Australian Transport Council should consider the cost to the National Transport Commission (NTC) of developing and maintaining dangerous goods regulation as part of the scheduled legislative review of the NTC in 2008.

Amalgamation of dangerous goods and explosives transport regulation

Improved governance arrangements and more nationally consistent regulatory outcomes in explosives transport regulation are needed before an amalgamation with dangerous goods would be prudent. If this consistency is achieved, the ATC and WRMC should examine the merits of amalgamating the regulation of dangerous goods and explosives transport.

Transition period for the introduction of the ADG7 package

Given the delays and uncertainty surrounding the introduction of ADG7 and the move to model legislation, the Commission considers a 12 month transition period is appropriate. This period should commence after fulfilment of the COAG directive for jurisdictional implementation of the ADG7 package by December 2008.

8. Agricultural and veterinary products

APVMA should accelerate its Chemical Review Program and work to eliminate the backlog of existing products identified for review.

APVMA should monitor the international developments on cumulative risk assessment methodology and policy, and investigate the feasibility of their implementation in Australia.

APVMA should apply data protection provisions for agricultural and veterinary products to the addition of new uses to registered products and to permit applications.

The case for a publicly funded research and registration program for minor pesticide uses has not been established.

The reforms facilitating the utilisation of provisions for 'listed' and 'reserved from registration' agricultural and veterinary chemical products should proceed as a matter of urgency.

Suppliers should not be required to apply to APVMA for approval of changes to aspects of the product label that are outside of the APVMA's scope of operations.

APVMA should establish a consultative mechanism that utilises industry experience on pesticide application issues.

APVMA should make a greater effort to recognise aspects of overseas hazard and risk assessments.

10. National security

Storage and handling

There is a case for further research to be undertaken to determine appropriate safety distances, and for the establishment of agreed evidence based criteria, for the storage and handling of SSAN.

1 What is this study about?

Key points

- In response to a request from the Australian Government this study examines Australia's system of chemicals and plastics regulation, including its efficiency and effectiveness in achieving public health, occupational health and safety, environment and national security outcomes. It makes recommendations for reform, including options for improving national uniformity and consistency.
- This study will provide input into the work of a ministerial taskforce established specifically to develop a streamlined and harmonised system of national chemicals and plastics regulation. That taskforce has already reported to COAG on a range of 'early harvest' initiatives, some to be implemented by the end of 2008.
- The scope of the study is broad. It includes chemical and plastic products across various industries, their complete product life cycles, and their regulation across all levels of Australian government.
- While there have been many studies of the chemicals and plastics industry in recent times, none has taken the broad, public interest focus of this study.

Chemicals and plastics are used for many purposes — in food, medicines, agriculture, and industrial and consumer products — and have become integral to the functioning of the Australian economy (appendix C). In 2005-06, for example, the chemicals and plastics industry accounted for around 9 per cent of manufacturing output in Australia and 0.9 per cent of gross domestic product (ABS 2007a, 2007b).

While chemicals and plastics use in Australia is widespread and vital to maintaining our current living standards, some can pose substantial risks to health and the environment. To manage these risks, chemicals and plastics are regulated to various degrees across their manufacture or import, transport, storage, use and disposal.

Since the report of the Taskforce on Reducing the Regulatory Burden on Business (Regulation Taskforce) in 2006, the Australian Government has focused on reforming areas in which there is overly burdensome, inconsistent or duplicative regulation. The chemicals and plastics industry has been identified as one such area. The aim of this commissioned study is to identify ways in which the effectiveness and efficiency of chemicals and plastics regulation could be improved.

1.1 What the Commission has been asked to do

Under the terms of reference, the Productivity Commission was required to undertake three broad tasks:

1. Assess Australia's current system of chemicals and plastics regulation, including its effectiveness and efficiency in achieving public health, occupational health and safety (OHS), environment and national security outcomes.
2. Investigate the costs and benefits of differences between Australian and international regulatory practice.
3. Recommend reforms to the current system of regulation, including options to enhance national uniformity and consistency, streamline data requirements and assessment processes, and use alternatives to regulation.

Under the terms of reference, the Commission is required to have regard to the Council of Australian Government's (COAG) Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard Setting Bodies (COAG 2004b).[1]

The study has also been guided by the *Productivity Commission Act 1998*, which requires the Commission to take an economy-wide view, promote productivity and the efficient development of Australian industries, and reduce regulation where this is consistent with social and economic goals.

Assessing the economy-wide impacts requires that all economic costs and benefits are considered. These include:

- financial costs and benefits to governments, businesses and consumers
- external costs and benefits including environmental and social costs and benefits.

1.2 Why was it initiated?

On 12 October 2005, the Prime Minister appointed a Taskforce on Reducing the Regulatory Burden on Business to identify options to reduce the compliance burden on business from government regulation. The Regulation Taskforce delivered its final report to the Prime Minister and Treasurer on 31 January 2006, identifying chemicals and plastics regulation as a priority area for review.

[1] This document has subsequently been replaced by Best Practice Regulation: A guide for Ministerial Councils and National Standard Setting Bodies (COAG 2007a).

In particular, the Regulation Taskforce raised concerns about:

- the volume and complexity of existing chemicals and plastics regulations
- duplication and inconsistency between Commonwealth, state and territory regulatory regimes
- the timeliness and cost of regulatory processes
- inadequate recognition of international standards and approval processes
- overly prescriptive regulation of chemicals and plastics labelling.

As one of six recommendations for the industry, the Regulation Taskforce (2006, p. 67) recommended that COAG 'establish a high-level taskforce to develop an integrated, national chemicals policy'. It also recommended an independent public review of regulation in the industry.

At its 10 February 2006 meeting, COAG agreed to establish a ministerial taskforce — comprising one nominated minister from each jurisdiction — to develop measures 'to achieve a streamlined and harmonised system of national chemicals and plastics regulation' (COAG 2006b, p. 6). In its response to the Regulation Taskforce, released on 15 August 2006, the Australian Government (2006) agreed to request the Commission to undertake a review of the industry — the findings of which would provide input into the work of the ministerial taskforce. COAG subsequently noted that the ministerial taskforce would 'report back to COAG with recommendations … drawing on the [current] Productivity Commission study and other related activity' (COAG 2007b, p. 7).

At its March 2008 meeting, COAG further agreed to '… accelerating the five remaining COAG hotspots', which include among others, chemicals and plastics regulatory reform (COAG 2008a, attachment B, p. 1). The Ministerial Taskforce met for the first time on 8 April 2008, and with the support of a Senior Officers Working Group, has subsequently developed a range of initiatives that were considered by COAG on 3 July 2008. These include a range of 'early harvest' initiatives that are to be implemented or ratified by COAG before the end of 2008, and some longer-term measures to be implemented after December 2008. These are mentioned, where relevant, in this report.

1.3 Scope of the study

This study adopts a broad definition of regulation, which includes Acts of parliament, subordinate legislation, and other less explicit forms of regulation such as self-regulation (box 1.1). It covers all regulations that specifically address chemicals and plastics.

Box 1.1 **Types of regulation**

Common categories of regulation include:

- *Acts of parliament*, which can also be referred to as *primary legislation*.
- *Subordinate legislation*, which comprises rules or instruments that have the force of law, but which have been made by an authority that parliament has delegated part of its legislative power to. These include statutory rules, ordinances, by-laws, disallowable instruments (such as *regulations*) and other subordinate legislation not subject to parliamentary scrutiny.
- *Coregulation*, which is a hybrid form of regulation for which industry typically develops and administers particular codes, standards or rules, but the government provides formal legislative backing to enable the arrangements to be enforced.
- *Quasi-regulation*, which encompasses those rules, instruments and standards by which government influences business to comply, but do not form part of explicit government regulation. Examples include government-endorsed industry codes of practice or standards, government-issued guidance notes, industry–government agreements and national accreditation schemes.
- *Self-regulation,* where industry formulates rules, standards and codes of conduct, with industry solely responsible for enforcement.

It also covers a variety of quasi-regulatory instruments developed by national bodies such as the Australian Safety and Compensation Council, and the National Transport Commission, among others. These instruments only have force once they are adopted by a jurisdiction under its own legislation, either by being referenced (or applied) or by being copied in whole or in part into regulation. They include model acts, model regulations, standards, and codes of practice. Except where a specific meaning is required, this report uses the general term 'standard' to describe all of these instruments, and it refers to the bodies that develop these standards as 'standard-setting bodies'. This is consistent with COAG's Best Practice Regulation: A Guide for Ministerial Councils and National Standard-Setting Bodies (COAG 2007a).

Regulation at all levels of government has been considered. In general, ministerial councils set policy, Commonwealth regulators are involved in the assessment and registration of chemicals and plastics, while states and territories typically control their use. The responsibility at the local government level typically includes planning and waste issues. The Commonwealth is also responsible for implementing international agreements and regulating international trade.

Industry coverage is also broad. As specified in the terms of reference, the chemicals and plastics industry is taken to comprise Australian and New Zealand

Standard Industrial Classification (ANZSIC) 2006 subdivision 18 (basic chemical and chemical product manufacturing) — less 184 (pharmaceutical and medicinal product manufacturing) — and subdivision 19 (polymer and rubber product manufacturing) (ABS 2006a). This includes business units mainly engaged in manufacturing:

- gasses (industrial, organic and inorganic)
- chemicals (industrial, organic and inorganic)
- polymers (including tyres, some packaging, foam, adhesive and paint)
- fertilisers
- pesticides
- cleaning compounds
- toiletries
- cosmetics
- photographic chemicals
- explosives
- rubber products (appendix B).

It therefore includes base and feedstock products, speciality and refined chemicals, intermediate goods and components as well as finished products.

Significant exclusions include petroleum and coal product manufacturing (including asphalt and bitumen), alcoholic beverages, food colouring, synthetic textiles, pharmaceutical and medicinal products (ANZSIC 2006, division 184), various paper products and ammunition.

The Commission recognises that the impact of chemicals and plastics regulation extends beyond the strict statistical bounds of the industry. Chemicals and plastics are used widely in the economy, including in industry sectors as diverse as food and packaging and the mining industry, and hence the impact of a particular regulation can be broad.

All stages of the product life cycle of chemicals and plastics — including manufacture or import, transport, storage, use and disposal — have also been considered. In particular, the Commission has sought to identify inconsistencies, instances of duplication and ‘gaps’ in the regulation.

Due to the large number of regulations applying to chemicals and plastics, not every piece of relevant regulation has been reviewed. Instead, the Commission has

focused on identifying broad regulatory problems and solutions, with the aim of producing a more effective and efficient regulatory framework.

1.4 How is this study linked to other reviews?

The plastics and chemicals industry has been the subject of numerous reviews and policy initiatives over many years. Recurring themes have been that regulations are poorly coordinated and complex, with fragmented administration (Allen Consulting Group 2003; CPAASG 2001; CPLG 2004; IC 1995; SBDT 1996). Governments have responded by implementing a number of policy changes, but fundamental concerns about the regulation of chemicals and plastics have persisted.

The Chemicals and Plastics Action Agenda

In 1999, the Australian Government announced a Chemicals and Plastics Action Agenda as part of its industry strategy to build partnerships between industry and government and to promote sustainable economic growth. Its objective was to reform government policies and regulations affecting the chemicals and plastics industry, in order to make the industry more efficient and competitive. A high level group — the Chemicals and Plastics Action Agenda Steering Group (CPAASG) — was established to advise on priorities for the Action Agenda (box 1.2). The CPAASG comprised representatives from Commonwealth, state and territory government agencies, academics, and industry members.

The Australian Government's response to the Action Agenda included establishing a group of industry representatives — the Chemicals and Plastics Leadership Group (CPLG) — to oversee implementation of the CPAASG recommendations (Australian Government 2002). The CPLG was also charged with developing alternative models for a national chemicals policy.

Box 1.2 **The Chemicals and Plastics Action Agenda**

Following extensive consultation, the report of the Chemicals and Plastics Action Agenda Steering Group (CPAASG) called for reform in four policy areas: investment, regulatory reform, education and training, and innovation.

In relation to regulation, the CPAASG found:

- inefficient regulatory systems imposing inappropriate costs
- systematic inflexibility and complexity impeding innovation and growth
- inconsistent treatment and overlapping responsibilities between regulatory agencies and across jurisdictions (CPAASG 2001, p. 27).

The CPAASG also noted that international inconsistencies often resulted in more stringent and costly regulations being enforced in Australia than overseas, resulting in the reduced efficiency and competitiveness of local industry.

The CPAASG made nine recommendations on regulatory reform:

1. All regulation should be consistent with the 1997 COAG principles and guidelines.
2. Mechanisms to ensure consistency with the COAG principles and guidelines should be put in place, including compliance audits.
3. Key national chemicals and plastics regulators should be reviewed.
4. Regulators should recognise data, approvals, definitions and classifications from overseas countries.
5. A national chemicals policy should be developed.
6. There should be enforceable productivity targets for regulators operating under cost recovery.
7. There should be monitoring of regulators in regards to achieving productivity targets.
8. The Australian Government should fund the public good aspects of regulators' activities.
9. Regulatory assessments should be open to alternative service providers.

It also called for the establishment of a Chemicals and Plastics Leadership Group (CPLG) — comprising senior executives from industry and government — to oversee implementation of its recommendations. This and many other recommendations were supported by the Australian Government.

Source: Australian Government (2002); CPAASG (2001); CPLG (2004).

Several of the recommendations made by the CPAASG have been implemented to varying degrees. However, in its final report to the Australian Government in 2004, the CPLG observed that 'while much has been achieved … there is still much work to be done to meet the goals of the original Action Agenda' (2004, p. 6). It also

noted that the implementation of best practice regulation had been *ad hoc* and piecemeal.

That said, reforms have continued to be implemented since the CPLG's final review in 2004. In particular, fast-track approval processes for low regulatory concern chemicals have been progressively implemented by the Australian Pesticides and Veterinary Medicines Authority (APVMA), and the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) (chapter 4).

A National Framework for Chemicals Environmental Management

In May 2002, the Environment Protection and Heritage Council (EPHC) established the National Taskforce on Chemical Management and Regulation, also known as the National Chemicals Taskforce.[2] The Taskforce was asked to:

> … investigate chemical management frameworks in Australia and to scope the issues associated with, and the need for, a national approach to ecologically sustainable chemicals management. (EPHCNCT 2003, p. v)

This led to a report for consideration by the EPHC and the subsequent establishment of the National Chemicals Working Group. The working group has progressed various initiatives to promote education and information on chemicals. More important, however, has been the development of its Framework for National Chemicals Environmental Management (NChEM). A discussion draft of NChEM was released in July 2006 and ministers subsequently signed a ministerial agreement committing them to implementing NChEM, subject to the outcomes of this study and COAG's response. The agreement detailed an action plan for NChEM including items for immediate delivery, for immediate action, for future work and for input into the COAG National Reform Agenda (chapter 9).

The COAG Review of Hazardous Materials

A COAG review of hazardous materials is also under way. In December 2002, COAG 'agreed to a national review of the regulation, reporting and security around the storage, sale and handling of hazardous materials' (COAG 2002, p. 1). The effectiveness of current arrangements was to be assessed and, where appropriate, specific recommendations made. It was decided that separate reviews would be conducted for four areas: security sensitive ammonium nitrate (SSAN); harmful biological materials; radiological sources; and hazardous chemicals.

[2] The taskforce comprised representatives from the health, work safety and primary industries ministerial councils and environment protection agencies. It was chaired by the Director-General of the NSW Department of Environment and Conservation.

The review of SSAN was completed in 2004 and following the development of guidelines, states and territories began revising their regulatory controls for its access (COAG 2004a) (chapter 10). The reviews for radiological and biological materials — while outside of the scope of this study — were considered by COAG in April 2007, and recommendations are currently being implemented. A draft report on chemicals of security concern was released in February 2008 (it is expected that the final report will be considered by COAG later in 2008). The draft report proposed new governance arrangements be established for developing responses to managing chemicals of security concern. Comment on these arrangements and the implications for the management of SSAN are addressed in chapter 10.

Other reviews

Several other reviews in response to the Regulation Taskforce's recommendations are either underway or have been completed:

- As part of a rolling program of reviews of regulatory burdens in the economy, the Commission completed a review of the primary sector in December 2007, and is currently reviewing the manufacturing sector and distributive trades:
  - Many participants in the primary sector review expressed concerns about the burden imposed on the agricultural sector through the regulation of farm chemicals. Participants also raised concerns regarding the regulation of ammonium nitrate, and inconsistencies over maximum residue levels in fresh food between food standards and chemicals regulation. The Commission discussed these issues in the report but recommended that they be assessed in greater detail as a part of this study.
  - Some participants in the current manufacturing review raised similar concerns to those raised in the primary sector review, the overlap being that some manufacturers deal with similar regulatory bodies, such as the APVMA. With a manufacturing focus, some participants have also raised concerns about the impact of NICNAS assessment processes (particularly on small business), overlaps and inconsistencies between regulatory agencies, and the imposition of unique Australian regulatory requirements.
- A review of agricultural and veterinary chemicals and products regulated by the APVMA has been initiated by a committee reporting to COAG's Primary Industries Ministerial Council. The review is considering whether different arrangements are needed for high and low risk agricultural and veterinary chemicals respectively (chapter 8).

- The report of a review of regulations for disinfectant products by NICNAS and the Therapeutic Goods Administration has recently been released. A key issue relates to when testing for efficacy is appropriate and who should be the regulator (chapter 4).
- The Commission was recently asked to review the Mutual Recognition Agreement and the Trans-Tasman Mutual Recognition Arrangement (TTMRA).
  - Under these schemes, jurisdictions in Australia and New Zealand recognise compliance with each other's laws for the sale of goods and the registration of occupations. But hazardous substances, industrial chemicals and dangerous goods have been exempted from the application of the TTMRA, under one of five special exemptions.
  - In this study, 'mutual recognition and harmonisation with New Zealand' is one factor the Commission is required to consider when investigating the degree to which Australian regulations diverge from accepted standards, and the costs and benefits of those divergences.
  - The Commission will consider the case for the chemicals special exemption in the context of the mutual recognition schemes study, but notes that the very different approaches taken in the two countries creates substantial obstacles for mutual recognition. For example, Australia's industrial chemicals regulator, NICNAS, assesses all new chemicals, whereas the New Zealand regulator only assesses hazardous chemicals, and the two countries define hazardous chemicals differently (sub. DR106, attachment 1).
  - For the purposes of this study, the Commission uses New Zealand and other countries as international benchmarks where appropriate.

1.5 Conduct of the study

The terms of reference for this commissioned study were received from the Treasurer on 27 July 2007. Under the terms of reference, the Commission was to report within 12 months of commencing the study and publish the report.

To ensure broad community input and transparency, the Commission consulted and invited feedback in the following ways:

- After the study was announced, the Commission advertised nationally and promoted the study on its website (http://www.pc.gov.au/study/chemicalsandplastics/index.html).

- A circular was mailed to people and organisations that the Commission thought might be interested in the study. Subsequent circulars were sent to those who had expressed an interest in the study to keep them updated on progress.
- Informal discussions were held with a wide range of organisations and individuals.
- An issues paper was released on 7 September 2007 to assist interested parties in preparing submissions to the study.
- In December 2007, a series of roundtable hearings were held in Canberra to canvas particular issues and options for reform. The roundtables were attended by 59 individuals representing 33 organisations. An additional meeting/roundtable was held in Sydney in May 2008, which addressed environmental management of chemicals. This was attended by members of the NChEM Working Group, and the Centre for International Economics (contracted by the Department of Environment, Water, Heritage and the Arts to undertake a cost–benefit assessment of NCHeM).
- The Commission addressed two meetings of the Ministerial Taskforce, and a meeting of the affiliated Senior Officers Working Group, and is expecting to provide briefings to both groups on this final report.
- The Commission received 63 submissions prior to releasing the draft report, and 53 between the draft report and the final report.

The Commission thanks all study participants for meeting with Commissioners and staff, facilitating visits to many industry sites and making submissions to the study (appendix A).

2 Study methodology and evaluative criteria

Key points

- The supply and use of chemicals in the community can result in various market failures, including externalities, information failures and public good characteristics. There is a case for regulating to manage the risks from chemicals, if it can be demonstrated that this would materially improve community wellbeing.
- Such regulation should reduce chemical-related risks to levels where community benefits continue to exceed costs, rather than minimise risks regardless.
- The effectiveness of current regulations is assessed by considering whether they achieve their intended outcomes, and, if not explicitly stated, by also considering whether they reduce risks to levels acceptable to the community.
- Efficiency is assessed by considering the potential for alternatives — including reliance on generic regulations and self regulation — to achieve greater community wellbeing.
- National uniformity is appropriate for most of the regulatory system for chemicals and plastics, because the potential gains in effectiveness and efficiency are likely to outweigh any benefits from having local differences. An exception is administration and enforcement of (nationally-agreed) regulations, where the local knowledge of a subnational regulator may improve effectiveness.
- A high degree of harmonisation with chemical regulations in other countries, especially our major trading partners, may also be appropriate, depending on how soundly based those regulations are. The case for uniformity is strongest where technical codes and standards are concerned.

This chapter outlines how the Commission has assessed existing chemicals and plastics regulations, and formulated recommended reforms. Regulations were assessed for their effectiveness, efficiency, and impacts on productivity and competitiveness. In order to explain this methodology, this chapter starts by discussing the rationale for regulating chemicals and plastics, and how the assessment criteria in the terms of reference were interpreted.

2.1 The rationale for regulation

Chemicals and plastics play a vitally important and beneficial role in the economy, but they also have the potential to harm human health and the environment. Allowing parties to act solely in their own private interest may not lead to the best possible outcomes for the community, given that there are several potential sources of 'market failure':

- externalities — the costs and benefits incurred by those using chemicals and plastics do not always fully reflect the impacts their use has on others (for example, when chemicals discharged from a factory cause health problems among nearby residents)
- information failures — individuals are not always able to make fully-informed decisions about chemicals and plastics in their best interest, because they do not have access to all relevant information, or do not have the technical expertise to interpret it (box 2.1)
- public goods — measures that protect human health and the environment can be underprovided by the private sector because 'free riders' cannot be excluded from enjoying the benefits (for example, security controls that prevent chemical-related terrorism and other crimes).

Regulation may be appropriate to address these sources of market failure, but only if the costs of intervening are materially outweighed by the benefits, and the regulation is the most cost-effective form of intervention. There is more likely to be a net benefit if regulation is tailored to the *risk* posed by a chemical in a particular circumstance (its use), rather than the blunter approach of intervening whenever there is a *hazard* (box 2.2).

The Commonwealth, state and territory governments have agreed to take account of costs, benefits and risks when formulating national regulations they intend to implement jointly. This commitment is outlined in the Best Practice Regulation: A Guide for Ministerial Councils and National Standard Setting Bodies by the Council of Australian Governments (COAG 2007a). Ministerial councils and national standard-setting bodies are to ensure that a regulation impact statement (RIS) is prepared for regulations they propose. Each RIS has to demonstrate the need for regulation, show that it would deliver a net benefit, and explain why alternatives were not preferred. The COAG principles and guidelines also outline how risk can be considered in preparing a RIS.

Box 2.1 **Information failures and the regulatory responses in the market for chemicals and plastics**

There are three kinds of information failure in the market for chemicals:

- Beyond what might be required under common law, chemical producers and importers have relatively weak incentives to assess potential hazards and risks to human health, the environment and national security from the use of chemicals
- Similarly there are weak incentives to communicate these hazards and risks to chemical users.
- Even if hazard information were provided to them, many users lack the technical expertise to interpret hazard and risk information or to determine appropriate risk management strategies.

These information failures can be addressed through regulations that require information on hazards and risks to be collected, and communicated to chemical consumers (farmers, workers, households). This information can be communicated in different ways depending on their level of knowledge about chemical hazard and risk management, the intended chemical use, and the potential for harm. These regulations:

- establish specialist scientific assessment agencies that require chemical producers and importers to submit information on the chemicals they supply, and assess hazards and risks on behalf of the community. This role is undertaken by NICNAS for industrial chemicals and the APVMA for agricultural and veterinary chemicals, and other agencies that provide input to them.
- require that information on hazards be disseminated through labels and the supply of Material Safety Data Sheets for chemicals that have undefined uses. This allows chemical users to do their own risk assessment according to how they are going to use the chemical, and to develop appropriate risk management practices. This is the approach used for most industrial chemicals in Australia.
- establish processes to facilitate the correct interpretation of assessment information:
  - in cases where use is defined, labels may be risk based with specific instructions on use and how risks should be managed (for example, pesticides under the Agvet Code)
  - standard-setting bodies set standards for chemical use where hazard communication alone is unlikely to be sufficient to allow users to adequately manage risks (for example the National Code of Practice for the Storage and Handling of Workplace Dangerous Goods (ASCC Model Regulations))
  - where chemicals are very hazardous or dangerous and there is a high risk of harm, use may be confined to people who have been specifically trained or authorised (for example, schedule 7 poisons).

To varying degrees, individual jurisdictions also require the preparation of impact statements outlining the case for a proposed regulation. For national regulations implemented solely by the Commonwealth, the requirements are specified in the Best Practice Regulation Handbook and are overseen by the Office of Best Practice Regulation (Australian Government 2007). Risk analysis is a part of these requirements.

Box 2.2 **Assessing hazards and risks and managing the risks**

A product is said to have *hazardous* properties if it has the potential to harm human health or the environment. The *risk* such a product poses to community wellbeing depends on the probability of harm occurring and the magnitude of the consequences.

Some products with hazardous properties pose little risk to the community because adverse impacts are minor or unlikely to occur. Products that expose the community to significant risk of harm may justify costly forms of regulation to manage the risk.

To ensure regulation is commensurate with the risk a product poses, the following four-step strategy should be followed:

1. develop a policy framework — establish a clear set of objectives and governance principles including adherence to regulatory impact assessment processes and *ex post* monitoring and review
2. undertake hazard and risk assessment — identify the hazard to human health or the environment, and determine the level of risk posed to community wellbeing
3. develop a risk management approach — consider all of the regulatory options (including self-regulation) and establish standards to manage the risk in a way that delivers the greatest expected net benefit to the community
4. administer and enforce the standards — choose the most effective and efficient way to implement the standard including through existing mechanisms.

Where a government imposes regulation, a key question is how far it should reduce risk. Incremental reductions in risk may initially deliver net benefits, but as increasingly restrictive regulations are imposed, a point will be reached where the costs exceed the benefits. To avoid this, a policy intention of governments should be to reduce the risks (to human health, the environment and national security) from chemicals only to the point where the marginal costs of taking additional action materially exceed the marginal benefits.

The alternative of minimising risks regardless of costs and benefits is inappropriate, because it could make the community worse off. To illustrate, in the extreme, banning all pesticides would reduce risk from their use to zero, but the costs to consumers and industry would be very high. Rather, risk is reduced to a level

acceptable to the general community through measures such as regulated maximum residue levels.

The terms of reference for this study identify four areas where the risks associated with chemicals and plastics are of particular concern:

- public health
- occupational health and safety (including transport and on-farm safety)
- environmental protection
- national security.

The specific market failures in each of these areas are detailed in following chapters.

2.2 Interpretation of assessment criteria

The terms of reference for this study require chemicals and plastics regulations to be assessed against various criteria. The Commission's interpretation of these criteria for the purposes of this study is outlined below.

Effectiveness

The Commission has been asked to assess chemicals and plastics regulations for their effectiveness.

Effectiveness measures how well a regulatory output achieves the intended policy outcome. The relevant objective is usually taken to be that stated in the preamble to the regulation, or by the government that formulated it. Stated objectives are sometimes inconsistent with efficiency. If, for example, the objective was to minimise risk regardless of costs and benefits, the regulation could be effective but make the community worse off.

To avoid this problem, both effectiveness and efficiency have been evaluated. Thus effectiveness has been interpreted not only in terms of stated objectives but also in terms of how well a regulation reduces risks to acceptable levels (that is, levels where regulation delivers the maximum possible improvement in economic efficiency, because no further reduction in risk can be achieved without imposing a net cost on the community).

Efficiency, productivity and competitiveness

The Commission has been asked to assess the impact of chemicals and plastics regulations on the *productivity* and *competitiveness* of the chemicals and plastics industry, Australian industry, and the economy as a whole. The Commission has also been asked to report on the *efficiency* of current institutional and regulatory frameworks for chemicals and plastics regulation, and existing arrangements for security sensitive ammonium nitrate.

The concepts of efficiency, productivity and competitiveness are related. In essence, productivity is the rate at which outputs are generated from inputs.[1] This is a major determinant of competitiveness, which is the ability to compete against others in markets to sell goods and/or services. Efficiency, in its broadest sense, refers to how well resources are used to benefit the wellbeing of the whole community. This broad interpretation is known as economic efficiency and has three components, one of which — productive efficiency — also depends on productivity (box 2.3).

Box 2.3 Components of economic efficiency

Economic efficiency is about maximising the wellbeing of the members of the community. There are three components:

- *Productive efficiency* is achieved when output is produced at minimum cost. It incorporates technical efficiency, which refers to the extent to which, in the production of any good or service, it is technically feasible to reduce any input without decreasing the output, and without increasing any other input.
- *Allocative efficiency* is about ensuring that the community gets the greatest return (very broadly defined) from its scarce resources. A nation's resources can be used in many different ways. The best or 'most efficient' allocation of resources is the one that contributes most to community wellbeing.
- *Dynamic efficiency* refers to the allocation of resources over time, including allocations designed to improve economic efficiency and to generate more resources. Investments in education, research, development and innovation are involved. Dynamic efficiency can also refer to the ability to adapt efficiently to changed economic conditions.

[1] Productivity is a general term that covers a variety of measures used to quantify output(s) relative to input(s). Partial productivity measures quantify output per unit of a single input, such as labour. Multifactor productivity quantifies the use of primary inputs — labour and capital — in generating value added (the return to labour and capital). Total factor productivity uses gross output as its measure of output and, in addition to capital and labour, includes intermediate transactions in materials and services as inputs. (Gretton and Fisher 1997)

In this study, the Commission has given priority to how well regulations improve economic efficiency (that is, how much regulations improve the way resources are used to benefit the wellbeing of the whole community). This is consistent with the requirements of the *Productivity Commission Act 1998*, which oblige the Commission to take account of the wellbeing of all members of the community.

The impacts of regulations on specific groups — including on the productivity and competitiveness of the chemicals and plastics industry, and Australian industry more generally — are considered in this study as part of the broader assessment of the impact on community wellbeing. Thus, regulations that impose costs on firms may nonetheless be supported by the Commission, because they deliver a net benefit to the community as a whole. Conversely, regulations are not supported if they do not make the community better off, or due to poor regulatory design, do not deliver the greatest possible improvement in community wellbeing.

2.3 Applying the assessment criteria

In light of the above, chemicals and plastics regulations have been assessed by addressing the following three questions:

1. Are the regulations effective in achieving the stated outcomes?
2. Are they efficient?
3. Is uniformity the best approach?

Are the regulations effective?

The Commission undertook a review of all available performance data, and found only a limited number of direct assessments of the effectiveness of the chemicals regime in achieving the required health, safety, environment and security outcomes. Indirectly, inferences can be drawn from an array of available statistics on public health outcomes and reported work safety incidents. Environmental outcome measures are generally restricted to location-specific research, although 'state-of-the-environment' reporting is progressively developing an integrated framework. There are little publicly available data on national security outcomes, and little inference can be drawn as to the effectiveness of the regulation of security sensitive ammonium nitrate.

It can also be difficult to determine how effective current regulations are, due to uncertainty about:

- outcomes under current regulations — impacts on human health and the environment can be hard to measure, and so there may not be sufficient data to establish outcomes with a high level of confidence
- what would have happened in the absence of current regulations — it is not possible to observe this hence the 'counterfactual' benchmark is also uncertain.

Where effectiveness could not be observed directly, the Commission made a judgement based on a range of indirect measures, such as the:

- clarity of objectives in regulations (assuming these would facilitate enforcement and compliance)
- prevalence of loopholes, gaps and inconsistencies among regulations (assuming these compromise effectiveness)
- number and severity of reported adverse events, and how this compares to other jurisdictions (subject to the caveat that observed differences may not be attributable solely to differences in regulations, and some types of adverse events may be under-reported)
- extent to which regulations are enforced (using indicators such as the resources devoted to publicising and enforcing regulations, and the degree to which different regulators and jurisdictions coordinate their enforcement activities, where this could aid effectiveness).

Another useful guide is a checklist for assessing regulatory quality that the former Office of Regulation Review (now the Office of Best Practice Regulation) prepared on the basis of a range of OECD and other reports (box 2.4).

Box 2.4 **Checklist for assessing regulatory quality**

Regulations that conform to best-practice design standards are characterised by the following seven principles and features:

- Minimum necessary to achieve objectives
  - Overall benefits to the community justify costs
  - Kept simple to avoid unnecessary restrictions
  - Targeted at the problem to achieve the objectives
  - Not imposing an unnecessary burden on those affected
  - Does not restrict competition, unless demonstrated net benefit
- Not unduly prescriptive
  - Performance and outcomes focused
  - General rather than overly specific
- Accessible, transparent and accountable
  - Readily available to the public
  - Easy to understand
  - Fairly and consistently enforced
  - Flexible enough to deal with special circumstances
  - Open to appeal and review
- Integrated and consistent with other laws
  - Addresses a problem not addressed by other regulations
  - Recognises existing regulations and international obligations
- Communicated effectively
  - Written in 'plain language'
  - Clear and concise
- Mindful of the compliance burden imposed
  - Proportionate to the problem
  - Set at a level that avoids unnecessary costs
- Enforceable
  - Provides the minimum incentives needed for reasonable compliance
  - Able to be monitored and policed effectively

Source: Argy and Johnson (2003).

Are the regulations efficient?

Could regulation improve the way resources are used to enhance community wellbeing?

Efficiency is enhanced where regulatory intervention addresses a market failure, and intervention would produce a net benefit to the community. The Commission was more likely to assess regulation as being justified on efficiency grounds if:

- there was a clear regulatory objective to reduce risks to human health and the environment to acceptable levels, rather than to minimise risks regardless of costs and benefits
- the case for regulation had been demonstrated in a RIS (or similar process) that included a thorough cost–benefit analysis
- existing generic (not chemical-specific) regulations could not adequately address the market failure. Generic regulation is common for the four risk areas identified in this study's terms of reference, and hence supplies a fall back option in many cases
- the regulatory response was proportionate to the problem.

Do current regulations deliver the greatest efficiency gains or are reforms required?

While there might be a case for regulating chemicals and plastics on efficiency grounds, the gains achieved in practice could be well below potential. Reasons for this include:

- loopholes and inadequate enforcement that make regulations ineffective
- overly complex requirements and administration that add to costs, change production methods or otherwise discourage innovation, impose opportunity costs (often from approval delays) and create barriers to competitive entry
- duplication and inconsistency among regulations and jurisdictions that results in an increase in the costs of administering and complying with regulations
- gaps in the regulatory framework that mean market failures are not currently being addressed and there would be a net benefit to the community from doing so.

Are administration and compliance costs higher than necessary?

The cost to government of administering regulations and to firms of complying with them should ideally be proportionate to the problem and the minimum necessary to achieve effective outcomes. Costs may be higher than necessary if best-practice approaches to regulatory design, administration and/or enforcement are not being used.

In principle, benchmarking administration and compliance costs across jurisdictions can identify the lowest cost arrangements.[2] The extent to which a regulation's costs are higher than necessary — termed the excess burden — can then be quantified as the difference between the regulation's costs and those under best practice. However, there are several challenges associated with quantifying a regulation's excess burden (box 2.5).

The Commission received only a limited amount of cost information that could be used to determine the relative efficiency of existing regulations. This can be partly attributed to the difficulty participants faced in isolating a regulation's incremental cost from the costs they traditionally record for accounting purposes. This was the case for government administration costs, as well as business compliance costs. Furthermore, it is unrealistic to expect participants to always know what the incremental cost would be under best-practice regulation, and hence, to calculate the excess burden of current arrangements.

In light of the limited quantitative evidence on costs, the Commission supplemented its analysis with a qualitative assessment of whether existing regulations have features likely to lead to unnecessarily high administration and compliance costs. The terms of reference suggest such features may include duplication and inconsistency within and across jurisdictions, unjustified divergences from accepted overseas standards, and overly complex data requirements and assessment processes. The evidence supplied by participants in this study is used throughout this report and summarised in appendix E. In addition, the Commission has previously published a comprehensive list of indicators that could potentially be used to assess compliance burdens (PC 2007b).

2 An alternative, but more speculative, approach would be to attempt to estimate what might be the costs under a theoretical best-practice regime.

Box 2.5 **Estimating excess regulatory burden**

Although intellectually appealing and conceptually intuitive, the excess burden created by regulation is difficult to quantify. Ideally such quantification should be based on the incremental cost a regulation imposes, netting out the cost of activities that would have occurred regardless. Some of these activities may be linked to other regulations, including generic requirements onto which chemical-specific rules are grafted, thus requiring the various costs to be disentangled. Some activities required by chemical-specific regulations, such as actions to clean up accidents, may occur regardless of regulation and so also need to be factored out of the cost calculation.

Conversely, a regulation may stifle some activities by creating 'opportunity costs' through, for example, delays to project implementation, impediments to innovation, and barriers to entry. Ideally, this should also be reflected in the calculation of regulatory costs. Another challenge is how to take account of different circumstances, objectives, and effectiveness in achieving those objectives when comparing regulatory costs between jurisdictions.

There is also the question of how to obtain the necessary cost data. The Commission asked all governments to provide data on the cost of administering their chemicals and plastics regulations. It was not practical to similarly contact all firms subject to those regulations about their compliance costs. A survey of firms was not pursued because of the difficulty of ensuring a representative sample, given the wide diversity of firms and regulations involved, and of designing questions firms could readily answer. In this respect, the Commission was mindful that the accounts of firms are not primarily set up to record the incremental compliance costs of government regulations. Instead, the Commission issued a general request to industry bodies and individual interested firms to submit evidence about cases where compliance costs are claimed to be excessive.

The challenges this study faced are consistent with observations the Commission previously made in a general review of regulation benchmarking:

> Many businesses would have to be surveyed in order to build up a picture of average costs so that aggregate burdens could be estimated. In addition, the relationship between indirect indicators and incremental cost would have to be quantified in order to reliably estimate actual compliance costs. Even if actual incremental compliance costs could be estimated, it would be difficult to enumerate aggregate costs. Currently, there is a paucity of information on the demographics of business, and a lack of understanding of the reach of regulations, to estimate the number of businesses affected by unnecessary regulatory burdens and the costs they incur. (PC 2007b, p. 6)

Should uniformity always be the goal?

The terms of reference for this study assume that, in general, gains could be achieved by streamlining and harmonising regulations into a national system, including by enhancing national uniformity and consistency, and by removing regulatory duplication and inconsistency within and between jurisdictions. It is also

assumed that reducing divergences from overseas standards and using alternatives to regulation would be beneficial.

Harmonisation and uniformity are key terms. Regulations are harmonised by aligning common elements, such as definitions, certification requirements, enforcement protocols, and measurement systems. National uniformity occurs when all jurisdictions across Australia have the same standards and codes of practice and, desirably, the same legislative base. Uniformity is therefore at one end of the spectrum of possibilities, with complete inconsistency at the other end, and a variety of harmonisation possibilities in between.

National uniformity

While the terms of reference assume a case in favour of converging on a uniform national system, there are often tradeoffs involved in favour of subnational jurisdictions tailoring regulations to their own circumstances and preferences. The Commission has previously noted that the 'subsidiarity principle' provides some guidance on how to handle this issue:

> Under this [subsidiarity] principle, responsibility for a particular function should, where practicable, reside with the *lowest* level of government (see, for example, CEPR 1993; Kasper 1995, 1996). This rests on four main considerations:
>
> - subnational governments are likely to have greater knowledge about the needs of the citizens and businesses affected by their policies
> - decentralisation of responsibility and decision making makes it easier to constrain the ability of elected representatives to pursue their own agendas to the disadvantage of citizens they represent
> - intranational mobility of individuals and businesses exposes subnational governments to a reasonable degree of intergovernmental competition
> - initial emphasis on the lowest level of government encourages careful consideration or testing of the case for allocating a function to a higher or national government and thereby guards against excessive centralisation. (PC 2005, p. 3)

On the other hand, the Commission has also previously noted there is broad support for a national regulatory system when:

- there are significant interjurisdictional spillovers associated with the provision of a good or service at the subnational level (for example, interstate transport systems)
- there are readily identifiable areas of shared or common interest or sizeable economies of scale and scope arising from central provision or organisation (for example, defence, international or external affairs and social welfare support)

- a diversity in rules or regulations is likely to give rise to high transaction costs with insufficient offsetting benefits (for example, regulation of companies, transport, the financial sector and trading provisions covering weights and measures)
- there is scope for mobility of capital and people across jurisdictions to undermine the fiscal strength of the subnational level of government (for example, as arises with the income, capital gains and corporate tax bases; or with welfare entitlements). (PC 2005, pp. 3–4)

Three of the abovementioned factors — interjurisdictional spillovers, economies of scale and scope, and transaction costs — provide the grounds for cross-jurisdiction uniformity of the standards and codes of practice for chemical regulation. This is underpinned by the fact that the hazardous nature of chemicals is the same nationwide and indeed internationally.

However, it does not necessarily follow that cross-jurisdiction coordination is always best administered by a national regulator. Common codes may need to be sufficiently flexible to allow some regulatory differences between jurisdictions when the market failure being addressed depends heavily on local circumstances. For example, a national approach to regulating pesticides may need to recognise that the conditions of use should vary according to local environmental conditions. Interjurisdictional differences could also arise where chemicals legislation is grafted on to differing underlying legislative frameworks, and where there are different institutional arrangements, enforcement mechanisms, and interpretation acts.

Thus, while cross-jurisdiction coordination is generally supported in this study, the merits of taking this as far as national uniformity and a national regulator have to be judged on a case-by-case basis. This issue is dealt with in chapter 3 and subsequent chapters.

International uniformity

Given that the hazards posed by chemicals are universal in nature and many risks are also common, there can be much to be gained from aligning Australian regulatory requirements with those of similar developed countries. Having compatible regulatory requirements can facilitate trade in many ways. For example, having the same or similar assessment requirements facilitates entry of new chemicals, and having the same packaging and labelling requirements decreases costs of imports and exports. And in some circumstances, harmonisation with international standards may be required under Australia's international obligations (such as our general obligations under such agreements as the GATT Technical Barriers to Trade Agreement (Standards Code) and chemical specific obligations under such treaties as the Stockholm Convention on Persistent Organic Pollutants).

In an international context, harmonisation rather than uniformity will most often be the more realistic approach, given that different countries have different institutional frameworks, and different attitudes to risk. There can be considerable scope to adopt consistent technical standards (subordinate to the necessarily different primary legislation), especially if many countries are converging on an accepted approach. International consistency can also be promoted through deemed-to-comply and mutual recognition arrangements.

Benchmarks provided by international standards are, therefore, a key part of the assessment framework and are considered throughout this report. As a rule, closer alignment with international standards is generally supported, provided that it is consistent with the wellbeing of the Australian community.

3 National policy formulation and system governance

Key points

- Chemicals policy formulation is fragmented and inconsistent. Policy tends to be developed in isolation within particular regulatory regimes (public health, workplace safety, transport, agriculture, environment protection and national security).
- Progress in developing consistency within these regimes is patchy.
  - In some cases, such as in the regulation of transport of dangerous goods, the governance arrangements are working well.
  - In other cases, national frameworks are incomplete (for example, environment protection) or are insufficiently developed to achieve the consistent outcomes warranted (for example, workplace safety).
- The Commission's proposed governance framework for the various regulatory regimes will help improve national consistency. It has four components:
  - policy development and oversight
  - assessment of chemical hazards and risks
  - risk management standard setting
  - administration and enforcement of standards.
- However, insufficient consideration is given to the effectiveness and efficiency impacts across the regulatory system as a whole.
- It is not realistic to try to amalgamate chemicals regulations under a single body of regulation or a single national regulator.
  - Chemicals regulation is grafted onto underlying regimes which have differing focuses, and hence is not a strong unifying influence in an institutional sense. This places a premium on coordination mechanisms.
- While there are various mechanisms to provide some coordination across the regulatory regimes, there is no governance mechanism currently in place to develop an integrated approach to national chemicals policy.
- The Commission recommends that a Standing Committee on Chemicals should be created. This committee would comprise senior officials representing all ministerial councils that have a responsibility for chemicals regulation. It would be a forum for promoting consistency of chemical-specific policy settings across all relevant regimes, and would make recommendations for specific actions by individual ministerial councils.

Chemicals and plastics policy in Australia has long been regarded as fragmented and inconsistent. This is partly because there are numerous policy making bodies, regulators and agencies involved at both the Commonwealth and state and territory levels. Although some national frameworks have been developed and there are some signs that more consistency may yet emerge, this is largely happening within individual regimes. This chapter looks at the arguments for developing a governance system that will improve high-level policy formulation and coordination, and facilitate a nationally uniform chemicals and plastics regulatory framework.

3.1 Background

In commissioning this study the Australian Government asked the Productivity Commission, among other things, to consider the effectiveness and efficiency of current institutional arrangements and make recommendations about a best practice governance framework. The Commission's recommendations will be considered by a ministerial taskforce established by Council of Australian Governments (COAG) to achieve a streamlined and harmonised system of national chemicals and plastics regulation. Thus, while the Commission makes a number of recommendations about specific reforms in later chapters, it is also being asked to consider high-level policy processes.

Findings of previous reviews

The need to develop a national chemicals policy has been a recurring theme in reviews of the chemicals and plastics industries over many years. These reviews almost invariably note that chemicals regulation is fragmented and inconsistent, and that a national policy is required.

A recent prominent review involved an Australian Government initiated 'Action Agenda' for the chemicals and plastics industry. A group of industry and government representatives — the Chemicals and Plastics Action Agenda Steering Group — was established to advise on priorities for the Action Agenda. The Steering Group made ten recommendations on regulatory reform, including that a national chemicals policy be developed. What this policy was meant to comprise, and how it would be implemented, were not addressed in great detail other than that the policy would 'focus on mutual commitment to a consistent national approach' for, among other things, environmental quality, and workplace and consumer health and safety (CPAASG 2001, p. 32).

To facilitate this process further, various industry groups commissioned the Allen Consulting Group (ACG 2003) to examine alternative models for chemicals industry regulation. The ACG recommended the creation of a new Ministerial Council (or if this was to prove difficult, attaching the responsibility for chemicals regulation to the then Industry and Technology Ministerial Council (now defunct)). It also recommended that the ministerial council should facilitate the development of a series of intergovernmental agreements (IGAs) (ACG 2003). The ACG recognised that achieving national uniformity in regulation would be extremely difficult and protracted, and hence that national consistency and cooperation were likely to be more pragmatic approaches.

More recently, chemicals industry regulation was addressed by the Taskforce on Reducing Regulatory Burdens on Business (Regulation Taskforce 2006). Noting business concerns with duplication and inconsistency in chemicals regulation, the Taskforce agreed with the idea of a national chemicals policy, implying that it should achieve national uniformity, or at least improve national consistency in regulation. Attention was directed to a number of issues including information sharing to reduce duplication and improve consistency with international standards (Regulation Taskforce 2006). While the Taskforce argued for the development of a national policy by a (now established) ministerial taskforce, it did not explicitly address the governance frameworks that might be needed to achieve a national policy.

Regulation of chemicals and plastics is fragmented

The regulatory regimes for chemicals and plastics outlined in the following chapters contain a large number of separate regulators with very limited coordination between them. Chemicals and plastics producers are required to deal with these regulators separately. There are several reasons for this fragmentation of chemicals regulation in Australia.

First, under the Constitution, the Commonwealth has powers over trade and corporations, but the states (and territories) have most of the constitutional powers to directly regulate the use of chemicals.

Second, regulation of chemicals has traditionally been organised around distinct end uses. Thus separate regimes are in place for industrial chemicals, agricultural chemicals and veterinary medicines, pharmaceutical and therapeutic goods, and food. Similar institutional arrangements apply in other countries. Merging some or all of these regimes, just to harmonise chemical regulation, could compromise the purpose of these different streams of regulation. For example, chemical contamination of food is an important public health issue, but it is only one among

many relevant regulatory issues concerning food, and hence is best considered through that particular regulatory lens.

Third, chemicals regulation largely exists within, or is grafted onto, generic regulatory frameworks that govern public health, occupational health and safety (OHS), transport safety, agriculture, the environment and national security. Chemicals regulation is a means to an end; it manages the risks that chemicals might pose to the achievement of broad social and economic objectives — such as achieving a safe workplace, safe disposal of waste, or achieving effective and efficient transport — but it is managing only one source of risk. Thus while there are genuine reasons for regulating chemicals at various stages of their lifecycle, chemical regulation is not of itself a strong unifying influence in an institutional sense.

Fourth, there is some industry self-regulation of chemicals. While this is in some cases quite effective, it adds to the variety of requirements that industry seeks to comply with.

The net result is that there are numerous Acts, regulations and codes, and there are many different regulators, government agencies and industry groups involved in chemical regulation. Some of this fragmentation is not only unavoidable, but desirable, in the sense that issues concerning a particular location or issue is devolved to those most appropriate to manage it. However, as this study concludes, in many instances the issues are national in nature, and a much greater degree of consistency across jurisdictions and regulatory frameworks is warranted. This means that good governance arrangements and associated coordinating mechanisms are important in developing a more systematic, integrated approach.[1]

3.2 A best practice governance framework

In the Commission's view, the governance framework needs to be built on clear objectives, responsibilities, and processes at each of the four broad levels of the regulatory task, as follows:

- policy development and regime oversight
- assessment of chemical hazards and risks
- risk management standard setting

[1] For the purpose of this study, the term 'governance framework' refers to how the responsibilities of, and relationships between, different bodies and jurisdictions are organised to form a system of regulation. A related concept is corporate governance, which refers to the arrangements used to govern a specific organisation.

- administration and enforcement.

Policy development and oversight of the regime is a high-level responsibility. In circumstances where responsibilities are held jointly by the Commonwealth, states and territories, and where the states have not referred their powers to the Commonwealth, policy formulation should reside at the ministerial level (supported by officials) and be held jointly by all jurisdictions to ensure their ongoing commitment to national coordination. An effective means of achieving this has been to assign responsibility to a ministerial council established under the auspices of COAG. Ministerial councils, supported by their respective standing committees of officials, should provide broad policy direction and be responsible for formally adopting policy relevant standards (see below).

Chemical hazard and risk assessment is a science-based task best undertaken by an independent national body of technical experts. Independence from policy making is desirable to ensure assessments are confined to the facts. A national body is preferred because the alternative of sub-national jurisdictions duplicating the chemical assessments of others is inefficient, as is any divergence in assessments. The economies of scale and scope available to a national body also enable it to maintain greater technical expertise, rather than have this scarce resource scattered amongst multiple jurisdictions and multiple agencies.

Standard setting involves designing the risk management rules by which chemicals and plastics are regulated. This also tends to be most effectively and efficiently undertaken by an independent national body made up of experts in the field, rather than representatives of the jurisdictions and stakeholders. However, unlike chemical assessment, this process needs to be constrained by the policy settings of the ministerial council. Jurisdictions should provide input, as it is important that they are all committed to the outcomes and prepared to adopt the standards. The standards should also align with community attitudes to risk and may need to be set sufficiently wide, or with appropriate exemptions, to encompass local conditions.

One characteristic of the chemicals regulatory regime is the diversity in the types of standards. There are policy-relevant standards that generally govern how chemicals are managed and standards that are set at the chemical-by-chemical level, with variations in between. The former warrant high-level policy decision making, a regulation impact statement (RIS), and ministerial council endorsement of the standards. The latter are best made by standard-setting bodies operating largely autonomously but within a defined policy environment. As a rule, these bodies may not need to undertake RISs though this will depend on how substantially their

decisions impact on the economy.[2] For example, depending on how a poison is scheduled, the impacts on business and consumers could be routine, or could be substantial, thus warranting a RIS (chapter 5).

The governance arrangements for standard setting should provide for appropriate multijurisdictional and public consultation, including, in some cases, the establishment of a more formal advisory group of representatives from governments, industry, the workforce, and the wider community. It would be inappropriate to give a decision-making role to such a group because they represent the interests of particular stakeholders. Rather, the members of the standard-setting body should be appointed on the basis of their knowledge and experience in making objective, evidence-based decisions in the public interest.

Whether administration and enforcement of regulations is best undertaken by a national body or sub-national regulators is less clear cut than for other regulatory tasks. A national regulator could be the best option if there are significant economies of scale and scope. On the other hand, if knowledge of local conditions and preferences is crucial to ensuring regulatory effectiveness and efficiency, it may be more appropriate to have sub-national regulators administering the national scheme. In this respect, states and territories also attach importance to their ability to respond quickly to local incidents, and to manage risks in accordance with local exposure pathways and environmental conditions. On balance, the Commission has tended to favour sub-national regulators in relation to chemicals and plastics.

The remainder of this chapter focuses on the first of the four broad levels of the regulatory framework: policy development and regime oversight. The Commission's preferred approach, outlined below, should be read in conjunction with table 3.1, which identifies and illustrates the various intergovernmental arrangements.

3.3 Policy development and regime oversight

Ministerial councils

Most areas of chemicals and plastics policy have elements that are most efficiently dealt with through a coordinated national approach (table 3.2). Ministerial councils established under the auspices of COAG play an important role in bringing together Commonwealth, state and territory ministers (and in some cases New Zealand

[2] COAG guidelines state that regulatory assessment is not required for regulations that are 'minor or machinery in nature'. (COAG 2007, p. 3)

Government ministers) to facilitate consultation and cooperation, to jointly develop policy, and to oversee regulatory regimes and other joint actions. Examples of the role of ministerial councils in policies related to chemicals and plastics regulation include the Primary Industries Ministerial Council, which oversees national regulation of agricultural and veterinary chemicals (chapter 8), and the Australian Transport Council, which oversees national regulation for the transport of dangerous goods (chapter 7).

Table 3.1 **Intergovernmental arrangements[a]**

Coordination option	*Description*	*Examples*
Transfer of powers to the Commonwealth		
Referral of powers to the Commonwealth	States refer their authority to legislate on a matter to the Commonwealth, making it the sole legislator and regulator (using subsection 51(xxxvii) of the Constitution)	• Victoria's referral of industrial relations powers to the Commonwealth • Regulation of financial products and services by ASIC
Conferral of powers to the Commonwealth	States confer some of their functions and powers to the Commonwealth so it can regulate on their behalf (differs from a referral of powers because states retain the right to regulate themselves or at least retain some role in the regulatory process)	• Controls on the supply of agvet chemicals up to the point of sale by the APVMA • Regulation of genetically-modified organisms by the OGTR • OHS regulations for offshore petroleum facilities by NOPSA
Interjurisdictional coordination of legislation		
Template legislation (sometimes called 'applied legislation' or 'incorporation by reference')	The legislation of one or more jurisdictions (for example, states and territories) applies legislation enacted by another jurisdiction (for example, the Commonwealth)	• State and territory adoption of the Agricultural and Veterinary Chemicals Code • Commonwealth dangerous goods transport regulations applied by NSW, Victoria & SA
National model regulations	Legislation is drafted as a model for individual jurisdictions to use in drafting their own regulations	• OHS model regulations developed by the ASCC • New dangerous goods transport regulations (ADG7) developed by the NTC
National codes of practice	Codes of practice (often addressing technical matters) that all jurisdictions refer to in their regulations	• List of Designated Hazardous Substances maintained by the ASCC • Food Standards Code maintained by FSANZ • Australian Explosives Code (for most states/territories) and old ADG Code (6th edn)

(Continued next page)

Table 3.1 (continued)

Coordination option	*Description*	*Examples*
Legislative instruments		
Legal obligation on agencies to consult other relevant bodies	One agency is required to inform others about a particular issue	• APVMA notification to FSANZ about maximum residue levels (MRLs) • OGTR requirement to consult APVMA, AQIS, FSANZ, NICNAS and TGA about applications to release GMOs into the environment
State/territory flexibility within a national system of regulation	States and territories vary some rules under a national system of regulation to better suit their local circumstances and preferences	• State/territory variations in the National Building Code
Mutual recognition	Jurisdictions recognise, on a reciprocal basis, status given by another jurisdiction	• Mutual Recognition Agreement between jurisdictions
Coordinating bodies		
Ministerial council	Council of ministers (supported by senior officials) of each jurisdiction develops policy, oversees formulation of nationally consistent regulations, and in some cases regulatory decisions	• Oversight of the APVMA by the Primary Industries Ministerial Council, and of the NTC by the Australian Transport Council
National advisory agency	National agency provides advice on matters relevant to multiple regulators or jurisdictions	• NICNAS (advises ASCC, NTC, NDPSC, states and territories) • NDPSC (advises states and territories on poison scheduling) • Commonwealth health and environment departments provide (technical advice to the APVMA and NICNAS on chemical assessments)
Interagency committee	Committee for agencies to coordinate their actions and discuss common issues	• APVMA–state/territory Registration Liaison Committee • NICNAS–state/territory MOU Group

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Table 3.1 (continued)

Coordination option	*Description*	*Examples*
Coordination agreements		
Intergovernmental agreement for a regulatory regime	A written agreement between jurisdictions defining the governance arrangements and coordination mechanisms to be used to regulate a specific issue	• Intergovernmental agreements leading to national regulatory regimes coordinated by APVMA, FSANZ, NTC and OGTR
Statement of common principles	Governments agree to a common set of principles for regulating a particular issue	• COAG Principles for the Regulation of Ammonium Nitrate
MOU between agencies	Written agreement between agencies as to how they will coordinate their actions	• NICNAS–ASCC for OHS matters • Victoria WorkSafe–EPA for major hazard facilities
Specific forms of coordination		
Merge agencies/ consolidate functions within a given jurisdiction	Amend administrative arrangements to consolidate functions in fewer agencies	• Victoria's reorganisation of regulatory responsibilities following the Longford Gas disaster
Incentive payments	Jurisdictions are given financial incentives to implement a national system of regulation	• Incentive payments associated with national transport reforms
Exchange of information	Regulators (within and across jurisdictions) exchange information	• Product safety regulators
Enforcement coordination	Jurisdictions coordinate their enforcement	• Competent Authorities Panel for the ADG Code (managed by DITRDLG)
Single government contact for a given jurisdiction	A single agency acts as an intermediary to assist firms in complying with the requirements of multiple regulators	• Government 'one-stop shops' to facilitate major investment projects

a Acronyms in this table are defined in the list of abbreviations at the front of the report.

In some cases, the governance arrangements are working well, and align closely with best practice. For example, the transport model vests decision making in the ministerial council, and is underpinned by a strong IGA to implement regulations as uniformly as possible and to report back to the ministerial council where states diverge from the model regulations. Appointments to the standard-setting body — the National Transport Commission — are based on expertise not representation, the standards are based on UN standards, and the Competent Authorities Panel maintains consistency on an ongoing basis (chapter 7).

In other cases, governance arrangements have not worked as well. Although the Australian Safety and Compensation Council (ASCC) is a tripartite body under the Workplace Relations Ministers' Council (WRMC), it has developed and declared standards and codes which are subsequently, though somewhat inconsistently, adopted by individual jurisdictions. The Commission's preferred governance model suggests that this is inappropriate on three grounds: declaration for policy-relevant standards should be the responsibility of the ministerial council; ASCC membership should be based on knowledge and experience, not representation; and the standards should be adopted in a uniform or nationally consistent manner (chapter 6). COAG's communiqué from 3 July 2008, and the associated IGA for regulatory and operational reform in OHS addresses these concerns in part (COAG 2008c) The creation of a statutorily independent body providing advice to the WRMC, explicit decision making procedures for ministers, and a very tight constraint on jurisdictions maintaining agreed model regulations are positive features. However, maintenance of a tripartite approach to membership of the body to replace the ASCC remains a concern (chapter 6).

The Commission also has concerns about the proposal to develop a national framework for the environmental management of chemicals by augmenting the powers of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). Establishing an independent body under the policy guidance of the Environmental Protection and Heritage Council (EPHC) that would set standards (to be referenced by the states and territories), and clarifying NICNAS's role as an assessment body, is the Commission's preferred approach (chapter 9).

The proposed governance arrangements for developing and implementing controls to regulate chemicals of security concern have some sound features including a role for the Australian Attorney-General and nominated state and territory ministers in developing policy, and an IGA that commits the parties to joint development and implementation of appropriate controls. However, the absence of a formal voting mechanism is a concern (chapter 10).

Table 3.2 **Selected institutional arrangements for chemicals regulation**[a,b,c]

	Australian Health Ministers' Conference	*Workplace Relations Ministers' Council*	*Australian Transport Council*	*Primary Industries' Ministerial Council*	*Environment Protection and Heritage Council*	*Council of Australian Governments*
Role of Ministerial Council (and relevant standing committees)	Oversees drugs and poisons scheduling policy	Oversees ASCC but has tended to rubber stamp declarations of codes and standards. WRMC will have a much more explicit and formal role under recently agreed COAG reforms	Oversees the National Transport Commission; votes on enactment of model legislation	Provides policy direction to the APVMA and oversees state and territory control-of-use regulation	Oversees the development of a framework for national chemicals environmental management (NChEM)	Oversees policy on chemicals of security concern including security sensitive ammonium nitrate (SSAN) directly
Standard-setting body	Yes — National Drugs and Poisons Scheduling Committee — includes representatives from government, industry and consumer groups	Yes — ASCC a tripartite, non-statutory body that can declare standards, but this is to be replaced by a statutorily independent body	Yes — National Transport Commission, a statutory agency. Commissioners appointed on the basis of expertise	Yes — the APVMA sets conditions-of-use on agvet products; also assesses and registers agvet products	No	No
Intergovernmental agreement	No	Yes — COAG's commitments to establishing a national OHS arrangement are spelt out in an IGA	Yes — jurisdictions commit to implement agreed reforms uniformly and consistently and to report back on any divergences	Yes — underpins the creation and operation of the APVMA, a national regulator created through conferral of powers	Yes — concerns the adoption and further development of NChEM, subject to Ministerial Taskforce on Chemicals	None specifically — though principles for regulating security SSAN were agreed by COAG
State and territory adoption of national codes and standards	Most poisons scheduling decisions adopted by reference, but states and territories may apply additional controls (for example, for licensing and storage)	Varies by jurisdiction and code/standard: some referenced, some rewritten, some jurisdictions have not acted on all codes (for example, major hazard facilities)	A high degree of uniformity has been achieved through template legislation, but now moving to model regulation approach	Template legislation to underpin APVMA and Agvet code But jurisdictions separately regulate control-of-use and this varies	No formal link, but jurisdictions take varying action in response to recommendations of NICNAS	Inconsistent application of SSAN principles

a Other ministerial councils that have an interest in chemicals regulation include: the Ministerial Council on Consumer Affairs and the Australia and New Zealand Food Regulation Ministerial Council. **b** NICNAS also makes recommendations to most of the standard-setting bodies shown (the exception being the APVMA, which undertakes its own assessments). **c** Acronyms in this table are defined in the list of abbreviations at the front of the report.

Intergovernmental agreements

Intergovernmental agreements play a pivotal role in establishing and maintaining national frameworks where policy responsibility is shared by the Commonwealth, states and territories. They generally set out the objectives and scope of responsibility of the council and of the various members, the governance arrangements including decision-making and voting rules, legislative commitments, institutional support and cost sharing. Overall responsibility for implementing such an agreement resides with the relevant ministerial council.[3]

Intergovernmental agreements are clearly essential where a national regulator is established by conferral of powers, as in the case of the Australian Pesticides and Veterinary Medicines Authority (APVMA). Such IGAs typically address the commitment of the parties to pass legislation to allow the creation of the national regulator and to maintain that legislation consistently over time.

Intergovernmental agreements in areas where individual jurisdictions have retained their powers generally commit the parties to use their best endeavours to adopt agreed changes in standards in a uniform or nationally consistent manner (for example, transport). They may also contain undertakings to maintain agreed regulations in a nationally consistent manner. For example, the transport IGA requires the Australian Transport Council (ATC) and National Transport Commission (NTC) to be notified of any 'exceptional circumstance' changes that a jurisdiction unilaterally makes, together with a statement of reasons. The IGA recently agreed by COAG to underpin a national approach to OHS regulation will bind the signatories even more tightly. It requires that they will not amend or introduce legislation that would materially affect the operation of proposed model legislation unless the WRMC expressly endorses it, in which case all jurisdictions would be required to follow suit.

Voting rules are an important feature of IGAs, legislation or other documentation that establish multilateral institutions. One of the better examples appears to be the OHS IGA signed on 3 July 2008, which requires a two-thirds majority for decision making (although a consensus decision is required for the declaration of national model legislation, regulations and codes of practice). Another example is transport, where there are several sets of voting rules: a simple majority vote at the ministerial council is required to approve most measures; while a two-thirds majority is

[3] For example, transport regulation is nationally coordinated according to the Inter-Governmental Agreement for Regulatory and Operational Reform in Road, Rail and Intermodal Transport. This makes the Australian Transport Council — the ministerial council for transport — the governing body for nationally coordinated arrangements (chapter 7).

required to approve a recommendation on road user charging principles. A unanimous vote is required to delegate the council's powers and functions to a minister (chapter 7). In contrast, a single member of the ministerial council for food regulation can call for a review of measures developed by its national standard-setting body (chapter 5).

Intergovernmental agreements can establish institutional structures, which are then embodied in legislation, such as the NTC and the APVMA. Supplementing the agreements, there can also be a set of formal arrangements in place which clarify the roles and responsibilities of agencies within the member jurisdictions, and the coordination mechanisms between them. This can involve one or more memoranda of understanding (MOU) between agencies, an interagency committee, the power to exchange confidential information, and/or a legislative requirement to consult other agencies about a particular issue.

The Commission considers that more widespread use of IGAs and MOUs is warranted in promoting consistent national frameworks for regulating chemicals. Agreements underpinning the proposed national frameworks for the environmental management of chemicals and the regulation of chemicals of security concern will be important in this respect.

Legislative arrangements

Whereas a referral of powers by the states to the Commonwealth ensures national uniformity, it is rarely used. Nationally coordinated regulations, where power has been retained by the states, can be achieved through other legislative arrangements:

- Conferral of powers to the Commonwealth — this has often been effective in establishing a national body that administers uniform regulations. States retain the option of regulating independently at some future time.
- State/territory regulation based on national standards — a national standard-setting body drafts regulations that states and territories incorporate or translate into their own legislation.

A regulatory system can draw on both of the above approaches. For example, agricultural and veterinary chemicals are currently subject to both a conferral of powers for chemical assessment and standard setting, and state/territory regulation for administration and enforcement (chapter 8).[4]

4 A conferral of powers can also be implemented using either a template or model approach. An example of the template approach is the national controls on the supply of agricultural and veterinary chemicals up to the point of retail sale (managed by the APVMA) (chapter 8). An example of the model approach is the national licensing regime for genetically modified

Where administration and enforcement is to occur at the sub-national level, the regulations drafted by a national body can be translated into state/territory law using either template legislation or national model regulations. The template approach could be considered best practice because it essentially involves a single piece of legislation being applied to every jurisdiction, thus minimising inconsistencies across jurisdictions. However, the negotiations required to reach common agreement on the template Act can be protracted and, in practice, referencing does not prevent jurisdictions from omitting or amending selected parts of the template.

Under the model approach, each jurisdiction separately adapts the text of nationally agreed regulations into their own laws. This increases the administrative burden and creates an opportunity for individual jurisdictions to unilaterally deviate from nationally agreed standards, possibly unintentionally because of different institutional structures, legislative drafting conventions and interfaces with other local legislation. The greatest strength of the model approach is its flexibility, but this is also its greatest weakness. Jurisdictions have an incentive to compromise on negotiating the model knowing that it could subsequently be amended anyway.

Sometimes a combination of template and model approaches is used. Under this arrangement, each jurisdiction specifies the broad regulatory requirements in its own legislation (model approach), but all refer to a common national code of practice for detailed technical requirements (template approach).[5] Such an arrangement can produce the greatest level of national uniformity at the operational level, through a single code, while recognising the diversity of the underlying legislation.

Corporate governance

Another important consideration is how well specific agencies responsible for chemical assessment, standard setting, or administration and enforcement are governed. The Australian Government commissioned a report on corporate governance in the public sector, known as the Uhrig Review (Uhrig 2003). It concluded that it is generally inappropriate for Commonwealth statutory authorities to have a governing board, where they have limited powers to act unilaterally (box 3.1). Instead, it was recommended that the executive management of statutory authorities report directly to the relevant minister. A governing board was, however,

organisms, which relies on state and territory legislation closely modelled on a Commonwealth Act (managed by the Office of the Gene Technology Regulator).

5 For example, each state and territory has its own legislation for food safety, but they all refer to the Australia New Zealand Food Standards Code for technical requirements.

considered appropriate for authorities not entirely the responsibility of the Commonwealth, or which undertook predominantly commercial operations.

While the Uhrig Review did not generally favour a governing board for statutory authorities, it noted that there could be a case for having an advisory board that reports to a minister:

> The creation of an advisory board on the implementation of policy will be useful in circumstances where the government is introducing policy which has the potential for significant impact on the community. Through an advisory board the government can receive feedback on how to implement policy in the most effective manner … Where an advisory board is appropriate … the board should operate based on references from a minister and should report directly to the minister with its findings. (Uhrig 2003, p. 93)

Commonwealth guidelines on governance arrangements for government bodies take a slightly different approach by envisaging that advisory boards report to an authority's chief executive or, where it exists, governing board:

> Advisory boards can provide a forum for the representation of stakeholder views without the stakeholders being involved in the governance of the body. It can also provide a useful consultative mechanism for the chief executive … The advisory board's main role might be to provide perspectives from key stakeholders, eminent persons and/or business and broader community interests … (DOFA 2005b, p. 38)

For example, in line with the Government's response to Uhrig, the APVMA's corporate governance arrangements were realigned. A governing board was abolished and in its place an advisory board to the chief executive was created:

> The role of the Advisory Board is to provide advice and make recommendations to the CEO. The Advisory Board does not have decision-making power, but assists to inform the CEO and provides an expert consultative mechanism. (APVMA nd)[6]

The Commission considers that such advisory boards can be useful in ensuring the effectiveness of the operation of the relevant organisation. Their appropriateness is considered on a case-by-case basis in following chapters.

6 Prior to 1 July 2007, the APVMA had a governing board comprising a similar range of skills and experiences to those of its current advisory board. The governing board was disbanded in response to the recommendations of the Uhrig Review.

Box 3.1 **The Uhrig Review of corporate governance**

In 2002, the Australian Government commissioned a review of corporate governance of Commonwealth statutory authorities and office holders. The resulting report — known as the Uhrig Review — concluded that most statutory authorities should not be governed by a board because it is not feasible for the minister and/or Parliament to give a board full power to act, including to set policy. It was noted:

> Where a board has limited power to act, its ability to provide governance is reduced and its existence adds another layer, potentially clouding accountabilities. (Uhrig 2003, p. 6)

The appropriate governance structure for most statutory authorities was deemed to be an 'executive management template' in which the executive management — headed by a chief executive or one or more commissioners — reports directly to the responsible minister. This included statutory authorities administering regulation.

The alternative of having a governing board (the 'board template') was only considered to be appropriate if either:

- the statutory authority undertakes predominately commercial operations (because a board is more likely to be given the necessary powers to govern such an authority)
- the Commonwealth does not fully own the equity of the authority, or is not solely responsible for outcomes (in which case it is unlikely that all parties will agree to an Australian Government minister solely governing the authority on their behalf). The main examples of this were said to be where there are multiple accountabilities, or where funding is predominantly from private sources (such as industry levies).

In 2004, the Australian Government endorsed the Uhrig Review's recommendation that boards should only be used when they can be given full power to act. It also announced that it would implement the recommended governance templates. This was subsequently reflected in official guidelines on the governance arrangements for Commonwealth bodies.

Source: DOFA (2005a); Uhrig (2003).

3.4 Developing a national chemicals policy

Currently there is no single forum for developing a national chemicals policy. Instead, there are various forums or mechanisms that provide for some coordination of policy development and service delivery both at the national level and at the state and territory level. As the Environment Protection and Heritage Standing Committee (EPHSC) has noted:

> Responsibility for system-wide chemical policy is unclear. No single agency, Minister or Ministerial Council at either Australian Government or State and Territory level has a designated policy leadership or oversight role in relation to chemicals. This can result in a system that is reactive rather than proactive in identifying and managing chemical issues and can result in inconsistencies of approach between sectors. (sub. 20, p. 25)

The Queensland Government commented similarly and suggested that:

> A coordinated approach to policy development should be considered as one of the first steps taken in addressing the proliferation of, and inconsistency in, chemicals and plastic regulation. (sub. 66, p. 2)

Some Ministerial Councils already include mechanisms for cross portfolio consultation on important matters. For example, the Product Safety and Integrity Committee, a committee of officials supporting the Primary Industries Ministerial Council:

> … involves representatives of other ministerial councils which have an interest in managing agricultural and veterinary chemicals:
>
> - the Workplace Relations Ministers' Council
> - the Australian Health Ministers' Conference and
> - the Environment Protection and Heritage Council. (PSIC nd)

Cross portfolio coordination can also be achieved through the use of taskforces or working groups to develop whole of government responses on an *ad hoc* basis. For example, in response to perceived inadequacies in the national management of the environmental impact of chemicals, the EPHC in 2002 established the National Taskforce on Chemicals Management and Regulation. The Taskforce comprised representatives from ministerial councils covering the environment, health, primary industries and workplace relations. And as noted, a special ministerial taskforce has been formed to develop a policy response to this report and to consider proposed reforms to the environmental management of chemicals (chapter 9). But this taskforce will be disbanded when it has done its job.

Various MOUs and service level agreements assist agencies within individual jurisdictions to coordinate their activities. For example, NICNAS and the Australian Safety and Compensation Council (ASCC) have an MOU to facilitate the application of OHS policy to NICNAS's assessments. And at the state level, an MOU between WorkSafe Victoria and the Victorian Environmental Protection Agency covers the joint inspection of major hazard facilities.[7] These arrangements have the effect of codifying the contractual obligations of each party.

Administrative arrangements have also helped coordinate policy development and service delivery. For example, in Victoria, many chemicals and plastics regulations are brought together under WorkSafe, including those covering OHS, transport, and major hazard facilities. Informal networks of officials within and across jurisdictions also facilitate policy development and service delivery. However, these can wax and wane as personnel change.

7 This MOU is currently being renegotiated.

A standing committee on chemicals

The Commission considers that while the mechanisms discussed above are generally necessary, they are not sufficient to achieve the level of policy coordination required, and hence there is a strong case for the creation of a new governance mechanism. Options include the establishment of either a new ministerial council on chemicals, or a body to coordinate policy advice to the existing ministerial councils, such as a standing committee.

Creating a new ministerial council would give chemicals policy much greater prominence but might not achieve a high degree of coordination. Most ministerial councils have a one-on-one correspondence between the policy area and the portfolio ministers who are members (for example, the Workplace Relations' Ministerial Council and employment ministers). As chemicals policy encompasses so many areas, it would be difficult to identify appropriate ministerial representation. In this respect it is instructive to observe that the COAG Ministerial Taskforce on Chemicals and Plastics Regulation Reform has membership drawn from portfolios such as: Environment and Climate Change; Industry and State Development; Transport, Trade, Employment and Industrial Relations; and Employment Protection and Regional Development. Whichever portfolio was chosen for a new council, ministers would have little knowledge of, and control over, regulations not within their direct portfolio interests. Furthermore, COAG generally discourages the creation of new ministerial councils (box 3.2).

The more effective option would be to establish a formal mechanism for coordinating policy advice on the range of chemical issues that are addressed by the relevant ministerial councils and other policy groups. As the Department of Agriculture, Fisheries and Forestry has stated:

> Further rationalisation of the regulatory requirements of different portfolios/agencies could be achieved by establishing a mechanism for cross-portfolio discussion of policy approaches or for generating awareness and understanding of programs and initiatives already in place which could be used to meet common risk management objectives. Improved cross-portfolio coordination would acknowledge that, whilst … some of the risk management objectives of the different chemical regulatory schemes are the same or similar, they have different purposes and, therefore, they also cover other aspects. (sub. 39, pp. 11–12)

The APVMA is of a similar view (sub. 59, p. 37).

Box 3.2 **COAG guidelines for the creation of new ministerial councils**

1. There should be a presumption against the creation of new Ministerial Councils.
2. If a new Council is to be created, the following tests should apply.
   - Could the work proposed for the new Council be done by an existing Council?
   - If not, could the new Council be brought under the umbrella of an existing Council or under an arrangement with an existing Council?
   - If not, is there scope for adjustment and/or rationalisation of the work of existing Councils to encompass the work proposed for the new Council?
3. If it is considered necessary to create a new Council:
   - Heads of Government must formally agree to its creation and terms of reference
   - it should be supported by existing Secretariats, wherever possible
   - it must comply with the Broad Protocols and General Principles for the Operation of Ministerial Councils
   - consideration should be given to inserting a sunset clause in its terms of reference.
4. If legislation is considered necessary to confer functions and powers on a Council, the Council should not specifically be named in the legislation, allowing for greater flexibility in the roles and responsibilities of statutory Councils.

Agreed to by COAG on 8 June 2001.

Source: COAG (2001).

The Commission is of a similar view and considers that this could be best implemented through a dedicated standing committee of officials that includes representation across all relevant ministerial councils. The committee would:

- be a forum for exchange of ideas and information
- provide recommendations to the respective ministerial councils on how chemicals policy initiatives that have cross-portfolio implications might be best progressed
- provide an ongoing monitoring role — after the Ministerial Taskforce on Chemicals and Plastics Regulation Reform has been wound up — in gauging the effectiveness and efficiency of chemicals regulation in the future
- oversee the development of RISs where regulations have implications for more than one regulatory regime, though carriage of the preparation of the RIS would continue to reside with the portfolio or standard-setting body most affected.

In the draft report, the Commission proposed that, for administrative reasons, such a standing committee on chemicals would need to report to a particular ministerial

council. It was suggested that as many chemical regulatory issues impact on human health in one way or another, there was some merit in establishing a standing committee on chemicals under the Australian Health Ministers' Conference (AHMC). However, it was stressed that it be set up with a charter that ensures it operates as a cross-portfolio coordinating committee.

The broad idea of creating such a committee received widespread support from many study participants, though there were some concerns:

- The committee should not become another layer of bureaucracy in an already complicated system (for example, Croplife, sub. DR80, p. 2; SA Government, sub. DR110, p. 4; Queensland Government, sub. DR121, p. 8).
- The committee should not replace other successful coordinating mechanisms, such as Product Safety and Integrity Committee (PSIC) (Victorian Government, sub. DR112, p. 6).
- Some industry participants were concerned about stakeholder input (for example, ACCI, sub. DR92, p. 4).
- The committee could create such a focus on chemicals that this could lead to inconsistencies in the way other dangerous goods were regulated for transport purposes (Australian Railways Association, sub. DR95, p. 9).
- Who the committee would be accountable to and the idea of housing it under the AHMC in particular.

The Commission shares the concern that this should not add to red tape. Rather its focus should be on developing a sound cross-portfolio perspective that would feed into better policy making by the stakeholder ministerial councils. It would not have a decision-making role and would not replace existing standing committees. Nor need it impinge on existing cross-portfolio consultation mechanisms set up under particular portfolios (such as the PSIC), though the Commission considers that governments should keep an open mind about this and rationalise the number of bodies where it is effective and efficient to do so.

The Commission appreciates industry concern about having appropriate stakeholder input. Industry groups have long fought for a coordinated approach to chemical policy and understandably would be concerned if its voice was not being heard. However, the Commission considers that stakeholder input is best achieved either through properly constituted governance arrangements within each of the policy portfolios (that is, that industry has an advisory role in developing but not setting standards) or though general consultative arrangements. Given that the standing committee on chemicals would be a coordinating mechanism it would not be necessary to establish its own formal consulting arrangements.

With respect to the Australian Railways Association's concern that a focus on chemicals could lead to inconsistencies, the Commission's view is that the transport of dangerous goods would continue to be the responsibility of the NTC and that it would continue to cover all dangerous goods, not just chemicals.

No issue attracted as much attention as the governance arrangements under which the standing committee on chemicals would operate. Some participants welcomed the suggestion that it be housed under the AHMC (for example, the SA Government, sub. DR110, p. 3). Others thought that, given its focus on ongoing regulatory reform, it should be responsible to the Chair of the COAG Business Regulation and Competition Working Group (for example, CPLG, sub. DR113, p. 21). Other possibilities were that it report to the WRMC (a view implied by the Victorian Government on the basis that workplace issues were paramount, sub. DR112, p. 6), or that it report directly to COAG itself (for example, Queensland Government, sub. DR121, p. 8; APVMA, sub. DR105, pp. 4–5; DAFF, sub. DR120, p. 6).

The Commission had proposed that it 'report' to the AHMC but only for administrative reasons, presuming that alignment with a particular ministerial council would give it greater legitimacy. However, the suggestion that it would be accountable directly to COAG also has merit. This would allow the standing committee on chemicals to operate more independently in providing advice to stakeholder ministerial councils and lessen the risk of capture. And as some participants have emphasised, if differences between portfolios remained, having the standing committee on chemicals report to COAG would allow those differences to be addressed at that level.

Having the standing committee on chemicals make recommendations to all ministerial councils, but being accountable to COAG would make it a more neutral arrangement. However, this leaves the question of where it would draw administrative support from. A Commonwealth Government agency would seem appropriate given the emphasis on a national approach to regulation. Whichever portfolio department was chosen there would be a risk that it could be captured to some extent, particularly if the department was also providing support for one or more of the standard-setting bodies. But even then a degree of independence can be created through having a clear charter for the standing committee on chemicals emphasising that it must provide advice that is in the broad public interest.

On balance, the Commission considers that the Department of Innovation, Industry, Science and Research would be an appropriate department to provide secretariat support. It has had a long association with chemicals regulatory reform, and is providing support for the current Ministerial Taskforce (chaired by one of the two ministers it serves, the Minister Assisting the Finance Minister on Deregulation, and

the Minister for Small Business, Independent Contractors and the Service Economy). When the Ministerial Taskforce completes its work the department could seamlessly move into supporting the standing committee on chemicals.

The implementation of any new governance structure like this will be most effective if it is supported by the various stakeholders and, to this end, a 'heads of agreement' that would set out the responsibilities of the standing committee on chemicals to the respective ministerial councils would seem appropriate. So to would a sunset clause requiring that the effectiveness and efficiency of the standing committee on chemicals be reviewed after five years.

This committee would help ensure that all ministerial councils are provided with appropriate policy advice on system-wide regulatory issues. But much would still depend on effective communication between respective councils and agencies, and on the arrangements that the states and territories put in place in their own jurisdictions.

RECOMMENDATION 3.1

Subsequent to the COAG Ministerial Taskforce on Chemicals and Plastics Regulation Reform having completed its reference, the Commonwealth, states and territories should establish a Standing Committee on Chemicals comprising representatives of all ministerial councils that have responsibility for chemicals regulation. It would:

- ***provide an ongoing forum for assessing:***
  - ***the consistency of chemicals-specific policy settings across the various areas of concern, including public health, workplace and on-farm safety, transport safety, environment protection and national security***
  - ***the effectiveness and efficiency of the overall chemicals-specific regulatory system***
- ***oversee the consistent application of chemical hazard and risk-assessment methodologies and international standards such as the Globally Harmonised System of Classification and Labelling of Chemicals***
- ***support the coordinated development of regulatory proposals that have cross-portfolio implications, including the conduct of regulatory impact assessments***
- ***make recommendations for specific actions by relevant ministerial councils***
- ***be supported by a secretariat in the Department of Innovation, Industry, Science and Research.***

4 National hazard and risk assessment

Key points

- Government involvement in hazard and risk assessment is warranted due to the information failures and public good nature of the information.
- The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) focuses on the assessment of hazards and risks of industrial chemicals, primarily producing recommendations to risk management standard-setting bodies.
- NICNAS has some regulatory powers to manage chemical risks, however it is recommended that these generally be transferred to other bodies to allow NICNAS to focus on chemical assessments.
- The internal governance structures of NICNAS could be strengthened with the introduction of a statutory advisory body to support its Director.
- The effectiveness of NICNAS assessments is limited given that the majority of currently used industrial chemicals have been grandfathered onto the scheme without prior assessment. Review of those chemicals has proceeded slowly to date and needs to be accelerated.
- The efficiency of NICNAS assessments could be improved through better arrangements for low regulatory concern chemicals; greater utilisation of modelling; and greater reliance on international assessment data.
- There may be gains in harmonising the assessment regimes via introducing a coordinating mechanism and consolidating common aspects of assessments.

The hazard and risk assessment of chemicals is one step in the regulation of their use in the workplace, their consumption by humans and animals, and their disposal or escape into the environment (discussed in following chapters). Only after the hazards have been identified and an assessment made of the likely risks, can appropriate risk-management decisions be taken for individual chemicals within agreed standards.

Two chemical assessment schemes — one applying to industrial chemicals and the other to agricultural and veterinary (agvet) chemicals — fall within the scope of this study. However, of these schemes, only the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is a standalone chemical assessment scheme. Agvet chemical product assessment and registration is part of a dedicated, vertically-integrated regulatory regime that manages the risks of agvet

chemicals. The primary focus of this chapter is on issues pertaining to the operation of NICNAS. The chapter also discusses the potential for future consolidation of chemical hazard and risk assessment functions within a single agency. Issues that are specific to assessment of agvet chemicals are discussed in the broader context of agvet chemicals regulation in chapter 8.

4.1 The case for regulatory assessment of chemicals

There is a number of reasons why government involvement in the hazard and risk assessment process may be appropriate.

First, there can be information failures. Much of the information needed to assess the possible risks posed by particular chemicals is held by chemical producers. These firms will have some knowledge of the hazards but will have only limited incentives to make this information available, or to more fully assess the risks to third parties of using the chemical. Hence, regulation to elicit information may be justified.

Even if full disclosure of information occurs, chemical risk assessment is also often highly technical in nature and not readily understood by many individuals or firms. Even presented with the raw data or hazards, few would be able to translate this into an appropriate risk management strategy. Hence, interpretation of the implications of this information by assessment agencies and standard-setting bodies, or other regulatory agencies, can be justified.

Second, there can be a public-good element to information provision. The appropriate level of private provision of chemical assessments would be difficult to achieve because of the cost and difficulty of charging the large number of individuals and firms who might benefit from it and of quarantining the information to those who had paid for it. Because the benefits of the assessment information are related to the extent to which it is disseminated, assessment agencies typically make this information freely available, except where there may be confidentiality concerns.

Third, independent government provision of this service or auditing of third-party assessment service providers helps ensure the integrity of the assessments, and provides a safeguard for the public interest.

While these arguments provide a basis for some form of regulatory intervention, regulatory agencies are still able to make use of market mechanisms or private sector involvement to improve the efficiency of the process — for example, parts of the assessment might be contracted out.

There are advantages in having the chemical assessments undertaken at the national rather than jurisdictional level. There are significant resource savings in having a single national assessment available to all jurisdictions and indeed international scale economies in assessments are arising from the increased cooperation between hazard-assessment bodies in different countries. A single national body can also better use the limited supply of technical expertise needed to undertake assessments and further develop that expertise. A national approach also avoids the costs to suppliers and users of different assessments in individual jurisdictions.

4.2 Regulatory arrangements for industrial chemicals

Scope

Under the *Industrial Chemicals (Notification And Assessment) Act 1989* (Cwlth) (ICNA Act), an industrial chemical is any chemical that has an industrial use. This includes specialty chemicals, dyes, solvents, adhesives, plastics, laboratory chemicals, chemicals used in mineral and petroleum processing, refrigeration, printing and photocopying, paints and coatings, as well as chemicals used in the home, such as cleaning products, cosmetics and toiletries.

Reflecting this broad scope, NICNAS defines industrial chemicals by the exclusion of other types of chemicals. Chemicals that are used solely as therapeutic agents, agricultural and/or veterinary chemicals, and/or food or food additives are subject to regulation by other bodies and are outside the scope of NICNAS. If the chemical that is being imported and/or manufactured does not fit solely into one of these categories, then notification to NICNAS may be required.

Institutional arrangements

NICNAS is a statutory scheme within the portfolio of the Minister for Health and Ageing. The Director of NICNAS is a statutory office holder with specific functions and powers under the ICNA Act. In the exercise of these functions, the Director is responsible to the Minister for Health and Ageing through the Parliamentary Secretary.

NICNAS's legislative role and responsibilities are focused on the scientific assessment of chemical risk to public health, occupational health and safety (OHS), and the environment. NICNAS then makes recommendations for controlling these risks at each stage of the life cycle of each chemical. NICNAS also has some power to regulate the use of new industrial chemicals via its mandate to prescribe

conditions of use for permits. In addition, the Director of NICNAS has the power to annotate particular conditions of use on the Australian Inventory of Chemical Substances (AICS), which has the effect of requiring a new assessment for uses that are outside those permitted. NICNAS also has a regulatory power in administering the Cosmetics Standard 2007 — a schedule to the ICNA Act that imposes labelling requirements on cosmetics manufacturers and importers (chapter 5). Finally, NICNAS is responsible for implementing Australia's obligations under two international treaties — the Stockholm Convention and the Rotterdam Convention.

NICNAS does not specifically register chemicals or products, in the sense that it can not prohibit their introduction after assessment. This is in contrast to the other national chemicals schemes, such as those that regulate agvet chemicals and medicines and medicinal products, all of which have a product registration function. NICNAS also does not have legislative powers to directly ban, or phase out chemicals. Instead, NICNAS can make recommendations to other regulatory authorities for such action.

Funding

NICNAS operates on cost-recovery principles and is principally funded via company registration fees, and fees and administration charges for new assessments. In 2006-07, total revenue amounted to $8.6 million. Around $5.9 million (69 per cent of total revenue) was collected via company registration fees, with most of the remainder collected via chemical assessment fees (DOHA 2007a).

Assessment of new chemicals

Chemicals currently available for use in Australia are listed on the AICS (box 4.1). The AICS is the legal device that distinguishes new from existing industrial chemicals and determines whether an industrial chemical can be used commercially in Australia.[1]

All new (to Australia) industrial chemicals must be notified to NICNAS for scientific risk assessment. Some aspects of the assessments (for example, OHS) are undertaken within NICNAS. NICNAS also contracts assessment work to other Australian Government agencies, such as the Department of the Environment,

[1] The AICS is not the exclusive legal device that allows the introduction of chemicals — AICS listing typically only occurs five years after assessment and during that period assessment certificates are the instrument that allows the manufacturer or supplier to introduce the chemical .

Water, Heritage and the Arts (DEWHA) (for environmental assessments) and the Department of Health and Ageing (for public health assessments, where there is likely to be any public exposure to industrial chemicals).

At the end of the assessment, NICNAS produces a report containing OHS, health and environment protection recommendations, and issues an assessment certificate, which allows the chemical to be imported into or manufactured in Australia.

Permits

NICNAS has powers to issue permits for the introduction of chemicals that have not undergone a full notification and assessment process. Permits can be issued in a number of circumstances, including: for low-volume uses; for commercial evaluation; and for early introduction while the assessment is being completed. NICNAS has powers to set conditions on permits.

Assessment of existing chemicals

Upon the establishment of NICNAS in 1990, all chemicals in commercial use in Australia were transferred (or grandfathered) onto the AICS (box 4.1).

Box 4.1 The Australian Inventory of Chemical Substances

The Australian Inventory of Chemical Substances (AICS) lists the industrial chemicals that are currently available for use in Australia. It is therefore used to distinguish 'new' from 'existing' industrial chemicals — that is, chemicals not on the AICS are deemed new chemicals.

Some chemicals may only be available for specific or conditional use and this is detailed in the AICS. The AICS is a list of chemical identity data and does not contain information on toxicity, manufacturers or importers. In some instances, however, the AICS does identify the classification of a chemical under another national scheme.

When the AICS was established, all industrial chemicals already in commercial use in Australia from 1 January 1977 to 28 February 1990 were included as 'grandfathered' chemicals. This included approximately 36 000 non-confidential chemicals, with 2500 in the Trade Name section and 1000 in the Confidential section. Additional (eligible) chemicals were added during a two-year amnesty from 1993 to 1995. Since 1990, there have been approximately 2000 new chemicals added to the AICS after NICNAS assessments.

Sources: DOHA (2004b); NICNAS (sub. 36).

Relatively few of these chemicals have been subsequently assessed. This means that most of the chemicals in use in Australia remain unassessed, or not fully assessed, for their health and environmental risks.

A formal process has been established to identify and assess Priority Existing Chemicals (PEC). A chemical on the AICS may be nominated for inclusion on the PEC list by anyone concerned about its impacts on human health or the environment. NICNAS assesses all nominated chemicals against a set of criteria to determine whether the concerns are sufficient to declare a chemical a priority existing chemical.

NICNAS (company) registration

From 1 September 2004, all importers and/or manufacturers of industrial chemicals for commercial purposes must register with NICNAS. Registration involves payment of an annual registration fee, based on the total value of industrial chemicals imported/manufactured each year.

Interface with other national schemes

The NICNAS industrial chemical assessments and recommendations inform a number of national regulatory frameworks that are currently in place in Australia. These include:

- national model regulations and codes developed by the Australian Safety and Compensation Council for the control of workplace hazardous substances, and for storage and handling of dangerous goods
- the national code for land transport of dangerous goods, as developed by the National Transport Commission
- National Drugs and Poisons Scheduling Committee decisions.

Interface with state government regulators

While NICNAS recommendations are advisory in nature, a memorandum of understanding (MOU) was signed in 1991 between the Commonwealth, state and territory governments, requiring each state and territory:

> … to consider and wherever possible implement each recommendation in an assessment report published by the Director of NICNAS and to inform the Director of any consequential action taken in respect of any recommendations. (DOHA 2003a, p. 96)

The States and Territories Memorandum of Understanding Group has been set up to act as a conduit for the free flow of information between the states and territories and NICNAS on OHS, environmental and health matters relating to the use of chemicals in Australia (DOHA 2006b). In all cases, states and territories have nominated OHS agencies to this group (NICNAS, sub. 36).

4.3 Effectiveness and efficiency of industrial chemicals assessment

Clarifying the objectives — recognition of effectiveness and efficiency principles

As discussed earlier (chapter 2), regulatory intervention should address market failures to the extent that doing so provides a net community benefit. NICNAS operations impose costs (such as the various requirements to be met by notifiers of new chemicals) and generate benefits to the public (through contributing to the risk management of industrial chemicals). However, there is no formal obligation on NICNAS to perform its functions in a manner that maximises net community benefit.[2] Without such an obligation there is a risk that NICNAS might not focus its risk assessment activity appropriately, and might become unduly risk averse in the way it conducts risk assessments and the demands it places on notifiers.

NICNAS argued that it already aimed to achieve a community benefit when setting its assessment requirements:

> In undertaking its risk assessment functions, NICNAS aims for the risk assessment effort to be commensurate with the hazard and/or exposure to the chemical, where this can be defined sufficiently in advance of the assessment. The reforms that have been progressively introduced into NICNAS's notification and assessment framework have sought to further this objective. (sub. DR106, p. 2)

The Commission accepts that some worthwhile improvements have been made in the design and administration of the scheme, which have had the effect of more appropriately balancing the costs of assessment with the benefits of reducing the risks posed by industrial chemicals. But in some cases, such as the administration of chemicals of low regulatory concern, elements of undue risk aversion are creeping back into the system. Further, the large backlog of unassessed existing chemicals raises questions of whether the scheme has been appropriately prioritising its

[2] Currently, the legislated objectives of NICNAS are to maintain a national chemical assessment scheme to protect human health and the environment, and to perform a range of assessment, information provision and regulatory functions.

resources and assessment effort to effectively manage aggregate chemical risk. (These issues are discussed later in the chapter.) However well the current administration might be achieving its stated aims, NICNAS lacks the explicit statutory basis to make this focus an ongoing feature of assessment.

A broad framework for an effective and efficient assessment regime should consist of the following complementary objectives:

- ensuring that the requirements of the scheme seek to reduce chemical risks to levels acceptable to the community
- ensuring that assessment effort is prioritised to most effectively manage the aggregate risk of all chemicals
- ensuring that the objectives of the scheme are achieved at the lowest cost to the community (box 4.2).

Box 4.2 **Features of an effective and efficient chemical assessment scheme**

- The requirements of the scheme should be set to reduce overall chemical risks to levels acceptable to the community, taking into account the associated costs and benefits.
  - At a minimum there should be recognition that zero risk is very costly to achieve and that there are tradeoffs (including between different risks) involved in reducing a particular risk.
  - The value imputed to accepted risk should be broadly consistent with other regulations that seek to address similar objectives. (This is because if a particular risk can be reduced at a lower cost to the community under a different scheme, resources should be shifted to that scheme.)
- Assessment effort associated with particular chemicals should be commensurate to their *relative* risk.
  - The assessment agency should have provisions for prioritising the allocation of its scarce resources on the basis of chemical risk. The administrative resources should be allocated in a way that minimises the aggregate risk of all chemicals irrespective of their status as new or grandfathered.
  - The assessment requirements should be calibrated in a way that minimises biases against the introduction of safer alternatives by manufacturers/importers.

(Continued next page)

Box 4.2 (continued)

- The assessment scheme should operate cost effectively.
  - The cost to the assessment agency of conducting the assessments should be minimised through choice of assessment methodology, as well as appropriate performance monitoring and review.
  - Unnecessary data requirements on introducers of chemicals should be eliminated.
  - Duplication with other national and international assessments should be minimised.
  - Licensing controls that complement or substitute the assessment should achieve their risk-management objectives at the lowest aggregate compliance and administrative cost.

The Commission considers that, as a matter of principle, there should be a formal obligation on NICNAS to ensure that the requirements of the scheme are commensurate with the chemical risks and that its assessment effort is directed to most effectively managing the aggregate risk of all chemicals. Recognition of the above objectives would be a useful starting point in improving the effectiveness and efficiency of NICNAS.

RECOMMENDATION 4.1

The Australian Government should impose a statutory obligation on NICNAS to ensure that:

- ***the costs of chemical assessments are commensurate with the risks posed by the chemicals concerned***
- ***its assessment priorities are directed to the most efficient management of the aggregate risk of all industrial chemicals.***

Improving governance structures

Good governance requires that the relationships between the agency performing the hazard and risk assessments and the relevant policy and standard-setting bodies are clearly defined and underpinned by appropriate consultation and coordination mechanisms.

NICNAS's external governance arrangements are broadly consistent with its functions as an assessment agency in that its Director is accountable to the Parliamentary Secretary to the Minister for Health and Ageing for the overall legislative and financial performance of NICNAS. If it were to retain or be given

greater powers over the control of use of chemicals it would be more appropriate to provide oversight through an interjurisdictional body. However, the Commission has concluded that NICNAS should be, for the most part, confined to assessment (discussed below), and, therefore, the current external governance arrangements are considered to be sound.

On the other hand, there are grounds to strengthen the internal governance structures. Currently, two non-statutory bodies — the Community Engagement Forum and the Industry Government Consultative Committee — provide for some consultation with stakeholders. However, there is currently no statutory requirement for an expert consultative body — similar to the advisory board of the Australian Pesticides and Veterinary Medicines Authority (APVMA) (chapter 8) and consistent with the Australian Government's response to the implementation of the Uhrig reforms to corporate governance (chapter 3) — to advise the NICNAS Director. Even though the Commission recommends that NICNAS functions be limited to assessment, it considers that there are still sufficient grounds for introducing such a statutory requirement. Without such support there is the risk that NICNAS would be more risk averse than it should. Formalising and strengthening the current consultative mechanisms established administratively by its Director should help NICNAS operate in a more strategic manner.

RECOMMENDATION 4.2

The Australian Government should establish a technical advisory committee within NICNAS, as a statutory requirement.

Scope of NICNAS

Separation of risk assessment and risk management functions

As discussed earlier, NICNAS currently has a combination of chemical assessment and standard-setting functions. The Commission's preferred institutional approach to the regulation of chemicals involves a separation of the four components of the regulatory task (chapter 3). Thus, industrial chemical hazard and risk assessments should ideally be performed by a dedicated technical expert agency, separately from the subsequent standard setting needed to manage the risks of those chemicals. The case for separation of assessment from standard setting is particularly strong for industrial chemicals because they are used in a variety of ways, and the standard setting would be more appropriately handled by bodies expert in the field.

NICNAS has already undergone some organisational change after a decision was made to separate it from the Office of Chemical Safety (OCS) — an agency with policy-making and other functions in industrial chemicals (DOHA 2007a).

Further functional separation is warranted and may be relatively easy to achieve. NICNAS is already primarily a chemical assessment body with limited regulatory powers. Limiting NICNAS's regulatory powers to those necessary to undertake the assessment function need not have a significant effect on the management of chemical risks.

Of particular concern to the Commission is NICNAS's power to annotate the AICS to restrict or phase out the use of chemicals. While this has been rarely used since its inception, and is a rather clumsy and limited way of setting controls on the use of chemicals, it has the potential to be used more frequently in the future, particularly if a perceived need arises from a priority existing chemical review.

However, well established frameworks are already in place for setting controls on chemicals for public health (poisons) and workplace safety reasons (chapters 5 and 6). Reflecting their primary function of standard setting, the governance structures of those agencies are also better suited to the task than are the NICNAS structures.

For example, one ACCORD Australasia member argued:

> This process of annotation was poorly discussed with Industry … and now appears to be a tool without transparency for NICNAS to randomly set category restrictions, percentage use maximums restrictions and conditions of use restrictions. This seems to be setting up AICS to be an alternative to the SUSDP [Standard for the Uniform Scheduling of Drugs and Poisons] but without the ability of Industry to comment. There is no mechanism to complain without paying a fee of $633 and further delays to the approval. (sub. 42, p. 28)

Furthermore, this regulatory device is not being systematically reviewed for its regulatory impacts. For example, the annotation of the AICS covering certain lead-based coatings for industrial applications was not subjected to a regulation impact assessment, yet the consequences of the annotation would seem to warrant such an assessment.

NICNAS argued that annotation of the AICS enables prompt action when an assessment concludes that a chemical poses unacceptable risks:

> Use of the regulatory power to annotate the inventory ensures that there is no time lag between conclusion of the risk assessment and controls being legally enforceable, ensuring health and environmental protection. This is in contrast to using national standards or recommendation[s] to state/territory regulators as the risk management mechanism. (sub. DR106, p. 4)

The Commission considers that improving linkages between NICNAS and the existing standard-setting bodies would be a more appropriate way of addressing the issue of regulatory lag. While there is currently no national standard-setting framework for managing the environmental risks of industrial chemicals, the Commission has supported addressing this gap through the establishment of a body that would examine NICNAS's recommendations and decide on the appropriate standards (chapter 9).

An additional issue concerning removal of the annotation power is the status of existing annotations. The Commission considers that, consistent with its preferred institutional approach, once the annotation power is removed, existing annotations, together with any supporting information or recommendations, should be referred to the relevant standard-setting bodies for a decision on appropriate controls. A timeframe should be prescribed for such decisions, and the existing annotations should be removed from the AICS at the expiration of that timeframe.

Two other control-of-use standard-setting functions of NICNAS should be removed. The first is maintaining the Cosmetics Standard. The Commission considers that the responsibility for regulating products should be vested in a dedicated standard-setting body such as the ACCC, rather than a chemical assessment agency (chapter 5). NICNAS should retain the responsibility for assessing new chemicals in cosmetics. It could also provide expert support to the ACCC in monitoring and enforcement of compliance and in updating the Standard under a service level agreement.

The second is the regulatory power to prohibit or restrict the introduction or export of industrial chemicals to give effect to Australia's obligations under international agreements (NICNAS, sub. 36). Currently NICNAS is responsible for implementing two international treaties — the Stockholm Convention and the Rotterdam Convention. The Stockholm Convention, among other things, requires parties to assess chemicals on their persistent organic pollutant characteristics. Its implementation is consistent with NICNAS being an assessment body.

The implementation of the Rotterdam Convention, on the other hand, could lead to restrictions or bans on the introduction or export of certain chemicals. Currently, DEWHA is the Designated National Authority responsible for international liaison and communication, with NICNAS being responsible for implementation of the Convention. The Commission considers that the responsibility for implementation could be transferred to DEWHA. This would result in an arrangement that is consistent with that applying to agvet chemicals, where the Department of Agriculture, Fisheries and Forestry is fulfilling both the Designated National Authority and implementation roles. On this issue, DEWHA observed:

> The department would be willing to exercise the implementation function and has appropriate familiarity with the Convention requirements since it leads Australia's international representation to the Convention. For the department to do so, however, may require legislative change. (sub. DR104, p. 18)

Several of NICNAS's regulatory powers that are incidental to chemical assessment should be retained. The power to issue assessment certificates at the end of an assessment is integral to the assessment process. The power to issue permits subject to prescribed conditions of use and the power to impose requirements on notifiers under low regulatory concern chemical provisions offer a way of delaying or circumventing the full assessment, provided certain conditions are met. These powers are also an important component of the assessment regime. While they provide NICNAS with some risk management responsibilities, these are subsidiary to risk assessment in the sense that they manage the risks of not subjecting a chemical to full assessment. The power to require secondary notification for significant variations to the originally notified uses is an important feature of the regime, because it ensures that the relevant new risks are assessed. To the extent that the AICS is utilised to convey the information on secondary notification, the power to annotate the AICS for *that purpose* should be retained.

In summary, the Commission considers that the current risk-management regulatory functions of NICNAS that are not integral to its primary function of administering a chemical assessment scheme should be removed.

RECOMMENDATION 4.3

The Australian Government should generally limit the role of NICNAS to the scientific assessment of the hazards and risks of industrial chemicals. The power to annotate the Australian Inventory of Chemical Substances to ban or phase out chemicals, and the responsibilities for administering the Cosmetics Standard 2007, and for implementing the Rotterdam Convention, should be removed from NICNAS.

Extending the scope of NICNAS to reflect emerging technologies

There has been limited focus both in Australia and overseas on analysing the regulatory implications for addressing the risks of emerging technologies, in particular, nanomaterials.

Nanomaterials are materials designed at the molecular (nanometre) level to take advantage of their small size and properties not in their conventional counterparts. In recent years, there has been significant growth in the research and development and subsequent commercialisation of nanomaterials in a broad range of applications

including textiles, cosmetics, sunscreens, electronics, paints and varnishes (NICNAS nd).

Nanomaterials could present challenges to the existing chemical assessment regimes because their novel properties may give rise to currently unknown impacts on human health and the environment. Consequently, the current data requirements for 'traditional' chemicals and polymers may not be appropriate for adequate risk assessment of nanomaterials.

To address the emerging technological and regulatory issues, the Australian Government announced the creation of a National Nanotechnology Strategy on 1 May 2007. The Strategy is being coordinated by the Department of Innovation, Industry, Science and Research.

Two key aspects of the Strategy are:

- allocating funding to the Department of Health and Ageing, Department of Education, Employment and Workplace Relations and DEWHA, to ensure regulatory systems adequately address the health, workplace and environmental implications of nanotechnology
- establishment of a Health, Safety and Environment Working Group, consisting of policy, regulatory and research funding agencies across the Australian Government. The Working Group will coordinate the assessment of existing regulations with all relevant agencies, including non-government bodies such as Standards Australia. It will also be responsible for coordinating international engagement on policy and regulation (DITR 2007).

NICNAS is currently engaging with the Working Group to determine if and how the ICNA Act needs to be modified to accommodate nanotechnology issues. It has made a voluntary call for information to industry to determine the volumes and applications of nanomaterials in Australia. A Nanotechnology Advisory Group has also been established within NICNAS (NICNAS nd).

The Commission supports the engagement of NICNAS in the National Nanotechnology Strategy.

Proposed reforms to the product scope of NICNAS — regulation of disinfectants

Disinfectant products are substances that are applied to an inanimate object or surface to kill a range of micro-organisms. Currently, all disinfectants are regulated by the Therapeutic Goods Administration (TGA) on their safety, quality and

efficacy under a category called 'related therapeutic products'.[3] The Taskforce on Reducing the Regulatory Burden on Business (Regulation Taskforce 2006) observed that Australian regulations set a higher standard than those of New Zealand, and that this restricted competition from New Zealand and placed Australian exporters at a competitive disadvantage. The Taskforce recommended that the Australian Government progress industry reforms for the regulation of disinfectants. Consequently, a review of the current regulatory arrangements was initiated by the Department of Health and Ageing and a report proposing a new regulatory framework has been prepared (DOHA 2008).

The report advocated a risk-based regulatory approach, where the responsibility for regulating disinfectants used in different environments is divided between TGA and NICNAS depending on the associated risk. Under the proposed arrangement, TGA would continue to regulate hospital-grade disinfectants as previously, because the consequences of poor quality or ineffectiveness of products used in a clinical setting were deemed to warrant regulatory oversight. On the other hand, non-hospital grade disinfectants would now be assessed by NICNAS under its regular provisions for assessing new industrial chemicals, and would not be formally evaluated on their quality and efficacy. The quality and efficacy of non-hospital grade disinfectants would be enforced through industry self-regulation via a code of practice developed by ACCORD, and through the *Trade Practices Act 1974* (Cwlth) and state and territory fair trading legislation. The report suggested that NICNAS could annotate the AICS to reference the self-regulatory efficacy standard and that NICNAS inspectors could refer potential breaches of the Trade Practices Act to the ACCC for enforcement action.

The report also recognised the possibility of duplication in assessments by NICNAS and TGA if the same chemical is used in hospital and non-hospital grade disinfectants. It noted that NICNAS had provisions for recognising assessments of other schemes, but recommended that NICNAS and TGA further investigate options for mutual recognition of assessments.

The Commission generally agrees with the proposed regulatory approach and with the recommendations of the review. However, the proposed use of the AICS to annotate efficacy standards is not supported. The current function of the AICS is to provide a list of existing industrial chemicals and their assessment status. Extending the scope of the AICS to recording the regulatory arrangements for disinfectants

3 Under the scheme, the TGA formally evaluates the quality, health risks and efficacy, and registers 'high grade' products, such as disinfectants for which specific claims are made in relation to sterilants, fungicides, sporicides, tuberculocides or virucides. 'Lower grade' disinfectants for which no specific claims are made, are required to comply with various product standards and labelling and advertising requirements maintained by the TGA.

would be inconsistent with the treatment of other chemicals and would confuse the purpose of the AICS. The Commission also does not agree that NICNAS should be responsible for initiating compliance monitoring and enforcement of breaches of the Trade Practices Act. This responsibility should rest entirely with the ACCC, while the role of NICNAS should be limited to provision of expert advice.

The Commission's broad agreement with the proposed reforms notwithstanding, ultimately, these reforms would need to be supported by a regulation impact statement.

Improving the coordination between NICNAS and the standard-setting bodies

Good coordination between NICNAS and the standard-setting bodies is essential for effective and efficient management of industrial chemical risks. The issue of poor linkages between NICNAS chemical assessment outputs and the subsequent risk management by the relevant standard-setting bodies has been raised in a number of forums and by several participants in this study.

A NICNAS review of its priority existing chemicals program identified a number of problems relating to the uptake of NICNAS recommendations by the relevant regulatory agencies and industry (DOHA 2006b). These included:

- a narrow focus on OHS issues by the current state and territory MOU group due to its representation
- poorly framed recommendations by NICNAS, meaning that some could not be implemented
- the need for greater monitoring by NICNAS of the uptake of recommendations by relevant agencies.

The review made several recommendations including:

- a proposal to broaden the representation on the MOU group to include public health and environment representatives
- a recommendation to increase consultation with stakeholders to improve the quality of NICNAS recommendations
- a recommendation for ongoing monitoring and reporting of the uptake of NICNAS recommendations.

The recommendations were accepted by the Director of NICNAS and an implementation plan was prepared (DOHA 2007b). More generally, the review concluded that a more rigorous investigation of the barriers to the uptake of

NICNAS recommendations was needed, and recommended that the proposal for such a review should be referred to the COAG Ministerial Taskforce on Chemicals and Plastics Regulation Reform.

One of the big issues in the plan was that of improving consultation. According to the plan, the implementation of recommendations on modifying the MOU group and improving consultation would not require significant changes to existing arrangements and could be undertaken within NICNAS in less than one year. The Commission understands that NICNAS has already taken steps to broaden its consultation to include the public health and environmental agencies of the states and territories. These steps are supported. The NChEM Working Group (sub. DR119) suggested that the requirement to consult with the relevant state and territory agencies be formalised in the ICNA Act. However, current initiatives to broaden the representation on the MOU group may be sufficient to address the problem and should only be supported by legislative change if they prove to be unsuccessful.

A potentially more important issue is to formalise the requirement that standard-setting bodies specifically address NICNAS recommendations.

NICNAS observed:

> There is no legal requirement either for standard setting-bodies to consider NICNAS's recommendations nor for states/territories to adopt … direct recommendations before NICNAS permits/certificates are issued. For both new and existing chemicals this can result in a situation where a chemical that NICNAS consider to warrant risk management measures, is on the market without controls in place and without any statutory or binding agreement on the timeframe within which such controls should be considered/adopted … For NICNAS recommendations to be effectively linked into the Commonwealth's risk management framework, it will be necessary to strengthen and formalise the linkages between NICNAS and national coordinating bodies. (sub. DR106, p. 9)

DOHA (sub. DR116, p. 4) also argued that 'risk management agencies should be compelled to consider recommendations within statutory timeframes'.

Such an arrangement could potentially improve the utilisation of NICNAS assessments and hence, the effectiveness and efficiency of the overall regime. However, some flexibility in setting such timeframes may be needed to allow the standard-setting bodies to balance priorities (for example, differentiated timeframes may be warranted for high and low risk chemicals).

The Commission would generally support establishing a formal requirement on the relevant standard-setting bodies to consider and respond to NICNAS recommendations within a set timeframe. There would be further benefit in

NICNAS establishing a consolidated public register of the responses of the standard-setting bodies as an information source for industrial chemical manufacturers and importers.

A similar linking mechanism (albeit in a different context) exists between NICNAS and the Office of the Gene Technology Regulator (OGTR), with NICNAS required by its legislation to seek advice from the OGTR in assessing chemicals containing a genetically modified product. There is also a legislative obligation on NICNAS to take that advice into account. The Commission considers that where the standard-setting bodies are established under statute, the requirement to respond to NICNAS recommendations should be incorporated into the legislation. Where no relevant legislation exists, the commitment to respond could form part of an agreement such as a MOU.

The Commission does not consider that the response of the standard-setting bodies should be a pre-requisite to NICNAS issuing an assessment certificate. First, general regulatory requirements already require some regard for chemical assessments. For example, a generic legislated duty for managing OHS risks applies regardless of any decisions by the standard-setting body on the specific chemical, making it prudent for employers to take into account relevant NICNAS recommendations. Similarly, generic duties not to cause an environmental hazard exist in state and territory environmental legislation. Second, provisions already exist for urgent decisions by some standard-setting bodies (for example, in poison scheduling), so the regulatory lag can be minimised when the risks are deemed sufficiently high. Third, requiring the standard-setting bodies to respond before an assessment certificate is issued could impose significant costs on introducers of chemicals through delays.

RECOMMENDATION 4.4

All relevant national standard setting bodies should be required to respond to NICNAS recommendations within defined time limits. NICNAS should maintain a public schedule of all responses.

Improving the efficiency of new chemical assessments

The Commission has received significant participant comment on the efficiency of new chemical assessments by NICNAS, particularly on the costs imposed by NICNAS notification requirements and on the effect of several initiatives adopted by NICNAS in recent years to improve efficiency.

This section focuses on:

- the appropriateness of compliance costs (including the financial costs of assessment, delays to introduction of chemicals and potential loss of commercial confidentiality following assessment) imposed by NICNAS on manufacturers and importers of new chemicals
- the impact of NICNAS on innovation and introduction of new chemicals
- the operation of NICNAS initiatives to improve the efficiency of its operations, including: initiatives for expedited assessment of low regulatory concern chemicals; efforts to integrate with overseas assessment schemes; and implementation of modern assessment methodologies that utilise data from previously assessed chemical analogues.

Are the financial costs of assessments appropriate?

The financial costs of obtaining an assessment certificate for an industrial chemical consist of two components — the fee for submitting an application and the cost of collecting data in support of the application. The financial fees for submitting an application to NICNAS vary between $2534 and $14 970, depending on the nature of the application. The Plastics and Chemicals Industries Association (PACIA, sub. 33) argued that fees were excessive compared to other OECD countries. Examination of assessment fees for non-polymer chemicals in different countries suggests that NICNAS fees are relatively high by international standards (table 4.1).

Table 4.1 **Assessment fees for non-polymer chemicals**

Country	*Assessment fee*
	A$[a]
Australia	14 418[b]
USA	2 863
Canada	3 892
EU	8 651
Japan	-
Korea	121
China	-

[a] Exchange rate as at 18 January 2008; [b] Standard notification fee for 2006-07. – No fee is levied.

Source: ACCORD Australasia (sub. 42).

However, some of the observed differences in fees are due to differences in cost-recovery arrangements. NICNAS assessment costs are fully cost recovered from assessment fees. On the other hand, none of the other assessment schemes listed above fully recover the costs of assessment. PACIA commented:

> … 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 … Only Canada has a scheme that captures a similar breadth and depth of chemicals, however Canadian fees are significantly lower in dollars and exchanged currency and [the scheme] is not 100% cost recovered. (sub. 33, attachment 4, p. 15)

It is, therefore, difficult to assess the appropriateness of the level of fees and charges. However, the Commission considers it appropriate that NICNAS assessment activities be fully cost recovered in accordance with the Australian Government Cost Recovery Guidelines (DOFA 2005a) including that these be periodically reviewed. The relatively modest budget of NICNAS ($8.6 million) suggests that its fees and charges are not a huge impost on the plastics and chemicals industry. However, this is not to say that compliance costs overall (and even the financial costs of undergoing assessment) are appropriate.

The more significant contributor to financial assessment costs is the cost of complying with application data requirements. Several participants suggested that the cost of preparing a data dossier for an application to NICNAS could be significant and could exceed the cost of complying with assessment requirements in other countries such as the United States (box 4.3).

Box 4.3 **Participant examples on NICNAS application data costs**

> In early 2007 the company asked its supplier to notify a fabric softening ingredient. NICNAS informed them that the toxicology data that had sufficed in the US for approval in that market wouldn't be sufficient for Australia. The testing required to generate the additional data would have cost $418 084 …
>
> In a recent case there was a new chemical to add in a liquid detergent to condition fabric. After discussion with the supplier, it appeared that they did not have the data package required for Australia. Some of the data gaps relate to unique Australian requirements for human and environmental toxicity … A standard application was required which meant €125 000 (about A$210 000) to generate the required data …
>
> This company would not consider the introduction of new chemicals due to the excessive cost. They recently took on an agency for a US manufacturer who was very keen to market their many novel chemicals in Australia. Their first attempt has cost $100 000 to date (still incomplete) and as a result they have lost interest in listing further chemicals on the Australian Inventory of Chemical Substances. (ACCORD Australasia, sub. 62, attachment 1, pp. 16–17)
>
> The laboratory tests required by US authorities to establish the safety in use and impact on the environment cost around US$20 000. In Australia, by contrast … the cost of carrying out the substantially more extensive testing required to achieve listing on the AICS can easily be of the order of ten times the cost of testing required in the USA. (Albright & Wilson (Australia) Limited, sub. 5, p. 3)

As discussed earlier, the appropriateness of the assessment requirements imposed on notifiers should be assessed in the context of whether these requirements are commensurate with the potential risk of the chemical in question. Several participants argued that this was often not the case. A survey of ACCORD Australasia members (sub. 62, attachment 1) showed that 44 per cent of respondents believed that irrelevant data was requested by NICNAS, while 64 per cent believed that the level of assessment was greater than warranted by the level of risk posed by the chemical. Implementation of recommendation 4.1 would be important in addressing this issue.

Are the provisions for ensuring timely assessments adequate?

Delays to the introduction of new chemicals could impose a significant cost on manufacturers and importers of chemicals, particularly if they result in the loss of first mover advantage from introducing a new product to the market.

Depending on the type of application, the statutory timeframes for NICNAS applications range between 14 and 28 days for permits, and 28 and 90 days for certificates. In contrast to the APVMA, the statutory clock does not start until the application passes all screening requirements (DOHA 2007a).

Data from ACCORD Australasia (sub. 42, attachment 2) indicate that, for standard non-polymer chemical assessments, the NICNAS statutory timeframes are similar to those in the United States and Canada, and significantly shorter than those in the European Union (10–12 months) and in Japan (up to 18 months).

Examination of NICNAS annual reports indicates that NICNAS met its statutory timeframes for 98 per cent of certificate applications in 2004-05, 100 per cent of applications in 2005-06, and 96 per cent in 2006-07. While NICNAS is not always achieving 100 per cent compliance with its statutory time frames — when arguably it should — timeliness is affected more by the quality of applications and the operation of the stop-the-clock provisions. In 2006-07, 60 per cent of non-self-assessed certificate applications were deficient and required rectification before the statutory clock could be started (DOHA 2007a). This is a slight improvement on previous years — the statutory clock did not start immediately after screening for 65 per cent of the applications in 2003-04 (DOHA 2004a); 71 per cent of the applications in 2004-05 (DOHA 2005a); and 73 per cent of the applications in 2005-06 (DOHA 2006a). Nevertheless, the high proportion of applications still failing NICNAS screening requirements is a concern.

NICNAS has introduced a number of initiatives to improve the quality of the applications. These focus primarily on providing a free consultancy service for

notifiers and conducting seminars and workshops for industry on avoiding common problems in applications. Industry appear to be supportive of these training and consultation initiatives. For example, 3M Australia observed:

> The NICNAS training seminars are an excellent forum for communicating and discussing chemical regulatory issues. NICNAS should continue to run such valuable sessions … It would be advantageous to provide advanced sessions that could target particular areas such as physicochemical properties, when a variation of schedule data requirements may be appropriate, mutagencity data when further data may be requested …(sub. 34, p. 13)

In 2007 NICNAS also introduced a new application screening framework aimed at improving the timeliness of NICNAS assessments. NICNAS now aims to complete all screening prior to starting the statutory clock and commencing the assessment. To facilitate faster completion of the screening, applicants are typically given deadlines of 14–28 days for resolving outstanding matters.

The new screening framework has only been in operation since February 2007 and its effectiveness is unclear. However, several participants have criticised its operation. ACCORD Australasia (sub. 42) suggested that the absence of any statutory time limits at the application screening stage meant that NICNAS had no incentive to conduct the process in a timely manner. PACIA (sub. 33) claimed that the time taken to screen applications was significant — approximately 30 per cent of total assessment time by NICNAS. Both participants argued that the stop-the-clock provisions should be altered to include application screening within the statutory timeframe.

The Commission considers that all stages of the assessment process should be subject to timeliness requirements. To that end, a statutory timeframe for completing technical screening is warranted.

RECOMMENDATION 4.5

The Australian Government should introduce a statutory timeframe for the technical screening of applications by NICNAS.

Are confidentiality provisions adequate?

Manufacturers and importers of industrial chemicals may derive a commercial advantage from retaining confidentiality on the identity of the chemicals they have introduced into Australia. Accordingly, the loss of confidentiality arising from the public listing of the chemical could impose a cost on those firms.

Currently, chemicals are typically not listed on the AICS until five years after assessment and the notifier has confidentiality protection for that period. Subsequently, the default position is no confidentiality, and the notifier has to apply for a confidential listing every five years. Industry participants (for example, PACIA, sub. 33, attachment) claimed that lack of certainty of confidential listing has imposed an unnecessary cost on firms and delayed the introduction of new chemicals in Australia.

A Technical Advisory Group operating under NICNAS considers whether to allow confidential listing of a chemical by comparing the commercial benefit of confidentiality with the public benefits of disclosure. Members of the group are selected on the basis of expertise in commercial and public interest. NICNAS has developed Guidelines on Establishing a Case for Confidentiality (DOHA 2005b). PACIA (sub. 33) have argued that chemicals that have been assessed as non-hazardous or are deemed non-hazardous (for example polymers of low concern) should have an automatic presumption of confidentiality.

The Commission considers that decisions on confidentiality should be made after an assessment of the community costs and benefits of disclosure of the information. An automatic presumption of confidentiality for non-hazardous substances is not supported because it would disregard other potential social benefits of disclosure, such as those flowing from knowledge dissemination. It could also lead to indefinite confidentiality protection for the notifier — a potentially undesirable outcome if the commercial costs and community benefits of disclosure change over time.

Analysis of NICNAS data shows that applications for confidential listing constitute a small percentage of all chemicals due for listing on the AICS. For example, in 2006-07, of the 167 chemicals due for listing on the AICS, confidential listing was only sought for 24 chemicals (DOHA 2007a). A significant majority of applications for confidential listing were successful (69 per cent in 2002-03, 100 per cent in 2003-04 and 2004-05, and 80 per cent in 2006-07) (DOHA 2007a).

Although the current arrangements within NICNAS appear generally sound, there are some shortcomings that should be addressed. In particular, the current Guidelines provide limited information on how the competing commercial and public interests are quantified and compared. Better guidance for the applicants could improve the transparency of the process and may improve its efficiency. One potential method is to supplement the guidelines with sample hypothetical applications, including successful, unsuccessful, and borderline applications.

Impact on innovation and the introduction of new chemicals

The assessment scheme could be expected to impose a cost on innovation activity by introducers of chemicals. A survey by ACCORD Australasia (sub. 62) of its member companies showed that 59 per cent of respondents cited the regulatory system as a barrier to innovation. On the other hand, analysis of Australian patent application data (table 4.2) shows an increase in applications since 1995 (when the last amnesty period for grandfathering industrial chemicals ended).

Table 4.2 **Patent applications, by industry group**

Industry	*Number of patent applications*		*Proportion of total patent applications*	
	1995	*2005*	*1995*	*2005*
	no.	no.	%	%
Basic chemicals	1 406	2 075	10.0	9.0
Soap, detergent, cosmetics and toiletries	582	1 094	4.1	4.7

Source: IP Australia (2006).

However, there are some problems in using these data. First, the number of patent applications that would have been made in the absence of regulation is unknowable, and second the number of patent applications is only a partial measure of innovation. It is more useful to examine the impact of NICNAS on the introduction of new chemicals.

Several participants (for example, Plastral, sub. 4; PACIA, sub. 33) argued that NICNAS requirements created a barrier to entry for new chemicals. A survey of ACCORD Australasia's member companies (sub. 62) showed that 93 per cent had some products available overseas but not in Australia; and 41 per cent reformulated their products to avoid assessment requirements. The survey also showed that, on average, 14 per cent of the companies' worldwide product portfolio was not introduced in Australia in the last two years for regulatory reasons. Some of these findings would not necessarily be attributable to the inappropriate burden of the regulations — for example, some variability in the products traded in different countries would usually be expected due to differences in market characteristics.

Introduction of new chemicals creates benefits both for producers of those chemicals (particularly if the firm is able to capture any advantages from being the first mover) and their users. These occur both immediately and over time from associated improvements in technology. However, to the extent that introduction of chemicals creates environmental and human health risks, these need to be addressed. The fact that some chemicals are not introduced due to the cost of assessment does not, *per se*, lead to inefficient outcomes. If the costs imposed on

the community by the assessment are outweighed by the benefits of avoided environmental and human health risks, any resultant cost barriers to the introduction of new chemicals are not a market failure. However, the current regime could lead to inefficient outcomes if:

- the costs of assessment are not minimised
- there are asymmetries in the regulatory treatment of new and existing chemicals.

To the extent that assessments are not currently as cost effective as they could be, new chemicals would face a greater than optimal barrier to entry. Thus, any reductions in assessment costs (assuming the effectiveness of the regime is maintained) would be expected to lead to more efficient outcomes in the introduction of new chemicals.

The second issue arises as a consequence of grandfathering the majority of currently used chemicals while requiring a full assessment for new chemicals. The result is a bias against the introduction of new chemicals, some of which might be safer or more environmentally-friendly than existing chemicals. The European Commission also identified the absence of testing requirements on existing chemicals as 'a barrier to innovation within the EU chemicals industry by discouraging research and invention of new substances' (EC 2006, p. 3).

The Commission does not support discounting assessment fees for new chemicals — as some have suggested — on the grounds that they might be more benign than existing chemicals. This could only be established after an assessment was made, making it operationally difficult to implement. The better approach is to improve the efficiency with which assessments are conducted, including through not making excessive data demands on notifiers.

The low regulatory concern chemicals initiative is underachieving

The ICNA Act was amended in 2004 to introduce new assessment categories for low regulatory concern chemicals (LRCC). The reforms included:

- increasing the volume thresholds for exempting chemicals from notification requirements (in combination with new reporting requirements)
- introducing an assessment category for polymers of low concern
- introducing audited self-assessment categories for polymers of low concern and non-hazardous chemicals and polymers.

Industry has had a mixed response to these reforms. While there is general support for increased flexibility, concerns have been raised that individual reforms were not

delivering on their cost-reduction objectives and that in some cases costs have increased.

Science Industry Australia (sub. 55) estimated the costs of the recent reporting requirements for chemicals introduced under the research and development exemption to a typical supplier of chemicals to laboratories at $16 000 per annum. Science Industry Australia argued that the reported data was irrelevant to risk management. It suggested that the chemicals were sold into laboratory environments for use by professionally-trained personnel and that the minimal risk that remained was addressed by the requirement under OHS regulation to provide material safety data sheets for all hazardous substances.

As a rule the cost of the reporting requirements should not exceed the incremental benefit that they provide. NICNAS should investigate whether the current reporting requirements for chemicals used in research and development are warranted, given the circumstances of the use of those chemicals and the existence of other risk management measures.

PACIA (sub. 33) argued that the provisions for self-assessment of polymers of low concern did not function because the associated reporting requirements and auditing of all self-assessed reports imposes greater cost on the notifier than if the alternative notification route were taken. It suggested that initial industry enthusiasm for this option evaporated once the costs became apparent. A survey of ACCORD Australasia members (sub. 62) showed that in 50 per cent of cases, where the company had an opportunity to select the self-assessment option, it chose not to do so due to reporting and auditing requirements.

NICNAS reported that in 2006-07, there were 21 applications under the polymer of low concern self-assessment category — a sharp decline on the 45 applications in both 2004-05 and 2005-06 (DOHA 2007a). Further, since 2004-05 there have been only two applications for self-assessment of non-hazardous chemicals and polymers (none in 2006-07). NICNAS suggested that 'industry is not fully exploiting cost savings and reduced time-to-market available following the reforms for low regulatory concern chemicals' (DOHA 2007a, p. 36).

There are also grounds for a more general consideration of whether the current arrangements for self-assessment of low concern chemicals are unduly conservative. In the regulation impact statement (RIS) that preceded the introduction of current self-assessment provisions, NICNAS observed that while overseas regimes typically provided exemptions from assessment requirements for some classes of polymers, all polymers had to be assessed in Australia (DOHA 2003b). NICNAS concluded:

> … under the current arrangement, the costs incurred by industry in compiling a notification package, and assessment by NICNAS, do not match the level of hazard or risk of the polymers assessed. (DOHA 2003b, p. 21)

NICNAS also suggested that of the chemicals identified as polymers of low concern, about 5–10 per cent were associated with some degree of health or environmental risk, and that this risk was usually identified during their pre-screening before assessment by NICNAS. Consequently, self-assessment provisions were introduced to align the assessment requirements with the level of risk. The current poor take-up of those provisions suggests that the problem has not been resolved, and that greater effort by NICNAS to promote self-assessment (by reducing its relative cost) may be warranted.

The Commission notes that NICNAS will shortly commence a review of the LRCC reforms already introduced (sub. DR106) and considers that the above concerns should be addressed as part of that review. The Commission further considers that the review committee should include expertise relevant to the stakeholder groups and be appropriately oversighted. To this end, the arrangements adopted for the priority existing chemical program review would be appropriate.

Use of analogue data and modelling in NICNAS assessments could reduce costs

As part of its LRCC reforms, NICNAS is currently implementing a mechanism for fast tracking the assessment of chemicals considered to be analogues to previously assessed chemicals. Under the new provisions, chemicals deemed analogues would be subject to modular assessment, which would reduce the costs of notification and data preparation, and result in faster assessments.

In the RIS on LRCC reforms, NICNAS analysed several options for introducing analogue assessment. Its preferred option was a case-by-case analysis of applications relying on analogue data to determine what additional data was required (DOHA 2003b). The ultimate objective was to use the data from initial assessments to develop analogue assessment criteria for future assessments. To date, those criteria have still not been developed. Further, PACIA (sub. 33) argued that NICNAS has adopted an unduly restrictive definition of an analogue.

International experience shows that utilisation of analogue data in chemical assessments can be significantly enhanced by modelling tools. Quantitative Structure Activity Relationship (QSAR) modelling, which relies on computer simulations of risks on the basis of a chemical's physiochemical properties, has been used in the United States, Canada, Denmark, and will be used in the EU REACH scheme.

QSAR modelling offers a number of benefits including reduced animal testing and significant cost savings over conventional assessment methods. The European Commission estimated that the use of QSAR under the EU REACH scheme could reduce assessment costs by 33–44 per cent (EC 2003).

A number of difficulties are typically associated with making QSARs a reliable predictive tool in chemical assessments:

- they require large data sets of observed relationships on which the models are built
- the data must be of high quality and generated using a consistent testing methodology
- the observed relationships that form the basis of the model must be statistically validated.

These shortcomings are being addressed in the countries that use QSAR modelling, via improving the quality of the data and the use of more sophisticated simulation tools. For example, the Danish Environmental Protection Agency (which uses an advanced QSAR system backed by a large database of test data) claimed 75–80 per cent accuracy for their QSAR modelling system (Price and Watkins 2003).

Further, there is international cooperation to improve the quality of QSAR modelling and to harmonise the different models currently in existence. QSAR Application Toolbox is an OECD project involving the United States, Canada, the European Union, Denmark and Japan, that aims to make specialised QSAR software and data from individual organisations accessible to all OECD stakeholders.

The Commission supports NICNAS investigating QSAR modelling for its assessments.

Making better use of international linkages

There are several methods for developing and utilising linkages with international chemical assessment schemes. These include both broad initiatives aimed at harmonising international methodologies of assessment (such as data requirements, reporting formats and risk-assessment methodology), and bilateral arrangements with other countries aimed at recognising aspects of their assessments (APVMA, sub. 59).

NICNAS is actively involved in various international harmonisation initiatives (box 4.4).

Box 4.4 **Some international harmonisation initiatives by NICNAS**

OECD New Chemicals Taskforce

NICNAS participates in the OECD New Chemicals Taskforce and is involved in projects aimed at developing a common standard for data sets and report formats as well as developing a common approach to chemicals that are subject to exemptions or reduced regulatory requirements.

International Programme on Chemical Safety

NICNAS participates in a range of projects under the International Programme on Chemical Safety aimed at harmonising risk assessment methodology and utilises methodologies already developed under the Programme.

Source: NICNAS (sub. 36).

In the longer term, these can result in benefits to: regulators (through savings in scientific resources and opportunities for international collaboration on emerging issues); industry (through reducing costs and delays of assessment); and the community (through assurance that the risks of chemicals are assessed and managed consistently with international best standards). However, to date, progress in incorporating aspects of completed international assessments into NICNAS processes has been patchy.

The ICNA Act allows recognition of assessments of new chemicals completed in other countries under the approved foreign scheme provisions. So far, NICNAS has entered into a bilateral agreement with Environment Canada to recognise the Canadian New Substances Scheme as an approved scheme. Under the agreement, notifiers receive a 40 per cent reduction in assessment fees when Canadian assessment reports are provided with the notification (NICNAS, sub. 36). NICNAS also accepts assessments from EU countries and provides rebates of up to 40 per cent to notifiers (DOHA 2007a). NICNAS commenced work on entering into a bilateral agreement with the US Environmental Protection Agency in 2004 (DOHA 2004a). The agreement has not been finalised to date.

Several participants (for example, PACIA, sub. 33) argued that NICNAS did not make sufficient use of foreign assessments. NICNAS reported that in 2006-07, out of a total of 190 notification applications, it received Canadian reports for 20 notifications and EU reports for 4 notifications (implying that 13 per cent of the applications relied on foreign assessment reports) (DOHA 2007a). There are no data on how many of the applications received by NICNAS have never been assessed overseas. However, the small proportion of applications relying on Canadian and EU assessments suggests a significant scope for further integration with

international assessment schemes. As noted earlier, the Commission supports the wider recognition of overseas assessment schemes as 'approved foreign schemes', provided they meet acceptable international standards.

Improving the assessment of existing industrial chemicals

When the ICNA Act was introduced in 1989, around 40 000 of the chemicals in commercial use at the time were given 'existing chemical' status. Since then, about 180 existing chemicals (mostly priority existing chemicals), together with around 2000 chemicals new to Australia, have been assessed by NICNAS (NICNAS, sub. 36).[4] The very high number of unassessed existing chemicals mirrors the situation in many other developed countries where systematic approaches to chemical assessment are relatively new.

NICNAS prioritises the assessment of existing industrial chemicals based on concerns about their possible adverse impacts on people and the environment. Any person or organisation with concerns about such adverse impacts may nominate it for assessment as a PEC. Nominated chemicals are screened and ranked for declaration by the Minister for Health and Ageing. Tailored or focused preliminary assessments are also undertaken, in lieu of an immediate full hazard and risk assessment, targeting particular issues relevant to an existing chemical. In addition, NICNAS undertakes more limited data collection and distribution studies for chemicals of concern as well as sourcing and publicising international assessments.

Concern has been expressed (for example, by the Australian Chemicals Trauma Alliance, sub. 9) about the slow rate of assessment of existing chemicals and the possible adverse impacts of their continued use.[5] While the actual adverse impacts of unassessed chemicals are unclear, the Commission agrees that the large quantity of unassessed chemicals coupled with the slow rate of their review undermines the effectiveness of a national chemical assessment regime.

4 Professor Ian Rae (sub. 11) argued that the extent of the assessment backlog is somewhat overestimated because many of the listed existing chemicals may not be being used in Australia and are unlikely to be used in the future.

5 However, even though chemicals have not been assessed by regulators, users of existing chemicals still face both common law and certain legislative duties of care. These would be expected to encourage actions to reduce the human and environmental costs of possibly dangerous existing chemicals, including their replacement by new safer chemicals.

Options for reform

Several countries have implemented or are currently implementing programs for assessing existing chemicals. Approaches range from a preliminary screening of all existing chemicals in combination with a more detailed assessment of chemicals identified as being of concern (for example, in Canada and the United States) to assessment of all existing chemicals with detailed assessment of all high volume chemicals (for example, under the new EU REACH scheme).

As observed earlier, production and use of chemicals creates benefits for both producers and users of those chemicals. However, it is important that the production and use of chemicals takes into account their potential adverse effect on human health and the environment. The net external cost to the public of an unassessed chemical is the appropriately risk-weighted cost of the possible human or environmental damage that might be avoided by assessment, less the cost of assessment. For some existing chemicals the failure to assess may generate net costs whereas for other low-risk chemicals the costs of assessment may outweigh likely benefits. In Australia, assessing the stream of around 200 new chemicals per year, has been considered affordable. However, to fully assess all existing chemicals using existing methodologies would be extremely costly and hence would only be warranted if there were reasonable prospects of the benefits materially exceeding the costs.

For example, even assuming that all of the relevant data are already available, the aggregate cost of assessing existing chemicals would be in the order of $400 million.[6] On the basis of industry information on the costs of collecting data for assessments of new chemicals (discussed earlier in the chapter), aggregate assessment costs of all existing chemicals could well be over 10 times the above figure.

Aggregate assessment costs under the EU REACH scheme — which imposes significantly lower testing requirements than those applying to new chemicals in Australia, and relies on cost-reducing modelling tools currently unavailable in Australia — have been estimated at €2.3 billion (A$3.7 billion) (EC 2003). While the benefits of the REACH scheme have not been comprehensively quantified, they can be expected to be significantly greater than for a similar scheme in Australia, due to the more than twenty-fold difference in populations.

NICNAS has recently undertaken a review of the existing chemicals program (DOHA 2006b) that made 23 recommendations for reform. These included

6 An estimate based on the current average application fee for new chemical assessments (which is set to recover the costs of reviewing the test data in the application) of $10 000.

improvements in engagement and communication with stakeholders, improved identification and screening of chemicals of concern together with more targeted assessments, and improvements to the efficiency of the selection and review process.

NICNAS has now prepared an implementation strategy to progress these reforms (DOHA 2007b). Timely and efficient implementation of the recommended program should produce more rapid and efficient assessment of existing chemicals and somewhat reduce public disquiet regarding unassessed chemicals.

In particular, the Commission strongly supports the following initiatives:

- Screening all chemicals would provide a low-cost way of assessing a large number of low-risk chemicals. It would also support the establishment of a scientifically prioritised list of higher risk existing chemicals that require more immediate and in-depth assessment. The Canadian Existing Substances program adopted this approach with apparent success.
- As discussed earlier, using information from overseas assessments or sharing research with overseas jurisdictions may often be cost effective, particularly with respect to hazard assessment. The Canadian and US existing chemical review programs are well advanced, while the EU REACH scheme would also likely generate a significant volume of useful information. The net benefits of extending foreign scheme recognition provisions of the ICNA Act to the *existing* chemical assessment schemes of Canada, the United States and the European Union should be assessed.
- Greater engagement with those who might have information on adverse impacts of existing chemicals and more targeted research into those impacts, together with the provision of full and easy access to information on existing chemicals to stakeholders, would improve the effectiveness of the screening and assessment process.

The Commission also considers that there is significant scope for improving the timeliness and cost-effectiveness of the screening process via the use of modelling approaches (discussed earlier). These have been utilised in the Canadian and US existing chemical schemes and will be used under REACH, and have proven to significantly accelerate the screening process. For example, the categorisation and screening of all existing chemicals was completed in Canada between 1999 and 2006.

The funding arrangements for the accelerated assessment program also need to be considered. The Commission generally considers that recovery of the costs of a chemical assessment regime from chemical manufacturers and importers is likely to

be more efficient and equitable than sourcing the funds from general revenue. This is because it is typically more efficient and equitable to attribute the costs of regulation to the source of the negative externality that the regulation seeks to address. However, a once-off proactive screening of all grandfathered chemicals is a response to a legacy issue that would be difficult to accurately attribute to current industrial chemical suppliers. Thus, on equity and efficiency grounds, the Commission considers that the costs associated with screening grandfathered chemicals on the AICS should be met from budget funding. Subsequent detailed risk assessments of chemicals identified to be of concern should continue to be cost recovered on the grounds that the continued use of these chemicals in the community might cause various problems, the costs of which should be internalised through regulation.

RECOMMENDATION 4.6

NICNAS should implement a program to greatly accelerate the assessment of existing chemicals that:

- ***screens all existing chemicals to develop a list of high-priority chemicals for assessment***
- ***makes greater use of simulation techniques based on the hazards of chemical analogues***
- ***reviews the scope for recognising the existing chemical assessment schemes of a range of other countries as 'approved foreign schemes'. Priorities should be the schemes operated by Canada, the European Union and the United States.***

The Australian Government should meet the cost of screening all existing chemicals from budget funding. NICNAS should continue to recover the costs of subsequent assessment of chemicals of concern.

Improving the feedback mechanisms to support assessment activity

To varying extents chemical assessments make assumptions about the risks that chemicals may impose that may or may not be borne out in practice. As DEWHA suggested:

> Important assumptions made during the assessment process to estimate safety cannot be validated or revised through measurement data. Put simply, regulators make decisions based on the best available information at the time, but cannot be sure how accurately they assessed risks. (sub. 18, p. 11)

In this context, post-market feedback mechanisms can be useful for verifying risk assessment conclusions, establishing a case for further assessment, and developing new ways for undertaking future assessments. DEWHA (sub. 18) observed that

where the feedback mechanisms are weak, chemical assessors are forced to be more conservative in their risk assessments.

NICNAS does not currently have an adverse experience reporting program and, as discussed earlier, its existing chemical review program (which includes feedback mechanisms that enable anyone to nominate a chemical for review) has operated slowly to date. A review of its existing chemicals review program recommended that NICNAS investigate the feasibility of establishing a nationally coordinated scheme of post-market monitoring and reporting of adverse experiences (DOHA 2006b). Elements of the proposed scheme would include (among others):

- clear articulation of the type, source, purpose, protection, and use of the information
- collation of information from existing monitoring programs and harmonisation of those programs
- potential incorporation of voluntary and coregulatory elements.

While the Director of NICNAS accepted the recommendation, it was seen as involving complex issues necessitating legislative change, and would, therefore, require one to several years to implement (DOHA 2007b).

Establishing an adverse experience reporting system for industrial chemicals can be a useful mechanism for fine tuning assessments. It can also provide the public with some assurance that chemical assessors are receptive to feedback. But, unlike agvet chemicals — which are used only in prescribed circumstances — industrial chemicals are used in a wide variety of circumstances, including in the household. An adverse experience reporting scheme could create an enormous number of real or perceived cases that would be costly to screen. Furthermore, a variety of existing reporting systems (such as state and territory environmental, poisons and other hotlines), consultative arrangements, and monitoring systems are already in place that would yield some information. NICNAS has noted that collation of existing information would be an integral part of any such scheme.

The adequacy of the current systems should be established before developing new systems. This would be consistent with the Commission's views on the need for additional monitoring of the environmental impacts of chemicals being considered within a well defined performance management framework (chapter 9). In the Commission's view further scoping of this proposal is required.

4.4 Consolidation of chemical assessment regimes

NICNAS and the APVMA are Australia's key chemical assessment agencies, focusing on industrial and agvet chemicals respectively. The separation of these functions has long been a feature of the regulatory landscape in Australia and is not uncommon in other countries (for example, the United States). But they undertake some similar functions, and given that some other countries have combined these functions (for example, New Zealand) some consideration of amalgamation options is warranted. Such consideration need not stop with these two organisations. For example, the current proposal for developing a risk-management framework for chemicals of security concern features the establishment of a risk-assessment unit within the Australian Government Attorney-General's Department (chapter 9). Creating one integrated assessment agency at the Commonwealth level could be a longer-term option.

What are the similarities and differences?

The similarities between NICNAS and APVMA mainly relate to their chemical hazard and risk-assessment functions (table 4.3). The hazard assessments of industrial and agvet chemicals start from a similar point because they relate to the inherent physical properties of the chemicals concerned. Both agencies also assess risks to public health, OHS and environment. Neither currently assesses chemicals for their risks to national security. Other similarities include that they maintain registers of chemicals (or products in the case of APVMA), and they both have links to other common regulatory agencies.

On the other hand, there are some substantial differences between the two schemes:

- NICNAS assesses chemicals only, whereas APVMA assesses chemicals and products (mixtures of chemicals).
- NICNAS assesses chemicals that may be used in a wide variety of ways whereas APVMA assesses products for specific purposes.
- NICNAS does not assess product efficacy, while APVMA does.
- NICNAS is a Commonwealth regulator, while APVMA is a national regulator created through a conferral of powers by the states and territories.
- NICNAS mainly relies on linkages to other national regulatory frameworks and the states and territories for the implementation of its recommendations. APVMA has much stronger powers to approve (register) or ban chemicals and set conditions of use.

The Commission's recommendations for NICNAS and APVMA would increase those differences (vertically integrating control of use of agvet chemicals, and making NICNAS an assessment only agency are the key changes).

Table 4.3 **Key similarities and differences between NICNAS and APVMA**

	NICNAS	*APVMA*
Legislative base	Commonwealth Act	Conferral of powers by the states and territories
Objective	Assessment of chemicals to manage the risks to public health, OHS and environment	Evaluation and approval of chemicals and products to manage the risks to public health, OHS, environment and trade; and supporting primary industries
Scope	Industrial chemicals	Agricultural and veterinary chemicals and chemical products
Hazard and risk-assessment activities	Hazard assessment and classification; assessment of risks to public health, OHS and environment	Hazard assessment; assessment of risks to public health, OHS and environment; assessment of residues and product efficacy
Risk management activities	Primarily recommendations to standard-setting bodies and the states and territories; but also setting use conditions via annotating the AICS; administering the Cosmetics Standard; implementing international treaties	Approval of manufacture or importation of chemicals and products; approval of conditions of use on product labels and regulation up to point of sale. Enforcement of conditions of use is by the states and territories

What are the options for amalgamation?

The broad options for amalgamation are: amalgamate NICNAS and APVMA as they are (or would be under the Commission's recommendations), or amalgamate their assessment functions only. There are advantages and disadvantages with both options, some of which were discussed by participants (box 4.5).

Full amalgamation

Amalgamating NICNAS and APVMA would create a one-stop-shop for many chemical producers and users and would reduce boundary issues where some chemicals may be assessed by both agencies. It would also achieve some economies of scale and scope by bringing specialist staff together under the one organisation.

However, it would create a hybrid regulator with quite disparate powers over industrial and agvet products that would confuse its purpose. In addition, some boundary issues would remain even under the Commission's recommendations. For example, disinfectant regulation would be shared between NICNAS and TGA,

while transferring the Cosmetics Standard to the ACCC would rationalise NICNAS regulatory responsibilities but might require ongoing technical support from NICNAS.

Amalgamating assessment functions

Under this second option a stripped-back NICNAS and the assessment functions of APVMA would be combined. This organisation could also include the national security risk-assessment functions planned for the proposed unit in the Australian Government Attorney-General's Department. The advantages of this option are that it would achieve the economies of scale and scope associated with bringing specialist staff together, and it would create an independent scientific assessor that would provide a service to all standard-setting bodies covering OHS, the environment, public health and national security. Also, APVMA outsources most of its assessment functions to other agencies such as the OCS, DEWHA and state and territory departments, so integration of APVMA's assessment functions into NICNAS would not require a significant operational change for APVMA.

Box 4.5 **Participant views on amalgamating NICNAS and APVMA**

DEWHA noted that there are advantages and disadvantages of amalgamating NICNAS and APVMA:

> One approach could include amalgamation of NICNAS and APVMA into a single regulator with access to advice from health, environment and other departments as appropriate. Potentially, this would bring economies of scale, pooling of skilled personnel, enhanced ability to resolve overlap and gaps in responsibilities for specific chemicals and the opportunity to critically compare the approaches taken in relation to industrial and agvet chemicals. In establishing a single body, this approach could benefit industry by providing a 'one-stop-shop' when importing, manufacturing, selling or using a chemical. On the other hand, there may be disadvantages to amalgamation, if industry or users perceive a single regulator to be less aware of or responsive to their particular needs and concerns ...
>
> Should changes at Commonwealth level be contemplated, however, the Department suggests that any new arrangement would need to take advantage of the full range of resources provided by the health and environment departments, and other agencies as appropriate. (sub. 18, p. 16)

Croplife Australia opposed amalgamation:

> The APVMA is able to give priority to agricultural considerations. Croplife supports the recognition and maintenance of the APVMA's separate risk-based assessment system and sees no net benefit from amalgamation of diverse regulators at any jurisdictional level. (sub 35, p. 16)

The disadvantages are that it might create some diseconomies by separating agvet chemical product assessment from standard setting, especially given that agvet

chemical products are evaluated for specific purposes. It would also require that the National Registration Scheme for agvet chemicals be renegotiated with some risk that this could jeopardise the effectiveness and efficiency gains already achieved.

Some of the benefits can be achieved without amalgamation

Some of the economies of scale and scope that would come from amalgamation can be achieved by outsourcing similar assessment tasks to common organisations or competitive market providers. For example, development of guidelines for conducting assessments (such as the environmental risk assessment manuals currently being developed for industrial and agvet chemicals (EPHC 2007a, 2007b)) would facilitate competitive provision by suitably accredited private providers. There may also be grounds for consolidation of some common aspects of hazard and risk assessment undertaken within NICNAS and APVMA (and other agencies such as FSANZ) (table 4.4).

Table 4.4 **Responsibilities for aspects of hazard and risk assessment, by regime**

	TGA[a]	*APVMA*	*NICNAS*	*FSANZ*[b]
Toxicology and public health	TGA	OCS[c]	NICNAS	FSANZ
OHS	..	OCS	NICNAS	..
Environment	..	DEWHA[d]	DEWHA	..
Residues in food	..	APVMA	..	FSANZ
Product chemistry and manufacturing	TGA	APVMA	..	..
Efficacy	TGA	APVMA; states and territories	..	..

a Therapeutic Goods Administration. **b** Food Standards Australia New Zealand. **c** Office of Chemical Safety. **d** Department of the Environment, Water, Heritage and the Arts. .. Not applicable

Source: APVMA (sub. 59).

APVMA argued that there are some disadvantages in having different agencies undertaking similar functions:

> The conduct of similar hazard and risk assessments for the same assessment component [such as toxicology or public health] by a number of groups or agencies creates opportunities for the encroachment of differing cultures or approaches to the application of policy and the potential for differing assessment methodologies. This in turn may increase the potential for inconsistencies in assessment outcomes unless managed by appropriate governance arrangements. It also disperses specialist staff, decreases flexibility and potentially increases administrative costs, particularly in terms of information sharing and national and international participation and representation. (sub. 59, pp. 39–40)

The Commission agrees that further consolidation of common aspects of chemical assessment could deliver additional economies of scale and scope. It would also improve consistency in the assessment methodology and outcomes and could facilitate a more efficient national approach to adopting international developments in hazard and risk-assessment methodology as well as international knowledge. In this respect, moving the responsibility for performing toxicology, public health and OHS hazard and risk assessments for APVMA from the OCS to NICNAS would be warranted. This change would also be appropriate in the context of the Commission's preferred governance framework (chapter 3) as it would separate the chemical assessment function from the current and proposed regulatory and policy making functions of the OCS.

Better communication between the regulators would also help. Some participants noted that there was a lack of formal mechanisms to coordinate the operation of different chemical assessment agencies (3M Australia, sub. 34, APVMA, sub. 59). ACCORD Australasia (sub. 62) provided several case studies, where poor communication between chemical assessors imposed significant costs on industry through duplication of assessments already completed for another body and through having to apply for assessments in multiple agencies where it was unclear which agency was responsible.

In some cases formal interagency agreements may help to clarify these roles. In other cases effective communication between agencies would be difficult to formalise and will rely on good officer-to-officer connections. At a broader level, the establishment of a Standing Committee on Chemicals, as proposed by the Commission (chapter 3) would help to establish a clear delineation of roles and reduce duplication.

Given all of the above, the Commission concludes overall that there is not a sound case for amalgamating NICNAS and APVMA at the moment. However, it can see benefits in amalgamating the assessment functions at some point in the future, when doing so would not jeopardise the integrity of APVMA's risk-management functions and the inclusion of current state and territory control-of-use functions in the national regime.

5 Public health

Key points

- Chemical-related risks to public health are subject to numerous regulations — including for poisons and pesticide residues in food — on the grounds that:
  - human health protection is a 'public good' that is underprovided by the private sector.
  - 'information failures' prevent consumers from making fully informed decisions about chemical-related risks to their health.
- Existing regulations generally appear to be effective in achieving their public health goals, but some reforms are warranted to improve that effectiveness and to overcome inefficiencies.
- Distinct regulatory regimes have been established for various public health concerns. There is no case for their amalgamation, but coordination can be improved.
- Poisons scheduling requires different skills and approaches to that of drugs, and so should be undertaken by a separate body:
  - The Australian Health Ministers' Conference should proceed with implementing the draft Australian Health Ministers' Advisory Council reforms to poisons as soon as is feasible
  - Poisons regulatory controls and scheduling decisions should be uniformly adopted, as published in the Standard for the Uniform Scheduling of Medicines and Poisons, by all jurisdictions to remove inconsistencies and duplication.
- Risks associated with chemicals in articles would be managed more effectively and efficiently if, along with the agreed national system of regulation for consumer product safety, there was a formal system of coordination between the national agencies responsible for assessing chemicals and regulating product safety.
- All labelling requirements for cosmetics and toiletries should be administered by a single agency — the Australian Competition and Consumer Commission.
- To prevent the diversion of chemicals into illicit-drug manufacturing, every jurisdiction should adopt the same regulations (and associated risk-based schedule) since current inconsistencies raise costs and could undermine effectiveness.
- Maximum residue limits set by the Australian Pesticides and Veterinary Medicines Authority for domestically grown produce should be included in food standards automatically, to avoid unnecessary duplication and delays.

This chapter investigates the effectiveness and efficiency of regulations used to manage the chemical-related risks that products pose to domestic users and the general public. The areas of health regulation investigated are:

- poisons in formulated products (such as household cleaning chemicals and paints)
- chemicals in consumer articles (such as toys, appliances and furnishings)
- ingredient labelling of cosmetics and toiletries
- diversion of chemicals into illicit-drug manufacturing
- food safety.

All of these areas fall within the broad category of public health, but this is not a sufficient unifying force to lead to a single system of regulation. Rather, distinct regulatory regimes have been established for each area. To some extent, this can be attributed to the regulations having been grafted onto different generic regulatory regimes (detailed in following sections of this chapter).

Governments have recognised that it would be worthwhile to have some degree of coordination between the different areas of public health regulation. As a result, it is common for specific government agencies to play a supporting role across two or more of the abovementioned areas, with this often formalised in regulations or inter-agency agreements (details provided in following sections). However, the lead agency in each area tends to differ. Broadly speaking, primary responsibility for administering the different regimes is as follows:

- health departments — poisons
- consumer-protection agencies — chemicals in consumer articles, and ingredient labelling of cosmetics and toiletries
- law-enforcement bodies — diversion of chemicals into illicit-drug manufacturing
- food regulators — food safety.

The Commission has not found a case for amalgamating the different areas of public health regulation into a single regime. Implementation of the Commission's recommended Standing Committee on Chemicals (chapter 3), in addition to reforms advocated in this chapter, would facilitate an appropriate level of coordination. Opportunities are identified in this chapter to improve policy-oversight mechanisms, decision-making mechanisms and national coordination for poisons scheduling and regulation, consumer-product safety arrangements and illicit-drug precursor controls. Improvements can be achieved through changes in decision-making responsibilities and processes, and stakeholder-input mechanisms.

Finally, this chapter identifies various overlaps and inconsistencies which arise across each area of regulation in their administration and enforcement.

5.1 Poisons scheduling and regulation

The regulatory framework

The Commonwealth, state and territory governments regulate the importation, manufacture, sale and use of poisons. For products containing substances classified as poisons, the poisons have to be identified on the label, with appropriate health and safety warnings, and in many cases be sold in particular types of packaging (requiring child-proof lids for example). Some chemical products are also subject to particular storage requirements, or can be manufactured, sold and used only by licensed parties.

The aims of poisons regulation include the reduction of:

- unintentional poisoning, of which most identified cases are acute poisonings of children
- intentional poisoning, of which most cases are adult suicides or attempted suicides (Galbally 2001).

Underlying the controls is an assumption that without government intervention, firms would not have sufficient incentives to fully inform consumers of the risks of exposure to poisons contained in chemicals, and consumers would be unable to conduct their own assessments of risk without this information. Labels can provide useful information to consumers on the relevant risks, and how to manage that risk. They can also inform emergency personnel of the contents of chemical products, where poisonings have occurred. Packaging requirements act to limit exposure risks to children. Licensing requirements for some high-risk chemicals limit their use to professionals who are adequately trained to manage the risks.

National coordination for poisons scheduling and regulation is provided by the Australian Health Ministers' Conference (AHMC) through one of its subcommittees, the National Coordinating Committee on Therapeutic Goods (NCCTG). The NCCTG's terms of reference are to 'take action necessary to bring about coordination of legislative and administrative controls on therapeutic goods and poisons and to make recommendations to the Australian Health Ministers' Advisory Council [AHMAC, the committee of senior officials underneath the AHMC] as necessary' (TGA 2007c). The NCCTG is comprised of representatives from the Australian Government's Therapeutic Goods Administration (TGA) and

key health authority officials (mostly chief pharmacists). The committee is serviced by the TGA.

National scheduling and regulatory decisions are made by the National Drugs and Poisons Schedule Committee (NDPSC). The Therapeutic Goods Regulations 1990 set out the process the NDPSC must follow. This includes the process for regular scheduling and a provision for urgent scheduling decisions. The NDPSC categorises (or schedules) poisons (and drugs) according to their potential adverse effects on human health, and develops guidelines for their labelling, packaging and other regulatory requirements. In making its scheduling decisions, the NDPSC considers a number of factors, including the poison's purpose, potential for abuse, safety and the need for the substance (Galbally 2001).

Scheduling and rescheduling decisions are made in response to recommendations from the:

- National Industrial Chemical Notification and Assessment Scheme (NICNAS) (following their assessment of new or existing chemicals)
- Office of Chemical Safety (OCS) (often as part of the Australian Pesticides and Veterinary Medicines Authority's (APVMA) agricultural and veterinary (agvet) chemical product assessments)
- approaches from industry or the wider community
- other sources of evidence of a public health concern (TGA 2007b).

NDPSC scheduling decisions are published in the Standard Uniform Schedule for Drugs and Poisons (SUSDP) (also published as the 'Poisons Standard', with the most recent being the Poisons Standard 2007 (Cwlth)) (box 5.1). The Commission's terms of reference limit this study to substances in schedules 5, 6 and 7 (other schedules are essentially for pharmaceuticals).

Poisons scheduling and controls set at the national level have little legal authority in Commonwealth law, but play an important role in advising state and territory governments on how poisons should be scheduled and regulated within their jurisdictions. State and territory governments maintain full control over the manufacture, sale and use of poisons in their jurisdictions, and there is no obligation on them to adopt NDPSC recommendations. As will be discussed below, in practice this sometimes means that controls on scheduled substances differ between jurisdictions. However, jurisdictional reporting on departures from the Poisons Standard is now a standing NDPSC agenda item.

Box 5.1 **The Standard for the Uniform Scheduling of Drugs and Poisons**

The Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) (also published as the 'Poisons Standard', with the most recent being the Poisons Standard 2007 (Cwlth)) contains a regularly-updated list of toxic substances, including drugs/medicines, agricultural and veterinary chemicals, domestic chemicals and prohibited substances, grouped into a number of schedules. The schedules are:

- **Schedule 1** — [This schedule is intentionally left blank]
- **Schedule 2** — Pharmacy Medicine …
- **Schedule 3** — Pharmacist Only Medicine …
- **Schedule 4** — Prescription Only Medicine, or Prescription Animal Remedy …
- **Schedule 5** — Caution — Substances with a low potential for causing harm, the extent of which can be reduced through the use of distinctive packaging with strong warnings and safety directions on the label.
- **Schedule 6** — Poison — Substances with a moderate potential for causing harm, the extent of which can be reduced through the use of distinctive packaging with strong warnings and safety directions on the label.
- **Schedule 7** — Dangerous Poison — Substances with a high potential for causing harm at low exposure and which require special precautions during manufacture, handling or use. These poisons should be available only to specialised or authorised users who have the skills necessary to handle them safely. Special regulations restricting their availability, possession, storage or use may apply.
- **Schedule 8** — Controlled Drug …
- **Schedule 9** — Prohibited Substance … (Poisons Standard 2007 (Cwlth), p. vii)

The appendixes to the SUSDP contain requirements for the packaging and labelling of drugs and poisons, which vary depending on the schedule of the substance. The SUSDP also has appendixes containing reduced labelling requirements for paints, tinters and related products that contain certain poisons and lists of chemicals for which greater regulatory controls in manufacture, storage, sale and use are suggested.

Effectiveness and efficiency

The scheduling and regulation of poisons are generally seen to be effective in dealing with the hazards and risks of toxic substances in non-industrial chemical products. The *National Competition Review of Drugs, Poisons and Controlled Substances Legislation* (Galbally 2001) concluded that most of the controls on poisons (and drugs) provided a net benefit to the community. It found that, although death and other adverse health effects continued to occur from exposure to poisons, the problems arising from poisons exposure would be much greater without the controls.

It is not possible to precisely quantify the incidence of poisonings from poisons that are within the scope of this study due to definitional issues with available data. Depending upon the source, some recorded poisonings may be due to exposure to smoke, animal and insect bites and stings, or other unspecified causes. Also, some adverse health effects from chemicals may be recorded under data for burns and corrosion injuries or other data categories. Furthermore, data on poisons-related causes of injury and death are likely to include exposure in workplace, domestic and other environments, thus incorporating adverse effects on humans of chemicals regulated by OHS or other requirements.

However, available data do suggest that death and injury rates from poisons within the scope of the scheduling and regulatory regime are relatively minor compared to those from drugs and other causes. In 2003-04, only 3 per cent of all community injury deaths were due to poisoning by 'other substances' compared to 8 per cent from drugs (Henley et al. 2007). Also, poisonings by non-pharmaceutical substances accounted for less than 1 per cent of total hospitalisations in 2003-04, compared to just over 2 per cent for pharmaceuticals (AIHW 2006).

Child-resistant packaging requirements, outlined in poisons scheduling requirements, have also been effective. The Australian Institute of Health and Welfare's National Injury Surveillance Unit argued that the introduction of child-resistant closures, in the late 1970s and early 1980s, has caused a significant decrease in deaths of young children from poisoning (Cripps and Steel 2006).

Participants in this study raised concerns about the institutional arrangements and decision-making process for poisons scheduling and regulation, inconsistencies in controls between jurisdictions and overlaps with other areas of regulation. Many of these issues were also raised by past reviews, including most recently Galbally (2001). Galbally concluded that, while most of the current controls on poisons (and drugs) provide a net benefit to the community, a number of reforms were needed to increase national uniformity, improve efficiency, reduce the level of control where possible, and improve the net benefit to the community as a whole.

Galbally (2001) made a number of recommendations, including for the:

- NDPSC to be broken into two separate committees — one for drugs (to be renamed medicines) and one for poisons
- NCCTG to develop template legislation that includes all provisions regulating the supply of medicines and poisons, which the states and territories would adopt by reference

- states and territories to automatically adopt all scheduling decisions in the SUSDP by reference and in accordance with timelines developed by the scheduling committees
- APVMA to make decisions regarding the labelling and packaging, and recommend the appropriate scheduling of agvet chemicals as part of the product assessment process
- removal of some jurisdictions' 'extra' regulatory requirements on poisons (over and above those in the SUSDP), such as a requirement for manufacturers and sellers of some poisons to be licensed.

The Commonwealth, state and territory governments released their response to Galbally (2001) in 2005, agreeing to most of the recommendations (AHMAC 2005). One important exception was that they agreed to aim for regulatory uniformity, not through the use of template legislation as recommended by Galbally, but by 'other means'.

AHMAC, through the NCCTG, is currently designing reforms to poisons scheduling and regulation in Australia. In the interests of ongoing consistency and cohesiveness, the NCCTG agreed to a single scheduling policy framework for both medicines and poisons. Key elements of the most recent proposal for changes to poisons scheduling and regulation would:

- split the scheduling committee into two (one for chemicals (poisons) and one for medicines (drugs)) and replace its current membership of representatives with nominated experts
- make the head of the Australian Government Department of Health and Ageing (DOHA) the final decision maker on poisons scheduling decisions, advised by the chemicals (poisons) scheduling committee, with the Department as secretariat
- have the states and territories adopt national scheduling decisions by reference (NCCTG 2007).

Under the AHMAC model there is no commitment to adopt regulatory controls by reference.

The NCCTG would continue to oversee regulatory policy relating to both drugs and poisons.

There are some differences between the agreed scheduling policy framework and that under current arrangements. While the guidelines for classification of substances are largely the same, the proposed framework reflects extensive work on developing scheduling criteria on a schedule by schedule basis. In addition, there

are some changes to the public consultation guidelines. It is expected that the consultation process for poisons would be broadly similar to that proposed for medicines. Under the proposed arrangements, public consultation on the scheduling of a new substance would not routinely occur, although all rescheduling proposals would be the subject of public consultation.

Under the AHMAC model, for chemicals (poisons) scheduling and rescheduling decisions, the Chemicals Scheduling Committee (CSC) would assess the evidence and send their scheduling recommendation to DOHA for a final decision. The CSC would be made up of appointed experts: one nominated expert member from each state and territory; one nominated expert member from each of OCS, NICNAS and APVMA; and OCS nominated members with professional expertise. The OCS nominated expert members would include professional expertise in areas such as toxicology, consumer and industry issues. Scheduling decisions made by DOHA would be communicated to stakeholders via an electronic register, the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), which would be administered by the TGA (NCCTG 2007).

While industry (for example, ACCORD Australasia, sub. 42; PACIA 2005; 2007b) supported Galbally's recommendations, it has expressed concern about the direction of, and processes followed, in reforms since that time. Industry concerns included that the states and territories had not made a commitment to uniformity in poisons scheduling and regulation, and proper regulation impact assessment and consultative processes had not been followed. Governments had only consulted on one reform option and no regulation impact statement (RIS) had been prepared to assess the impacts of the proposed reforms. Governments had also only started to consult late in the process after the drafting process for legislation had already begun.

The case for the reform of the administration of drugs and poisons regulation

Reviews dating as far back as 1954 have recommended that poisons and drugs be scheduled and regulated separately,[1] citing the efficiency gains in splitting up decision making responsibility between the two areas, differences in the risk profiles associated with each area and the different decision-making paradigms required (Galbally 2001; IC 1996b).

[1] The National Health and Medical Research Council first recommended that national standards for regulating drugs, poisons and foods be developed in 1954, with the intention that these areas be regulated separately (Galbally 2001). Subsequent moves to develop national standards created separate regulation for foods, but drugs and poisons continued to be regulated together.

Regulatory controls and scheduling decisions in the areas of drugs and poisons require different approaches, and having them under the same framework has the potential to lead to less effective and efficient outcomes than if they were regulated separately. As stated by ACCORD Australasia:

> Scheduling decisions are based on different outcomes. Medicines scheduling decisions are made in regard to access and availability of scheduled medicines and the level of healthcare intervention while for domestic and agvet chemicals, scheduling decisions are about risk management and communication through packaging and labelling requirements. This represents two different approaches to scheduling decisions. The unified framework approach does not recognise this fundamental difference in decision making and therefore cannot be expected to represent good practice. (sub. 42, p. 23)

The membership of the current NDPSC includes individuals who have a background in either drugs *or* poisons, and consideration of therapeutic substances is seen to dominate (SA Government sub. DR110). Membership is based on representation from government (the Commonwealth, states and territories), industry and consumers. All members vote on scheduling decisions (though the vote is only passed if a majority of the committee is also a majority of jurisdictional representatives).[2] The NDPSC is large in membership, and where member experience and expertise is in either drugs or poisons, scheduling decisions are not always cost-effective in the use of member time and expertise. The NDPSC process has been criticised as slow and cumbersome due to the long consultation process, and the fact that it meets just three times a year means scheduling decisions are delayed (Galbally 2001). As discussed in chapter 3, best-practice arrangements for a standard-setting body are for decisions on technical standards such as scheduling decisions to be made by independent experts who are informed by public consultation processes and are required to act in the public interest. On matters of policy significance, decisions would be made ultimately by the relevant Ministerial Council.

The Commission considers that there is an overwhelming case for responsibility for the scheduling process of drugs to be separated from that of poisons. This would allow stronger focus on poisons assessments and encourage greater efficiency and more detailed consultation. The AHMAC model does not have all of the features the Commission considers appropriate, but it is an improvement over current arrangements. While the proposed CSC would retain representative membership, this would no longer be a concern given its advisory only nature.

The NCCTG should continue to have responsibility for the overall design of schedules and attached appendixes, and be overseen by the AHMAC. The CSC

2 *Therapeutic Goods Act 1989*, part 6, division 3A, subdivision 4.

should make scheduling recommendations within the scheduling framework developed by the NCCTG.

The Commission considers this should be supported by a strong intergovernmental agreement (IGA) that sets out the institutional arrangements and regulatory processes. In order to ensure consistency, states and territories should adopt scheduling decisions by reference, as proposed by AHMAC. To achieve uniform regulatory outcomes nationally, jurisdictions would also need to implement consistent schedule-based poisons controls across Australia. The Commission considers the jurisdictions should adopt poisons regulatory controls by reference.

Any amendments to the overall design of the schedules, or attached appendixes, undertaken by the NCCTG in the Standard, should require the preparation of a COAG RIS where they are not minor or machinery in nature. As well, some scheduling advice by the CSC, particularly where schedule 7 substances are concerned, would meet the requirements for undertaking a RIS, and the CSC should be charged with the responsibility to determine whether a RIS should be undertaken.

Where decisions need to be made quickly in an emergency, the Secretary of DOHA should be empowered to make some decisions out of session, with limited or no consultation. Such a provision would require strict criteria to identify what constitutes an 'emergency' and the decision would need to be reviewed, following the normal advisory and consultation processes, as soon as practicable.

In negotiating the proposed reforms to medicines and chemicals scheduling, the NCCTG agreed to a single secretariat to support both the chemicals and medicines committees, as well as a single scheduling Standard. Coordination between the new scheduling committees would be provided by the single secretariat, and would enable appropriate handling of those substances classified as both drugs and chemicals. Where there are scheduling issues that potentially impact across the medicines and chemicals divide, meetings of the medicines and chemicals committees may be run over consecutive meeting days to facilitate consultation (NCCTG 2007).

The Commission considers that scheduling decisions could have been left to the CSC rather than with the Secretary of DOHA — however, this would only have been appropriate if the committee was not representational. On balance the Commission considers that the AHMAC model should be implemented at the earliest possible time, but that a post implementation review of its effectiveness and efficiency should be undertaken as soon as is practicable. Among other things this review should analyse any DOHA decisions that depart from recommendations by

the CSC, the reasons for these and the subsequent actions of individual jurisdictions in implementing the DOHA decisions.

Inconsistencies in the controls on poisons between jurisdictions

Inconsistencies exist in the regulations applying to poisons between jurisdictions, creating costs for firms operating across borders and, ultimately, consumers. While most jurisdictions adopt Part 4 of the SUSDP by reference, the remainder of the Poisons Standard is adopted inconsistently by the jurisdictions, if at all. The differences include retail storage requirements for schedule 5 and 6 poisons, controls on the sale and use of schedule 7 poisons, and inconsistent implementation of Appendix I of the SUSDP (the Uniform Paint Standard) (ACCORD Australasia, sub. 42; APMF, sub. 8; TGA 2007a). There are also inconsistencies between jurisdictions in the scope of their controls on schedule 7 poisons (which in some cases apply to both domestic and industrial use) (ACCORD Australasia, sub. 42). This last issue will be discussed later in this section.

One example is the inconsistency in retail storage controls on schedule 5 and 6 poisons between jurisdictions (ACCORD Australasia, sub. 42). Each jurisdiction takes a different approach in this area, with quite prescriptive requirements applying in New South Wales[3] and South Australia,[4] and either more general or no requirements applying in other jurisdictions (South Australia is currently implementing a number of initiatives including removal of licensing requirements for manufacturers and wholesalers of Schedule 5 and 6 substances (South Australian Government, sub. DR110)).

These differences may create unnecessary costs for chemicals manufacturers, distributors and retailers that operate across borders:

> For example the retail storage requirements for Schedule 5 poisons differ across all jurisdictions, yet this controls the way a large number of consumer products are managed in Australia. The lack of consistency has recently encouraged retailers to attempt to impose their own conditions across Australia which is potentially more onerous than that arising out of some of the legislation. (ACCORD Australasia, sub. 42, p. 24)

Some national retailers with some degree of market power seek to simplify their supply chain management by requiring their suppliers to always meet the most stringent regulatory requirements among all jurisdictions. These costs are likely to be passed on to consumers. A more efficient outcome would be achieved if controls

3 Poisons and Therapeutic Goods Regulation 2002 (NSW), part 2, Division 2, clause 12.

4 Controlled Substances (Poisons) Regulations 1996 (SA), section 25.

were uniform in all jurisdictions, and set at a level commensurate with the relevant risks. One option would be to set performance-based standards that these chemicals be kept out of the reach of children, allowing firms to find the most cost-effective way in which these requirements could be met.

The Commission is of the view that the nature of the risks from poisons warrants a nationally-uniform approach. The risks of adverse health effects from exposure to poisons in the domestic, public space, or agricultural environment are unlikely to vary according to jurisdiction. Variations from the agreed national standards in this area are likely to impede interstate trade and increase costs to business and consumers, with little offsetting benefit in public health outcomes.

The Commission notes that, at COAG's meeting of 3 July 2008, there was agreement to implement the national harmonisation of poisons scheduling regulation and mutual recognition of decisions, as well as uniform implementation of scheduling of poisons by states and territories. COAG directed the Ministerial Taskforce on Chemicals and Plastics to present recommendations to the October 2008 meeting for endorsement by the December 2008 COAG meeting.

The Commission is of the view that notwithstanding the mutual recognition of decisions as agreed to by COAG, state and territory governments should continue to report any variations to nationally-agreed poisons scheduling or regulatory decisions to the Australian Health Ministers' Conference and include a statement of reasons for the variations.

RECOMMENDATION 5.1

The Australian Health Ministers' Conference should:

- ***proceed as soon as feasible with implementing its proposed reforms to separate poisons and medicines scheduling processes, including that poisons scheduling decisions be made by the Secretary of the Department of Health and Ageing, upon advice from a Chemicals Scheduling Committee***
- ***undertake a review of the Australian Health Ministers' Advisory Council model for poisons two years after commencement, including:***
  - ***an analysis of the consistency between the recommendations of the Chemicals Scheduling Committee and the decisions of the Secretary of the Department of Health and Ageing***
  - ***an analysis of the impact of the model on national uniformity of poisons regulations.***

State and territory governments should:

- ***adopt poisons scheduling decisions made by the Department of Health and Ageing directly by reference, as published in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)***
- ***uniformly adopt regulatory controls for poisons through either a template or model approach, as published in the SUSMP***
- ***continue to report any variations to nationally-agreed poisons scheduling or regulatory decisions at the state and territory level to the Australian Health Ministers' Conference, and include a statement of reasons for the variations.***

Overlaps between poisons controls and workplace substances regulation

ACCORD Australasia (sub. 42) noted two examples where controls on Schedule 7 poisons were inadvertently applied to industrial users in some jurisdictions, despite the relevant hazards being adequately addressed by OHS regulations. One example was the scheduling of HF (Hydrofluoric Acid), and while the intention was to ensure that products containing a concentration of more than 1.0% HF were not available for domestic use, in general it had the unintended consequence of requiring bona-fide industrial users (e.g. welders) to seek certain authorities/licenses. Another example related to Methylcyclopentadienyl Manganese Tricarbonyl (MMT), where the same in-principle issues arose.

This overlap between domestic poisons controls and those on workplace substances could impose unnecessary costs on firms that have to meet additional requirements, with little benefit to public health (or occupational health and safety) outcomes. It also imposes unnecessary costs on governments administering poisons controls that apply to both industrial and domestic uses. The intent of poisons controls is to protect public health by managing the risks from chemicals in domestic use. Occupational health risks are best dealt with through the existing regulatory framework for occupational health and safety.

ACCORD Australasia (sub. 42) was concerned that despite governments having recognised this as an issue, more regulatory reform was needed to better delineate between controls on domestic poisons and workplace substances. It noted that New South Wales has dealt with this by amending its poisons regulations to exclude schedule 7 substances with an industrial purpose. However, industrial users of schedule 7 poisons in Western Australia and the Northern Territory still need to obtain approval from their jurisdiction's health department.

However, concerns were raised that exempting authorised users of poisons in the industrial environment from poisons controls could result in a regulatory gap such as in relation to atypical workplaces (SA Government, sub. DR110). For example, in WA poisons regulations pick up a gap left by workplace regulations that do not cover small workplaces. In most cases, poisons controls are not needed in the industrial environment as workplace regulations are adequate. However, there are some particularly hazardous substances, such as cyanides, where it would be appropriate to limit access to those poisons. Workplace hazardous substances regulations do not provide such controls.

RECOMMENDATION 5.3

Where a poison is adequately covered under workplace substances regulations and there is demonstrated compliance with those regulations, state and territory governments should exempt those users from poisons controls.

5.2 Controls on chemicals in consumer articles

The regulatory framework

Some chemicals contained in consumer articles (such as toys, electronic appliances, furniture or carpets) may pose health and safety risks to certain consumers if they are released from articles after purchase. These risks are sometimes immediately obvious and can be easily traced back to the use of, or close proximity to, the article. However, other risks may take a longer time to become apparent, or may arise from cumulative exposure.

Although firms face a number of incentives to supply safe articles — including market incentives, the threat of adverse media publicity, legal liability and ethical considerations — the effectiveness of these mechanisms may be reduced where:

- suppliers know more than consumers about the hazards of a product, and find it in their interest to withhold some of that information for commercial advantage
- suppliers do not have a strong or long-term commitment to particular product types and markets, and so have less need to maintain the long-term patronage of customers
- both suppliers and consumers do not have full knowledge of the hazardous characteristics of the products because the hazardous characteristics of the chemicals contained in them have not been assessed.

These issues are exacerbated where there is a lag between the initial exposure to chemicals released from articles and their effects on health and safety, or where their effects are cumulative. In these cases, causation between exposure and adverse health effects cannot easily be proven, and it may be difficult to implement appropriate market or legal remedies.

Governments may intervene to address the abovementioned concerns through public research on the health, safety and environmental hazards and risks of chemicals, and controls on how chemicals are used in articles.

NICNAS

NICNAS has the authority to assess chemicals released from articles and make recommendations to the relevant regulators:

> NICNAS's assessment role in chemicals contained in articles is dependent on the method of their introduction into Australia. Articles themselves are excluded from the operation of the [Industrial Chemicals (Notification and Assessment)] Act [1989], however, chemicals released from articles can be subject to NICNAS assessment. In addition, if an article is manufactured in Australia NICNAS requirements would apply to the chemicals used in its manufacture. (NICNAS, sub. 36, p. 4)

NICNAS is informed of emerging concerns about chemicals released from articles through:

- chemical assessments and research conducted internationally (such as the European Union's work on phthalates)
- collaborative chemical assessments and research with international bodies
- approaches from other government agencies within Australia.

NICNAS also publishes information sheets for public consumption summarising its findings on the known risks and appropriate risk management methods for chemicals in consumer articles (such as for formaldehyde in blankets, furniture and mobile homes) (NICNAS 2008).

ACCC

The generic consumer product safety regulatory system allows governments to issue product warning notices, impose product bans, mandate safety and information standards and order compulsory product recalls. Product liability provisions also provide some protection to consumers from unsafe consumer products. Controls and

bans on products set by the Commonwealth are supported through customs controls.[5]

The generic consumer product safety regulatory system is overseen by the Ministerial Council on Consumer Affairs (MCCA) and administered by the ACCC under the *Trade Practices Act 1974* (TPA), and by state and territory government consumer protection agencies under each of their respective Acts.

The MCCA — which consists of Commonwealth, state, territory and New Zealand Government ministers responsible for fair trading, consumer protection and credit laws — facilitates the development of new national standards or bans. A sub-committee, the Consumer Products Advisory Committee (which also includes a representative from Standards Australia), provides advice to the MCCA on consumer safety policy matters and conducts reviews of Australian product safety standards, bans and recalls.

The Commonwealth TPA and the relevant state and territory Acts operate concurrently to regulate consumer product safety in different business sectors. The TPA applies to all corporations, interstate traders, and traders that sell goods through the post or electronic means (including e-commerce). All other suppliers of goods are regulated under the relevant Acts of the jurisdiction in which they operate.

The various governments' generic consumer product safety regulations contain only a limited number of narrowly-focused controls or bans on articles emitting hazardous chemicals. Some jurisdictions control or ban a greater number and variety of products than others.

The ACCC and its state and territory counterparts conduct regular surveys of consumer products for compliance with mandatory standards. However, most consumer protection agencies do not conduct their own product testing to check compliance with chemicals-related standards. Rather, they will either call on the appropriate firm(s) to undertake the testing of their products, or will arrange for another government or private body to undertake such testing on an as-needs basis. For example, the ACCC (2007) commissioned two recognised Australian testing authorities to test for formaldehyde in clothing and consulted with NICNAS about the issue.

5 Customs (Prohibited Imports) Regulations 1956, under the *Customs Act 1901*.

Poisons

Some controls affecting the use of chemicals in articles are also contained in the poisons scheduling and regulatory requirements, mainly in the area of paints and other surface coatings (section 5.1). Appendix I of the SUSDP contains a number of controls on how certain paints may be used, controlling their use on furniture and toys (as well as roofs, water tanks, fences and other places in the domestic environment). As discussed earlier (section 5.1), not all jurisdictions have implemented Appendix I, and so its effect on firms and consumers is likely to be limited.

Voluntary standards

Many product standards set limits on the substances that may be contained in or emitted from articles. Not all of these are mandatory, and many voluntary standards are administered by Standards Australia and incorporated into industry self-regulatory schemes.

Effectiveness and efficiency

Given the number and variety of consumer articles available on the market, and the lack of publicly available information on their chemical composition, it is difficult to determine the size of the overall health risks posed to consumers from chemicals in articles. Where studies have been conducted, they are often based on limited survey samples or anecdotal evidence, and while chemical compositions may be identified, the likely risks to human health from these chemicals may not.[6]

Nevertheless, there is some scope to improve the effectiveness and efficiency of regulations affecting chemicals in consumer articles, given the current lack of systematic hazard and risk assessment, and limited coordination by key regulators in this field.

The absence of a single national system of generic consumer product safety regulation is also likely to be hindering the effective and efficient management of chemicals in articles. In 2006, the Commission reviewed Australia's generic consumer product safety system and found that — in combination with other mechanisms including market forces, the product liability regime, media scrutiny

6 This is highlighted in research by the World Health Organisation's Intergovernmental Forum on Chemical Safety (2006) into the health risks posed to children by chemicals in toys. It highlighted that information about a toy's chemical composition, toxicological profile, and risks to human health from the chemicals contained within are often lacking.

and consumer advocacy — it was effective in maintaining a reasonable level of product safety (PC 2006b). However, the Commission also concluded there was scope for more efficient, effective and responsive regulation by establishing a single national consumer product safety law administered by the ACCC (along with other reforms).

The need for national uniformity

In its recent Review of Australia's Consumer Policy Framework, the Commission recommended a new national generic consumer law, including consumer product safety provisions. A nationally coherent consumer policy framework should be facilitated through making the Australian Government (through the ACCC) responsible for enforcing the new law nationally (PC 2008).

The Commission argued that its proposals would result in 'more effective, efficient, consistent and responsive policy and regulation, leading to better outcomes for consumers and greater certainty and lower costs for business' (PC 2008, p. 58).

The Commission further recommended that if the COAG determines that the jurisdictions should retain the power to issue interim product safety bans, these should lapse after 30 days if not extended nationally (PC 2008, Recommendation 4.3). These latter recommendations built on proposals in an earlier study looking at the issue of consumer product safety (PC 2006b).

In responding to the Commission's Report, COAG and the MCCA have endorsed the introduction of a new single national generic consumer law, and have also agreed to a set of arrangements for product safety. These include:

- The Commonwealth will assume responsibility for the making of permanent product bans and standards under the Trade Practices Act 1974 … The States and Territories will retain their power to issue interim product bans. Interim bans will apply for 60 days. Interim bans can be extended for 30 days and then for a further 30 days in exceptional circumstances at the discretion of the Commonwealth Minister.
- The Australian Competition and Consumer Commission and the State and Territory offices of fair trading will share responsibility for enforcement of the product safety law.
- Any jurisdiction may refer a proposal for a permanent ban or standard to the ACCC and there will be requirements for the ACCC to communicate its assessment to the Commonwealth Minister and to MCCA.

It is anticipated that the revised regulatory arrangements will be fully implemented by mid 2010 and will be subject to review by MCCA two years after commencement.

> Procedures will be put in place for States and Territories to have input into the policy development process as part of a comprehensive intergovernmental agreement. (MCCA 2008)

Regulatory coverage of imported articles

Some participants in this study argued that it is often unclear who has responsibility for dealing with imported articles containing hazardous chemicals, and that controls are often developed and implemented in an ad hoc, uncoordinated manner:

> Identifying and managing risks from articles containing industrial chemicals is a major system gap. NICNAS is responsible for chemicals only. Responsibilities for ensuring imported articles (such as blankets) are safe are incomplete, under-resourced, scattered across agencies and portfolios and have generally been applied reactively. When combined with the lack of labelling/information requirements in Australia this results in a significant gap in our ability to ensure that consumers, the general public and the environment are safe. (Environment Protection and Heritage Standing Committee, sub. 20, p. 26)

> Exposure to many lead-containing pre-painted objects imported from overseas is also inadequately regulated … This gap in regulation raises concerns about the potential health risks resulting from imported goods and adverse effects on the competitiveness of Australian paint manufacturers and product manufacturers who would comply with future phasing out of lead-containing paints while imported goods are unregulated. (SA Government, sub. 56, pp. 12–13)

The perceived gap in the regulation of imported articles that release chemicals is not due to a lack of regulatory options. Existing frameworks appear to be underused and inconsistent, due perhaps to the lack of systematic hazard and risk assessment, and regulatory fragmentation. Of all of the product safety standards applied to consumer goods, only a small proportion relate to the issue of chemicals in articles, and even where they are used they usually apply to only a small number of narrowly-defined articles (such as specific brands and models of toys).

Both NICNAS and the ACCC have jurisdiction over chemicals released from imported products. Regardless of the origin of their manufacture, NICNAS can assess chemicals released from articles, and the ACCC can impose product standards. Recent examples relating to imported articles containing toxic chemicals include the recall and testing of formaldehyde in blankets, lead paint used on toys, and the Bindeez Beads toy.

However, it is not possible to eliminate all health and safety risks arising from articles. As Graeme Samuel, Chairman of the ACCC, wrote in a response to the Commission's consumer product safety review:

> … improving protection against dangerous goods is not a simple case of beefing up regulations or calling for more tests by authorities … It is not possible to predict or test for every potential safety issue with every imported product, but it is possible to respond quickly when a problem emerges, as the regulator did in relation to lead levels in toys. (Samuel 2007, p. 10)

European Union regulations

The Department of Environment and Water Resources (sub. 18) noted that the European Union's new regulatory regime for industrial chemicals (REACH) includes provisions for the mandatory assessment (and possible regulation) of chemicals in or released from consumer articles. These provisions are subject to threshold criteria:

> REACH requires all substances that are intended to be released from articles during normal and reasonably foreseeable conditions of use to be registered according to the normal rules, including tonnage deadlines and information requirements, if those substances are present in the articles above 1 tonne per year.
>
> In addition, all substances of very high concern (on a list of candidate substances for authorisation that will be published on the Agency-website) present in articles above a concentration limit of 0.1% weight by weight and present above 1 tonne per year must be notified to the Agency except where exposure to humans and environment can be excluded during normal conditions of use including disposal. In such cases safety instructions should be provided. Information will also be made available to consumers on request.
>
> As a safety net, the Agency can require the registration of a substance in an article at any time when it considers that its release poses a risk to human health or the environment. (EC 2006, pp. 9–10)

Introducing similar requirements could impose significant costs on industry and the community more generally, and be difficult to implement. Thus, the Commission suggests that the European Union's experience in implementing these new requirements, including its net impacts on the European community, should be monitored before a similar approach is considered for Australia.

Information provision to business and consumers

ACCORD Australasia (sub. 42) suggested that concerns about the lack of regulatory coverage of chemicals in consumer articles were the result of a lack of information, both in the public arena and in the government sphere, about how the current generic consumer product safety system works, and a lack of communication and coordination within and between governments.

The Commission, in its 2006 review of the generic consumer product safety system, also found that there was scope for improving the provision of information about the consumer product safety regulatory regime (PC 2006b). It recommended the creation of:

> … an internet-based 'one-stop shop', administered by the ACCC, to provide information about all state, territory and Australian government product safety laws and regulations, including a link to the Recalls Australia website … (PC 2006b, p. xxxvii)

It would also include information about consumer product safety — targeted at consumers — and possibly a national consumer complaints mechanism (PC 2006b). This would address current difficulties for firms and consumers in understanding the regulatory regime and obtaining other relevant related information that arises from the current wide dispersion of information across multiple government agencies.

The need for more systematic hazard and risk assessment

The Commission's review of consumer product safety found that a more systematic approach was needed to identify the relevant hazards and risks from consumer products and determine the appropriate regulatory controls (PC 2006b). Little research had been done on the incidence, nature and severity of various consumer-product-related accidents in the community, and so it was difficult to determine the best places to target government action.

The Commission called for a national clearing house to be developed through which information, data sources and analysis of consumer product safety incidents and issues would be collated in one location, and disseminated to all jurisdictions (PC 2006b). This system would include:

- hospital emergency and admissions data
- linked consumer complaints information …
- recalls and other information provided by business …
- international product warnings and research
- mortality and epidemiological research. (PC 2006b, p. 208)

It was envisaged that this system would be coordinated by the ACCC, possibly through the Auzshare information sharing database, which is currently used to share information between jurisdictions on consumer complaints and scams (PC 2006b).

The Commission's proposed national clearinghouse system could be designed to incorporate information about the hazards and risks due to the chemicals contained in and released from articles.

The Commission notes that the MCCA is now developing the broadly-based hazard identification system, based on a clearinghouse approach, in line with the recommendations of the Commission's 2006 report. Following the COAG July 2008 endorsement of a harmonised national model for product safety it has been confirmed that the clearinghouse function will reside within the ACCC. Where health and safety issues are identified relating to chemicals released from consumer articles, they will be investigated and referred where appropriate[7].

Improved assessment may also arise from accelerating NICNAS's existing chemicals review process (recommended in chapter 4). If significant health or safety issues are identified in the chemical review process, NICNAS can recommend regulatory action to the ACCC, such as legislating a product standard. NICNAS and the ACCC have cooperated on a number of recent issues.

There is scope to strengthen cooperation between NICNAS and the ACCC on chemicals-in-articles issues through more formal institutional links. This could be facilitated through the negotiation of a memorandum of understanding between the two agencies spelling out matters such as the:

- overall goals of cooperation
- roles and responsibilities of each agency
- design and operation of a systematic research program to better identify and deal with the risks of chemicals in articles
- processes for communication between agencies.

Any new regulatory action arising out of these arrangements should be developed according to best-practice principles. Identification of the problem, and the range of options available (including self-regulation and no action) should be considered.

If regulatory action were found to be required, consideration should be given to the use of hazard-specific standards, rather than standards that are confined in scope to a particular product (PC 2006b). Hazard-specific standards can be more widely applied than product-specific standards, and are therefore likely to be more cost effective than developing individual standards for every product for which a hazard is identified.

[7] A number of submissions to the draft report argued that any hazard identification system for chemicals in consumer products should also include environmental hazards. This is addressed in chapter 9.

RECOMMENDATION 5.4

The ACCC and NICNAS should negotiate formal arrangements for cooperation on issues regarding chemicals in consumer articles. These arrangements should include the establishment of a more systematic research program to identify and deal with the risks of chemicals in consumer articles.

5.3 Labelling requirements for consumer products

The regulatory framework

Cosmetics and toiletries ingredient and product-claim labelling requirements are set by the ACCC and NICNAS respectively. Cosmetic and toiletry products may also need to meet state and territory labelling requirements for poisons, dangerous goods, and trade measurement. The ACCC and NICNAS regulations mandate that the full list of ingredients be shown on cosmetic and toiletry product labelling, that certain product claims only be made under specified conditions, and impose some product packaging requirements.

Some of this information may be provided through market mechanisms. Firms often label their products to promote features that consumers value. For example, some cosmetics and toiletries highlight the absence of added fragrances or other substances known to cause allergic reactions. However, without government intervention, it is likely that many firms would be unwilling to provide a full list of ingredients. This would make it difficult for consumers and medical professionals to determine which ingredients may be causing health problems when they occur.

ACCC

Mandatory information standard regulations are made under the Trade Practices Act 1974. The Information Standard administered by the ACCC — specified in the Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991 (Cwlth) — requires all cosmetics and toiletries ingredients (except incidental ingredients) to be specified on the label or associated information material. Where possible, ingredients have to be listed in descending order by volume or mass. The Information Standard is intended to inform consumers who may suffer allergic reactions from exposure to certain ingredients, or who wish to identify certain ingredients in products for their beneficial properties. Most of the

states and territories do not directly reference, or duplicate, the ACCC's Information Standard.[8]

The ACCC is responsible for enforcing the Information Standard. The ACCC conducts regular compliance checking surveys on cosmetics and toiletries to see if they meet labelling requirements. This generally involves visual checks of product packaging and displays in store to determine whether ingredient lists are displayed in the appropriate format.

The ACCC employs monitoring and enforcement resources to undertake this function.

NICNAS

The Cosmetics Standard 2007, under subsection 81(1) of the *Industrial Chemicals (Notification and Assessment) Act (ICNA) 1989*, administered by NICNAS, regulates the product claims made on labels of cosmetics and toiletries, and sets a limited number of other requirements, such as in relation to packaging, to support this. For example, skin care products with a sun protection factor (SPF) of greater than 4 and less than 15 must meet the Australian standard for the evaluation of secondary skin care products (AS/NZS 2604:1998) and not (among other requirements):

- be presented as having an SPF greater than 15 and/or being water-resistant
- have a pack size larger than 300ml or 300g
- make a therapeutic claim, including any representation about skin cancer (Cosmetics Standard 2007 (Cwlth)).

Policy direction for the Cosmetics Standard is provided by DOHA, through the Office of Chemical Safety.

The Cosmetics Standard contains controls on only a limited number of product types. NICNAS checks compliance with the Cosmetics Standard as part of its program of systematic compliance audits, and may conduct investigations in the case of potential breaches or accidents (NICNAS, pers. comm., 29 February 2008). As part of these activities, it may require firms to provide them with product test data to verify claims made on labels and packaging.

8 The exceptions are Queensland and South Australia, which directly reference the Information Standard. South Australia nominates its Minister rather than the Commonwealth Minister as the appropriate person for firms to apply to for confidentiality exemptions (and the appeals process related to this exemption) (Trade Standards Regulations 2000 (SA)).

NICNAS employs technical, monitoring and enforcement resources to undertake this function.

Effectiveness and efficiency

There is some evidence that the cosmetics and toiletries labelling requirements are meeting the objectives of informing consumers. As part of a 1998 RIS on changes to the Information Standard, the Australasian College of Dermatologists advised:

> … that the regulations have greatly facilitated their ability to identify potential allergens without delay, and, once this has been done, consumers have been able to avoid products containing allergens, resulting in health care and pharmaceutical savings. (ACCC 1998)

ACCC annual reports also suggest that firms are generally compliant with the controls — in the three years to 2006, only a limited number of firms required administrative action or court-enforceable undertakings for non-compliance (ACCC 2004, 2005, 2006).

There are, however, opportunities to improve the efficiency of cosmetics and toiletry labelling requirements, as discussed below.

Transferring responsibility for the Cosmetics Standard from NICNAS to the ACCC

As part of the reforms to NICNAS's arrangements proposed in chapter 4 of this report, most of NICNAS's (limited) risk management responsibilities would be moved out of the agency to allow it to focus on its chemicals assessment responsibilities. As part of this process, consideration should be given to transferring the Cosmetics Standard 2007 to another government agency.

As discussed earlier, the Cosmetics Standard regulates the claims that can be made on labels for specific classes of cosmetic and toiletry products (and also sets some packaging requirements). These requirements are to assist in providing accurate information to consumers about the nature of the products concerned. Most cosmetic products were, until recently, the regulatory concern of the TGA, but a 2005 review of cosmetics regulation determined that NICNAS should have more responsibility in this area (box 5.2).

In maintaining and enforcing the Cosmetic Standard, NICNAS's role includes a technical, scientific function as well as a compliance and awareness raising function. The technical role includes, for example, determining the particular conditions and testing requirements when adding new products to the Standard. Technical expertise is also required when reviewing existing entries, for example if

new information becomes available, to ensure that the condition(s) listed in the Standard are appropriate. When undertaking enforcement activities, the skills required are mainly compliance skills. The main compliance functions include conducting audits, responding to reports of non-compliance, and conducting awareness raising programs. Compliance auditing may, in some limited circumstances, require technical skills to examine and interpret study reports to determine whether products meet required test methodology.

The Commission is concerned with the overlap and confusion that results from having more than one regulator involved in cosmetics regulations and, as noted, it is recommending NICNAS be reconstituted to focus solely on scientific assessment of the hazards and risks of industrial chemicals.

One option would be to transfer the Cosmetics Standard to the Office of Chemical Safety (OCS) in DOHA. The OCS may be suitable, because it already has portfolio responsibility for public health issues, and it has the experience and resources to design and maintain the Standard. The difficulty with this option is that there is no relevant Act or authority under its administration to which this Cosmetics Standard could be attached, and the OCS lacks the appropriate compliance monitoring and enforcement powers and mechanisms needed for the Standard.

It could also be transferred to the TGA, though this is unlikely to be a good fit due to the TGA's focus on therapeutic goods, which are distinctly different from cosmetic products, and the Cosmetic Standard focus on product claims. Besides, it has only recently been excised from the TGA for sound reasons.

The Commission considers the most effective and efficient option is to transfer the standard to the ACCC to administer. It contains the relevant compliance monitoring and enforcement powers and mechanisms. As well, it already regulates similar issues through its consumer information standards and other regulations on product claims. It does not, however, have the relevant technical expertise to be able to test products for compliance purposes.

Box 5.2 **Reforms to cosmetics regulation**

As part of the Chemicals and Plastics Action Agenda 2002, the Australian Government agreed to consider and develop options for the regulation of low regulatory concern chemicals (LRCC), including cosmetics (NICNAS and TGA 2005). Products that lie at the interface between cosmetic and therapeutic goods were identified as products for which there was potential to reduce regulatory requirements while maintaining public health outcomes. Products were generally identified as a cosmetic only if they did not meet the criteria for a therapeutic good, as set by the Therapeutic Goods Act.

In 2005, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) completed a review of cosmetics regulation in Australia under its wider LRCC reform program (NICNAS and TGA 2005). In its review, NICNAS found that the Australian cosmetics industry was concerned that:

- cosmetics classified as therapeutic goods in Australia were subject to more onerous data and assessment requirements than compatible cosmetics in other countries
- a paucity of assessed cosmetic ingredients in Australia compared to overseas, and slow assessment processes, was delaying or preventing the introduction into Australia of cosmetics already in use overseas.

In response to these concerns, NICNAS and the TGA developed new criteria for the definition of cosmetic products, based on that used in the Trade Practices (Consumer Product Information Standards) (Cosmetic) Regulations 1991. Under new requirements, manufacturers and importers of substances for use in products meeting the criteria of cosmetics will require registration with NICNAS, and new cosmetic substances will require NICNAS assessment and listing on the Australian Inventory of Chemical Substances. Cosmetic products will also be regulated by NICNAS (under the Cosmetics Standard 2007).

This could be overcome through cooperative arrangements with another government agency or contractual arrangements with an independent private laboratory. The ACCC's cooperation with NICNAS on testing for chemicals in consumer articles provides a precedent for such cooperative arrangements.

Following the release of the Commission's draft report, the ACCC objected to the Cosmetics Standard being transferred to it on the grounds that inefficiencies could arise as a result of, among other reasons, the division of chemical expertise between agencies (the ACCC does not currently have the chemical or scientific expertise of NICNAS). However, the Commission considers that there remain significant synergies with respect to monitoring and enforcement (compliance) resources and activities. For example, the ACCC conducts random surveys of retail outlets to check compliance with consumer product safety and information standards. When checking whether a cosmetic is compliant with the list of ingredients required under

the Information Standard it could also check to see if the product claims on that same cosmetic comply with the Cosmetics Standard.

RECOMMENDATION 5.5

The Australian Government should transfer responsibility for the administration and enforcement of the Cosmetics Standard 2007 (Cwlth) from NICNAS to the ACCC.

Recognition of foreign labels

The Commission believes that the Information Standard should be consistent with our major trading partners where a convincing counterargument does not exist. Having the same labelling requirements decreases costs of imports and exports. As a rule closer alignment with international standards is generally supported provided that the benefits exceed the costs (chapter 2 and appendix G).

ACCORD Australasia (sub. 42) proposed that a 'deemed-to-comply' provision be added to the Information Standard to allow fully-imported cosmetic products to be sold in Australia without the need for overlabelling, if the label satisfies the requirements of the European Union, the United States, Canada or New Zealand.[9] It argued that:

> … while there is general consistency regarding cosmetic ingredient labelling, there can be minor differences which requires a product imported into Australia to be overlabelled with no identifiable benefit regarding health and safety or improved consumer information outcomes. (ACCORD Australasia, sub 42, p. 11)

Overlabelling of cosmetics can result from inconsistencies with trading partners in a number of legislative areas, including trade measurement regulations as well as the Information Standard. Potential areas for revising the Information Standard include acceptable use of terms (such as 'eau') and additional ingredient listings (active ingredients). Industry estimates the cost to overlabel a product because of a unique Australian requirement is approximately $0.50 per unit (ACCORD, pers. comm., Melbourne, 7 July 2008). No data are available on overlabelling costs specifically associated with the Information Standard.

In New Zealand, after June 2008, suppliers will have the choice to adopt the labelling requirements of the EU, US, Australia, or label hazardous substances over a certain threshold only (ACCC 2008).

9 ACCORD Australasia noted that New Zealand has already implemented such an exemption for cosmetics satisfying the labelling requirements of Australia, the European Union, or the United States.

Deemed-to-comply provisions in Australia would allow firms to avoid the overlabelling of imported cosmetic products due to minor differences in requirements between Australia and regimes with comparable policy outcomes. Such a provision would reduce costs to firms, and ultimately consumers. Many of Australia's trading partners have cosmetics labelling requirements that are broadly similar to those applied in Australia. The European,[10] United States,[11] and Canadian[12] requirements, for example, all require the ingredients of cosmetics to be labelled in descending order in terms of volume, and contain other similar provisions such as the use of terms for flavours and fragrances. This provision, however, would only address one part of the issue, and some overlabelling costs to industry related to other regulations would remain.

Such a provision would not exempt the importing firm from consumer protection provisions in the TPA such as misleading conduct, false advertising, or product liability. Nor would it negate the need to update the domestic Information Standard for cosmetics as international labelling requirements change (as the ACCC has recently done), but it would add flexibility to how the Information Standard is applied and enforced.

In line with best practice regulation, and in response to industry concerns, the ACCC recently undertook the Review of the Trade Practices Cosmetic Regulations (a RIS). The ACCC considered the costs and benefits associated with a number of proposals including deemed-to-comply provisions. The RIS resulted in a minor change to the Information Standard (change to the definition of flavour). The ACCC concluded that deemed-to-comply, and other proposals, would be impractical to implement. Deemed-to-comply provisions were not supported because of the difficulty in enforcing multiple labelling requirements and the 'current state of flux of cosmetic regulation' in New Zealand[13] and the European Union (ACCC 2008).

It is not clear that the benefits of deemed-to-comply provisions would be significant. Industry were unable to provide any examples of additional substantial costs incurred from complying with the regulations (Information Standard) (ACCC sub. DR103). Further, while ongoing efforts to harmonise labels internationally would make deemed-to-comply provisions more feasible to adopt, it would simultaneously make the need for them less.

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10 Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (76/768/EEC).

11 Code of Federal Regulations, Title 21: Food and Drugs, Part 701 — Cosmetic Labelling.

12 Cosmetic Regulations (Food and Drugs Act).

13 New Zealand's new cosmetics requirements were introduced in July 2008. New proposed European cosmetics regulations are about to be submitted to the European Council and Parliament for consideration (ERMA NZ, Wellington, pers. comm., 15 January 2008; EC 2008).

The Commission does not regard it as appropriate to introduce such provisions at this time. However, the ACCC should review the Information Standard and scope for deemed-to-comply arrangements once EU reforms have been completed, if stakeholders identify ongoing alignment issues.

Overlaps with OHS labelling requirements

ACCORD Australasia argued that there is an overlap between OHS and cosmetics and toiletries ingredient labelling (Information Standard) requirements for industrial hand cleaners:

> We are unsure as to why the ACCC requires cosmetic ingredient labelling information when industrial hand cleaners are covered under well established occupation[al] health and safety legislation under Australia's hazardous chemicals management framework. We consider that the imposition of additional labelling requirements is an unnecessary burden which should be removed by taking industrial hand cleaners from the scope of the Cosmetic Regulations as outlined in the ACCC's Guidance material. This change would not undermine the existing public health and safety arrangements in workplaces. (sub. 42, p. 11)

The ACCC advised the Commission that it had recently investigated this issue and found that there were insufficient grounds to exempt industrial hand cleaners from the Information Standard. The ACCC concluded that industrial hand cleaners would not fall within the scope of the Information Standard unless they were sold to consumers,[14] in which case consumers were entitled to the protection of the standard. It also concluded that workplace substances controls made adequate provision to prevent overlap between it and the Information Standard.[15]

The Commission agrees with the ACCC's conclusion, and, therefore, does not recommend a specific exemption from the Information Standard for industrial hand cleaners that are sold to consumers.

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14 Section 4.3 of the TPA states: 'For the purposes of this Act, unless the contrary intention appears-(a) a person who acquires goods shall be taken to be a consumer of the goods if the goods are of a kind ordinarily acquired for private use or consumption and the person does not acquire the goods or hold himself out as acquiring the goods for the purposes of re-supply'. Section 63 of the TPA, which outlines provisions for consumer product information standards, appears to use this definition.

15 The National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012 (1994)] section 3.2 lists a number of 'substances, when packed and sold as end use products, [that] should be regarded as being appropriately labelled' including 'cosmetic products'.

Is there a need for ingredient labelling on other chemical products and consumer articles?

Many consumer products containing chemicals are currently not subject to ingredient-labelling requirements. Some participants raised concerns about this issue, including the problems it causes for people with 'multiple chemical sensitivities':

> The labelling of industrial chemicals or articles containing industrial chemicals represents another inconsistency and system gap. For example, consumers can see full ingredient listings on labels for some cosmetics such as hand creams but not for their household cleaners and they are not able to determine what chemicals may be in their furnishings, carpets and other products. (NSW Government, sub. 31, p. 17)
>
> Much consumer concern about chemicals could be overcome by the simple provision of ingredient listings in product/merchandise labels. This would be particularly beneficial for those consumers with particular chemical sensitivities/vulnerabilities who may otherwise lobby to restrict chemicals in products. (Environment Protection and Heritage Standing Committee, sub. 20, p. 26)
>
> … [current requirements for] labelling may not provide enough relevant information to minimise potential health risks for sensitive populations such as asthmatics or persons with 'Multiple Chemical Sensitivities'. (South Australian Government, sub. 56, p. 13)

The Commission supports current government efforts to conduct more research on 'multiple chemical sensitivities' to assist in developing appropriate policy and regulatory mechanisms to deal with this issue (box 5.3).

There are two broad areas where ingredient labelling could be expanded to assist people with chemical sensitivities:

- domestic chemical products (such as household cleaners)
- articles containing chemicals of concern (such as carpets, furniture and electrical appliances).

Box 5.3 **Multiple Chemical Sensitivity**

A number of participants in this study raised concerns about the lack of official recognition of, and support mechanisms for, sufferers of 'multiple chemical sensitivity' (MCS). MCS has been described as a condition whereby sufferers may experience severe adverse physiological reactions to exposure to everyday chemicals at levels below that which would normally affect the general population. Characteristic symptoms can include skin and respiratory problems, 'headaches, burning eyes, nose or throat, concentration or memory lapses, nausea, muscle pain, dizziness, breathing problems and fatigue' (Parliament of South Australia 2005, p. 1).

Internationally, few governments or medical bodies officially recognise MCS as a condition, and consensus has yet to be reached on its symptoms, appropriate procedures for diagnosis, or appropriate treatment. However, the condition is officially recognised in Germany and has gained the attention of governments in the United States, Canada and Sweden (Australian Chemical Trauma Alliance, sub. 9; Knott 2007). It is also listed in the International Classification of Diseases (ICD-10).

A Parliament of South Australia inquiry into MCS, conducted in 2005, made a number of recommendations calling for increased access to disability and medical support for MCS sufferers, greater controls on the use of pesticides, and the implementation of hospital protocols for MCS sufferers.

The South Australian Government agreed to many of the recommendations in principle (many of these actions were already being undertaken for other reasons), though it did not support recommendations to expand disability and medical support due to the lack of consensus on the cause, diagnosis and treatment of MCS (Hill 2005). It agreed in principle to MCS being referred to the Australian Health Minister's Advisory Council for further research, citing its support for research being conducted at the time by the Office of Chemical Safety (OCS) and the National Industrial Chemical Notification and Assessment Scheme (NICNAS).

Research by the OCS and NICNAS will act as a first step in reporting on the causation of MCS, current diagnosis and clinical management strategies, and considering practical measures to improve the management of MCS patients. It will identify priority areas for further study to inform and engage the clinical and scientific research community (OCS and NICNAS 2007). MCS interest groups are currently being advised of consultation arrangements prior to the public release of the study — planned for late August/early September. Copies of the study will be available from NICNAS.

Ingredient labelling is likely to be easier for the former than the latter. Imposing ingredient labelling requirements on manufactures or importers of consumer articles would impose significant costs on firms where they had to verify the chemical composition used in the products they sell. This would be difficult where components are derived from multiple manufacturers, as is often the case, and even more difficult for importers (who are not directly involved in the production process).

For domestic chemical products, existing regulations deal with the risk of allergic reaction or sensitisation in the following manner:

- The Information Standard requires the full disclosure of ingredients for cosmetic and toiletry products on the label.
- Poisons regulations include controls on substances that pose a sensitisation hazard (section 5.1).
- Poisons regulations require labelling on domestic chemicals to inform consumers of how to reduce the risks of exposure (such as through the use of gloves, or use in well-ventilated areas).

Furthermore, the marketing of many products emphasizes their health or environmental characteristics (such as 'fragrance free' or 'soap free' cosmetics and toiletries), giving choice to those consumers who have identified allergies.

The Commission also notes that accelerating NICNAS's review of existing chemicals (recommended in chapter 4) should provide additional valuable information about the toxicity of chemicals. This is likely to lead to more, and better informed, regulatory action to deal with the risks of chemical sensitivities and allergic reactions.

5.4 Diversion of chemicals to illicit-drug manufacture

Industry and government have adopted measures to prevent diversion of chemicals to illicit-drug manufacture. Limiting the availability of such chemicals, some of which are readily available and have legitimate purposes, makes it more difficult for illicit-drug manufacturers to source their required inputs.

Regulatory Framework

The Ministerial Council on Drug Strategy (MCDS) functions as the peak policy and decision-making body in relation to licit and illicit drugs in Australia. The National Working Group on the Prevention of the Diversion of Precursor Chemicals (Precursor Working Group), which reports to the MCDS, endorsed the development of the National Framework for the Control of Precursor Chemicals and Equipment Project. The aim of the Framework is to promote consistency of precursor chemical regulation for the entire supply chain through the development of a Best Practice Framework and guidelines for precursor chemicals and equipment. The Precursor Working Group is made up of more than 40 members from the Australian Government, state and territory law enforcement agencies, forensic and health services, and the pharmaceutical and chemicals industry (Australian Government

Attorney-General's Department, sub. 32). PACIA is an active member of the Precursor Working Group.

The Australian Government controls the import and export of precursor substances and coordinates national efforts to monitor and control their dissemination and use. The states and territories legislate against the unauthorised possession and sale of these substances above prescribed amounts, and in some cases also specify procedures to which firms must adhere in their storage and sale.

State and territory government regulations are largely derived from the voluntary Code of Practice for Supply Diversion into Illicit Drug Manufacture (the Supply Diversion Code). The Code is sponsored by the National Precursor Strategy in association with the Australian Government Attorney-General's Department, the Australian Crime Commission, Science Industry Australia, PACIA, and law enforcement agencies. The National Precursor Strategy is funded and chaired by the Australian Government and forms part of the National Illicit Drug Strategy.

The Supply Diversion Code categorises chemicals and apparatus that could be used to manufacture illicit drugs into categories according to their risk of diversion, and sets out recommended controls on their storage and supply (PACIA and SIA 2007). Category I chemicals have the greatest level of controls, and category II and III less so:

- Category I chemicals should only be sold to account customers who have signed an End User Declaration (EUD). The EUD includes the purchaser's identification and contact details, and information about the intended use of the chemicals. Category I chemicals cannot be paid for in cash, and delivery of orders must not take place within 24 hours of the order being placed. Additionally, such chemicals must be kept under locked storage with restricted access and regular checks.
- Category II chemical purchasers must complete EUD requirements where they are not account customers.
- Category III chemicals, while not subject to specific controls, do have a requirement that suppliers report suspicious purchasing behaviour.

Law enforcers and PACIA work closely to update the Supply Diversion Code regularly (PACIA, sub. 2). Chemicals deemed to be of significant interest for diversion purposes are typically proposed for incorporation into the Code by law enforcement agencies (PACIA, sub. 33). The most recent version of the Code was released in October 2007, following a review process led by the Australian Crime Commission with input from stakeholders.

Effectiveness and efficiency of current arrangements

There are inconsistencies between each jurisdiction's regulations and the Supply Diversion Code (PACIA, sub. 33). This is despite each jurisdiction's regulations being largely derived from the Code. A notable inconsistency is that some jurisdictions do not use risk categories and risk-tailored controls for each category. Failure to tailor controls to the level of risk could lead to regulatory burdens being greater than necessary, and, therefore, greater compliance costs for firms. It could also impose a competitive disadvantage on firms operating in multiple jurisdictions compared with some single jurisdiction firms. Inconsistencies can result in unwarranted costs due to the burden of monitoring, understanding and fulfilling different controls.

Inconsistencies can also undermine the effectiveness of the regulations. This can include difficulties in complying with requirements in multiple jurisdictions, as firms attempt to understand the different controls, and regulatory gaps, that can be exploited by illegal elements (including 'jurisdiction shopping'). A uniform approach across jurisdictions would address these issues.

The Precursor Working Group has been given responsibility for the coordinated development of the framework referred to above. It aims to promote greater consistency of precursor chemical regulation through the development of best-practice frameworks and guidelines for precursor chemicals and equipment (Australian Government Attorney-General's Department, sub. 32). This project is looking at appropriate controls across the supply chain on a national basis. This includes consideration of a nationally-consistent legislated approach to the control of precursor chemicals and has made significant in-roads, including development of a risk assessment framework. The framework will provide a more systematic approach to rating chemicals and determining appropriate regulation, and is an improvement on the current more ad hoc approach. The risk assessment tool will take into account considerations such as harm, industry use, and intent. The application of the tool will advance a consistent, risk-based approach to regulation while also taking into account both industry and law enforcement needs (Australian Government Attorney-General's Department, sub. DR75). However, the focus of the framework is limited to 'promoting' consistency and falls short of ensuring nationally uniform regulation.

The Commission considers there is a strong case for nationally uniform controls to prevent chemicals from being diverted into illicit drug manufacture. While existing inconsistencies do not appear significant at present, they have the potential to undermine the effectiveness of the controls and/or lead to material regulatory

burdens over the longer term. The only relevant consideration is how best to graft the controls onto specific jurisdictional generic legislation.

The Commission's preferred approach is a single risk-based schedule of drug precursors that each jurisdiction adopts by reference. This should be maintained by an expert body drawn from Commonwealth, state and territory agencies, that currently sponsor the Supply Diversion Code and other experts as appropriate,[16] and be overseen by the Ministerial Council on Drug Strategy. Industry associations and others should be consulted about proposed changes to the schedule. While the Commission recognises the important achievement so far of the Precursor Working Group in developing the framework, and the need for its ongoing involvement, it is a representational committee and hence not an appropriate body to be deciding policy on behalf of the wider community.

To ensure the associated controls are also nationally uniform, the Ministerial Council on Drug Strategy should ideally decide on supporting regulations that are adopted as a template. Alternatively, model regulations could be developed. The regulations would still be administered by state and territory agencies as they have the local knowledge to ensure effectiveness.

Adoption of the abovementioned approach would effectively make the Supply Diversion Code redundant by largely incorporating its features and associated procedures into legislation. While the Code has been useful, the jurisdictions would pursue a legislative path in order to ensure a greater level of effectiveness than is likely under a voluntary code.

PACIA has argued that drug-precursor controls should be managed jointly with those for chemicals of security concern, because they involve common issues:

> Unfortunately, the developments for drug precursors and chemicals of security concern are currently proceeding in parallel with very little interaction, much to the concern of the impacted industry ... The goal and objective of both are the same — to prevent illegal diversion — and should attract the same integrated regulatory framework that works in harmony and with no overlap … (sub. 33, attachment 3, pp. 10–14)

Subsequent to PACIA's submission, the draft framework for security sensitive chemicals has been released. It proposes that any controls on such chemicals will build on existing arrangements, including those for drug precursors:

> Building, wherever possible, on appropriate existing industry and/or government arrangements will ensure that controls for chemicals of security concern do not conflict

[16] The government agencies that currently sponsor the Supply Diversion Code are the Australian Government Attorney-General's Department, the Australian Crime Commission, the Australian Federal Police, and state and territory police forces.

> with current arrangements for chemicals, do not unnecessarily introduce new controls and minimise the impact on stakeholders.
>
> ... most measures identified in the risk assessment process are likely to be implemented by modifying existing safety, health or environment control measures, or for the diversion into illicit drug manufacture … (SCCRHM 2008, pp. 26–32)

Furthermore, the lead agency for drug-precursor controls — the Australian Government Attorney-General's Department — is expected to also oversee measures for chemicals of security concern. Nevertheless, some controls aimed at preventing chemical-related terrorism may need to differ from those used to prevent drug-related crime.

RECOMMENDATION 5.6

The Ministerial Council on Drug Strategy should develop illicit drug precursor regulations for adoption by reference by all jurisdictions. The associated risk-based schedule of chemicals and apparatus, which are to be subject to the regulations, should be maintained by a committee of experts overseen by the Ministerial Council, and also be adopted by reference in each jurisdiction.

5.5 Food safety

Regulatory framework

Australia and New Zealand have a joint system for regulating food safety (summarised in figure 5.1). This system is underpinned by an intergovernmental agreement — the Food Regulation Agreement — between the Commonwealth, state and territory governments (and a treaty with New Zealand). The Australia and New Zealand Food Regulation Ministerial Council is responsible for setting policy, and amending or rejecting food standards. The standards are developed by Food Standards Australia New Zealand (FSANZ), a trans-Tasman standard-setting body. Within Australia, the states and territories administer and enforce the standards for all foods offered for sale. The Australian Quarantine and Inspection Service inspects and samples imported foods at the border to ensure they comply with the standards.

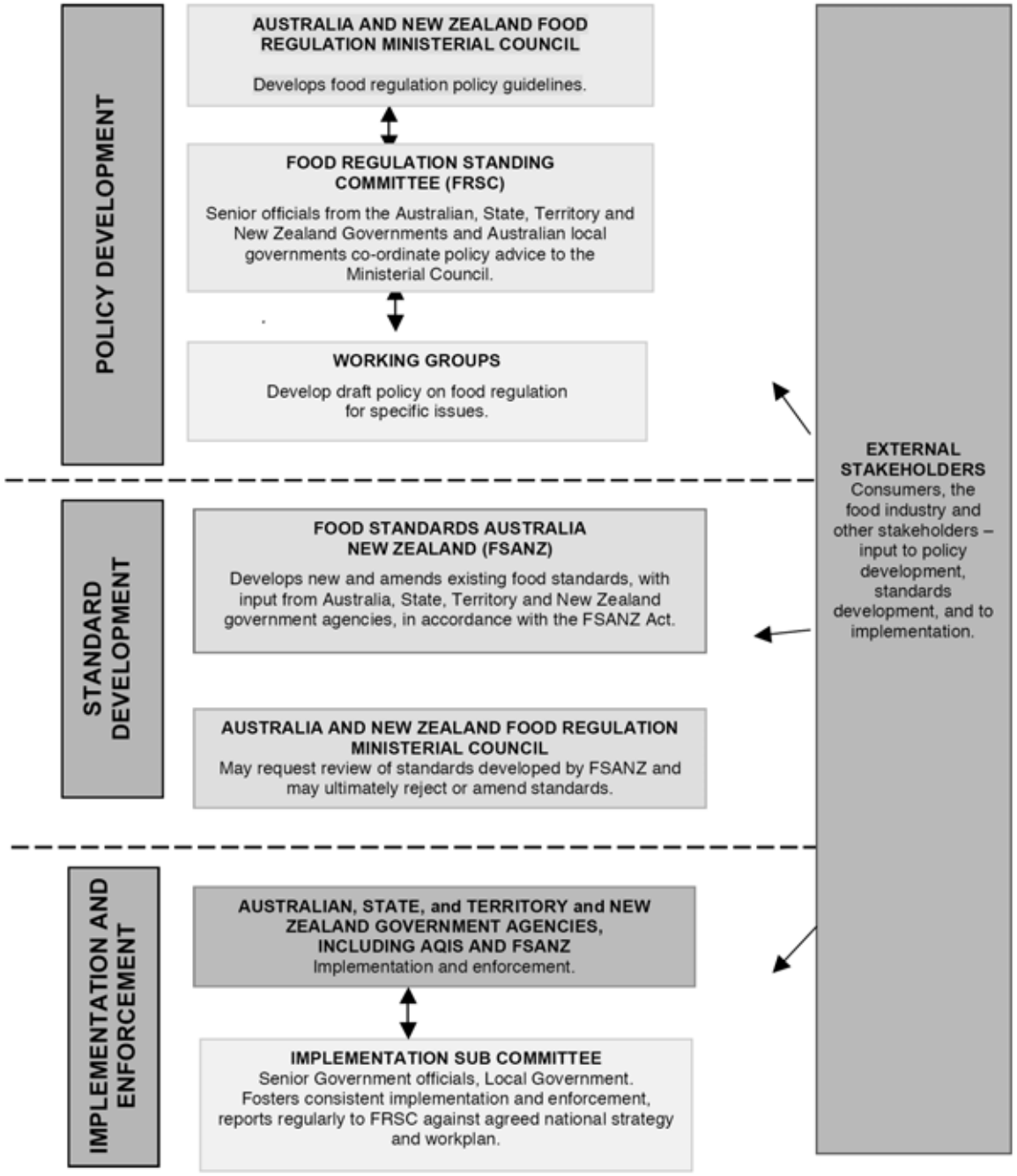
FSANZ (sub. 22) noted that chemicals and plastics are subject to three areas of food regulation. These involve limits on the extent to which foods may contain:

1. residues from agvet chemicals
2. food additives and processing aids

3. contaminants, including residues from plastics used in packaging.

The NSW Government (sub. 31) favoured more prescriptive controls on the latter two areas, which it referred to collectively as ‘food-contact chemicals’. No evidence was provided on the associated benefits and costs. This is a matter that can be raised in the Australia and New Zealand Food Regulation Ministerial Council. Any proposed regulatory changes should be subject to a RIS that includes a thorough cost–benefit analysis.

Figure 5.1 **Food regulation system**[a]



a In the box for FSANZ it is noted that FSANZ develops food standards with input from other government agencies. This includes input from the Australian Pesticides and Veterinary Medicines Authority regarding maximum residue limits, as detailed in the text of this chapter.

Source: FSANZ (nd).

Two agencies — APVMA and FSANZ — prescribe limits on agvet chemical residues in food — termed maximum residue limits (MRLs) — and do so in separate regulations:

- APVMA prescribes MRLs that reflect 'good agricultural practice' so breaches of agvet control-of-use requirements can be detected (chapter 8)
- FSANZ prescribes MRLs so that crops and animals treated with chemicals can be verified as being safe for human consumption[17].

APVMA consult with a wide range of groups through a number of consultative and liaison committees. In addition to these consultative structures, the APVMA routinely conducts consultations with its stakeholders, seeks their input on issues, decisions and scientific assessment outcomes relating to registration activities and the review of existing chemicals, as well as on proposals to reform requirements or procedures (APVMA sub. 59). FSANZ assessments are developed through public consultation (sub. 22), and provide an opportunity for importers to have input into the setting of residue standards (FBIA, sub. DR84).

Limits on agvet chemical residues in food is an area where there have been long-standing concerns about duplication and inconsistency. There is potential for two different MRLs to be prescribed for the same chemical in the same food by the two agencies. In such cases, primary producers in most jurisdictions would have to comply with the most stringent MRL.

In order to mitigate duplication and inconsistency, the two agencies coordinate their actions. The usual procedure has been that APVMA first prescribes an MRL as part of its conditions of approval for an agvet product, and then submits an application to FSANZ to include the MRL in the Australia New Zealand Food Standards Code[18].

FSANZ has never rejected an MRL application from APVMA. This can be attributed to the fact that APVMA assesses the human-health impacts of an MRL before approving it, and does so using dietary models and reference health standards from FSANZ and DOHA[19]. For this reason, FSANZ does not usually undertake its

17 Food regulations in all states and territories (and Commonwealth regulations for imported foods) refer to MRLs prescribed by FSANZ in Standard 1.4.2 of the Australia New Zealand Food Standards Code.

18 This discussion applies to MRLs prescribed by APVMA for human foods (table 1 of the MRL Standard). APVMA also sets MRLs for pesticides in animal feeds (table 4 of the MRL Standard) but these are not incorporated into food standards managed by FSANZ.

19 This arrangement is formalised in a memorandum of understanding between APVMA and FSANZ, which includes an attached protocol for dietary risk assessments. DOHA's Office of Chemical Safety assesses the toxicology of agvet chemicals and establishes the reference health standards.

own dietary exposure assessment when considering an MRL submitted by APVMA[20].

Inconsistencies do arise, however, because there is a time lag between when APVMA prescribes an MRL and when FSANZ mirrors it in food standards. This has led to situations where farmers complying with agvet control-of-use requirements set by APVMA cannot sell their produce because FSANZ has yet to duplicate a relevant MRL in food standards. Participants noted there can be a long delay between APVMA and FSANZ decisions, sometimes up to a year or more:

> Protracted delays create situations where approval for use has been granted, making it legal to apply a pesticide to a crop but once the crop is harvested it is, in effect, illegal to have the residue in the raw agricultural commodity derived from that crop. Such delays can and have resulted in growers being found in breach of the Food Standards Code. This potentially puts them at risk of noncompliance with state regulations and any quality assurance scheme under which they may operate. (AUSVEG Ltd, sub. 52, p. 2)

> This dual system involving two Commonwealth Government agencies [APVMA and FSANZ] causes unnecessary delays of up to one year in formalising MRLs. It can lead to the situation where farmers can use a registered pesticide product according to the label and follow good agricultural practice to meet the APVMA's recommended MRL, but still not meet the Food Standards Code because of delays in FSANZ assessing, approving and listing the MRL. (Croplife Australia Limited, sub. 57, p. 6)

> … when a new pesticide use is gazetted by APVMA, it is not gazetted in the Food Standards Code by FSANZ simultaneously. There can be lengthy delays of up to 15 months, where some fresh produce can technically be a MRL violation despite the fact the chemical is legal. This is a national issue that has been raised by industry stakeholders for many years, however it must be recognised that this issue has still not been rectified. (Growcom, sub. 12, p. 12)

In response to such concerns, recent legislative amendments were made to reduce the time lag between APVMA and FSANZ decisions.[21] If APVMA receives a product-registration application involving a new active constituent, and its approval is likely to require a new MRL, APVMA now has to notify FSANZ at least 30 working days before inviting public comment on the application.[22] APVMA will

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20 FSANZ has the authority to effectively delegate dietary exposure assessments to APVMA under s.112 of the *Food Standards Australia New Zealand Act 1991* (Cwlth), which allows FSANZ to rely on the work or processes of other government agencies when this would avoid duplication.

21 The amendments were included in the *Food Standards Australia New Zealand Amendment Act 2007* (Cwlth) and came into effect on 1 October 2007.

22 In particular, s.13 of the *Agricultural and Veterinary Chemicals Code Act 1994* (Cwlth) requires APVMA to invite public comment on all applications to register a product with a new active constituent. Under s.13A of the Act, APVMA must notify FSANZ at least 30 days before inviting public comment on such applications, if it is likely an MRL would have to be prescribed.

follow the same procedure for any application to extend an existing product's approved uses to a major export commodity, because public consultation is also conducted for such applications.

APVMA is not required to (and generally does not) invite public comment on MRLs for minor export commodities, or for MRLs associated with permits and emergency situations (temporary MRLs). As a result, the recent reforms do not apply in such cases. Comments by AUSVEG Ltd suggest this is a cause for concern, because historically there has been an:

> … apparent inability of FSANZ to accommodate temporary MRLs established by the APVMA. These MRLs are frequently the result of permit applications submitted on behalf of minor vegetable crops at the instigation of AUSVEG. The absence of these MRLs from the Food Standards Code has potentially serious implications for many growers. Many state authorities and accreditation bodies rely upon the Code to assess compliance resulting in legitimate uses prompting enforcement action. AUSVEG therefore believes that greater efforts are needed to ensure that the MRL setting process in Australia is harmonised to ensure that such anomalies no longer occur. (sub. 52, p. 2)

For cases where the recent reforms do apply, FSANZ will now be able to commence its MRL assessment procedures earlier than previously. However, FSANZ still expects a time lag of six to nine months before it adopts an MRL prescribed by APVMA:[23]

> In general, FSANZ [prior to the recent reforms took] … between nine to twelve months to complete the assessment of MRLs from the APVMA. Under the new legislative requirements this should be reduced to between six to nine months. (sub. 22, p. 6)

Much of the remaining delay can be attributed to the governance arrangements for food standards. If relevant experts in FSANZ conclude that a proposed MRL would be an appropriate food standard, their decision has to be submitted to the FSANZ Board for approval. If the Board agrees, the decision then has to be submitted to the Australia and New Zealand Food Regulation Ministerial Council for its consideration. The Ministerial Council has 60 days to request a review of FSANZ's decision before it is incorporated into the Food Standards Code. A single jurisdiction can prompt such a request under the Ministerial Council's voting rules.

These governance arrangements are not consistent with the best-practice model outlined in chapter 3. The role of a ministerial council should be to provide high-level policy development and oversight of regulatory arrangements. The task of determining standards for specific chemicals and products under those

[23] The amended Food Standards Australia New Zealand Regulations 1994 (s. 10) direct FSANZ to complete its consideration of an MRL within nine months.

arrangements should be fully delegated to a national standard-setting body that has the necessary technical expertise and undertakes a public consultation process.

Another reason for delays in adding MRLs to the Food Standards Code has been that FSANZ typically waits until it has a batch of MRL applications to process. For example, in October 2007, FSANZ invited public comment on a draft assessment report for MRLs notified by APVMA in January, February and March 2007 (FSANZ 2007).

Effectiveness and efficiency

Regular surveys are used to monitor compliance with MRLs. The Australian Government Department of Agriculture, Fisheries and Forestry manages a National Residue Survey that regularly measures chemical residues in raw animal products (meat, egg, honey and fish) and plant products (grain, oilseed and horticulture). This survey is largely funded by industry levies and is used to facilitate Australia's access to export and domestic markets (DAFF 2007). FSANZ conducts the Australian Total Dietary Survey about every two years to monitor dietary exposure to residues in a range of 'table-ready' foods (FSANZ 2005). Various state government agencies and marketing bodies also monitor MRL compliance (Croplife, sub. 35; PSIC nd). For example, the Victorian Department of Primary Industries regularly tests residues in locally-grown fresh produce through its Victorian Produce Monitoring Program (DPI Victoria 2006). The abovementioned surveys typically find relatively few instances of MRLs being exceeded, and so the regulatory arrangements for MRLs appear to have been largely effective in keeping chemical residues in food to safe levels.

With respect to efficiency, recent reforms have only partially addressed long-standing concerns about duplication and inconsistency. There will still be a time lag while an MRL prescribed by APVMA is considered for incorporation into the Food Standards Code. There would be a case for retaining this dual process if APVMA did not consider food safety when determining MRLs. However, s. 14 of the *Agricultural and Veterinary Chemicals Code Act 1994* (Cwlth) specifically directs APVMA not to approve an active constituent or chemical product that would be an 'undue hazard to the safety of … people using anything containing its residues'. And, as noted previously, APVMA assesses human-health impacts using dietary models and reference health standards developed by FSANZ and DOHA.

The case for retaining a dual process is further weakened by the fact that APVMA's approach typically leads to MRLs being set at a level that is very conservative from the perspective of food safety:

> MRLs are … normally set at levels well below those that would cause an adverse health effect. MRLs act to protect public health and safety by ensuring that residues are no higher than is necessary for effective control of pests and disease. (FSANZ 2003)
>
> If an MRL is exceeded, it usually indicates a misuse of the chemical but does not normally indicate a public health or safety concern. (APVMA 2004a, p. 2)
>
> MRLs are normally set well below the level that would harm health. When an MRL is exceeded, it usually indicates a chemical is being misused, rather than a public health or safety concern. (PSIC nd, p. 2)

In light of the above, it is not surprising that FSANZ has never rejected any of the MRLs submitted to it by APVMA over the years. The process managed by FSANZ has proven to be unnecessary duplication, with the added drawback that it has led to regulatory inconsistencies for as long as a year or more. A more efficient approach would be for MRLs for domestically grown produce, set by APVMA, to be automatically incorporated into the Food Standards Code.

However, the Ministerial Council (with input from FSANZ) would retain the option to amend any MRL specified in the Food Standards Code, where sufficient evidence exists to warrant it.

In its draft report the Commission recommended that MRLs, as set by the APVMA, be automatically incorporated into the Australia and New Zealand Food Standards Code, and that any decision to the contrary should be based on a cost–benefit analysis and be reported publicly. The Commission notes that COAG, at its meeting of 3 July 2008, agreed to implement recognition of MRLs set by APVMA for domestically grown produce.

FSANZ should continue to undertake its own assessments to accommodate imported foods, and public consultation arrangements for importers should remain unchanged.

6 Occupational health and safety

Key points

- Governments regulate chemicals in the workplace for a number of reasons:
  - Exposure to chemicals in workplaces can cause injury, illness and death.
  - Workplace chemicals can pose complex risks to people, property and the environment. Because the hazards and risks are not easy to observe, adequate safety precautions may not be taken.
  - Common law liability for negligence or breach of contract may not ensure appropriate levels of workplace safety.
- Overall, the system for regulating chemicals and plastics in the workplace appears to be effective in that it contributes to a reduction in the incidence of workplace injury, illness and death. The total costs of the regulatory system to businesses and governments are not known. Elements of the system could be delivered more efficiently by reducing costs, improving occupational health and safety (OHS) outcomes, or both.
- In some areas of workplace chemicals regulation — including classification, labelling and material safety data sheets (MSDS) — regulatory requirements are nationally consistent. In other areas, such as major hazard facilities and the storage and handling of workplace dangerous goods, regulations are less consistent across jurisdictions.
- National consistency and overall effectiveness and efficiency in chemicals and plastics OHS regulation would be enhanced by an intergovernmental agreement between the Commonwealth, state and territory governments to implement national standards and codes of practice without variation.
- Replacing the existing parallel systems of regulation for hazardous substances and dangerous goods with a single system of regulations for all workplace hazardous chemicals would potentially reduce some of the costs faced by firms, and could increase compliance. Moving to a new system would also involve significant costs. Under current circumstances, the costs of implementing a new system would likely exceed the benefits.
- Australia should continue to monitor the implementation of the United Nations' Globally Harmonised System of Classification and Labelling of Chemicals overseas, and consider implementing the system for workplace chemicals if, at some time in the future, it is found to deliver a net benefit.

6.1 The case for regulating workplace chemicals

Work-related injuries, illnesses and fatalities impose significant costs on individuals, their families, businesses, the community and the economy as a whole. There are financial costs such as compensation, medical treatment and time off work, and non-financial costs such as the pain and suffering of people injured at work and their families. In 2004-05, there were 140 655 compensation claims made for work-related injuries or illnesses that involved one week or more absence from work. Compensated fatalities accounted for 214 of these claims (ASCC 2007a).

Contact with chemicals and plastics is one cause of work-related injury, illness and fatalities in Australia. In 2004-05, there were 29 compensated fatalities that were caused by long-term contact with chemicals or substances (ASCC 2007a), and many more people die each year from past exposure to workplace hazardous substances (ASCC 2005).

In addition, in 2004-05 there were 1675 claims for compensation for injuries caused by chemicals and other substances (this was down from 1890 compensated injuries in 1997-98). The median loss of working time from injuries caused by chemicals and other substances was 1.8 weeks and the median compensation payout was $3400 (ASCC nd2).

Workplace chemicals can present complex risks to people, property and the environment. The physical properties of some chemicals — such as flammability and toxicity — are hazardous. These hazards and the risk of exposure to, and adverse impacts on, people, property and the environment, are not necessarily obvious. This potential information failure could lead to inadequate safety precautions in the workplace.

Employers can benefit from exercising a duty of care for their employees — workplace safety increases worker satisfaction and productivity, and can enhance a firm's reputation. However, the desire to exercise a duty of care is unlikely to be sufficient in all cases to ensure levels of workplace safety that meet community expectations.

One approach to managing the risks posed by workplace chemicals would be to rely on the common law system to supplement employers' own interests. Under common law, people who are injured at work can claim compensation from their employer for negligence or breach of contract. While the potential for such claims gives employers an added incentive to prevent workplace injuries, there are some weaknesses in the common law system:

- Employers may underestimate the risk of workplace injury, leading them to not take adequate safety precautions or insurance.
- Claims can involve high legal 'transaction costs'.
- Compensation that is awarded by courts may not be delivered if firms are not adequately insured.
- The adversarial nature of common law actions does not necessarily encourage early return to work.

As a consequence, governments directly regulate some workplace practices, including the use of hazardous chemicals, to reduce the risks of injury, illness and death. This chapter assesses the effectiveness and efficiency of the Australian system of chemicals and plastics occupational health and safety (OHS) regulation, and makes recommendations on reforms that could improve the system.

6.2 The regulatory framework

Under the Australian Constitution, the power to legislate for OHS was not explicitly referred to the Commonwealth Government. Consequently, ten principal OHS statutes have been developed — six State, two Territory and two Commonwealth (one relating to Commonwealth Government workers and the other relating to the maritime industry). While maintaining responsibility for OHS regulations within their jurisdictions, the Commonwealth, state and territory governments have made some effort to enhance the consistency of OHS regulations across jurisdictions, and to harmonise Australian regulations with international standards.

This section describes the current regulatory framework, the role of the different levels of government and the mechanisms for national and international harmonisation.

State and territory legislation, regulations and codes of practice

All states and territories have a principal OHS Act that codifies the duties of care under common law. The general duties of care are supported by more detailed requirements that are set out in regulations. Codes of practice describe ways in which the requirements that are set out in regulations can be met.

Compliance with regulations is mandatory, and non-compliance can lead to penalties. Compliance with codes of practice is not mandatory, but offers certainty to firms with regulatory obligations. Firms that choose to meet their regulatory

obligations in other ways may have to prove that their chosen approach satisfies the required outcomes.

Basic elements of workplace chemicals regulation

Regulations for workplace chemicals impose three broad obligations on employers:

1. *Hazard identification* — Employers must determine whether a chemical used in the workplace has hazardous properties (such as toxicity, flammability or corrosiveness).
2. *Information provision* — If a workplace chemical has hazardous properties, it must be labelled and employers must ensure that people likely to be exposed to it have access to a material safety data sheet (MSDS) that sets out the properties of the chemical and the measures that should be taken to reduce the risk of injury.
3. *Risk assessment and control* — Employers must assess the risks that workplace chemicals pose to workplace health and safety, and take actions to control and reduce the risks. This may include bans on using certain chemicals in any circumstances.

Hazardous substances and dangerous goods

In Australia, workplace chemicals are regulated under different sets of regulations depending on the types of hazard they present. Substances that pose a hazard (either acute or chronic) to the health of people who are exposed to them, are regulated as 'hazardous substances'. Goods that pose a physical hazard to people, property or the environment (for example, flammable, explosive or corrosive materials), are regulated as 'dangerous goods'.

History of workplace hazardous substances regulations

Until 1992 there were no overarching hazardous substances regulations in Australia. Some states and territories regulated specific substances (such as lead and asbestos) for their potential health effects, and set exposure standards for others. The National Occupational Health and Safety Commission (NOHSC) introduced national Approved Criteria for Classifying Hazardous Substances and National Model Regulations for the Control of Workplace Hazardous Substances. The Approved Criteria and Model Regulations were implemented reasonably consistently across the states and territories. Participants in this study have identified two factors that contributed to this outcome:

- Because the states and territories did not have an existing set of overarching regulations for hazardous substances, it was relatively straightforward to overlay the national model regulations onto the existing state and territory regulations.
- The states and territories committed to a timeframe for the implementation of the national model regulations.

History of workplace dangerous goods regulations

The National Standard for the Storage and Handling of Workplace Dangerous Goods (declared by the NOHSC in 2001) has not been implemented as consistently as the workplace hazardous substances regulations (section 6.4). Before the declaration of the National Standard, the states and territories all had some regulations in place for workplace dangerous goods. Many of these regulations drew on the Australian Code for the Transport of Dangerous Goods by Road and Rail (the ADG Code).

State and territory regulations for workplace dangerous goods were administered by a range of departments and agencies, and not necessarily through OHS agencies. The regulators had historically made efforts to harmonise their regulations through annual meetings between the heads of the regulatory agencies. While the classification of dangerous goods and requirements for labels and MSDS are all relatively consistent, regulations for risk assessment and control are not. Factors that contributed to this outcome include:

- The National Standard is a performance-based regulation — it imposes a general duty of care on people who manage or control the storage and handling of dangerous goods. Regulated parties have flexibility to determine how to satisfy their duty of care. Before the declaration of the national standard, state and territory regulations had been more prescriptive, and many regulators were reluctant to move to a performance-based system.
- There was no commitment to a timetable for implementing the National Standard.

The existence of separate regulatory systems for hazardous substances and dangerous goods leads to duplication, regulatory overlaps and inefficiency in chemicals and plastics OHS regulation. Regulators have recognised that this is a significant problem, and are moving to a single system of regulation for all workplace hazardous chemicals. The Commission's assessment of the proposed system is set out in section 6.5.

Institutional arrangements

Responsibilities for chemicals and plastics OHS regulations are split between Commonwealth, state and territory governments.

The role of Commonwealth Government departments and agencies

A number of Commonwealth Government departments and agencies have a role in chemicals and plastics OHS regulation. The two with the most direct role are the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and the Australian Safety and Compensation Council (ASCC).

NICNAS

NICNAS's primary role is to assess industrial chemicals. Formally, its role in OHS regulation is limited. When NICNAS assesses chemicals, it publishes reports on its findings, including recommendations on the contents of labels and MSDS. NICNAS recommendations that relate to OHS are reviewed by the Office of the ASCC (OASCC) and many of the listings on the Hazardous Substances Information System (HSIS) are based on information supplied by NICNAS. NICNAS stated:

> To facilitate this process, NICNAS OHS recommendations are framed in accordance with nationally agreed frameworks, the National Model Regulations for the Control of Hazardous Substances in the Workplace and the National Dangerous Goods Framework. (sub. 36, p. 4)

The National Code of Practice for the Control of Workplace Hazardous Substances recommends that employers should make NICNAS summary reports available to employees and their representatives:

> Where they exist and are applicable to the workplace, summary reports produced under the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) should be made available on request to employees and employee representatives. (NOHSC 1994a, p. 41)

It should be noted that unless this provision is enforced under state or territory OHS legislation and regulations, it does not impose any obligations on employers to provide (or even be aware of) NICNAS summary reports.

The ASCC

The ASCC is an advisory body that is established by administrative decision by the Australian Government Minister for Employment and Workplace Relations. The ASCC was first established in October 2005, when it succeeded the NOHSC. The

ASCC is a tripartite council of 18 representatives from employer and employee organisations and Commonwealth, state and territory government OHS agencies. The ASCC provides a forum for those parties to consult and participate in the development of national standards and codes of practice for OHS and workers' compensation. The regulatory documents that are declared by the ASCC are intended to form the basis of a nationally-consistent system of OHS regulation.

The ASCC is supported by the OASCC, which is part of the Department of Education, Employment and Workplace Relations.

The ASCC is not a regulatory authority and does not make or enforce laws. The national standards and codes of practice that it declares and maintains have no legal authority unless they are adopted by a state or territory government. The states and territories are under no obligation to adopt any of the national model regulations, standards or codes of practice that the ASCC declares.

The ASCC has declared and maintains seven national standards and model regulations, and 11 national codes of practice (box 6.1). These have been implemented to varying degrees by the states and territories.

As well as declaring national standards and codes of practice, the ASCC maintains the HSIS, a database of:

> … substances that have been classified in accordance with the Approved Criteria for Classifying Hazardous Substances 3rd Edition and/or have National Exposure Standards declared under the NOHSC Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment. (ASCC nd1)

The HSIS assists manufacturers, importers and suppliers of chemicals to identify chemicals with hazardous properties. It also includes advice on how chemicals should be labelled and on the maximum exposure limits that should not be exceeded in the workplace.

The data set that forms the basis of the HSIS is updated from time to time. The most recent update of the data set occurred in June 2008. Prior to that, the system had not been updated since March 2007. Delays in updating the information on the HSIS reduce its usefulness as a source of information. The Commission considers that it should be mandatory for the ASCC to update the HSIS whenever a new National Exposure Standard is declared under the NOHSC Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment.

The ASCC has the power to ban workplace chemicals

While the ASCC is not a regulatory authority, it can trigger a ban on workplace chemicals, or exclude them from certain uses, by adding them to schedule 2 of the National Model Regulations for the Control of Workplace Hazardous Substances (the National Model Regulations). Currently, there are only six substances listed on the schedule, all of them different types of asbestos. As with other national standards and codes of practice maintained by the ASCC, the bans or restrictions can only be enforced by the states and territories. Some jurisdictions (for example, the ACT) refer directly to the National Model Regulations in their OHS legislation. Other jurisdictions have to specifically adopt the changes to schedule 2 of the National Model Regulations into their own regulations. Jurisdictions can also ban or limit the use of substances that are not banned by the ASCC. For example, the Northern Territory bans the use of a number of substances for spray painting and abrasive blasting.

Some participants in the study wanted to see more use made of the ASCC's power to ban chemicals by adding them to schedule 2 of the National Model Regulations. There were concerns that the process of adding a substance to the schedule is excessively complex and time consuming.

For example, in 2004 the Australian Paint Manufacturers' Federation (APMF) sought government support for an industry ban on paint products containing lead. One avenue the APMF explored was adding lead-containing paint to schedule 2 of the National Model Regulations. The NOHSC stated to the APMF at the time that:

> … attempting to restrict the use of lead based paint through provisions of the Model Regulations or its Schedules is both complex and slow from a legislative perspective. (APMF, sub. 8, p. 5)

Adding a substance to schedule 2 of the National Model Regulations would have required agreement from the NOHSC, which would have required consultation with:

> … State and Territory jurisdictions, employer and employee representatives and the public, and endorsement by NOHSC's committees and Workplace Relations Ministers, prior to declaration by the National Commission. (APMF, sub. 8, p. 6)

The APMF subsequently approached the NSW WorkCover Authority with the proposal to ban lead-containing paint. The Authority recommended that the proposal should be pursued through the NOHSC (APMF, sub. 8).

As a result, the APMF has been unable to convince any regulatory agency to support the ban on lead in paint that was self-imposed by industry.

Banning a chemical outright is a blunt instrument that should be the last resort in the management of chemical hazards and risks. Any ban should be subject to all the relevant COAG requirements, including a full regulation impact statement (RIS). While the fact that adding a substance to schedule 2 of the National Model Regulations is complex and slow may not indicate a failing system, it may indicate that the system is not capable of achieving a ban through adding substances to the schedule. Any proposal to reform the system that would make it easier for regulators to ban substances should be subject to a thorough analysis of benefits and costs to all sectors of the community.

Box 6.1 **ASCC model regulations, standards and codes of practice that apply to workplace chemicals and plastics**

National model regulations and standards

- National Standard for the Storage and Handling of Workplace Dangerous Goods
- National Model Regulations for the Control of Workplace Hazardous Substances
- National Model Regulations for the Control of Scheduled Carcinogenic Substances
- Approved Criteria for Classifying Hazardous Substances
- National Standard for Synthetic Mineral Fibres
- National Standard for the Control of Inorganic Lead at Work
- Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment

National codes of practice

- National Code of Practice for the Storage and Handing of Dangerous Goods
- National Code of Practice for the Control of Workplace Hazardous Substances
- National Code of Practice for the Control of Scheduled Carcinogenic Substances
- National Code of Practice for the Labelling of Workplace Substances
- National Code of Practice for the Preparation of Material Safety Data Sheets
- National Code of Practice for the Safe Use of Synthetic Mineral Fibres
- National Code of Practice for the Control and Safe Use of Inorganic Lead at Work
- Code of Practice for the Safe Removal of Asbestos
- Code of Practice for the Management and Control of Asbestos in the Workplace
- National Code of Practice for the Safe Handling of Timber Preservatives and Treated Timber
- National Code of Practice for the Safe Use of Vinyl Chloride

Development of national standards and codes of practice

Under the *Australian Workplace Safety Standards Act* 2005 and the Australian Workplace Safety Standards Regulations 2005, the ASCC is obliged to invite representations on proposed national standards and codes of practice. The Workplace Relations Ministers' Council (WRMC) approves the ASCC's work program, but has no formal role in the declaration of national standards or codes of practice.

Development and declaration by the ASCC of a new national standard or code of practice can take a number of years. The ASCC has the power to establish 'technical groups' or 'reference groups' to examine specific issues (for example, to decide what information should be required on a hazardous chemicals label). These are tripartite groups of representatives from the jurisdictions, industry and employee organisations. They typically have around 12 to 15 members. Where necessary, the OASCC prepares 'issues papers' that are sent out to all ASCC members for their input.

One or more drafts of the national standard or code of practice are made publicly available for comment.

The final document is submitted by the OASCC to the ASCC for declaration. The ASCC's constitution encourages it to make decisions by consensus, but if this is not possible, standards and codes of practice can be declared by a two-thirds majority. That the WRMC has no formal role in the declaration of standards is a concern (section 6.6).

The role of the states and territories

In most states and territories, an OHS agency administers regulations that cover workplace hazardous substances and dangerous goods, including the transport of dangerous goods.

In Queensland, the situation is more complicated. The Plastics and Chemicals Industries Association (PACIA) stated that, as well as four state government agencies, local governments also enforce elements of workplace chemicals regulation in that state:

- Major Hazard Facilities and Dangerous Goods legislation is under CHEM Services in the Department of Emergency Services
- Class 3 Dangerous Goods (Flammable Liquids) licensing is carried out by local government

- Hazardous Substances are regulated by Workplace Health and Safety in the Department of Employment and Industrial Relations
- Explosives and security sensitive ammonium nitrate are regulated by the Department of Natural Resources, Mines and Energy
- Transport of Dangerous Goods is regulated through Queensland Transport. (sub. 33, pp. 4–5)

The greater the number of agencies involved in OHS regulation, the more complex the system is for businesses that use chemicals. The complexity increases the costs of compliance and can undermine the effectiveness of the regulations.

The Queensland Government acknowledged that the current framework in Queensland 'is difficult for obligation holders to navigate and creates jurisdictional overlaps between agencies' (Queensland Government sub. DR121, p. 3). The Queensland Government stated that 'steps are currently being taken to correct this situation … from a whole-of-government perspective' (sub. DR121, p. 3).

International harmonisation

Because the intrinsic properties of chemicals do not depend on their location, countries that have compatible hazard classification systems can benefit from sharing chemical assessment data. Systems of classification, labelling and MSDS that are compatible, can facilitate trade in chemicals and plastics.

Currently, the Australian system of classification for hazardous substances is aligned with the classification system used in the European Union (ASCC 2006f). For dangerous goods, Australia uses a classification system that is aligned with the United Nations Transport of Dangerous Goods Model Regulations.

The Globally Harmonised System of Classification and Labelling of Chemicals

Australia is currently moving toward implementation of a system based on the United Nations' Globally Harmonised System of Classification and Labelling of Chemicals (GHS). The GHS is a hazard-based system for classification and labelling of workplace chemicals. The GHS consists of:

- a set of criteria for determining whether a chemical has hazardous properties such as flammability, explosiveness or carcinogenicity
- requirements for the content of GHS-compliant labels and safety data sheets (SDS). (The GHS uses 'SDS' instead of the Australian term 'MSDS'.)

Many countries have indicated that they intend to implement GHS-based systems for workplace hazardous chemicals. However, to date, only New Zealand has implemented a GHS-based system. Full implementation in other countries is not expected for a number of years. Europe is planning to begin implementing a GHS-based system in 2008, and abandon its current system of hazard classification (which is also currently used in Australia) in 2015.

Implementation of the GHS could deliver benefits by internationally harmonising classification, labelling and SDS for workplace chemicals, but switching to a new system would involve costs to industry and governments. The Commission has assessed some of the costs and benefits of GHS implementation (section 6.5).

6.3 Effectiveness of workplace chemicals regulations

The overriding objective of Commonwealth, state and territory government OHS legislation and regulations is to minimise the incidence of workplace injury, illness and death. The effectiveness of OHS regulations depends on how successful they are in meeting this objective.

International comparisons

Data from the International Occupational Safety and Health Information Centre suggest that rates of workplace injury and death in Australia compare favourably with many other developed countries (table 6.1). It should be noted, however, that international comparisons of workplace injury, illness and death are complicated by a lack of data and often — where data are available — by differences in definitions, systems of compensation and industry structure.

Table 6.1 **Rates of workplace injury and fatalities, international comparisons, 2004**

Country	*Workplace fatalities*	*Workplace injuries*
	(per 100 000 workers employed)	(per 100 000 workers employed)
Australia [a]	2.0	1 270
Austria [b]	5.0	3 890
Belgium [a]	4.4	3 797
Canada [a]	5.8	2 135
Denmark [b, c]	2.0	1 574
Finland [a]	2.1	2 715
France [a]	3.5	3 949
Germany [a]	2.6	2 948
Italy [a]	5.0	3 097
Sweden [b]	1.4	782
UK [b]	0.7	585
US [a]	4.0	**na**

a Data refer to compensated injuries and fatalities. **b** Data refer to reported injuries and fatalities. **c** Data are from 2001. **na** Not available.

Source: Adapted from International Occupational Safety and Health Information Centre (nd).

Workers' compensation claims are falling over time

Between 1997-98 and 2005-06, overall rates of workers' compensation claims for workplace injuries and fatalities in Australia have fallen from 12.2 per million hours worked to 9.4 per million hours worked. Rates of claims for injuries and fatalities related to chemicals fell slightly, from 1.5 per million hours worked to 1.4 per million hours worked (table 6.2).

Table 6.2 **Rates of claims for workers' compensation, per million hours worked, Australia, 1997-98 to 2005-06**

Year	*1997-98*	*1998-99*	*1999-00*	*2000-01*	*2001-02*	*2002-03*	*2003-04*	*2004-05*	*2005-06*
Total claims	12.2	11.6	11.2	11.2	10.9	10.6	10.5	10.1	9.4
Chemicals-related claims [a]	1.5	1.6	1.5	1.5	1.4	1.5	1.4	1.4	1.4

a Refers to claims where the mechanism of injury was a chemical or chemical product, a material or a substance.

Source: ASCC (nd2).

Diseases of long latency are a significant problem

Exposure to hazardous substances can have both acute and chronic effects on people's health. Acute reactions to substances include skin or eye irritation, respiratory problems and other effects that manifest within a short period after exposure. Chronic effects can include carcinogenicity, germ cell mutagenicity, reproductive toxicity and other long-term effects on specific organs or systems. These diseases can have long latency periods — that is, symptoms may not appear until many years after exposure.

Diseases of long latency are believed to cause a significant number of deaths and illnesses in Australia:

> … it has been estimated that over 2000 people die per year from past occupational exposures to hazardous substances. (ASCC 2005, p. 1)

Another ASCC report (ASCC 2006g) estimated that occupational exposure to carcinogens is responsible for about 5000 cases of cancer per year. (It should be noted that this figure includes exposure to carcinogens that are not related to chemicals or plastics, such as solar radiation.)

Current Australian OHS regulations require employers to identify substances that have long-term health effects, and to ensure that people in workplaces are not exposed to harmful levels of hazardous substances. Employers may also be required to monitor the health of people who could be exposed to chemicals with adverse long-term effects. This can include periodic blood or urine tests and, for some substances, chest X-rays.

It is difficult to assess how effective OHS regulations are in reducing the incidence of diseases of long latency. However, actions such as the strict controls placed on asbestos demonstrate the seriousness of the concerns.

A simpler system would increase effectiveness

Regulations that overlap or are unnecessarily complex have been identified as a barrier to compliance and to improved OHS outcomes.

For example, the ASCC (2006a) surveyed 91 small and medium enterprises (SMEs) to determine whether they had adequate measures in place to control hazardous substances. The ASCC focused on measures to control ten hazardous substances, including a number with carcinogenic properties and other long-term health effects. The report identified a number of factors that act as barriers to the implementation of controls for hazardous chemicals, including:

- difficulty in understanding and applying the regulations
- the technical complexity of controls
- lack of appropriate information
- lack of readily accessible expertise
- lack of practical advice from the OHS Regulator (ASCC 2006a).

Measures to simplify the regulatory system could lead to increased compliance and reduced incidence of injury, illness and death.

'Generic' material safety data sheets undermine OHS regulations

State and territory regulations require suppliers of hazardous substances and dangerous goods to provide current MSDS to all purchasers of the products. This provision is intended to ensure that employers have sufficient information to manage the risks posed by hazardous substances and dangerous goods. The provision of accurate MSDS contributes to effective OHS regulation.

The Commission is aware of a number of suppliers of documents that appear to be MSDS but are not prepared by the manufacturer, importer or supplier of the product. These documents are sold (often in databases) as 'generic' or 'third-party' MSDS. Under state and territory regulations, these documents may not be considered to be valid MSDS. For example, in a guidance note WorkSafe Victoria stated:

> Generic or third party MSDS are not considered to be the manufacturer's or importer's MSDS. (WorkSafe Victoria 2005)

A similar guidance note issued by the Western Australia Commission for Occupational Safety and Health stated:

> An MSDS produced by the manufacturer or importer of a hazardous substance must be obtained and used as the main source of information. "Third party MSDSs" which are produced by other parties and not the manufacturer or importer can be used as supplementary information, but should never be relied upon as the sole source of information. (Western Australia Commission for Occupational Safety and Health 2007, p. 6)

The use of 'generic' MSDS poses two problems:

- 'Generic' MSDS may not contain complete or up-to-date information about a hazardous substance or dangerous good. For example, the information in 'generic' MSDS may not be updated when product formulations change. This has the potential to undermine workplace safety.

- Employers may, in good faith, be using 'generic' MSDS under the assumption that they are sufficient to meet their regulatory obligations. Use of these documents could expose employers to legal liability in the event of a workplace accident.

The Commission considers that the use of 'generic' or 'third-party' MSDS has the potential to undermine the effectiveness of chemicals and plastics OHS regulations. The Commission supports the approach taken by Worksafe Victoria and the Western Australian Commission for Occupational Safety and Health of warning users of these documents that they may not be meeting their obligations under OHS regulations if they use 'generic' MSDS.

6.4 Efficiency of workplace chemicals regulations

Regulatory systems can be made more efficient by increasing the net benefits they deliver to the community. This section describes elements of the regulatory system that function relatively efficiently and others elements that could be made more efficient. Options for reform are considered below (sections 6.5 and 6.6).

The classification of workplace chemicals functions efficiently

Classification of workplace chemicals with hazardous properties is a central element of chemicals and plastics OHS regulations. In all states and territories, the classification of hazardous substances is based on a system developed and maintained by the European Union. Dangerous goods are classified using the ADG Code, which is in turn based on the United Nations' Transport of Dangerous Goods Model Regulations. This high level of consistency between jurisdictions within Australia and with overseas classification regimes reduces the costs to industry and increases the efficiency of the regulatory regimes.

Labelling and MSDS regulations are nationally consistent

All states and territories require that workplace chemicals that have been classified as hazardous substances or dangerous goods (or both) must be labelled, and MSDS must be provided. State and territory regulations on labels and MSDS differ in their form and content. While the primary legislation and regulations may not appear nationally consistent, regulatory requirements in all jurisdictions can be satisfied by labels and MSDS that are prepared in accordance with the National Code of Practice for the Labelling of Workplace Substances and the National Code of Practice for the Preparation of Material Safety Data Sheets respectively.

National consistency in the regulations for labels and MSDS has contributed to the efficiency of the OHS regulatory system.

Some dangerous goods regulations have not been implemented consistently

Participants in this study have asserted that regulations for the storage and handling of workplace dangerous goods have not been implemented consistently by all states and territories. Some examples of the inconsistencies are set out below.

South Australia still has prescriptive regulations

The National Standard for the Storage and Handling of Workplace Dangerous Goods is a performance-based regulation. That is, it imposes a general duty of care on people who manage or control the storage and handling of dangerous goods, while permitting regulated parties to meet the general duties in the way that is most appropriate to their circumstances. The South Australian Dangerous Substances Regulations (2002) are not consistent with this approach. Instead, they prescribe certain actions that people must take to control dangerous goods. This approach excludes potentially more efficient or effective practices that may be developed and adopted by industry under the performance-based regulations in place in other jurisdictions.

Class five substances are regulated under different systems

Under the ADG Code, oxidizing substances or organic peroxides are classified as class five substances. For example, ammonium nitrate is classified as a class five substance. In most jurisdictions, class five substances are regulated as dangerous goods. In South Australia, some class five substances are regulated under the *Explosives Act* 1936, and are, therefore, subject to requirements that do not apply in other jurisdictions.

Queensland regulates 'large dangerous goods locations'

Under the Queensland Dangerous Goods Safety Management Regulation 2001, premises where dangerous goods are present are classified as either a 'minor storage workplace', a 'dangerous goods location', a 'large dangerous goods location' or a 'major hazard facility'. The classification depends on the quantity of dangerous goods on the premises. Other jurisdictions have specific regulations for major hazard facilities, but do not classify other premises in this way.

Major hazard facilities regulations have not been implemented consistently

Major hazard facilities (MHFs) are workplaces that store, handle or process large quantities of hazardous materials. Incidents at such facilities have the potential to cause serious injuries to people on the site and in surrounding areas, and damage to property and the environment, and are broadly described as 'low probability–high cost' (NOHSC 2002a, p. 2). Governments tend to impose stricter controls on MHFs than those applying to other facilities under general chemicals regulations, including OHS regulations.

The National Standard and Code of Practice for the Control of Major Hazard Facilities (the MHF Standard and Code) was declared by the NOHSC in 1996 and is maintained by the ASCC. As with other national standards and codes of practice, these documents have no legal authority unless they are adopted and enforced by state or territory regulators.

Currently, the Commonwealth, Victorian, Queensland, WA and NT Governments have introduced regulations for the control of MHFs based on the MHF Standard and Code. More than a decade after its declaration, the other jurisdictions — except for the ACT, which does not have any MHFs — have now drafted or are in the process of enacting MHF regulations.

Jurisdictions that have implemented the MHF Standard have not implemented it uniformly. Some jurisdictions have more effective and efficient systems of MHF regulation than others (appendix D).

The MHF Standard and Code are currently being reviewed by the ASCC. While the MHF Standard and Code apply both to chemicals and plastics facilities, and also to facilities that fall outside the scope of this study, the Commission considers that there are a number of generic issues that should be covered by the review, including best-practice policy making principles and alternative approaches to regulation.

RECOMMENDATION 6.1

As part of its review of the National Standard and Code of Practice for the Control of Major Hazard Facilities, the Australian Safety and Compensation Council should:

- ***determine whether there is a case for regulation of Major Hazard Facilities beyond existing generic regulation in areas such as occupational health and safety, environmental protection, and planning, based on cost–benefit analysis***

if such a case exists, identify strategies and opportunities for achieving greater consistency in the adoption and application of the Standard across jurisdictions, than has been achieved to date.

Differences in interpretation complicate the regulatory system

Even where national standards and codes of practice have been consistently implemented by state and territory governments, the practical experience of firms suggests that jurisdictions interpret them differently. For example, in all jurisdictions, an MSDS prepared in accordance with the National Code of Practice for the Preparation of Material Safety Data Sheets is sufficient to meet regulatory requirements for workplace hazardous substances and workplace dangerous goods. However, different jurisdictions have different practices relating to when MSDS have to be supplied.

In its submission to this study, 3M Australia stated that it has been attempting to ascertain the legal requirements to provide MSDS for obsolete products — products that have not been supplied for more than two years. 3M Australia asked the ASCC and each state and territory whether it had to supply an MSDS for obsolete products. Some jurisdictions advised that an MSDS was required. Others said it wasn't. Some jurisdictions were unsure and still others didn't respond at all (even after several months) (table 6.3). 3M Australia described the time and cost involved in dealing with multiple agencies as 'astronomical' (sub. 34, p. 7).

Table 6.3 **Responses to 3M Australia inquiries about MSDS for obsolete products**

Agency or jurisdiction contacted	*Time taken to get an answer*	*MSDS Required for obsolete products?*
ASCC	Less than one week	To comply with the regulations, technically yes
WorkCover NSW	More than 90 days	Still waiting for a reply
WorkCover Victoria	Less than one week	No
ACT	2 weeks	Unclear — referred to National Codes of Practice
Workplace Standards Tasmania	Less than 30 days	Yes
Workplace Health and Safety Queensland	1 week	No
Northern Territory	More than 60 days	Still waiting for a reply
WorkSafe Western Australia	More than 60 days	Still waiting for a reply
SafeWork South Australia	2 days	Unclear — referred to NICNAS

Source: 3M Australia, sub. 34, p. 7.

Reforms could improve effectiveness and efficiency

The Commission has considered a number of reforms that could improve the effectiveness and efficiency of the chemicals and plastics OHS regulatory system. These reforms are set out below (sections 6.5 and 6.6).

6.5 A single system for all workplace chemicals

In 2002, the NOHSC initiated a review of the hazardous substances regulatory framework (HSRF). The report, completed in July 2003, made 12 recommendations for changes to the regulatory framework, including:

> That the duties, requirements, controls, and processes of the Hazardous Substances and Dangerous Goods Standards be integrated to achieve consistency. It is anticipated that integration of these Standards may result in simplification of the HSRF, assist in compliance, achieve better health and safety outcomes for workers, and reduce the costs of regulation. (ASCC 2006f, p. 119)

The ASCC has developed drafts of a consolidated system of national standards and codes of practice for 'workplace hazardous chemicals' to replace the existing national standards, model regulations and codes of practice for hazardous substances and dangerous goods. The proposed new systems of classification, labelling and SDS are based on the GHS. The new regulations would apply to all workplace hazardous chemicals, whether they exhibit health hazards, physical hazards or both.

Between September and December 2006, the ASCC published drafts of the national standards and codes of practice that would be the basis of the new system, as well as a draft RIS that included estimates of some of the costs and benefits of the proposed system. The draft RIS found that the benefits of the new system would exceed the costs of implementation. The ASCC invited public comment on the draft national standards and codes of practice and the draft RIS.

The proposal to move to a single system of regulation for all workplace hazardous chemicals has in-principle support from industry. However, industry has expressed reservations about some elements of the system proposed by the ASCC, and concerns about the costs and benefits as set out in the draft RIS. Industry concerns are assessed in the following sections.

Implementing a new system will involve costs

Moving to a consolidated system of regulation for all workplace hazardous chemicals will impose costs on industry and on Commonwealth, state and territory governments. The sources of the costs include:

- developing the new national standards and codes of practice and incorporating them into state and territory law
- training regulators and people working in the industry to use the new system
- classifying workplace chemicals in accordance with the new system
- developing new labels and SDS for workplace chemicals.

According to ASCC estimates, implementation of the new system would cost the ASCC around $230 000 over five years. All state and territory governments combined were estimated to face costs of less than $1 million over five years. The costs to industry were estimated at over $90 million per year over the five year implementation period (table 6.4).

Table 6.4 **ASCC estimates of the costs of implementing the new system**

	Cost driver	*Cost over the five year implementation period*
Costs to the ASCC		
	Establishing and implementing framework	No additional cost
	Information dissemination and training	$80 000
	Establishing a list of GHS classifications	$150 000
	Total cost to the ASCC	$230 000
Costs to state and territory governments (total for all jurisdictions)		
	Establishing and implementing framework	$630 000
	Information dissemination and training	$240 000
	Total cost to states and territories	$870 000
Costs to industry		
	Information dissemination and training	$149 million
	Chemicals reclassification according to GHS	$109.5 million
	Relabelling of chemicals according to GHS	$129 million
	Revising SDS according to GHS	$64.5 million
	Total cost to industry	$452 million

Source: ASCC (2006f).

Industry has stated that the ASCC's estimates of the costs to industry were too low. For example, ACCORD Australasia, the Australian Industry Group and PACIA all included the following comment in their separate submissions to the ASCC:

> … many of the average costs (e.g. reclassification, SDS preparation, labelling and others) used in the Draft RIS are considered to be low and will serve to distort the analysis. (ACCORD Australasia Ltd 2007, p. 23); (AIG 2007, p. 5); (PACIA 2007c, p. 22)

The Huntsman Chemical Company stated that the ASCC may have underestimated the costs of relabelling by 67 per cent (Huntsman Chemical Company 2007, p. 2). If accurate, this implies that relabelling of chemicals alone would cost industry over $40 million per year over the first five years of the new system.

The ASCC stated that the costs of implementing the new system are likely to fall disproportionately on SMEs:

> … the impact of business regulation can fall disproportionately on small firms which might not have the resources that large business have to comply with business regulatory requirements. These additional costs faced by SMEs can reduce their competitiveness in the market.
>
> Similar to other industries, SMEs make up a large proportion of chemical manufacturers, importers, exporters and suppliers. Stakeholder consultations revealed that due to the relative complexity of the workplace chemicals regulatory framework, SMEs generally do not have the time or resources to stay informed of the changes and requirements of the legislation. (ASCC 2006f, p. 46)

Respondents to the ASCC, commenting on the draft RIS, also questioned the estimates of the costs to government of implementing the new system. For example, the ASCC estimated that the total cost of retraining inspectors and agency personnel in New South Wales would be $15 900 (ASCC 2006f, p. 64). WorkCover NSW stated:

> … the training of WorkCover NSW Inspectors appears to be significantly underestimated and therefore not properly costed eg currently there are approximately 300 inspectors and all would require training (including not only the technical aspects of the National Workplace Hazardous Chemical Framework but also the legal implications). (WorkCover NSW 2007, p. 5)

It is likely that retraining 300 personnel in the new system would cost significantly more than $53 per person (the figure implied by the ASCC estimate).

The high costs of implementing a new system for workplace chemicals regulation serve to emphasise the importance of ensuring that the new system delivers net benefits to the community.

Benefits of a single system for workplace chemicals

A significant benefit of a single system of regulation for workplace chemicals would be the simplification of risk assessments for substances that are classified as both hazardous substances and dangerous goods. Replacing the existing systems of regulation of hazardous substances and dangerous goods with a single system of regulations for all workplace hazardous chemicals has the potential to reduce the time required to carry out risk assessments.

The ASCC's draft RIS estimated the benefits to industry of such time savings[1]. The estimate was based on a number of assumptions, such as the number of firms affected and the number of risk assessments each firm carries out per year. The ASCC concluded that if the new system were to reduce the time taken for risk assessments by 10 per cent, industry would reap savings of a net present value of over $174 million.[2]

The Commission accepts that a unified system could simplify the process of risk assessment for workplace hazardous chemicals. The ASCC's estimate of a 10 per cent time saving may be a reasonable estimate of the benefits to industry.

Benefits of a GHS-based system

A unified system of workplace chemicals regulation would require new or revised systems of classification, labelling and MSDS. The systems that are currently used for workplace hazardous substances and workplace dangerous goods could be consolidated into a single system. However, the consolidation of the new system provides an opportunity for governments to implement the United Nations' GHS in the workplace sector. This system has several advantages.

One advantage is that the GHS provides a single system for the classification, labelling and provision of SDS for all workplace chemicals with hazardous properties.

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[1] The draft RIS identified the savings as arising from 'avoidance of dual risk assessment requirements'(ASCC 2006f, p. 73). This was based on the assumption that if a chemical is classified as a hazardous substance and a dangerous good, state and territory regulations required employers to carry out two separate risk assessments. The Australasian Institute of Dangerous Goods Consultants (sub. DR76) noted that under New South Wales legislation there is no requirement to carry out two separate risk assessments for one chemical. The Commission has determined that this is the case in other jurisdictions as well. While the assumption in the draft RIS is not accurate, the way the ASCC modelled the benefits is a useful estimate of the benefits to industry if the new system reduces the time taken for risk assessments.

[2] This figure is the ASCC's estimate of the net present value of the savings calculated over a period of 30 years using a discount rate of 7 per cent.

As well as meeting technical requirements, a GHS-based system could deliver other benefits to Australia. One is that countries that use the GHS as the basis of their hazard classification system would be able to share information on chemical assessments, thus reducing costs to firms and regulators.

GHS implementation could also reduce the costs incurred by importers and exporters of chemicals, thereby reducing barriers to trade in chemicals. The ASCC stated that implementing a GHS-based system would mean that exporters would not have to reclassify, relabel or prepare new SDS to comply with regulations in GHS-compliant export destinations (ASCC 2006f). Likewise, importers could avoid the need to reclassify, relabel or prepare new SDS to comply with Australian regulations. The ASCC estimated that the net present value of the costs avoided over the next 30 years would be approximately $442 million (ASCC 2006f).

Industry has disputed the ASCC's estimate of the benefits of trade facilitation. The estimate was based on the assumption that all of Australia's major trading partners would implement GHS-based systems at the same time as Australia, and that the Australian system would be consistent with all of the overseas systems. Industry considers this an unrealistic assumption.

Not all countries are intending to implement the GHS in the same way

Although the GHS is intended to be a single global system for classification, labelling and SDS, the reality is that not all countries will implement all elements of the system in the same way or within the same time frames. In its submission to this study, ACCORD Australasia raised the issue of countries implementing 'brands' of the GHS that are not consistent with each other. For example:

> … the European Commission has proposed that its scope of GHS Implementation will not include a number of GHS hazard categories but will include a number of hazards not currently included in the scope of the GHS.
>
> The Environmental Risk Management Authority (ERMA) [the New Zealand regulator] has been attempting to implement an early 2003 version of the GHS. ERMA has made a number of changes and additions to hazard classifications and used codification not adopted up in the GHS official text or in proposals by any other country.
>
> … there is no detailed information yet available on GHS implementation in North America. (sub. 42, pp. 32–33)

The Commission considers that some key assumptions underpinning the ASCC's estimate of the benefits of trade facilitation and information sharing are unlikely to materialise. In particular, the assumption that 'our major trading partners, accounting broadly for 50 per cent of the value of exports and imports, will adopt GHS' (ASCC 2006f, p. 77) within a similar timeframe to Australia is not realistic.

Hence the Commission has concluded that some of the benefits of the new system have been significantly over-stated in the draft RIS, as set out below.

Costs and benefits of the proposed system

The Commission's analysis of the costs and benefits of the proposed system of regulation of workplace hazardous chemicals is based on the draft RIS published by the ASCC and evidence provided by industry and government agencies on the proposed system. The Commission has assessed the assumptions and methodology used in the draft RIS, and the estimates of the benefits and costs of the proposed system. The Commission considers that:

- The estimated cost to industry of $90 million per year over the proposed five year implementation period may be understated.
- The estimated costs to state and territory governments of $870 000 over the five year implementation period are also understated.
- The benefits of simplified risk assessments may be of the order of $174 million over 30 years in net present value terms, as estimated in the RIS.
- The benefits of trade facilitation and information sharing have been significantly overstated in the draft RIS.

The Commission therefore considers that at this stage the benefits to industry of simplified risk assessments are likely to be materially less than the costs of implementing the new system.

Under what conditions should Australia implement the GHS in the workplace sector?

The decision to implement a GHS-based system for workplace hazardous chemicals should be based on a thorough assessment of all of the costs and benefits of the system. In light of this, it is worth noting that the final RIS for the ASCC's proposed system is forthcoming.

While the Commission does not intend to pre-empt the RIS process, based on the available evidence, the Commission has concluded that unless there are significant trade and information-sharing benefits from the new system, it will not deliver a net benefit at this stage. Such benefits will only arise if GHS-based systems are implemented in a number of Australia's major trading partners.

As noted above, New Zealand uses the GHS as the basis of its system of hazard classification. The EU is the only major trading bloc to have committed to

implementing a GHS-based system (box 6.2). Aside from New Zealand, none of Australia's major trading partners in the Asia-Pacific region (such as the US, China and other APEC countries) have committed to implementing the GHS for workplace hazardous chemicals. The final RIS for the proposed system should reflect the stated intentions of Australia's major trading partners.

Box 6.2 **Implementation of the GHS in Europe**

The GHS will be implemented in Europe over a period of approximately seven years, commencing 2008, after a vote by the European Parliament. The process will proceed in two stages, starting with substances (single chemicals) and progressing to mixtures. From 30 November 2010:

- Substances
  - Must be classified and labelled according to the GHS
  - Safety data sheets will have classification data based on both the existing system and the GHS.
- Mixtures
  - Must comply with existing European regulations for classification, labelling and safety data sheets
  - Manufacturers have the option of also using GHS classification, labelling and safety data sheets

From 1 June 2015, all substances and mixtures must be classified, labelled and have safety data sheets prepared in line with the GHS. The existing European system will be repealed.

Source: United Nations Economic Commission for Europe (2008).

The Commission's analysis strongly suggests that if the final RIS accurately reflects the slow pace of GHS implementation among most of Australia's major trading partners, it would conclude that implementing the system would not deliver a net benefit under current conditions. If this is the case, implementation of the system should be delayed until more significant trade benefits can be realised.

If the proposed system is not supported under current conditions, the ASCC should continue to monitor developments in Australia's major trading partners. If other countries implement GHS-based systems of workplace chemicals classification, labelling and MSDS, the benefits of implementing a GHS-based system in Australia may exceed the costs.

RECOMMENDATION 6.2

The Workplace Relations Ministers' Council should implement the Globally Harmonised System of Classification and Labelling of Chemicals in the

workplace sector in Australia only when it can be shown that adoption of the new regime would produce net benefits.

The Australian Safety and Compensation Council should undertake a further regulatory impact assessment when some of Australia's key trading partners, such as China and the United States of America, have commenced implementation of systems of regulation for workplace chemicals that are based on the Globally Harmonised System of Classification and Labelling of Chemicals.

Benefits of consistency with other labelling systems

Current regulations for the control of workplace hazardous substances recognise some other labelling schemes as being sufficient to meet workplace requirements. Domestic products that are scheduled poisons and are labelled in accordance with the Standard for the Uniform Scheduling of Drugs and Poisons do not require separate hazardous substances labels for workplace use. Under the proposed new system for workplace hazardous chemicals, the exemption for appropriately labelled consumer products would continue, provided the chemicals:

> … will only be used in the workplace for purposes incidental to the nature of the work and in quantities that are consistent with consumer household use. (ASCC 2006f, p. 39).

Likewise, agricultural and veterinary (agvet) chemical products labelled according to the Australian Pesticides and Veterinary Medicines Authority labelling code currently do not need separate workplace labels (ASCC 2006f). However, under the ASCC's proposed new system for workplace hazardous chemicals, all agvet chemical products, other than those supplied and used exclusively in the home, will have to carry both an approved agvet label and a workplace hazardous chemicals label.

Some participants raised concerns about the use of agvet labels in the workplace (ACTU, sub. 47, sub. DR88; Haztech Environmental sub. DR73). The main concern was that agvet labels do not include all of the hazard identification elements that are found on workplace chemicals labels (such as pictograms and hazard statements).

While approved agvet labels include extensive information on the appropriate precautions to take when using the products for registered uses, if they are used for purposes other than those for which they were registered ('off-label use'), the absence of pictograms and hazard statements on risk-based labels could lead to inadequate risk assessment and hence inadequate safety precautions being taken.

Other participants in this study and respondents to the ASCC's proposed regulatory framework were concerned that removing the recognition of approved agvet labels

would lead to confusion, increase costs and potentially harm people and the environment. Nufarm Limited (2007, p. 2) expressed concerns that:

> … agvet chemicals will be required to conform to two separate labelling regimes. Additionally, end users will be subjected to two separate, and potentially conflicting, regulatory regimes. This "dual-label" scenario will result in confusion as to the appropriate use of agvet chemicals and may lead to illegal off-label use as well as possible harm to health or the environment.

Croplife Australia agreed:

> Adoption of GHS … for pesticides would have no net benefits, and could potentially place additional regulatory and cost burdens on agricultural industries. (sub. 35, p. 16)

The Commission recognises that the DEEWR, the ACTU, Haztech Environmental and other participants in this study have legitimate concerns about the potential effects of recognising approved agvet labels as sufficient for workplace use. The Commission also notes that producers and users of agvet chemicals have valid concerns about the implications of the proposed changes.

Commonwealth, state and territory governments have agreed (through COAG) that regulatory processes should adhere to a number of principles. This includes establishing the case for any proposed change, assessing the costs and benefits of a range of alternatives (including non-regulatory and co-regulatory approaches) and choosing the option that delivers the greatest net benefit to the community. While the ASCC has published a draft RIS on the proposed workplace hazardous chemicals regulatory framework, it did not include any analysis of the costs and benefits of the proposal to overturn the current recognition of approved agvet labels in the workplace. Nor were any alternatives canvassed (such as changes to agvet labels).

The Commission considers that the proposed changes to the workplace labelling regime should be subject to the normal regulatory process, including a formal analysis of various reform options, and the costs and benefits of those options. This may include changes to agvet labels so that they meet the requirements of the workplace labelling regulations. Unless it can be demonstrated that the change would deliver a net benefit to the community, the current recognition of agvet labels in the workplace should remain in place.

RECOMMENDATION 6.3

The Australian Safety and Compensation Council should conduct a regulatory impact assessment of the proposal to require agricultural and veterinary chemical products that are also workplace hazardous chemicals to carry workplace hazardous chemicals labels. The assessment should identify alternatives and the

costs and benefits of the options. The Workplace Relations Ministers' Council should only adopt the proposal if it can be demonstrated that it would deliver a greater net benefit to the community than any alternative.

Until the regulatory impact assessment has been completed, recognition of agricultural and veterinary chemical product labels for occupational health and safety purposes should continue to apply.

6.6 Reforms to the national OHS framework

On 3 July 2008, the Prime Minister, Premiers and Chief Ministers signed an Inter-Governmental Agreement for Regulatory and Operational Reform in Occupational Health and Safety (the OHS IGA). The agreement commits the signatories to the implementation by 2011 of a nationally uniform OHS legislative framework. The Commission is encouraged by many of the features of the OHS IGA, including:

- The agreement by all parties to uniformly adopt and implement national model OHS legislation, regulations and codes of practice.
- The agreement by all parties to 'take all necessary steps to enact or otherwise give effect to model OHS legislation … within the timeframes agreed by WRMC' (COAG 2008c, p. 8).
- The agreement that the WRMC will be responsible for the final decision on the adoption of national model OHS legislation.
- The voting arrangements that enable the passage of a measure with a two-thirds majority of members of the WRMC, and count members that do not vote as having approved a proposal.
- The agreement by all parties to submit to the WRMC any amendments to legislation or new legislation that could 'materially affect the operation of model OHS legislation' (COAG 2008c, p. 11), and to not proceed with the amendment or new legislation unless it is endorsed by the WRMC. In addition, all parties agreed that if an amendment or new legislation is endorsed by the WRMC, all parties will 'undertake all necessary steps to introduce appropriate changes to their legislation with a view to ensuring that OHS legislation remains nationally consistent' (COAG 2008c, p. 11). This is a stronger mechanism than those found in some other IGAs (for example, transport (chapter 7)), though the Commission notes that the commitment to national uniformity is downgraded to a commitment to consistency.

One weakness in the IGA is that model OHS legislation, regulations and codes of practice can only be declared by a consensus decision of the WRMC. Requiring

consensus could lead to undesirable trade-offs in the content of the model Act, regulations and codes of practice. The Commission's view is that the OHS IGA would be more likely to deliver national uniformity in a timely manner if decisions on model legislation, regulations and codes of practice were made by a two-thirds majority vote.

Replacing the ASCC

Under the OHS IGA, the Commonwealth, state and territory governments have agreed to replace the ASCC with a new, independent body. The role of the new body will include to 'research, develop and recommend national OHS standards as appropriate' (COAG 2008c, p. 6)

The Commission considers that in some respects the new body will be an improvement on the ASCC:

- Rather than being established by administrative decision, the new body will be statutorily independent. This may increase the legitimacy of the new body in the eyes of stakeholders and enhance its power to drive reform.
- The power to declare national standards or codes of practice will rest with the WRMC, not the body that replaces the ASCC. This reflects principles of good governance.
- The new body will be funded jointly by the Commonwealth Government and the state and territory governments. This may lead to greater engagement with the policy-making process than if the body was solely funded by the Commonwealth.

While these measures mark an improvement on the current ASCC, the Commission considers that the proposed tripartite structure of the new body is not consistent with best practice principles of regulation. The new body is to consist of:

- an independent chair, nominated by the Commonwealth Minister
- a non-voting chief executive
- one member representing each state and territory government and the Commonwealth Government
- 2 members each from bodies that represent employees and employers.

In a previous report (box 6.3) and in the draft report on chemicals and plastics regulation the Commission has raised concerns about the tripartite structure of the ASCC (and its predecessor, the NOHSC) and the unwieldy size of those bodies. Those concerns apply equally to the new body, and are set out below.

Box 6.3 **The Commission's 2004 report on national OHS frameworks**

In 2004 the Commission released an inquiry report on National Workers' Compensation and Occupational Health and Safety Frameworks (PC 2004a). That report included a detailed assessment of the NOHSC and recommendations for changes to its structure. While the NOHSC was replaced by the ASCC in 2005, many of the structural problems carried through to the ASCC, and will likely remain in the body that replaces it.

The ASCC is a tripartite body — it includes representatives of Commonwealth, state and territory governments, unions and employer groups. The NOHSC was also a tripartite body, as will be the body that replaces the ASCC. The Commission noted that the tripartite structure led to a number of problems, including:

- Membership of the board was determined by representation, not by expertise in developing and implementing best practice OHS regulations.
- Decisions could be influenced by the lobbying ability of board members.
- Some groups were not represented on the NOHSC board (for example, small business groups and the mining industry).
- The 18-member board was too large to be effective.

Supporters of the tripartite structure emphasised the importance of consultation in the development of OHS regulations. The Commission agreed that the involvement of stakeholders is essential, but stated:

> … there is a significant difference between a consultation process, and a situation where those being regulated have direct control over the drafting of that regulation. Where stakeholder interests diverge significantly and where agreement or consensus becomes a major consideration, the chance that necessary change will be introduced in a timely fashion is put at risk. It also introduces the likelihood that compromise will result in something well short of best-practice. (PC 2004a, p. 91)

The Commission recommended that the NOHSC should have a board of between five and nine members appointed on the basis of their expertise and skills in OHS regulation. The members would be appointed by the Commonwealth Minister and their appointment would have to be approved by the WRMC. Membership would not be based on representation of any constituency.

The Commission recommended that the NOHSC should be given the power to establish advisory committees that would consist of representatives from unions, employer groups, Commonwealth, state and territory OHS agencies and experts in OHS policy implementation. These bodies would seek stakeholder input into the development of standards and codes of practice, but would not have any authority to make decisions on their content. Standards and codes of practice would have to be approved by the WRMC.

The Commission's assessment of the body to replace the ASCC

The body that replaces the ASCC will retain a tripartite structure, and will have an unwieldy 15 members. The Commission considers that setting national risk management standards for the use of chemicals in the workplace (and other OHS standards) is a task that is most effectively and efficiently undertaken by a national body of persons appointed for their knowledge and experience, and who would make decisions in the public interest (chapter 2). Membership of the body should not be based on representation of any jurisdiction or stakeholder group. The expert body should be small enough to effectively manage the development and implementation of nationally consistent OHS regulations. As the Commission has previously noted, the appropriate size of the new body is between five and nine members.

The Commission considers that stakeholders views can be sufficiently accommodated through advisory committees, and that stakeholder membership of standard-setting bodies is both unnecessary and inconsistent with best-practice regulation. Although under the OHS IGA the WRMC is responsible for making decisions on model legislation, regulations and codes of practice, the body that replaces the ASCC may retain some decision-making powers and is the body which makes recommendations to the WRMC.

The OHS IGA includes an agreement to review the operation of the body that replaces the ASCC 'no later than the sixth anniversary of the commencement of the Act establishing [ASCC replacement body] or as agreed by WRMC' (COAG 2008c, p. 11). This review should include an assessment of the effect of the tripartite structure of the new body on the quality of the advice it provides, and should consider replacing the body with a smaller body made up of people appointed for their knowledge and experience.

RECOMMENDATION 6.4

The review of the operation of the body that replaces the Australian Safety and Compensation Council that is planned to commence within six years of its creation should assess its effectiveness and efficiency, including the impact of the tripartite structure of the body on the quality and nature of advice that it provides to the Workplace Relations Ministers' Council. The review should also consider the case for replacing the new body with a smaller, statutorily independent body comprised of experts in standard setting, rather than representatives of particular constituencies.

7 Transport safety

Key points

- Dangerous goods and explosives transport regulations aim to reduce the risks to the public, employees, property and the environment, from accidents and incidents.
- Regulation of dangerous goods and explosives transport appears to have been effective in producing a lower rate of accidents among dangerous goods vehicles.
- The transport of dangerous goods has been regulated consistently across jurisdictions within a national policy framework. Australian Government template legislation and regulations and the Australian Dangerous Goods (ADG) Code have been largely adopted by all jurisdictions. This consistency has delivered significant benefits to industry and consumers.
- New model legislation and regulations, together with a significantly restructured ADG Code, are being introduced in 2008. Individual jurisdictions have agreed to develop their own legislation and regulations based on the national models, in a uniform or nationally consistent manner. Technical regulations will still be largely implemented through a common code (ADG7) which reflects international standards. In view of the risks in moving from template to model legislation, the National Transport Commission (NTC) needs to closely monitor how consistently the new framework is implemented.
- The transport of explosives is regulated under legislation and regulations developed in individual jurisdictions, but which refer in varying degrees to the Australian Explosives Code on technical matters. These differences impose unnecessary costs on firms and should be removed. As a first step, the new Code should be uniformly adopted. A further process to develop uniform legislation and regulations should follow.
- Transport of dangerous goods and explosives by air and sea is regulated nationally, in line with international standards.
- Nationally, dangerous goods land transport regulation is developed by the NTC, reporting to transport ministers, while in most jurisdictions the regulation is administered by workplace safety authorities. The strong governance framework in transport, together with problems in introducing national reforms in the workplace safety area, favours retention of dangerous goods policy in the transport forum.
- Charges for printed and web-based copies of the dangerous goods and explosives codes appear high and should be reduced to cover only avoidable costs. Governments should address any resultant shortfalls in agency funds.

This chapter examines the domestic regulation of the transport of chemicals, the bulk of which are carried by road and rail. In addition to being subject to generic and freight transport regulation, chemicals transport is also subject to dangerous goods and explosives legislation, regulations and codes.

7.1 The case for regulating the transport of dangerous chemicals

The transport of dangerous goods (most of which are chemicals covered by this study) poses a number of risks relating to accidents, leakages or theft. Chemical spills or leaks from transport vehicles can create risks to the health of the general public, occupational health and safety (OHS) risks to drivers and workers involved in dealing with chemical discharges, and can cause harm to the environment. The extent of such risks and associated costs will depend on the location of the incident, the chemical, and the quantity involved.

Potentially, such risks could be managed by imposing all of the costs of any such incidents on those responsible for transporting chemicals, either by legislation or through common law. In this situation, transporters would have an incentive to seek out and undertake those actions that were cost effective in reducing the potential (risk-adjusted) costs of incidents.

However, there are a number of reasons why regulation might be considered as an alternative, or coincident, means of efficiently achieving optimal levels of safety in chemicals transport:

- Individuals and firms may systematically underestimate the risk of such incidents and the costs involved. In the extreme, firms that do not adequately insure could be bankrupted by very large claims.
- There may be considerable difficulty and expense in assessing the full costs imposed by a dangerous goods incident and significant uncertainty and expense in determining and enforcing liability through common law.
- The community has a high aversion to risk (possibly increasingly so), including placing high costs on death or serious injury. Government intervention may see this valuation more rapidly incorporated into firms' behaviour.
- There are likely to be high political consequences from significant dangerous goods accidents.

In addition, there are threats to public safety and national security from thefts of certain explosives, chemicals that could be used to manufacture explosives, and chemicals that are illicit drug precursors. Because the costs of such thefts may be

both widely dispersed and potentially catastrophic, reliance on common law as the only response would be problematic.

The mix of regulation and insurance is similar to that relating to the costs of passenger vehicle accidents. However, for regulation to be an efficient approach to dealing with the issues raised by chemical transport, it needs to be well targeted at specific areas where the benefits of intervention are greater than the costs.

7.2 The current regulatory framework

The transport of chemicals is subject both to generic regulations that cover all freight transport and, for certain chemicals, specific regulations relating to bulk dangerous goods, explosives, and security sensitive chemicals. Most generic heavy vehicle regulation, and the specific regulation of dangerous goods, has delivered nationally consistent outcomes due to a strong national governance framework. Policy is developed by an independent national body — the National Transport Commission (NTC) — reporting to the ministerial Australian Transport Council (ATC). The policy development process is highly consultative and the ATC's majority decision-making rules when dealing with transport reforms, prevents single jurisdictions from stalling reforms.

Generic regulation of freight transport

In addition to the road laws applying to all motor vehicles, specific regulations and programs govern the transport of freight, including chemicals and plastics. These cover issues such as speed, fatigue management, vehicle roadworthiness, wearing of seat belts, load sizes, and compliance and enforcement. Much of this regulation aims to lower the risk of road accidents involving trucks and to reduce the severity of those accidents that do occur.

In Australia, heavy vehicles carrying generic freight are over represented in fatality and injury crashes compared to both light vehicles and to heavy vehicles in overseas countries, and the impact of those accidents on people and property can be particularly severe. In addition, heavy vehicles impose 'amenity' impacts on other road users and residents. These include noise, pollution and concerns for safety.

Some of the efforts to improve safety have involved a combination of regulation and cooperation between government and industry. For example, the National Heavy Vehicle Safety Action Plan, initially adopted by the ATC in 2003, has involved regulatory, enforcement and industry initiatives aimed at reducing accidents and fatalities involving heavy vehicles.

Some of these regulations are specific to individual jurisdictions, while others have been developed nationally under the reform agenda for road and rail transport, largely coordinated by the NTC. This national agenda has resulted in consistent heavy-vehicle regulation across jurisdictions in areas such as licensing, road rules, mass limits, noise standards, and roadworthiness standards.

Generic regulation of rail freight is largely imposed by jurisdiction-based coregulation, reflecting the long period of self regulation under government ownership and the much more concentrated ownership structure in rail freight operations. There has been substantial progress in developing nationally-uniform operating and safety regulations and practices, particularly under the auspices of the NTC. For example, a model Rail Safety Bill was developed by the NTC and implemented by individual jurisdictions by 2007.

Chemicals-specific regulation

As well as the policy issues raised by freight transport in general, the transport of chemicals imposes significant additional risks that have elicited specific regulatory responses.

Dangerous goods (land transport)

In order to reduce the risks to public and employee safety and the environment, specific, more stringent regulation has been developed for the land transport of goods classified as dangerous. This mirrors the special treatment given to dangerous goods in other areas such as manufacture, storage and waste disposal. These regulations aim to both reduce the risk of accidents involving vehicles carrying dangerous goods and lessen the consequences of those incidents that do occur.

Many of these dangerous goods are chemicals, although not all of these are covered by the terms of reference of this study.[1] There are also many chemicals that are not dangerous goods. Additional jurisdictional regulations apply to the transport of explosives, security sensitive substances, radioactive material and infectious (biohazardous) substances.

Dangerous goods transport governance arrangements

Since the early 1990s, development, initial implementation and review of dangerous goods land transport policy has been the responsibility of the NTC (originally the

1 In particular, petroleum products are not covered by this study.

National Road Transport Commission (NRTC)). The NTC's main function is to develop, monitor and maintain uniform or nationally consistent regulatory and operational reforms relating to road, rail and intermodal transport. A number of features of its governance framework and mode of operation have created a strong sense of jurisdictional shared ownership of transport reforms.

The NTC is an independent, national statutory authority established by the Australian Government under an intergovernmental agreement (IGA) for land transport regulatory reform signed by Transport Ministers. It reports to the ATC and all jurisdictions contribute to NTC funding. Commission members are appointed by the Australian Government on nomination from the ATC. The NTC's budget, work program and strategic plan are all subject to ATC approval or input. The ATC generally meets biannually, with out-of-session processes (including voting on NTC proposed reforms) also used to progress issues.

To be implemented, legislative proposals put forward by the NTC must obtain a majority vote of the ATC. However, ministers cannot amend NTC recommendations. NRTC (2002) considered that formal majority decision making was particularly important in achieving national reform, as it prevented single jurisdictions from vetoing reforms and helped to develop ministerial and agency ownership of reforms. Similarly, Wilson and Moore (2006, pp. 282–83) argued that:

> The requirement for a formal vote to take place is of significance, as it forces Ministers to make decisions on items forwarded by the Commission. It also ensures that 'lowest common denominator' solutions need not apply, as a mechanism is provided which enables impasses to be overcome.

The NTC process for developing and introducing regulatory reforms for dangerous goods transport involves extensive formal and informal consultation with jurisdictional authorities (including environment agencies), the trucking and chemicals industries and Australian Government policy makers.[2]

Under the IGA, each jurisdiction is then required to use its best endeavours to implement and maintain agreed reforms in a uniform or nationally consistent manner except in 'exceptional circumstances'. In such exceptional circumstances, the jurisdiction concerned is to advise the ATC of the reasons for its decision.

2 Affleck and Meyrick (2002) noted that often one cost of this wide-ranging consultation was some delays in the implementation of reforms.

The unique policy development and implementation framework in which dangerous goods land transport regulations have been framed is an important factor in their success. In this regard, Affleck and Meyrick (2002, p. 17) argued:

> The NRTC has been an outstanding and rare example of joint action by the Commonwealth, States and Territories to fix common problems of inconsistency, inefficiency and safety management. The role of industry in the processes facilitated by the Commission has also been very significant.

This framework has, up to now, delivered a high degree of national consistency in dangerous goods transport regulations, which has been well received by the chemicals and transport industries.

The achievement of uniform dangerous goods policy reform was also significantly assisted by its inclusion in the National Competition Policy Agreement. As a result, reform of dangerous goods policy (along with other road transport reforms) was part of the National Competition Council's assessment of jurisdictional performance for recommending competition payments.

In most jurisdictions, dangerous goods transport regulation is implemented by workplace health and safety authorities, which are also responsible for regulating the storage and use of dangerous goods in the workplace. Exceptions are New South Wales (environment), Queensland (transport) and Western Australia (resources safety).

A further forum for maintaining consistency between jurisdictions is the quarterly meetings of a Competent Authorities Panel (CAP), bringing together the dangerous goods land transport regulators (competent authorities under the dangerous goods Acts) from each jurisdiction, with the competent authorities for air and sea transport as observers. This panel issues approvals under the regulations, and exemptions from the regulations, and facilitates mutual recognition of decisions taken across jurisdictions.

The ATC is currently reviewing transport policy governance arrangements to broaden the scope of jurisdictional cooperation to include matters such as planning, infrastructure provision and pricing and to further enhance national regulatory cooperation and consistency. A new transport IGA is being developed and the use of Commonwealth Government financial contributions to assist in achieving national reforms is to be considered. In addition, a legislative review of the NTC is scheduled for 2008, in which broader issues relating to co-operative federal arrangements in the portfolio may be considered (NTC 2008).

The Australian Dangerous Goods Code

Land transport of dangerous goods is regulated under jurisdictional dangerous goods Acts and regulations. For road transport, since the late 1990s, this regulation has reflected Australian Government template legislation and regulations enacted to apply in the ACT and the Jervis Bay Territory. These templates have been adopted by individual jurisdictions either by direct reference or alternatively by repeating most of the provisions of the template in their own legislation.[3] The absence of direct referencing in some jurisdictions has not led to additional inconsistency over time, because the template legislation has not been changed since its adoption.

These regulations brought into operation the Australian Code for the Transport of Dangerous Goods by Road and Rail Sixth Edition (ADG6), which sets out technical requirements as well as non-mandatory guidelines for the land transport of dangerous goods. Much of ADG6 is based on, or is consistent with, the United Nations Recommendations on the Transport of Dangerous Goods, Model Regulations (UN Model Regulations) (11th edition).

Reflecting this template approach, all jurisdictions require vehicles and drivers involved in the transport of dangerous goods in bulk to have special licences, involving approved specialised training and health assessment. There is also compulsory training for those undertaking other dangerous goods tasks. In addition, uniform regulations cover the securing of loads, packaging and labelling, signage on vehicles, design of tanks, safety equipment and types of loads. The transport of dangerous goods may be prohibited in certain areas (for example, the central business district and underground tunnels). Transport operators are also required to develop Transport Emergency Response Plans to be instigated in the event of an incident involving the transport of dangerous goods.

Revised jurisdictional dangerous goods legislation and regulations covering both road and rail and a new edition of the dangerous goods-code (ADG7) will take effect during 2008. The new regulatory framework involves a different approach to achieving national consistency. Model legislation (scheduled as regulations to the *National Transport Commission Act 2003* (Cwlth)) is provided to guide jurisdictions in developing their own legislation. The Model Act contains provisions that allow the appointment of competent authorities and authorised officers to administer the Act and establishes their powers. It also allows specified regulations to be made under the Act, establishes offences and sanctions, and allows competent authorities to make exemptions to the subordinate law. The Model Subordinate Law

3 The NRTC commissioned a barrister to 'trawl through' the various jurisdictional dangerous goods transport Acts and regulations (Shepherd 1999). He found that the legislation of each jurisdiction had the same or substantially the same effect as the template legislation.

(regulations) establishes the responsibilities of those transporting dangerous goods by road and rail in regard to matters such as licensing, packaging, labelling, placarding, stowage, documentation, insurance and emergency procedures. It also gives effect to the provisions of the ADG Code, which provides more detailed definitions and technical provisions on many of the matters covered by the regulations.

The new regulatory package was developed in order to more closely align Australian regulations with the most recent UN Model Regulations (fourteenth and fifteenth revised editions)[4] and to establish a single set of regulations for road and rail. Alignment with the latest UN Model Regulations has created greater harmonisation of dangerous goods regulations for land, sea and air transport. The package has also implemented other changes considered necessary since the previous regulatory package was introduced in 1998. Provisions derived from the NTC's Model Compliance and Enforcement Bill have been included, thereby increasing the likelihood of achieving industry compliance.

Explosives (land transport)

The focus of dangerous goods transport regulations has essentially been on safety rather than security — the ADG Code does not contain detailed security provisions. However, for completeness and consistency with the UN Model Regulations, it includes limited provisions regarding transport of explosives when carried with other dangerous goods.

Instead, all jurisdictions have developed their own explosives legislation to address both the potentially very severe consequences of an accident involving explosives and the possibility of theft. To varying degrees, this legislation mandates compliance with some or all of the current Australian Code for the Transport of Explosives by Road and Rail (AEC).[5]

The AEC provides much of the technical detail of explosives transport regulations for road and rail. It contains more stringent safety requirements than the ADG Code and introduces security provisions. There are more demanding licensing requirements for both drivers and vehicles carrying explosives. Drivers must meet 'suitable person' criteria including a national criminal history and security check, undertake an approved course on explosives regulations, complete an approved

4 Some UN regulations are not incorporated in ADG7 and certain Australia-specific clauses are included, for example, excluding certain goods from the code in particular circumstances and some limited differences in packaging and labelling requirements.

5 Second edition (2000), including a 2003 security Addendum covering high-security risk loads of explosives.

health assessment and not have demonstrated unsafe driving behaviour. Vehicles and packaging must have enhanced security features.

The AEC was last fully updated in March 2000, after consultations with advice from regulators and industry through the Explosives Competent Authority Safety Sub-Committee and the Advisory Committee on the Transport of Dangerous Goods. That revision brought the AEC into line with the 11th edition of the United Nations Recommendations on the Transport of Dangerous Goods, Model Regulations. However, explosives legislation is not harmonised between jurisdictions. A revised AEC is currently being developed.

Explosives transport governance arrangements

Unlike dangerous goods, there is no national model to guide jurisdictional explosives legislation and regulations for the land transport of explosives and there is no formal commitment by jurisdictions to implement the AEC uniformly. Hence, important regulatory differences remain. The Office of the Australian Safety and Compensation Council (OASCC), in its secretariat role for the Australian Forum of Explosives Regulators (AFER), is currently coordinating the updating of the AEC and a draft code was released for public comment in March 2008. The AEC review process also involves consultation with firms and industry bodies such as the Australian Explosives Industry and Safety Group (AEISG). A finalised version of the revised code is expected to be considered by the Workplace Relations Ministerial Council (WRMC) later in 2008.

The AFER comprises the explosives regulators from all jurisdictions (mostly workplace health and safety authorities) as well as the Australian Maritime Safety Authority (AMSA), the Civil Aviation Safety Authority (CASA) and the Defence Department. Unlike the CAP for dangerous goods transport regulation it is not a statutory body. It had not met for several years before September 2006 and now reports to the WRMC via the Australian Safety and Compensation Council. These reporting arrangements provide a potential mechanism for implementing AFER recommendations for nationally consistent regulation, including transport.

Security sensitive dangerous goods

More recently, the threats to national security from the misuse of what have been termed ‘security sensitive’ substances, has led to an agreed set of national principles, but has been implemented, in separate codes and regulations which contain more stringent licensing and other requirements for transporters. These goods are not regulated under the ADG7 package. These issues are discussed further in chapter 10.

Regulation of air transport of dangerous goods

Freight transport of dangerous goods by air in Australia is regulated by CASA under the *Civil Aviation Act 1988* (Cwlth) and part 92 of the Civil Aviation Safety Regulations 1998. The Act calls up the International Civil Aviation Organisation's (ICAO[6]) Technical Instructions for the Safe Transport of Dangerous Goods, which are currently based on the UN Model Regulations (14th edition). These regulations include packaging, labelling, handling, stowage and declaration requirements, as well as training courses for those accepting dangerous goods and for airline staff. The adoption of ADG7 will harmonise land transport regulations with those for sea and air (NTC, sub. 21).

Many airlines also adopt the International Air Transport Association dangerous goods regulations, which incorporate the ICAO standards and include some provisions that provide an even higher safety standard.

Regulation of sea transport of dangerous goods

The Australian Government is responsible for regulating interstate and international sea transport. Carriage of dangerous goods by sea is regulated by Marine Orders issued under the *Navigation Act 1912* (Cwlth), and administered by AMSA. There are generic requirements for all cargo and special Marine Orders for dangerous goods that implement the International Maritime Dangerous Goods Code. As with air transport, the sea transport regulations are based on the UN Model Regulations.

Self-regulation

The trucking and chemicals peak industry associations have both implemented programs to improve the safety and reliability of road freight transport (box 7.1). Explosives industry codes are referenced in explosives regulations. The NTC (sub. 21) suggested that, in view of the limited resources available to administrators for regulating the use and transport of dangerous goods, greater resort to industry self-management may be appropriate to improve regulatory outcomes.

6 The ICAO was established in 1944 by an international intergovernmental agreement aimed at developing international civil aviation in a safe and orderly manner.

7.3 Assessment of current regulations

This section considers how effective chemicals transport regulation has been in achieving its objectives and the efficiency of the development and implementation of the regulatory regime.

Effectiveness

Section 3 of the Model Act on the Transport of Dangerous Goods by Road or Rail 2007 states that the purpose of the Act is to 'regulate the transport of dangerous goods by road and rail in order to promote public safety and protect property and the environment'. The effectiveness of the processes can be gauged indirectly, by assessing reductions in both the number of dangerous goods accidents and the severity of the outcomes from those accidents.

Box 7.1 **Self-regulation of chemicals and plastics transport**

TruckSafe (Australian Trucking Association)

The Australian Trucking Association has developed an industry accreditation programme to assist trucking firms to operate safely and professionally, and to signal to road freight users that the firms meet certain standards in these areas. TruckSafe includes systems and standards for vehicle maintenance, workplace and driver health (including fatigue management) and training. There is an auditing requirement for firms to obtain and retain TruckSafe accreditation.

Carrier Accreditation Scheme (Plastics and Chemicals Industries Association)

In 2001 the Plastics and Chemicals Industries Association (PACIA) introduced the Carrier Accreditation Scheme in order to improve the safety performance of chemicals transport and specifically to reduce the costs to industry of complying with PACIA's Responsible Carrier Storage and Transport Safety Code. Carriers self assess their operations and performance and this is then verified by an auditor before accreditation is given. Chemical companies are advised which carriers are accredited. The scheme obviates the need for individual chemical companies to undertake comprehensive audits on all potential carriers. Since 2005, the auditing processes for the Carrier Accreditation Scheme and TruckSafe have been mutually recognised.

Explosives

The Australian Explosives Industry and Safety Group has developed a number of codes of practice for the explosives industry — including one covering transport of explosives in mobile processing units — which jurisdictions refer to in their explosives regulations.

Sources: ATA (nd); PACIA (nd).

Regulations to reduce the risks of dangerous goods transport have operated for many years — at the national level the first edition of the ADG Code was published in 1980. Hence, it is now more difficult to empirically assess outcomes under regulation with those that might have occurred if the regulation did not exist. Nonetheless, the NTC estimated that around 10 to 15 per cent of heavy vehicles carry dangerous goods (including explosives), while in 2000, fatalities involving dangerous goods vehicles were less than 1 per cent of the total for all heavy vehicles (NTC 2005, appendix B). This indicates a substantially superior safety performance for dangerous goods vehicles relative to other heavy vehicles with likely associated savings in personal, property and environmental harm. NTC (2006b, p. 1) noted that there have been few major incidents involving dangerous goods transport in recent years. It argued that:

> This is to a large extent explained by the transport industry having embraced the various editions of the Australian Dangerous Goods Code published since 1980.

Significant improvements in heavy vehicle safety have been observed over the last 20 years. For example, the number of fatalities from heavy articulated vehicle accidents has fallen by around one third since 1991 (ATSB 2007). Because there has been a large increase in kilometres travelled, fatalities per kilometre would have fallen significantly more than this. This reflects a wide range of factors, including general road safety programs and those targeted at heavy vehicles, as well as safety gains flowing from transport infrastructure investment. Accordingly, it would be difficult to attribute any improvements in dangerous goods safety outcomes directly to changes to dangerous goods regulations over that time.

For the ADG7 package, the NTC (2005) estimated safety benefits of $5 million per annum as a result of reduced incidents and accidents flowing from assumed increased industry compliance.

Efficiency

There are several indicators of efficiency in chemicals transport regulation. At the aggregate level, Affleck and Meyrick (2002) reported estimates of net benefits from road transport reform under the NRTC until 2003 of $400 million. McIntyre and Moore (2001, p. 7) observed that dangerous goods laws (the ADG6 package) were widely regarded as one of the ‘more successful of the Commission’s legislative outputs’. This suggests that national reform of dangerous goods transport regulation has delivered substantial net benefits through improved efficiency.

In moving to the ADG7 package, the NTC lists a number of benefits to industry, particularly from greater international and intermodal harmonisation of the regulations, and a greater ability to transport small quantities of dangerous goods

under an exemption from the ADG Code. The NTC (2005, p. 27) noted that these benefits were diffuse and intangible and that 'due to the range of industries and substances involved it is difficult to provide quantitative estimates of these savings'.

There are also costs (for example, staff training) for firms adjusting to the new regulations. The NTC indicated that it could not quantify these costs. It argued that, in any event, training should be ongoing for employees of bulk dangerous goods distributors, hence not all training costs of introducing the new system should be seen as additional to ongoing requirements. The provision of a transition period, including the extension of existing exemptions provided under ADG6, should also reduce costs for regulated firms in moving to ADG7.

The support for the package from industry suggests that anticipated benefits to them from the package as a whole are expected to be greater than the costs.

The NTC estimated that various one-off documentation and training costs to government of introducing the reform package would be at least $10.4 million, with ongoing maintenance costs of $150 000 per year. This compares to the estimated ongoing additional safety benefits of $5 million per year.

Interjurisdictional consistency

Because freight transport (including chemicals) regularly involves interjurisdictional journeys, a seamless regulatory environment is particularly important, especially in enabling efficient operations and reducing compliance costs. Wilson and Moore (2006, p. 279) noted the costs of previous inconsistencies:

> The situation for heavy transport trying to run an efficient interstate operation became so intolerable in the late 1980s that major road blockades were initiated, as well as other forms of protest. Regulatory disparities that rendered drivers and operators illegal as borders were crossed made the conduct of interstate trucking operations in Australia unnecessarily difficult.

National reforms to the regulation of dangerous goods land transport introduced in 1998 (ADG6) have achieved substantial national uniformity and have generally received the endorsement of the chemicals and trucking industries. For ADG6, the Plastics and Chemicals Industries Association (PACIA, sub. 33, attachment 5, p. 27) noted that 'the outcome of the process in states and territories was extremely encouraging'.

There has been no indication that national uniformity has been achieved at the expense of good regulation, possibly reflecting the highly effective and cooperative governance arrangements surrounding policy development and implementation —

although this is not to say that existing national regulations cannot be further improved.

In principle, a high degree of national consistency could be continued under the new ADG7 package. However, industry is concerned that the new model legislation approach may see greater diversity between jurisdictions. While the ADG Code of technical requirements is likely to be implemented more or less uniformly, there is much greater potential for the jurisdictions to adopt the model legislation and regulations inconsistently or to include additional measures. For example, PACIA (sub. 33) noted that Western Australia intends to vary its regulations to introduce the approval of persons and entities that can respond to transport emergencies, even though this measure was not considered for inclusion in the ADG7 regulatory package. COAG (2008d) has now agreed to nationally consistent implementation of ADG7 and directed that the regulatory package be implemented by December 2008.

Also, compared to the ADG6 package, there is currently no indication that Australian Government financial incentive payments will be available, thus lessening the impetus for uniform implementation.

Relative to dangerous goods regulation, there is greater national variation in explosives transport regulation and this has imposed unnecessary costs on industry. Each jurisdiction has independently developed its own legislation and regulations, and implementation of the AEC is not totally uniform. The AEISG (sub. 63) noted costs created by differences in regulation between jurisdictions, such as requirements in some jurisdictions for seven days notice of the transport of explosives into the jurisdiction. It commented:

> The existence of multiple regulatory regimes with different treatment of explosives across the country creates barriers in achieving the maximum efficiencies, and in many cases, creates specific, expensive inefficiencies. (sub. 63, p. 1)

Other interjurisdictional regulatory differences include external signage requirements, restrictions on joint carriage of explosives and detonators, products defined as explosives and licensing regimes for trucks and drivers. The AEISG noted that these additional regulatory costs are particularly onerous because the mining industry's global competitors generally did not face multiple regulatory regimes.

Consistency between jurisdictions for dangerous goods and explosives driving licences has been enhanced by the COAG Skills Recognition Steering Committee achieving agreement for mutual recognition of these licences between jurisdictions by the end of 2008 (COAG 2008b).

Regulation of international and interjurisdictional air and sea transport is undertaken nationally and hence is uniform between jurisdictions.

Consistency between transport modes and international compatibility

The alignment of land transport regulations with the UN Model Regulations, on which air and sea transport regulations are based, has significantly increased the compatibility of dangerous goods transport regulations across modes. Intermodal consistency has been further enhanced by the ADG7 package setting out a single set of regulations for both road and rail. PACIA commented on the increase in intermodal and international uniformity:

> This will leave Australian industry well placed to move dangerous goods around Australia and the world more efficiently and safely. (sub. 33, attachment 5, p. 28)

Nonetheless, the costs and benefits will not be distributed evenly across affected sectors. In arguing for government contributions toward adjustment costs for the new package, the Australian Trucking Association (ATA, 2005, p. 2) argued:

> The approximately 100 to 150 small, medium and large [dangerous goods transport] operators in Australia will be the losers of this proposal. That is, compliance with the new code and supporting legislation and regulation will accrue little to no net benefit to the industry with 'others' (importers and exporters for example) deriving the primary benefits.

However, if sufficient benefits accrue to the chemicals industry from the package, they should be in a position to absorb some increase in transport charges arising from any higher costs incurred by the transport distribution sector in implementing ADG7.

Australian regulations for air and sea transport of dangerous goods have already been established nationally and are closely aligned with international requirements. The linking of the new land transport regulatory framework to the most recent UN Model Regulations achieves a similar outcome. However, some Australia-specific provisions remain. For example, certain emergency information panel requirements not contained in the UN Model Regulations have been retained in ADG7 to assist emergency services responses to accidents (NTC 2007, p. G14). These will impose some additional costs on exporters and importers of dangerous goods but might provide offsetting benefits in terms of better emergency responses. ACCORD Australasia (sub. DR91) noted departures from the UN Model Regulations in ADG7 for inner package labelling and exemptions of limited quantity loads from dangerous goods regulation, which would lead to higher labelling costs for the consumer goods and cosmetics industry.

Policy development and administration

Much of dangerous goods transport policy is developed centrally by the NTC, in close consultation with jurisdictional authorities and industry. Proposed changes are submitted for approval to the ATC. This model of policy development offers potential cost savings by limiting duplication of effort across jurisdictions.[7] However, if there were significant jurisdiction-specific issues, local knowledge and proximity to local decision makers would be important, and would need to be incorporated into the national framework to avoid detracting from the cost advantages of a single regime.

The transport of dangerous goods and explosives raises a number of policy issues — public safety (particularly road safety), OHS, damage to the environment, and national security — that cut across the responsibilities of a number of policy making and regulatory agencies at the national and jurisdictional levels. Hence, there is no simple administrative arrangement for developing and implementing policy — it needs to build on the underlying jurisdictional structures.

Currently, at the national level, dangerous goods transport policy has been successfully developed in a transport ministers' forum (ATC). However, with the exception of Queensland, administration of dangerous goods transport policy is not the responsibility of jurisdictional transport departments. In most cases, OHS regulators are responsible for dangerous goods (including transport), reflecting the potential workplace safety risks posed by the production, storage and use of such goods as well as the fact that a truck is a workplace. The NTC (sub. 21) noted some additional costs and complexity to government from transport departments having to inform and consult other departments in developing national reforms, and to industry in dealing with multiple regulators.

The implementation of the Commission's recommended Standing Committee on Chemicals (SCOC) (chapter 3) would facilitate cross-portfolio coordination generally and hence should assist the further development of regulations governing the transport of chemicals.

7 In some other areas of transport policy, individual jurisdictions have been appointed as 'lead agencies' in developing national policy. This approach further increases the input of jurisdictional regulators with practical experience of the operation of regulations, while maintaining the advantages of scale economies in developing detailed policy proposals.

7.4 Options for reform

Although the regulation of dangerous goods transport has generally been successfully developed and implemented over the last decade, several process and governance issues still need to be addressed. In addition, important jurisdictional differences remain in the regulation of explosives transport.

Template or model legislation

As noted above, the new dangerous goods regulatory package involves a different approach to achieving consistency of legislation and regulations across jurisdictions. Rather than the Australian Government passing template legislation and regulations that the jurisdictions can adopt by reference or copy into their own legislation, model legislation is attached to the NTC Act, but has no operational effect. Individual jurisdictions can then develop their own legislation based on the provisions of the model legislation, or reference the model act. The NTC (sub. 21) indicated that most jurisdictions intend to implement the model legislation under their omnibus OHS legislation rather than amend current dangerous goods Acts.

The switch towards model legislation in delivering national transport reform (including dangerous goods) had been mooted quite early in the NRTC's existence, because of the time taken to achieve agreement for template legislation. Shepherd (1999) considered that further road transport reform was likely to be delivered in model legislation form in order to speed up the reform process. McIntyre and Moore (2001) argued that although, in principle, model laws are not as effective as template, in practice they may work as well. The formal review of the NRTC Act (Affleck and Meyrick 2002) recommended that model legislation replace template legislation for delivering land transport legislative reforms.

There are several reasons for using model legislation, including arguments that suggest its use might not substantially reduce uniformity.

While template legislation was used to implement ADG6, not all jurisdictions directly referenced the Commonwealth template in their own Acts. For these jurisdictions the Commonwealth Act was effectively model legislation that they used to draft their own legislation.[8]

In principle, model legislation and regulations could produce largely uniform outcomes. The NTC (2006a) suggested that direct referencing of the model could be

[8] While in practice only four jurisdictions (including the ACT) adopted the 1990s reforms in pure template form, the others largely adopted it by copying provisions into their legislation.

more timely and cost effective for jurisdictions than rewriting it into state-based legislation. The NTC (2007) expected that, as with ADG6, the states and territories would either directly reference the model legislation, or incorporate it into their own legislation and regulations.

In addition, the model legislation approach was specifically written into the IGA and the Act establishing the NTC. It has been used in recent years to introduce regulations in areas such as heavy vehicle driver fatigue, rail safety and the intelligent access program for heavy vehicles. The jurisdictions — through the ATC — supported its use for dangerous goods regulation.

There are also arguments for favouring template legislation. In particular, it minimises differences in style, interpretation and content in the drafting of legislation by the individual jurisdictions. Even if effective outcomes are similar, different wordings between jurisdictions under model legislation can create unnecessary uncertainty for those trying to understand and conform with the regulations. Also, future changes are more easily incorporated if template legislation is directly referenced by jurisdictions.

A number of participants have expressed concern about the impact of the shift from largely uniform legislation. Both ACCORD (sub. DR91) and the ATA (2005) noted the critical importance of jurisdictional consistency for efficient transport operations and were concerned that model legislation left greater scope for differences between jurisdictions. The ATA commented:

> Given the inherent nature of trucking operations, non-uniformity often leads to high compliance costs, lower profitability and can lead to operational and legal uncertainty ...
>
> Whilst it remains to be seen whether jurisdictions will adopt the drafted model legislation and regulation uniformly, precedent would suggest that it is unlikely (Compliance and Enforcement legislation is a case in point). (ATA 2005, p. 1)

The ATA argued that the use of model legislation had led to inconsistencies in fatigue management regulation.

> The state premiers and chief ministers all agreed that uniform fatigue management laws were needed. The National Transport Commission … went ahead and prepared a model text, but the states and territories are now pressing ahead with their own, inconsistent versions. (sub. DR102, p. 1)

The AEISG (sub. DR94, p. 4) expressed similar concerns based on its members' 'adverse experiences' with SSAN and major hazard facilities regulations. PACIA (sub. 2) indicated satisfaction with the consistent outcomes achieved when implementing ADG6 by template legislation supported by National Competition Policy incentive payments.

Under either approach there are mechanisms that will assist in maintaining national uniformity in transport reforms. The ADG7 package was approved as an 'Agreed Reform' by a unanimous vote of the ATC and, under the IGA, all jurisdictions have agreed to use their best endeavours to implement and maintain Agreed Reforms in a uniform or nationally consistent manner. If a jurisdiction does not intend to implement Agreed Reforms, or intends to implement them with changes, it must notify the NTC and ATC, providing reasons for these variations. In addition, COAG (2008d) has now endorsed nationally consistent implementation of the ADG7 package, Hence, there is considerable formal impetus for achieving nationally consistent reforms.

In addition, the detailed technical regulations (ADG Code) should be almost totally uniform across all jurisdictions and this may be the most critical element of the regulatory package in determining compliance costs. Also, the CAP is another forum for maintaining national consistency of outcomes.

The model regulations and ADG7 Code have been under development for several years and implementation of the package is well advanced. In these circumstances, and in the absence of compelling evidence of significantly inferior outcomes, it is not practicable to consider reversion to template legislation.

The Victorian Government (sub. DR112, p. 14) noted that, by necessity, the NTC's model law will be 'adopted in a different manner in each jurisdiction'. Nonetheless, even if the exact form and wording of legislation varies somewhat, it is important that jurisdictions comply with their IGA commitments to implement reforms in a uniform or nationally consistent manner. This would involve uniform adoption and implementation of the ADG Code and achievement of equivalent regulatory outcomes from their specific legislation and regulations.

In this regard, in its draft report the Commission recommended that jurisdictions consistently adopt the model act and regulations and uniformly reference the new ADG Code. COAG has now adopted the intent of this recommendation by resolving that it:

> … agrees to the nationally consistent implementation by all jurisdictions of the 7th edition of Australian Dangerous Goods Code and attendant regulations within a 12 month period, and directs that all jurisdictions are to adopt the Code and supporting legislation and regulation by December 2008 and directs the Australian Transport Council to report its completion to the December 2008 COAG meeting. (COAG 2008d, p. 1)

This effectively reaffirms COAG's 1995 commitment (which was then part of a much broader economic reform agenda) to achieving the benefits of nationally consistent regulation of dangerous goods transport.

PACIA (sub. DR101) argued for a 12-month transition period during which both ADG6 and ADG7 would coexist, as was the case when ADG6 was introduced. The Victorian Government (sub. DR112) was similarly concerned about the implications of a possible short (six-month) transition period. Given the delays and uncertainty surrounding the introduction of the new Code and the move to model legislation, the Commission considers a 12-month transition period is appropriate. This period should commence after fulfilment of the COAG (2008d) directive for jurisdictional implementation of the ADG7 package by December 2008.

Given the level of industry concern regarding the potential for greater interjurisdictional inconsistency under model legislation, the requirement under the IGA for the NTC to maintain and review 'Agreed Reforms' is particularly important. With its expertise in developing and implementing national transport reform, the NTC is well placed to undertake evaluations of transport reforms. However, some conflicts of interest could be involved in an NTC review in this case. The NTC will need to continue working on future reforms to dangerous goods regulations with the jurisdictional administrations it is evaluating. Further, the NTC's role in introducing ADG7 has been criticised by some participants in this study and the outcome of the review could reflect on the NTC's performance,

In view of this, the Commission considers that the IGA review of the ADG7 package should be independent and should involve public submissions and the publication of the evaluation report.

RECOMMENDATION 7.1

The Australian Transport Council should commission an independent public assessment of the consistency with which the Australian Dangerous Goods Code is adopted by jurisdictions, and of the regulatory outcomes produced by their implementation of the associated legislation and regulations. The review should commence not later than twelve months after the reforms have been implemented by all jurisdictions.

Responsibility for national policy development and oversight

While the NTC has primary responsibility for developing national dangerous goods land transport regulations, in most jurisdictions responsibility for implementing them resides with OHS regulators. Hence, the NTC has argued that policy development would be better undertaken by an organisation operating in the workplace policy area:

> To maintain the current arrangements hampers expeditious and responsive reform (given the necessity for a transport reform body to coordinate non-transport agencies

under the governance of a Ministerial transport council) and imposes considerable and avoidable burden on regulators. (sub. 21, pp. 5–6)

There are arguments for transferring national responsibility to a workplace policy governance arrangement under the WRMC:

- Currently, jurisdictional transport ministers respond to and ratify proposed changes to dangerous goods policy at the ATC, but in most cases they need to seek advice from their jurisdictional OHS departments and authorities that are responsible for implementing dangerous goods transport regulations.
- Transferring responsibility for developing risk-management standards to a body which also develops OHS standards might also further improve the coordination of regulation on packaging and labelling between the workplace and transport.
- Many of the activities regulated by ADG7 (packing, labelling and loading) are undertaken outside the on-road transport sector.
- A truck and related loading/unloading facilities are a workplace and hence are already subject to the OHS regulatory framework.
- The AEC is currently being revised by the OASCC.

However, there are also reasons for retaining dangerous goods transport policy with the NTC:

- The main focus of dangerous goods transport regulation is community and environmental safety during the transport journey, rather than workplace matters.
- It would be desirable to retain a number of features of the transport institutional structure which have contributed to effective and efficient regulatory outcomes. These include: the focus on uniformity; the formal review function of the NTC; the forums for the chemicals and transport industries and other interested parties to have input into both policy development and the ongoing review of regulatory performance; and the operation of the CAP. Also, there is a strong IGA for land transport regulatory reform, and the majority decision making rules when ATC considers such reforms assist in achieving efficient and consistent outcomes. It would be difficult to recreate in another regulatory environment both the forums and culture for achieving national uniformity that has existed in transport regulation.
- The NTC's expertise in general transport regulation would not be as easily accessible if responsibility was shifted to a workplace regulator.
- The NTC has a long history of using a wide range of different approaches to developing transport policy reform, most involving significant consultation, in

some cases outside the transport field (for example, with environmental and OHS regulators and interest groups).

- Placing national transport regulation into the much larger field of OHS regulation, and its associated tripartite governance structure, might result in some loss of focus on transport issues. Transport groups may be concerned about potentially reduced access to the policy-making body.
- Australian Government policy development and international discussions on dangerous goods transport regulations are the Department of Infrastructure, Transport, Regional Development and Local Government's responsibility. That department also provides secretariat support to the ATC and the CAP.

Several major industry associations — the ATA (sub. DR102), PACIA (sub. DR101), the AEISG (sub. DR94), ACCORD Australasia (sub. DR91) and the Australian Paint Manufacturers Federation (sub. DR98) — have supported the continuation of the NTC's role in this field. At the government level, New South Wales favoured retention with the NTC, while the SA Government (sub. DR110) argued for continued development by the NTC or another federal transport agency. ACCORD Australasia argued:

> The NTC is Australia's premier transport authority and as such should continue to have responsibility for all aspects of transport within a national transport system. (sub. DR91, p. 21)

Conversely, some participants — including the Australasian Railways Association (sub. DR95) and Wacker Chemicals (sub. DR86) — have argued that policy development should be shifted to the OHS arena. They considered that the development of ADG7 had been too protracted and felt that the NTC now lacked dangerous goods expertise.

The NTC, in response to the Commission's draft recommendation that policy development responsibility remain with it, commented:

> … this draft recommendation emphasises the procedural strength and capacity of governance arrangements of transport reform at the expense of the subject matter. (sub. DR90, p. 1)

The Victorian Government argued that:

> Significant efficiencies in the administration and maintenance of DG [dangerous goods] transport, hazardous substances and dangerous goods storage and handling legislative schemes are available through consolidation of oversight under WRMC. (sub. DR 112, p. 15)

There appear to be some benefits in the Australian context of having a single national expert body that develops work safety and transport safety risk

management standards. However, there are also transport issues involved in the dangerous goods regulatory framework and national uniformity is very important for the transport industry. Significant cross-portfolio coordination will be necessary, regardless of where the ADG Code is located — a task that would be facilitated by the creation of SCOC (chapter 3).

In addition, the development and implementation of nationally uniform transport policy — including the introduction of ADG6 — under the NTC framework has generally been very successful. There has been some criticism of the process and outcomes in developing the ADG7 package (for example, ACCORD Australasia (sub. DR91), Tasmanian Government (sub. DR107), SA Government (sub. DR110)), Nonetheless, in submissions to this study, there has been general industry support for continued NTC oversight and the impetus for achieving efficient national uniformity is particularly strong in the transport arena. As noted above, further broadening and strengthening of transport governance arrangements has been proposed (NTC 2008).

In contrast, as discussed in chapter 6, attempts to introduce nationally-uniform OHS policy have taken considerable time with limited success. However, significantly different governance arrangements are now proposed for the development of national workplace safety policies (COAG 2008c). While these changes appear to significantly strengthen the framework for achieving nationally agreed policies, several aspects still leave cause for concern (chapter 6). If and when the new governance arrangements are successful in progressing the implementation of efficient and nationally consistent OHS policy, the issue of transferring responsibility for national dangerous goods transport policy could be reconsidered. Any such consideration should involve a public process and be cognisant of the preferences of a number of participants to this inquiry for continued oversight in the transport forum.

The NTC (and the NRTC before it) has traditionally been a tightly-resourced organisation, and one which has been innovative in attracting funding and resources to undertake its work program. In reviewing the NRTC's performance, Affleck and Meyrick (2002, p. 22) noted that:

> The pace of reform has disappointed some stakeholders, and could be improved with more resourcing of NRTC and jurisdictions responsible for implementation, but is reasonable in the circumstances.

Affleck and Meyrick (2002) noted the increased demands placed on the NTC's resources by the need to maintain the growing body of national transport regulation as well as developing new reforms. To the extent that the development and ongoing maintenance of dangerous goods regulation places unnecessary strain on the NTC's

resources, this should be addressed by the ATC in the context of the scheduled legislative review of the NTC in 2008.

RECOMMENDATION 7.2

Responsibility for policy development and monitoring should remain with the National Transport Commission, reporting to the Australian Transport Council.

Once proposed revised governance arrangements have become operational in the transport and workplace relations arenas, the Australian Transport Council should undertake a public review, involving consultation with all stakeholders and including consideration of necessary funding, to determine the most appropriate forum for developing and implementing future national dangerous goods transport policy.

Explosives regulation

Important differences in jurisdictional regulation of explosives transport are imposing unnecessary costs on industry. The AEISG noted the need for resource mobility and flexibility in mining — the main client of the explosives industry — but argued that this flexibility was being hindered by differing jurisdictional regulatory regimes for explosives. It commented:

> The removal of these multiple regulatory barriers, which can be achieved by streamlined and consistent legislation and regulation without usurping States rights, will enable real and significant benefits to flow through to the community as a whole by assisting in maximising the productivity potential of the mining sector. (sub. 63, p. 1)

The Australian Explosives Transport Safety and Security Group (sub. DR82) noted costs imposed by some jurisdictions requiring seven days' formal notice of transport of explosives into their territory and South Australia's disallowance of mixed loads of detonators and packaged explosives, which requires either running two vehicles or detouring via the Northern Territory. The AEISG (sub. DR94) pointed out that considerable compliance costs and inconvenience were imposed on importers by Australian-specific packaging and labelling requirements which differed from international regulations.

The AFER could provide a potential forum for resolving some interjurisdictional differences, but until recently it had only been meeting intermittently and it is not a statutory body. The AEISG (sub. 63) noted that informal networking between regulators had delivered some degree of consistency, but considered that this was not an efficient regulatory mechanism. In this regard, it argued for an expert explosives regulatory body similar to the CAP in dangerous goods.

The AEC is currently being updated (AEC3) under the auspices of the WRMC, with the objective 'to improve the current safety and security levels for the transport of explosives in Australia and to enhance the level of consistency in explosives regulation across jurisdictions' (AFER 2008, p. 9). However, the supporting legislation and regulations are not being harmonised and there is currently no framework for ensuring legislative consistency between jurisdictions or that the AEC is applied uniformly.

In its draft report, the Commission recommended that the AEC review be expanded to include associated legislation and regulations. However, the review of the AEC is now well advanced, with a revised code likely to be approved by the WRMC by the end of 2008. Several participants (AEISG (sub. DR94) and the Queensland Government (sub. DR121)) argued that it was important to complete the consistent national adoption of AEC3, and this should not be delayed pending a review of the legislation and regulations. The Commission concurs with this view — expeditious and effective completion of the current AEC review offers significant benefits to industry.

The Department of Education Employment and Workplace Relations (sub. DR96) indicated that the AFER was considering a further review to harmonise explosives legislation. In this regard, the AEISG (sub. DR94) considered that not all necessary changes to the AEC would be achieved in the current AEC3 process and that further revisions would be appropriate when the legislation was reviewed. The Department of Consumer and Employment Protection (WA) (sub. DR114, p. 2) noted that a review of the explosives transport regulatory framework should also consider 'the baseline level of regulatory intervention'.

The long period since the last review and the extent of current interjurisdictional regulatory anomalies suggest that the current review may not lead to complete consistency in the application of AEC3. In this event, a further updating of the code in conjunction with the proposed review of explosives transport legislation would be appropriate, with a focus on assessing the merit of existing regulatory interventions and establishing mechanisms that can efficiently and speedily deal with specific regulatory issues as they arise.

Combining the dangerous goods and explosives codes

The NTC (sub. 21) argued that there are benefits of regulatory consistency in amalgamating the development of the dangerous goods and explosives codes into a combined code to be administered in the workplace safety regulatory environment. The Australasian Railways Association (sub. DR95, p. 12) noted that lack of harmonisation of the two codes was a 'severe impediment to efficient interstate

transport of explosives by our members'. The AEISG (sub. DR94) supported, in principle, the inclusion of the AEC as a separate volume of the ADG Code. The Queensland Government (sub. DR121) supported continued parallel revisions of the two codes, but considered that in the longer term, while amalgamation was feasible, the resultant significantly larger and more complex code may not necessarily benefit industry.

The SA Government (sub. DR110) argued that, because of the potentially high consequences of an explosives accident, explosives regulation will have a different focus to, and should be separate from, dangerous goods regulation. However, separate treatment of explosives within an integrated dangerous goods regulatory package, supported by rigorous RISs, would appear to offer the potential for avoiding the unnecessary costs of separate regimes, while retaining appropriate explosives-specific provisions.

That said, in view of the achievement of nationally consistent dangerous goods transport regulations, combining their policy development with the more problematic explosives regulations may place these benefits at risk at this time. Improved governance arrangements and more nationally consistent regulatory outcomes in explosives transport regulation are needed before an amalgamation with dangerous goods would be prudent. The potential benefits of such an amalgamation further emphasise the importance of the current review of the AEC, and the Commission's proposed review of the entire explosives transport regulatory framework, delivering consistency between jurisdictions. If this consistency is achieved, the ATC and WRMC should examine the merits of amalgamating the regulation of dangerous goods and explosives transport.

RECOMMENDATION 7.3

The current review of the Australian Explosives Code by the Australian Forum of Explosives Regulators (AFER) should be completed as expeditiously as possible to produce uniform regulations that are adopted and consistently applied by all jurisdictions.

The AFER should then immediately undertake a review of jurisdictional legislation and regulations for explosives transport, with the aim of achieving nationally consistent legislation and regulations to complement the uniformly adopted technical code. Any technical code issues not adequately resolved in the current review of the Australian Explosives Code (AEC3), should also be considered.

Other issues

The NTC (2006a) has indicated that some policy issues were not considered in ADG7 in the interest of developing and obtaining approval for the significant structural, content and enforcement changes that were eventually implemented. The NTC (2006a, summary) commented:

> This is primarily a revision exercise. The intention is not to make major changes to underlying policy on the transport of dangerous goods but to update the Code and the supporting regulatory framework.

One such policy issue is the absence of a national training package for the various regulatory requirements and licences under ADG7. For example, the Victorian Workcover Authority (2005) considered that a national program of accrediting training providers and training could have been included in the ADG7 package.

The NTC (2006a) considered that training policy was outside the scope of the ADG7 exercise, but indicated that it might be addressed in future work programs. In addition, the NTC indicated that some issues raised by industry or regulators that would involve variations in the UN Model Regulations will be raised for discussion at the UN level.

At the more general level, the NTC (sub. 21) has suggested that the absence of a mechanism for linking with international regulations may result in the regulatory framework lagging behind international best practice. PACIA (sub. 33) also expressed concern about future uniformity with UN Model Regulations.

A major benefit of the ADG7 package is establishing consistency with the current UN Model Regulations, on which the regulations of many other countries and Australian air and sea regulations are based. It will be necessary to quickly and easily revise the ADG Code in line with the UN's approximately two-yearly revision cycle if these benefits are to be fully maintained.

Charges for purchasing regulatory codes

The cost of purchasing the new ADG Code is not insignificant ($140 hard copy and $120 CD-ROM), particularly when organisations require multiple copies. The AEC (second edition) costs $90. However, electronic copies of supplements to ADG6 and an addendum to the AEC are free on the internet. Web-based versions of the Model Legislation and Regulations are also free, as is the legislation of all jurisdictions.

PACIA (2006b, p. 3) argued that higher levels of compliance would be achieved by making the technical details available at low cost:

> … if high levels of compliance are to be achieved then dangerous goods information and requirements must be available in formats that assist users and be freely available. In this regard, the Government must demonstrate its commitment through making web-based versions of ADG7 available free-of-charge to all users and the community.

In this regard, Underwood and Hunt (2007) undertook a survey of members of the Australian Institute of Dangerous Goods Consultants concerning dangerous goods regulations. The survey indicated that, particularly among small to medium-sized clients, there was a considerable lack of knowledge and non-compliance with key requirements of the revised New South Wales regulations.

Haztech Environmental (sub. DR73) argued that many small companies refrained from purchasing the ADG Code and that cheaper availability of the Code would facilitate better compliance by such firms. The Queensland Government (sub. DR121, p. 19) noted that 'OHS standards and codes are freely available in Queensland in an effort to increase and improve compliance with regulatory requirements'.

The NTC (2006a, p. 50) indicated that development of the ADG Code was partly funded by revenue from sales of the Code:

> The time and resources required, in this instance, to update the Code and model legislation has dictated that the 7th Edition of the Code is made available on a cost recovery basis since NTC funding is limited. The 7th Edition will be made available at an affordable cost equivalent with other model codes of a similar nature. Since the same amount of effort should not be required for future editions the NTC may consider making these available free of charge.

However, the Commission has previously argued that the costs of policy development activities should not be recovered directly from users:

> It is important that these 'higher level' Government policy activities maintain both the appearance and reality of independence and accountability to Government. Recovering the costs of such activities from industry may compromise that independence. (PC 2001, p. 158)

In addition, in order to facilitate the high compliance needed to meet the objectives of regulatory standards and codes, they need to be readily available at low cost. The Commission has also previously argued (PC 2001, 2004b, 2006d) that as a principle of good regulation, legislative requirements (including associated codes and standards) imposing obligations should be readily available to those affected.

The NTC (sub. DR90) noted that it has contractual obligations for the sale of ADG7 and that these could be costly to renegotiate. To the extent that reasonable

compensation for existing distributors can be readily negotiated, the Commission favours immediate switching to avoidable cost pricing for the ADG Code. However, if compensation payments (including negotiation costs) are excessive compared to the potential benefits of greater access to the ADG Code, a change in pricing policy should be deferred.

The new AEC, for which no such contractual relationships or funding commitments have been made, should be available at avoidable cost.

Net revenue from sales of the ADG Code goes to the NTC, which had anticipated revenue in excess of $300 000 from sales of ADG7 (sub. DR90). To avoid inhibiting the NTC's reform program, revenue losses from implementing avoidable cost pricing, as well as any compensation payments to the contracted distributor of the code, would need to be made up by additional jurisdictional contributions. The SA Government (sub. DR110) indicated that it would be unwilling to increase its NTC contributions, as it did not provide free hard copies of its own legislation. However, the Commission is recommending free provision only on the internet, with other mediums being provided at avoidable cost.

In its draft report the Commission recommended that the ADG Code be available free on the internet and at avoidable cost for hard copies. COAG (2008d) has now agreed that ADG7 be made available free on the internet by December 2008 .

The Commission considers that there are regulatory benefits in making other mediums for purchasing the Code — such as hard copy or CD — available at avoidable cost of production and distribution. However, it is also important that the NTC's work program not be disrupted by the funding implications of efficient pricing of ADG7. COAG (2008d) has directed that the ATC consider a submission by the NTC on funding and contractual implications.

RECOMMENDATION 7.4

The National Transport Commission should price all modes of provision of the Australian Dangerous Goods Code at avoidable cost, including free provision on the internet. The resultant revenue loss for the National Transport Commission, together with any compensation payable to the Code distributor, should be offset by increased jurisdictional contributions. Pricing of the Australian Explosives Code should also follow these principles.

8 Regulation of agricultural and veterinary chemical products

Key points

- Agricultural and veterinary (agvet) chemical products are regulated under the National Registration Scheme (NRS) — a partnership between the Commonwealth and state and territory governments.
- Under the NRS, a national regulator — the Australian Pesticides and Veterinary Medicines Authority (APVMA) — undertakes the assessment and registration of agvet chemical products, while states and territories are responsible for regulating agvet chemical use after retail sale.
- The effectiveness and efficiency of APVMA assessments could be improved by introducing a formal obligation on the APVMA to ensure that the costs of chemical assessments are commensurate with the risks of the chemicals concerned and that APVMA assessment priorities are directed to the most efficient management of aggregate risks of all agvet products.
- The efficiency of APVMA assessments could be further improved by rectifying the currently dysfunctional arrangements for registering low regulatory concern products and through greater use of international assessment data.
- Interjurisdictional inconsistency in control-of-use regimes limits the effectiveness of the APVMA and the overall effectiveness and efficiency of the NRS. Vertical integration of regulations governing agvet chemical use into a single national regime delivered by the states and territories would improve effectiveness and efficiency.

The additional costs of the national control-of-use regime should be cost recovered by the APVMA.

The use of agricultural and veterinary (agvet) chemical products can pose potentially significant risks to human health and the environment. In particular, due to their function, pesticides[1] are frequently toxic and are applied directly on the environment including various food producing crops. In addition, the use of agvet chemical products on exported primary produce can affect Australia's international

[1] The terms of reference for this study exclude veterinary chemicals from its scope. The Commission's approach has been to only consider issues relating to them that are common to agricultural and veterinary chemicals regulation.

trade. In recognition of their hazardous properties, direct environmental and human exposure paths, and direct trade impacts, agvet chemical use is regulated via a dedicated regime. This regulatory treatment is similar to arrangements adopted in most OECD countries.

8.1 Regulatory arrangements for agricultural and veterinary chemicals

Scope

The National Registration Scheme (NRS) for agvet chemicals regulates the introduction and use of all agvet chemicals and products. This includes: the assessment and registration of agvet chemicals and products; development of conditions of use and product quality monitoring; and control-of-use of agvet products after retail sale. Agricultural chemicals are defined to include all pesticides including herbicides, fungicides, insecticides and plant growth regulators, but exclude fertilisers, which are defined as industrial chemicals for the purpose of assessment. Veterinary medicines are defined broadly to include all substances that can be used to prevent, cure or alleviate a disease or injury of an animal.

Institutional arrangements

The NRS is a partnership between the Commonwealth, state and territory governments underpinned by an intergovernmental agreement (IGA). Under the agreement, state and territory governments conferred their power to regulate the supply of agvet chemicals to the Commonwealth, and adopted a template Agricultural and Veterinary Chemicals Code (Agvet Code). The responsibility for regulating the use of agvet chemicals after retail sale remained with the state and territory governments.

The Australian Pesticides and Veterinary Medicines Authority (APVMA) — a statutory authority within the portfolio of the Commonwealth Minister for Agriculture, Fisheries and Forestry — derives its powers from the *Agricultural And Veterinary Chemicals (Administration) Act 1992* (Cwlth). Its functions include (among others):

- to assess the suitability for sale in Australia of chemical products, active constituents for proposed or existing chemical products, and labels for containers for chemical products
- to provide information to governments about approved active constituents,

registered products, and approved labels

- to fund a program to ensure compliance
- to evaluate the effects of the use of chemicals in states and territories
- to facilitate the introduction of uniform national standards on controlling the use of chemicals.

APVMA obtains policy direction from the Primary Industries Ministerial Council (PIMC), which is supported by the Primary Industries Standing Committee (PISC) and the Primary Industries Health Committee (PIHC). In turn, the PISC and PIHC obtain policy advice from the Product Safety and Integrity Committee (PSIC), whose members include representatives from the:

- Commonwealth Government Department of Agriculture, Fisheries and Forestry (DAFF)
- Australian state and territory departments responsible for agriculture
- New Zealand Food Safety Authority
- CSIRO
- APVMA
- Environment Protection and Heritage Council
- Workplace Relations Ministerial Council
- Australian Health Ministers' Advisory Council.

Funding

APVMA operates on cost-recovery principles and is principally funded via a levy imposed on sales of registered agvet products[2] and via application and annual registration fees. APVMA also collects licensing fees from manufacturers of veterinary medicines. In 2006-07, total revenue amounted to $25.3 million, of which $17.7 million, or around 70 per cent, came through the sales levy. APVMA has recorded operating surpluses in 2005-06 and 2006-07 of around $3.1 million and $2.1 million respectively (APVMA 2007a).

Assessment and registration of new products

APVMA assesses a chemical or product on its potential impact on human health, the environment, and trade as well as on its efficacy (box 8.1). Some aspects of

2 The levy applies to individual products and is tiered on the basis of value of the sales.

assessment are performed within APVMA after consultation with other agencies. A number of subject matters are assessed entirely by other government agencies. For example, the Office of Chemical Safety (OCS) assesses the toxicology of the product or chemical and looks at worker safety issues, while the Department of the Environment, Water, Heritage and the Arts (DEWHA) assesses the risks to the environment. Some of the risk-management decision making is also done externally — for example, dietary and occupational exposure standards are set by the OCS, while DEWHA can recommend risk-management strategies to mitigate environmental impacts (APVMA, sub. DR105).

Box 8.1 **Criteria for approving applications**

The Agricultural and Veterinary Chemicals Code (s. 14(3)(e)) states that the Australian Pesticides and Veterinary Medicines Authority must approve an application where (among other things) it is satisfied that the product or constituent would:

- not lead to an undue hazard to the safety of people exposed to it during its handling, or people using anything containing its residues
- not be likely to have an effect that is harmful to human beings
- not be likely to have an unintended effect that is harmful to animals, plants or things, or to the environment
- not unduly prejudice trade or commerce between Australia and places outside Australia
- be effective if done according to instructions.

Where the application is for approval of a label, the label must contain adequate instructions covering a range of issues prescribed by the Code.

On completion of the evaluation, if APVMA is satisfied that the product is safe and effective and that the label contains adequate instructions, it will grant the application. APVMA may refuse an application if it is not satisfied that the above conditions have been met.

APVMA may put conditions on the manufacture and supply of the product. For example, it can require the product to be supplied in a container of a particular kind. The product label also has to be approved by APVMA. Product labels are predominantly based on managing the *risks* of the product, although some *hazard* information may also be included. Matters that are required to be included on labels include:

- circumstances in which the product should be used and how it should be used
- approved times and frequency of product use

- withholding period after use of the product
- re-entry period after use of the product
- disposal of the product and its container when they are no longer required
- safe handling of the product and first aid in the event of an accident caused by the handling of the product.

Permits

In addition to registering agvet products, APVMA can, in some circumstances, issue permits for using an unregistered agvet product, or for using a registered product in a manner that contradicts the registration conditions. Permits can be issued in response to an application for a minor use, emergency use, or for research purposes.

Assessment of existing chemicals and products

When the NRS was introduced in 1995, APVMA assumed responsibility for over 5000 agvet products that were registered under prior state and territory arrangements (APVMA 2007a). APVMA runs a Chemical Review Program for assessing previously approved chemicals and products. Reviews decide whether the product is safe, requires reformulating, requires restrictions on conditions of use, or whether it should be suspended, cancelled or withdrawn from the market.

Interface with other national schemes

Some of the outcomes of APVMA assessments serve as inputs into other national schemes:

- When APVMA sets a maximum residue limit in food, it also makes a recommendation to Food Standards Australia New Zealand (FSANZ) to incorporate this maximum residue limit into the Food Standards Code (chapter 5).
- As part of the APVMA assessment, the product may also be classified as a poison. The product is then referred to the National Drugs and Poisons Schedule Committee.

Interface with state regulators

APVMA cooperates with state and territory governments in monitoring and enforcing compliance with the Agvet Code provisions. Also, while the scope of the NRS does not extend to controlling product use, the conditions of use specified by APVMA during product registration form part of the state and territory control-of-use regimes.

8.2 Effectiveness and efficiency of agricultural and veterinary chemicals assessment

Clarifying the objectives — recognition of effectiveness and efficiency principles

The assessment and registration provisions of the Agvet Code generate benefits and impose costs on the community. As noted previously (chapter 4), the Commission considers that an effective and efficient chemical assessment scheme should have provisions for prioritising its assessment effort and calibrating assessment requirements in a way that maximises net community benefit.

There is some acknowledgment in the legislation underpinning the NRS of the potential tradeoffs involved in the operation of the scheme. For example, the long title of the *Agricultural and Veterinary Chemicals Act 1994* (Cwlth) recognises among other things:

> a) that the protection of the health and safety of human beings, animals and the environment is essential to the well-being of society and can be enhanced by putting in place a system to regulate agricultural chemical products and veterinary chemical products …
>
> c) that the furthering of trade and commerce between Australia and places outside Australia, and the present and future economic viability and competitiveness of primary industry and of a domestic industry for manufacturing and formulating such products, are essential for the well-being of the economy and require a system for regulating such products that is cost-effective, efficient, predictable, adaptive and responsive …

The Agvet Code also requires that the APVMA satisfy a public interest test or consider different risk management options for some of its regulatory decisions.[3]

[3] Section 93 of the Agvet Code requires the APVMA to satisfy a public interest test when declaring a product to be a 'restricted product' (subject to greater post-registration control). Section 34 of the Agvet Code requires the APVMA to consider risk management alternatives

However, such provisions offer only a limited and fairly fragmented recognition of community wellbeing. There is little specific instruction in the Code on how to promote the achievement of the objectives outlined in the long title of the *Agricultural and Veterinary Chemicals Act*. The only general legislative instruction to the APVMA on the exercise of its functions pertains to the requirement to have regard to the principle of ecologically sustainable development (s. 7(4) of the *Agricultural and Veterinary Chemicals (Administration) Act 1992* (Cwlth)).

The APVMA (sub. DR105) argued that it was pursuing the objective of efficient regulation through a series of reforms to its operations that are currently in progress. Those reforms are addressed later in the chapter. However, industry comment to this study and to the Commission's study of regulatory burdens on primary sector businesses (PC 2007a), as well as some of the findings of the Australian National Audit Office review of APVMA operations (ANAO 2006), suggest that the APVMA is not as clearly focused on the objective of net community benefit as it might be. The Commission considers that, as a matter of general principle, there should be a formal obligation on the APVMA to set its assessment requirements to be commensurate with the risks and to appropriately direct its assessment and regulatory effort to managing the risks in the most effective way. The features of an efficient assessment regime specified in box 4.2 could help inform the pursuit of that objective.

RECOMMENDATION 8.1

The Australian Government, in consultation with the states and territories, should impose a statutory obligation on the Australian Pesticides and Veterinary Medicines Authority to ensure that:

- ***the costs of chemical assessments are commensurate with the risks posed by the chemicals concerned***
- ***its assessment priorities are directed to the most efficient management of the aggregate risk of all agvet chemicals.***

Governance structures

The NRS provides for extensive governance structures to address APVMA's current dual roles of chemicals and products assessment and risk-management standard setting. A ministerial council (PIMC) is responsible for policy development and scheme oversight, and is supported by a hierarchy of committees including PSIC, which provides expert advice to the Council. APVMA can provide

when reconsidering the conditions of registration of an existing product due to new information about its risk.

advice on emerging issues via its membership on PSIC. In addition, APVMA has a number of consultative committees including the Registration Liaison Committee — consisting of representatives from APVMA, Commonwealth, state and territory agencies, which operates as a forum for consulting on the operational management issues of the NRS.

In line with the Commonwealth Government's response to the Uhrig review of corporate governance (chapter 3), APVMA's Governing Board was recently abolished and replaced with a statutory advisory board appointed by the Minister. The board comprises representatives of a range of stakeholder interests from:

- regulation of chemical products at state and territory level
- agricultural chemical industry
- veterinary chemical industry
- primary production
- environmental toxicology
- protection of consumer interests
- public health and occupational health and safety (OHS) (APVMA 2007a).

The board provides expert advice to the Chief Executive Officer and is an internal governance mechanism aimed at improving the performance of APVMA in achieving its policy objectives.

Scope of APVMA — separation of risk-assessment and risk-management functions

APVMA's functions include both agvet chemicals assessment and subsequent setting of controls on those chemicals. As stated earlier, the Commission's preferred approach involves effective separation of the chemicals assessment and standard-setting functions. While this option should be kept open, it is not a high priority at the moment. First, most of the scientific assessment of agvet chemicals is already outsourced to other agencies. Second, the hybrid nature of APVMA as an assessment and regulatory body is an integral feature of a nationally agreed regime for agvet chemicals. The NRS has delivered significant effectiveness and efficiency benefits over past arrangements through national uniformity. Any moves to substantially alter the scheme would need to proceed with great caution so that those gains are not jeopardised. Nevertheless, the Commission considers that the devolution of the current technical assessment responsibilities of APVMA to a specialist assessment agency may be warranted as a longer-term objective.

Quality and rigour of APVMA assessments

The APVMA Principal Scientist Program is an internal program that has operated since 2002 with the aims of managing the science-related issues and projects within APVMA, and improving the quality of scientific assessments and the domestic and international credibility of AVPMA's scientific work. APVMA is also currently implementing a quality-assurance framework for its external service providers by requiring a performance assessment before sign-off on all work orders (APVMA 2008). In 2007, the Principal Scientists audited APVMA evaluation reports and found them to be 'in the range good to excellent' (APVMA 2007a, p. 36).

APVMA assessments also appear to be accepted internationally — for example, APVMA participates in the OECD pesticide work-share program.

Animal health industry surveys undertaken by Business Decisions Limited (2007) for Animal Health Alliance suggest that APVMA assessments were seen as being of high scientific quality. However, a common concern pertained to the quality of product efficacy testing. Efficacy testing is undertaken by state governments for APVMA. Survey participants have argued that the selection processes for engaging efficacy reviewers were opaque, that reviewers were frequently less competent than APVMA reviewers, and that there was inadequate oversight by APVMA of those external reviewers.

The Australian Academy of Technological Sciences and Engineering (AATSE) reviewed APVMA risk-assessment processes for pesticides and concluded:

> The assessment of pesticides by the National Registration Authority for agricultural and veterinary chemicals appears to be generally a rigorous process that uses internationally accepted principles of risk assessment. In particular, assessments reported in the full texts of recent reviews of products under the Existing Chemicals Review Program are indicative of a careful scientific approach and use of all available information and literature in the assessment. (AATSE 2002, p. 246)

Nevertheless, AATSE identified some gaps and limitations in APVMA assessments. The most significant limitation is that APVMA hazard and risk assessments are product specific and do not consider the cumulative and synergistic environmental and health effects of multiple chemicals. There is no routine assessment of multiple exposures or of all likely workplace mix combinations of pesticides. Further, there is no assessment of the cumulative or synergistic effects of multiple pesticide residues on human health, or on the environment. Australian Chemical Trauma Alliance argued:

> … with so many chemical products being used in our every-day environment (not just in pesticides) there has not been any meaningful attempt to assess synergism: assessing each chemical on its own is not in the real world. (sub. 9, p. 1)

Internationally, the issue of assessing the cumulative risks of multiple chemicals is beginning to generate considerable attention. For example, the US Environment Protection Agency (US EPA 2007a), as part of its program of review of existing pesticides, is required to assess the cumulative risks of pesticides that 'share a common mechanism of toxicity, or act the same way in the body'. A number of pesticides have been placed into four groups that share common toxicity characteristics. The cumulative risks of pesticides in each group will be assessed to determine whether the current risk-management standards are appropriate. The World Health Organization, under its International Programme on Chemical Safety, is currently developing a framework for 'assessing the combined risk from exposure to one or more agents (with or without a common mechanism-of-action) via all relevant routes and pathways' (WHO 2007). The Commission encourages APVMA to monitor the international developments on cumulative risk assessment methodology and policy and to investigate the feasibility of their implementation in Australia.

Feedback mechanisms supporting assessment activity

Strong feedback mechanisms supporting assessment activity can improve the accuracy of assessments and relieve the pressure for overly conservative data requirements and conclusions. Such mechanisms could include post-market monitoring of adverse experiences and a well-functioning existing chemicals review program that is responsive to public and industry feedback.

The NRS has an Adverse Experience Reporting Program consisting of voluntary reporting by the general public, health workers and state agencies and mandatory reporting by registrants of pesticides of any adverse experiences with their products that are drawn to their attention. The operation of the program has been criticised by some participants. Croplife Australia (sub. 35) argued that the program was not comprehensive due to its largely voluntary nature,4 and poorly coordinated, with no national database to collate the information.

Thus, a strengthening of the feedback mechanisms may be warranted. However, as in the case of industrial chemicals, any substantial increase in the scope of the

4 The Environment Protection and Heritage Council Chemicals Working Group also suggested that the program was limited by its voluntary nature, and has sought a commitment from state and territory government agencies with a role in agvet chemicals to report adverse events through this program (chapter 9).

existing Adverse Experience Reporting Program would need to be preceded by a comprehensive consolidation and evaluation of existing post-market monitoring information on agvet chemicals.

Grandfathered agricultural and veterinary chemicals

The NRS was introduced in 1995, replacing the previous state and territory-based systems. Over 5000 of the 6500 agvet chemical products currently available in Australia were registered under the previous arrangements, often involving less rigorous assessments, some of which dated back to the 1950s.

Where potential safety or performance risks have been identified, APVMA, as part of its Chemical Review Program (CRP), undertakes public reviews of already registered chemicals (including those assessed under the previous jurisdictional regimes) to assess whether they still work as intended and are safe for humans and the environment.[5] Potential reviews are prioritised and scoped, based on the level of concern about possible adverse effects determined against agreed selection criteria. There have been around 100 reviews completed or underway under this program, with over 40 existing chemicals currently nominated for future review.

As existing agvet chemical products have already received some form of assessment under previous state and territory registration schemes, the problem is not as significant as for industrial chemicals. In addition, about 75 per cent of agvet chemical products were registered pre-1995, compared to around 95 per cent of grandfathered industrial chemicals.

An Australian National Audit Office audit of APVMA's regulation of pesticides and veterinary medicines (ANAO 2006) considered that it had reasonable arrangements for identifying and prioritising existing chemicals requiring review. However, even for the relatively small subset of existing chemicals identified and prioritised for review, ANAO noted the slow rate of progress in commencing and completing reviews.[6] It observed that this meant that the risks of using many existing chemicals remained. Hence, ANAO recommended that APVMA assess whether the time taken to complete reviews adequately incorporated the risk of delaying reviews of other products. In addition, the ANAO observed that even if the rate of formal CRP reviews was slow, communication with stakeholders about

5 The CRP was established in 2000 by rolling together two previous review programs which had operated since 1995.

6 ANAO found that the average time to review an existing product was nearly three years, and this was set to increase because many of the reviews in progress have already taken more than five years.

concerns relating to existing chemicals being reviewed or being considered for review, would assist in reducing the risks associated with using such chemicals.

APVMA accepted the above recommendations and has engaged a consultant to assess the current approaches to prioritisation, review and communication with the public under the CRP. Part of that review will involve international benchmarking of APVMA's performance against the performance of similar agencies. APVMA also argued that where areas of significant concern were identified with a particular chemical, it took rapid action to manage those risks (sub. DR105). As with industrial chemicals, the Commission considers that effectively working through the backlog of unassessed chemicals is an important priority.

Funding of the CRP is an issue. Currently, it is cost recovered by agvet product registrants. Several participants (for example, Croplife Australia, sub. DR80) suggested that aspects of the program should be budget funded. As discussed in chapter 4, a proactive screening of all grandfathered industrial chemicals is a one-off response to a legacy issue and should, therefore, not be cost recovered for equity and efficiency reasons. Subsequent steps in NICNAS's existing chemicals review program are similar to the APVMA CRP program, and would continue to be cost recovered. The Commission considers, therefore, that a cost recovery arrangement for the CRP is warranted.

Registration costs — agricultural and veterinary chemicals

APVMA registration fees range between $320 and $48 860 (APVMA 2004b). Examination of overseas pesticide registration schemes suggests that APVMA fees are low by international standards (table 8.1).

Table 8.1 **Registration fees for new pesticide products[a]**

Country	*Registration fee*
	$A[b]
Australia	48 860
Canada	230 000
USA	360 000
UK	405 000

a Typical registration fees for a complete evaluation and registration of a new product with a new active constituent. **b** Exchange rate as at 18 January 2008.

Sources: Agriculture and Agri-Food Canada (2006); APVMA (2004b); DEFRA (2007); US EPA (2007b).

Part of the observed differences can be explained by differences in cost-recovery arrangements. APVMA recovers 40 per cent of the product evaluation cost through the registration fees and the remainder through the industry levy (APVMA 2005)

(implying an average cost of a full assessment to APVMA of around $120 000), whereas other countries recover the full assessment cost through the registration fees alone.

The Commission has not received any data from participants on the costs of data collection for registering a product with APVMA. However, given that APVMA's evaluations incorporate all aspects of NICNAS assessments and also impose additional testing requirements — such as to prove product efficacy — data costs could be expected to be even greater than for industrial chemicals assessments.

Timeliness of APVMA assessments

APVMA is required to finalise all agvet product evaluations within statutory timeframes. The timeframes consist of two components — a one-month timeframe for technical screening for application completeness and timeframes for completing the evaluation itself, which vary from 3 to 15 months, depending on the nature of the application. The statutory clock runs while APVMA is conducting the application screening and evaluation but is stopped while applicants respond to APVMA requests to remedy defects in their applications.

A number of industry groups (Croplife Australia, sub. 35; Veterinary Manufacturers and Distributors Association, sub. 48) have claimed that the timeliness of APVMA assessments were a problem.

A report by Business Decisions Limited (2007) prepared for Animal Health Alliance suggests that mandatory local testing of non-controversial animal health products by APVMA typically requires less time than the testing in Canada and Japan. Nevertheless, industry survey results presented in the report indicate that assessment times have increased over the last five years. Several reasons are listed including the introduction of additional safety and efficacy testing requirements and gaps in expertise or insufficient resources within APVMA.

An audit by ANAO (2006) found that in the period between 2001-02 and 2005-06, APVMA had failed to meet its statutory obligation to assess all pesticides and veterinary medicines within the statutory timeframes. The number of evaluations finalised within statutory timeframes was between 94–98 per cent for veterinary medicines, while for agricultural chemical products it declined from 95 per cent to 87 per cent. In addition, the average APVMA processing time for pesticide applications has more than doubled over that period.

However, several initiatives introduced by APVMA in the latter part of that period — including consolidation of application categories, greater use of modular

assessment categories and reduction or elimination of application requirements for some minor applications — allowed it to reverse the trend of declining performance against timeframes. In 2006-07, 90 per cent of pesticide applications (93 per cent for applications received after 1 July 2005) and 95 per cent of veterinary medicine applications were finalised within statutory timeframes (APVMA 2007a).

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 submission to registration. ANAO (2006) found that a large number of applications were deficient (74 per cent of pesticide and 76 per cent of veterinary medicine applications had at least one error or omission). It recommended that APVMA establish a framework for systematically analysing the types and causes of errors in applications to identify initiatives to improve the quality of applications.

APVMA has accepted that recommendation and has, consequently, established mechanisms for ongoing monitoring of errors and omissions in applications, and directed resources to the analysis of those errors.

The impact of registration costs on innovation and introduction of new products

The cost of registering an agvet chemical (including delays) may discourage innovation.

Australian patent application data (IP Australia 2006) show a 103 per cent increase in applications for pesticides between 1995 (when the NRS was established) and 2005, with an increase in pesticide applications as a proportion of total patent applications from 0.4 to 0.5 per cent. However, it is difficult to draw any meaningful conclusions from these data. The number of applications may have increased despite changes in compliance costs, and, as with industrial chemicals, the number of patents is an incomplete measure of innovation.

Animal health industry surveys undertaken by Business Decisions Limited (2007) for Animal Health Alliance suggest that Australian regulations governing the registration of veterinary medicines were seen as a barrier to innovation by 58 per cent of the firms. Contributing factors cited in the survey included high registration costs and research and development resources consumed while defending existing products. Survey results also suggested that the key reason for non-introduction of new chemicals was the cost of registration compared to the

small size of the Australian market. The problem is particularly acute in the case of agvet chemicals for specialty products (discussed below).

Barriers to entry of agvet products — the minor use issue

Agvet product suppliers make commercial decisions about introducing products based on the private benefits and costs. For some low-volume uses the registration and assessment costs (in particular, the costs of conducting the requisite testing) may be enough to outweigh the commercial benefits.

The Agvet Code provides for a minor use permit system with a permit fee of $320. There are approximately 500 minor use permit applications per annum lodged with APVMA (with over 95 per cent of the applications succeeding) (MULO 2007). Even so, industry, DAFF and APVMA agree that there is a lack of approved crop protection products for minor uses, due to the costs of registration (MULO 2007; Horticulture Australia, sub. 49).

Several reforms are currently being developed to facilitate the registration of more minor use products. These include:

- development of assessment requirements that would utilise crop grouping and extrapolation from existing registered uses
- amending data protection legislation to provide protection for data used to register additional minor uses on existing products and to obtain permits. Currently data protection only applies to registration of new products
- enhancing international collaboration including development of equivalent zones for acceptance of international efficacy and residues data.

Further, in 2006, DAFF and APVMA established a Minor Use Liaison Office (MULO) to develop a long-term strategy for managing minor uses in Australia. MULO (MULO 2007; DAFF, sub. DR120, attachment 1) has suggested that there are several costs in not addressing the issue including:

- illegal use of pesticides registered for major uses, with potential adverse environmental, health and trade effects
- animosity towards regulators.

MULO proposed that a publicly-funded research and development program be established to promote the registration of minor use products. This would involve annual funding of $3 million to fund the research and registration activity and $1–1.5 million to fund its administrative operation.

The Commission supports efforts to address the minor use issue, provided they lead to a net public benefit (to this end, its preferred approach would have the features specified in box 4.2). Reforms that reduce the cost of registering minor uses such as crop grouping, extrapolation from existing uses and improving utilisation of international assessments would help in this context. The Commission also supports extending data protection to registering new uses on existing products and to permit applications, because it could provide an important incentive to industry. Croplife Australia (sub. 35) argued that inadequate data protection provisions were an important contributor to the minor use problem. The Commission can see no compelling reason for inconsistent treatment of new and existing products in product registrations, nor for different treatment of permit and registration applications in this respect.

With regard to the publicly-funded registration program, MULO claimed that the program would lead to health, environmental and trade benefits by reducing the incentive to resort to illegal use of other pesticides in the absence of registered minor use products. There may also be positive externalities associated with pesticide research under the MULO proposal. And, there may be a collective action issue for some specialty crop growers as claimed by APVMA (sub. DR105). However, these must be clearly articulated, and, where possible, quantified to determine whether such a substantial subsidy is warranted. Further, it is important that the case for this program is investigated against other policy options that could address the identified problems more directly and, potentially, more efficiently.

APVMA referred the Commission to an economic impact study of the US IR-4 program (Miller 2007). The IR-4 program is generally considered the most successful minor use subsidy program in the world in terms of numbers of registered minor use products, and the study showed that it had a significant positive economic impact. However, the Commission considers that the study is severely flawed and its conclusions can not be used to justify a similar program in Australia.[7] Some participants (for example, HAL, sub. DR81) also referred to studies that showed a large commercial return on investment in pesticide research.

[7] The study assumed that none of the research output of the IR-4 program would be provided privately if the program had not existed. The study also misattributed the impacts of other policies to the program. For example, it attributed the entire economic benefit of the provision for expedited approval of pesticides in emergencies to the IR-4, because IR-4 data is sometimes utilised in such assessments. In estimating the benefit of that provision, the study relied on untested claims by crops producers that applied for the emergency registrations. Finally, the study assumed the program funding represented an external injection into the economy that led to a multitude of direct and indirect benefits, rather than a relocation of funds from other, potentially more valuable, uses.

A large commercial return on investment is not a ground for government intervention. A publicly-funded registration program can only be justified if: there is a market failure; the program supports activity that would not have been privately undertaken; and the program leads to the greatest net benefit of all policy options. The Commission understands that MULO is currently conducting an economic analysis of the proposed program (DAFF, sub. DR120, attachment 1), and considers that the program should only proceed if it is supported by a comprehensive analysis of the costs and benefits that also evaluates other policy options.

How can the efficiency of assessments be improved?

APVMA arrangements for low regulatory concern chemicals

In addition to the standard registration path, amendments to the Agvet Code in 2003 provided for quicker and less costly alternatives to normal registration, where the product is deemed to impose a low risk to public health and the environment. Listed registration can be granted subject to compliance with a standard previously developed by APVMA for the product or class of products. In addition, products deemed very low risk can be approved for reservation, which exempts them from the requirement to be registered, provided their use is in accordance with particular conditions determined by APVMA (sub. 59).

These registration provisions have not worked to date. ANAO (2006) found that, as of July 2006, no products were registered under those categories. A substantial barrier to the operation of these provisions appeared to be the requirement to have Ministerial approval and the drafting of subordinate legislation for every new registration under the provisions. The problem has been recognised and a new system is currently being implemented, where standards for listed registration and conditions for reservation from registration will be approved by the APVMA Chief Executive Officer. The Commission supports this change and considers that the implementation should proceed as a matter of urgency.

Other APVMA initiatives to reduce assessment costs

APVMA has been consulting with industry on other cost-saving initiatives. Several are currently being considered in a range of areas, including:

- reducing elapsed time of applications — several projects are being considered, including a review of key registration processes, reduced technical screening, process mapping, changes to some permits, improvements in label approval processes, clock audits, flow charts of processes on APVMA's website,

improvements to application guidelines, and meetings with industry to improve the quality of applications

- reducing data requirements — investigating the potential for waiving some data requirements and for reducing chemistry data requirements
- improving performance of evaluators — providing training to APVMA staff and establishing a performance-monitoring framework for external evaluators
- self-assessment — investigating the scope for self-assessment of some aspects of applications by approved registrants under a quality-assurance scheme, including allowing applicants to complete efficacy testing by approved reviewers prior to submitting the application (Croplife Australia, sub. 35; APVMA, sub. 59)
- simplifying the label approval processes — reforms have been introduced that allow specified administrative changes to the product label without the need to apply to APVMA. APVMA (sub. 65) has argued for further change that would remove the requirement for registrants to apply for APVMA approvals for changes to labels that are outside of the scope of APVMA operations (such as poisons scheduling and dangerous goods classification).

The Commission strongly supports the above initiatives. In particular, the introduction of self-assessment options for approved applicants could result in significant benefits through improvements in assessment timeliness. The Commission also agrees that requiring registrants to apply for APVMA approval for label changes that are outside the scope of APVMA operations leads to unnecessary regulatory duplication. The Commission also supports initiatives to reform the current system, whereby the registrant would only be required to apply for approval of changes that require a risk assessment by APVMA.

Moving to performance based standards on labels

The Aerial Agricultural Association of Australia (AAAA, sub. DR108) claimed that a combination of a prescriptive approach to label directions and poor expertise within APVMA concerning pesticide drift issues has led the APVMA to approve label directions that encourage outdated practices and result in environmental and human health risk. The AAAA suggested that the APVMA should be given powers to approve performance based labels. The Commission understands that the APVMA is currently implementing a new spray drift policy that should address this concern for new products by introducing performance-based standards for achieving minimum spray quality. It is intended that labels for new products will allow the use of new technology provided there is no increase in risk levels. APVMA will maintain information on new application technology that has been assessed as leading to equal or lower health and environmental risk.

With regard to old labels, the APVMA is initiating a review program to assess the relevance of prescribed application methods and equipment and intends to progressively replace those labels with new performance based labels. In addition to this initiative, applications for off-label permits can be utilised by applicators using new application technology.

The AAAA also argued for an urgent establishment of an application reference group to provide industry expertise on pesticide application issues and observed that this has been promised by the APVMA for several years. The Commission supports the establishment of a consultative mechanism that would utilise existing industry expertise on pesticide application issues as a matter of priority.

Utilisation of international linkages

Acceptance of test data generated overseas

APVMA is given the power under s. 160 of the Agvet Code to take into account information generated overseas to the extent that the information is relevant. The Manual of Requirements and Guidelines specifies the standards to which the data must conform and these standards are typically internationally accepted (APVMA, sub. DR105). Currently, APVMA decides on whether to accept international test data on a case-by-case basis. APVMA suggested that it accepted data if it supported the claims made by the applicant for the use patterns proposed in Australia. Generally, the APVMA provisions governing the acceptance of international test data appear adequate.

Acceptance of aspects of risk assessments completed overseas

APVMA engages in several international harmonisation initiatives. For example, it is an observer in the Veterinary Medicines International Cooperation on Harmonisation program, and participates in OECD pesticide work-share projects (APVMA, sub. 59).

Nevertheless, there has been very limited progress to date in developing arrangements for incorporating aspects of completed international assessments into APVMA assessment processes. APVMA observed that there were some opportunities in using international risk assessments of human and environmental toxicology (sub. 59). However, with the exception of the OECD work-share project (which involves a very limited number of assessments), APVMA has not entered

into any formal bilateral agreements nor made any unilateral undertakings to consistently accept aspects of other countries' risk assessment reports.[8]

APVMA (sub. DR105) argued that international best practice entails acceptance of hazard-assessment reports, rather than risk assessments or subsequent risk-management decisions. It suggested that the relevance of international risk assessments is often limited because of the differences in proposed uses (and exposure patterns). It also observed that risk management is country specific due to societal differences in acceptance of risk, and claimed that no OECD country applied the principle of mutual recognition of registration decisions. However, there is mutual recognition of pesticide registration decisions by EU member states, provided it can be shown that the agricultural, plant health and environmental conditions relating to the use of the product are comparable in the regions concerned (DEFRA 2008).

The Commission considers that greater effort is warranted with regard to developing arrangements where some or all of the content of assessment reports from other countries (hazard assessments in particular) are deemed to satisfy APVMA requirements without the need to fully re-evaluate the supporting data.

8.3 The case for national regulation of agricultural and veterinary chemical use

Under the NRS, the responsibility for managing the risks of using agvet chemicals is shared between the APVMA and state and territory governments that control the use of agvet chemical products after retail sale. Several participants (for example, Croplife Australia, sub. 35; Aerial Agricultural Association of Australia, sub. 17) argued that this arrangement has worked poorly to date and supported replacing the state and territory control-of-use regulations with a single national regime. DAFF (sub. 39) and APVMA (sub. DR105) observed that the current regime has been operating since 1995 and it might now be appropriate to reconsider the current structure of the NRS. This section analyses the case for vertical integration of control-of-use regulation into national regulation.

8 APVMA has signed a number of memoranda of understanding with the relevant authorities in the United States, Canada, United Kingdom and New Zealand. However, these appear to be primarily aimed at improving international consistency.

What are the problems with the current control-of-use regulations?

State and territory control-of-use regulations are fragmented

The controls imposed on the use of agvet chemicals at a state and territory level are varied and complex. They include: licensing and training of chemical users; notification and record-keeping requirements for chemical spraying; administration of jurisdiction-specific codes of practice, policies and guidelines; as well as the monitoring and enforcement of the conditions of use imposed by APVMA as part of the registration of the product. The controls are typically spread over several generic and chemical-specific legislative instruments. For example, in New South Wales, Queensland and Western Australia, at least six pieces of primary legislation apply to the use of pesticides.

Various coordinating mechanisms have been utilised within each state and territory to address the issue. For example, in New South Wales formal interagency memoranda of understanding exist to define the relative responsibilities of different departments and reduce inconsistencies and duplication.

In Western Australia, a Pesticides Advisory Committee with membership from various state departments — the Department of Health, the Department of Environment and Conservation, WorkSafe, the Chemistry Centre, the Department of Food and Agriculture and the Department of Water — coordinates the approach on pesticide management. In a recent review of the pesticides regulation in Western Australia, the Pesticides Advisory Committee recommended that a comprehensive code of practice on pesticide use be developed and referenced by the various relevant pieces of legislation (WA Department of Health 2006).

Nevertheless, several participants (for example, Growcom, sub. 12; Croplife Australia, sub. 35) argued that the regulatory fragmentation at state and territory level led to stakeholder confusion and duplication of regulatory burden (although little evidence on the resulting costs to industry and government was provided). DAFF (sub. 39, p. 11) also observed generally that ‘cross-portfolio overlap and duplication of regulatory requirements at state/territory level appear to be the area where greatest concern rests, particularly for users’.

State and territory regulations are inconsistent

There are significant differences in the regulatory approaches across Australia, including in those relating to enforcing APVMA requirements (table 8.2).

Some jurisdictions (for example, New South Wales and Western Australia) have adopted a prescriptive interpretation of APVMA conditions, while others (for example, Victoria) have favoured a performance-based approach that allows some diversion from product label requirements.

Table 8.2 **Major differences between state and territory regulations on pesticide use**

Controls		*NSW*	*Vic*	*Qld*	*WA*	*SA*	*Tas*	*NT*	*ACT*
Rates of application	Lower rate than on label	Yes	Yes[a]	Yes[b]	No	Yes	Yes	Yes	No
	Lower frequency than on label	Yes	Yes[a]	Yes[b]	No	Yes	Yes	Yes	No
	Higher frequency or rate than on label	No	No	No	No	No	No	No	No
Pests	Different pest than on label	No	Yes[a]	Yes[b]	No	Yes	Yes	Yes	No
Crops and situations	Different crop or situation than on label	No	Yes[a]	No	No	No	No	No	No
Application equipment	Different application equipment than on label	No	Yes[a]	Yes[b]	No	na	No	No	No
Record keeping	Records of use must be maintained	Yes	Yes[d]	Yes	Yes[f]	Yes[h]	Yes[i]	No	No
Training and licensing of users	General user training required	Yes	Yes[d]	No	No	Yes[d]	No	No	Yes[h]
	Commercial applicators licensing required	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Neighbour notification	Required for general pesticide use	No	No	Yes[e]	No	No	No	No	Yes[j]
	Required for vertebrate poisons	Yes[c]	No	Yes	Yes	Yes[g]	Yes[g]	No	Yes[e]

a Subject to some conditions and restrictions. **b** Unless the label explicitly prohibits such use. **c** Only if specified in a control order. **d** Schedule 7 poisons and restricted chemical products only. **e** Only if required by label. **f** Aerial application only. **g** Only for 1080. **h** Only for commercial operators. **i** Only for commercial and occupational uses. **j** Only for schedule 7 poisons. **na** Not available.

Source: Croplife Australia (sub. 35).

The are also significant differences in licensing and training requirements imposed on pesticide applicators. One clear example is the aerial application of pesticides, which is currently subject to inconsistent requirements in different states and territories (box 8.2).

Box 8.2 **State and territory inconsistencies in regulating aerial pesticide applicators**

- All jurisdictions except Western Australia recognise Spraysafe pilot training (an industry-run training and accreditation program) for issuing a chemical distribution licence. New South Wales does not recognise the Spraysafe program for accreditation of aerial spray mixers.
- Licensing fees and the scope of licences vary between jurisdictions.
- All jurisdictions except Queensland and South Australia require aerial operators to obtain insurance for spray-drift damage.
- Record-keeping requirements differ between jurisdictions.

Sources: Aerial Agricultural Association of Australia (sub. 17); Croplife Australia (sub. 35).

In addition to the differences in the content of state and territory regulations, there is variability in compliance monitoring and enforcement effort. Croplife Australia observed:

> A major concern of CropLife members is … state and territory enforcement of state control-of-use legislation. Some jurisdictions admit to inadequate resources, particularly inspectorate/compliance staff, for enforcement of broad industry compliance. Questions of inadequate staff expertise and program priority arise in states where agricultural chemicals are regulated by a department other than agriculture/primary industries. (sub. 35, p. 9)

Similarly, DAFF acknowledged:

> User and manufacturer concerns that state/territory enforcement of compliance with COU [control-of-use] regulations is inconsistent and inadequate have been made known to PSIC at stakeholder workshops in recent years. (sub. 39, p. 9)

Why move to a national control-of-use regime?

Past and current attempts to harmonise state and territory regulations have failed

Several participants (for example, NSW Government, sub. DR111; SA Government, sub. DR110) suggested that harmonisation of control-of-use regimes could be effectively pursued while retaining the current division of responsibilities under the NRS. However, past experience doesn't support this claim.

A report by AATSE (2002) analysed state and territory control-of-use regulations and detailed several unsuccessful attempts (dating from the establishment of the NRS) to harmonise them. These included: state and territory undertakings to

harmonise regulations arising out of various National Competition Policy reviews; establishment of an Agricultural and Veterinary Chemicals Policy Committee working group in 1996 to develop a common approach to off-label use; and appointment in 2000 of a control-of-use taskforce under the Agriculture and Resource Management Council of Australia and New Zealand.

More recently, an Allen Consulting Group report (2002) prepared for the Board of the APVMA proposed two reform options for harmonising control-of-use regulations. These involved either integration of all registration and control-of-use functions under a single agency, or development of National Operating Principles of the NRS, incorporating an undertaking by states and territories to achieve consistent risk management outcomes. Allen's preferred option, of the integration of all regulatory functions within a single agency, was subsequently rejected in favour of the National Operating Principles approach.

The introduction of National Operating Principles meant that, with PSIC and the Registration Liaison Committee, there are currently three mechanisms in the NRS for promoting consistent approaches to control of agvet chemical use. However, there is general agreement that these mechanisms have struggled to meet this objective.

AATSE (2002) concluded that regulatory variability was often a function of different approaches to risk management between jurisdictions. DAFF (sub. 39) identified a number of barriers to harmonising control-of-use regulations under the current regulatory arrangements:

- difficulty in achieving agreement on policy approaches, particularly when different portfolios with different approaches to risk are involved
- different jurisdictions having different priorities and political imperatives, affecting the level of resources directed towards agvet-chemical work
- periodic reviews of legislation undertaken by states and territories individually, rather than through PSIC, leading to inconsistencies.

The history of unsuccessful attempts to harmonise state and territory regulations indicates that a change in the structure of the NRS through a move to a single nationally-uniform control-of-use regime should again be considered.

Benefits from improved consistency

Establishing a national control-of-use regime would likely lead to improved overall effectiveness of the NRS in achieving consistent risk management outcomes across

Australia, particularly if all of the complementary instruments utilised by current control-of-use regimes were vertically integrated.

The greatest benefits are likely to come from having a uniform approach to off-label use of chemicals. Inconsistent implementation of the APVMA product label conditions by state and territory regimes can lead to several costs:[9]

- The effectiveness of APVMA in providing a uniform national system for registration and use of agvet chemical products is compromised.
- The relevance of APVMA's risk assessments is reduced as those assessments typically focus only on the uses permitted on the label. This could, potentially reduce the overall effectiveness of the risk management regime.
- The incentive for product registrants to undergo the full assessment and registration process for new uses is undermined (Croplife Australia, sub. 35). This might particularly affect the decision to add minor uses to an application.
- There may be anticompetitive effects. Ausveg (sub. 52) suggested that the latter issue was particularly significant for specialty crop producers, because they had limited registered pest-control options and allowing off-label use by some producers provided them with a significant competitive advantage.
- There is potential for confusion for users that operate in multiple jurisdictions and for pesticide suppliers advising customers, leading to poor compliance.

Another area where national consistency could deliver significant benefits is in licensing and training requirements. PSIC has identified user awareness and training as a key determinant of the risk of agvet products (DAFF, sub. 39). Similarly, the control-of-use component of the National Operating Principles also places a strong emphasis on user training and licensing. A nationally-consistent training and licensing regime is likely to contribute significantly to achieving consistent risk-management outcomes. It would also lead to cost-savings for product users operating in multiple jurisdictions (such as aerial applicators), and could have competition benefits. Finally, to the extent that a national training and licensing regime would overcome the problem of inconsistent state and territory implementation of industry initiatives (such as the various training and accreditation courses developed by the AAAA), it could encourage greater industry involvement and lead to greater utilisation of industry expertise.

9 It does not follow however, that the preferred approach is a blanket prohibition on all off-label uses, as suggested by Croplife Australia (sub. 35). Allowing some off-label uses may be a low-risk way of reducing the costs of some agvet chemical users. PSIC recognised some off-label uses as falling in this category including: use on an unspecified pest on a registered crop; use at a lower rate or frequency of application; and use on a crop and pest combination registered in another jurisdiction (WA Department of Health 2006).

In addition to improving regulatory consistency between states and territories, a single national control-of-use regime would consolidate the regulatory requirements applying to agvet chemical use. This could address some of the current intrastate fragmentation, duplication and inconsistency of regulations applying to agvet chemicals.

Cost savings in policy development

A national control-of-use regime could also improve efficiency through cost savings in policy development and implementation. Some states provided the Commission with estimates of the costs to governments of regulating agvet chemicals. For example, in Victoria these costs are around $2.9 million per annum (Victorian Department of Premier and Cabinet, pers. comm., 15 January 2008); in South Australia — $900 000 per annum (SA Government, sub. 56); and in Tasmania — $750 000 per annum (Tasmanian Department of Premier and Cabinet, pers. comm., 30 January 2008). An extrapolation of these figures suggests that the aggregate Australian cost of regulating the use of agvet chemicals after retail sale is of the order of $10 million. This estimate is an aggregate of the costs of policy development (which could be rationalised under a national regime) and administration (where the opportunities for consolidation are much smaller, because monitoring and enforcement of compliance would still need to be undertaken at the local level). Further, the establishment of a national control-of-use regime would involve some set-up costs in the short run. Thus, while a national control-of-use regime is likely to lead to cost savings in policy development and implementation in the long run, the extent and timing of accrual of those savings is unclear.

The Commission supports vertical integration of agvet chemical control-of-use regimes into a national regime. This would improve consistency in risk-management outcomes, reduce interstate competition distortions and would likely increase the net community benefit of agvet chemical regulation.

Implementation issues

While there are likely to be benefits in moving to a national regime, there are also some implementation issues.

Conferral of power on the APVMA

As discussed earlier, the APVMA derives its current powers to regulate the supply of agvet chemicals from a conferral of powers on the Commonwealth by state and territory governments under an IGA. The conferral was required to overcome the

constitutional restrictions preventing the Commonwealth from regulating the supply of chemicals. Vertical integration of control-of-use regulations would involve an increase in the scope of APVMA responsibilities and powers. Thus, a new agreement would need to be negotiated by the Commonwealth, state and territory governments conferring additional powers on the APVMA and specifying the new division of regulatory responsibilities.

Administrative arrangements for the new regime

Consistent with its preferred institutional framework, the Commission considers that the states and territories should retain involvement in the policy development for the new regime via their representation on the PIMC and PSIC. Further, the new regime may be best administered at the state and territory level under service level agreements with the APVMA. This approach would utilise existing local expertise in managing on-the-ground risks of agvet chemical use, as well as provide for greater responsiveness to emergencies.

Care would be needed to ensure that boundaries between a national control-of-use regime and state regulations are clearly defined. As discussed earlier, the legislation that currently governs the use of agvet chemicals at a state and territory level covers a broad range of areas including environmental protection, OHS and public health. Some of that regulation has generic, rather than agvet chemical-specific, objectives. Horticulture Australia argued:

> To regulate control of use via the Agvet Code, presumably through the APVMA would … potentially lead to a significant duplication of regulatory activity, e.g., State environmental controls cover a range of human activities not just pesticide use, whereas an Agvet Code based approach would focus solely on pesticides. Such a separation could conceivably result in confusion where the cause of an environmental incident is uncertain, i.e., who has jurisdictional authority. (sub. 49, p. 2)

However, most of these boundary issues appear to be existing problems. In the above example, it is likely that more than one agency would be involved already, including the environment department and the department of primary industry. Given that on-the-ground administration of a national code would be best delivered by statutory agencies under a service-level agreement, this situation would not change. Thus, the issue would need to be addressed via intrastate coordinating mechanisms.

The need to retain flexibility

One drawback of establishing a single national regime would be if this led to some loss of flexibility in addressing local issues. Several participants suggested that

some variability between states and territories would always be warranted due to the differences in geography, climate and primary industry structure. The NSW Government argued:

> States and territories will always need some flexibility to vary regulatory requirements to meet local needs … A state should not be required to remove a product use restriction or regulation provision solely for the purposes of harmonisation, where these have been judged necessary to manage the community's real or perceived view of risk in that state. (sub. 31, p. 20)

Consequently several participants (for example, Victorian Government, sub. DR112) suggested a single national regime would need to include exemption provisions to allow states and territories to respond to local circumstances.

However, much of the need for flexibility derives from differences in environments that do not correspond to state and territory borders and would, therefore, not justify retaining jurisdiction-specific regulatory approaches. Croplife Australia argued that regions with similar agricultural conditions often spread across borders and that different climatic conditions existed within jurisdictions (sub. DR80). In addition, the Agvet Code contains provisions for addressing the variability between regions. Product label instructions are already required to account for the climatic and geographic conditions associated with product use in different regions. Further, the permit provisions of the Code allow APVMA to approve off-label and emergency uses. Finally, several participants argued that incorporating significant exemptions into the new regime would compromise the purpose of establishing a single national regime.

Thus, on balance, the Commission agrees that introducing substantial additional exemption provisions into the national control-of-use regime is undesirable. The onus should be on the states and territories to justify the need for incorporating any new exemptions into the regime, taking into account the potential costs of reduced inter-jurisdictional consistency.

Funding arrangements

Currently, control-of-use regulation of agvet chemicals is funded by states and territories largely from consolidated revenue. As estimated earlier, this cost appears to be roughly of the order of $10 million. Expenditure on a national regime may need to increase if an evaluation of the existing arrangements for monitoring and compliance enforcement finds them to be insufficient for appropriate management of the risks. On the other hand, as suggested earlier, consolidation of existing regimes could lead to some cost savings. Also, some of the regulatory costs could be expected to be recovered via licensing charges on chemical users. For example in

Victoria, over $200 000 per annum would be recovered via chemical user licence fees.[10] Nevertheless, moving the responsibility for the control-of-use regime to the APVMA (including the responsibility for funding the state and territory administration of the regime through service level agreements) is likely to require a net increase in the funding of the agency.

There are two options for funding the additional costs: cost recovery or budget funding. Several participants (for example, Croplife Australia, sub. 35, sub. DR80; PACIA, sub. DR101) argued in favour of a budget-funded control-of-use regime. The following points were raised in support of this position:

- APVMA in its current form as an assessment and registration agency does not have the legal authority to impose charges for control-of-use regulations.
- Cost recovery would lead to inefficiencies because it would increase the cost of manufacturing and supplying agvet chemicals.
- Control-of-use regimes lead to public benefits rather than private benefits that accrue to product registrants and thus should be budget funded for equity reasons.
- The links between agvet chemical manufacture or supply and adverse effects on human health and environment are often tenuous. Other factors, such as user training, condition of equipment used to apply the product, and use of the product in accordance with instructions frequently play a decisive role.

In responding to these comments, the Commission considers:

- If a national regime were established, a conferral of regulatory responsibility for control of use on APVMA would be required and this would give it the legal authority to raise the requisite funds.
- A potential increase in the costs of manufacturing agvet products does not of itself constitute an economic inefficiency as defined in chapter 2, nor as referred to in the Australian Government Cost Recovery Guidelines (DOFA 2005a). An increase in the cost may be efficient, if it creates an improved signal of the true cost to the community of using a particular product.
- The Commission does not consider that from an equity perspective the outcomes of control-of-use regimes should be perceived as a public benefit. Control-of-use regimes are in place to manage the adverse impacts of the use of pesticides and their outcomes are more appropriately described as a reduction in the negative externalities of pesticides. Further, as observed by Croplife Australia (sub. 35),

[10] Estimate based on the number of licensed commercial and non-commercial ground operators and aerial applicators (DPI 2007) and the relevant annual licence fees. The estimate does not include receipts from permit fees for off-label use of restricted chemical products.

in the absence of effective control-of-use regulations, the APVMA may be required to set significantly more restrictive assessment and registration requirements and, potentially, withdraw some products from the market. Thus, it could be argued that control-of-use regulations might create some benefit to agvet product manufacturers.

- To be efficient and equitable, cost recovery arrangements should be as closely linked to the activities generating the need for regulation as is practicable to do so. In this context, a mix of user charges and sales levies differentiated according to product risk may be appropriate. The Agvet Code already provides for recognising low concern products (under listed and reserved categories) and high risk products (under the restricted category). Those categories could form the basis for this tiered approach to cost recovery.

The Australian Government Cost Recovery Guidelines (DOFA 2005a) suggest that a control-of-use regime should be subject to cost recovery, provided budget funding is not more efficient, cost effective and more consistent with policy objectives. The Commission can see no inconsistency between the policy objectives of the control-of-use regime and cost recovery of the regulatory costs. With regard to cost effectiveness, mechanisms such as the product sales levy and user licensing fees already exist to recover part of the cost of administering the NRS. Resetting those mechanisms to reflect the full cost of the regime is unlikely to have significant cost-effectiveness implications.

The Commission acknowledges that the new regime could lead to a significant change to current funding arrangements. In view of that, it would support a phased introduction of the cost-recovery arrangements.

RECOMMENDATION 8.2

The Australian Pesticides and Veterinary Medicines Authority (APVMA) should regulate the use of agricultural and veterinary chemical products after the point of retail sale through amendments to the Agvet Code:

- ***The scope of the new control-of-use regime should be negotiated through the Primary Industries Ministerial Council, and should include, at a minimum, uniform approaches to enforcing conditions of use on product labels and to the licensing and training of users.***
- ***The Commonwealth, state and territory governments should renegotiate the intergovernmental agreement to confer the necessary powers on the Commonwealth, and develop service level agreements for the regime to be delivered by the states and territories.***
- ***The APVMA should recover additional costs through a mix of charges and levies.***

9 Managing the impact of chemicals on the environment

Key points

- Chemicals have the potential to impact adversely on the environment during their manufacture, use and disposal. Governments have a role in intervening to ensure that the risks of adverse impacts are managed where that is effective and efficient.
- Governments have regulated to address the impact on the environment of a number of chemicals with known hazards. However, a large number of chemicals in use have not been subject to environmental (or other) hazard and risk assessment.
- There are some differences in the way that each state and territory regulates for environmental protection, including with respect to chemicals and plastics. This can reflect the different environments across jurisdictions and the manner in which different regulatory regimes have evolved.
- The regulatory framework for managing the impact of chemicals on the environment could be improved. Reforms are being progressed under a national chemicals environmental management (NChEM) framework to improve effectiveness, efficiency and national consistency.
- Under the current arrangements, there is no institutional mechanism to coordinate the implementation of the National Industrial Chemical Notification and Assessment Scheme's (NICNAS's) environmental recommendations by the states and territories. A new environmental standard-setting body should be established that would consider NICNAS's recommendations on the environment and set nationally consistent standards as necessary. The states and territories should uniformly adopt the standards by reference.
- Environmental labelling should be considered by the Environment Protection and Heritage Council, based on cost–benefit analysis. Any environmental labelling scheme should be aligned with that of Australia's major trading partners and incorporated into the workplace labelling scheme.
- A performance management framework should be established to identify the data that are needed to evaluate outcomes against environmental objectives. Any additional data collection should be targeted at filling gaps in the existing data collection systems and informing outcomes, and only collected where cost effective.

Chemicals play a beneficial and important role in the economy, but some have the potential to harm the environment. There are numerous chemicals present in the environment as a result of human activity. Chemicals can reach the environment through a number of pathways, including intentional application (for example, application of pesticides), unintentional byproduct (for example, from industrial processes), domestic activity (for example, from application of cosmetics) or waste disposal (for example, chemicals contained in electronic equipment that is released into landfill). The main concerns about chemicals in the environment are 'their persistence and their possible toxicity' (Rae 2006, p. 1).

Significant work has been undertaken to develop a framework to improve the regulation of the impact of chemicals on the environment in the last five years. As discussed in chapter 1, the Environment Protection and Heritage Council (EPHC) has undertaken a number of initiatives to improve the environmental management of chemicals in Australia. This has included establishing a National Chemicals Taskforce in 2002 to scope issues associated with, and the need for, a national approach to ecologically sustainable chemical management and regulation in Australia. The proposed framework for national chemicals environmental management (NChEM) is discussed in section 9.4.

9.1 The case for regulating for the environment

The rationale for regulation is discussed in chapter 2. If a source of market failure exists in relation to the environment, government intervention may be warranted if the benefits of intervention materially outweigh the costs. Some market failures that occur in relation to chemicals and the environment include:

- negative externalities from use. Pesticides come under particular regulatory attention because they are designed to control target species of plants and insects. But the use of pesticides can result in the destruction of beneficial species, air pollution, land contamination, and chemical residues in surface water and groundwater.
- negative externalities from the discharge of chemicals and waste disposal. This may occur, for example, with an industrial plant discharging chemical byproduct into a river, which imposes a cost on downstream water users. Similarly, inappropriate waste disposal can cause water and soil contamination. The costs of damage to the environment are often borne by the community, including through the loss of amenity and the funding of rehabilitation.
- information failures. Market failures can arise if consumers are unable to make fully informed decisions about the safe use and disposal of a chemical. Information about the impact of chemicals on the environment is technically

complex and costly to provide, and is likely to be underprovided by the market. If chemicals producers and suppliers do not obtain information on a chemical's impact on the environment, and do not provide adequate information to help consumers safely use and dispose of a chemical, governments may have a role in requiring that this information be provided (box 2.1).

There are numerous examples of negative externalities from waste disposal and chemical use that have caused environmental damage (box 9.1). Many of these are legacies from a time when environmental controls were less stringent.

Box 9.1 **Examples of legacies caused by chemical contamination of the environment**

A paper prepared for the 2006 Australian State of the Environment Committee identified a number of examples of the presence of chemicals in the environment.

> … concentrations of dioxins, furans and dioxin-like polychlorinated biphenyls (PCBs) derived from limited sampling of agricultural commodities, human blood and breast milk, soils, sediments, air and fauna. The levels were generally low by international standards. The environmental risk assessment was hampered by lack of toxicological data for Australian animals, but concluded that only marine mammals living near industrial areas and some raptors were at risk …
>
> PCBs have been detected in biosolids and in the fat of fish and marine mammals as a result of leakage of these substances from electrical equipment …
>
> The presence of persistent organic pollutants such as aldrin, dieldrin, and dichloro-diphenyl-trichloroethane (DDT) can still be detected at contaminated sites, in sewage biosolids, and in the fat of fish and marine mammals even though the use of these chemicals was phased-out over a decade ago …
>
> A major stockpile of hexachlorobenzene remains at Botany, New South Wales, and there is significant contamination of groundwater in the area from other chemicals …
>
> There are legacy issues with persistent organic pollutants at Sydney's Homebush Bay, where remediation is progressing …
>
> The discharge of metals to the environment has left legacy issues. Where land is to be reused, remediation is required under state and territory legislation and large quantities of contaminated soil have been removed to secure landfills …
>
> In rural areas of New South Wales and Queensland, a large number of cattle dip sites contaminated with arsenic and slowly-degrading DDT are under management …
>
> Lead and zinc from smelting operations and mercury from electrolytic production of chlorine contaminate the sediments in the Derwent estuary near Hobart …
>
> The discovery in 2006 that biota in Sydney Harbour contained significant levels of dioxins, and that people consuming much seafood were thereby affected, emphasises the need for careful monitoring around hotspots …
>
> At a number of inland sites, mercury contamination from former gold mining operations can be detected in local streams and, courtesy of biomethylation, in their biota …

Source: Rae (2006, pp. 1-3).

9.2 Overview of regulatory arrangements

Under the Australian Constitution, the Commonwealth has limited power to regulate for the environment. Day to day environmental regulation is mostly undertaken by the states and territories, with some roles carried out by local government. There is a range of coordinating mechanisms to link the various aspects of the regulatory regime, as well as a number of self-regulatory arrangements.

In the last three decades, environmental regulation has tightened significantly and many of the practices of the past that resulted in the types of legacies listed in box 9.1 would not be permitted today. Most of the current regulation of chemicals in the environment is undertaken through general environment protection (including waste disposal) regulation, administered primarily by the states and territories through their environment protection Acts and National Environment Protection Measures (NEPMs). Some self-regulation programs are also undertaken by the industry. The manufacture, use and disposal of chemicals is of particular interest to environmental regulators. Each state and territory also regulates to manage environmental legacies.

Some environmental regulations specifically address the market failures associated with chemicals, recognising that the generic arrangements will not always be sufficient to adequately protect the environment. These include:

- regulations requiring the assessment of environmental risks undertaken by the National Industrial Chemical Notification and Assessment Scheme (NICNAS) and the Australian Pesticides and Veterinary Medicines Authority (APVMA)
- regulations relating to chemicals that are internationally recognised as causing harm to the environment (box 9.2), including:
  - organochlorine pesticides (which include dichloro-diphenyl-trichloroethane (DDT) and Aldrin), dioxins and polychlorinated biphenyls (PCBs) subject to the Stockholm Convention on Persistent Organic Pollutants
  - organotin anti-fouling paint subject to the Convention on the Control of Harmful Anti-fouling Systems on Ships (the AFS Convention)
  - ozone depleting substances that are subject to the Montreal Protocol on Substances that Deplete the Ozone Layer
  - hazardous chemicals and pesticides that are subject to the Rotterdam Convention on Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade

- Chemical Control Orders (CCOs)/Notifiable Chemical Orders (NCOs) in New South Wales and Victoria (used to implement international commitments and to address local issues)
- environmental aspects of labelling and Material Safety Data Sheets (MSDS) information provision
- some self-regulatory arrangements.

Policy development and oversight

Policy development and oversight for national environmental regulation is the responsibility of the EPHC, formerly the Australian and New Zealand Environment and Conservation Council (ANZECC), and as such is collectively developed by the jurisdictions.

Intergovernmental Agreement on the Environment

In 1992, the ANZECC[1] signed the Intergovernmental Agreement on the Environment (IGAE) (Australian Government 1992) that lists agreed general principles of environmental governance, including:

- clarification of the roles, responsibilities and interests of the three tiers of government in regulating the environment
- a requirement that regulatory measures should be cost effective
- acceptance of the precautionary principle, intergenerational equity, the importance of biological diversity and ecological integrity
- improved environmental valuation, pricing and incentive mechanisms, the polluter pays principle and prices based on full life-cycle costs.

The IGAE also included an agreement to establish the National Environment Protection Council (NEPC) with responsibility for setting NEPMs.

National Environment Protection Council

The *National Environment Protection Council Act 1994* establishes the NEPC and aims to protect air, water and soil from pollution through the creation of NEPMs. NEPMs outline agreed national objectives for protecting or managing aspects of the environment and may consist of a combination of goals, standards, protocols, and guidelines. Each state and territory has its own mirror National Environment

1 The Australian Local Government Association was also a signatory.

Protection Council Act to enable the provisions in the Commonwealth Act to be enforced at the state and territory level. The implementation of NEPMs is the responsibility of each jurisdiction. Particular NEPMs that relate to the environmental regulation of chemicals and plastics include:

- ambient air quality
- the national pollutant inventory
- general guidelines for the assessment of site contamination
- movement of controlled wastes
- used packaging materials
- diesel vehicle emissions
- air toxics (EPHC 2006a).

Chemical assessment

Both NICNAS and the APVMA assess chemicals for their impact on the environment.

NICNAS's assessment of environmental impacts

As part of the assessment process of a new or existing industrial chemical, NICNAS considers the environmental risk of a chemical over its life cycle and makes recommendations to safeguard the environment. To enable NICNAS to assess the environmental risk of a new chemical, the company or person importing or manufacturing the chemical is required to provide NICNAS with information on the chemical including its manufacturing process, proposed uses, physico-chemical properties, toxicological data (including ecotoxicological data for at least three aquatic organisms), exposure information, degradation and bioaccumulation information, transport, storage and disposal procedures. The proposed MSDS (including any information on handling and storage, accidental release, ecological impact and disposal) and the proposed label are also required (DOHA 2004b).

Environment assessments are conducted by the Department of Environment, Water, Heritage and the Arts (DEWHA) and provided to NICNAS under a service agreement. DEWHA makes an assessment of the potential environmental hazard of a chemical using data on chemical release patterns and the environmental effect the chemical would have. Each possible route for release of a chemical into the environment (for example, air, soil and water) during all stages of the life cycle (for example, manufacture, use and disposal) is considered. When considering potential

Box 9.2 **International treaties and chemical regulation**

The Stockholm Convention on Persistent Organic Pollutants

Dioxins are released into the environment mainly as unintended by-products of combustion processes. Australia fulfils its obligations under the Stockholm Convention through the National Action Plan for Addressing Dioxins in Australia (NAP), which adopts international limits on dioxin emissions and promotes adoption of international best practices to manage dioxins. The NAP will be implemented in consultation with other ministerial councils with an interest in dioxins.

Polychlorinated Biphenyls (PCBs) were once produced for use in electrical appliances, and are now released into the environment as byproducts of chemical manufacturing, incineration and waste disposal. The National PCB Management Plan was adopted in 1999 and meets Australia's obligations under the Stockholm Convention. The plan was incorporated into state and territory regulation in a variety of ways.

The Convention on the Control of Harmful Anti-fouling Systems on Ships

Organotin was once widely used in anti-fouling paint applied to ship hulls to control the growth of algae and other fouling organisms. In 2007, Australia became a party to the Convention on the Control of Harmful Anti-fouling Systems on Ships, which has been implemented in Australia by the *Protection of the Sea (Harmful Anti-fouling Systems) Act 2006*.

The Montreal Protocol on Substances that Deplete the Ozone Layer

Ozone depleting substances were widely used in Australia in refrigerators, air-conditioners, fire extinguishers and dry cleaning. The Commonwealth *Ozone Protection and Synthetic Greenhouse Gas Management Act 1989* and its regulations ensure Australia meets its obligations under the Montreal Protocol. Queensland, Western Australia, South Australia, Tasmania and the ACT regulate ozone through their generic environmental regulation. Victoria uses its Industrial Waste Management Policy. New South Wales has a specific Act dealing with ozone protection. New regulations developed under a 2003 amendment to the Commonwealth Act are replacing current state and territory ozone protection legislation. A number of states and territories have indicated that they intend to repeal their regulations to ensure there is no confusion.

The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade

Australia became a party to the Rotterdam Convention on 18 August 2004. It requires companies that want to export certain hazardous industrial chemicals and pesticides to obtain written permission from a relevant government agency (the National Industrial Chemical Notification and Assessment Scheme and the Department of Agriculture, Fisheries and Forestry in Australia).

Source: DEH (2004); DEWHA (2007, 2008); DITRDLG (2007); EPA NSW (2007); EPA Victoria (2006); EPHC (2002, 2005); NABSW/SWMG (2001).

environmental impacts, parameters including volatility, solubility, mobility and the potential for biodegradation and bioaccumulation are evaluated (DOHA 2004b).

NICNAS can make recommendations to safeguard the environment in relation to importation, manufacture, handling, storage, use, emission limits or disposal of a chemical. Like its other recommendations, implementation of NICNAS's recommendations on the environment are not mandatory and are adopted by state and territory environment protection agencies and industry at their discretion. A Memorandum of Understanding (MOU) between the Commonwealth, state and territory governments — under which the jurisdictions undertook to implement NICNAS's recommendations wherever possible and to advise the director of NICNAS of any consequential actions they took — has largely been ineffective with respect to environmental recommendations. While a MOU working group was established to facilitate these links, it has largely functioned as a forum for discussing workplace safety issues.

APVMA's assessment of environmental impacts

As part of a wider assessment and registration process for agricultural and veterinary (agvet) chemicals, the APVMA evaluates the environmental safety of chemicals and products over their life cycle before they can be registered. It also undertakes risk management functions by approving the product label and setting out conditions of use to ensure the safety of the environment (APVMA 2004b).

To enable assessment of a chemical's potential environmental impact, information on the chemical's structure and manufacture, toxicology, metabolism and toxicokinetics, potential for environmental exposure, physicochemical and biodegradation, bioaccumulation in aquatic organisms, mobility in soil and ecotoxicological studies on birds, mammals, non-target invertebrates and native vegetation must be provided to the APVMA. Environment assessments are conducted by DEWHA under a service agreement. DEWHA considers potential hazards and likely exposure, and recommends risk management strategies (sub. DR105). An example of the proposed label must also be provided to the APVMA for approval (APVMA 2004b).

Administration and enforcement

State and territory environment protection regulation

Each state and territory has legislation protecting the environment from pollution that requires licensing or authorisation of activities of environmental significance,

outlines offences, and sets penalties for breaches of licensing conditions and environmental harm.[2]

Waste management issues, including disposal of hazardous chemicals and the products that contain them, have been included in the environmental regulation of most jurisdictions. In some jurisdictions, a separate Act has been created to specifically deal with waste management and resource recovery issues. Most states and territories also have legislation controlling the development of new industries and changes to land use, with impacts on the environment taken into consideration. While these Acts do not deal with chemicals issues directly, they play an important role in assessing and placing conditions on industrial development in Australia and have a role in controlling chemicals.

Contaminated sites, including contamination from chemicals, are managed using a range of regulatory instruments that differ across jurisdictions. New South Wales and Western Australia have specific legislation targeted at contaminated sites, Victoria and the ACT use a State Environment Protection Policy, and Queensland has issued guidelines on how to deal with contaminated sites. Other states and territories use their waste management legislation. In addition, a NEPM to improve national consistency in the assessment of contaminated sites is in effect.

All of these regulations deal mainly with the use of chemicals, focusing on discharges and emissions. Misuse of chemicals or inappropriate storage of chemicals that leads to environmental harm can also be covered under these Acts. Most states and territories also have provisions for the creation of environment policies and codes of practice under their environment Acts.

Pesticide use

In addition to APVMA conditions, which are imposed at the assessment and registration phase, the states and territories regulate the impact of pesticide use on the environment beyond the point of retail sale. This is done through training requirements for users, licensing commercial pest control operators and ground and aerial spraying operators, residue monitoring and enforcement of the safe use of chemicals.

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2 In Victoria, Queensland, Western Australia, South Australia and the ACT, this legislation is known as the Environment Protection Act. New South Wales has the *Protection of the Environment Operations Act 1997*, Tasmania has the *Environmental Management and Pollution Control Act 1994* and the Northern Territory has the *Waste Management and Pollution Control Act 1998*.

Local government

The roles and responsibilities of local government in relation to chemicals and plastics regulation vary from state to state. Local government functions that relate to environmental aspects of chemical regulation include:

- waste collection and management
- planning and development approval
- water and sewerage services in some states.

Local government can also develop, enforce and monitor laws and regulations governing public health, building, and environmental management, in order to promote good health, hygiene and environmental practices. Some local governments monitor and control water and air pollution, and collect water samples for chemical and microbiological analysis to ensure it complies with standards. Local government may also receive reports of adverse chemical impacts such as spray drift, and report this information to the APVMA. They may also work with the chemical industry and the EPHC on self-regulatory programs such as the drumMUSTER and ChemClear programs, and provide information on safe handling and disposal of chemicals and incident reporting.

Environmental information provision

Some protection of the environment from the harmful effects of chemicals is achieved through occupational health and safety (OHS) regulations, which impose obligations on employers to provide information on chemical hazards through the provision of labels and MSDS (chapter 6). Labels and MSDS are prepared under the hazardous substances and dangerous goods regulatory framework. Under the framework, a chemical can be classified as a dangerous good on the basis of, among other things, hazards that may affect the environment (NOHSC 2001a). Labels and MSDS, while primarily focused on protecting workers' health and safety, may contain some information about how to manage a particular chemical's impact on the environment.[3]

[3] The objective of the National Model Regulations for the Control of Workplace Hazardous Substances is to protect workers from adverse health effects. The Approved Criteria for Classifying Hazardous Substances provides mandatory criteria for determining health hazards, and optional criteria for determining environmental hazards. The National Code of Practice for the Preparation of Material Safety Data Sheets recommends that environmental information be included on MSDS, but its inclusion is not enforceable.

Labels

Under Commonwealth, state and territory OHS regulations, workplace hazardous substances (substances that present a hazard to people's health) must be labelled in accordance with the National Code of Practice for the Labelling of Workplace Substances (NOHSC 1994b). The Code makes no direct reference to environment specific labelling requirements for hazardous substances. However, labels must include instructions on emergency procedures including the control of leaks, spills and fires. Labels must also refer users to MSDS which may contain environmental information.

Dangerous goods (goods that present hazards such as flammability or explosiveness) for transport or use in the workplace are labelled in accordance with the Australian Code for the Transport of Dangerous Goods by Road or Rail (the ADG Code). The ADG Code includes provisions for the labelling of goods that are hazardous to the aquatic environment (NTC 2007).

The Australian Safety and Compensation Council (ASCC) is in the process of revising the national standards and codes of practice for workplace chemicals (unifying regulation of workplace hazardous substances and dangerous goods). The ASCC has published a Draft National Standard for the Control of Workplace Hazardous Chemicals (ASCC 2006e) and a Draft National Code of Practice for the Labelling of Workplace Hazardous Chemicals (ASCC 2006c). This draft Code contains the proposed labelling provisions for workplace hazardous substances and dangerous goods in the one document.

The draft National Standard and Code are based on the UN Globally Harmonised System of Classification and Labelling of Chemicals (GHS) which includes environmental labelling provisions. The GHS has classification and labelling provisions for chemicals that are hazardous to the aquatic environment (table 9.2). However, under the draft National Standard, it would not be mandatory to classify a substance as hazardous to the aquatic environment, and even where this classification has been determined, it would not be mandatory to include the hazard warning. The draft Code provides guidance on the voluntarily inclusion of information on environmental hazards on labels.

This information may be mandatory in other countries that adopt the GHS environmental labelling provision, and may need to be added to labels on Australian exports to comply with foreign labelling requirements. Some labels on imports into Australia may therefore carry the environmental information. NICNAS has been including the information needed to meet the GHS environmental labelling provisions in new and priority existing chemical assessment reports since its inception in 1990.

Labels provided to the APVMA for assessment must meet the requirements outlined in the APVMA Manual of Requirements and Guidelines (APVMA 2004b). The APVMA requires labels to include: any limits on use, and other limitations and prohibitions to minimise impacts on the environment; protection statements[4] to prevent harm to other crops, native and other non-target plants, livestock (including bees), wildlife, fish, crustaceans and the environment generally; storage and disposal statements; a reference to the MSDS; and emergency information.

Material safety data sheets

Commonwealth, state and territory OHS regulation requires employers to make MSDS available to anyone likely to be exposed to hazardous substances or dangerous goods in workplaces. MSDS describe the chemical and physical properties of materials and provide advice on their safe handling and use. The National Code of Practice for the Preparation of Material Safety Data Sheets (NOHSC 2003) sets out the information that is recommended to be included on MSDS to minimise potential environmental harm (box 9.3).

As part of the ASCC's review of the national regulatory requirements for workplace chemicals, it has published a Draft National Code of Practice for the Preparation of Safety Data Sheets (ASCC 2006d). The draft Code is based on the GHS, and has a greater emphasis on environmental matters than the current national code of practice. For example, the draft Code recommends that the section of the safety data sheet that deals with transport should include information on whether the substance is environmentally hazardous. As with labelling, under the draft National Standard for the Control of Workplace Hazardous Chemicals, it will not be mandatory to classify a substance as hazardous to the aquatic environment nor to include ecological information or hazard communication elements that relate to aquatic toxicity on Safety Data Sheets (SDS). The draft SDS Code provides guidance on the voluntary inclusion of information on environmental hazards in SDS (ASCC 2006d).

4 Protection statements can include risk management statements such as 'do not spray across open bodies of water' or hazard statements such as 'dangerous to fish and other aquatic organisms' (APVMA 2004b).

Box 9.3 Environmental information on Material Safety Data Sheets

Workers who use hazardous substances or dangerous goods at work must be provided with a material safety data sheet (MSDS). There are mandatory criteria for classifying health hazards, and optional criteria for classifying environmental hazards.

The National Code of Practice for the Preparation of Material Safety Data Sheets recommends the following environmental information provisions be included.

- Accidental release measures detailing appropriate responses to spills, leaks, or releases such as keeping spills away from drains, surface water and groundwater, methods and materials for clean up.
- Handling and storage measures to minimise the release of the hazardous chemical to the environment.
- Ecological information – ecotoxicity, persistence and degradability, mobility in soil environmental fate and bioaccumulation potential. While the Code recommends this information be on MSDS, it is not a mandatory requirement under current Commonwealth, state and territory hazardous substances regulations. However, under dangerous goods regulation, some states and territories require information such as ecotoxicity, persistence and degradability.
- Disposal considerations for safe disposal, recycling or reclamation of the hazardous chemical and/or containers.
- Other regulatory information not provided elsewhere in the MSDS such as whether the chemical is subject to domestic environmental legislation.

The Draft National Code of Practice for the Preparation of Safety Data Sheets (SDS) contains environmental information provisions similar to the National Code of Practice for the Preparation of Material Safety Data Sheets. In addition, there are provisions for transport information, which include whether a hazardous substance is a known marine pollutant according to the International Maritime Dangerous Goods Code, and whether the substance is environmentally hazardous according to the UN Model Regulations.

However, the Draft National Standard for the Control of Workplace Hazardous Chemicals exempts substances from classification as hazardous to the aquatic environment, and ecological information provisions relating to these hazards would not be mandatory on SDS. If a hazardous chemical has been classified into a hazard class, the Standard recommends that this classification and available ecological information be included in the SDS.

Source: NOHSC (2003); ASCC (2006d, 2006e).

Self-regulation

There is a range of self-regulatory agreements in the chemicals and plastics industry covering labelling, storage, use, disposal and the recycling of chemicals and packaging. Many of these agreements aim to manage the impact of chemicals on the environment (table 9.1).

Table 9.1 **Self-regulatory agreements**

Agreements	*Partners*	*Main aims / activities*
ChemClear	CropLife Australia/Agsafe, National Farmers Federation (NFF), Veterinary Manufacturers and Distributors Association (VMDA), Animal Health Alliance (AHA), Australian Local Government Association (ALGA)	Collects and safely disposes of unwanted and deregistered agricultural and veterinary chemicals.
drumMUSTER	CropLife Australia/Agsafe, NFF, VMDA, AHA, ALGA	Collects and recycles used agricultural and veterinary chemical containers.
Code of Practice for the Management of Plastic Bags	Australian Retailers Association (ARA), Environment Protection and Heritage Council (EPHC)	Promotes reduced use and increased recycling of lightweight plastic bags.
National Packaging Covenant	Industry and industry associations, EPHC, state, territory and local governments, community groups	Aims to improve environmental performance and life-cycle management of consumer packaging and paper.
PVC Product Stewardship Commitment	Industry, Vinyl Council of Australia, Department of Environment, Water, Heritage and the Arts	Promotes measures to address the health and environmental concerns with PVC products.
Phosphorous Content and Labelling of Detergents Scheme	ACCORD Australasia	A voluntary standard for labelling detergents that contain 5 per cent phosphorus or less.

Source: ACCORD Australasia nd; ARA (2003); NPCC (2005); NSW DEC (2006); VCA (2002).

9.3 The effectiveness and efficiency of environmental protection regulation

Ways of assessing effectiveness and efficiency are outlined in chapter 2. Those that are most relevant to the environment include:

- monitoring the impact of chemicals on the environment by collecting performance data and adverse event reports to assess the effectiveness of regulations in achieving objectives

- evaluating mechanisms to promote good governance and cross-jurisdictional coordination, and the degree to which these mechanisms achieve consistent, if not uniform, regulatory outcomes
- examining the case for environmental labelling through cost–benefit analysis
- considering whether there are more effective and efficient alternatives to regulation, such as financial assurances and self-regulation.

Monitoring the impact of chemicals on the environment

Assessing the effectiveness of environmental protection regulation in reducing the impact of chemicals on the environment is a difficult task. There are little data on environmental outcomes in Australia, let alone data specifically relating to the impact of chemicals. This was noted recently in State of Environment reporting:

> It is still not possible to give a comprehensive national picture of the state of Australia's environment because of the lack of accurate, nationally consistent environmental data. Therefore, the need for an enduring environmental data system remains a high priority if Australia is to measure progress and make sound investments in the country's environmental assets. (DEH 2006, p. 2)

It is also difficult to assess effectiveness when there is no way of knowing what the outcomes would have been in the absence of regulation (although some of the examples of legacies of the past can give a reasonable indication).

Examples of the limited data that the Commission has identified that report on outcomes of regulated chemicals are presented in box 9.4. The evidence relates to specific chemicals that have well established histories of being environmental and human health hazards (and in some cases are the subject of international treaties), and to particular environments or regions. For the most part, the impact of these chemicals appears to be reducing over time. This view is supported by the Organisation for Economic Co-operation and Development (OECD) that found:

> Although there are no consolidated data on emissions of known hazardous substances across OECD countries, it is probable that, overall, such releases from the chemicals industry in these countries are declining. (OECD 2001a, p. 226)

This view was generally consistent with comments made by participants to a roundtable on the environment conducted by the Commission in December 2007. Discussion at the roundtable indicated that generic environmental regulation has been broadly effective in managing the impact on the environment of chemicals with known hazards. However, there was concern about the possible impacts on the environment of the many chemicals that have not been assessed. As the OECD also noted:

The primary problem today is the lack of knowledge about the properties, effects and even exposure patterns of the great majority of chemicals (and, by extension, of preparations and consumer products made with them) on the market today. Whereas known hazardous chemicals are being managed to a large extent, there may be many unknown hazardous chemicals whose potential risks are neither being evaluated nor managed because the necessary information is not available. (OECD 2001a, p. 223)

Box 9.4 Examples of quantitative evidence of environmental outcomes relating to regulated chemicals and plastics

Ozone

It is estimated that global production and consumption of ozone depleting substances were reduced by 89 and 91 per cent respectively between 1986 and 2004. Australia has met or exceeded all of its phase out commitments under the Montreal Protocol. Observations and model calculations suggest that the global average amount of ozone depletion has now approximately stabilized and the ozone layer is expected to begin to recover in coming decades.

Dioxins

Dioxin levels in the environment (air, soil and water) are generally low compared with other countries. However, the concentrations in sediments at a few areas, and particularly in the lower Parramatta estuary and the western part of Port Jackson, are substantially elevated. Commercial fishing has been suspended in Sydney Harbour and Homebush Bay as a result of elevated levels of dioxins being detected in fish samples.

Organochlorine pesticide residues

There are data on the number of food samples where organochlorine pesticides were detected. In 2006-07, low level organochlorine residues were observed in a number of animal product samples but no results were above the relevant Australian Standards. No organochlorine residues were detected in sampled plant products.

Air quality

Since 1998 carbon monoxide has not exceeded the National Environment Protection Measure standard in any Australian city, most probably as a result of vehicle emission controls that were introduced in 1997.

In rural and regional Australia, levels of most pollutants are well below actual or proposed standards. Sulphur dioxide emissions and lead remain a concern in a few limited localities. The data from the National Pollutant Inventory indicates that benzene may be of concern in the Pilbara.

Source: DAFF (2007); DEH (2004, 2006); IPCC/TEAP (2005); UNEPOS (2005).

The difficulties in assessing the effectiveness and efficiency of environmental regulation in reducing the impact of chemicals on the environment highlight the importance of monitoring and information capture systems. In Australia, monitoring has been largely piecemeal and uncoordinated. In this respect the EPHC's National Chemicals Taskforce noted:

> … better feedback loops and understanding of chemical impacts in the Australian environment would be required to make a more definitive statement about the efficacy of current chemical management frameworks in protecting the environment. (EPHCNCT 2003, p. 47)
>
> While there are clearly some information gaps, there is also a concern that existing information is not being used optimally to support the assessment, control and monitoring of the environmental impacts of chemicals. A 1997 report to Environment Australia (Monitoring the Environmental Effects of Agricultural and Veterinary Chemicals in Australia – Preliminary Investigations) noted that state/territory programs were so disparate in nature and scale that collating the results would not be feasible …
>
> Options could be explored to facilitate more effective monitoring of environment and health impacts by ensuring optimal use of existing information; identifying gaps; and facilitating a nationally consistent approach by governments and industry. (EPHCNCT 2003, p. 43)

While monitoring often involves top down systems to collect data, it can also utilise bottom up feedback systems drawing on industry and public experiences, including through state and territory environment protection agencies and primary industry departments. For example, as noted in chapter 8, the agvet regime provides a feedback loop through APVMA's Adverse Experiences Reporting Program, which facilitates reporting of problems with the use of agvet products. One measure of effectiveness is the number and severity of reported adverse events or experiences (chapter 2). In 2005, of the 196 adverse experiences reports evaluated, assessed and classified by the APVMA, only four related to the environment (APVMA 2006) and in 2006, six out of 63 adverse experiences reports related to the environment (APVMA 2007c).

A more systematic attempt at monitoring effectiveness of agvet regulation is being implemented by the Product Safety and Integrity Committee (PSIC).5 It has taken steps to evaluate the effectiveness of the agvet framework by developing a performance management framework. Some of its objectives relate to the environment, including:

- unacceptable residues in potable water are avoided …
- unacceptable residues in surface water, groundwater and raw water are avoided
- adverse environmental impact from off-target spray drift are avoided

5 A committee of officials providing advice to the Primary Industries Ministerial Council.

- off-target wildlife and companion animal deaths are avoided. (sub. 39, p. 7)

The preliminary results suggest that the current agvet framework is reasonably effective in reducing risks of contamination of the environment by agvet chemicals, including pesticides, although one indicator identified a possible environmental concern relating to off-target spray drift:

> An initial assessment by states/territories of their performance against the indicators established for each performance outcome suggests that there are three areas where performance may need to be improved - exported Australian produce meets the importing country MRLs [maximum residue limits]; off-target spray drift incidents on primary produce are avoided; and adverse, non-occupational, public health incidents from contact with pesticides are avoided. (sub. 39, pp. 7–8)

Coordination mechanisms to facilitate good governance and nationally uniform regulations

Effectiveness and efficiency can be influenced by the mechanisms put in place to coordinate regulatory processes. Introducing such mechanisms can be crucial where regulatory issues are national in scope but are addressed differently across the states and territories.

Many aspects of the environmental management of chemicals are national in scope. A national approach to risk management would be best where it:

- reduces costs to firms (especially those operating in more than one jurisdiction), governments (through reduced administration and increased access to expertise) and consumers (from lower prices of products)
- enables better control of externalities that transcend state borders (such as chemical pollution of the air and waterways)
- simplifies the implementation of international agreements (such as the Stockholm Convention on Persistent Organic Pollutants)
- encourages greater compliance with regulations, and greater support and understanding in the community.

On the other hand, while the states and territories regulate for environment protection in broadly similar ways and to achieve similar objectives, some differences have emerged. These may reflect the differing environments within jurisdictions, different ways in which the regulatory systems have evolved, different priorities or different community attitudes to risk. These differences mean that the costs of moving to more nationally consistent arrangements may not be trivial, and hence would need to confer even greater benefits over time. They also indicate that

national approaches will require a degree of flexibility in administration and enforcement to accommodate the needs of the jurisdictions.

Links between risk assessment and risk management

Currently there is no formal national framework for the environmental regulation of chemicals other than what exists through the National Registration Scheme for agvet chemicals, and even that differs beyond the point of retail sale in the way it is implemented and enforced across jurisdictions. On the industrial chemical side little exists. As noted earlier, an MOU between the Commonwealth and the states and territories was meant to facilitate the take up of NICNAS's recommendations but this has been largely ineffective with regard to environmental recommendations. In practice, it has been more oriented to workplace safety issues than the environment. Informal links between NICNAS and state and territory environment agencies have been developing, and there has been some consideration of using the MOU to establish a more formal environment regulation working group (EPHCCWG 2006).

The absence of formal mechanisms to coordinate hazard and risk assessment with environmental risk management by the jurisdictions has been noted for some time. For example, the National Chemicals Taskforce noted that:

> There is no … framework that clearly articulates the environmental issues to be considered in assessing and managing potential risks from exposures to industrial, therapeutic and food additive chemicals; and the kind of risk management outcomes that would be expected by regulators. This gap creates a cycle in which jurisdictions cannot respond rapidly and consistently to assessments, and assessments are not framed to facilitate a consistent response by jurisdictions. (EPHCNCT 2003, p. 34)

Many submissions to this study have also raised this issue.

Prior to the recent NChEM reforms (referred to in section 9.4), the absence of a national framework linking risk assessment with risk management for industrial chemicals was having two impacts on effectiveness and efficiency. First, assessments were not as effective as they could have been because NICNAS was not making sufficient use of links with its state and territory counterparts in the environment agencies. NICNAS did not consult with the states and territories on the scope or content of draft risk management recommendations and as a result they may not have adequately captured on-the-ground environmental issues. Recommendations tended to be impractical or impossible for the states and territories to implement (EPHC 2006b).

Second, the absence of a formal legislative link between NICNAS's recommendations and state and territory action was leading to inconsistent take up

of its recommendations, or recommendations not being taken up at all. There was also confusion over roles and responsibilities (EPHC 2006b).

In response to the Taskforce's concerns, a Working Group on the Environmental Risk Management of Chemicals (the EPHC Chemicals Working Group (CWG)) developed a framework for National Chemicals Environmental Management, known as NChEM.

Other national frameworks

As noted earlier in the chapter, strategies have been developed by the EPHC (and its predecessor) to manage the impact on the environment of specific chemicals and groups of chemicals on a case-by-case basis[6], often in response to international treaties. These have met with mixed success. On the plus side, the agvet system provided an efficient way of banning organochlorine pesticides, which were subject to the Stockholm Convention. The ban was implemented by adding the pesticides in question to the Agvet Code Regulations, avoiding the need for each state and territory to use its own regulation. NEPMs have been used to introduce uniform national approaches to some specific issues, such as developing guidelines for assessing contaminated sites.

In other cases, responses have tended to be piecemeal and inconsistently implemented by the states and territories. Implementation of the National PCB Management Plan involved a range of approaches across jurisdictions. Some relied on existing environmental regulations, some made changes to waste regulations, while others incorporated the principles of the plan into their environmental licensing (NABSW/SWMG 2001).

Coordination mechanisms will become more important in the future

Despite the relatively fragmented nature of the various regulatory arrangements governing chemical use in the environment, regulation appears to have been relatively effective at managing risks from known hazardous chemicals. But these arrangements are likely to come under increasing pressure as more and more chemicals are assessed for their environmental impacts. The National Chemicals Taskforce has noted that greater responsiveness and flexibility will be needed in the future to address emerging issues, particularly if chemicals assessments, and the

6 Such as the regulatory framework for ozone depleting chemicals, the national waste management strategy for organochlorine pesticides and the national strategy for the management of PCB materials in use and PCB wastes (EPHCNCT 2003, p. 34).

number of chemicals identified as of concern to the environment, increases (EPHCNCT 2003).

While the Commission has recommended elsewhere that the assessment of existing industrial chemicals be greatly accelerated (chapter 4), this information may need to be used to develop appropriate national standards. The Commission's views on the NChEM initiative and a national framework for the environmental management of chemicals are set out in section 9.4.

Environmental labelling

The release of chemicals into the environment can have detrimental impacts. Some protection of the environment is provided by existing generic environmental waste disposal regulation, and market and common law incentives facing chemical suppliers and users. Environmental labelling could have additional benefits if it led to behavioural changes in the use, transport, storage and disposal of chemicals that reduced their impact on the environment.

Under current arrangements, labels for industrial chemicals, used in both the workplace and in domestic situations, do not require information on environmental hazards, although the GHS provides a framework for environmental hazard classification and labelling (table 9.2). By comparison, agvet products may be labelled with instructions on how to manage the impact of the chemical on the environment and may include risk management instructions or hazard statements in relation to the environment.

Mandatory environmental hazard classification and labelling was considered for inclusion in the proposed system for workplace hazardous chemicals, but its implementation was not recommended (ASCC 2006f). The main barrier to its mandatory inclusion appears to be a perception that it would be difficult to enforce under OHS legislation (ASCC 2006h). For example, the WA Department of Consumer and Employment Protection indicated that its OHS Act is restricted to occupational safety and health issues, and it could not enforce environmental label or MSDS information (sub. DR114).

Most industrial chemicals in use in Australia have not been assessed for environmental impacts. Determining the environmental hazards of all chemicals and including this information on labels would be costly. However, this information is available where chemicals have been assessed.[7] As labels need to be reviewed

[7] DEWHA assesses toxicity to aquatic organisms and has done so since 1986 for agvet chemicals and 1990 for industrial chemicals. NICNAS is accelerating its review of existing chemicals. This will produce more information on the environmental hazards of chemicals.

following assessment and at least every five years, the additional costs of phasing in environmental hazard labelling could be expected to be reasonably low. Assessments from approved foreign schemes might also be used in classifying environmental hazards (section 4.2).

Table 9.2 **GHS environmental hazard classifications and labelling**

HAZARDOUS TO THE AQUATIC ENVIRONMENT – ACUTE HAZARD			
Category 1	Category 2	Category 3	
	No pictogram	No pictogram	
Warning Very toxic to aquatic life Avoid release to the environment Collect spillage Dispose of to…	No signal word Toxic to aquatic life Avoid release to the environment Dispose of to…	No signal word Harmful to aquatic life Avoid release to the environment Dispose of to…	
HAZARDOUS TO THE AQUATIC ENVIRONMENT – CHRONIC HAZARD			
Category 1	Category 2	Category 3	Category 4
		No pictogram	No pictogram
Warning Very toxic to aquatic life with long lasting effects Avoid release to the environment Collect spillage Dispose of to…	No signal word Toxic to aquatic life with long lasting effects Avoid release to the environment Collect spillage Dispose of to…	No signal word Harmful to aquatic life with long lasting effects Avoid release to the environment Collect spillage Dispose of to…	No signal word May have long lasting harmful effects to aquatic life Avoid release to the environment Dispose of to…

Source: ASCC (2006e).

Requiring labelling of only those chemicals that have been assessed could lead to a perverse outcome. Users may choose products containing unassessed chemicals that do not carry the environmental hazard warning on the label in the potentially mistaken belief that they were not hazardous to the environment. If substituted products contained chemicals that were equally or more hazardous, a worse outcome could eventuate. Thus, if a partial scheme was introduced, users might need to be educated on the meaning and scope of the new labelling arrangements.

The Commission considers that any new environmental labelling requirements for industrial chemicals would be best incorporated into the existing or proposed workplace labelling arrangements, in preference to creating a new scheme. This would simplify the requirements on firms in meeting their labelling obligations. However, it may require state and territory environment protection legislation to be amended to give legislative backing to inclusion of environment hazard classification and labelling in the workplace labelling scheme. Administrative arrangements could be put in place to ensure that the agency with the appropriate responsibilities and skills had carriage of environment issues in the relevant standard or code. This matter could be coordinated by the Standing Committee on Chemicals (section 3.4).

The incorporation of environmental labelling into the existing or proposed workplace labelling arrangements would not, however, address the labelling of products targeted at domestic or household consumption. Under current arrangements, hazardous substances targeted at domestic and household use do not have any labelling requirements, unless they are a cosmetic or a scheduled poison (appendix G). There are some market and common law incentives for manufacturers to provide instructions on safe use and disposal, and governments regulate what households are permitted to dispose of in municipal waste. Any decision to apply environmental labelling to products targeted at households should be based on a demonstrated improvement in environmental outcomes that offset the additional cost.

Any decisions on mandatory environmental labelling will hinge on the extent of the additional benefits to the environment arising from behavioural change, and the uses (for example, domestic or workplace) where behavioural changes are most likely to occur. Any environmental labelling requirements should not be implemented until there is certainty about the systems being implemented by our major trading partners to ensure that the trade facilitation benefits can be realised, and should not precede a decision on whether to adopt a workplace hazardous labelling system based on the GHS.

RECOMMENDATION 9.1

The Environment Protection and Heritage Council should examine the costs and benefits of mandatory environmental labelling of chemicals. Mandatory environmental labelling should only be introduced if there is a demonstrated net benefit to the community.

Other regulatory mechanisms

Financial assurances

Some participants to the study have suggested that greater use of financial assurances could improve the effectiveness and efficiency of environmental regulation. In most states and territories, environment protection legislation allows the relevant authority to require upfront financial assurances from operators. Financial assurances can improve the likelihood that the future costs of addressing an environmental legacy are borne by its operator, even if the operator becomes insolvent or leaves the country.

There are two potential applications for financial assurances in environmental regulation. For one, they can be used to cover liabilities that are certain to occur in the future, such as post-closure rehabilitation of mining or manufacturing sites. When used in this manner, assurances act as a performance bond imposed on the operator. Another potential use is as insurance to cover contingent liabilities — for example, remediation of the consequences of accidental or unforseen pollution. In this latter case, an additional objective is to efficiently manage the risks of those liabilities that may arise (PC 2006d).

Boyd (2001) outlined several implementation challenges with financial assurances which could undermine their effectiveness. Calculation of the correct size of assurances can be difficult, especially in the case of long-term, uncertain environmental legacies. Compliance costs can be high in cases where regular monitoring and review of the size of the assurance is required to ensure its size reflects the potential liabilities. Disputes may arise over whether the operator has met its obligations and could discharge the assurance, resulting in litigation costs.

The Commission has found that financial assurances are most relevant where there is a high risk of environmental damage that otherwise would not be effectively managed or remediated under existing regulation. Financial assurances can reduce the risks and costs of polluters defaulting on their obligations to rectify environmental damage, and can encourage restoration and clean up. There is,

however, a difficulty in calculating a realistic amount for the assurance, which should be:

- based on a robust and transparent assessment of the potential remediation and rehabilitation costs, and be subject to regular review
- designed and applied in a way that minimizes compliance costs. For example, there should be a requirement to release components of the assurance as soon as the relevant obligation has been satisfied, as well as flexibility in the choice of assurance instruments (IC 1997; PC 2006d).

Self-regulation – an alternative to regulation

The EPHC National Chemicals Taskforce noted that industry had developed a number of self-regulatory and coregulatory programs that have delivered significant benefits to the environment and the community (table 9.1) (EPHC 2006b).

The NSW Department of Environment and Conservation requested that drumMUSTER establish performance targets that aim to increase end user participation and sought the support of state and territory governments for formal national arrangements, including increased data collection and target setting (NSW DEC 2006).

Measuring the effectiveness of ChemClear is difficult because the total amount of chemicals, including unwanted chemicals, being held by farmers is not known (NSW DEC 2006). The collection of more data to evaluate the effectiveness of self-regulatory initiatives should be considered in the context of the overall information collection arrangements.

9.4 A Framework for National Chemicals Environmental Management

The Framework for National Chemicals Environmental Management (NChEM) (EPHC 2006b) proposes key reforms to improve the environmental management of chemicals in Australia (box 9.5).

Box 9. **The National Chemicals Environmental Management (NChEM) Framework**

The NChEM framework includes four action areas.

1. Strengthening Environmental Risk Assessment — better consideration of environmental impacts in national chemical assessments
2. Streamlining Environmental Controls — nationally agreed actions to control risks to the environment from high risk chemicals across all states and territories
3. Informing Decisions — improving the capture of chemical impact information so that it is used effectively to inform decision making on chemicals
4. Prioritising Action — strategic consideration of priority and emerging chemical issues affecting the environment

Source: EPHC (2006b).

There is widespread support for most of the NChEM initiatives, from both government and industry. This support is reflected in the Ministerial Agreement on Principles for Better Environmental Management of Chemicals and the Chemicals Action Plan for the Environment (EPHC 2007c) signed by Commonwealth, state and territory environment ministers in June 2007. The Chemicals Action Plan prioritised steps to implement NChEM, including:

- the public release in August 2007 of Environmental Risk Assessment Guidance Manuals for industrial and agvet chemicals
- implementing improvements in consultation between NICNAS and state and territory environmental protection agencies on risk assessments
- drafting a manual of environmental controls
- all jurisdictions agreeing to implement the environmental controls recommended in NICNAS's chemical assessment reports, where the controls have been negotiated with environment agencies (EPHC 2007c).

The proposal to 'streamline environmental controls' was referred to the Ministerial Taskforce on Chemicals and Plastics Regulation Reform and the Commission's study. The Commission's report will provide input into decisions on this matter by the Ministerial Taskforce.

The effectiveness and efficiency of NChEM

It is difficult to judge the magnitude of the impact of NChEM on effectiveness and efficiency. NChEM involves a number of proposals within the four action areas outlined in box 9.5, which are to be implemented over time. Parts of the proposals are yet to be implemented, and those parts that have been implemented have only been operating for a short time. However, there is early indication that some parts of NChEM are producing positive outcomes, with a successful trial of early integration of state and territory environment agency input into NICNAS's assessment during 2007 (sub. 20).

The EPHC CWG will report on the implementation of NChEM and its effectiveness in promoting ecologically sustainable chemicals management every two years. It has also commissioned two cost–benefit analyses of the impact of NChEM — one on the impact on government and another on the impact on business and the community — but neither were available before this report was published.

Specific comments on proposals from the NChEM action areas are outlined below.

Strengthening environmental risk assessment

A key aspect of this NChEM action area is to improve the linkages between national chemicals assessment agencies and state and territory environment agencies responsible for implementation, administration and enforcement during the assessment phase, and to make risk assessment processes more accessible and transparent. This involves:

- developing risk assessment manuals, for both industrial and agvet chemicals, to detail the approach to undertaking environmental risk assessments (EPHC 2007a, 2007b)
- NICNAS alerting state and territory environment agencies about chemicals that have been assessed as a high concern
- NICNAS obtaining information from state and territory environment agencies to input into chemicals assessments
- NICNAS consulting with state and territory environment agencies on the scope of assessments and on draft recommendations
- strengthened risk assessment of agvet products (including on disposal), non-active ingredients and the volatility of product formulations (EPHC 2006b).

The public release of, and opportunity to comment on, the risk assessment manuals used by DEWHA in their environmental assessments is a positive step towards

increasing transparency of environmental risk assessments that they undertake on behalf of NICNAS and the APVMA, and improving their quality. It will also facilitate the contestability of environmental risk assessments, as recommended by the Australian National Audit Office in 2006 in relation to the agvet regime (ANAO 2006).

Streamlining environmental controls

This NChEM action area involves a regulatory arrangement for environmental risk management of industrial chemicals to ensure that NICNAS's recommendations on the environment are adopted uniformly and automatically by the states and territories. Under the current NChEM framework, it is proposed that NICNAS's role as the assessor of industrial chemicals would be augmented to include setting environmental risk management controls, including whether and how industrial chemicals can be used in Australia. Under the proposal NICNAS would have expanded powers to directly control many aspects of chemicals management. The states and territories would agree to enforce NICNAS's controls in their jurisdictions, and would review their legislation to ensure they have adequate powers to implement this complementary legislative framework for the environmental control of chemicals.

The proposed new arrangements would be underpinned by a Manual of Environmental Controls (currently being drafted) that would set out the tools available in setting standards for managing the impact of chemicals on the environment. Some of the environmental controls that could be used include restrictions on discharges to air and water, handling and storage specifications, bans and phase-outs, and waste management and disposal requirements.

An interjurisdictional agreement between NICNAS and state and territory environment agencies would be put in place to underpin the proposal. The agreement would outline consultation, implementation and enforcement arrangements (EPHC 2006b).[8] A committee of officials, reporting to the EPHC (replacing the CWG), would also have an ongoing role in implementing the proposal and reporting to COAG on progress (EPHC 2006b).

8 This could build on the existing MOU, or be a separate agreement between NICNAS and state and territory environment protection agencies.

ACCORD Australasia has expressed some concerns about the efficiency of these proposed arrangements:

> … the proponents of more onerous NChEM interventions, such as new regulation for industrial and consumer chemicals, have not demonstrated a compelling case that within Australia significant environment impacts are occurring that would warrant action above and beyond that which could be instituted using existing powers and regulations. (sub. 42, p. 13)

Concerns were also raised by the Plastics and Chemicals Industries Association (PACIA):

> PACIA believes the current failures in the existing regulatory system are not due to the lack of powers. They are due to deficiencies and failings to best use existing powers resulting from poor implementation and/or a lack of commitment for effective communication within and between government agencies … PACIA also supports the recommendation for NICNAS to explore with states and territories for an improved process for engaging with its MOU group. (sub. 33, attachment 1, p. 1)

Other concerns include:

- that the arrangement would create a disjointed regulatory framework, with NICNAS having a role of setting chemicals risk management standards as they relate to the environment, but having only an advisory role in relation to risk management standards for public health and OHS
- whether or not the proposal would replace existing state and territory regulations — if not, it could become an additional layer of regulation.

While there are various concerns with the proposal, there are also several efficiency advantages. The proposal would:

- provide industry with greater certainty on how, whether and when NICNAS's recommendations on the environment will be implemented
- improve national consistency in the take up and implementation of NICNAS's recommendations on the environment across jurisdictions
- reduce the administration costs to state and territory governments of implementing NICNAS's recommendations on the environment. Part of the reduction of cost would arise from removing the need to conduct regulatory impact analysis in each state and territory (for those states and territories in which it is required)
- allow the states and territories to respond to emerging chemicals issues in a timely way, without having to wait for them to become a priority in their jurisdiction

- be likely to become more valuable over time as the assessment of existing chemicals for their environmental impact and the likely need for new risk management measures to be taken increases.

These advantages would be enhanced if it could be demonstrated that the arrangement would replace existing state and territory regulations and lead to a reduction in regulatory burden.

Alternative arrangements for environmental risk management

There is considerable support among the states and territories for reform to chemicals environmental management, and the Commission considers that this momentum should be harnessed. In the Commission's view it is possible to draw on the underlying intent of the NChEM proposal while avoiding some of the significant concerns of having NICNAS set environmental management controls.

There is currently only a small number of chemicals assessed as requiring risk management action to protect the environment. DEWHA asserts that about 13 chemicals per year require environmental risk management actions (sub. DR104) although the Commission's own analysis of NICNAS's recommendations on the environment suggests that only a small number of assessments undertaken since NICNAS's inception have recommended significant action by the states and territories. However, improved communication between NICNAS, DEWHA and the states and territories on chemical assessments is expected to change the nature of environmental recommendations, and an increase in the rate of chemical assessments is likely to result in an increased number of risk management recommendations in the future.

The current Ministerial Agreement includes a commitment to implementing NICNAS's recommendations on the environment (EPHC 2007c). However, while there appears to be considerable goodwill among the current participants of the EPHC CWG, implementing risk management recommendations may not be a priority within jurisdictions on an ongoing basis without statutory compulsion.

The Commission has identified three options for reform that are consistent with its best practice governance framework.

- Option 1: Delay decision on formalising NICNAS having responsibility for environmental risk management pending review of early stage NChEM initiatives to establish a need for a standard-setting body. The states and territories have committed in the Ministerial Agreement to implement NICNAS's recommendations on the environment. Over the next two or three years, the CWG (or other group) could examine the nature and number of

NICNAS's recommendations on the environment and report to the EPHC on whether the arrangements under the Ministerial Agreement were operating successfully, or whether there were a sufficient number of risk management recommendations that were not being implemented, with subsequent identifiable risk to the environment, to justify a standard-setting body.

- Option 2: Rather than formalise the function in NICNAS, implement a modest standard-setting body to consider NICNAS's recommendations on the environment and set standards for managing the exposure to the environment of particular chemicals as needed. Any other work would need to be explicitly approved by the EPHC.
- Option 3: Implement a standard-setting body that sets standards it considers necessary to protect the environment from the impact of chemicals, including those arising from examining NICNAS's recommendations. For example, the body could consider whether a standard was needed on the disposal of chemicals. It could also examine whether past NICNAS assessments required standards to be set.

Option 1 has the advantage of being a low cost approach to ensuring that a new standard-setting body is necessary before it is implemented. Participants to the study representing industry argued that it needed to be demonstrated that the costs of any environmental standard-setting body (ESSB) should not exceed its expected benefits (ACCORD Australasia, sub. DR91; PACIA, sub. DR101). However, with risk management recommendations likely to increase over the next few years, there is a concern that necessary action to protect the environment would not be undertaken in a timely way, if at all, resulting in potential long term legacy costs. It would also leave the industry with considerable uncertainty as to whether, when and how the states and territories might take action on an issue.

Option 2 is consistent with the scope envisaged under the NChEM proposals while also being consistent with the Commission's preferred governance framework of standard setting being a function undertaken separately from the assessment body. It would be a low cost option that could result in nationally consistent and timely standards, and provide more certainty for industry. For many of NICNAS's recommendations, no action would be needed to ensure adoption.[9] Accordingly, the standard-setting body would be able to focus on the small number of assessments that recommend risk management action and may require a standard to be set. The Tasmanian Government indicated that there were several ways such a mechanism could be implemented, including referencing or adopting a national environment

[9] For example, action relating to waste disposal or spills containment are mostly addressed by existing state and territory waste management legislation.

standard or code through amendment to the dangerous substances regulations or through Ministerial approval of recognised codes (sub. DR107).

Option 3 would provide a comprehensive approach to managing the impact of chemicals on the environment, although at a higher cost.

The Commission considers that the most suitable option is option 2, a modest ESSB which would meet as and when required. It would provide a mechanism for a nationally consistent framework for the management of chemicals in the environment and address the anticipated emerging need for a national framework while containing its scope and potential costs.

Chapter 3 outlines the Commission's views on good governance and coordination. An ESSB that considers NICNAS's recommendations on the environment and sets standards as needed should be made within this framework.

- Responsibility for the policy development and oversight would rest with the EPHC as the multi-jurisdictional ministerial council, supported by the Environment Protection and Heritage Standing Committee (EPHSC).
- The regime would be underpinned by an intergovernmental agreement (IGA) that would specify governance arrangements, coordination mechanisms and consultation arrangements, and commit the parties to implement and maintain the agreed reform in a uniform manner. This IGA could formalise the consultation arrangements between NICNAS and the states and territories on industrial chemical assessments.[10]
- Hazard and risk assessment of industrial chemicals would continue to be undertaken by NICNAS, which would make recommendations on the environment, as it does for public health and OHS. NICNAS would continue to receive input from expert bodies.
- Environmental risk management standard setting would be undertaken by a national body of experts with mechanisms to allow jurisdictions to provide input on specific local issues and for advisory bodies to be established as necessary.
- Regulatory impact assessments would be undertaken by the ESSB where the reform had a material impact on the economy, and may require coordination with other regulatory bodies.
- The ESSB would draft standards (drawing on the Manual of Environmental Controls) for the approval of the EPHC[11], that the states and territories would

[10] The NChEM Working Group (sub. DR119) suggested that the consultation arrangements could also be enshrined in the ICNA Act.

[11] With scope for the standard-setting body to make decisions on minor matters.

adopt uniformly and automatically.[12] Administration and enforcement would continue to be undertaken by state and territory environment agencies. Where actions were directed at the Australian Government, for example, aimed at preventing the import or export of certain chemicals, this would be achieved through Commonwealth legislation.[13]

- The standard-setting body would have formal linkages to NICNAS and would be required to respond to NICNAS's recommendations within a statutory timeframe. The response would be made publically available (recommendation 4.4).
- The need for the standard-setting body would be reviewed after a period of, say, five years to ensure its functions are effective and efficient, consistent with regulatory best practice. A sunset provision could be incorporated into its charter.
- The new regime would be funded by jurisdictions on a cost sharing basis.
  - This funding model is consistent with the funding arrangements for the ASCC the NTC. It avoids the compliance costs associated with levying a broadly based industry for a relatively small regulatory cost (appendix F).

The interaction between the standard-setting body and the APVMA would also need to be considered. The Animal Health Alliance was concerned that introducing an ESSB would duplicate the existing role of the APVMA (sub. DR68). DEWHA already assesses agvet chemicals for their impact on the environment and makes risk management recommendations. These are communicated to users through labels, which may also include hazard statements.

Under option 2, the ESSB would be confined mostly to considering NICNAS's recommendations, and standards would therefore be mostly confined to industrial chemicals. However, industrial chemicals may be present in agvet products, and meeting any environmental standards would need to be a component of the agvet product registration process.

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[12] The NChEM Working Group (sub. DR119) suggested that automatic adoption could be facilitated through a link between state and territory legislation and environmental decisions collated in the ICNA Act. The Commission suggests that the state and territories referencing standards and codes drafted by the ESSB would be a more suitable option.

[13] The NChEM Working Group (sub. DR119) suggested that this could be done by creating a provision in the ICNA Act that can be referenced in customs regulations. The Commission considers that this change is not warranted. First, customs regulations can incorporate some restrictions on the import of chemicals without formal links to other Commonwealth legislation. One example is the importation of asbestos. Second, utilising the ICNA Act and NICNAS for this purpose would confuse the chemical assessment focus of the scheme.

The agvet system currently interacts with other regulatory arrangements for chemicals, including for scheduled poisons and dangerous goods. The APVMA is currently undertaking reforms to streamline its approval processes and its interaction with an ESSB should be consistent with these reforms. For example, the APVMA should not be required to approve information on labels that are the subject of another regulatory regime (section 8.2).

Submissions have indicated that establishing an ESSB is feasible, with DEWHA suggesting that one option would be to establish a statutory committee under the NEPC Act (sub. DR104). This committee could be serviced by a secretariat set up under the NEPC Service Corporation, and could meet as needed. It could reject, modify or add to NICNAS's recommendations for approval by EPHC.

Drafting of the Manual of Environmental Controls is being progressed by the CWG and could be adopted and changed as necessary by any new ESSB. The ESSB would also need to work closely with other standard-setting agencies to ensure that implementation of a particular environment control did not create overlaps and inconsistencies with other regulations, for example, any requirements relating to:

- labelling, packaging, storage or handling during supply chain activities which would need to be consistent with existing OHS and agvet regulations (section 9.3)
- waste disposal which would need to be consistent with existing waste regulations.

RECOMMENDATION 9.2

The Commonwealth, state and territory governments should negotiate an intergovernmental agreement to create an independent standard-setting body to manage the impact of chemicals on the environment. This body should:

- ***report to the Environment Protection and Heritage Council (EPHC)***
- ***develop standards for the environmental risk management of chemicals and undertake regulatory impact assessment where appropriate***
- ***comprise members who are experts in standard setting, and have the ability to appoint advisory bodies as necessary***
- ***assess and respond to the NICNAS recommendations on the environment, with any other work to be agreed specifically by the EPHC***
- ***meet only as required and be funded by jurisdictions.***

The standards developed by this body should be submitted to the EPHC for consideration and approval, and adopted uniformly and automatically by the states and territories by reference. Once adopted, any variation by a jurisdiction

should, at a minimum, be reported to the EPHC and include a statement of reasons for the variation.

A sunset clause should apply to the new body, which would require that it be dissolved unless a review of its effectiveness and efficiency showed an ongoing need.

Informing decisions and setting priorities

Developing and implementing NChEM in the most effective and efficient manner will require good information systems and processes for setting priorities. In this respect the EPHC proposed that NChEM would:

- obtain any necessary information about chemicals in use to inform decisions
- establish feedback systems between the states, territories, DEWHA and NICNAS to evaluate the effectiveness[14] of chemical management controls
- develop, and utilise effectively, information capture and feedback mechanisms
- establish a nationally coordinated priority setting process based on transparent criteria
- use the capacity of environment ministers and regulators to take issues forward (EPHC 2006b).

The NChEM proposal also recognises the importance of ensuring that information capture and feedback systems do not overburden industry with reporting requirements, and that they are used effectively and efficiently by regulators.

There are several initiatives in environmental monitoring underway.

- To meet Australia's commitments under the Stockholm Convention, DEWHA is developing a national network of measurement reference sites where sampling for POPs will begin in air, human blood or milk then expand to other media such as water, sediment, soil and wildlife. DEWHA is reviewing past and current POPs monitoring programs and will work with state and territory health and environment organisations, industry and the community. DEWHA has indicated the POPs monitoring program could be extended beyond the monitoring of Stockholm Convention chemicals to meet the wider NChEM monitoring objectives.
- DEWHA, under the NChEM framework, is preparing a national chemicals monitoring database providing a comprehensive inventory of chemical

[14] This implies that a framework would be developed and data collected to evaluate effectiveness.

monitoring programs conducted in Australia over the past ten years. The database is expected to be on the DEWHA website in August 2008.

- NChEM contains three reforms designed to improve the capture of data on the environmental impacts of chemicals, and the feedback of this data into the chemicals prioritisation and assessment processes of NICNAS and the APVMA.
  - Where assessment data is limited or there is uncertainty on the environmental impacts of a chemical, NICNAS and APVMA chemical assessment reports may recommend that states and territories evaluate and report on the effectiveness of the chemical controls to be implemented.
  - Where a chemical is judged to pose a high risk to the environment, NICNAS and APVMA chemical assessment reports may recommend that chemical users undertake and report on specific monitoring (for example, water sampling) to verify the accuracy of assessment test data and assumptions.
  - NICNAS developing, and the APVMA reforming, their respective information feedback systems to better allow the public, industry and government agencies to report information on adverse environmental impacts of chemicals to regulators (EPHC 2006b).

The release of chemicals from consumer products, creating a potential hazard for human health or the environment, is an exposure pathway that has been raised as a particular concern by some participants to this study. For example, chemicals from products disposed to landfill may leach into the soil and contaminate ground water, or chemicals in cosmetics or therapeutic goods could enter the aquatic environment via sewage or household drainage.

A number of submissions to the Commission's draft report argued that any hazard identification system for chemicals in consumer products should also include environmental hazards (DEWHA, sub. DR104; the Queensland Government, sub. DR121; and the Tasmanian Government, sub. DR 107. The Ministerial Council on Consumer Affair's (MCCA) proposal to develop a hazard identification system could provide a model or vehicle for information on products with environmental hazards, if the need for such a system is established.

Any adverse environmental impacts from chemicals in consumer products could be identified by the expanded environmental monitoring proposed under NChEM, or reported to NICNAS or the APVMA through their adverse environmental information capture systems for further investigation.

The MCCA is developing a hazard-based identification system for consumer products, coordinated by the ACCC. Where health and safety issues are identified that relate to chemicals released from consumer articles, they will be investigated

and referred where appropriate (section 5.2). The European Union's experience in implementing its new provisions for the mandatory assessment (and possible regulation) of chemicals in or released from consumer products may also provide information on the environmental hazards associated with chemicals in products that is relevant to Australia. The Commission has suggested that this reform should be monitored before a similar approach is considered for Australia (section 5.2).

Increasing the rate of chemical assessments would also improve the information on environmental hazards from chemicals, and this could assist in examining issues relating to chemicals in consumer products (recommendation 4.6). The EPHC should monitor developments in this area in the context of its priority setting processes.

The Commission recognises the need for data to assess the effectiveness of environmental regulation but considers that as a general rule, the potential for better utilisation of existing information systems needs to be evaluated before collecting further data. Additional data collection systems should only be put in place where they produce net benefits (and prioritised according to those that produce the greatest net benefits), or are essential for monitoring achievement of international commitments (such as Australia's commitments under the Stockholm Convention). Consideration should also be given to how easily data can be aggregated and used to evaluate outcomes consistently across jurisdictions.

Examination of the need to collect more data on the environmental impacts of chemicals would benefit from having an overarching, nationally consistent, strategic framework that identifies environmental objectives and how to measure outcomes against them. While the DEWHA database should reveal where monitoring is (and is not) being undertaken, it will not show where monitoring should be targeted. To identify genuine needs for environmental monitoring, the Commission recommends that Commonwealth, state and territory governments develop a performance measurement framework similar to the PSIC exercise (sub. 39).

Benefits of this proposal include:

- providing a transparent, outcomes based and cost-effective approach to determining the need for, and resource allocation to, monitoring and reporting activities
- reducing the risk of excessive monitoring and reporting requirements on business, governments and regulators
- delivering the right type of environmental data to regulators to allow robust and informed decisions on the prioritisation and assessment of chemicals.

RECOMMENDATION 9.3

Commonwealth, state and territory governments should develop a performance measurement framework for monitoring the impact of chemicals on the environment that identifies national environmental monitoring and reporting objectives, and includes performance indicators for measuring outcomes against these objectives.

- ***The data needed to construct these performance indicators should be compared to what is already collected (using the Department of Environment, Water, Heritage and the Arts database) to determine if any gaps exist.***
- ***The case for further monitoring should be based on cost–benefit analysis and consider options for reallocating monitoring resources on a budget neutral basis.***

10 National security: regulation of ammonium nitrate

Key points

- In 2004, Australian governments agreed to a set of principles for the regulation of ammonium nitrate. The proposed control measures were intended to improve national security by reducing the potential for ammonium nitrate to be obtained for illegitimate purposes (terrorism), but allow continued access for legitimate users — primarily miners and farmers.
- States and territories have not implemented the principles consistently. As a result, the arrangements for controlling security sensitive ammonium nitrate (SSAN) are imposing unnecessary administration and compliance burdens. Extending these regulatory arrangements to other chemicals of security concern could have significant costs for business, and should therefore not be considered.
- Further, farming groups argue that the resulting regulations have unnecessarily reduced the availability of ammonium nitrate fertilisers.
- The regulations vary across jurisdictions due to fundamental differences in state and territory government attitudes to the appropriate legislation to use, licence coverage, and approaches to assessing the probity of applicants.
- To enhance security outcomes of the current arrangements, Commonwealth, state and territory governments should commit to a nationally coordinated system for background checking of individuals seeking access to SSAN.
- The efficiency of the current arrangements could also be improved by the states and territories progressing regulatory reforms that reduce other inconsistencies.
- Australian governments are working to establish a framework for assessing the security risks and appropriate control measures associated with chemicals of security concern. Such a framework should include governance arrangements that ensure measures are implemented consistently across jurisdictions. Once established, this framework should be used to re-examine the SSAN controls.

In response to growing concerns about terrorism, in 2002 the Council of Australian Governments (COAG) made a commitment to improve security arrangements for the storage, sale and handling of hazardous materials. The regulation of ammonium nitrate was made a priority because of the ease with which the substance could be obtained and potentially used as an explosive for the purposes of terrorism.

In Australia, ammonium nitrate is primarily used as an oxidising agent for explosives in the mining sector. To a far lesser extent, it is used as a fertiliser in the agricultural sector. Internationally, there have been accidental explosions and deliberate terrorist acts involving ammonium nitrate, resulting in significant numbers of deaths. Therefore, the substance poses risks for both public safety and national security.

In 2004, COAG agreed to a set of Principles for the Regulation of Ammonium Nitrate (agreed principles) to address the security risks (COAG 2004a). The objective of the agreed principles was to provide a nationally consistent approach, which involved limiting access to ammonium nitrate to only those persons with a demonstrated legitimate need for the product. The agreed principles were to guide the states and territories in their regulation of ammonium nitrate, given that the control of dangerous goods and explosives is their responsibility.

The agreed principles lay down core regulatory requirements for licensing the use, manufacture, storage, supply, import and export of security sensitive ammonium nitrate (SSAN). Under this approach, states and territories were given the flexibility to determine the appropriate legislative arrangements for implementing the agreed principles. All states and territories have now adopted SSAN regulations.[1]

In 2006, the Regulation Taskforce raised concerns about how ammonium nitrate regulations have been implemented across Australia, and whether the stated policy objectives have been met. Given this, COAG requested that the Productivity Commission assess the efficiency of existing arrangements for SSAN as part of this study.[2]

10.1 The case for regulating ammonium nitrate

Ammonium nitrate is widely used as an explosive ingredient. In isolation, it is relatively stable, however, its oxidising properties allow it to support explosions if mixed with fuel and initiated with an explosive charge. In fact, the mixture of ammonium nitrate and fuel oil, commonly referred to as ANFO, is the most widely used commercial explosive in the world (COAG 2004c).

1 The WA Government proclaimed SSAN regulations on 1 March 2008, which will be phased in over a 12-month period.

2 The terms of reference state that the Commission is required to examine the efficiency of existing arrangements for SSAN, taking into account the requirement to achieve the Government's national security outcomes, and having regard to the work being progressed by COAG's Review of Hazardous Materials.

Ammonium nitrate is also used as a fertiliser. In certain physical environments it can be a highly efficient means of improving the nitrogen content of soil. However, this use only accounted for around 5 per cent of all ammonium nitrate sales in Australia prior to the introduction of the new regulatory controls on SSAN (COAG 2004c).

Traditionally, ammonium nitrate has been regulated to mitigate the safety concerns associated with accidental explosions. Such explosions can occur when the ammonium nitrate is present in sufficient concentrations in fertiliser products to support the combustion of other materials, even in the absence of air.

There have been major accidents around the world involving ammonium nitrate, which have resulted in significant explosions and fatalities. For example, in 2007, an accident involving a truck carrying 25 tonnes of ammonium nitrate explosive resulted in an explosion that killed 28 people and injured 154 others in Mexico City (Herald Sun, 12 September 2007). Other recent incidents have included explosions in a fertiliser factory in France in 2001, a train wagon in North Korea in 2004, and a truck containing ammonium nitrate fertiliser in Romania in 2004 (COAG 2004c).

Governments around the world have recognised the security risks posed by the use of ammonium nitrate for terrorist purposes. A notable example is the Oklahoma City bombing in 1995 — two tonnes of ammonium nitrate were used to destroy a government building, killing 168 people and injuring 500 others.

Ammonium nitrate has also been linked to terrorist organisations active in Australia's region. In Singapore, police arrested 13 members of Jemaah Islamiyah for planning attacks that would have used ammonium nitrate truck bombs (COAG 2004c). Further, attacks such as the Bali bombings on 12 October 2002, and the bombing outside the Australian Embassy in Bali on 9 September 2004, demonstrate that terrorist groups have targeted Australian interests.[3]

Internationally, a range of regulatory approaches have been adopted to mitigate the security risks posed by ammonium nitrate. Some countries, such as the United Kingdom, have taken a light-handed approach, emphasising education, training and information sharing rather than legislative controls. In contrast, Indonesia, South Africa, Peru and Colombia have banned the use of ammonium nitrate fertilisers (box 10.1). Differences in the reliance on ammonium nitrate fertilisers, and in the capacity of regulators to administer more complex regulatory regimes, may account for some of the divergence in approaches.

3 There is no evidence that ammonium nitrate was used in either of these attacks.

Box 10.1 International approaches to regulating ammonium nitrate

In the United States, about half of the 1.8 million tonnes of ammonium nitrate sold each year is used for fertiliser (COAG 2004c). However, only a few states have introduced regulations for controlling the sale of ammonium nitrate fertilisers. These regulations require retailers to be licensed, obtain valid identification from the buyer, keep transaction records and report any suspicious purchases. Retailers in other US states have adopted a voluntary security campaign, Be Aware America, where they report suspicious transactions involving ammonium nitrate.

In 2007, the Department of Homeland Security introduced national standards for chemical facilities of high risk. These standards, which are still being implemented, impose tight security measures, with the certification of chemicals stores requiring the implementation of security plans and inventory management procedures.

Canada is in the process of implementing regulations that are somewhere in between the voluntary approach and the COAG agreed principles. Under the proposed Canadian regulations, retailers will be required to obtain valid identification of farmers, such as a pesticides licence, and determine whether the amounts of ammonium nitrate fertiliser purchased are consistent with the farms' needs. The regulations also impose some requirements on the security arrangements for storage facilities and record keeping through the supply chain (NRCan 2006).

The UK Government has taken a light-handed approach to regulation, even though it is one of the greatest users of ammonium nitrate fertilisers in the world. Specifically, it has taken a layered approach to security of ammonium nitrate fertiliser, utilising regulation and industry partnerships to achieve security outcomes. It manufactures and imports about four million tonnes of ammonium nitrate products per year (NaCTSO 2007). It restricts the types of ammonium nitrate fertilisers that can be sold — they must be certified as detonation resistant, and must satisfy other technical requirements pertaining to porosity and particle size. Further, farmers are provided with advice regarding appropriate storage and security measures for their ammonium nitrate fertilisers. The Government also supports the Fertiliser Industry Assurance Scheme, which is a voluntary scheme for businesses to improve ammonium nitrate fertiliser supply chain security (NaCTSO 2007).

Indonesia, South Africa, Peru and Colombia have all banned the use of ammonium nitrate fertilisers. Other countries have imposed bans on the fertilisers based on their ammonium nitrate content. For example, China has banned the use of 100 per cent ammonium nitrate fertilisers, while in the Republic of Ireland and Northern Ireland, fertilisers containing more than 79 per cent ammonium nitrate are banned.

The New Zealand Government has not introduced controls on ammonium nitrate fertilisers due to the relatively low usage of the substance. However, the Government has introduced controls on other essential elements of an explosive device — such as detonators and primers — that can be used to set off an ammonium nitrate based explosion (Dawson, P., ERMZ, New Zealand, pers. comm., 8 September 2007). Such controls are standard in Australia and internationally.

10.2 The principles and practices of regulating ammonium nitrate in Australia

In late 2002, in response to concerns about ammonium nitrate (and other hazardous materials) being used for terrorist purposes, COAG commenced a review of the security risks associated with the use of hazardous materials, and how such risks could be mitigated.[4] The aim of the review was to enhance national security by limiting opportunities for, and enhancing detection of, the illegal or unauthorised use of hazardous materials by improving regulations and other controls (SCCRHM 2008).

The *Report on the Regulation and Control of Ammonium Nitrate* was completed by mid–2004. Based on this analysis of the existing arrangements, the report (SCCRHM 2004) concluded the following:

- The unregulated sale of ammonium nitrate fertilisers posed the most serious risk to national security, and measures should be introduced to control their sale.
- The security risks from manufacturing ammonium nitrate products and their use in the mining sector were not significant.
- Banning access to ammonium nitrate products is not feasible for the mining sector and would have detrimental impacts on certain sections of the agricultural sector, primarily small horticulturalists and dairy farmers.
- The importation, storage and transportation of ammonium nitrate should be improved, and there would be benefit in establishing nationally uniform security standards for these activities.

The 2002 review steering committee recommended the development of a licence and permit system to control the availability of ammonium nitrate (SCCRHM 2004).[5] State and territory governments would be required to administer the system because they have responsibility for dangerous goods and explosives legislation.

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4 The review comprised four priority areas: explosive precursors, including fertilisers (ammonium nitrate); radiological sources; harmful biological materials; and other hazardous substances (chemicals of security concern). On 13 April 2007, COAG agreed to recommendations relating to the control of radiological materials and biological agents. The review of the other hazardous substances (chemicals of security concern) is due to be considered by COAG later in 2008.

5 The review's steering committee was chaired by a representative from the Department of the Prime Minister and Cabinet, and comprised representatives from the Attorney-General's Department, the Department of Transport and Regional Services, and the NSW, Victorian and Queensland governments.

On 25 June 2004, COAG agreed to:

> … a national approach to ban access to ammonium nitrate for other than specifically authorised users. The agreement will result in the establishment in each jurisdiction of a licensing regime for the use, manufacture, storage, transport, supply, import and export of ammonium nitrate. (COAG 2004a)

To achieve this outcome, COAG (2004a) endorsed a set of agreed principles that set out the policy aims, as well as the minimum requirements for the licensing and permit system.[6] The policy aims were to ensure that:

- the approach to limiting access to SSAN is nationally consistent
- safety and security concerns are addressed at all stages of the ammonium nitrate supply chain
- the framework used to control SSAN could be applied to other materials that pose security concerns.

Under the agreed principles, SSAN is defined as:

> … ammonium nitrate, ammonium nitrate emulsions and ammonium nitrate mixtures containing greater than 45 per cent ammonium nitrate, excluding solutions. (These include dangerous goods under the Australian Dangerous Goods Code with the UN numbers 1942, 2067, 2068, 2069, 2070, 2071, 2072, 3375 and 3139 where applicable.) (COAG 2004a, attachment D, p. 1)[7]

The agreed principles require that an authorisation be obtained at each stage of the supply chain — the use, storage, manufacture, supply, transport, import, export or disposal of SSAN. To obtain an authority, an entity (person or company) must demonstrate a legitimate need for the SSAN product and prove their probity through police and Australian Security Intelligence Organisation (ASIO) background checks (COAG 2004a).[8]

The agreed principles then specify the minimum information provision, reporting and security planning requirements that should underpin the authorisation of the various activities. The mix of these requirements depends on the activity.

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6 On 25 June 2004, the Office of Regulation Review endorsed a classified version of the *Regulatory Impact Statement in Relation to the Regulation and Control of Ammonium Nitrate*. In 2006, the Office of Regulation Review became the Office of Best Practice Regulation.

7 This definition classifies calcium ammonium nitrate — a fertiliser that is not classified as a dangerous good — as SSAN. However, ammonium nitrate products that are classified as Class 1 explosives are excluded from SSAN-specific regulation and continue to be regulated as explosives (AG 2006).

8 Listed examples of legitimate need for SSAN include use in: a commercial production process; mining; quarrying; research and laboratory use; and commercial farming. It is further noted that household and domestic use will not constitute a legitimate need (COAG 2004a).

For example, the import or export licensing requirements are largely focused on information management. The relevant entities are to inform the relevant regulator and the Australian Customs Service of the quantities and exact movements (for example, vessel identification) of the SSAN products. In contrast, the requirements for manufacturing, storing and transporting SSAN are focused on the implementation of approved security plans based on a risk assessment. For example, the manufacturing security plan should provide 'details of the ingredients used, and their sourcing of dangerous goods', whereas transport requires 'precautions to ensure [SSAN] is secure for the duration of the entire journey' (COAG 2004a, attachment D, pp. 4–5).

Requirements for authorising the supply, use and disposal of SSAN are primarily focused on information and record management, to ensure that all SSAN products can be accounted for.

State and territory officials also developed a range of ammonium nitrate guidance notes to act as national standards that could be used to assist states and territories in the development of consistent legislation and regulations.[9] These guidance notes have also been made publicly available, to assist businesses to better understand their responsibilities under the SSAN regime. However, the guidance notes do not take precedence over requirements specified in state and territory legislation.

Implementation of the agreed principles

In drafting the legislative arrangements, states and territories were given flexibility to implement the requirements of the agreed principles, particularly in relation to:

- the choice of legislation and structure of the regulation
- licence design and coverage
- arrangements for background checks.

Differences in the regulatory framework

In the *Report on the Regulation and Control of Ammonium Nitrate* (SCCRHM 2004) it was recommended that state and territory governments use their explosives legislation to control SSAN because it was perceived to be a security risk due to its potential to be used in explosives. In addition, using explosives legislation

9 Guidance notes have been prepared for transport (AG 2004a), storage (AG 2004b), agricultural use (AG 2004c) and the siting of new facilities (AG 2004d).

would expedite the implementation of regulatory controls in some jurisdictions,[10] and ensure that governments met the stated objective of bringing their explosives security requirements into line with the SSAN controls (SCCRHM 2004).

While some jurisdictions have used explosives legislation, others have used dangerous goods legislation (table 10.1). Dangerous goods legislation could provide greater flexibility for jurisdictions to use their SSAN regulatory regime to control other security sensitive hazardous substances that have no explosive (or explosive precursor) properties. Being able to use the SSAN regulatory regime to control other hazardous substances was one of the stated policy aims for the agreed principles.

Table 10.1 **SSAN legislation by jurisdiction**

Jurisdiction	*Relevant legislation*	*Classification of SSAN*	*Enforcement date*[a]
New South Wales	*Explosives Act 2003* Explosives Regulation 2005	Explosive precursor	1 January 2006
Victoria	*Dangerous Goods (Amended) Act 2004* Dangerous Goods (HCDG) Regulations 2005	High consequence dangerous good	1 January 2006
Queensland	*Explosives Act 1999* Explosives Regulation 2003	Explosive / Security sensitive explosive	1 July 2005
South Australia	*Explosives Act 1936* Explosives (Security Sensitive Substances) Regulations 2006	Explosive / Security sensitive substance	25 July 2006
Western Australia	*Dangerous Goods Safety Act 2004* Dangerous Goods Safety (Security Risk Substances) Regulations 2007[b]	Security risk substance	31 December 2008
Tasmania	*Security-sensitive Dangerous Substances Act 2005* Security-sensitive Dangerous Substances Regulations 2005	Security sensitive dangerous good	21 May 2006
Northern Territory	*Dangerous Goods Act* Dangerous Goods Regulations	Security sensitive substance	20 October 2004

[a] This is the date from which the licensing requirements for SSAN became enforceable, not the date when the legislation was enacted. [b] Regulations were proclaimed on 1 March 2008 and will become fully enforceable after a 12-month phase-in period.

The choice of legislation has also been influenced by the historical treatment of ammonium nitrate. For example, the SA Government has historically used explosives legislation rather than dangerous goods regulation to control class 5 oxidising agents and organic peroxides. Jurisdictions have also had to consider which agencies would be responsible for administering SSAN legislation,

10 This recommendation was primarily based on a review of the Queensland explosives legislation. It was argued that, at least under Queensland legislation, SSAN could be declared an explosive by the Chief Inspector of Explosives, which would expedite the government's capacity to introduce security controls.

and how the requirements for SSAN would interact with other reporting, labelling, storage and handling requirements within the different pieces of legislation.

Some jurisdictions have enacted dedicated regulations, while others have incorporated the regulations into existing regulations. Victoria, South Australia, Western Australia and Tasmania have enacted dedicated regulations for SSAN (or similar security sensitive substances). In contrast, New South Wales and Queensland have chosen to incorporate SSAN controls into explosives regulations, and the Northern Territory controls have been incorporated into the dangerous goods legislation.

Differences in licence design

In line with the agreed principles, all jurisdictions require that an entity wanting to use, store, manufacture, supply, transport, import, export or dispose of SSAN must be authorised. However, there is little consistency across jurisdictions in the specific licensing arrangements (table 10.2). In particular, the jurisdictions have taken different approaches to:

- the terminology used
- licence coverage
- issuing licences for unsupervised access to SSAN.

States and territories vary in some of the most basic aspects of the terminology they have adopted. For example the terminology used to categorise substances deemed to be of security concern, such as SSAN, varies across jurisdictions (table 10.1). They also vary in their use of the terms 'licence' and 'permit'. In Victoria, activities are licensed, and individuals receive a permit to have unsupervised access to SSAN. In contrast, South Australia and Tasmania provide permits to conduct restricted activities.[11]

[11] In this chapter, the term 'licence' refers to the authorisation of activities, and 'unsupervised handling licence' (UHL) will be used to refer to the authorisation of individuals to handle SSAN without supervision.

Table 10.2 **Summary of SSAN licensing of activities by jurisdiction**

	NSW	*Victoria*	*Qld*	*SA*	*WA*	*Tas*	*NT*
Single licence can cover all SSAN related activities	No	Yes	No	Yes	No	Yes	No
Licence to use allows entity to possess, use, store, transport and dispose of SSAN	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Single licensing agencies in the jurisdiction	Yes	Yes	Yes	Yes	Yes	Yes	No
Single agency oversees compliance with regulations	Yes	Yes	No	Yes	Yes	Yes	No
Licence length (years) — use licence	5	5	5	3	3	3	1
Individuals provided with unsupervised handling licence to undertake authorised activities	No	Yes	No[a]	No[a]	Yes	Yes[b]	No[a]
Agency responsible for determining 'appropriateness' of individuals with unsupervised access — police (P), worksafe authority (WA), employer (E)	P	WA	E[c]	WA	WA	WA	WA
Seller has responsibility of verifying validity of SSAN buyers	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Temporary recognition of licences from other jurisdictions	Yes	Yes[d]	Yes	No	Yes	Yes	Yes[e]

[a] Individuals who have unsupervised access in these jurisdictions must undergo probity assessments. However, they do not receive a licence or permit from the regulator. [b] A worker is authorised to have unsupervised access to SSAN under their employer's permit. However, this authority is not transferable to other employers. [c] If the individual seeking unsupervised access is self-employed, the regulatory authority will determine the individual's appropriateness. [d] Victoria may not recognise a licence issued in Queensland. [e] Northern Territory will require clarification of types of police checks other jurisdictions use prior to recognition of licences (must include finger print check).

The jurisdictions also vary in the way in which they authorise multiple activities. In some jurisdictions a single licence will allow the entity to conduct multiple activities associated with SSAN. For example, in Victoria, South Australia and Tasmania, a single licence authorises an entity for any or all of the restricted activities, as long as the entity provides the relevant security plans and documentation.

In New South Wales, a single licence can be used to authorise multiple activities that are deemed to be legitimately required for a business's operations. For example, a license to manufacture can also permit the entity to export SSAN.

In the other jurisdictions, the types of activities that can be conducted under a single licence varies. For example, in Queensland and Western Australia separate licences are required for manufacturing, importing, supplying, transporting or using SSAN. In some cases, however, more than one activity can be covered by a single licence.

In relation to use licences, the Tasmanian Government has banned the use of SSAN for agricultural purposes. Although, as set out later, the practical impact is not significant, this decision is in direct contradiction of the agreed principles and departs from the arrangements in other jurisdictions.

The states and territories have adopted different approaches for authorising individuals to have unsupervised access to SSAN. Based on the agreed principles, all jurisdictions require criminal record and politically motivated violence checks for any individual who has unsupervised access to SSAN.[12] However, the jurisdictions vary as to how that activity is authorised.

In New South Wales and Victoria, authorised individuals with unsupervised access to SSAN can be issued with an unsupervised handling licence (UHL). In Tasmania, individuals are issued with a non-transferable identity card demonstrating that they are authorised to have unsupervised access to SSAN under their employer's permit. In Queensland, the licensed employer determines whether an employee should have unsupervised access to SSAN based on their background check.

Individuals in South Australia must be listed on a licensed entity's security plan but are not issued with a physical licence. The SA Government (sub. 56) stated that issuing licences for unsupervised access to SSAN contradicts advice from ASIO. This is because such licences could potentially be forged and used to gain access to SSAN without arousing suspicion.

Differences in assessing probity

Although most jurisdictions require ASIO to conduct politically motivated violence checks, the states and territories have differing views about what information the individual should provide, what information should be used to make the assessment, and which agency or entity should determine an individual's appropriateness for having unsupervised access to SSAN (table 10.2).

In most jurisdictions, individuals must meet the standard 100-point requirement for identification. However, some jurisdictions also require individuals to provide fingerprints as part of the identification process.

In most jurisdictions, the decision to exclude an individual based on their criminal record resides with the SSAN regulator. However, these decisions will take into account the recommendation of the local the police before determining an individual's appropriateness. In some cases, the police might consider matters other than convictions — such as whether an individual has any known association with criminal activity — when making determinations about an individual's probity. In New South Wales, the police are required to conduct the criminal record check and make a determination about whether the individual is fit to receive a SSAN licence

12 These checks are not required in Western Australia until 1 March 2009. The Northern Territory undertakes criminal record checks, but is yet to implement legislation necessary for requesting ASIO checks.

or permit. Once the legislation is enacted, the NT police will be responsible for determining an individual's probity in that jurisdiction.

Queensland is unique in its administrative arrangements for licensing. In the first instance, the entity seeking to conduct the activity has its appropriateness determined by a representative from the Department of Mines and Energy, based on the results of the ASIO and police checks. However, as noted above, it is the responsibility of the licence holder to subsequently determine an employee's appropriateness to have unsupervised access to explosives such as SSAN. In this case, the employer would have access to the results of the employee's police and ASIO checks.

Approach to licence fees and charges

There is a considerable degree of variation in licensing fees and charges across jurisdictions (table 10.3). However, it is difficult to draw clear comparisons because of differences in licence coverage and duration.

Table 10.3 **Summary of SSAN licensing charges by jurisdiction[a]**

	NSW	*Victoria*	*Qld*	*SA*	*WA*	*Tasmania*	*NT[b]*
Licence (permit) for all SSAN related activities ($)	..	80[c]	..	45	..	162	**na**
Licence to use ($)	100	..	212	..	50	..	10
Licence length (years)	5	5	5	3	3	3	1
Licence to store ($)	250	..	1 527.50	..	140	..	10-300[d]
Licence to manufacture ($)	2 500	..	1 527.50	..	300	..	10
Licence to import ($)	2 350	..	1 206.50	..	160	..	**na**
Licence to supply ($)	600	..	298.50	..	130	..	10-15
Licence to export ($)	..	..	1 206.50	..	160	..	**na**
Licence to transport ($)	1 850	..	..	..	150	..	10
Unsupervised handling licence ($)	..	No fee	..	..		..	..
Police criminal record check[e] ($)	150[f]	40	23.10	49	150[f]	4 232	..
ASIO check[g] ($)	..	19	19	18		2 620	..

a Charges are reported for the 2007-08 financial year. However, the grouping of licences is for convenience. The extent of the activities actually authorised by licences of the same name might not be aligned across jurisdictions. **b** Does not include cost of police and ASIO checks set by police and ASIO. **c** Victoria does not charge a fee for unsupervised handling permits, other than for a background check. **d** Charges vary for differing quantities. **e** All jurisdictions require the local authority (police) probity check. This check must be repeated every time the licence/permit is renewed. **f** This charge covers both the police and ASIO background checks. **g** All jurisdictions, with the exception of the Northern Territory, currently require applicants to undergo an ASIO 'politically motivated violence check' when issuing the initial licence/permit. This check is only required for the first licence/permit. **na** Not available. .. Not applicable.

Variation in licence charges across jurisdictions reflects differences in licence design, and differences in the level and composition of the licence uptake. For example, one would expect more licences to be issued in the states that manufacture SSAN or that have a large mining sector. Further, the resources required to assess some security arrangements will be greater than others. For example, assessing security arrangements for a manufacturing plant could be more resource intensive than assessing the security arrangements for the use of SSAN fertilisers. The cost and availability of those resources will also vary across jurisdictions.

Each jurisdiction's charges will also be influenced by differences in the application of cost-recovery practices in relation to SSAN licensing. Most jurisdictions have chosen to initially charge fees that are below full cost recovery.

The Commission's assessment

Based on a review of the relevant legislation and guidance material, most jurisdictions could demonstrate that their particular arrangements are generally consistent with the COAG agreed principles for regulating SSAN. However, there is a significant degree of inconsistency in regulatory requirements across jurisdictions.

10.3 Assessing the SSAN regulatory regime

The effectiveness and efficiency of the SSAN regulatory regime can be assessed according to:

- the extent to which the arrangements have achieved national security objectives
- the impact of the arrangements on the availability of SSAN products
- the administration and compliance costs associated with the regulations.

Achieving national security objectives

It is difficult to determine the extent to which the current arrangements have improved national security outcomes. There have been no major reported terrorist incidents involving SSAN in Australia, either before or after the controls were introduced. Whether the controls have prevented the use of SSAN for terrorist purposes is largely unknowable, as is the incremental gain over general security and law enforcement measures. That said, some features of the SSAN regime could be limiting the intended benefits for national security.

Enacting the regulations

For security measures to be fully effective on a national basis, it is important that they take force across the country at the same or a similar time. This prevents the possibility of an individual or group acquiring the relevant security sensitive substance from a jurisdiction that has lesser security measures in place. Given the porous nature of the borders between the states and territories, once SSAN is obtained for illegitimate purposes, the security of all jurisdictions is compromised. COAG expressed the need for an urgent response by all jurisdictions:

> … the States and Territories would use their best endeavours to ensure the legislative arrangements for the licensing regime would be in place by 1 November 2004, with administrative arrangements to be finalised as soon as possible thereafter. (COAG 2004a)

Yet only two jurisdictions — Queensland and the Northern Territory — achieved the 1 November 2004 target. Although the Northern Territory implemented the SSAN principles for storage and transport, it is yet to enact legislation to facilitate ASIO background checks. Most other jurisdictions did not enact their legislation until late 2005. The WA Government proclaimed its SSAN regulations on 1 March 2008, and these will become fully enforceable after a 12-month phase-in period.[13]

Coordinated, national approach to probity checks

To achieve national security objectives, it is necessary to ensure that only those persons who are considered fit and proper have access to substances deemed to be of security concern. The agreed principles require that 'the person responsible for the security of SSAN at a workplace' and 'any person who has unsupervised access to SSAN' have police and ASIO background checks (COAG 2004a, attachment D, p. 2).

The agreed principles do not, however, specify what level of criminality should exclude a person from unsupervised access to SSAN, or how states and territories should share information about an individual's security status. The variation in administrative arrangements for SSAN background checks, as well as differences in criminal codes in each jurisdiction, mean that the level of criminality that disqualifies an individual is inconsistent across jurisdictions.

In addition, there are no formal means of sharing information about the probity of individuals who have, or have sought, access to SSAN. In effect, an individual who is deemed unfit to hold a licence on security grounds, or who has had their licence

13 The Commission has not been provided with any evidence that suggests individuals have been exploiting the lack of SSAN controls in Western Australia.

revoked due to security concerns in one jurisdiction, could try to obtain authorisation to access SSAN in another jurisdiction.

Availability of SSAN

The availability of SSAN fertilisers for legitimate users has decreased since the introduction of the SSAN regulations. The most emphatic example was the outright ban on using SSAN fertilisers in Tasmania by the Tasmanian Government. However, the net effect has not been that large — only 139 tonnes were used on Tasmanian farms during the 2000-01 financial year (ABS 2002) — and substitute products are available (DPIW nd).

In other jurisdictions, the National Farmers' Federation (NFF) argued that the SSAN regulations have resulted in a de facto ban on SSAN fertilisers because:

> … manufacturers and retailers did not produce or stock the product due to a perception that the additional costs of compliance and use (incurred throughout the supply chain and passed on to the end-user) means that the product is unaffordable to most farmers. (NFF 2007, p. 5)

Some reduction in the availability of SSAN fertilisers was expected following the introduction of the regulations. In fact, a rationalisation in the number of retailers stocking SSAN fertilisers was perceived to provide a benefit for national security if only those retailers that were familiar with the product and its appropriate uses continued to stock it (SCCRHM 2004).

However, not all of the reduction in the availability of SSAN fertilisers can be attributed to the introduction of the SSAN regulations. Some of the main domestic producers of SSAN fertilisers decided to cease supplying the product for commercial reasons prior to the commencement of the 2002 *Review of Hazardous Materials* (SCCRHM 2004).

The Commission has seen no evidence that the regulations have reduced the availability of SSAN to the mining sector.

Administration and compliance burdens

COAG (2004a) endorsed the approach of using agreed principles on the basis that the states and territories required the flexibility to develop regulatory controls and administrative processes that were consistent with their existing regulatory frameworks. However, the manner in which jurisdictions have implemented the agreed principles, and the resulting variation across jurisdictions, has imposed unnecessary burdens on both businesses and administrative agencies. These burdens

take the form of unnecessary costs and delays resulting from impediments to mutual recognition of licences, additional reporting requirements, additional storage and handling requirements, and complexity of the administrative arrangements.

Impediments to the mutual recognition of licences

Mutual recognition has the potential to reduce the compliance burden associated with variation in licensing regimes across jurisdictions. Under the principle of mutual recognition, possession of a licence from one jurisdiction is usually sufficient grounds to obtain an equivalent licence in another jurisdiction.

Australia has specific legislation covering some types of mutual recognition. The *Mutual Recognition Act 1992* (Cwlth) (MR Act) sets out states' and territories' obligations with respect to the mutual recognition of goods and registered occupations. SSAN licensing, in the context of mutual recognition, will be considered in more detail as part of the Commission's current Review of Mutual Recognition Schemes.

A preliminary analysis suggests there is ambiguity about the application of the MR Act to SSAN licensing. To the extent that SSAN licences are issued to individuals and cover activities that are equivalent between jurisdictions, they may be subject to the provisions of the MR Act. To the extent that SSAN licences are not covered by the MR Act, it is desirable that some other type of mutual recognition scheme apply.

SSAN regulations in some jurisdictions include provisions for licence recognition, but approaches vary. Victoria has explicit, comprehensive provisions regarding mutual recognition of security clearances and licences in its regulations (PACIA 2007a). Other jurisdictions have capacity within their regulations to recognise each other's licences on a temporary basis. For example, Western Australia has provisions for the recognition of Security Risk Substances transport drivers not permanently resident in that state. And, in Tasmania:

> If you already have a permit, or its equivalent, issued by another State or Territory authorising you to have access to ammonium nitrate for a certain activity, it is unlikely that you would need a Tasmanian permit to use or transport SSAN for a period of less than three months. In any transaction involving ammonium nitrate you would have to produce the permit. (WST 2007)

In New South Wales, SSAN and explosives related licences from other jurisdictions are recognised, with individuals being allowed to undertake those activities that they are authorised to conduct in the primary jurisdiction. However, the relevant New South Wales regulator might also require the individual to demonstrate their competency to undertake certain activities relating to explosives.

The SA Government has also:

> … built into its administrative system for SSAN a process for recognising security clearances granted in other jurisdictions to allow the granting of a reciprocal licence for specified activities involving SSAN. (sub. 56, attachment B, p. 3)

However, the SA Government stated that its capacity to recognise security clearances from other jurisdictions is currently inoperable because other jurisdictions do not have systems in place to:

> … ensure any change of security status of the individual licensed in the primary jurisdiction would be immediately transferred to the secondary licensing jurisdiction (i.e. South Australia). (sub. 56, attachment B, p. 3)

Irrespective of how mutual recognition is pursued — whether under the MR Act or through some other approach — concerns about the lack of a nationally consistent approach to background checking creates a barrier to achieving the mutual recognition of licences on an ongoing basis. As previously noted, states and territories variously rely on probity determinations by the police, regulatory agencies or employers. These variations in approach create uncertainty across regulatory agencies about whether background checks from other jurisdictions should be recognised.

Another factor that frustrates mutual recognition is the variation in licence coverage that is, the scope of activities permitted under a licence. The Australian Explosives Industry and Safety Group (AEISG) stated:

> The coverage of licences in different jurisdictions differ[s] markedly. As a result it is difficult to impossible to purchase a licence in the new jurisdiction which will duplicate all the functions of the licence you already hold … (AEISG sub. 45, p. 13)

The AEISG (sub. 45) reported that up to 15 per cent of operational employees within the explosives sector spend some time every year working interstate, and would obtain similar licences (or authorisations), including repeated background checks, from each jurisdiction in which they intend to operate. It further estimated that the SSAN regulations impose compliance costs of approximately $3 million per year for the explosives industry, and that a system of national regulation could reduce these costs by 50 per cent. These costs are exacerbated by similar inconsistencies in explosives licensing arrangements across jurisdictions (box 10.2).

The costs to business that arise from multiple licences are further inflated by time delays. For example, the Plastics and Chemicals Industries Association (PACIA) (2007a) has reported that it can take up to nine months to obtain SSAN related licences in New South Wales.

Box 10.2 **Explosives legislation**

The mining sector accounts for almost all security sensitive ammonium nitrate (SSAN) products used in Australia. As SSAN is used as an explosives ingredient, many firms in that sector require authorisation for access to both SSAN and explosives. As noted previously, this led some jurisdictions to incorporate SSAN arrangements into their explosives legislation.

However, like the SSAN regulatory regime, there are also many inconsistencies in explosives legislation across jurisdictions. In particular:

> … the procedures for licensing explosives personnel and equipment differ substantially among jurisdictions … [this] significantly impede[s] the movement of these resources between jurisdictions … (AEISG, sub. 63, p. 2)

Although regulators have systems in place to help facilitate the movement of people and equipment between jurisdictions on a temporary basis, inconsistencies in regulatory requirements impede ongoing or permanent recognition of licences across jurisdictions. The introduction of SSAN regulations appears to have added an additional layer of complexity to how mining related activities are authorised.

Reporting requirements

Jurisdictions vary in the information that they require businesses to provide as part of the authorisation arrangements. The security benefits generated by some information provision requirements have been questioned by industry. In particular, AEISG (sub. 45) and PACIA (sub. 33) have questioned the value that regulators attain from the seven-day notification requirement to transport goods into or through South Australia, and Queensland's requirement that monthly sales data be provided from all levels of the SSAN distribution chain.

In South Australia, imports of SSAN from other Australian jurisdictions are treated in the same way as international imports, in that businesses are required to provide the regulator with notification of the date that SSAN will be entering the state. The SA Government (sub. 56) contends that this is necessitated by the large quantities of SSAN that pass through the state, as it is transported between manufacturers and customers on opposite sides of the country. The SA Government considered that such information assists the regulator in being prepared to respond to an emergency situation or incident involving SSAN. Under existing regulations, states and territories require the substance to be transported along routes prescribed in the licence holder's transport security plan. No other state requires notification for the transport of SSAN across their jurisdiction.

Participants in this study have provided little specific information on the costs associated with meeting the information requirements of the various regulatory

regimes. Individually, the reporting requirements are unlikely to generate significant costs, particularly now that businesses have adapted to meeting the requirements of the SSAN regulatory regime. However, these reporting requirements create an unnecessary nuisance for businesses operating nationally and provide little demonstrable benefit in relation to achieving national security objectives. Information requirements should only be imposed if there is a demonstrable net benefit.

Storage and handling arrangements

Both safety and security considerations are important for the storage and handling of SSAN. Its potential to contribute to accidental explosion, and for it to be used in explosives, makes it prudent to store it at a safe distance from built-up areas, yet there is currently no agreed position, nationally or internationally, on appropriate storage and handling controls, including satisfactory safety distances.

Participants in this study questioned the appropriateness of the storage and handling requirements for SSAN imposed by some jurisdictions with the introduction of the SSAN controls. Specifically, the requirement by some jurisdictions for SSAN to be stored and handled as an explosive could result in controls that are more stringent and more costly to adhere to than those imposed on dangerous goods. PACIA (2007a, p. 19) argued that legislation requiring SSAN products to be stored and handled as an explosive — in Queensland, South Australia and Western Australia — does 'not reflect the scientific reality of SSANs'.

The AEISG (sub. 45) noted that prior to the introduction of SSAN controls, consequence-based measures for storage and handling were applied only to explosives, while risk management principles were applied to all other dangerous goods, and further, that the risk-based regulation had the flexibility to accommodate additional security measures if needed. It expressed concern that if the consequence-based storage measures were to be applied retrospectively to existing SSAN storage facilities the costs to industry would be significant.[14]

There appears to be a case for further research to clarify this issue, and for the establishment of agreed evidence-based criteria for the storage and handling of SSAN.

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14 No state or territory government has indicated that it intends to apply SSAN storage controls retrospectively. However, should this position change, AEISG (sub. 45) estimated that the capital costs associated with relocating facilities to meet the regulations would be in the order of $20 million for a 5000 tonne storage facility and that the operating costs would increase by $15 to $20 per tonne of SSAN.

Administrative complexity

The complexity of administrative arrangements can result in unnecessary costs for businesses. Complexity can arise from having to deal with multiple regulators within a single jurisdiction, with multiple, varying sets of regulations across jurisdictions, or with multiple, and in some places conflicting, regulatory arrangements.

PACIA (2006a) contended that legislative structures for controlling access to SSAN are more complex in Queensland and New South Wales than the other jurisdictions. In Queensland, five departments have a role in administering the control of SSAN, explosives and dangerous goods (PACIA 2007a). The responsibilities for SSAN transport safety and licence issuing are split between three agencies in New South Wales (AEISG sub. 45). This separation of regulatory responsibilities across agencies makes it more difficult for businesses to comply with SSAN controls.

For businesses that operate in more than one jurisdiction, the difficulties and costs associated with SSAN regulatory regimes are compounded. Science Industry Australia stated that:

> … [state and territory SSAN requirements] for labelling, paperwork trails, reporting, monitoring and implementation dates, are far from standardised. In some cases other minor changes are laid on top of previous minor divergences to create larger divergences, thus increasing the burden on industry to [remain] up-to-date and compliant with (each) state/territory requirements. (sub. 51, p. 4)

Orica (2007) noted that the lack of uniformity in how jurisdictions have introduced their legislation hampered the company's efforts to assist customers to adapt to the changing regulatory and operational environment.

In addition, businesses operating in multiple jurisdictions face the ongoing costs associated with monitoring their compliance across jurisdictions. These costs are exacerbated by the variations in licence coverage and duration, and the lack of fully effective mutual recognition arrangements.

Materiality of the impact of SSAN arrangements on compliance costs

While it is clear that the current SSAN regulatory regime is not delivering national security objectives in the most effective and efficient way, the materiality of the impacts on the costs of doing business is uncertain.

There have been some impacts on the availability of SSAN fertilizers, and the costs for those farmers who continue to use them have increased. But given the relatively low usage of SSAN fertilizers in Australia and the availability in many cases of

substitute products, the extent to which the regulations have had a detrimental impact on the productivity and quality of farm produce is less clear.

AEISG (sub. 45) argued that interjurisdictional differences in the regulations are imposing some unnecessary costs on businesses in the mining sector. And, the duplicated administrative processes are undoubtedly imposing unnecessary costs on governments. However, based on the information provided to the Commission, it is difficult to assess the full extent of these costs.

Some evidence is available that costs can be reduced in parts of the SSAN regulatory regime, as set out below (section 10.4). More important, there is also a well founded concern that current SSAN regulations pose a risk of generating significant economic costs if they were to be extended to other security sensitive hazardous materials — Chemicals of Security Concern (CSCs) (section 10.5).

10.4 Improving the SSAN arrangements

The inconsistencies permeating the current SSAN regulations compromise both the effectiveness and efficiency of the control measures. The Commission considers that states and territories should review some of the more significant variations in the regulations.

A national approach to administering background checks and information sharing

Fully effective mutual recognition of licences across jurisdictions would improve the effectiveness and efficiency of the SSAN arrangements. However, there are a number of steps that would need to be taken in order to reduce impediments to the achievement of mutual recognition:

- Agreement on a core set of information requirements for background checking — the information considered necessary to determine an individual's probity — would enable jurisdictions to recognise each other's security checks.
- An information sharing mechanism — such as a national database — would enable all licence issuing authorities to access security checking outcomes, clearance and licensing information.
- Agreement on the criteria that would determine an individual's eligibility for access to SSAN — such as a common set of offences — would enable jurisdictions to recognise each other's security clearances.

An agreed set of information requirements for background checks, and a system of information sharing would go some way towards reducing compliance and administration burdens, and limit the capacity of individuals to obtain a licence in the least rigorous jurisdiction. Further, these are steps that could be undertaken within a reasonably short timeframe, and therefore efforts should be directed towards achieving them in the first instance.

A single system for background checking

Currently jurisdictions independently conduct background checks on individuals wishing to gain access to SSAN by requesting information from various sources, such as databases containing information relating to criminal history and other matters relevant to security. For example, National Criminal History Checks are obtained from CrimTrac and the Australian Federal Police, and politically motivated violence checks are conducted by ASIO.

Utilising a single national background checking service to conduct these checks, according to agreed information requirements, would improve the consistency of outcomes and minimise duplication. The provider of this service would request the necessary information about individuals from the relevant agencies and databases, maintain a separate database of outcomes, and provide recommendations to the respective state and territory SSAN licensing agencies.

AusCheck — a centralised government vetting agency within the Australian Attorney-General's Department — currently administers a national security checking process for Aviation Security Identification Cards and Maritime Security Identification Cards.[15] As such, there would be synergies in it providing this service for jurisdictions' SSAN licensing agencies. The specific parameters for background checking for SSAN would be agreed by jurisdictions and legislated for in the *AusCheck Act 2007*.

A national database to facilitate information sharing

The establishment of a database of current, refused and revoked security clearances would also facilitate mutual recognition, because every jurisdiction would have access to the clearance information, regardless of which jurisdiction initially issued the SSAN licence. Ideally such a database would also include information on what licence/s each individual holds.

15 In contrast to dangerous goods and explosives legislation, aviation and maritime security are the responsibility of the Australian Government.

In addition to reaching agreement on the core set of information requirements that should be used for background checks, and the establishment of a national database, other challenges would remain to achieving mutual recognition. Jurisdictions would need to agree on the criteria that would determine eligibility of individuals for access to SSAN. Further, regulations would need to be amended to transfer the authority to determine an individual's probity to another agency and implement the relevant appeals processes. Once established, however, the arrangements could be extended to other security sensitive substances, such as explosives, security sensitive biological agents and radiological sources, and some CSCs as required.

RECOMMENDATION 10.1

Commonwealth, state and territory governments should implement a nationally uniform approach to conducting security checks for access to security sensitive ammonium nitrate, irrespective of other harmonisation measures. The background checking process should be managed by a single agency such as AusCheck. A database that reports current, refused or revoked security clearances should be established, and the information shared across jurisdictions.

Other measures to improve the national consistency of the current arrangements

Other inconsistencies with the current SSAN regulatory arrangements also result in unnecessary compliance and administration costs. Some beneficial amendments that should be considered include:

- removing inconsistent reporting requirements — such as South Australia's domestic importation notifications
- making licence durations nationally consistent
- basing storage requirements on agreed physical properties of SSAN, provided adequate security requirements are met
- ensuring that applications that require approvals in more than one jurisdiction (such as some security plans for transporting SSAN) can be lodged in the primary jurisdiction, then circulated to other relevant agencies (the agencies would be able to recover costs associated with circulating the plan)
- regulators committing to target timeframes for assessing licence applications (these timeframes should be reported against, but there should be no other penalties incurred if agencies fail to meet the target timeframe).

These reforms, if implemented, are likely to deliver a small, but material economic benefit. This is because:

- the benefits of having greater national consistency are mainly associated with greater recognition of licences across jurisdictions, and these could largely be attained through coordinating background checking arrangements and sharing the information nationally
- the impacts on compliance costs could be ambiguous because the ongoing savings from changing the regulations might not be significantly greater than the one-off transition costs incurred as companies change their systems
- the transaction costs involved in state and territory governments reaching agreement about regulatory amendments and then implementing the changes could be significant

Further, these amendments would only marginally improve a fundamentally inappropriate national regulatory regime. And, as the Commission argues in section 10.5, state and territory governments should not use the current SSAN regulations to control other security sensitive hazardous materials.

RECOMMENDATION 10.2

State and territory governments should consider the following improvements for achieving greater national harmonisation of the security sensitive ammonium nitrate (SSAN) regulations:

- ***removing major inconsistencies in reporting requirements***
- ***basing storage requirements on agreed physical properties of SSAN, provided adequate security controls are met***
- ***ensuring that a single security plan can be lodged for transporting SSAN nationally***
- ***making licence durations nationally consistent***
- ***requiring regulatory agencies to commit to, and report on, timeframes for assessing licence applications.***

10.5 Addressing the security risks associated with other chemicals

Ammonium nitrate is not the only chemical that raises security concerns. Recognising this, COAG endorsed a report on CSCs as the fourth and final component of the review of security risks associated with hazardous materials. The

Steering Committee for the COAG Review of Hazardous Materials (SCCRHM) released the draft of this report on 11 February 2008 (box 10.3).

The *Draft Report on Chemicals of Security Concern* (SCCRHM 2008) sets out the proposed Chemical Security Management Framework (CSMF). The CSMF provides a structured process for developing and implementing control measures that are proportionate to the CSC's assessed security risk. The CSMF appears to address many of the shortcomings of the development and implementation of SSAN regulations. In particular, it provides a systematic approach for developing risk-based controls to address security concerns, and governance arrangements that promote stakeholder engagement and more appropriate ministerial accountability for the implementation of security arrangements.

While the Commission is generally supportive of the CSMF, there is some scope for improvement. Of some concern is that the Draft Report does not rule out the addition of other chemicals to the current SSAN regulatory regime. Further, some elements of the CSMF could be strengthened to ensure that the resulting control measures are efficient and nationally consistent.

Box 10.3 Review of Hazardous Materials — Draft Report on Chemicals of Security Concern

The Review of Hazardous Materials — Chemicals of Security Concern (CSCs) forms the final part of the COAG national review of the regulation, reporting and security surrounding the storage, sale and handling of hazardous materials.

On 30 November 2006, the Steering Committee for the Review of Hazardous Materials (SCCRHM) released a discussion paper that covered: the guiding principles for the control framework for CSCs; international approaches; the risk assessment methodology that could be used to identify and group CSCs based on their security risk; possible security control measures; and mechanisms for their implementation.

The 101 submissions, as well as feedback from workshops involving representatives from governments and industry, helped SCCRHM craft its draft report, which was released on 11 February 2008.

The draft report recommended COAG agree to a Chemical Security Management Framework that comprises:

- an agreed approach to conducting security risk assessments across all elements of the supply chain of chemicals of potential security concern based on risk and terrorist interest
- measures to improve the existing chemical security arrangements by enhancing community awareness, better engaging industry to improve existing security activities and voluntary programs, and improving the coordination between chemical regulatory and law enforcement agencies
- management and governance arrangements to allocate roles and responsibilities and establish ongoing coordination and consultation arrangements across governments and between governments and industry.

The draft report also recommended the following governance arrangements:

- The Australian Government establish a chemical security coordination unit to oversee the development of capacity building measures and work with reference groups comprising security agencies, industry and existing Commonwealth, state and territory government regulators.
- The Australian Attorney-General be the Minister responsible for the coordination of the framework. The Attorney-General will consult, coordinate and seek agreement where appropriate with a nominated Minister from each state and territory government on relevant aspects of the framework.
- An intergovernmental agreement be established that describes the roles, responsibilities and mechanisms by which governments will agree to develop and implement appropriate and nationally consistent actions for chemical security.

It is expected that SCCRHM will present its final report to COAG later in 2008.

Source: SCCRHM (2006); SCCRHM (2008).

The SSAN arrangements should not be used to control other substances

The Commission considers that any regulation of other CSCs should not be based on the current inefficient and cumbersome SSAN regime.

Many industry participants in this study were concerned about the impact that replicating these arrangements would have on the availability of other chemicals, as well as the potential costs that firms would face when required to either use less effective substitute chemicals or meet the additional handling and storage requirements (Croplife Australia Limited, sub. 35; Growcom, sub. 12). For example, PACIA stated that it:

> … strongly recommends that the SSAN model NOT be used to regulate other materials identified by the COAG Review of Hazardous Materials. (sub. 33, p. 31)

And, the Fertiliser Industry Federation of Australia (FIFA 2006), estimated that if potassium nitrate — a commonly used fertiliser that can potentially be used as an explosive precursor — was effectively banned, the agricultural sector would incur a $160 million loss in production of Australian fruits and vegetables. As potassium nitrate use would not be banned outright under the SSAN regime, this is likely to be an overestimate, nevertheless it provides some indication of the perceived costs to industry.

In addition, concerns have been raised about the additional costs that more stringent storage and handling requirements could impose, particularly for other fertilisers that are used in far greater volumes than SSAN fertilisers.

Further, based on the delays experienced in obtaining licences in some jurisdictions, some participants have questioned whether regulatory agencies would have the resources to administer these arrangements for other CSCs.

RECOMMENDATION 10.3

State and territory governments should not add any additional security sensitive chemicals to the current security sensitive ammonium nitrate regulations.

Implementing the chemical security management framework

The CSMF addresses many of the limitations of the principle-based approach used for SSAN. However, by considering certain elements of the design and implementation of the SSAN regulations, it is possible to identify some aspects of the proposed CSMF that could be refined to increase the likelihood that the resulting control measures are efficient and implemented consistently across

jurisdictions. The CSMF could then be used to re-examine controls on ammonium nitrate.

Choosing effective and efficient control measures

Compared to the framework used to develop the agreed principles for SSAN, the CSMF provides for significantly improved consideration of non-regulatory control measures, and industry consultation in the development of the policies to address the risk of chemicals being diverted for the purposes of terrorism.

PACIA (sub. 33) argued that when the SSAN agreed principles were being developed, sufficient weight was not given to the success of some co-regulatory and self-regulatory arrangements in limiting the potential for diversion of SSAN for illicit purposes. In particular, PACIA (2006a) noted the success of the co-regulatory approach adopted to address the potential diversion of illicit drug precursors (chapter 5).

PACIA (sub. 33), AEISG (sub. 45) and NFF (2007) suggested that the lack of industry consultation contributed to the failure of governments to consider non-regulatory controls for SSAN. PACIA stated that the affected industry groups were excluded from the development of the agreed principles for SSAN, and that:

> Industry was not able to see any of the draft documents as they were developed, nor were they able to provide any input on practical or technical business implications of the approach under consideration. Even when a number of peak industry associations were invited to meet with PM&C to discuss the recommendations to go to COAG, industry was not provided the draft documents under consideration. (sub. 33, pp. 32-33)

Unlike the approach used for SSAN, a principle of the CSMF is that mandatory (legislation and regulation) and voluntary (such as industry standards and codes) measures for achieving security outcomes would have to be considered. Further, a national industry reference group would be established and consulted throughout the assessment of chemicals and development of risk-based control measures. The proposed chemical security coordination unit (box 10.3) would also work cooperatively with appropriate industry sectors, users, businesses and supply chains to determine control measures.

The Commission supports these features. However, consistent with good regulatory practice, it considers that as part of the CSMF, the criteria that would be used to assess alternative control measures should also be specified. For example, if more than one viable security control measure is identified through the CSMF, the alternative measures should be compared using criteria such as the costs of compliance, administration and enforcement, and the administrative simplicity of

the arrangements.[16] In addition, the effectiveness of the alternative measures to achieve security outcomes, such as the expected levels of compliance, should also be compared. Ultimately, the choice and combination of criteria used and the weightings applied will depend on the chemical being assessed and the respective security risks.

Governance arrangements

The Department of the Prime Minister and Cabinet (2008) has argued for governance arrangements for the CSMF (box 10.3) that include a single body to both conduct chemical security risk assessments and develop security measures nationally, and ministerial oversight for both the policy development and implementation of recommended measures. These arrangements would be underpinned by an intergovernmental agreement (IGA).

The Commission considers that the lack of ministerial oversight contributed to the inconsistencies in the SSAN regulations across jurisdictions. This is because under the COAG (2004a) commitment, no mechanisms were set in place to ensure that states and territories implemented the agreed principles consistently.

The Commission generally supports the proposed governance arrangements, and notes that the proposal is, for the most part, consistent with the good governance frameworks (chapter 2). However, there are a number of issues that warrant further consideration.

As detailed in chapter 3, the Commission's preferred governance arrangements for chemical regulation are for hazard and risk assessment to be undertaken separately from risk management functions. It is considered, in the long term, that economies of scale and scope could be achieved by consolidating hazard and risk assessment for all chemicals in a single agency. However, the Commission acknowledges that there may be advantages to combining risk assessment and risk management where synergies exist and there is a high level of interdependence between these functions. There may also be scope for the use of expert groups to develop standards for the consideration of the ministerial group.

The Commission notes the intention to provide policy oversight through what amounts to a quasi-ministerial council made up of the Commonwealth Attorney-General and nominated ministers from each state and territory. While not explicitly stated, it is presumed that this group would meet as needed to provide

16 The *Best Practice Regulation Handbook* (Australian Government 2007) provides examples of the type of criteria that can be used to assess alternative regulatory measures.

policy oversight and consider recommendations from the chemical security coordination unit.

The Commission recognises that no particular existing ministerial council would be particularly well suited to overseeing regulation of chemicals of security concern and that the case for establishing a dedicated council for this purpose is weak. To this end the *ad hoc* nature of the Commonwealth Attorney-General consulting with nominated ministers on an as–needs basis has some merit. Further, the establishment of the Commission's proposed standing committee on chemicals would help ensure the coordination of policy covering chemicals of security concern with other national policy frameworks.

The proposed arrangements leave open how the group of ministers would reach agreement about reforms. Much will depend on the robustness of the consultation leading up to the development of the reforms and the extent to which agreement can be reached across jurisdictions. The Commission considers that consistency would be facilitated if the proposed group of ministers were required to formally approve more significant measures or regulatory reforms by way of a vote (requiring a two-thirds majority).

While the Commission strongly supports the intention to underpin these new arrangements through an IGA, the draft agreement could be tightened. The Commission considers that the IGA should commit the jurisdictions to use their best endeavours to implement agreed reforms in a uniform or nationally consistent manner, and discourage variations in all but exceptional circumstances. Furthermore, where a decision is taken to vary from the agreed reform, the relevant Minister should be required to advise the ministerial oversight body of the reasons for the decision.[17]

Using model or template legislation

In some instances, the security control measures proposed by the chemical security coordination unit will require the use of regulation. As discussed in chapter 2, using model or template legislation greatly enhances the likelihood that control measures will be implemented consistently across jurisdictions. In relation to achieving national security outcomes, the challenges associated with drafting model or template legislation — such as reaching agreement across jurisdictions, and drafting provisions that can be incorporated into different rootstock legislation — should be outweighed by the benefits from greater national consistency.

[17] For example, such provisions exist in the intergovernmental agreement supporting the Australian Transport Council. The roles and responsibilities of the Council in relation to chemicals and plastics transport are discussed in chapter 7.

Re-examining ammonium nitrate controls under the Chemical Security Management Framework

If Commonwealth, state and territory governments agree to the proposed CSMF, the Commission considers that the framework should then be used to re-examine the controls on ammonium nitrate. Among other things, this would allow for a thorough assessment of alternative control measures that were inadequately assessed in the initial report on ammonium nitrate controls, including the use of co-regulatory or self-regulatory arrangements to prevent the substance being diverted for illegitimate purposes. Incorporation of ammonium nitrate into the CSMF would also increase the likelihood that the proposed measures for SSAN would be implemented consistently across jurisdictions.

RECOMMENDATION 10.4

Commonwealth, state and territory governments should establish an agreed framework for assessing the security risks and appropriate control measures associated with chemicals of security concern. This framework should incorporate strong governance arrangements, underpinned by an intergovernmental agreement, that ensure control measures are implemented consistently across jurisdictions. Once established, this framework should be used to re-examine the controls on ammonium nitrate.

11 Reforming national approaches

The Australian Government asked the Commission to undertake this study to assist a COAG Ministerial Taskforce to develop a streamlined and harmonised system of national chemicals and plastics regulation. The Commission's report recommends ways in which the effectiveness and efficiency of chemicals and plastics regulations can be improved, including through measures to enhance national uniformity and consistency.

This chapter summarises the Commission's views on good national governance principles for regulating chemicals, and how the present arrangements and current reform proposals compare to this ideal. It then lays out a pathway of future actions that would address remaining concerns.

11 Introduction

The design and implementation of national approaches to chemicals and plastics regulation needs to accept several realities. These include: the division of powers between the Commonwealth and the states and territories; the need to graft chemical regulation onto different legislative rootstocks that are focused on achievement of broader objectives (such as providing workplace safety); and the fact that there are different institutional structures within the states and territories. While these factors inevitably result in some complexity, they do not necessarily have to lead to the considerable degree of inconsistency and inefficiency that plagues the sector today.

Through this study the Commission has concluded that almost invariably the regulatory issues concerning chemicals and plastics are national in nature, with the hazards posed by the chemicals being, indeed, universal. There are few benefits in varying regulations from one jurisdiction to another (other than to integrate them into a jurisdiction's institutional architecture). Although risk can vary according to local circumstances, sufficient flexibility can be built into national schemes.

One counter argument, that it might be better to have regulatory competition between different regimes in different jurisdictions to reduce the risk of relying on a defective single national regime, is not a strong one in relation to chemicals regulation. In most cases, international benchmarks help to design best practice

approaches, and national collective processes for developing regulation can harness the different views of the jurisdictions to develop robust approaches. Ongoing monitoring and periodic review also act as safeguards.

Nationally consistent regulation will improve both effectiveness and efficiency, with uniformity being the ideal in many cases. One set of national rules are more effective by facilitating compliance, and efficiency is enhanced by lower compliance costs for business, and lower transaction costs in developing and implementing regulations. Of course, regulation also needs to be well designed and soundly based, and this is where appropriate governance structures, and regulatory assessment processes are important.

12 National approaches to chemicals policy

In chapter 3 the Commission presented a four-tiered governance framework for chemicals management that includes: policy development and oversight; assessment of chemical hazards and risks; risk management standard setting; and administration and enforcement of standards. In relation to chemicals assessment and regulatory administration and enforcement, the former is already being undertaken by Australian Government agencies, and the latter is best decided on a case-by-case basis, with a presumption in favour of the states and territories undertaking this task. Further improvements to national policy frameworks should focus, therefore on the policy and standard setting levels.

Previous chapters have looked at individual policy areas — such as workplace safety — and advised on the governance approaches that should apply. This chapter summarises the governance principles developed in this report focusing on: key institutional features for policy and standard setting; the achievement of consistent legislation; and standard setting processes (box 11.1).

Box 11 **A national governance framework for policy and standard setting**

Key institutional features

- A ministerial council (or equivalent), supported by a standing committee of officials, sets policy directions:
  - Ministers represent their respective governments, and undertake their own consultation on issues as necessary.
- The ministerial council makes decisions on policy-relevant standards.
- The ministerial council considers recommendations from:
  - a dedicated national standard-setting body (or equivalent)
  - the Standing Committee on Chemicals (proposed by the Commission).
- A national standard-setting body reports to the ministerial council.
  - Appointments to the standard-setting body should be based on expertise in the relevant area, either in a regulatory or technical sense, and not on representation.
- The standard-setting body:
  - develops policy-relevant standards for the ministerial council's consideration and approval
  - manages directly issues that are 'minor or machinery' in nature that have been delegated to it by the ministerial council
  - consults with stakeholders as needed (including through advisory committees, where considered appropriate).
- An intergovernmental agreement underpins the operation of the standard-setting body (including its purpose, funding, functions, and membership) and commitment to agreed reforms:
  - All jurisdictions contribute to the funding of policy-relevant standard setting.
  - Cost recovery may apply to technical standard setting (for example, where product registration occurs).
- The ministerial council and standard-setting body adhere to COAG guidelines for best practice regulation, and engage with other ministerial councils and their institutions as required.
- The need for the ministerial council and the standard-setting body are periodically reviewed according to COAG guidelines.

Achieving consistent legislation

- Jurisdictions commit to uniform standards, and to vary from the national approach only in exceptional circumstances, and provide an explanation to the ministerial council.
- Template or reference approaches are used as widely as possible.

(Continued next page)

Box 11.1 (Continued)

- Periodic reviews of the consistency with which national reforms are adopted are conducted.

Standard-setting procedures

- The ministerial council and standard-setting body establish criteria for deciding when an issue is not 'minor or machinery' in nature, and hence must be referred to the ministerial council for decision making and be subjected to a regulatory impact assessment.
  - As a rule, the ministerial council considers all policy-relevant standards and may need to make decisions on technical standards (such as the scheduling of a chemical) depending on the materiality of the impacts on business compliance costs or other impacts on business and individuals.
  - Consultation with the Office of Best Practice Regulation (OBPR) as necessary.
- In the case of policy-relevant standards and technical standards having a material impact:
  - Standard-setting body takes directions from ministerial council about developing new or revising old standards.
  - Standard-setting body consults widely in the development of the standard, including through preparing a consultation regulation impact statement (RIS), which is submitted to OBPR before release.
  - Standard-setting body finalises recommendations and decision making RIS and submits to ministerial council.
  - Ministerial council accepts or rejects recommended standards through formal voting. A decision requires a two thirds majority.
- In the case of technical standards of a minor or machinery nature:
  - Standard-setting body secretariat considers issues and consults as necessary.
  - Standard-setting body accepts or rejects recommended standards through formal voting. A decision requires a two thirds majority.

Some themes that emerge from this study include:

- there has been a stronger commitment to formalising national approaches, but this needs to extend to more areas of regulatory concern
- there has been a move to model approaches over templates, which may result in less uniformity
- there are mixed approaches to decision making by ministerial councils
- representational approaches to membership has been retained for several standard-setting bodies.

Each of these issues is discussed below, and a summary of the Commission's outstanding concerns is presented (table 11.1).

Commitment to formalising national approaches

Two reforms that have been occurring during this study suggest that the jurisdictions, under the guidance of COAG, are more prepared to formalise national approaches to chemical regulation through intergovernmental agreements. In particular, the omnibus intergovernmental agreement covering occupational health and safety (OHS) should result in the more consistent adoption of workplace standards covering chemicals. An intergovernmental agreement is also being negotiated to cover a planned national approach to developing measures or regulations for Chemicals of Security Concern.

Other national frameworks that could benefit from explicit intergovernmental agreements include managing the environmental impact of chemicals (under a proposed standard-setting body), and poisons scheduling. The intergovernmental agreement underpinning the National Registration Scheme for agvet chemicals will also need to be revised to allow for the additional conferral of powers on the Australian Pesticides and Veterinary Medicines Authority (APVMA) to give it the power to administer control-of-use regulations developed under the auspices of the Primary Industries Ministerial Council.

Model approaches to developing national standards

Using template or reference approaches to translate national standards into state and territory regulations achieves a high degree of uniformity, but they can be relatively more difficult to negotiate than model approaches. On the other hand, the latter are vulnerable to inconsistent adoption. Irrespective of which approach is adopted, national standards should be varied only to the extent required to adapt them to suit institutional differences in the jurisdictions.

A variety of approaches have been used in developing, and then applying, national standards. Despite some success with the template approach, the Australian Transport Council has decided to move to a model approach for the ADG7 package. This move is not without some advantages, but it carries the real risk of inconsistencies returning to the regulation of the transport of dangerous goods.

Table 11 **National reforms in chemicals and plastics regulation**

	Key elements of current arrangements or proposed reforms			***Outstanding concerns***
Policy area	*Key institutional features*	*Consistency of legislation*	*Standard-setting procedures*	
Public health — poisons	AHMC sets policy framework for scheduling of poisons. No SSB as such under proposed arrangements; new poisons committee would retain representative membership but be advisory only.	Some jurisdictions reference the schedules, some use schedules as a model. Overall consistency quite high. COAG commitment to adopt schedules uniformly. Jurisdictions can have own control-of-use regulations.	Secretary of DOHA will make decisions on scheduling (proposed) based on advice from poisons committee. Committee would consult as needed. Regulatory controls that are appended to schedule developed by AHMAC.	• Scheduling decisions are to be made by DOHA, not an independent expert body. • COAG have not committed to uniform adoption of regulatory controls for poisons. • New arrangements should be reviewed within two years.
Public health — illicit drugs	Ministerial Council on Drug Strategy oversees policy issues. A Precursor Working Group advises on illicit drugs.	Inconsistent adoption of an industry code of practice.	Precursor Working Group has developed a risk assessment framework for rating chemicals and recommending risk-management approaches more systematically.	• Inconsistencies can undermine effectiveness of national approach to drug strategy; hence regulations should be developed and applied uniformly. • Precursor Working Group is unwieldy and representational in nature. It should be replaced by an expert-based body, and industry should be involved through consultative arrangements. • Regulation of illicit drug precursors should be integrated with the proposed Chemicals of Security Concern framework.
Workplace safety	WRMC operating under new IGA will set policy directions and make decisions on standards. Statutory body to replace ASCC to be introduced. Tripartite membership to be retained.	Consistency has varied in the past: some standards being referenced; others used as a model. Switching to a model approach for all standards, that is, a model act and model regulations and codes of practice.	Adoption of models by consensus, but once adopted, jurisdictions wanting to change own legislation agree to WRMC voting, and if agreed by a two thirds majority, all jurisdictions must then adopt the same amendment..	• Although new arrangements place more onus on WRMC, influence of the tripartite structure is still a concern. • Planned review after six years of operation should include assessment of influence of tripartite structure. • Effectiveness of new mechanism for maintaining uniformity should be assessed for poss ble adoption in other IGAs.

Transport of dangerous goods	ATC sets policy direction, and votes on recommended standards. NTC — a statutorily independent organisation, commissioners appointed on basis of expertise. Long standing IGA. National Competition Policy incentive payments applied.	High degree of uniformity in adoption of template legislation passed by Commonwealth. ADG7 package has been developed on a model basis and is now being implemented (WA has adopted already).	ATC must accept or reject recommendations of NTC; it cannot amend them. Simple majority required. NTC drafts models.	• Move to model approach for the ADG7 package could undermine the high level of consistency achieved in the past. • Independent review of consistency of adoption of ADG7 package should be undertaken 12 months after it has been implemented.
Agvet chemicals	PIMC oversees operation of APVMA and NRS. IGA underpins NRS, and confers powers on the Commonwealth to regulate.	Agvet code adopted by template, but jurisdictions can have additional control-of-use regulations.	PIMC oversees the Agvet Code. APVMA sets technical standards (i.e. registration and labelling of agvet chemicals). Advisory committees assist director of APVMA to make registration decisions.	• Varying control-of-use regulations and practices by States and territories compromises effectiveness and efficiency of national approach. Control of use should be consolidated under APVMA. • A post-implementation review should be undertaken.
Environment	EPHC is overseeing development of a national chemicals environmental management framework (NChEM).	Currently there is little consistency in approaches adopted. NCHEM proposal would automatically link NICNAS recommendations to state and territory controls.	To make NICNAS recommendations more implementable, NCHEM includes: closer involvement of state and territories in assessment process; manuals for undertaking environmental assessments; and a manual of controls.	• NChEM approach would place inappropriate respons bilities on NICNAS. • A new independent environmental standard-setting body should be introduced to deal with NICNAS recommendations. This body would have governance features consistent with the Commission's model (box 11.1).
Chemicals of security concern (including SSAN)	Australian Attorney General and relevant state and territory ministers would consider policy on an 'as needs' basis. A unit within Department of Attorney General would provide support. IGA being negotiated.	SSAN regulations implemented inconsistently despite being based on 'agreed principles'. A new Chemicals of Security Concern (CSC) framework will facilitate a more systematic approach to development of controls or measures for other CSCs.	A unit within Department of Attorney General would undertake risk assessments and recommend risk management controls or measures.	• SSAN principles were implemented in inconsistent ways that compromise effectiveness and efficiency. SSAN regulations should be reassessed within the context of the CSC framework. • Proposed CSC framework does not explicitly include formal voting by ministers. • Appropriateness of combining risk assessment and risk management in one unit within AG should be monitored.

Note: Acronyms in this table are defined in the list of abbreviations at the front of the report.

The Australian Safety and Compensation Council (ASCC), on the other hand, has traditionally relied on drafting standards or codes of practice that the jurisdictions adopt in various ways and with different degrees of consistency. A feature of the recently signed intergovernmental agreement on OHS is that a replacement body for the ASCC will develop model standards (that is, a model act, model regulations and model codes of practice). While it may appear that little will have changed over the current arrangements, the strong commitment to national uniformity in the recently signed intergovernmental agreement suggests a more consistent adoption of chemicals-related standards in the future.

In both cases, the consistency with which jurisdictions subsequently adopt model standards should be monitored and reviewed.

While model approaches are often adapted for policy-relevant standards, there is some indication that governments are prepared to uniformly adopt technical standards. For example, COAG has agreed to the states and territories uniformly implementing poisons scheduling decisions.

Decision-making mechanisms of ministerial councils

Decision-making rules used by ministerial councils are not always spelt out or, in the Commission's view, soundly based. The Commission's model was based in part on the Australian Transport Council (ATC) and its associated intergovernmental agreement, a favourable feature of which is the voting arrangement for adopting standards developed by the National Transport Commission. This requires a majority approval, and can help ensure that more rigorous standards are adopted than might be expected under a consensus approach. Transport ministers are also required to use 'best endeavours' to implement reforms consistently, and report back to the ATC where they don't, giving reasons.

The recently signed intergovernmental agreement for OHS has some positive features with respect to decision making. While decisions concerning the adoption of a model act, model regulations and model codes of practice are to be made by consensus, once agreement is reached, a very tight conformance mechanism then operates. This requires the Workplace Relations Ministers' Council to vote on whether an amendment made by a jurisdiction should be allowed, and once it is allowed, it must then be adopted by all other jurisdictions. In this case, a two thirds majority is required. The effectiveness of this newly designed mechanism should be monitored for its possible inclusion in other intergovernmental agreements.

In comparison, the proposed Chemicals of Security Concern framework is not based on a defined group of ministers, nor is voting required. While some flexibility may be needed in being able to bring appropriate ministers together to deal with particular chemicals of security concern, a formal voting mechanism would be appropriate if a regulatory solution is the proposed approach. This should be clearly spelt out in the proposed intergovernmental agreement.

Representational membership of standard-setting bodies

The Commission has long argued that the membership of national standard-setting bodies should not be representational in nature. The inclusion of stakeholders on such bodies can create conflicts of interest that compromise policy development, particularly where non-government members are representing industry or other sectional interests. In relation to jurisdictional membership, there is opportunity for them to be involved in the standard-setting process through the policy direction that ministerial councils and their standing committees provide, and through consultation with the standard-setting body during that process. This is the way the National Transport Commission has operated for some time, with considerable success.

In this study, the Commission has observed some different approaches to membership of standard-setting bodies emerging. Most notably, while substantial changes are being made to the national framework governing OHS, the body to replace the ASCC will maintain a tripartite approach. On a slightly different note, a proposal to create a poisons committee would retain a representative approach for scheduling poisons, but the role of that committee would be advisory, with decisions to be made by the secretary of Department of Health and Ageing. Over time consideration should be given to migrating both of these governance arrangements to the Commission's preferred approach.

A six year review of the operations of the new OHS arrangements has already been set by COAG. This should include the effectiveness and efficiency of those arrangements, including the influence of the tripartite approach to membership of the new standard-setting body. In the case of the poisons committee, a review within two years of its operation should consider whether it could be reconstituted as a decision making but expert based body.

13 The way ahead

As part of good regulatory practice, reviews of current and proposed reforms should be undertaken in the future. In some cases, the Commission has endorsed current and proposed reforms that contain some elements of concern, but which, nevertheless, are either an improvement over current arrangements and/or have only been achievable with the considerable good will of all parties involved. Suggesting that these should be modified would be counterproductive at this stage, but they should be reviewed as soon as is practicable after implementation. This would allow them to be aligned more closely with the Commission's governance and operational principles.

The Commission recognises that, in some circumstances financial support for the states and territories might be necessary to facilitate national reforms (PC 2005). Their use might be justified where there are transitional costs, where reform dividends accrue more to the Commonwealth than the states and territories, and where it can be demonstrated that national uniformity warrants the self-tempering of jurisdictional sovereignty. Such payments played a role in the implementation of National Competition Policy reforms in the 1990s and 2000s, including in the uniform adoption of regulations governing the transport of dangerous goods. At its March 2008 meeting, COAG announced that it would consider proposals for the use of National Partnership Payments at its October 2008 meeting (COAG 2008a).

Chemicals and plastics regulation has been an issue of concern for a long time, but some reforms have been made in recent times, and there is an active current agenda. Prompted by the establishment of the Ministerial Taskforce, and the commissioning of this study, many worthwhile reforms that were in train have been further developed. Indeed, several recommendations made by the Commission in its draft report have already been accepted by the Ministerial Taskforce and adopted by COAG (these are listed at the front of this report). The Taskforce will be meeting again shortly and will use this report to refine its priorities.

A Conduct of the Study

This appendix outlines the study process and lists the organisations and individuals that have participated.

Following receipt of the terms of reference on 27 July 2007, the Commission placed a notice in the press inviting public participation in the study and released an issues paper to assist study participants in preparing their submissions. The Commission received 63 submissions before releasing the draft report. A further 53 submissions were received following the release of the draft report (a total of 116). Those who made submissions are listed in table A.1.

The Commission also held informal discussions with organisations and government departments and agencies. This visit program assisted the Commission in obtaining a wide understanding of the issues and the views of study participants. Organisations visited by the Commission are listed in table A.2.

In December 2007, the Commission held roundtables in Canberra. The roundtables were attended by 59 individuals representing 33 organisations listed in table A.3. Following the release of the draft report, an environment workshop was held in Sydney on 29 May 2008, attended by 20 individuals representing nine organisations listed in table A.4.

Table A.1 **Submissions received**

Individual or organisation [a]	*Submission no.*
3M Australia	34*
ACCORD Australasia	42, 62#, DR91
Acohs Pty Ltd	19*
Aerial Agricultural Association of Australia	17, DR108
Agsafe Limited	DR87
Albright & Wilson (Australia) Ltd	5
Animal Health Alliance (Australia) Ltd	7, DR68
Attorney-General's Department (Australian Government)	32, DR75, DR78
Australasian Institute of Dangerous Goods Consultants	DR76
Australasian Railways Association Inc.	DR95
Australian Association of Leather Industries	DR117
Australian Chamber of Commerce and Industry	13, DR92
Australian Chemical Trauma Alliance Inc	9
Australian Competition and Consumer Commission	DR103
Australian Council of Trade Unions	47, DR88
Australian Explosives Industry and Safety Group Inc	45, 63, DR94
Australian Explosives Transport Safety and Security Group	DR82
Australian Institute of Building Surveyors	DR70
Australian Paint Manufacturers' Federation	8, DR98
Australian Pesticides and Veterinary Medicines Authority (APVMA)	59, 65, DR105
Australian Trucking Association	DR102
Australian Vinyls Corp. Ltd	6, DR71
AUSVEG Ltd	52
Ausway Chemical Industries Pty Ltd	DR109
Break O'Day Catchment Risk Group	1, DR69
Chamber of Commerce and Industry of Western Australia	23, DR97
ChemCARE Consulting Pty Ltd	37
Chemicals and Plastics Leadership Group	58, DR113
Chem-Trend Australia Pty Ltd	41
Community Engagement Forum NICNAS	46
Croplife Australia Limited	35, 57#,DR80
Degussa Australia Pty Ltd	DR85
Department of Agriculture, Fisheries and Forestry	39, DR120
Department of Consumer and Employment Protection (Western Australia)	14#, DR114
Department of Employment and Workplace Relations (Australian Government)	15, DR96
Department of Health and Ageing (Australian Government)	40, DR116
Department of the Environment and Water Resources (Australian Government)	18#
Department of the Environment, Water, Heritage and the Arts (Australian Government)	DR104
DIC Australia Pty Ltd	27
DuPont (Australia) Ltd	DR118*
Endeavour Chemicals and Plastics Pty Ltd	DR67
Environment Protection and Heritage Standing Committee	20#
Environment Risk Management Authority New Zealand	25

Continued next page

Table A.1 (continued)

Individual or organisation [a]	*Submission no.*
Food & Beverage Importers Association (FBIA)	DR84
Food Standards Australia New Zealand (FSANZ)	22#
Glen Elva Pty Ltd	24
Growcom	12, DR89
Haztech Environmental	26, DR73
Horticulture Australia Ltd	49, DR81
Ian Wright & Associates	29
Interchem Agencies Limited	38
National Farmers' Federation	53, DR79
National Transport Commission	21, DR90
National Industrial Chemicals Notification and Assessment Scheme (NICNAS)	36, DR106
NChEM Working Group	61, DR119
NEPC Service Corporation (EPHC)	DR100
New South Wales Government	31, DR111
Pathya, Raj	DR83
Plastics and Chemicals Industries Association (PACIA)	2, 33, DR101
Plastral Pty Ltd	4#
Public Health Association of Australia	50
Queensland Government	66, DR121
Regscom Pty Ltd	28
Remove Obstacles to Australian Manufacture	3, DR99
Riskom International Pty Ltd	30
Royal Australian Chemical Institute Inc	11, DR93
Science Industry Australia	51, 55
Solvay Interox Pty Ltd	10#
South Australian Government	56#, DR110
Standards Australia	16#
Tasmanian Government	64, DR107
Veterinary Manufacturers and Distributors Association (Inc.)	48
Victorian Government	60, DR112
Wacker Chemicals Australia Pty Limited	DR86
Whamcorp Pty Ltd	DR77
Name withheld*	DR115

[a] An asterisk (*) indicates that the submission contains confidential material not available to the public. A hash (#) indicates that the submission includes attachments.

Table A.2 **Visits**

Organisation

Adelaide

Business South Australia
South Australian Department of Health

Brisbane

Department of Employment and Industrial Relations (Queensland)
Environment Protection Agency Queensland
Local Government Association of Queensland Inc
Queensland Department of Primary Industries and Fisheries

Canberra

Agsafe Limited
Animal Health alliance (Australia) Ltd
Australian Pesticides and Veterinary Medicines Authority (APVMA)
Croplife Australia Limited
Department of Agriculture, Fisheries and Forestry
Department of Health and Ageing
Department of Industry, Tourism and Resources
Department of Prime Minister and Cabinet
Department of the Environment and Water Resources
Food Standards Australia New Zealand
Minerals Council of Australia
National Farmers' Federation
Office of the Australian Safety and Compensation Council
Security Sensitive Ammonium Nitrate Working Group
Veterinary Manufacturers and Distributors Association (Inc.)

Melbourne

Australian Explosives Industry and Safety Group Inc
Department of Primary Industries (Victoria)
Environment Risk Management Authority New Zealand
Environment Protection Agency Victoria
National Toxics Network Inc.
National Transport Commission
Orica Australia Pty Ltd
Plastics and Chemicals Industries Association (PACIA)
WorkSafe Victoria

Perth

CSBP Limited
Department of Agriculture and Food (Western Australia)
Department of Consumer and Employment Protection (Western Australia)
Department of Health (Western Australia)
Department of Treasury and Finance (Western Australia)

Sydney

ACCORD Australasia
National Industrial Chemicals Notification and Assessment Scheme

Table A.3 **Roundtable participants**

Canberra 11 December 2007

3M Australia
ACCORD Australasia
Animal Health Alliance (Australia) Ltd
Australian Chemical Trauma Alliance Inc.
Australian Council of Trade Unions
Australian Pesticides and Veterinary Medicines Authority
Croplife Australia
Department of Agriculture, Fisheries and Forestry (Australian Government)
Department of Health and Ageing (Australian Government)
Department of Innovation, Industry, Science and Research (Australian Government)
Department of the Environment, Heritage and the Arts (Australian Government)
Horticulture Australia Ltd
National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
National Toxics Network Inc.
New South Wales Department of Environment and Climate Change
New South Wales WorkCover Authority
NICNAS Community Engagement Forum
Office of Chemical Safety
Office of Parliamentary Counsel (Australian Government)
Office of the Australian Safety and Compensation Council
Plastics and Chemicals Industries Association (PACIA)
Queensland Department of Employment and Industrial Relations
South Australian Department of Premier and Cabinet
South Australian Department of Trade and Economic Department
Veterinary manufacturers and Distributors Association
Victorian Department of Primary Industries
Western Australian Department of Agriculture and Food
Western Australian Department of Consumer and Employment Protection
WorkSafe Victoria

Canberra 12 December 2007

ACCORD Australasia
Animal Health Alliance (Australia) Ltd
Australian Capital Territory Department of Territory and Municpal Services
Australian Chemical Trauma Alliance Inc.
Australian Council of Trade Unions
Australian Pesticides and Veterinary Medicines Authority
Croplife Australia
Department of Agriculture, Forestry and Fisheries (Australian Government)
Department of Health and Ageing (Australian Government)
Department of Innovation, Industry, Science and Research (Australian Government)
Department of the Environment and Water Resources (Australian Government)
Minerals Council of Australia
National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

Continued next page

Table A.3 (continued)

Canberra 12 December 2007

New South Wales Department of Environment and Climate Change
NICNAS Community Engagement Forum and the National Toxics Network
Office of Chemical Safety
Plastics and Chemicals Industries Association (PACIA)
Queensland Environmental Protection Agency
South Australian Department of Environment and Heritage
Victorian Department of Primary Industries

Table A.4 Draft report workshop on the impact of chemicals on the environment - participants

Sydney 29 May 2008

Centre for International Economics
Department of the Environment, Water, Heritage and the Arts (Australian Government)
National Industrial Chemicals Notification and Assessment Scheme
NEPC Service Corporation
NSW Department of Environment and Climate Change
Queensland Environmental Protection Agency
South Australian Department of Environment and Heritage
Victorian Environmental Protection Agency
Western Australian Department of Environment and Conservation

B Industry definition

Basic Chemical Manufacturing — ANZSIC

Table B.1 **Industrial gas manufacturing — ANZSIC[a]**

Primary Activities
• Acetylene gas manufacturing
• Ammonia gas manufacturing
• Argon gas manufacturing
• Arsine gas manufacturing
• Butane gas manufacturing
• Carbon dioxide manufacturing
• Carbon monoxide manufacturing
• Chlorine gas manufacturing
• Deuterium gas manufacturing
• Dry ice manufacturing
• Ethane gas manufacturing
• Ethylene gas manufacturing
• Helium manufacturing
• Hydrogen chloride gas manufacturing
• Hydrogen manufacturing
• Hydrogen sulphide gas manufacturing
• Industrial gas manufacturing not elsewhere classified
• Inorganic gas manufacturing
• Isobutane gas manufacturing
• Krypton gas manufacturing
• Liquefied natural gas manufacturing
• Medicinal gas manufacturing
• Methane manufacturing
• Neon gas manufacturing
• Nitrogen (gas and liquid) manufacturing
• Nitrous oxide manufacturing
• Organic gas manufacturing
• Oxygen manufacturing
• Phosphine gas manufacturing
• Propane gas manufacturing
• Refrigeration gas manufacturing

Continued next page

Table B.1 (continued)

Primary Activities

- Silane gas manufacturing
- Sulphur dioxide gas manufacturing
- Sulphur hexafluoride gas manufacturing
- Xenon gas manufacturing

Exclusions/References

Units mainly engaged in:

- Manufacturing fuels from the liquefication of petroleum gases are included in Class 1701 Petroleum Refining and Petroleum Fuel manufacturing
- Manufacturing mixed cylinder gases formulated for use as a pesticide (for example, phosfume) are included in Class 1832 Pesticide Manufacturing

a This class consists of units mainly engaged in manufacturing industrial organic and inorganic gas in compressed, liquid or solid forms.

Source: ABS (2006).

Table B.2 **Basic organic chemical manufacturing — ANZSIC[a]**

Primary activities

- Acetaldehyde manufacturing
- Acid, acetic, manufacturing
- Acid, organic, manufacturing
- Activated carbon/charcoal manufacturing
- Carbon black manufacturing
- Charcoal briquette manufacturing
- Citric acid manufacturing
- Ethanol manufacturing
- Ether manufacturing
- Ethylene glycol manufacturing
- Extraction and/or distillation of wood and gum
- Formaldehyde manufacturing
- Glycol manufacturing not elsewhere classified
- Gum chemical manufacturing
- Industrial alcohol manufacturing
- Lactic acid manufacturing
- Lake colour manufacturing
- Methanol manufacturing
- Organic dye or pigment manufacturing
- Tall oil manufacturing
- Tanning extract, organic, manufacturing
- Turpentine (except mineral turpentine) manufacturing
- Vinyl chloride manufacturing
- Wood tar manufacturing

Continued next page

Table B.2 (continued)

Exclusions/References
Units mainly engaged in: • Manufacturing briquettes from petroleum coke other than charcoal are included in class 1709 Other Petroleum and Coal Product Manufacturing • Manufacturing mineral turpentine are included in Class 1709 Other Petroleum and Coal Product Manufacturing • Manufacturing electrostatic and photographic toners are included in Class 1916 Paint and Coatings Manufacturing • Manufacturing food colourings are included in Class 1199 Other Food Product Manufacturing not elsewhere classified • Distilling liquors (alcoholic beverages) are included in Class 1213 Spirit Manufacturing

a This class consists of units mainly engaged in manufacturing basic organic chemicals, including wood or gum chemicals (for example, organic tanning extracts and charcoal briquettes); high grade activated charcoal and/or carbon black; organic dyes and pigments. This class also includes units mainly engaged in manufacturing organic acids and industrial alcohols such as ethanol, methanol, ethylene glycol and ether.

Source: ABS (2006).

Table B.3 **Basic inorganic chemical manufacturing — ANZSIC[a]**

Primary Activities

- Acid, inorganic, manufacturing not elsewhere classified
- Alkaline salt manufacturing not elsewhere classified
- Aluminium hydroxide manufacturing
- Ammonium hydroxide manufacturing
- Chromium sulphate manufacturing (for application in leather tanning)
- Calcium chloride (lime) manufacturing
- Fluoride manufacturing
- Hydrochloric acid manufacturing
- Hydrofluoric acid manufacturing
- Hydrogen peroxide manufacturing
- Hypophosphite manufacturing
- Industrial salt manufacturing
- Inorganic dye or pigment manufacturing
- Nitric acid manufacturing
- Nitrite manufacturing
- Phosphoric acid manufacturing
- Silicate manufacturing
- Sodium bicarbonate manufacturing
- Sodium carbonate manufacturing
- Sodium hydroxide manufacturing
- Sulphide manufacturing
- Sulphur compound manufacturing
- Sulphuric acid manufacturing (except smelter by-product)
- Zinc oxide manufacturing
- Zinc peroxide manufacturing

Exclusions/References

Units mainly engaged in:

- Manufacturing bleaches and disinfectants are included in Class 1851 Cleaning Compound Manufacturing
- Manufacturing synthetic organic dyes and pigments are included in Class 1812 Basic Organic Chemical Manufacturing
- Manufacturing fertilisers are included in Class 1831 Fertiliser Manufacturing
- Manufacturing sulphuric acid as a smelter by-product are included in Class 2133 Copper, Silver, Lead and Zinc Smelting and Refining
- Manufacturing inorganic herbicides, insecticides, fungicides and pesticides are included in Class 1832 Pesticide Manufacturing.
- Manufacturing photographic chemicals are included in Class 1891 Photographic Chemical Product Manufacturing

a This class consists of units mainly engaged in manufacturing basic inorganic chemicals, including dyes and pigments; chromium sulphate (used in leather tanning); acids; and salts. This class also includes units mainly engaged in manufacturing chlorine, sodium hydroxide and other alkali using electrochemical processes.

Source: ABS (2006).

Basic polymer manufacturing — ANZSIC

Table B.4 Synthetic resin and synthetic rubber manufacturing - ANZSIC[a]

Primary Activities

- Cellulosic resin manufacturing
- Cresol formaldehyde manufacturing
- Dendritic polymer (dendrimer) manufacturing
- Melamine formaldehyde manufacturing
- Non-cellulose resin manufacturing
- Non-vulcanisable elastomer manufacturing
- Phenol formaldehyde manufacturing
- Polyacrylate manufacturing
- Polybutadiene manufacturing
- Polycarbonate manufacturing (except polycarbonate sheet)
- Polyethylene manufacturing
- Polymethacrylate manufacturing
- Polypropylene manufacturing
- Polystyrene manufacturing
- Polyurethane manufacturing
- Polyvinyl acetate manufacturing
- Polyvinylchloride (PVC) manufacturing
- Synthetic resin manufacturing
- Synthetic rubber composite manufacturing
- Synthetic rubber manufacturing
- Urea formaldehyde manufacturing

Exclusions/References

Units mainly engaged in:

- Manufacturing polymer products are included in the appropriate classes of Group 191 Polymer Product Manufacturing
- Manufacturing natural rubber products are included in Class 1920 Natural Rubber Product Manufacturing
- Manufacturing polycarbonate sheets are included in Class 1912 Rigid and Semi-Rigid Polymer Product Manufacturing
- Custom compounding of resins made elsewhere are included in Class 1919 Other Polymer Product Manufacturing
- Manufacturing tyres are included in Class 1914 Tyre Manufacturing

a This class consists of units mainly engaged in the manufacture of synthetic resins, non-vulcanisable elastomers and mixing and blending of resins and polymeric materials. This class also includes units mainly engaged in manufacturing synthetic rubbers and blends.

Source: ABS (2006).

Table B.5 **Other basic polymer manufacturing — ANZSIC[a]**

Primary activities

- Basic polymer manufacturing not elsewhere classified
- Carbon fibre manufacturing (including kevlar material manufacturing)
- Cellulose acetate manufacturing
- Cellulose fibre or filament manufacturing not elsewhere classified
- Ethyl cellulose manufacturing
- Methyl cellulose manufacturing
- Methylstyrene manufacturing
- Non-cellulose fibre or filament manufacturing not elsewhere classified
- Nylon manufacturing
- Polyester manufacturing
- Polyolefin manufacturing
- Rayon manufacturing
- Synthetic fibre or filament manufacturing

Exclusions/References

- Units mainly engaged in manufacturing textiles using synthetic or artificial fibres through spinning, weaving or further processing are included in Class 1313 Synthetic Textile manufacturing

a This class consists of units mainly engaged in manufacturing other basic polymers (except synthetic This class consists of units mainly engaged in manufacturing other basic polymers (except synthetic resins and synthetic rubbers). Included in this class are units mainly engaged in manufacturing cellulose (for example, rayon and acetate) and non-cellulose (for example, nylon, polyolefin and polyester) fibres and filaments.

Source: ABS (2006); Australian and New Zealand Standard Industrial Classification, Canberra.

Fertiliser and pesticide manufacturing — ANZSIC

Table B.6 **Fertiliser manufacturing - ANZSIC[a]**

Primary activities

- Ammonium phosphate manufacturing
- Ammonium sulphate manufacturing
- Animal and vegetable fertiliser manufacturing
- Bonedust manufacturing
- Bonemeal fertiliser manufacturing
- Calcium sulphate manufacturing
- Controlled release fertiliser preparation manufacturing
- Fertiliser manufacturing not elsewhere classified
- Fishmeal fertiliser manufacturing
- Humic substance manufacturing
- Nitrogenous fertiliser material manufacturing
- Phosphate fertiliser material manufacturing
- Potash fertiliser manufacturing
- Potassium chloride fertiliser manufacturing
- Prilled ammonium nitrate manufacturing
- Sodium nitrate fertiliser manufacturing
- Sulphuric lime manufacturing
- Superphosphate manufacturing
- Urea, fertiliser grade, manufacturing

a This class consists of units mainly engaged in manufacturing and mixing fertilisers.

Source: ABS (2006).

Table B.7 **Pesticide manufacturing — ANZSIC[a]**

Primary activities

- Animal dip manufacturing
- Animal spray manufacturing
- Flyspray manufacturing
- Formulated pest control product manufacturing
- Fungicide manufacturing
- Insect repellent manufacturing
- Insecticide manufacturing
- Pesticide manufacturing not elsewhere classified
- Rat poison manufacturing
- Soil fumigant manufacturing
- Weedkiller manufacturing

Exclusion/References

- Units mainly engaged in manufacturing fertilisers are included in Class 1831 Fertiliser Manufacturing

a This class consists of units mainly engaged in the formulation and preparation of pest control chemicals.

Source: ABS (2006).

Pharmaceutical and medicinal product manufacturing — ANZSIC

Table B.8 **Human pharmaceutical and medicinal product manufacturing — ANZSIC[a]**

Primary activities
• Ampoule manufacturing
• Analgesic manufacturing
• Anthelmintic manufacturing
• Antibacterial manufacturing
• Antibiotic manufacturing
• Antibody manufacturing
• Antigen manufacturing
• Antitoxin manufacturing
• Biotechnological manufacture of pharmaceutical and medicinal products
• Blood serum manufacturing
• Contraceptive, medicinal, manufacturing (except rubber contraceptives)
• Diagnostic substance manufacturing
• Drug manufacturing (except veterinary)
• Herbal drug manufacturing
• Hormone manufacturing (except veterinary)
• Medicinal capsule manufacturing
• Medicinal chemical manufacturing
• Medicinal ointment manufacturing
• Medicine manufacturing (except veterinary)
• Morphine manufacturing
• Saccharin manufacturing
• Serum manufacturing
• Vaccine manufacturing (except veterinary)
• Vial manufacturing
• Vitamin product manufacturing

Continued next page

Table B.8 (continued)

Exclusions/References

Units mainly engaged in:

- Manufacturing sanitary paper-based products from paper or cellulose wadding, such as disposable paper nappies, sanitary napkins, tampons and other sanitary paper-based products not elsewhere classified are included in Class 1524 Sanitary Paper Product Manufacturing
- Manufacturing ether are included in Class 1812 Basic Organic Chemical Manufacturing
- Manufacturing medicinal gas are included in Class 1811 Industrial Gas Manufacturing
- Manufacturing animal dips and sprays, blowfly specifics or other pesticides are included in Class 1832 Pesticide Manufacturing
- Packaging and labelling of pharmaceutical and medical products on fee or contract are included in Class 7320 Packaging Services
- Manufacturing scientific or diagnostic equipment are included in Class 2412 Medical and Surgical Equipment manufacturing

a This class consists of units mainly engaged in manufacturing pharmaceutical and medicinal products for human use from both natural (plants) and synthetic sources (chemicals). This class also consists of units mainly engaged in manufacturing diagnostic substances for antibodies, antigens and chemical/diagnostic testing agents.

Source: ABS (2006); Australian and New Zealand Standard Industrial Classification, Canberra.

Table B.9 Veterinary pharmaceutical and medicinal product manufacturing — ANZSIC[a]

Primary activities

- Veterinary drug manufacturing
- Veterinary medicinal preparation manufacturing not elsewhere classified

Exclusions/References

Units mainly engaged in:

- Manufacturing human pharmaceutical products are included in Class 1841 Human Pharmaceutical and Medicinal Product Manufacturing
- Manufacturing animal dips and sprays, blowfly specifics or other pesticides are included in Class 1832 Pesticide Manufacturing

a This class consists of units mainly engaged in manufacturing drugs, medicines, medicinal chemicals, vaccines, serums and other pharmaceutical products for veterinary use.

Source: ABS (2006); Australian and New Zealand Standard Industrial Classification, Canberra.

Cleaning compound and toiletry preparation manufacture — ANZSIC

Table B.10 **Cleaning compound manufacturing — ANZSIC[a]**

Primary activities

- Candle manufacturing
- Denture cleaner manufacturing
- Detergent manufacturing
- Dishwashing detergent manufacturing
- Disinfectant manufacturing
- Emulsifier manufacturing
- Glycerine manufacturing
- Hypochlorite-based bleach manufacturing
- Laundry detergent manufacturing
- Penetrant manufacturing
- Peroxide preparation manufacturing
- Polish manufacturing
- Scouring compound manufacturing
- Soap manufacturing
- Toothpaste manufacturing

Exclusions/References

Units mainly engaged in:

- Manufacturing hair shampoos and shaving preparations are included in Class 1852 Cosmetic and Toiletry Preparation Manufacturing
- Manufacturing solvent cleaners are included in Class 1701 Petroleum Refining and Petroleum Fuel Manufacturing
- Manufacturing agents used to tan leather are included in Class 1813 Basic Inorganic Chemical Manufacturing

a This class consists of units mainly engaged in manufacturing cleaning compounds, including toothpastes, soaps and other detergents, surface active agents, polishes and speciality cleaning preparations.

Source: ABS (2006).

Table B.11 **Cosmetic and toiletry preparation manufacturing — ANZSIC[a]**

Primary activities

- After-shave lotion manufacturing
- Barrier cream manufacturing
- Cosmetic deodorant manufacturing
- Depilatory manufacturing
- Eye shadow manufacturing
- Face cream and lotion manufacturing
- Hair preparation manufacturing
- Lip balm manufacturing
- Lipstick manufacturing
- Mascara manufacturing
- Nail polish preparation manufacturing
- Perfume manufacturing
- Shaving preparation manufacturing
- Sunscreen preparation manufacturing
- Talcum powder manufacturing

Exclusions/References

Units mainly engaged in:

- The contract packaging of cosmetics and toiletry items are included in Class 7320 Packaging Services
- Manufacturing sanitary paper-based products from sanitary paper or cellulose wadding, such as toilet or facial tissues, disposable paper nappies, sanitary napkins, tampons and other sanitary paper-based products, are included in Class 1524 Sanitary paper Product Manufacturing

a This class consists of units mainly engaged in manufacturing cosmetic and toiletry preparations.

Source: ABS (2006); Australian and New Zealand Standard Industrial Classification, Canberra.

Other basic chemical product manufacturing — ANZSIC

Table B.12 **Photographic chemical product manufacturing — ANZSIC[a]**

Primary activities

- Photographic chemical manufacturing
- Photographic sensitised cloth manufacturing
- Photographic sensitised film manufacturing
- Photographic sensitised paper manufacturing
- Photographic sensitised plate manufacturing

Exclusions/References

Units mainly engaged in:

- Manufacturing carbon black are included in Class 1812 Basic Organic Chemical Manufacturing
- Manufacturing unsensitised papers and other paper products are included in class 1510 Pulp, Paper and Paperboard Manufacturing

a This class consists of units mainly engaged in manufacturing photographic sensitised film, paper, cloth, plates and chemicals.

Source: ABS (2006).

Table B.13 **Explosive manufacturing — ANZSIC[a]**

Primary activities

- Ammonium nitrate, explosive, manufacturing
- Blasting powder manufacturing
- Cellulose nitrate manufacturing
- Detonator manufacturing (cap or fuse)
- Dynamite manufacturing
- Explosive fuse manufacturing
- Fireworks manufacturing
- Gun cotton manufacturing
- Match manufacturing
- Propellant powder manufacturing
- Pyrotechnic goods manufacturing
- Pyrotechnic manufacturing
- Safety fuse manufacturing
- Signal flare manufacturing

Exclusions/References

- Units mainly engaged in manufacturing ammunition are included in class 2299 Other Fabricated Metal Product Manufacturing not elsewhere classified

a This class consists of units mainly engaged in manufacturing explosives.

Source: ABS (2006).

Table B.14 **Other basic chemical product manufacturing not elsewhere classified — ANZSIC**[a]

Primary activities
• Antifreeze manufacturing
• Beeswax manufacturing
• Concrete additive or masonry surface treatment manufacturing
• Dry cleaning compound manufacturing
• Embalming compound manufacturing (formaldehyde and additives)
• Eucalyptus oil distilling
• Extraction of essential oils
• Flux manufacturing (welding and soldering)
• Sandalwood oil distilling
• Tea-tree oil distilling

a This class consists of units mainly engaged in manufacturing chemical products not elsewhere classified.

Source: ABS (2006).

Polymer product manufacturing — ANZSIC

Table B.15 **Polymer film and sheet packaging material manufacturing — ANZSIC**[a]

Primary activities
• Bag, plastic, manufacturing
• Bag, sack or packet (plastic film or sheeting), manufacturing
• Bubble packaging manufacturing
• Film, plastic, manufacturing
• Food wrapping, plastic, manufacturing
• Garbage bag, plastic, manufacturing
• Plastic lamination with paper

a This class consists of units mainly engaged in manufacturing unsupported polymer film or polymer sheet into packaging materials. This includes bubble packaging, bags, coatings or laminates in a variety of forms.

Source: ABS (2006).

Table B.16 **Rigid and semi-rigid polymer product manufacturing — ANZSIC[a]**

Primary activities

- Badge, plastic, manufacturing
- Bathtub, plastic, manufacturing
- Bottle, plastic, manufacturing
- Bucket, plastic, manufacturing
- Clothes peg, plastic, manufacturing
- Cultured marble surfacing product manufacturing
- Dinnerware, plastic, manufacturing
- Drinking fountain, plastic, manufacturing
- Electrical insulation box, polymer, manufacturing
- Food container, plastic, manufacturing (including microwave safe)
- Furniture, plastic, manufacturing
- Gutter and spout, plastic, manufacturing
- Light switch and plug, polymer, manufacturing
- Pipe fittings, plastic, manufacturing
- Pipe, plastic, manufacturing
- Plastic union manufacturing
- Plumbing fittings, plastic, manufacturing (including joints, elbows and flanges)
- Polycarbonate sheet manufacturing
- Polymer container manufacturing not elsewhere classified
- Profile shapes, plastic, manufacturing not elsewhere classified
- Rod or tube, plastic, manufacturing
- Safety goggle, plastic, manufacturing
- Shower stall, plastic, manufacturing
- Toilet fixture, plastic, manufacturing
- Toilet, plastic, manufacturing
- Watering can, plastic, manufacturing

a This class consists of units mainly engaged in manufacturing rigid or semi-rigid polymer products.

Source: ABS (2006).

Table B.17 **Polymer foam product manufacturing — ANZSIC[a]**

Primary activities

- Bicycle safety helmet manufacturing
- Cooler and ice chest, polymeric foam, manufacturing
- Cup, polymeric foam, manufacturing
- Food container, polymeric foam, manufacturing
- Insulation and cushioning material, polymer, manufacturing
- Polymeric foam product manufacturing not elsewhere classified
- Sheet foam manufacturing

a This class consists of units mainly engaged in manufacturing polymer foam products. Also included in this class are units mainly engaged in manufacturing polymer filler products used to fill cavities in walls, as well as insulation and cushioning materials for swimming pools and spas, and for marine flotation.

Source: ABS (2006).

Table B.18 **Tyre manufacturing — ANZSIC[a]**

Primary activities

- Aircraft tyre manufacturing
- Inner tube manufacturing
- Motor vehicle tyre manufacturing
- Retread or rebuilt tyre manufacturing
- Tyre manufacturing (pneumatic, semi-pneumatic or solid)

a This class consists of units mainly engaged in manufacturing tyres from synthetic polymers and/or natural rubber, tyre repair materials and inner tubes. This class also includes units mainly engaged in manufacturing retread or rebuilt tyres using both natural and synthetic rubber.

Source: ABS (2006).

Table B.19 **Adhesive manufacturing — ANZSIC[a]**

Primary activities

- Adhesive manufacturing
- Casein glue manufacturing
- Glue manufacturing
- Rubber adhesives manufacturing

Exclusions/References

Units mainly engaged in:

- Manufacturing synthetic resins are included in Class 1821 Synthetic Resin and Synthetic Rubber Manufacturing
- Manufacturing cellulose nitrate and gun cotton are included in Class 1892 Explosive Manufacturing
- Manufacturing asphalt and bituminous materials are included in Class 1709 Other Petroleum and Coal Product Manufacturing

a This class consists of units mainly engaged in the manufacture of glues, adhesives and other bonding materials of an organic nature.

Source: ABS (2006); Australian and New Zealand Standard Industrial Classification, Canberra.

Table B.20 **Paint and coatings manufacturing — ANZSIC[a]**

Primary activities

- Carbon ink manufacturing
- Caulking compound manufacturing
- Drawing ink manufacturing
- Enamel manufacturing
- Filler and putty manufacturing (including spray forms)
- Ink manufacturing not elsewhere classified
- Inkjet ink manufacturing
- Lacquer manufacturing
- Paint or varnish remover manufacturing
- Paint tinting manufacturing
- Primer manufacturing
- Printing ink manufacturing
- Rubbing compound (frits) manufacturing
- Shellac manufacturing
- Silk screen ink manufacturing
- Stain manufacturing (including decking stains and oils)
- Toner manufacturing not elsewhere classified
- Undercoat and top coat paint manufacturing
- Varnish manufacturing
- Water repellent coating manufacturing (for concrete and masonry)
- Writing ink manufacturing

Exclusions/References

Units mainly engaged in:

- Manufacturing wallpaper are included in Class 1529 other Converted Paper Product Manufacturing
- Manufacturing bituminous paint and creosote are included in class 1709 Other Petroleum and Coal Product Manufacturing

a This class consists of units mainly engaged in mixing pigments, solvents and binders into paints and coatings. This class also includes manufacturing allied paint products (for example, putties, caulking compounds, paint and varnish removers) and rubbing compounds. This class also includes units mainly engaged in manufacturing inks and toners.

Source: ABS (2006).

Table B.21 **Other polymer product manufacturing — ANZSIC[a]**

Primary activities

- Awning, fibreglass, manufacturing
- Conveyor belt, plastic or composite, manufacturing
- Floor covering, resilient polymer, manufacturing
- Garbage bin, plastic, manufacturing
- Garden hose, plastic or composite, manufacturing
- Gloves, plastic, manufacturing
- High-density safety equipment manufacturing (for example, military helmets)
- Hose, plastic or composite, manufacturing
- Hull, boat building, manufacturing
- Motor vehicle and boat parts, fibreglass, manufacturing
- Polymer product manufacturing not elsewhere classified
- Radiator and heating hose, plastic or composite, manufacturing
- Refrigeration container insulation sheet manufacturing
- Transmission belt, plastic or composite, manufacturing
- Vacuum cleaner belt, plastic or composite, manufacturing
- V-belt, plastic or composite, manufacturing

Exclusions/References

Units mainly engaged in:

- Texturising fibres and filaments made elsewhere are included in Class 1829 Other Basic Polymer Manufacturing
- Manufacturing textile glass fibres are included in Class 2090 Other Non-Metallic Mineral Product Manufacturing
- Manufacturing fibreglass furniture are included in Class 2519 Other Furniture Manufacturing

a This class consists of units mainly engaged in manufacturing polymer composite products such as fibreglass products and resilient floor coverings, as well as other polymer products not elsewhere classified.

Source: ABS (2006).

Natural rubber product manufacturing — ANZSIC

Table B.22 **Natural rubber product manufacturing — ANZSIC[a]**

Primary activities

- Bath mat, natural rubber, manufacturing
- Condom, natural rubber, manufacturing
- Conveyor belt, natural rubber, manufacturing
- Diaphragm, natural rubber, manufacturing
- Dummy, natural rubber, manufacturing
- Floor covering or underlay, resilient natural rubber, manufacturing
- Garden hose, natural rubber, manufacturing
- Hose, natural rubber, manufacturing, not elsewhere classified
- Hot water bottle, natural rubber, manufacturing
- Mattress protector, natural rubber, manufacturing
- Pillow or cushion, natural rubber, manufacturing
- Plug, natural rubber, manufacturing
- Rubber balloon, natural rubber, manufacturing
- Rubber band, natural rubber, manufacturing
- Rubber glove, natural rubber, manufacturing
- Sponge, natural rubber, manufacturing
- Teething ring, natural rubber, manufacturing
- Tubing, natural rubber, manufacturing
- Washer, natural rubber, manufacturing

Exclusions/References

- Units mainly engaged in manufacturing synthetic rubber are included in Class 1821 Synthetic Resin and Synthetic Rubber Manufacturing

a This class consists of units mainly engaged in manufacturing products made solely of natural rubber.

Source: ABS (2006).

C History and economic profile of the industry

This appendix provides background information on the chemicals and plastics industry. It begins with a history of the industry, including past tariff protection. It then examines some data, including output, employment, trade and global production.

C.1 History of the industry

The chemicals and plastics industry in Australia has its origins in meeting the needs of the agriculture and mining sectors. The earliest manufacture of fertiliser for agricultural production was at Yarraville in Melbourne by Cuming Smith and Company in 1878. Other plants were built by the Adelaide Chemical Works Company at Torrensville near Adelaide in 1883, and by CSR at Balmain in Sydney in 1886.

Mining was the other main driver of the early importation and manufacture of chemicals in Australia. The discovery of precious and base metals in Queensland, gold in Kalgoorlie and Victoria, and lead, zinc and silver in Broken Hill all increased demand for explosives. Black powder, an early explosive, was imported as early as the 1820s. A fuse factory was established in 1867, a black powder factory in Victoria in 1873 and by 1876 there were at least five producers in Australia. Later, dynamite came into more common use and manufacture began in 1874, assisted by Victorian Government policy — aimed at supporting local manufacture — which imposed a significant duty on imported dynamite.

The production of industrial chemicals had its origins in pharmaceutical houses, which provided the financial basis for manufacturers to diversify into the production of other chemicals, such as ‘colonial-made ink’, mineral acids, superphosphate, soap, sulphuric acid and nitric acid (AATSE 2001).

Plastic manufacture began in Australia in 1927, when the Australian Moulding Corporation (which later became Nylex) began importing moulding powders and making simple plastic products. Rubber bicycle tyres were first imported into

Australia in 1889, and in 1902 a tyre factory was established at Port Melbourne (AATSE 2001).

C.2 Border protection

The protection granted by the Victorian Government to dynamite manufacturing preceded protection provided by the Commonwealth Government for Australian industry, including chemicals and plastics. In the 1930s, tariff barriers were substantially increased across all industries. Tariffs tended to be imposed in a piecemeal manner, without assessment. When the Industries Assistance Commission (IAC) conducted its inquiry into the chemicals and plastics industry in 1986, it found:

> There are 17 different general rates of duty that apply to imports of chemicals and plastics. These range from free to 45 per cent. In addition, specific rates of duty apply to 10 tariff items covered by the reference. In a number of instances, the differences between rates of duty are 2.5 percentage points or less. (IAC 1986, p. 5)

Non-tariff protection, such as anti-dumping provisions, also served to prevent or impede imports. The IAC found that:

> The chemicals and plastics industries as a group account for a large number of the goods subject to anti-dumping duties. At the end of November 1985, 32 commodities under reference in this inquiry were subject to anti-dumping actions. In some cases, these actions applied to most of the countries from which imports were sourced. (IAC 1986, p. 143)

Protection also came via the deferral of the requirements of the Australia/New Zealand Closer Economic Relations Trade Agreement. It was considered that the Australian plastics industry would be disadvantaged by New Zealand's ability to source raw materials (in this case, resins) at world prices not inflated by tariffs, known as 'prejudicial intermediate goods situations' (IAC 1986). This protection was to be removed by 1989 at the latest.

Since the early 1970s, Australia's average tariff levels have been reduced, both through a series of across-the-board measures and as the result of inquiries into particular industries and commodities. Border protection changes were the catalyst for significant industry restructuring. Manufacturing facilities that had hidden behind border protection and were no longer viable were closed, or restructured to increase scales of production. In some cases, domestic demand was sufficient to justify production (for example, ammonium nitrate for the mining industry). In other cases, other barriers, such as transport issues (for example, transport of hazardous or unstable chemicals) became a natural barrier to imports that justified domestic production.

C.3 The chemicals and plastics life cycle

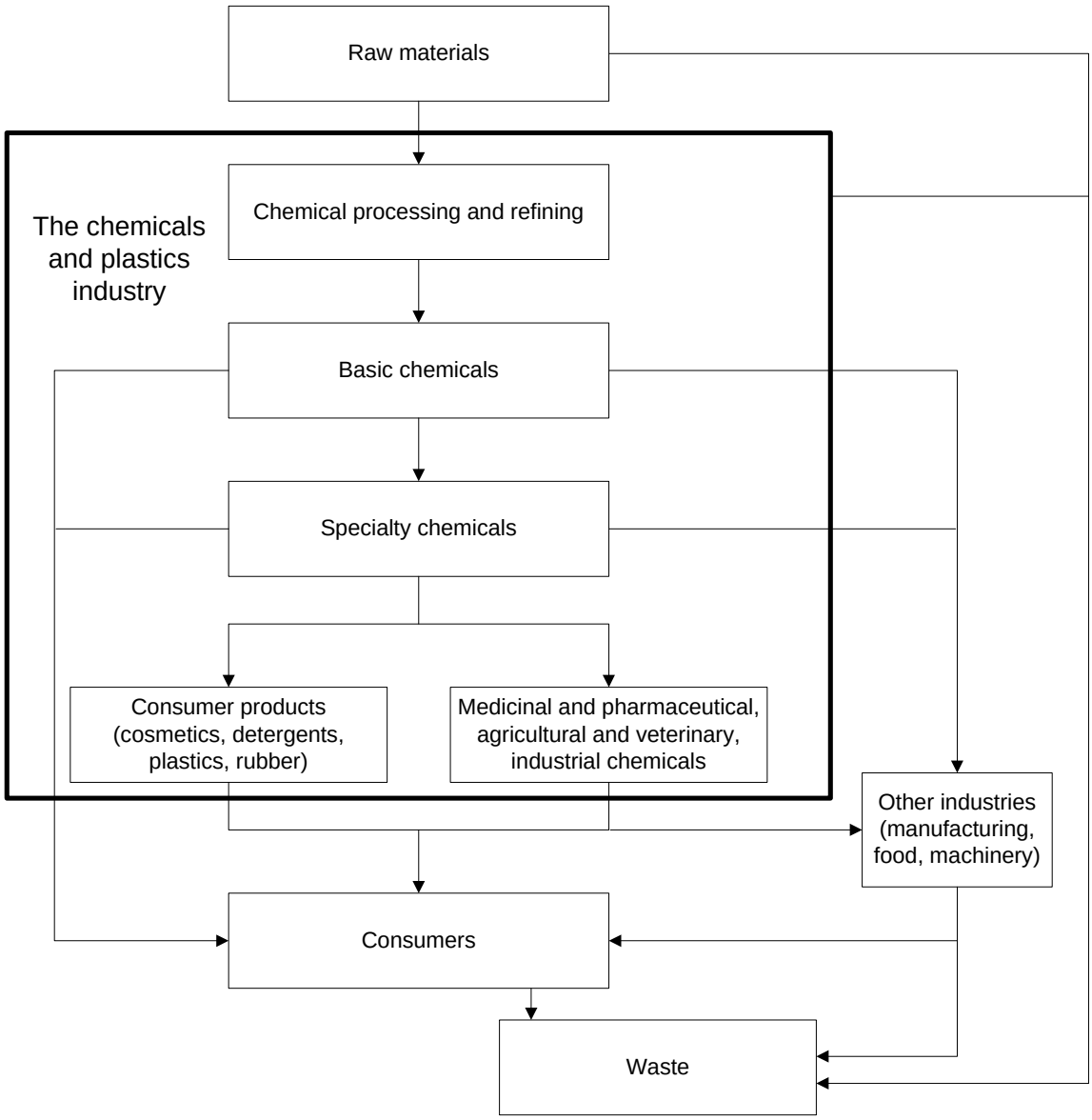
The life cycle of products in the chemicals and plastics industry begins with the transformation of raw materials such as water, minerals, oil, gas, wood, coal and air, into basic chemicals. Some basic chemicals are used in final consumption (such as chlorine for swimming pools and ammonia for cleaning). Others are used to make more complex chemicals and plastics, and in turn other products which are then consumed. Chemicals and plastics, and the products made from them, are later disposed (either to landfill or incineration) or recycled. This life cycle is set out in figure C.1.

C.4 The chemicals and plastics manufacturing industry

The chemicals manufacturing industry is characterised by considerable diversity, such that it is not possible to generalise about typical firms or typical products. This diversity also makes it difficult to generalise about long term trends at anything but an aggregated level. Output of the industry, as measured by industry value added (IVA)[1], was around $9 billion in 2005-06. This represented around 9 per cent of total manufacturing output and 0.9 per cent of GDP (ABS 2007a, 2007b). Of this output, around 62 per cent was chemical production (total basic chemicals plus total other chemicals), 32 per cent plastics and 6 per cent rubber (table).

1 IVA is the industry's contribution to GDP.

Figure C.1 **Life cycle of chemicals and plastics**



Source: Adapted from OECD (2001b).

Table C.1 **Chemicals and plastics industry, industry value added, 2005-06[a]**

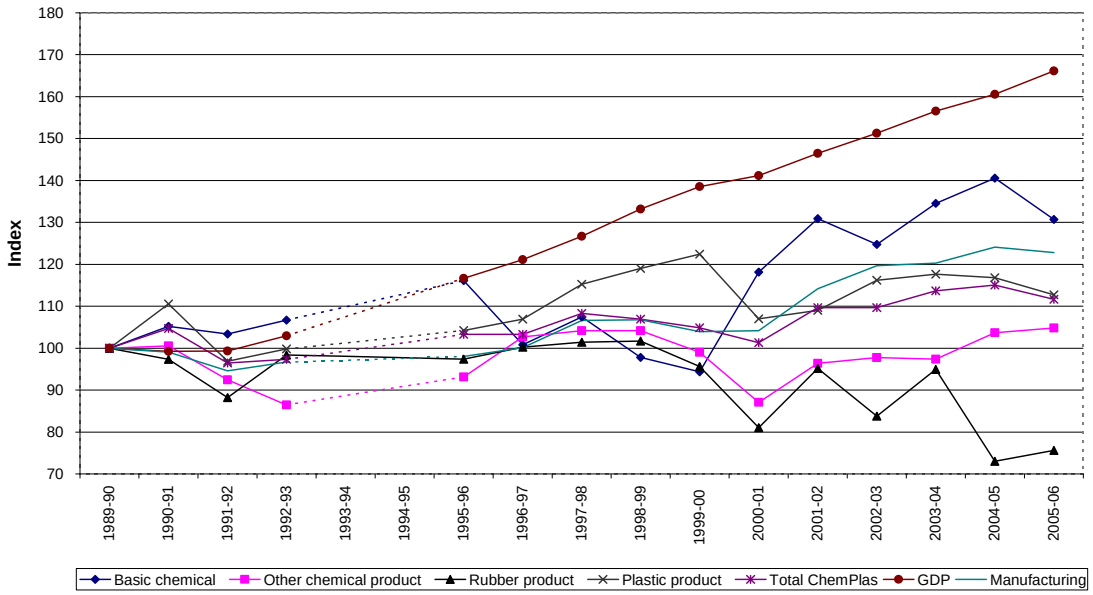
Industry sectors	*Industry value added*	*Proportion of industry*
	$m	%
Fertiliser	**np**	**np**
Industrial gas	**np**	**np**
Synthetic resin	757	8.4
Organic industrial chemical, **nec**	165	1.8
Inorganic industrial chemical, **nec**	930	10.3
Total basic chemical	**2 880**	**31.9**
Explosive	**np**	**np**
Paint	715	7.9
Pesticide	215	2.4
Soap and other detergent	604	6.7
Cosmetic and toiletry preparation	218	2.4
Ink	**np**	**np**
Chemical product, **nec**	408	4.5
Total other chemical	**2 703**	**29.9**
Rubber tyre	169	1.9
Rubber product, **nec**	395	4.4
Total rubber product	**564**	**6.2**
Plastic blow moulded product	386	4.3
Plastic extruded product	437	4.8
Plastic bag and film	676	7.5
Plastic product rigid fibre reinforced	395	4.4
Plastic foam product	171	1.9
Plastic injection moulded product	829	9.2
Total plastics	**2 893**	**32.0**
Total chemicals and plastics	**9 040**	**100.0**

a Excluding medicinal and pharmaceutical products. **np** Not published. **nec** Not elsewhere classified.

Source: ABS *(Manufacturing Industry, Australia*, Cat. no. 8221.0).

Between 1989-90 and 2005-06, chemicals and plastics industry output grew by around 12 per cent. (This compares to growth of 66 per cent for GDP and 22 per cent for manufacturing (figure C.2).) When broken down into product groups, growth rates have varied. For example, between 1989-90 and 2005-06, basic chemical manufacturing output grew by 31 per cent, plastics by 13 per cent, other chemicals increased by 5 per cent while rubber products manufacturing declined by 24 per cent (figure C.2). Output also tended to fluctuate significantly over this period for all types of products.

Figure C.2 **Industry value added (1989-90 = 100)[a, b]**

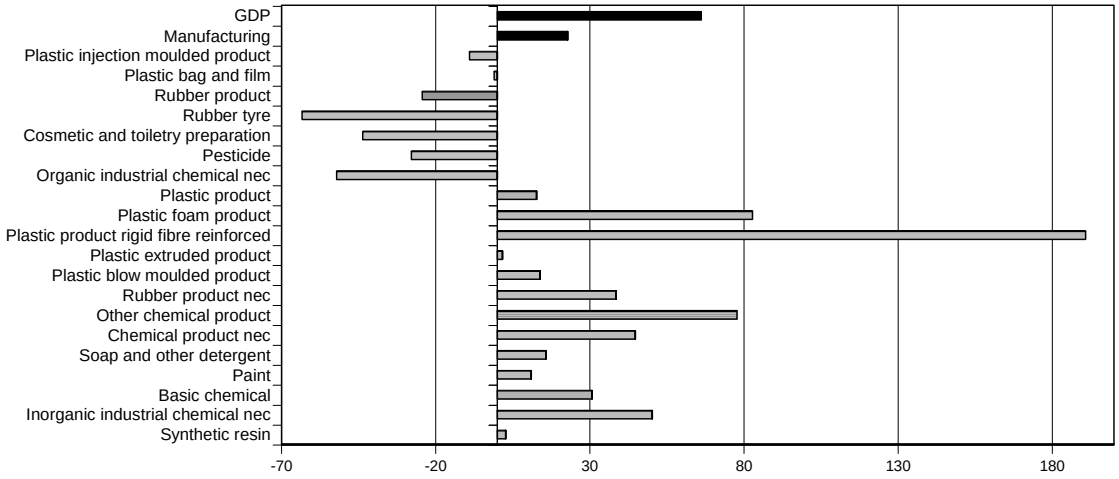


a This chart shows the real change (2005-06 dollars) in industry value added (IVA) between 1989-90 and 2005-06, using 1989-90 as the base year. **b** IVA is used between 1997-98 and 2005-06, industry gross product for 1995-96 and 1996-97, and gross product at factor cost between 1989-90 and 1992-93. Data were not available for 1993-94 and 1994-95.

Data sources: ABS *(Manufacturing Industry, Australia*, Cat. no. 8221.0 various years; *Australian System of National Accounts, 2006-07*, Cat. no. 5204.0).

Even within these product groupings, however, growth rates differed (figure C.3). Between 1989-90 and 2005-06 some product classes, such as rigid fibre reinforced plastic product, had very high rates of growth, while other product classes declined.

Figure C.3 **Real growth in industry value added between 1989-90 and 2005-06[a]**



a 1989-90 is the first year industry value added by class is available for plastics. **nec** Not elsewhere classified.

Data sources: ABS *(Manufacturing Industry, Australia*, Cat. no. 8221.0 various years; *Australian System of National Accounts, 2006-07*, Cat. no. 5204.0).

C.5 The use of chemicals and plastics

The use[2] of chemicals and plastics in the economy also varies significantly across the various products. Overall, 72 per cent of all chemical products are used as intermediate goods, 19 per cent are used as final consumption and 9 per cent are exported. However, this varies significantly across products (table C.2). For example, while 93 per cent of paints[3] are used as intermediate goods, only 27 per cent of cosmetics and toiletries are used in this way.

2 Data on the use of chemicals and plastics is from ABS input-output tables, which classify industries differently from ANZSIC 1993. Data on use includes medicinal and pharmaceutical products, unless otherwise specified.

3 The proportion of paint that is used as final consumption (1 per cent) rather that intermediate use is estimated using information from various ABS surveys, including the Household Expenditure Survey.

Table C.2 **Use of chemicals and plastics, 2001-02**

Description	*Intermediate use*	*Final consumption*[a]	*Exports*
	% total supply	% total supply	% total supply
Basic chemicals	84	5	11
Paints	93	1	6
Medicinal and pharmaceutical products, pesticides	47	40	13
Soap and detergents	50	43	7
Cosmetics and toiletry preparations	27	62	11
Other chemical products	89	3	8
Rubber products	78	18	4
Plastic products	86	10	4
Total	**72**	**19**	**9**

[a] Includes household consumption, government consumption, gross fixed capital accumulation and changes in inventories.

Source: ABS (*Australian National Accounts: Input-Output Tables – Electronic Publication 2001-02*, Cat. no. 5209.0.55.001).

Chemicals and plastics are used as inputs into most industries. In 2001-02, the largest user was the manufacturing industry, which used 35 per cent of the total supply of chemicals and plastics. Other large users include the construction industry, which used 6 per cent, and the agriculture, forestry and fishing industries which between them also used 6 per cent (ABS 2006b).

Of the 35 per cent of chemicals and plastics used as intermediate inputs by the manufacturing sector in 2001-02, 11 per cent were used in the food, beverage and tobacco industry, 8 per cent in the printing industry and 9 per cent in the machinery and equipment industry (ABS 2006b).

The chemicals and plastics life cycle is characterised by transformation of raw materials into chemicals, which are themselves used as intermediate inputs. In 2001-02, nearly half of chemicals and plastics output was used to manufacture more specialised chemicals and plastic products (ABS 2006b). Consistent with this, the OECD noted that ‘the chemicals industry is its own best customer’ (OECD 2001b, p. 23).

Industries other than manufacturing used large quantities of particular products in 2001-02. For example:

- 24 per cent of paints are used in the construction industry
- 17 per cent of rubber is used in government business and defence, and 11 per cent is used in the transport and storage industry
- 17 per cent of soap and detergents are used in property and business services
- 13 per cent of other chemicals and plastics (which includes explosives) are used in the mining industry
- 10 per cent of basic chemicals (which includes fertiliser) is used in the agriculture industry (ABS 2006b).

This broad use of chemicals and plastics demonstrates the economy-wide implications of their regulation, and reinforces the importance of effective and efficient regulations.

C.6 Employment

There were around 80 500 people employed in manufacturing chemicals and plastics in 2005-06, comprising around 8 per cent of employment in manufacturing and 0.8 per cent of total employment. Of these, 22 per cent were employed in basic chemical manufacturing, 29 per cent in other chemical manufacturing, 8 per cent in rubber manufacturing and 41 per cent in plastics manufacturing (ABS 2007b).

Between 1989-90 and 2005-06, employment in the chemicals and plastics industry decreased marginally by 0.1 per cent. This compares to an increase of about 4 per cent in the manufacturing industry as a whole, and 30 per cent economy-wide. Employment growth in sections of the chemicals and plastics industry varied significantly. Employment grew by 12 per cent in basic chemicals manufacture, 5.4 per cent in other chemical products and by only 0.3 per cent in plastics. Employment in rubber manufacturing declined by 50 per cent over the period (ABS 2007b).

C.7 Location of activity

Data on the chemicals and plastics industry across states and territories is often limited for confidentiality reasons: a small number of businesses can account for most or all of a particular sector's output. Most of the activity takes place in NSW, Victoria and to a lesser extent, Queensland (table C.3). Compared to manufacturing and GDP, Victoria appears to have a relatively high proportion of chemicals and plastics manufacturing.

Table C.3 **Industry value added by state and territory, 2001-02**

	NSW	*Vic*	*Qld*	*WA*	*SA*	*Tas*	*ACT*	*NT*
	%	%	%	%	%	%	%	%
Basic chemicals	27	**np**	**np**	**np**	5	1	**np**	**np**
Other chemicals	39	38	12	6	4	2	–	**np**
Rubber	**np**	46	9	5	**np**	**np**	**np**	**np**
Plastic	32	44	11	5	7	1	–	**np**
Total manufacturing	**31.6**	**31.8**	**15.1**	**9.7**	**8.2**	**2.3**	**0.4**	**0.8**
GDP	**35.3**	**25.2**	**16.9**	**10.9**	**6.9**	**1.7**	**2.0**	**1.2**

– Nil or rounded to zero. **np** Not published.

Source: ABS *(Manufacturing Industry, Australia*, Cat. no. 8221.0; *Australian National Accounts*, Cat. no. 5220.0).

C.8 Imports and exports

Imports

Imports comprise a significant proportion of the supply of chemicals and plastics in Australia. In 2001-02, around $18 billion[4] of chemical and plastics products, including medicinal and pharmaceutical products, were imported. This was 37 per cent of the supply of chemicals and plastics products. This was higher than for the manufacturing sector more generally (29 per cent) and for the total economy (9 per cent). Import penetration varied across the sectors. For example, 10 per cent of paints were imported, while 56 per cent of rubber products were imported (table C.4).

4 This is different from the ABS International Trade in Goods and Services figure of $14.5 billion on the next page. The difference is explained by the use of data from different years, and the fact that the 2001-02 figure includes medicinal and pharmaceutical products.

Table C.4 **Proportion of supply of chemicals and plastics that is imported, 2001-02**

Description	*Intermediate use*	*Final consumption*	*Total supply*
	%	%	%
Basic chemicals	50	34	44
Paints	11	19	10
Medicinal and pharmaceutical products, pesticides	49	48	42
Soap and detergents	23	23	21
Cosmetics and toiletry preparations	44	53	44
Other chemical products	28	21	26
Rubber products	59	57	56
Plastic products	29	20	27
Total chemicals and plastics	**40**	**43**	**37**
Total manufacturing	**29**	**42**	**29**
Total imports	**11**	**9**	**9**

Source: ABS (*Australian National Accounts: Input-Output Tables – Electronic Publication 2001-02*, Cat. no. 5209.0.55.001).

Some industries import chemicals and plastics to a greater extent than others. Of the largest users in 2001-02, the agriculture, forestry and fishing industry imported 72 per cent of its chemicals and plastics, the manufacturing industry 39 per cent and the construction industry 30 per cent. Other industries that use chemicals and plastics also vary in the extent to which they import. For example, the transport industry imported 70 per cent of the chemicals and plastics it used, while the mining industry imported only 29 per cent, and the accommodation industry 27 per cent (ABS 2006b).

Other data on imports are available from the Australian Bureau of Statistics' (ABS) International Trade in Goods and Services (ITGS) series. The ITGS series reports data under the Standard International Trade Classification (SITC) and has different disaggregation of imports and exports to manufacturing data. According to ITGS data from 2006-07, Australia imported around $14.5 billion of chemicals and plastics products (table C.5). This figure excludes medicinal and pharmaceutical products.

Table C.5 **Imports of chemicals and plastics, 2006-07**

Description	*Import value*	*Change since 1988-89*
	$m	%
Organic chemicals	3 341	188.0
Inorganic chemicals	1 066	56.5
Dyeing, tanning and colouring materials	593	174.5
Essential oils and resinoids and perfume materials; toilet, polishing and cleansing preparations	1 579	442.6
Fertilisers (excluding crude)	760	255.1
Plastics in primary forms	1 664	131.8
Plastics in non-primary forms	1 293	190.6
Chemical materials and products, **nes**	1 776	214.3
Rubber manufactures, **nes**	2 465	262.5
Total	**14 537**	**192.5**

nes Not elsewhere specified.

Source: ABS *(International Trade in Goods and Services, Australia 2008*, Cat. no. 5368.0) .

Exports

Australia produces a modest amount of chemicals and plastics for export. In 2001-02, 9 per cent of chemicals and plastics that were produced were exported — with a value added of $4.4 billion[5]. This compares to 15 per cent for the manufacturing industry and around 9 per cent for the total economy (table C.6).

5 This is different from the ABS ITGS figure of $3.9 billion below. The difference is explained by the use of data from a different year, and the fact that the 2001-02 figure includes medicinal and pharmaceutical products.

Table C.6 **Exports of chemicals and plastics, 2001-02**

Description	*Exports as a proportion of total supply*
	%
Basic chemicals	10.9
Paints	6.0
Medicinal and pharmaceutical products, pesticides	12.9
Soap and detergents	6.8
Cosmetics and toiletry preparations	11.2
Other chemical products	7.7
Rubber products	4.1
Plastic products	4.3
Total chemicals and plastics	**9.0**
Total manufacturing	**15.1**
Total exports	**9.4**

Source: ABS (*Australian National Accounts: Input-Output Tables – Electronic Publication 2001-02*, Cat. no. 5209.0.55.001).

International Trade in Goods and Services data on exports show that around $3.9 billion in chemicals and plastics products were exported in 2006-07. Fertiliser exports have increased dramatically since 1988-89 (although from a low base) (table C.7).

Table C.7 **Exports of chemicals and plastics, 2006-07**

Description	*Export value*	*Change since 1988-89*
	$m	%
Organic chemicals	108	17.4
Inorganic chemicals	775	770.8
Dyeing, tanning and colouring materials	623	323.8
Essential oils and resinoids and perfume materials; toilet, polishing and cleansing preparations	469	416.7
Fertilisers (excluding crude)	153	1 812.5
Plastics in primary forms	338	123.8
Plastics in non-primary forms	365	498.4
Chemical materials and products, **nes**	801	310.8
Rubber manufactures, **nes**	218	246.0
Total	**3 877**	**329.8**

nes Not elsewhere specified.

Source: ABS *(International Trade in Goods and Services, Australia 2008*, Cat. no. 5368.0).

C.9 The global industry

The OECD estimated that the global chemicals industry[6] had output of around US $1500 billion in 1998, and accounted for around 9 per cent of international trade (OECD 2001a). Australia accounts for around 0.9 per cent of the world's chemical industry output. This compares to 1.6 per cent of world GDP (World Bank 2008).

The bulk of world chemical production is in industrialised countries, with around 80 per cent of world production being produced by 16 countries[7] (OECD 2001a). OECD countries accounted for 78 per cent of world output in 1998, down from 83 per cent in 1970.

Data are available from the OECD on the chemicals industry since 1970. In the period between 1970 and 1998, the industry experienced rapid growth, from US $171 billion in 1970 to US $1500 billion in 1998.

The use of chemicals is highest in developed[8] countries, demonstrating a correlation between GDP and chemical consumption per person (OECD 2001b). The OECD also predicts that the use of chemicals will grow more rapidly in developing countries than in industrialised countries over the next 20 years, and that by 2020, the developing world may account for 33 per cent of world chemical demand, compared with 23 per cent in 1995.

6 The definition used for output in the global chemicals industry includes pharmaceuticals and excludes rubber.

7 The United States of America, Japan, Germany, China, France, the United Kingdom, Italy, Korea, Brazil, Belgium/Luxemburg, Spain, the Netherlands, Taiwan, Switzerland and Russia.

8 The OECD includes Japan, the United States of America, Canada, Western Europe, Australia and New Zealand as developed countries (OECD 2001b).

D Major hazard facilities

Major hazard facilities (MHFs) are workplaces that store, handle or process large quantities of hazardous material. Although MHF regulatory reform, of itself, does not fall within the scope of this study, it is relevant because MHFs include chemical manufacturing and storage facilities. Incidents at such facilities have the potential to cause serious damage to employees, people in surrounding areas and the environment. They can be broadly described as 'low probability–high cost' (NOHSC 2002b, p. 2). Controls that are stricter than those generally found in standard occupational health and safety (OHS) legislation are often used by governments to regulate these facilities.

D.1 Background

Major hazard facilities typically include chemical manufacturing sites, oil refineries, gas processing plants, liquid petroleum gas facilities, and other manufacturing and transport depots. Around 200 workplaces in Australia are considered to be MHFs (ASCC 2004b).

There have been several major incidents at facilities in Australia. Some recent examples include:

- The explosion at the Longford gas plant in 1998, which resulted in the loss of two lives and eight serious injuries, a fire that lasted for two days, and the gas supply to south-eastern Australia being cut off for almost three weeks. The cost to the Victorian economy was estimated to be more than $1 billion (NOHSC 2002b). The Longford Royal Commission (1999) found that Esso was in breach of s. 21 of the *Occupational Health and Safety Act 1985* (Vic), and in addition observed that:

  > The failure to conduct a HAZOP study or to carry out any other adequate procedures for the identification of hazards in [gas plant 1] contributed to the occurrence of the explosion and fire. (p. 235)

- Three incidents at the Moomba gas plant between 2001 and 2004, which resulted in the loss of one life and denied gas supply to heavy industrial users.

- Fires at Seven Hills in 1989, St Peters in 1990, Coode Island in 1991 (NOHSC 2002a), and at the Binary Industries factory in Queensland in 2005.[1]

Australian governments, through the National Occupational Health and Safety Commission (NOHSC), completed the drafting of a national standard and code of practice for the control of MHFs in 1996.

D.2 The regulatory framework

Standard setting

The policy framework for managing MHFs in Australia is similar to the framework adopted for other areas of OHS controls. The *Control of Major Hazard Facilities — National Standard* and *National Code of Practice* were developed by NOHSC — a tripartite body established by the Australian Government to facilitate a national approach to OHS policy — taking into account existing domestic initiatives and international approaches.[2]

The National Standard and Code of Practice are maintained by the Australian Safety and Compensation Council (ASCC), which succeeded NOHSC in 2005. Implementation and enforcement is the responsibility of each jurisdiction. As the ASCC is not a statutory body, it has no power to administer legislation, nor to enforce the codes it oversees.

The objective of the Standard 'is to prevent major accidents and near misses, and to minimise the effects of any major accidents and near misses' resulting from the operation of a MHF (NOHSC 2002a, p. 6). It sets out the process for administering MHFs at a high level. For example, it provides definitions of key terms and explains the responsibilities of the various stakeholders — facility operators, employees and public authorities. The Code of Practice provides guidance on how to meet the requirements of the Standard. The criteria for classifying a MHF and obligations of the operators are summarised in box D.1.

1 The Binary Industries factory was subject to provisions under the *Dangerous Goods Safety Management Act 2001* (Qld) relating to MHFs and Large Dangerous Goods Locations. A subsequent inspection program was undertaken at the Narangba Industrial Estate (Queensland 2007).

2 In particular, the International Labour Organisation's Convention for the Prevention of Major Industrial Accidents and the European Community's Draft Council Directive on the Control of Major Accident Hazards Involving Dangerous Substances were drawn upon (NOHSC 2002a).

Box D.1 Overview of the National Standard for the Control of Major Hazard Facilities

In accordance with the National Standard for the Control of Major Hazard Facilities, a facility would be classified as a major hazard facility (MHF) if one of the following applies:

- a scheduled substance (as listed in Schedule 1 of the Standard) is, or may be present, at the facility in a quantity in excess of the relevant threshold quantity
- multiple scheduled substances are present, if for all chemicals present, the sum of the quantity stored divided by its threshold quantity exceeds one.

In these instances, the facility would automatically be classified as a MHF.

In circumstances where the amount of scheduled substances present at the site is between 10 and 100 per cent of the threshold value or aggregate quantity, the regulator has the option to classify the facility based on risk, taking into account a variety of issues including the types of material present, the processes involved at the facility and offsite issues such as surrounding land use. However, its classification is not mandated by the Standard.

Under the Standard, the regulator can classify a facility where radioactive and/or biological material or any other unscheduled material are present at the site.

The Standard obligates operators of MHFs to notify the regulator where the amount of materials present at the site exceeds 10 per cent of the threshold value or aggregate quantity.

Obligations of MHF operators

Once a facility is classified as a MHF, the operator is required to:

- carry out and document a systematic risk assessment identifying hazards and potential events that could lead to a major accident, and the type, likelihood and consequences of potential major accidents
- minimise the risks associated with the facility by eliminating hazards and implementing mitigation measures and procedures at the facility
- establish, implement and maintain a documented safety management system that sets out safety objectives, systems and procedures by which these are to be achieved and performance standards to be met, and the means by which these standards are to be maintained
- prepare a safety report. A safety report is a written presentation of the technical, management and operational information covering the hazards and risks of a MHF, and their control, and which provides justification for the measures taken to ensure the safe operation of the facility.

Source: NOHSC (2002a).

The current review of the Standard and Code is consistent with a COAG agreement (2004b)[3] that requires all national standards and codes to be reviewed at least every ten years to ensure their currency.

D.3 Adoption and implementation of the National Standard and Code

Although representatives from the Commonwealth, state and territory governments (as well as employer and employee groups) agree on national standards and codes developed under the NOHSC framework, when and how they are applied is determined by each jurisdiction.[4]

The Commonwealth, Victoria, Queensland, Western Australia, the Northern Territory, and most recently, New South Wales, have introduced MHF regulations. While new regulations took effect in Western Australia on 1 March 2008, the Standard had been applied there via licensing conditions for some time. South Australia and Tasmania (ACT does not have any MHFs) have drafted or are in the process of enacting MHF regulations (table D.1). Facilities in Commonwealth, state and territory coastal waters are regulated under a separate framework by the National Offshore Petroleum Safety Authority.

There are several inconsistencies in the adoption and implementation of the Standard and Code, some of which have implications for the effectiveness and efficiency of the control of MHFs.

3 The review requirement is set out in *Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard Setting Bodies*, endorsed by COAG in April 1995 and most recently amended in June 2004.

4 For NOHSC to declare national standards and codes, there had to be unanimous support from the members. Under the ASCC, the decision making rule has been reduced to a two-thirds majority.

Table D.1 **Administration and enforcement of MHF regulations[a]**

Jurisdiction	*Legislation*	*Lead regulators/agencies*	*Number of facilities*[b]
Commonwealth	*Occupational Health and Safety Act 1991* Occupational Health and Safety (Safety Standards) Regulations 1994	Comcare	40
Australian coastal waters	*Petroleum Submerged Lands Act 1967* Petroleum Submerged Lands (Management of Safety on Offshore Facilities) Regulations 1996 Equivalent state legislation	National Offshore Petroleum Safety Authority (NOPSA)	149**c**
New South Wales	*Occupational Health and Safety Act 2000* Occupational Health and Safety Amendment (Major Hazard Facilities) Regulations 2008	NSW WorkCover Authority	32
Victoria	*Occupational Health and Safety Act 2004* Occupational Health and Safety Regulations 2007 (Part 5.2)	WorkSafe Victoria	45
Queensland	*Dangerous Goods Safety Management Act 2001* Dangerous Goods Safety Management Regulations 2001	Chemical Hazards and Emergency Management Services Unit (Department of Emergency Services)	32
Western Australia	*Dangerous Goods Safety Act 2004* Dangerous Goods Safety (Major Hazard Facilities) Regulations 2007	Resources Safety Petroleum and Major Hazard Facilities Safety Branch (Department of Consumer & Employment Protection)	26
South Australia	Dangerous Substances and Major Hazard Facilities Bill 2006[d]	SafeWork SA	12
Tasmania	Dangerous *Substances (Safe Handling) Act 2005* Dangerous Substances (Safe Handling) Regulations[e]	WorkPlace Standards Tasmania	**na**
Northern Territory	*Workplace Health and Safety Act* Workplace Health and Safety Regulations *Dangerous Goods Act* Dangerous Goods Regulations	Northern Territory WorkSafe	5

a Correct at June 2007. **b** Numbers of facilities frequently vary and are included here only as a guide. **c** Total number of offshore facilities regulated by NOPSA, not all of which are classified as MHFs (or equivalent). **d** Legislation yet to be passed or yet to take effect. **e** Regulations in draft form. **na** Not available.

Adoption of the Standard has been patchy

Although the National Standard was drafted in 1996, the tardiness in adopting regulations arguably exposes the affected communities and the environment to unwarranted additional risk. This is not to ignore, however, the commercial, common law and other regulatory incentives that exist for operators to put systems in place to mitigate such risks.

Delays in regulation create uncertainty for MHF operators regarding their future regulatory obligations. As a result, operators might choose to defer investment in

safety related infrastructure until the compliance requirements have become known. Operators in jurisdictions that impose MHF controls may also suffer some competitive disadvantage, as they incur the compliance costs that their competitors located in regulation-free jurisdictions may choose to avoid.

The Plastics and Chemicals Industries Association (PACIA) (sub. 33, attachment 2) suggested part of the reason that jurisdictions delay implementing MHF regulations is that they lack expertise. They noted that it is difficult for governments, particularly those of smaller jurisdictions, to attract and retain staff with the relevant experience in MHF regulation and control.

Variation in the regulatory provisions

There is a degree of inconsistency in technical specifications and definitions. Box D.2 contains some examples of inconsistencies provided by PACIA (sub. 33, attachment 2). The first refers to discretionary provisions allowing a facility that exceeds the threshold limits of scheduled chemicals to not be classified as a MHF if it is determined that the associated risk does not warrant MHF-type controls. For example, Queensland and Western Australian regulations include such discretionary provisions, whereas facilities in Victoria will be classified as MHFs wherever scheduled chemical quantities exceed the specified threshold. Technically, this means that similar facilities could have MHF classification in one jurisdiction and not in another.

Box D.2 Some examples of inconsistencies across jurisdictions

In its submission to this study, the Plastics and Chemicals Industries Association (PACIA, sub. 33, attachment 2) identified a number of ways in which jurisdictions have applied the National Standard for the Control of Major Hazard Facilities in legislation, including the following:

- The definition of what is a major hazard facility (MHF) — some regulators have the discretion to not classify a facility as a MHF even where scheduled substances exceeding the thresholds set in the National Standard are present.
- The scope of the regulations — in some jurisdictions the safety case need only deal with health and safety issues, while in others it must also address environmental or land use planning issues, or property issues. These differences impact on the scope and complexity, and hence cost, of the safety case that facilities must develop.

(Continued next page)

Box D.2 (continued)

- The choice of lead agency — MHF regulation is administered by different lead agencies, for example, WorkSafe in Victoria and Emergency Services in Queensland. This results in some differences in the focus of implementation.
- The definition of what is a 'major incident' — for example, Queensland deems a damage bill of $50 000 or a very short stay in hospital as the threshold. This may capture many more incidents within the regime than would occur in other jurisdictions.
- Formal coverage of security — while most jurisdictions address security at MHFs in a generic way consistent with the National Standard, New South Wales regulations contain more prescriptive and detailed security requirements.

Source: PACIA (sub. 33, attachment 2).

Another area of variation across jurisdictions, which has been of some concern to industry, is in the application of licensing and registration models. For example, MHF operators must be licensed in Victoria, Western Australian and the Commonwealth, and under proposed legislation in South Australia. In other jurisdictions — New South Wales, Queensland and the Northern Territory — operators do not require licences, but instead require either classification or registration. Fees are charged (or proposed) in some jurisdictions and not in others.

New South Wales has recently introduced MHF regulations and has included new security requirements that depart from those in the National Standard and differ from security requirements for MHFs in other jurisdictions. It has taken this position on the basis that the provisions in the Standard no longer reflect the current security environment and that new provisions aim to 'reflect the most up-to-date assessment of the nature and level of potential local security threats' (sub. DR111, p. 9). Industry has expressed concern, however, that moves to introduce specific requirements for security at MHFs will add further complexity and inconsistency to the regulatory framework. PACIA argued that the scope of security provisions in the regulations should be kept consistent with the National Standard and that any additional security requirements be considered as part of the current national process underway in the *COAG Review of Hazardous Materials*, and agreed at a national level (pers. comm., 4 June 2008). It is expected that any new requirements will also be considered as part of the current review of the National Standard.

Inconsistency in institutional arrangements

Jurisdictions have chosen various lead agencies to regulate MHFs, and in some instances have allocated responsibility for the National Standard across multiple pieces of legislation. For example, some jurisdictions use OHS legislation, and the lead OHS regulatory agency to administer MHF controls. However, other jurisdictions use dangerous goods legislation and other regulatory agencies (table D.1). Inconsistency in institutional arrangements across jurisdictions can add to complexity, and therefore, the compliance burden for operators with facilities in multiple jurisdictions.

At a jurisdictional level, the responsibility for the regulation of MHFs often lies with a number of agencies. This adds to complexity and potential duplication in both regulatory and compliance functions. Regulatory agencies, other than the lead agency, such as environmental protection regulators, fire and emergency services, and planning bodies/local councils, need to be well coordinated in order to provide consistent advice to operators.

Cost recovery

Jurisdictions have taken different approaches to cost recovery for assessing MHFs. Table D.2 contains cost information for a sample of PACIA member companies that have facilities in multiple jurisdictions, and indicates a significant degree of variation in fees charged by regulators. Queensland does not currently recover costs of assessing MHFs. WorkSafe Victoria sets a maximum fee of $56 560, with licences typically costing between $30 000 and $40 000 (WorkSafe Victoria, pers. comm., 11 February 2008). The costs to facilities in New South Wales were based on fees proposed prior to the introduction of the legislation, and indicated that costs to operators would be significantly higher in that jurisdiction.[5]

Differences in fees may also reflect the size and characteristics of the industries in each jurisdiction. Governments should ensure that fees are set transparently and are consistent with their respective cost recovery policies.

5 New South Wales regulations for major hazard facilities became effective on 14 July 2008. The relevant fees had not been finalised at the time of printing this report.

Table D.2 **Classification fees across jurisdictions, selected PACIA member companies**

Sample Company	*Queensland*	*Victoria (1st licence)*	*Victoria (renewal)*	*NSW Proposed*
	$ per 5 years	$ per 5 years	$ per 5 years	$ per 5 years
A	–	35 000	..	400 000
B	–	34 187	..	350 000
C	–	36 000	30 000	440 000
D	..	52 000	..	440 000
E	..	52 000	39 000	400 000
F	–	52 000	..	440 000
G	..	50 000	25 951	400 000

– Nil or rounded to zero. .. Not applicable.

Source: PACIA (sub. 33, attachment 2).

D.4 Existing mechanisms to address concerns about interjurisdictional inconsistency

Major hazard facility stakeholders — governments, employer and employee groups — have been aware of the concerns relating to interjurisdictional inconsistency in application of the national standard for some time. For example, in 2001, the Workplace Relations Ministers' Council (WRMC) endorsed five strategies (and three related actions) to achieve national consistency in MHF regulation. Among other things, the WRMC asked NOHSC to:

- facilitate a consistent regulatory framework in all jurisdictions (including a review of Schedule 1)
- facilitate the sharing of expertise among jurisdictions
- facilitate the development of practical guidance and training material.

The NOHSC was also asked to report on the progress in implementing the National Standard across jurisdictions and the level of consistency. Annual Situation Reports were produced for 2002 through to 2004, and are available on the ASCC website.

A further government-led initiative to facilitate greater coordination of MHF regulation across jurisdictions was the establishment of the Major Hazard Facilities Working Group in 2005. This Working Group comprises Commonwealth, state and territory government regulators, and meets once or twice each year to share information about MHF regulation and safety issues.

D.5 The case for reform

The Commission has not received any submissions suggesting that MHF regulations are not warranted for chemicals facilities. However, there appears to be little quantitative information available regarding the net benefit of regulation.

In the original regulatory impact statement for its MHF regulations in 2000, the Victorian Government estimated that the average cost of (compliance with) MHF regulation would be between $1.00 and $1.58 per Victorian, and judged that '[t]o the extent that Victorians value the potential benefits accruing to the proposed Regulations at more than $1.58 per year, then the benefits would exceed the costs' (sub. DR112, p.13). The Commission acknowledges that quantifying the benefits associated with this type of regulation is problematic. As this approach apportions costs only, without making any comparisons with incremental gain, it is difficult to make conclusions about net benefit. Further, reducing the cost to a per capita basis could appear to trivialise a cost to industry that is significant at a facility level. To more accurately estimate the true cost of the regulation to the community, administration costs such as the preparation and passage of the legislation, and the costs of regulating (that are not recovered through fees and charges), should also be taken into account.

It is also difficult to make broad conclusions about the effectiveness of MHF regulation based on the number and frequency of major incidents that have occurred before or after its implementation. Qualitative assessments about the causes of incidents might be more informative but the counterfactual is not easily estimated: that is, what would have happened if the MHF had (or did not have) the appropriate plans in place.

Australian governments, at least since 2001, have recognised that there are advantages to implementing the National Standard and Code consistently. In practice, achieving consistency has been difficult given that: jurisdictions have legislated under varying circumstances, including in response to a major accident; they have adopted, then built on, different regulatory approaches for hazardous substances, dangerous goods and OHS; there are differences in regulatory culture and in how legislative drafters across jurisdictions have interpreted national standards and codes. It has been difficult to assess the material impact of the resulting variation on the effective operation of the regulations due to limited cost-benefit analyses.

It is unclear that moving to a nationally-uniform system from the current set of arrangements would provide a net benefit to the community given the one-off costs associated with doing so. However, a greater degree of national consistency would reduce unnecessary complexity and ongoing compliance and administration costs,

create scale economies, and avoid fragmentation of scarce policy and regulatory expertise. It could also facilitate enforcement. Regulation of MHFs requires a level of specialised expertise that is in short supply. A critical mass of expert resources that could be more effectively employed across multiple jurisdictions could improve both the effectiveness and efficiency of regulation in this area.

D.6 Potential reform areas for consideration

The Commission endorses the ASCC review of the National Standard, and highlights potential areas for further investigation as part of that process. In particular, the review should assess the case for the regulation of MHFs over and above generic legislative requirements relating to OHS, environmental protection, land use planning and the like. The review could consider the options for co-regulation and self-regulation, examining whether firms' own commercial incentives, obligations under common law and other regulatory requirements are sufficient for adequate systems and controls to be put in place to avoid an incident.

The review should gather data from both industry and regulators, wherever possible, to gain some understanding of the costs of unnecessary complexity and duplication in administration that can be attributed to a jurisdiction's institutional arrangements (this includes compliance costs for operators as well as administration costs for regulators). Such information about the nature and degree of unnecessary complexity and duplication within a jurisdiction's regulatory framework would highlight areas for either reform or improved interagency coordination, such as through memorandums of understanding.[6] Other analyses should include the costs of compliance for operators of comparable facilities in different jurisdictions, in terms of capital and operating costs, and any impacts that the inconsistent adoption of MHF regulations has had on competitive neutrality across jurisdictions.

A greater sense of the practical implications of the inconsistencies that exist between jurisdictions, and a rationale for their existence, could assist the review to determine whether these represent substantive issues, and how easily they can be addressed. It will also be important to consider reasons for the delays in the uptake of the National Standard in legislation by some jurisdictions.

6 A memorandum of understanding between WorkSafe Victoria and the Environment Protection Authority enables these agencies to coordinate some inspection and enforcement activity. It is currently being renewed.

E Compliance and administration costs

E.1 Background and purpose

Regulation necessarily imposes compliance costs on industry, and administration costs on governments, even when it is well designed and implemented.

The compliance costs of chemicals and plastics regulation include licence and registration fees, assessment and approval of new chemicals, and resources used for record keeping, reporting and other compliance related activities. The generally more significant costs of compliance are in the changes firms make to the way they operate, in order to comply with regulations.

Administration costs include conducting legislative processes — from community consultation through to enacting legislation — the establishment and operation of agencies to undertake risk assessment and risk management functions, and administration and enforcement of the regulations. In many cases, administration costs are partly or wholly cost recovered from regulated entities.

The cost to government of administering regulations, and to firms of complying with them, should ideally be proportionate to the problem and the minimum necessary to achieve effective outcomes. Costs may be higher than necessary if best-practice approaches to regulatory design, administration and/or enforcement are not being used. The extent to which a regulation's costs are higher than necessary is termed excess or unnecessary regulatory burden. Box E.1 describes some of the ways in which unnecessary burden can impact on industry.

Box E.1 **Impacts of unnecessary regulatory burden on firms**

- Unnecessary (administrative) compliance costs can reduce firms' profitability and influence production decisions in ways that are unintended by the regulation.
- Regulatory arrangements can create a competitive disadvantage for firms depending on their size and geographical location.
- The introduction of safer or more effective chemicals can be impeded as a result of regulatory burden.
- Some regulatory reforms can reduce the net benefit to the community by increasing compliance costs with no offsetting benefit, or replacing some compliance costs with other larger costs.

The Commission asked all governments to provide data on the cost of administering their chemicals and plastics regulations. A survey of firms subject to those regulations was not pursued given the diversity of firms and regulations involved, and the difficulty of ensuring a representative sample, and designing questions firms could readily answer. Instead, the Commission issued a general request to industry bodies and individual interested firms to submit evidence about cases where compliance costs are claimed to be excessive.

However, compliance and administration costs can be difficult to quantify, and the costs of unnecessary burden even more so. Chapter 2 discusses unnecessary burden and the difficulties inherent in obtaining cost data related to chemicals and plastics regulation. It is difficult for firms to identify the incremental costs of regulation from the costs they would otherwise record for accounting purposes. Further, it is unrealistic to expect individual businesses to know what compliance costs would be under best practice regulation, and to calculate that part of the cost that comprises unnecessary burden. Similarly, regulators (such as a workplace safety authority) often operate across a range of industries and products, and may have difficulty attributing costs to regulating for any one particular industry or product.

The Commission has sought to include stakeholder evidence, including cost data, in the relevant chapters of the study. As it was not possible to include all the information contained in submissions, the purpose of this appendix is to consolidate the compliance and administration cost information that was submitted to the study. This information is intended to provide examples of the types of compliance and administration costs faced by firms and governments respectively, and some broad indicators of their likely magnitudes.

The Commission received a limited amount of cost information that could be used to determine the relative efficiency of existing formal regulation, and therefore the

information contained here is largely anecdotal. The Commission has not attempted to quantify the compliance or administration burden — neither the overall burden nor any element that may constitute that unnecessary burden — of chemicals and plastics regulation. The costs highlighted in this appendix do not represent a comprehensive inventory of costs related to chemicals and plastics regulation, nor has the Commission attempted to verify any of the information.

Further, this appendix considers cost information only, and does not include information relating to the benefits of regulation, nor does it take into account the potential costs to the community of any regulatory gaps.

E.2 Compliance costs can reduce firms' profitability and unduly influence production decisions

Firms are typically required to demonstrate compliance with various regulations through reporting and documentation, which takes time and resources. Regulation will also often involve the payment of fees for registrations, licences, inspections and security checks.

If regulation is unjustified, excessively prescriptive, overly complex, duplicative or inconsistent, it is likely to impose unnecessary costs on firms and influence production decisions in ways that are unintended by the regulation. For example, firms may need to spend additional time trying to understand complex requirements and fulfil duplicative reporting and documentation obligations.

Firms may also need to adopt procedures or use inputs in order to meet regulatory requirements, over and above that required for profitable operation. Further, firms may indeed choose to use alternative procedures or inputs in order to avoid becoming subject to regulatory requirements. For example, a firm might choose a certain input, manufacturing or transportation method over an otherwise cheaper, more effective, alternative, to avoid the costs and inconvenience brought about by regulation imposed on that alternative.

Hazard and risk assessment

A significant proportion of the compliance cost information provided by industry was in relation to hazard and risk assessment (chapters 4 and 8). Table 4.1 contains international comparative data on assessment fees for non-polymer chemicals provided by ACCORD Australasia (sub. 42). Box 4.3 contains participant examples of National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

application data costs for products they maintain are already established in the US market.

Science Industry Australia provided an example from Eppendorf South Pacific Pty Ltd relating to the cost of complying with regulation for very small quantities of silicon grease and reagent grade water that it imports for laboratory uses:

> … NICNAS requires companies to pay a relatively large annual fee of $381 for very small quantities of Tier 1 chemicals. DHA [Department of Health and Ageing] sets the annual fee according to the monetary value of the chemical in question. In this instance, the annual fee is $381 for each incidence of chemicals valued at between $1 and $499 000. The NICNAS fee is aimed at recovering costs associated with the implementation of the *Industrial Chemicals Act 1989*.
>
> … the science industry includes suppliers and users of small to medium amounts of high purity chemicals. The chemical transactions often involve less than 1 gram of material. However, these quantities are regulated in the same or similar ways as bulk chemicals are regulated elsewhere in the chemicals and plastics industry. (sub 55, pp. 1–2)

Chapter 8 also provides discussion of the costs of registration for agricultural and veterinary (agvet) chemicals. Table 8.1 contains international comparative data on registration fees, noting that part of the observed differences can be explained by the differences in cost-recovery arrangements of the agencies that charge the fees.

Control-of-use for agvet chemicals

Industry maintained it incurs unnecessary costs as a result of variation in jurisdictions' control-of-use regulations for agvet chemicals. Specifically, users operating in multiple jurisdictions incur costs as a result of variation in the training, licensing, insurance and record keeping requirements, and off-label use arrangements.

Section 8.3 discusses issues relating to control-of-use in more detail and table 8.2 highlights the differences in jurisdictions' regulation of pesticide use. The Aerial Agricultural Association of Australia (sub. 17) and Croplife Australia (sub. 35) identified areas where unnecessary compliance costs arise for aerial applicators who operate in multiple jurisdictions (box E.2). Further, inconsistency in requirements across jurisdictions has implications for competitive neutrality, with operators in some jurisdictions facing higher compliance costs than operators in other jurisdictions. Competitive neutrality is discussed in section E.3.

Box E.2 **Interjurisdictional inconsistency in control-of-use regulations: aerial application**

Croplife Australia and the Aerial Agricultural Association of Australia (AAAA) expressed concern that inconsistent regulations for aerial application of pesticides in different states and territories are imposing unnecessary costs through duplication of licensing, differing training and record keeping requirements, and approaches to compliance and education:

> For example, despite the Federal/State Product Security and Integrity Committee and various working groups considering the issue since 2001, there is still not an agreed nationally consistent licence regime for the licensing of pilots and businesses engaged in aerial application. Each State still pursues their own licensing regime and charges.
>
> Similarly, States have different record keeping and training requirements. A key issue for AAAA is the ongoing lack of requirement in all States except NSW for mandatory training for all chemical applicators, including ground applicators and farmer applicators.
>
> State by State reform of control of use regulation is disjointed and uncoordinated, with each State adopting a different philosophical approach to the management of chemical application.
>
> The reviews in each jurisdiction take up valuable industry time, result in different compliance regimes and add to confusion and cost for the increasing number of aerial applicators that operate in a number of jurisdictions for good economic reasons. (AAAA, sub. 17, p. 5)

Croplife Australia also raised the following:

> All states except South Australia and Queensland have a requirement for aerial agricultural operators to carry $30 000 insurance to cover potential spray drift damage. It is questionable whether state governments should regulate businesses for what should be a business decision. (sub. 35, p. 30)

Public health

A number of examples of unnecessary costs for firms related to the public health aspects of chemical use (chapter 5). With regards to poisons, participants identified institutional arrangements and decision making processes for poisons scheduling and regulation, inconsistencies in controls between jurisdictions, and overlaps with other areas of regulation as factors adding to the compliance burden (section 5.1).

Inconsistencies across jurisdictions in retail storage controls for schedule 5 and 6 poisons were identified by participants as a source of unnecessary compliance costs for chemicals manufacturers, distributors and retailers who operate in multiple jurisdictions (section 5.1). New South Wales and South Australia take a quite prescriptive approach, and either more general or no requirements apply in other

jurisdictions.[1] This could also have some impact on competitive neutrality, potentially giving a competitive advantage to those firms operating in a less costly regulatory environment (discussed in section E.3).

An issue was raised in relation to recognition of foreign labels and unique Australian labelling requirements for consumer products (section 5.3). In its submission, ACCORD Australasia (sub. 42) provided member examples of compliance costs relating to over-labelling (box E.3). Appendix G (section G.2) discusses potential costs and benefits associated with aligning with, or deviating from, labelling schemes of Australia's major trading partners.

Box E.3 **Burden of unique Australian labelling requirements**

An ACCORD member noted that certain products must display specific weights and measures information on packaging of 'low risk products' for the Australian market, and that the labels on certain products originating from the EU and the USA do not comply with these specifications:

> [This requires] us to either go to the lengths of having our own packaging artwork for Australia, which is not a very large market and therefore the costs are high for us, or overlabel our products often with two or more overlabels per product. To have our own packaging, we need to order large quantities of stock to justify the dedicated production run and this can result in high overstocks in our warehouse as well. The overlabelling of products results in double-handling which poses a logistical obstacle which is time-consuming and expensive. (ACCORD Australasia, sub. 42, p. 9)

Another ACCORD member estimated the cost to over-label a product because of unique Australian requirements is approximately 50 cents per unit. Based on the number of units sold in Australia in 2006 (130 million), the additional costs to industry in any one year, could be as high as $65 million.

In the past, other ACCORD members have provided the following advice regarding costs of over-labelling:

> Over labelling of products, both primarily and secondarily, which involves the double-handling of the product affecting the quality and retail image of the product (i.e. removal of cellophane, removal of jar from carton and application of sticker to front and back jar label, application of sticker to front and back of carton). Using a particular product example, 7300 units ordered requiring local over labelling where the cost of compliance affected the profit margin by a 9 per cent loss on the net profit for this product.
>
> Labelling changes can be costed - it ranges from $25 000 to $75 000 depending on the type/quality/extent of packaging. (ACCORD Australasia, sub. 42, p. 9)

[1] However, the Commission notes that South Australia is currently implementing a number of initiatives including removal of licensing requirements for manufacturers and wholesalers of Schedule 5 and 6 substances (SA Government, sub. DR110).

Another example provided by ACCORD Australasia referred to overlaps in the controls for domestic (household) poisons, and for those used in the workplace (section 5.1). This can impose unnecessary compliance and administration costs on firms and governments respectively.

Duplication and inconsistency in the decision making arrangements for regulating food safety were cited as an issue for industry (section 5.5). In particular, the operation of a dual system where the Australian Pesticides and Veterinary Medicines Authority (APVMA) prescribes minimum residue levels (MRLs) and Food Standards Australia New Zealand later writes those MRLs into the Food Standards Code can lead to lengthy delays, and therefore costs, for farmers.

Transport

Participants in this study noted that jurisdictional variation in explosives transport regulations — developed by individual jurisdictions, which refer to Australian Code for the Transport of Explosives by Road and Rail (AEC) — imposes unnecessary compliance costs, especially for firms operating in multiple jurisdictions (chapter 7). According to the Australian Explosives Industry and Safety Group Inc. (AEISG) the inconsistencies that currently exist in the AEC 'are a costly irritant to the nationwide transport of explosives' (sub. DR94, p. 1).

Further, the AEISG stated that the current version of the AEC includes unique Australian requirements in relation to packaging and labelling (sub. DR94, p. 4). The AEISG maintained that these involve considerable compliance costs and inconvenience, given the extent to which explosives are now imported and exported.

The Australasian Railways Association (sub. DR95, p. 6) argued that for rail operators transporting explosives and other dangerous goods on the same rail services, the lack of integration of the AEC and the Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG Code) is a source of inefficiency, given the added regulatory complexity and paperwork involved for operators. The Commission has noted the possible merits of amalgamating the two codes, but considers that inter jurisdictional differences in explosives transport regulation should be addressed first.

The current updating of the ADG Code and AEC to largely align with the latest version of the UN Recommendations on the Transport of Dangerous Goods Model Regulations, will lessen compliance costs for importers and exporters. The compatibility of land transport regulation with that of domestic air and sea transport, which are already based on the latest UN Code, will also be enhanced.

Occupational health and safety

Use of chemicals in the workplace is subject to occupational health and safety regulation, which is based on national standards and implemented at a jurisdictional level. Inconsistency in the implementation and interpretation of the standards by jurisdictions was raised by industry as a source of unnecessary compliance costs (chapter 6).

The Australian Safety and Compensation Council (ASCC) developed drafts for a consolidated system of national standards and codes for workplace hazardous chemicals to replace the existing national standards, model regulations and codes for hazardous substances and dangerous goods (section 6.3). The proposed new system is based on the Globally Harmonised System of Classification and Labelling of Chemicals. The ASCC estimated the costs for it to implement the new system would be around $230 000 over five years. In addition, it was estimated that the cost to states and territories would be less than $1 million, and to industry more than $452 million, over the same period. However, some industry participants and regulators suggested that the costs may have been underestimated.

The ASCC estimated the benefits to industry of a 10 per cent reduction in the time taken for risk assessments would deliver savings to industry with a net present value of over $174 million.[2] The new system is also considered to offer benefits to industry through information sharing and trade facilitation. The ASCC estimated the net present value over 30 years of these benefits to be $442 million, however, the Commission considers this to be a significant overestimate.

Environment

Regulation for managing the impact of chemicals on the environment is discussed in chapter 9.

The Plastics and Chemicals Industries Association (PACIA) (sub. 33a, pp. 30–31) identified the increasing overlap and inconsistency of regulation in relation to climate change as an area of concern:

> An area of significant concern to PACIA is the increasing overlap and inconsistency of regulation in relation to climate change … The growth in regulation is further complicated when considering the inextricable link between energy use and greenhouse emissions. As such, there is significant overlap in the areas of emissions reporting, emissions trading, energy efficiency programs and environmental approvals process.

2 This figure is the ASCC's estimate of the net present value of the savings calculated over a period of 30 years using a discount rate of 7 per cent.

The reporting burden is the single biggest concern to the plastics and chemicals industry in relation to greenhouse and energy policy. Companies currently report to a number of voluntary and mandatory schemes, including:

- Greenhouse Challenge Plus programme;
- Energy Efficiency Opportunities (EEO) programme;
- Requirements under the State and Territory Government Approvals processes;
- State and Territory Government Greenhouse Gas Inventories, such as the Western Australian Greenhouse Gas Inventory (WAGGI); and
- State and Territory Greenhouse, Energy and Water Schemes, such as the Victorian Government Environment and Resource Efficiency Plans (EREP).

… a PACIA member company estimates that the cost of dealing with duplicate legislation would be $30 000 per site each year. The cost comprised mostly additional labour required to duplicate reporting etc, but there is also an additional cost that is caused by having to prepare and conduct different inductions and training programs in each state due to the need to cater for local differences in legislation.

PACIA also provided compliance costs information associated with the National Pollutant Inventory (box E.4 and table E.1).

Box E.4 PACIA cost estimates for compliance with National Pollutant Inventory requirements

PACIA provided the following description of costs relating to compliance with the National Pollutant Inventory requirements:

> To help determine the financial impacts of the amended variation, the Department of the Environment and Water Resources commissioned EECO Pty Ltd to investigate and report on the financial impact associated with transfer reporting under the new requirements.
>
> This report investigates the costs of reporting transfers to the National Pollutant Inventory (NPI). The obligation to report transfers is part of a variation to the current NPI NEPM [National Environmental Protection Measure] requirements. A case study on the chemical industry was completed very late in the review stage to explore the tasks necessary for industry to report transfers and their associated costs.
>
> For the industrial estate, the total cost for transfer reporting in the first year is $26 300 and includes the set-up costs plus ongoing costs.
>
> The total cost of transfer reporting in the second year (and thereafter) is $12 200. The approximate cost of ongoing transfer reporting per facility is $2440.
>
> The estimates represent the additional costs of mandatory transfer reporting. In some cases, a facility may determine that they do not need to report transfers, but they nonetheless incur costs in learning the transfer requirements and determining the facility's reporting obligations. Ongoing costs beyond the first year are lower as the reporting obligations are known and the need for waste characterisation (including chemical analysis) is reduced or eliminated.
>
> To properly self-assess the need to report transfers, a facility needs to:
>
> - review regulatory requirements
> - review the NPI substances for which they exceed the reporting threshold
> - identify the waste streams that may contain these NPI substances
> - review existing data including waste stream analyses
> - identify any data gaps and if required, obtain the required data.
>
> Where significant data gaps exist, laboratory analyses may be required. Analytical costs are mostly incurred in the first year as transfer factors should be developed for subsequent years. Ongoing analyses are only needed for highly variable waste streams or to modify transfer factors to account for significant process changes.

Source: PACIA (sub. 33, attachment 1, p. 33)

Table E.1 **PACIA reporting cost estimates: National Pollutant Inventory**

Task	*Staff 1 ($200 p/hr)*	*Staff 2 ($150 p/hr)*	*Staff 3 ($100 p/hr)*	*Staff 4 ($50 p/hr)*	*Analyses*	*Subtotal*
First year						
Understanding regulatory requirements	2 hrs	8 hrs	2 hrs	1 hr	..	$1 850
Determining reporting obligations	..	19 hrs	6 hrs	..	..	$3 450
Performing calculations, measurements and estimates	..	30 hrs	11 hrs	1 hr	$1 500	$7 150
Reporting transfers	2 hrs	7 hrs	1 hrs	2 hrs	..	$1650
Total staff hours	**4 hrs**	**64 hrs**	**20 hrs**	**4 hrs**	**..**	**..**
Total	**$800**	**$9 600**	**$2 000**	**$200**	**$1 500**	**$14 100**
Subsequent years						
Understanding regulatory requirements	1 hr	4 hr	1 hr	..	..	$900
Determining reporting obligations	..	10 hrs	6 hrs	..	..	$2 100
Performing calculations, measurements and estimates	..	28 hrs	12 hrs	1 hr	$1 500	$6 950
Reporting transfers	2 hrs	10 hrs	3 hrs	1 hrs	..	$2 250
Total staff hours	**3 hrs**	**52 hrs**	**22 hrs**	**2 hrs**	**..**	**..**
Total	**$600**	**$7 800**	**$2 200**	**$100**	**$1 500**	**$12 200**

.. Not applicable

Source: PACIA (sub. 33 attachment 1, p 34).

E.3 Regulatory arrangements can have anti-competitive outcomes

Firms in different jurisdictions — national and international — invariably operate in different regulatory environments, and therefore the compliance costs they face vary in magnitude and nature. This can have implications for competitive neutrality — that is, firms in one jurisdiction may enjoy a competitive advantage over similar firms in other jurisdictions if they operate in a less costly regulatory environment.

Regulation can also impact on competitive neutrality when the relative compliance burden is greater for smaller firms, which may find it more costly to understand and meet regulatory obligations than larger, more established firms operating in the same regulatory environment. For example, a small firm may need to engage external consultants to deal with complexity in legislation, staff time taken to

perform compliance related activities will be at a higher premium, and up-front costs such as those associated with testing and registration to introduce new chemicals will be relatively more costly for a smaller firm.

However, firms in a highly regulated environment will not necessarily be at a competitive disadvantage to similar firms operating in other less regulated jurisdictions. In their report to the Royal Commission on Environmental Pollution, Mahdi, Nightingale and Berkhout cited an argument that:

> … countries adopting stricter regulations can achieve competitive advantage by stimulating socially desirable innovations and gaining first mover advantages for their firms which can, in turn, be exploited in other markets. (2002, p. 25)

A number of examples were provided to this study that highlighted the areas where industry considered that inconsistency and gaps in various areas of regulation across jurisdictions have the potential to create anti-competitive outcomes.

Participants raised concerns in relation to the implementation of the National Registration Scheme through control-of-use regulations (for agvet chemicals) administered by states and territories. One of the issues raised was the costs imposed by the lack of consistency across jurisdictions. The inconsistent regulation of off-label uses in particular — allowing off-label use in some jurisdictions and not others — is identified as an area where anti-competitive outcomes could occur (section 8.3).

The AAAA also raised the following issue regarding inconsistencies in the regulation of aerial application and ground application of pesticides:

> A key economic and competition issue is the unlevel playing field between aerial application and ground application. Despite state regulators publicly and consistently indicating they receive considerably more complaints and undertake more investigations regarding poor ground application than aerial application, most states continue to require licensing and high training and other standards from aerial application, but no or limited licensing, training or record keeping for most ground applicators. (sub. 17, p. 5)

In relation to chemicals in consumer products, the absence of a single national system of generic consumer product safety has led to the duplication of effort and inconsistent treatment of similar risks and hazards across jurisdictions, while providing little demonstrable offsetting benefit to the community (section 5.2).

Jurisdictional inconsistencies in controls to prevent the diversion of chemicals to illicit drug manufacture — in particular the failure of some jurisdictions to tailor controls to the level of risk, potentially leading to more stringent regulation than is necessary — can impose unnecessary costs on firms and result in anti-competitive

outcomes for national firms compared to firms operating in a single jurisdiction (section 5.4).

PACIA provided a case study (box E.5), which it used to illustrate the implications of inconsistencies in the application of the Illicit Drug Code for firms dealing with ammonia gas on a national level. PACIA maintained that inconsistency added to compliance costs as a result of complexity, which also undermined compliance. In addition, PACIA sought to demonstrate the anti-competitive outcomes that inconsistent adoption of voluntary schemes can have.

Box E.5 **PACIA case study: the Illicit Drug Code and treatment of ammonia gas**

PACIA provided the following case study to highlight inconsistencies in the application of the Illicit Drug Code:

> Western Australia legislated some provisions of the Illicit Drug Code in 2004. However, that state made a decision to alter the nationally agreed categories of a number of chemicals it scheduled. As an example, the legislation categorised ammonia gas as a Category I chemical with all the attached obligations. The Code categorises ammonia gas as a Category II chemical, and thus this alteration presented significant change and issues for the companies who deal with ammonia gas on a national level.
>
> Clearly ammonia gas has widespread use in refrigeration processes, and practical aspects of dealing with repeat and regular orders from account customers means that provision of End User Declarations on each and every supply is a[n] … unnecessary and burdensome requirement. Furthermore, the requirement to delay supply for 24 hours has significant unintended consequences in some situations (such as dealing with refrigeration breakdowns etc), yet the regulations have no exemption power to allow discretion in application.
>
> One PACIA member deals with approximately 260 orders for ammonia each year. That company has a centralised national call centre which deals with supply in all states. The cost of having very different processes in only one state has made business operation complex, and contributed to the additional cost of training staff.

Source: PACIA (sub. 33, p. 16).

There are also inconsistencies in the dangerous goods regulations and major hazard facilities (MHF) regulations (section 6.4). For example, large variations in charges for obtaining a licence or registering a MHF (depending on the jurisdiction's requirements) coupled with the absence of formal regulation in some jurisdictions could place some firms at a competitive disadvantage (table D.2).

E.4 The introduction of safer or more effective chemicals can be impeded

There are costs associated with the introduction of new chemicals. New industrial chemicals that are not listed on the Australian Inventory of Chemical Substances (AICS) must be assessed by NICNAS before they can be used in Australia. Firms must cover the costs of data preparation (testing) for the application and the assessment of the application. Industry participants to this study expressed concerns that these costs are often prohibitively high, and discourage innovation and the uptake of new technologies.

Industry argued that, not only are the assessment and notification charges higher in Australia than other jurisdictions such as the US, the EU and Japan, but often the relevant testing and evaluation has already been done in other jurisdictions and the chemicals well established in their respective markets. It further argued that these high costs, together with the small size of the Australian market, can make the introduction of new chemicals commercially unviable — even though those chemicals, in some instances, may be safer and more effective.

It is interesting to note an argument cited by Mahdi, Nightingale and Berkhout in their report to the Royal Commission on Environmental Pollution with reference to the impact of regulation on innovation in the chemical industry:

> There is no consensus about whether regulation inhibits or stimulates innovation in industry; it is likely that in most cases regulation both inhibits and stimulates innovation, playing a modulating role. For instance, in many countries the most successful firms and industries are also those that face the highest levels of regulation – pharmaceuticals in the UK compared to France, chemicals in Germany, pulp and paper in Sweden and aerospace and finance in the US. Despite a long tradition of research on the question of how regulation influences innovation in different industries and in different countries, it is far from clear where the balance between these two effects falls. (2002, p. 1)

Whether the environment is highly regulated or otherwise, it is reasonable to expect that the effectiveness and efficiency of that regulation will be relevant to both the uptake and creation of new products and technologies. The issues most frequently raised by industry focused on the reduced profitability and lost opportunities for Australian firms as a result of regulatory burden associated with the introduction of new chemicals.

Impacts on profitability and decision-making for importer–suppliers

Some examples that were submitted to this study aimed to demonstrate the ways in which the costs of introducing new industrial chemicals impacted on firms' profitability and decisions about whether or not to proceed with introduction.

Albright & Wilson (Australia) Ltd. provided the following, in which it compared the costs to firms of obtaining new product approval/registration in Australia and the US:

> Albright & Wilson (Australia) Limited has recently taken on a new Agency. Our Principal is a small innovative US company which has developed and patented several new chemical entities which have significant advantages over products using existing technologies, in terms of performance, use of renewable resources, etc. The cost of listing one of these new products on the TSCA [Toxic Substances Control Act] Inventory is USD 100. The laboratory tests required by US authorities to establish the safety in use and impact on the environment cost around USD 20 000. In Australia, by contrast, a standard NICNAS notification costs close to AUD 15 000, with a number of additional costs if any of the information is to be treated in confidence etc., and the cost of carrying out the substantially more extensive testing required to achieve listing on the AICS [Australian Inventory of Chemical Substances] can easily be of the order of ten times the cost of testing required in the USA. (sub. 5, pp. 2–3)

Care should be taken when comparing such fees and charges, as the various cost recovery arrangements for each of the agencies will determine the degree to which these are reflective of true assessment costs.

PACIA provided an example of a member who recently completed the notification of two new chemicals, which are components of new water-borne epoxy systems developed for protective coatings:

> Such technology is slowly starting to replace solvent-containing systems which present serious problems for both workers and the environment. The notifications cost the company approximately $40 000 AUD each, which means virtually no profit will be made for several years in Australia from either of the two systems. Clearly the replacement of chemicals with safer alternatives is not happening unless a high cost is paid. Even allowing for the use of a Commercial Evaluation permit to test the market [for] specified customers, there is the underlying issue of the company really not knowing the commercial viability of a product until the notification has been completed and the large amount of money spent. (sub 33a, p. 19)

Access to new technologies for local industry and consumers

Industry provided examples that aimed to demonstrate ways in which arguably unduly high costs for the introduction of new industrial chemicals and technologies can disadvantage industry and consumers. One issue raised by industry was the loss

of competitiveness by local manufacturers who compete with imported products that contain substances not listed on the Australian Inventory of Chemical Substances.

Endeavour Chemicals provided the following example as a representative of a medium size coatings resin company in Europe producing speciality resins (binders) for paint systems:

> Most of [the] work is in new developments in the water based area. What we tend to find is that we have new products we would like to introduce which would be better for ecology and health and safety at the factory level but when we get to the evaluation stage, it becomes obvious that the volumes in the Australian market do not compensate for the costs involved in getting the product registered.
>
> This tends to leave the Australian market languishing with old technology. This old technology is usually more harmful to environment and worker combined, hence NICNAS is effectively working against [its] own charter which is to protect environment and worker/public safety. A lot of the evaluation of these polymers has been already done in Europe, the USA, and Japan etc and are readily used, so the evaluation is duplicated just for our small 20 million population country.
>
> The set up of NICNAS tends to favour the large multi-national [which has] much greater resources. It undeniably stifles innovation and entrepreneurial activities. (sub. DR67, p. 1)

Remove Obstacles to Australian Manufacture (ROAM) provided the following case studies:

- A water repellent coating primarily for use on aircraft windshields cannot be manufactured in Australia because the key ingredient is not listed on the AICS. The total volume of the ingredient that could be used (if accredited) is such that the cost of accreditation cannot be justified.
- Currently a liquid photopolymer is used within the printing industry for use in printing corrugated cardboard. In principal an excellent closed loop system where all unused polymer is recycled. However the polymer contains a monomer that has a high odour and high skin sensitisation levels. A new monomer enjoying wide use in the USA is available that does not have these shortfalls [but is] not listed on the AICS. Either we put up with a process that impacts negatively on worker health or we export the job of printing cartons!
- An importer wanted to introduce a new bacterially active substance for use in anti-perspirant/deodorants. The substance is accredited for use in Europe, USA and Japan. The cost of NICNAS accreditation was such that introduction was not completed and large export contracts for a local personal care manufacturer were lost.
- A major producer of printing inks in competition with imports finds that imports often contain ingredients not listed on the AICS or on the MSDS [Material Safety Data Sheet]. Those ingredients cannot be used in Australian manufactured inks but

the imported products are not assessed/tested by NICNAS in spite of referrals from local makers.

- Plastic bags as supplied in supermarkets of the biodegradable type manufactured from a corn starch derived polymer are being imported into Australia. However that same polymer is not listed on the AICS so it cannot be imported and converted into safe, environmentally desirable plastic bags by Australian producers. (sub. 3, pp. 4-5)

ACCORD Australasia (sub. DR91) argued that unique Australian requirements are an impediment to the integration of Australian businesses into global supply chains and have negative implications for Australian export manufacturers as well as importers of new technologies. ACCORD's member survey of impacts of NICNAS regulation highlighted that an estimated 38 per cent of assessments required unique Australian data for chemicals and ingredients already in use in other major economies (sub. DR91, p. 3).

E.5 Reforms can add to the regulatory burden

Regulatory 'fixes' and additional layers of regulation can add to complexity, and therefore to the compliance burden for industry. Regulatory reforms are sometimes undertaken to accommodate exceptions or special circumstances of various industry sectors. If a regulatory 'fix' falls short of achieving its objectives, it may not be adopted by its target group, or can create new costs for industry and regulators alike.

In addition, new layers of regulation are often introduced to deal with emerging issues or changing public expectations. These can add to compliance costs through duplication and inconsistency with existing regulation, which are then exacerbated if inconsistently adopted and implemented across jurisdictions.

Regulatory 'fixes': low regulatory concern chemicals (LRCCs)

Some industry stakeholders argued that the costs associated with new mechanisms for regulating LRCCs remain too high, and controls are not commensurate with risks, which they maintain, has resulted in a poor uptake of these mechanisms (section 4.3). Science Industry Australia provided a case study to support this view in the context of the research and development exemption. Similarly PACIA argued that the provisions for self-assessment of polymers of low concern did not function for similar reasons.

Science Industry Australia also provided a breakdown of the estimated costs of reporting to 100 science industry companies each importing an average of 600 chemical entities in laboratory quantities each year (table E.2).

Table E.2 **Science Industry Australia estimates of reporting costs associated with low regulatory concern chemicals**

Item	*Cost per year*
	$'000
Indirect costs per company of the paperwork – assuming 600 chemical entities per company	6
Opportunity costs (loss of strategic time)	10
Total cost per company	**16**
Total cost to science-industry companies	**1 600**

Source: Science Industry Australia (sub. 55).

PACIA (sub. 33a, p. 20) provided a case study containing compliance cost information associated with the Low Regulatory Concern Chemical Program, which is discussed in chapter 4. PACIA's comparison of NICNAS's fees for self-assessment for polymers of low concern and standard polymers of low concern at September 2007 provided an upfront saving of $1689. However, PACIA estimated the additional costs of annual reporting and auditing to be $1800 — thus more than offsetting the initial saving (assuming a near zero discount rate) (box E.6).

Box E.6 **PACIA case study: self-assessment of polymers of low concern**

This case study provides a comparison of costs associated with standard and self-assessment polymer of low concern notification fees respectively:

Costs of annual reporting

Administrative cost factors

a) Yearly Data Extraction of product data for specific products containing the new chemical

There will be … up to 25 or more products each containing a different percent composition of the new chemical and each has to be tracked each year for five years using non-routine reporting periods August–September.

Consider a simple case with only three products containing the self assessed chemical (three products is a low estimate for paint, adhesives, lubricants, moulding plastics)

Time to extract end use product data from one business with senior management approval 3 x 0.5 hr = 1.5 hr

b) Unique and varying data calculation

Apply the unique percentage concentration per product to produce total kilograms used 0.25 hr

c) Data Entry

Enter above data in NICNAS report for each chemical 0.25 hr

Total hours 1.8 x fully loaded hourly rate $180 per hr = $324 per year

Over 5 years = $1620

Cost of Audit:

Post preparation (collation and binding) of the data file and support papers for a NICNAS application is 1 hour = $180.

(If NICNAS have further questions an additional 1–3 hours may be added but this is ignored for this example)

Cost Comparison

Difference between SA [self-assessment]/PLC [polymers of low concern] and Standard PLC = $1689 (Saving)

Total reporting and audit costs = $1800 (Additional cost)

Source: PACIA (sub. 33a, p. 21).

Additional regulatory layers: security sensitive ammonium nitrate controls

The special controls placed on security sensitive ammonium nitrate (SSAN) are an example of an additional regulatory layer aimed at dealing with an emerging issue. These controls were imposed to improve national security when a risk was identified for certain ammonium nitrate products to be obtained for illegitimate purposes.

The SSAN regulations impose direct costs on industry in the form of charges for various licences, permits and security background checks. These are summarised in table 10.3.

As discussed in section 10.3, there is a significant degree of inconsistency across jurisdictions in a number of areas including: licensing arrangements; reporting requirements; and storage and handling requirements. This creates administrative complexity, particularly for firms operating in multiple jurisdictions.

The lack of recognition of licences across jurisdictions imposes unnecessary administrative costs on industry. As there is no nationally coordinated system for background checking, a background check on an applicant wishing to gain licences for multiple jurisdictions would be repeated by the licence issuing agency in each jurisdiction. The additional costs to firms are in fees for background checking and the time taken to conduct the check on each occasion. PACIA (2007a) has reported that it can take up to nine months to obtain SSAN related licences in New South Wales.

Participants in this study also argued that controls in some areas of SSAN regulation are excessive. For example, some groups argued that requirements in some jurisdictions for SSAN to be stored as an explosive may be too stringent, although there is no nationally agreed position on appropriate storage and handling requirements for SSAN. Industry also questioned the value of some of the reporting that is required by regulators in different jurisdictions.

AEISG estimated that the regulation imposes approximately $3 million per year in compliance costs for the explosives industry (table E.3), and further, that a system of national regulation would reduce these compliance costs by 50 per cent:

> The SSAN Regulations have required a paradigm shift in the manner in which member companies employ their operating staff and secure their activities to the requirements of the relevant regulator. The following table is an estimate of the additional costs imposed on the industry by the SSAN Regulations. These are aggregated over all AEISG members dealing with SSAN and cover all identifiable security costs in all jurisdictions but do not cover the impact of Major Hazards Facilities Regulations … (sub 45, pp. 11–12)

Table E.3 **AEISG estimated costs to the explosives industry arising from SSAN regulation**

Item	*Capital*	*Operating*
	$m	$'000
Licensing and operating cost	..	3 000
Global Positioning System (GPS)	2.5	1 000
Unsupervised Handling Licences (UHLs)	..	500
Security and validation staff	..	530
Dual licences where necessary	..	75
TOTAL	**2.5**	**5 630**

.. Not applicable

Source: AEISG (sub. 45, p. 12).

E.6 Cross-cutting issues

The Productivity Commission's 2006 research paper on the Potential Benefits of the National Reform Agenda (PC, 2006b) estimated that compliance costs across all industries in Australia could be as high as 4 per cent of GDP. Using this estimate, and an extrapolated measure of industry output of $31 billion[3], the Chemicals and Plastics Leadership Group (sub. DR113, p. 9) estimated that the chemicals and plastics industry compliance burden could be in the order of $1.3 billion annually. This is considered to be a very blunt assessment of compliance burden — it assumes a constant 4 per cent compliance burden across industries, and bases this calculation on already broad approximations of compliance burden and inconsistent measures of output. For example, the ABS estimated industry output in 2005–06 to be $9 billion (table C.1).[4]

Chemicals and plastics regulation also imposes compliance costs on users of chemicals. Firms across many industries must comply with workplace, environmental, transport, public health and national security regulation, in relation to their use and disposal of chemicals.

ACCORD Australasia — which represents the consumer, cosmetics, hygiene and specialty products sector — undertook a survey in order to gain members' views on the impact of the current chemicals regulatory arrangements. The issues touched upon in the survey relate mainly to industrial chemicals and cut across the issues

3 Based on the 2006 National Institute of Economic and Industry Research report, which notes that in 2004, output of the Victorian chemicals sector was $12 billion, 39.6 per cent of national level.

4 Based on industry value added and excluding medicinal and pharmaceutical products.

discussed in previous sections of this appendix. The key results of the survey, as reported by ACCORD, are in box E.7.

Box E.7 **Summary of results of ACCORD Australasia survey**

ACCORD reported the key findings of its survey as follows:

- 89 per cent of ACCORD industry and regulatory consultant members responded to the ACCORD Industry Survey.
- 92 per cent of survey participants having experience with NICNAS reported negative impacts from this association.
- 93 per cent of respondents who have experienced difficulties with NICNAS reported that products/formulations from their worldwide portfolio are unavailable in Australia due to Australian regulatory factors.
- Products are formulated/re-formulated to avoid dealing with NICNAS.
- The current regulatory system is a barrier to innovation.
- The consequences of regulatory burden reported by members show that Australia is placed at a disadvantage with regard to commercial opportunity, compared to the major EU and US markets.
- Costs, data and time factors are individually cited in over 50 per cent of cases as causes of regulatory burden.
- Based on financial estimates provided by a reasonably representative sample of ACCORD member companies, it is estimated that the lost-opportunity cost to the industry represented by ACCORD for the last few years (in terms of products being unavailable on the Australian market) is $400 million.
- The current regulatory system is biased against innovation and product introduction by SMEs [small and medium enterprises] (companies with a turnover of less than $10 million).
- 36 per cent of non-SMEs were still prepared to pursue Australian market entry for a chemical/product despite saying that the data requests in Australia were too great, compared to 5 per cent of SMEs.
- 16 per cent of non-SMEs were still prepared to pursue Australian market entry despite saying that regulatory costs in Australia were too high, compared to nil for SMEs.
- In around 50 per cent of cases where a company has the opportunity to self-assess through the LRCC [low regulatory concern chemicals] initiative, they choose not to do so, for reasons such as onerous auditing requirements.

(Continued next page)

Box E.7 (continued)

- In general, with the various LRCC reforms, at the time of introduction of the chemical the regulatory burden is reduced, but annual reporting has significantly increased the ongoing regulatory compliance and red-tape burden for industry.
- Irrelevant data is often requested and it is frequently considered that the level of assessment is greater than the level of risk.
- An average of 38 per cent of assessments required unique Australian data.
- 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.

Source: ACCORD Australasia (sub. DR91, p. 3).

E.7 Administration costs

Administration costs refer to the costs of designing and implementing regulation. Administration includes undertaking consultation and legislative processes, and establishing and operating regulatory agencies or regulatory functions. As with the costs of compliance to industry, government (and therefore communities) can incur unnecessary costs as a result of regulation that could be designed and/or implemented more effectively and efficiently.

In Australia, the administration of chemicals and plastics regulation can be broadly described as follows:

- Ministerial councils and relevant standing committees set policy and oversee its development and implementation.
- Bodies such as NICNAS and APVMA undertake hazard and risk assessment functions.
- Standard-setting bodies, such as ASCC, the National Transport Commission and APVMA perform risk management functions, developing standards and codes.
- Governments legislate, administer and enforce the regulations.

In general, policy setting functions tend to be funded from general revenue, therefore the community covers the associated cost.

Regulatory agencies can operate on a partial or full cost-recovery basis, where industry contributes to or fully funds their operating costs. Agencies can raise revenues through various premiums, fees, levies and other charges.

NICNAS operates on cost-recovery principles and is principally funded by company registration fees, and fees and administration charges for new assessments. In 2006-07, total revenue was $8.6 million. Around $5.9 million (69 per cent of total revenue) was collected via company registration fees, with most of the remainder collected through chemical assessment fees (DOHA 2007a).

APVMA also operates on cost-recovery principles and is principally funded by a levy imposed on sales of registered agvet products, and application and annual registration fees. APVMA also collects licensing fees from manufacturers of veterinary medicines. In 2006-07, total revenue was $25.3 million, of which $17.7 million, or around 70 per cent, was through the sales levy (APVMA, 2007a).

The funding arrangements for other agencies relevant to this study are discussed in more detail in appendix F.

Overall, the Commission noted the small amount of data received from jurisdictions in relation to administration costs. While the costs of chemicals-specific regulation, for some agencies, may not always be separately identified by their respective accounting systems, it is expected that these costs could be fairly accurately estimated. Such cost data, along with measures of regulatory quality, would provide a starting point for quantifying the effectiveness and efficiency of regulatory administration in each jurisdiction.

Meaningful comparison of administration costs for chemicals-specific regulation across jurisdictions would be complex given the differences in institutional arrangements, size and population, cost structures, and other factors such as community preferences. In addition, there would be the need to make judgements about the size of the net benefit to the community, or otherwise, that is delivered by each jurisdiction's regulatory regime. A benchmarking exercise would enable reasonable comparisons to be made of administration costs across jurisdictions.

Another useful exercise would be to consider opportunities to increase administrative efficiencies. This could include for example, looking for opportunities to reduce duplication across jurisdictions, and to consolidate functions and pool resources.

Chapter 8 provides discussion of the opportunities to consolidate functions of jurisdictional control-of-use regimes for the regulation of agvet chemicals. Administration cost data for three jurisdictions are provided (table E.4) in the context of this discussion, rather than for the purpose of making comparisons, noting the reasons above.

Table E.4 **Costs of regulating agvet chemicals**

Jurisdiction	*Cost per annum*
	$'000
Victoria	2 900
South Australia	900
Tasmania	750

Source: Victorian Department of Premier and Cabinet (pers. comm. 15 January 2008); SA Government (sub. 56); Tasmanian Department of Premier and Cabinet (pers. comm. 30 January 2008).

As noted in chapter 8, some proportion of these costs could be rationalised under a national regime, such as those for policy development, however, opportunities for consolidation in (local level) monitoring and enforcement would be much smaller.

Although lacking cost information, a number of other areas are highlighted for further examination throughout the study, where it is anticipated that administrative efficiencies could be achieved through reform.

F Funding mechanisms for chemicals and plastics regulatory agencies

This appendix outlines the methods that have been used to fund a number of the agencies involved in assessing the hazards and risks of chemicals, or in establishing regulatory standards for chemicals and plastics use, consumption and disposal (table F.1). Some agencies are focussed solely on chemicals and plastics — for example, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and the Australian Pesticides and Veterinary Medicines Authority (APVMA) — while others have a much broader regulatory ambit, of which chemicals and plastics is only a relatively small part — for example, the Australian Safety and Compensation Council (ASCC) and the National Transport Commission (NTC).

A variety of funding mechanisms have been adopted, ranging from total budget funding to full cost recovery. The methods of cost recovery also vary and include output-based levies across the regulated sector, compulsory charges to individual firms reflecting the cost of regulating or providing services to them, and charges more closely akin to prices in that they reflect the regulator's costs but also offer firms the opportunities to reduce charges by varying the services or method of service delivery they use.

The Commission (PC 2001) has previously identified a number of benefits of cost recovery, including:

- improving economic efficiency by charging the costs of regulation to activities that generate the need for regulation or to those who benefit from regulation. The more closely charges can be linked to the costs of the activities or products involved — for example, by using fee-for-service charges — the more efficient cost recovery becomes
- improving the operation of regulatory agencies by creating incentives for regulated entities to monitor their efficiency
- avoiding the adverse efficiency impacts of raising general taxation
- improving equity by imposing regulatory costs on those being regulated.

The Commission noted that in some circumstances — such as where there are high transaction costs of collecting fees or inconsistency with other policy objectives — cost recovery may not be appropriate.

In general, for chemicals and plastics regulators, where the costs of a regulatory activity or service can be linked to individual enterprises, specific charges are usually made. Industry levies are used where whole groups of enterprises create the need for regulatory activity. Budget funding is used where cost recovery would be impractical (for example, due to high transaction costs).

F.1 National Industrial Chemicals Notification and Assessment Scheme

NICNAS is the Australian Government's regulatory body for industrial chemicals. It is a statutory body with the primary role of undertaking scientific assessments of the human health and environmental impacts of all new (to Australia) industrial chemicals and of those existing industrial chemicals where concerns exist about their health and/or environmental impacts (chapter 4). It is also responsible for administering a cosmetics standard that regulates cosmetics and toiletries claims.

NICNAS operates on a full cost recovery basis. Since 2005, NICNAS activities, which include chemical assessment, compliance, and information and education awareness programs, have been fully cost recovered.[1] Revenue is raised mainly from compulsory registration fees, fees and administrative charges for new chemicals assessments and charges and fees for the provision of technical services to other government agencies.

The Commission has recommended (chapter 4) that the review program for existing chemicals be greatly accelerated and that the cost of conducting initial screening be met from Australian Government budget funding. Costs of any resulting full assessments of existing chemicals would still be recovered from the industry.

1 Before July 1997, NICNAS operated on a 50 per cent cost recovery basis. Up to 2005-06 there was a small government subsidy to assist with the compliance program — in 2004-05 this was $120 000 or 1.7 per cent of NICNAS revenue (22 per cent of compliance and registration costs).

Table F.1 **Funding methods for bodies regulating chemicals and plastics**

Organisation	*Fully cost recovered*	*Partially cost recovered*	*Fully budget funded*	*Comment*
NICNAS	✓			Tiered firm registration fees (70 per cent) Cost-based chemical assessment fees (24 per cent)
APVMA	✓			Tiered levy (70 per cent) Product registration fees (12 per cent) Assessment fees (11 per cent)
OCS		✓		Full cost recovery for APVMA assessments
National Residue Survey		✓		Small government CSO contribution
NDPSC			✓	
FSANZ		✓		Predominantly budget funded
ASCC/OASCC			✓	
NTC		✓		Receives revenue from profits on the sale of the ADG Code
AMSA	✓			Cost recovered for regulatory activities.
CASA	✓			Cost recovered for regulatory activities
ACCC			✓	

a Acronyms in this table are defined in the list of abbreviations at the front of the report.

It is compulsory for all importers and/or manufacturers of relevant industrial chemicals for commercial purposes to register with NICNAS and pay registration fees and charges based on the value of industrial chemicals manufactured and imported.[2]

In 2007-08, the annual registration fees for firms importing or manufacturing relevant industrial chemicals involved a $381 administration fee, plus a further three tiered fee based on the total value of industrial chemicals imported or manufactured each year:

- Tier 1: less than $500 000 imported or manufactured, $381 (equivalent to the administration fee for tiers 2 and 3)
- Tier 2: $500 000 to under $5 million, $1141

2 As well as raising revenue, a key objective of compulsory registration is to improve industry knowledge of chemicals regulation and establish partnerships between the regulator and industry. NICNAS also provides information services (for example, chemical safety information) free of charge to registered entities.

- Tier 3: over $5 million, $8500.

Hence for a firm importing and/or manufacturing $1 million worth of relevant industrial chemicals, the registration fee in 2007-08 would have been $1522, or 0.15 per cent of the value of the relevant chemicals. Of the more than 5000 firms registered with NICNAS, about 80 per cent are in Tier one. Registration fees provided around 70 per cent ($5.9 million) of NICNAS total revenue ($8.6 million) in 2006-07.[3]

Newly introduced industrial chemicals must be assessed by NICNAS and a certificate (for chemicals to be used for an extended period) or permit (for chemicals to be used for a short period and in restricted quantities) is issued, containing recommendations/permit conditions for safe use. Some exemptions from assessment apply for low risk chemicals. There are a number of categories of certificates and permits, with assessment fees varying depending on the category of certificate or permit sought and the method of lodgement and assessment.

New chemical assessment fees cover the estimated costs involved and raised $2.1 million in 2006-07. These fees are much like cost-based prices as they are only charged if a specific (legislated) regulatory function is provided and charges vary according to the costs of undertaking that function. There are several means by which applicants can influence the charges they pay. For example, applicants may undertake an audited self-assessment of non-hazardous chemicals and polymers, and polymers of low concern. Further, utilising electronic template lodgement of applications is estimated to have saved over $100 000 in fees in 2006-07. Fee rebates are available when assessment reports from comparable OECD countries are provided. Permits allow conditional entry into Australia of low risk chemicals without a full assessment, with commensurately reduced assessment fees.

F.2 Australian Pesticides and Veterinary Medicines Authority

APVMA is an Australian Government statutory authority within the Agriculture, Fisheries and Forestry portfolio. It assesses and registers pesticides and veterinary medicines for their safety to human health and the environment, their efficacy and to determine that they will not jeopardise Australia's international trade, before they can be supplied or used (chapter 8). It also manages a number of programs that monitor the ongoing safety and performance of registered products.

3 In 2006-07, NICNAS revenue also included $521 000 in interest and $74 000 in publication sales, industry education and research projects (fees for technical services).

APVMA is fully funded by the agricultural and veterinary (agvet) chemicals industry. Of total revenue in 2006-07 of $25.3 million, $24.4 million came from charges on industry — interest earnings making up most of the remainder. A tiered levy imposed on the sale of registered agvet products provided $17.7 million (70 per cent of total revenue). From July 2006, the levy has been 0.8 per cent for the first $1 million in sales of a product, 0.45 per cent for the next $4 million and 0.3 per cent for sales over $5 million. APVMA monitors sales forecasts and adjusts the levy rates if necessary to cover anticipated expenditure and to meet its target for retained surpluses. The levy payable on a product with $3 million in sales is $17 000 (0.57 per cent) while sales of $10 million attract a levy of $42 000 (0.42 per cent).

Application fees for assessment of locally produced and imported agvet products for registration raised $2.9 million in 2006-07. In addition, annual fees of $390 per product are payable in order to maintain a product's registration. In 2006-07 these fees amounted to $3.1 million. A number of participants (for example, Horticulture Australia sub. DR81) have indicated that the expense of generating data for APVMA assessments, rather than APVMA fees, is the main cost of the approval process, particularly for products used on minor crops.

Australian based veterinary chemicals manufacturers (at all stages of the manufacturing process) are required to be licensed by APVMA and the fee for issuing a manufacturers' licence is $6000, payable over a number of years. DAFF (2005) indicated that the majority of APVMA's costs of operating this scheme would be met from the product levy. Manufacturers are subject to periodic audits to retain registration and manufacturers are required to arrange and meet the costs of these audits.

Overseas manufacturers are not licensed by APVMA. However, for veterinary chemical products manufactured overseas, the registrant must demonstrate that the product is manufactured to quality standards comparable to those applied to Australian registered manufacturers.

APVMA also issues a variety of permits — for example, permits for minor use, research and export — for which small fees are charged, but which are cross subsidised from the product levy. APVMA also obtains expert advice to assist in chemical assessments from the Office of Chemical Safety (OCS) (human health risk assessments), the Chemical Assessment Section of the Department of Environment, Water, Heritage and the Arts (environmental risks) and state and territory

government departments (efficacy and safety).[4] APVMA pays fees for these assessments under service level agreements.

F.3 Jurisdictional control of use of agvet chemicals

The use of agvet chemicals is controlled by relevant agencies in the states and territories. These authorities charge an array of relatively minor fees, particularly for licences such as for aerial spraying and commercial application of pesticides. The type and size of charges varies between jurisdictions. However, these fees would cover only a small part of the total cost of regulating agvet chemical use, with the remainder financed by consolidated revenue. For example, in Victoria, fees for licences for ground and aerial application of agvet chemicals is likely to have exceeded $200 000 in 2006-07 (chapter 8). This compares to estimates of Victorian Government annual costs to regulate agvet chemicals of $2.9 million (Victorian Department of Premier and Cabinet, pers. comm., 15 January 2008).

In addition to costs to government, regulation of chemical use imposes various costs on the users, such as training and record keeping. These requirements vary between jurisdictions. In some cases, training courses and codes of practice developed by industry are deemed as adequate to meet regulatory requirements.

The Commission has recommended (chapter 8) that responsibility for regulating the control of use of agvet chemicals be transferred to APVMA, with the costs of this activity to be recovered from the industry through a mix of charges and levies. Based on information provided by several states, it is likely that the current Australia-wide cost of regulating control of use is in excess of $10 million (chapter 8).

F.4 Office of Chemical Safety

The OCS is part of the Office of Health Protection in the Department of Health and Ageing (DOHA). Its main functions are:

- providing human health risk assessments for new and existing pesticides and veterinary medicines for APVMA
- providing advice on potential human health risks of chemicals and setting public health based standards for pesticides and veterinary medicines, including

[4] In 2004-05 APVMA spent $4.4 million (over 20 per cent of its annual expenditure) on obtaining scientific advice from government agencies and consultants.

acceptable daily intake values, acute reference dose values, poisons schedules and first aid instructions and safety direction

- provide secretariat support for the National Drugs and Poisons Schedule Committee (NDPSC)
- undertaking the import and export and national monitoring for prohibited and controlled substances under the National Drug Strategy
- providing policy direction on environmental health and support for the enHealth and related activities
- providing technical expertise and advice on counter terrorism.

The OCS operates under full cost recovery for services provided to APVMA and is budget funded for its remaining activities. These fees are effectively passed on to the chemicals industry through APVMA charges.

F.5 National Drugs and Poisons Schedule Committee

The National Drugs and Poisons Schedule Committee (NDPSC) is a statutory committee established under the *Therapeutic Goods Act 1989* (Cwlth), which makes recommendations on national scheduling (categorisation) of medicines (not covered by this study), agricultural and veterinary chemicals, and household chemicals. NDPSC decisions are purely advisory. State and territory authorities are responsible for making enforceable decisions regarding drugs and poisons. The NDPSC is budget funded.

Scheduling and rescheduling decisions are often made on the basis of recommendations from NICNAS or the OCS (often as part of its assessments of agvet products for APVMA, for which it charges fees). The cost of these recommendations and assessments are already met by industry through NICNAS and APVMA fees.

F.6 Food Standards Australia New Zealand

Food Standards Australia New Zealand (FSANZ) is an independent statutory agency that develops food standards, including labelling and maximum residue limits (chapters 5 and 8).

In 2006-07, $16.8 million (90 per cent) of FSANZ's $18.8 million revenue came from the Australian and New Zealand Governments. In addition, FSANZ charges fees for certain applications for changes to the Australia New Zealand Food

Standards Code. Fees are charged where an applicant has an exclusive, capturable commercial benefit or where applicants want assessment to commence immediately, rather than under the anticipated time frame established by FSANZ. FSANZ fully cost recovers assessments for such applicants through charges. In 2006-07, cost recovery fees amounted to $382 000 or 2 per cent of total revenue.

There are other costs of the food safety system which are not related to FSANZ, which are budget funded — for example, the activities undertaken by Australia and New Zealand Food Regulation Ministerial Council, the Food Regulation Standing Committee and its various working groups, and jurisdictional authorities implementing and enforcing standards.

F.7 National Residue Survey

The National Residue Survey — which is conducted by a unit in the Department of Agriculture, Fisheries and Forestry (DAFF) — monitors residues of agvet chemicals and environmental contaminants in selected Australian raw food (animal and plant) and fibre commodities. Participation is not compulsory, however, for several commodities, surveying is necessary in order to meet international trade requirements.

Products tested are meat, eggs, honey, fish, grain, oilseed and horticulture. The cost is largely industry funded through levies on producers of each of the commodities tested. In 2006-07 there were nearly 30 different products tested, with a further 13 new grains joining the programme in 2007-08. These levies vary between commodities depending on the costs of monitoring. Some industry groups fund the NRS directly under contract.

There is also an Australian Government Community Service Obligation (CSO) appropriation reflecting use of the testing to provide residues information to Government and to assist participation in national and international food regulation committees.

In 2006-07, the National Residue Survey cost $9.4 million, of which $8.9 million came from a wide range of industries and $0.5 million from the Australian Government. Economies in levy collection costs are achieved by using DAFF's Levies Revenue Service which coordinates all levies across the Department.

F.8 Australian Safety and Compensation Council

The ASCC is an advisory body which develops national standards and codes of practice for occupational health and safety and workers' compensation, including standards and codes related to the use of chemicals in the workplace. It also undertakes research and analysis of workers' compensation data, and provides policy advice. It receives secretariat support from the Office of the Australian Safety and Compensation Council (OASCC),

The ASCC was established by administrative decision by the Australian Government, while the OASCC is part of the Department of Education, Employment and Workplace Relations (DEEWR). Both bodies are Australian Government budget funded — in 2005 DEEWR was directly appropriated the resources and budget of the former National Occupational Health and Safety Commission.

COAG (2008c) has announced that a new statutory body is to be established to replace the ASCC. This body will be jointly funded by the Commonwealth (50 per cent) and the states and territories (50 per cent allocated according to population) with an initial budget of $17 million for 2008-09.

Decisions on the standards to be applied to workplace use of chemicals rest with individual jurisdictions. These standards, often in the form of regulations under the relevant Act, will usually be developed by compensation and work safety authorities (for example, Worksafe Victoria) and/or employment and industrial relations departments. The authorities are largely funded by workers' compensation premiums (and investment earnings on those premiums), while the departments are taxpayer funded.

F.9 National Transport Commission

The NTC leads the development and maintenance of agreed (by jurisdictions) national land transport reforms. This includes setting standards in areas such as road and rail safety. As part of this role it develops model legislation and regulations and the Australian Dangerous Goods (ADG) Code (all for approval by the Australian Transport Council) for the transport of dangerous goods by road and rail (chapter 7).

The NTC has been largely funded by Commonwealth, State and Territory Governments. It has also obtained revenue from other agencies which have contracted it to undertake certain tasks. The NTC also sometimes uses jurisdictional departments or authorities as lead agencies to develop reform packages in certain

areas and these costs will be met by the jurisdiction concerned either from general revenue or from revenue sources used to fund the department concerned.

For chemicals regulation, the NTC has received small amounts of income from the sale of the ADG Code — in the five years to 2006-07 it received around $215 000 for the sale of ADG6. The NTC (2006, p. 50) had planned to set charges for ADG7 to 'loosely' cover the cost of developing the Code:

> The time and resources required, in this instance, to update the Code and model legislation has dictated that the 7th Edition of the Code is made available on a cost recovery basis since NTC funding is limited. The 7th Edition will be made available at an affordable cost equivalent with other model codes of a similar nature. Since the same amount of effort should not be required for future editions the NTC may consider making these available free of charge.

The NTC (sub. DR90) estimated that it would likely forego over $300 000 if it does not receive revenue from sales of the new ADG Code. As recommended in the Commission's draft report, COAG (2008d) has announced that ADG7 will be available free on the internet. The Commission has recommended that copies on other mediums be made available at avoidable cost (chapter 7).

F.10 Australian Maritime Safety Authority

The Australian Maritime Safety Authority (AMSA) is an Australian Government statutory authority with the objectives of minimising the risk of shipping incidents and pollution in Australian waters and to effectively respond to those incidents that do occur. Part of this role involves participating in development and implementation of international and national safety standards under which the transport of dangerous goods by sea in Australian waters is regulated (chapter 7).

AMSA's expenditure is largely cost recovered from the maritime industry. Around half of its 2006-07 operating revenue of $97 million came from three levies on shipping.[5] The regulatory functions levy ($25.5 million) funds AMSA's ship regulatory and standards compliance monitoring functions, including involvement in international regulatory forums. The levy rate is 17 cents per net registered ton for the first 50 000 tons and 15.5 cents per ton thereafter.

[5] The bulk of the remaining revenue was an Australian Government appropriation to cover CSOs such as search and rescue functions.

F.11 Civil Aviation Safety Authority

The Civil Aviation Safety Authority (CASA) is an Australian Government statutory authority which conducts the safety regulation of civil air operations in Australia and of the operation of Australian aircraft overseas. Part of this function is the regulation of the transport of dangerous goods by air and provision of comprehensive safety education and training programmes (chapter 7). In 2006-07, it received 55 per cent of its revenue from aviation fuel excise, 32 per cent from government appropriations and 11 per cent from cost based regulatory service fees.

F.12 Australian Competition and Consumer Commission

The Australian Competition and Consumer Commission (ACCC) is responsible for enforcing the *Trade Practices Act 1974* (Cwlth), which contains consumer protection provisions. In particular, the generic product safety regulatory system is administered by the ACCC and jurisdictional consumer protection agencies and allows for product warning notices, product bans, safety and information standards and product recalls. In addition, the ACCC administers an information standard on labelling requirements for cosmetics and toiletries.

In 2006-07, the ACCC received nearly all of its $108 million in revenue from the Australian Government.

G Labelling

This study examines Australia's system of regulating chemicals and plastics in the context of the five main areas of public policy concern that relate to the hazardous nature of some chemicals — public health, workplace and transport safety, agricultural and veterinary (agvet) safety, environment protection and national security. It also assesses the efficiency and effectiveness of current institutional and regulatory frameworks.

The study considers the efficiency and effectiveness of the various chemical labelling schemes in the context of the abovementioned policy areas. To complement this approach, this appendix examines labelling regulation more generally, and brings together all the elements of the Commission's investigation of the labelling arrangements.

G.1 Labelling regulation in Australia

Rationale for labelling regulation

The market failures which are addressed by labelling are discussed throughout the report. Generally, these market failures relate to insufficient market incentives for some firms to obtain, assess and provide the information required to manage risks to human health and the environment, and to the inability of some chemical users to understand and translate information into appropriate risk management strategies (box 2.1).

Labelling schemes

As with the wider regulatory framework for chemicals and plastics in Australia, labelling regulation is organised around end use covering industrial chemicals, agricultural and veterinary chemicals, pharmaceutical and therapeutic goods and food. National labelling codes and standards require chemical importers, manufacturers and suppliers to inform consumers about chemical hazards to human health and the environment (box G.1). This appendix covers labelling schemes for industrial chemicals (including cosmetics, explosives and poisons) and agvet

chemical products. This appendix does not consider labelling of alcoholic beverages, food, tobacco, pharmaceutical and medicinal products, radioactive or infectious substances, or veterinary medicines as they are outside the scope of this inquiry.

Box G.1 **Labelling schemes in Australia**

The following national codes and standards provide guidance on how to meet labelling requirements under Commonwealth, state and territory legislation:

- Standard for the Uniform Scheduling of Drugs and Poisons (for scheduled poisons) — administered by the National Drugs and Poisons Schedule Committee.
- Information Standard (for cosmetics ingredient labelling) — administered by the Australian Competition and Consumer Commission.
- National Code of Practice for the Labelling of Workplace Substances (for the labelling of hazardous substances in the workplace) — administered by the Australian Safety and Compensation Council (ASCC).
- Australian Code for the Transport of Dangerous Goods by Road and Rail 6th Edition (ADG6), based on UN Recommendations on the Transport of Dangerous Goods, Model Regulations (11th edition) — administered by the National Transport Council (NTC), (soon to be replaced by ADG7, based on UN Model Regulations (14th and parts of the 15th edition) being developed by NTC).
- Australian Code for the Transport of Explosives by Road and Rail 2nd Edition(AEC2) based on UN Model Regulations (11th edition) — administered by the NTC.
- Agriculture and Veterinary Codes (for agvet chemicals) — administered by the Australian Pesticides and Veterinary Medicines Authority.

Proposed labelling schemes:

- Draft Code of Practice for the Labelling of Workplace Hazardous Chemicals (for the labelling of hazardous chemicals (including dangerous goods) in the workplace) — based in part on the Globally Harmonised System of Classification and Labelling of Chemicals, being developed by the ASCC.
- Australian Code for the Transport of Explosives by Road and Rail 3rd Edition (AEC3), based on UN Model Regulations (15th edition) — being developed by the Australian Forum of Explosives Regulators.

As outlined in chapter 3, states and territories have most of the constitutional power to regulate the use of chemicals and plastics in Australia. Chemicals labelling regulations are based on national labelling codes and standards which have no legal power[1] unless they are implemented and enforced by a Commonwealth, state or

[1] With the exception of the Agvet Code under which it is illegal to supply an agricultural chemical product with a label that has not been approved by the APVMA.

territory regulatory agency. However, the codes and standards provide model documents for state and territory governments to use as a basis for regulation and industry to refer to. These codes and standards promote national consistency in labelling regulation by providing state and territory governments with uniform text and requirements for adoption into their legislation. States and territories adopt the codes and standards using various legislative mechanisms (for example, conferral of powers, template and model legislation) and to varying degrees of consistency. National codes and standards also provide industry with a degree of clarity and certainty about how to meet the various state and territory legislative requirements in labelling chemicals. Box G.1 lists the main current and proposed national labelling schemes and the bodies that administer them.[2]

Material Safety Data Sheets (MSDS) form part of the regulatory response to information failures associated with the use of hazardous substances and dangerous goods in the workplace (chapters 6 and 9). This appendix refers to MSDS regulation to the extent it interacts with labelling.

Approaches to labelling regulation

Chemical substances or products introduced into the Australian market require labels which comply with the relevant labelling schemes. In preparing a label, chemical suppliers, manufacturers and importers use the labelling codes and standards to find out the information required on the label and how it should be presented. Information on the label is drawn from a number of sources, including the chemical suppliers and chemical assessment reports.

Hazard versus risk-based approaches to labelling

There are two main approaches to chemicals labelling in Australia. Where uses of a chemical are defined, risk-based labelling systems are generally used. A risk-based label provides specific instructions for use which, if followed, can help manage the risks posed to human health and the environment. Where uses are undefined, hazard-based systems are generally used, providing information on the potential hazards to people and the environment.

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2 Other elements of labelling include: trade measurement regulation; the references to the Australian Safety and Compensation Council Labelling Code (NOHSC 1994b) included in the National Code of Practice of the Storage and Handling of Workplace Dangerous Goods (NOHSC 2001b); the First Aid Instruction and Safety Directions for Agricultural and Veterinary Chemicals Handbook containing advice provided to the APVMA by the Office of Chemical Safety; and the labelling associated with cosmetic product claims regulated by the Cosmetics Standard administered by NICNAS.

In Australia, hazard and risk assessments must be carried out by the manufacturers and importers of any chemical used in a workplace. National regulatory agencies (National Industrial Chemical Notification and Assessment Scheme (NICNAS) and the Australian Pesticides and Veterinary Medicines Authority (APVMA)) assess new and priority existing chemicals. In making a risk assessment, the magnitude of the hazard, as well as the potential exposure and the probability of a hazardous event occurring, is evaluated. National regulatory agencies conduct risk assessments for chemicals based on their hazard classifications and patterns of use. How a chemical is used is a significant determinant of the potential exposure pathways to people and the environment, as well as the probability of a hazardous event. Chemical use includes where, when, how, how often, in what quantity, and in which combination with other chemicals a chemical is used.

If the use of a chemical is known, potential exposure pathways to humans and the environment can be determined. Instructions on labels can provide greater certainty that risks to human health and the environment are managed. For example, a cleaning product may be applied to surfaces around the house and enter water ways via drains and the sewage system. Based on this pattern of use, instructions can be developed which, if followed by chemical consumers, should manage risks to human health and the environment.

However, where the type and nature of the use is undefined, and potential exposure pathways[3] are unknown or variable, hazard based labelling systems can be an effective regulatory solution to managing risk. Identified chemical hazards are communicated through labels. Users undertake their own risk assessment, combining hazard information provided on labels with the intended use of the chemical and other information to develop a risk management strategy. Improved risk management practices may result from incorporating local information on use and allowing ongoing feedback and innovation into safe use practices. Ongoing training and monitoring may be required to enable users to maintain and refine risk management strategies.

Label approval versus self-assessment

Effective regulation depends not only on establishing the right type of regulations, but also on ensuring compliance with them. Once a supplier has prepared a label for a chemical or product, there are two approaches to label assessment and approval in Australia. Agvet labels must be approved by the APVMA before an agvet product can be registered and sold. Other codes rely on self-assessment by chemical

3 In this context, use includes transport, storage and disposal, and potential exposure pathways include those arising from accidents.

suppliers, based on established labelling frameworks, to comply with labelling requirements in state and territory legislation. A range of monitoring and enforcement systems operate to encourage ongoing adherence with labelling regulation.

Agvet chemicals are applied widely to the environment and incorrect use could pose a high risk to human health and the environment (including food safety and agricultural exports). The risk-based approach used on agvet labels places a heavy onus on providing appropriate instructions for use, and use according to label instructions.

All agvet chemical products must carry a label approved by the APVMA containing the information required by the Agvet Code. Agvet product suppliers must prepare and submit a label to the APVMA for approval. The APVMA will approve labels that are compliant with the Agvet Code and assessed to contain adequate instructions for safe and effective use. Non-compliant labels will not be approved, preventing the agvet product from being registered. Changes to agvet labels also require APVMA approval (except for minor changes). Labels not conforming to that approved may be identified through compliance activities. The APVMA investigates label non-compliance when it comes to their attention. The APVMA also issues some permits for off-label use.

Under the other labelling schemes, covering hazardous workplace chemicals, poisons, cosmetics and dangerous goods, labels do not require approval.[4] It is the legal responsibility of suppliers of these chemicals or products to ensure their labels comply with labelling requirements under state and territory legislation. Compliance with labelling requirements is encouraged through legal liability and penalties for noncompliance. Workplace safety agencies may check label compliance during workplace inspections and investigations, and may respond to complaints about the quality of the information on the label. Label checks are undertaken by NICNAS for the Cosmetics Standard and the Australian Competition and Consumer Commission (ACCC) for the Information Standard. State and territory health departments are responsible for ensuring compliance with poisons legislation.

4 NICNAS may make recommendations on labels of industrial chemicals in chemical assessment reports. NICNAS recommendations on labelling are provided to companies applying for chemicals assessment and are publicly available (chapter 4). NICNAS and the OCS identify necessary controls in relation to poisons scheduling during assessment which are referred to the National Drugs and Poisons Schedule Committee (chapter 5).

Interpreting label information to manage risks

The labelling schemes aim to provide the right type of information to different chemical users, including adequate instructions for safe use, in a comprehensible format to allow users to effectively manage risks to human health and the environment. The ability of chemical users to interpret labelling information and their private incentives to act can be significant determinants of the effectiveness of the regulation.[5] Table G.1 summarises how different chemical users can combine their own knowledge with information on a label to manage risks to human health and the environment.

G.2 Effectiveness and efficiency of labelling regulation

Chapter 2 discusses the criteria applied in the report to assess the efficiency and effectiveness of chemicals regulation in Australia. This appendix has drawn on these general assessment criteria to develop the following framework for assessing the efficiency and effectiveness of the various labelling schemes. The framework involves:

- national consistency in labelling regulations across jurisdictions
- consistency with Australia's major trading partners
- potential for streamlining labelling systems
- ensuring interactions between labelling schemes are efficient and effective.

Box summarises the main issues, findings and recommendations relating to labelling in the report.

National consistency of labelling schemes

Uniform national regulation can deliver benefits through interjurisdictional spillovers, economies of scale and scope, and lower transaction costs. While there can be arguments in favour of states and territories tailoring regulations to their own requirements in certain circumstances, labelling regulation appears particularly suited to a nationally uniform approach. This is because:

[5] Labelling regulation can mandate that information such as instructions for use or hazard warnings appear on a label. There may be no legal requirement for users to follow the instructions or act on the hazard information. The degree to which they act to manage risks may depend on their abilities to interpret label information, other legal requirements to act in a manner consistent with the label, and their private incentives. In the case of agvet products, the control-of-use arrangements also provide incentives to comply with label directions.

- labels, where they are hazard based, inform users about the hazardous nature of chemicals which is the same nationally and internationally
- chemical products tend to be sold on national markets
- relabelling for subnational markets is costly.

Table G.1 **Labels inform chemical users on risk management**

Schemes	*Label information*	*Other information*	*Risk management action*
Agvet Labelling Code	Environment, health and safety information. Instructions for use.	Licensing for some activities such as aerial spraying. Local weather and environment knowledge. Can call information hotline.	Follow instructions for use. The Agricultural Pesticides and Veterinary Medicines Authority issues permits for some 'off-label use'. Victoria allows some 'off-label' use.
Poisons Schedule appendixes	Poisons signal heading. Warning statements. Instructions for use. Safety and emergency directions.	Some schedule 7 poisons only available to authorised or licensed users. Can call information hotline.	Follow instructions for use.
Cosmetics Information Standard	Ingredients list.	Knowledge of personal allergies. Can call information hotline.	Follow instructions for use. Avoid products containing known irritants.
Workplace Labelling Code	Hazard warnings. Health and safety, disposal and emergency information.	Pattern of chemical use and knowledge of workplace conditions, occupational health and safety (OHS) training, signage. Can call emergency services.	Consider use pattern and training, conduct risk assessment, develop risk management strategy.
Australian Dangerous Goods Code	Hazard warnings. Emergency contact information.	Pattern of chemical use and knowledge of workplace conditions, OHS training, workplace signage. Driver training and licensing. Can call emergency services.	Consider use pattern and training, conduct risk assessment, develop risk management strategy.
Australian Explosives Code	Hazard warnings. Emergency contact information.	Driver training and licensing. Can call emergency services.	Consider hazards and risks, conduct a risk assessment, develop risk management strategy.

Labelling schemes in Australia are based on agreed national codes and standards. However, their implementation and enforcement mostly rests with the states and territories. A national code or standard, and its uniform adoption and implementation by states and territories, increases the efficiency of a national labelling scheme by reducing compliance costs from relabelling, provides regulatory certainty for industry, and facilitates interstate trade and competition.

Box G.2 Issues, findings and recommendations relevant to labelling

National consistency of regulatory arrangements

Recommendation 5.2: State and territory governments should … uniformly adopt regulatory controls for poisons [and] continue to report any variations to nationally-agreed poisons scheduling or regulatory decisions at the state and territory level to the Australian Health Ministers' Conference, and include a statement of reasons.

Section 6.6: COAG has agreed to uniformly adopt and implement national model occupational health and safety (OHS) legislation, regulations and codes of practice.

Section 7.4: COAG has agreed to the nationally consistently implementation by all jurisdictions of the 7th edition of the Australian Dangerous Goods (ADG) Code, which is based on UN Recommendations on the Transport of Dangerous Goods, Model Regulations.

Recommendation 7.3: The current review of the Australian Explosives Code by the Australian Forum of Explosives Regulators (AFER) should be completed as expeditiously as possible to produce uniform regulations that are adopted and consistently applied by all jurisdictions. The AFER should then immediately undertake a review of jurisdictional legislation and regulations for explosives transport, with the aim of achieving nationally consistent legislation and regulations to complement the uniformly adopted technical code.

Recommendation 8.2: The Australian Pesticides and Veterinary Medicines Authority (APVMA) should regulate the use of agricultural and veterinary chemical products after the point of retail sale through amendments to the Agvet Code. The scope of the new control-of-use regime should … include, at a minimum, uniform approaches to enforcing conditions of use on product labels and to the licensing and training of users.

Consistency with foreign schemes

Section 5.3: The Commission does not regard it as appropriate to introduce deemed-to-comply provisions for foreign cosmetics labelling at this time. However, the Australian Competition and Consumer Commission (ACCC) should review the Information Standard and scope for deemed-to-comply arrangements once EU reforms have been completed, if stakeholders identify ongoing alignment issues.

Recommendation 6.2: The Workplace Relations Ministers' Council should implement the Globally Harmonised System of Classification and Labelling of Chemicals in the workplace sector in Australia only when it can be shown that adoption of the new regime would produce net benefits. The Australian Safety and Compensation Council should undertake a further regulatory impact assessment when some of Australia's key trading partners, such as China and the United States of America, have commenced implementation of systems of regulation for workplace chemicals that are based on the Globally Harmonised System of Classification and Labelling of Chemicals.

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Box G.2 continued

Streamlining labelling regulation

Section 8.2: The Commission supports an APVMA initiative to simplify its label approval processes so that changes to content on agvet labels which is not part of the agvet labelling code would no longer require a label approval application.

Compliance costs from multiple schemes

Section 5.3: The Commission does not recommend a specific exemption from the Information Standard for industrial hand cleaners that are sold to consumers.

Recommendation 6.3: The Australian Safety and Compensation Council should conduct a regulatory impact assessment of the proposal to require agricultural and veterinary chemical products that are also workplace hazardous chemicals to carry workplace hazardous chemicals labels. The assessment should identify alternatives and the costs and benefits of the options. The Workplace Relations Ministers' Council should only adopt the proposal if it can be demonstrated that it would deliver a greater net benefit to the community than any alternative. Until the regulatory impact assessment has been completed, recognition of agricultural and veterinary chemical product labels for occupational health and safety purposes should continue to apply.

Other

Recommendation 9.1: The Environment Protection and Heritage Council should examine the costs and benefits of mandatory environmental labelling of chemicals. Mandatory environmental labelling should only be introduced if there is a demonstrated net benefit to the community.

Any jurisdictional variations from a national labelling standard should only be allowed where a cost–benefit analysis demonstrates that the benefit to the community from increased effectiveness outweighs the higher compliance cost from inconsistency. Under the Commission's governance model (chapter 3), jurisdictions should report any variations to the overseeing ministerial council with their reasons. This is the case under the intergovernmental agreement (IGA) on transport, for poisons scheduling, and the Occupational Health and Safety (OHS) IGA[6], and the Commission has recommended this approach for an environment standard-setting body (recommendation 9.2).

6 In the OHS IGA, the states and territories agreed that any amendments to legislation or new legislation that would materially effect the operation of national model OHS legislation would have to be endorsed by the Workplace Relations Ministers' Council. If changes are endorsed, the parties agreed to introduce changes to their own legislation to ensure that OHS legislation remains nationally consistent.

Nationally consistent agvet labelling requirements are achieved through state and territory adoption of the national Agvet Code. However, some, off-label uses of agvet chemicals can be allowed by the APVMA under its permit provisions. Permits can be jurisdiction-specific. There are also significant differences across jurisdictions in the regulatory approaches to off-label use not authorised by the APVMA, leading to stakeholder confusion and competition distortions (table 8.2). To address this issue, the Commission has recommended that agvet chemicals, after the point of retail sale, be regulated by the APVMA through national legislation (recommendation 8.2).

Apart from the inconsistencies in off-label regulations of agvet chemicals, the Commission has not been presented with any evidence of significant deviation by states and territories from the national labelling standards. Table G.2 summarises the level of national uniformity of the various labelling schemes. Apart from minor variations listed in the table, there appears to be a high degree of national uniformity in labelling regulation.

Consistency with foreign labelling schemes

As mentioned previously, the hazardous nature of chemicals is the same internationally. While risk assessment and the development of risk management standards must necessarily ensure relevance to local circumstances, international consistency in labelling can deliver benefits by reducing the need to relabel Australian exports and imports to meet foreign and local labelling regulations.[7]

International labelling systems can provide a framework within which countries can align their labelling regimes with those of their major trading partners, where there are net benefits in doing so. Recognition of foreign labelling schemes and deemed-to-comply provisions can also assist in aligning schemes.

[7] Box E.3 provides examples of the costs to Australian business of relabelling imported products.

Aligning labelling requirements with those of our trading partners can also involve costs, including:

- costs to chemical importers, manufacturers and suppliers of amending labels, and retraining staff
- reduced effectiveness of risk-based labelling schemes that do not take into account Australian environments or conditions, or that include aspects not relevant to Australia
- administrative costs to government of assessing whether foreign schemes or international systems are sufficient for Australian requirements
- ongoing administrative costs to government and compliance costs to business of keeping up-to-date with changes to international systems or recognised foreign schemes to ensure compliance of labels on Australian imports and exports.

Table G.2 describes the level of consistency between Australian and foreign labelling schemes. There is a broad range in the degree of alignment with foreign schemes, from close alignment for an international system for transport labelling to unique Australian requirements for agvet and poisons labelling.

Although agvet labelling codes and poisons regulatory controls are not aligned to international schemes, the Commission has not been presented with examples of compliance costs resulting from this.

The UN Recommendations on the Transport of Dangerous Goods, Model Regulations and the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) are examples of international systems for labelling to which Australia has aligned or is aligning its domestic labelling regulation.

Australian regulations for air and sea transport of dangerous goods are closely aligned with international requirements. The linking of the new land transport regulatory framework (ADG7) to the most recent UN Model Regulations (14^{th} and part of the 15^{th} edition) achieves a similar outcome. The alignment of land transport regulations with the UN Model Regulations has significantly increased the compatibility of dangerous goods transport regulations across transport modes within Australia.

However, some Australia-specific provisions remain. For example, certain emergency information panel requirements not contained in the UN Model Regulations have been retained in ADG7 to assist emergency services responses to accidents (NTC 2007, p. G14). These will impose some additional costs on exporters and importers of dangerous goods, but may provide offsetting benefits in terms of more effective emergency responses. ACCORD Australasia (sub. DR91)

Table G.2 **National and international consistency of labelling schemes**

Scheme	*Degree of national uniformity*	*Degree of international uniformity*
Agvet Labelling Code	Uniform adoption of template Agvet Code. Some jurisdictions permit off-label uses, which are nationally inconsistent and may reduce the effectiveness of the agvet regime (section 8.3). The Commission has recommended that agvet chemical products after point of retail sale be regulated by the Australian Pesticides and Veterinary Medicines Authority (APVMA) through national legislation (recommendation 8.2).	No recognition of foreign labels. Imported agvet chemicals must be registered by the APVMA for use in Australia and their labels approved for the Australian market.
Poisons Schedule appendixes	Some interjurisdictional variations (NSW, WA) but no issues raised with respect to labelling. The Commission has recommended that the states and territories uniformly adopt poisons regulatory controls through either a template or model approach (recommendation 5.2).	No recognition of foreign labels. Imported scheduled poisons need to be labelled for the Australian market.
Cosmetics Information Standard	Made under the *Trade Practices Act 1974* (Cwlth) and applied nationally. However, Qld and SA have mirrored the Commonwealth legislation in their own legislation.	Labelling requirements broadly similar to major trading partners.
Current Workplace Labelling Code	The current Code is picked up consistently by occupational health and safety (OHS) legislation in states and territories. Under the new OHS IGA, states and territories have committed to uniformly adopt and implement national model OHS legislation. Any proposed amendments must be endorsed by the Workplace Relations Ministers' Council and the states and territories will 'undertake all necessary steps to introduce appropriate changes to their legislation with a view to ensuring that OHS legislation remains nationally consistent' (OHS IGA clause 5.5.3) (COAG 2008c).	The Code is broadly aligned with the system for classification and labelling of hazardous substances used in the EU.
Draft Code of Practice for the Labelling of Workplace Hazardous Chemicals		Based on the Globally Harmonised System of Classification and Labelling of Chemicals (GHS). The draft Australian Safety and Compensation Council workplace standard proposes that some hazard classes be exempted (for example, hazard to aquatic environment). The Commission has recommended that the Environment Protection and Heritage Council examine environmental labelling (recommendation 9.1).

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Table G.2 continued

Scheme	*Degree of national uniformity*	*Degree of international uniformity*
Australian Dangerous Goods Code (ADG7)	The COAG Ministerial Taskforce has required nationally consistent implementation of the Model Transport of Dangerous Goods Act and referencing of the ADG Code including labelling requirements (section 7.4).	ADG7 based on UN Model Regulation (15th edition), improves labelling uniformity with imports and exports meeting UN 15th edition. Departures from UN Model Regulations are present, such as emergency information panel requirements, inner packaging requirement and the removal of the limited quantities exemption (sub. 91) (section 7.3).
Australian Explosives Code (AEC)	The Commission has recommended that the review of the AEC produce uniform regulations that are consistently adopted across jurisdiction (recommendation 7.3).	AEC3 would be based on the UN Model Regulations (15th edition), but will incorporate some departures from UN Model Regulations (intermodal repackaging and relabelling requirements (subs. 82 and 63).

noted departures from the UN Model Regulations in ADG7 for inner package labelling and exemptions of limited quantities, which would lead to higher labelling costs for the consumer goods and cosmetics industry (section 7.3).

Alignment of Australian labelling requirements with international systems may provide trade facilitation benefits to the extent that our major trading partners also align with the international system (section 6.5). The current system of classification and labelling for workplace hazardous substances is broadly aligned with that of the European Union. Although the GHS is intended to be a single global system for labelling, not all countries will implement all elements of the system in the same way. Different 'brands' of the GHS may be implemented in different countries that are not consistent with each other. The implementation of the GHS in Australia could result in benefits arising from trade facilitation, but may also impose substantial costs (section 6.5).

The GHS contains provisions for the classification of a substance as a hazard to the aquatic environment and environmental labelling provisions (section 9.3). However, under the draft National Standard for the Control of Workplace Hazardous Chemicals (ASCC 2006e) it will not be mandatory to classify a substance as hazardous to the aquatic environment, nor to include information or hazard communication elements that relate to aquatic toxicity on labels even if the substance has been classified. The draft National Code of Practice for the Labelling of Workplace Hazardous Chemicals (ASCC 2006c) provides guidance on the voluntary inclusion of information on environmental hazards on labels (section 9.2). Approaches to environmental labelling and its associated costs and benefits are discussed in chapter 9.

Many of Australia's trading partners have labelling requirements that are broadly similar to those applied in Australia, although not based on an international system. For cosmetics ingredient labelling, the EU[8], the US[9], and Canadian[10] arrangements all require the ingredients of cosmetics to be labelled in descending order in terms of volume, and contain other similar provisions such as the use of terms for flavours and fragrances (section 5.3).[11] ACCORD Australasia (sub. 42) proposed that a 'deemed-to-comply' provision be added to the Information Standard to allow fully-imported cosmetic products to be sold in Australia if the label satisfies the

8 Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (76/768/EEC).

9 Code of Federal Regulations, Title 21: Food and Drugs, Part 701 — Cosmetic Labelling.

10 Cosmetic Regulations (Food and Drugs Act).

11 The International Nomenclature Cosmetic Ingredient names provides some international consistency.

requirements of the EU, the US, Canada or New Zealand.[12] The Commission does not regard it as appropriate to introduce such a provision at this time. However, the ACCC should review the Information Standard and scope for deemed-to-comply arrangements once EU reforms have been completed, if stakeholders identify ongoing alignment issues (section 5.3).

Streamlining labelling systems

An effective and efficient labelling system relies on labels being easy for consumers to understand and interpret, and easy for producers to comply with. A key determinant of the ease of understanding a label is the amount of information on it. The Industry Commission noted in its report on Packaging and Labelling Regulations (IC 1996a) that '[c]rowding out, whereby the information required competes for space on the product label, is a significant problem' (p. xxxii). To this end, performance-based labelling can assist by specifying objectives, rather than prescribing label information. This approach can confer benefits, including:

- reducing the need to have multiple labels that meet the prescriptive requirements of multiple schemes. Instead, one label that contains all the information to meet the various objectives could be developed
- greater potential for aligning Australian requirements with those overseas, which reduces the need for relabelling.

There are, however, costs associated with performance-based labelling, including establishing that labels meet the requirements of legislation. These costs can be reduced by having prescriptive regulations that are 'deemed to comply'. This approach allows firms to choose whether to meet performance or prescriptive based regulations, depending on their circumstances.

The cost of complying with regulations is also a component of the efficiency of labelling systems. For most of the labelling schemes covered by this study, it is the responsibility of the manufacturer or distributer to ensure compliance with the relevant regulations. The APVMA product registration process, however, requires approval of labels by the APVMA (table G.3). This approach reflects the risk-management nature of agvet labels that are more prescriptive than performance-based, and the risks to human health and the environment of providing noncompliant labels. But it also imposes additional compliance costs on registrants, including longer product approval times and requiring approvals for minor matters.

12 ACCORD Australasia noted that New Zealand has already implemented such an exemption for cosmetics satisfying the labelling requirements of Australia, the EU, or the US.

Table G.3 **Label assessment and compliance processes**

Scheme	*Assessment*	*Compliance*
Agvet Labelling Code	The APVMA checks agvet labels and approves those that comply with the Agvet Code. Changes to any information on labels, apart from that exempted under permits 686 and 9523, including poisons and dangerous goods information requires reapproval of the label by the APVMA.[a]	Labels not conforming to that approved by the APVMA may be identified through APVMA compliance activities. The APVMA investigates label noncompliance when it comes to their attention. Suppliers are subject to litigation or penalty for noncompliance.
Poisons Schedule appendixes	NICNAS makes recommendations on label compliance with the SUSDP as part of chemical assessment process. Office of Chemical Safety makes recommendations for agvet chemicals for poisons scheduling, and First Aid Instruction and Safety Directions label elements. It is the responsibility of the manufacturer, packer or distributor of a poison to ensure that a product is correctly and adequately labelled.	States and territories can investigate noncompliance if information comes to hand. Suppliers are subject to litigation or penalty for noncompliance.
Cosmetics Information Standard	It is an offence to sell or supply a cosmetic that is not labelled in accordance with the Trade Practices Act regulations.	Label audits conducted by the Australian Competition and Consumer Commission. Suppliers are subject to litigation or penalty for noncompliance.
Workplace Labelling Code	It is the legal responsibility of the chemicals supplier to assess their own labels and ensure they comply with state and territory legislation. NICNAS makes recommendations on label compliance with the Australian Safety and Compensation Council (ASCC) Code for assessed new or existing chemicals.	Workplace audits, including checking label compliance, may be conducted by state and territory workplace authorities. Employers are subject to litigation or penalty for noncompliance.
Australian Dangerous Goods Code	It is the legal responsibility of the chemicals supplier to assess their own labels and ensure they comply with state and territory legislation.	States and territories can investigate noncompliance if information comes to hand. Suppliers are subject to litigation or penalty for noncompliance.
Australian Explosives Code	It is the legal responsibility of the chemicals supplier to assess their own labels and ensure they comply with state and territory legislation.	States and territories can investigate noncompliance if information comes to hand. Suppliers are subject to litigation or penalty for noncompliance.

a The APVMA label reform will establish three modes of regulatory approval for agvet label information. Agvet Code information would require APVMA approval. Information not relating to the Agvet Code would be controlled by a condition of label approval. Commercial information would be controlled by permit. This would reduce compliance costs for the APVMA and registrants (section 8.2).

There may be some aspects of the label approval process that can be streamlined to reduce costs to both registrants and governments. The APVMA has already

introduced reforms to allow specified administrative changes to the product label without the need to apply for APVMA approval. It has also proposed changes that would remove the requirement for registrants to apply for APVMA approval for changes to labels that are outside of the scope of APVMA operations (such as poisons scheduling and dangerous goods classification) (section 8.2). Further streamlining could be considered as part of ongoing reforms.

Interaction between labelling schemes

Where a chemical or chemical product falls under more than one labelling scheme, issues arise as to the compliance burden arising from multiple schemes and inconsistencies between schemes. Table summarises how the various labelling schemes operate together.

Burdens arising from compliance with multiple labelling schemes

Reduced effectiveness and efficiency may occur where manufacturers or suppliers have to comply with more than one labelling scheme. The use of multiple labelling schemes can improve effectiveness if the combined information enhances a user's ability to manage risks. It also has the potential to cause confusion among users if information from one scheme crowds out other information, or requirements are inconsistent between schemes. Being subject to more than one scheme does not necessarily result in overlap or duplication. Where both schemes require a particular piece of information, it need only be provided once (that is, there do not have to be two labels that have the same information). However, multiple labelling schemes may raise compliance costs for chemical importers, manufacturers and suppliers, and could create uncertainty for business if the interactions between labelling schemes are not clear.

Compliance with multiple schemes should only be required where it provides a net benefit to the community, and should not impose an unnecessary administrative burden. It was beyond the scope of this study to assess the net benefit of using multiple labelling schemes for chemicals and chemical products. However, the study has addressed issues raised by stakeholders, including:

- a potential regulatory overlap where industrial hand cleaners may be subject to both workplace labelling requirements and ingredients labelling (section 5.3)
- a proposal to require agvet chemicals used in the workplace to be subject to both workplace and agvet labelling requirements (section 6.5)
- reform to the APVMA's label approval process for information not covered by the Agvet Code (poisons and dangerous goods information) (section 8.2).

Table G.4 **Current and proposed labelling requirements for chemicals in Australia[a]**

Type of chemical	*Industrial chemicals*	*Agvet chemicals*
Used in the workplace		
Hazardous substances	Labelled under the current Australian Safety and Compensation Council (ASCC) Code (unless an agvet product, cosmetic product or end-use domestic product covered by the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP). Environmental labelling not required.	Labelled under Agvet Code. Recognition of agvet labels in the current ASCC Code.
Scheduled poisons	Reasonably expected to be used in workplace or industrial and lab products: labelled under current ASCC Code and exempt from the SUSDP.[b] Incidental use in workplace: exempt from current ASCC Code and labelled by SUSDP.	Labels approved by the Australian Pesticide and Veterinary Medicines Authority (APVMA), including poisons information. APVMA approval will not be required for changes to poisons information.
Hazardous chemicals (draft ASCC Code based on the GHS replaces classification, labelling and safety data sheet systems for hazardous substances and dangerous goods)	Labelled in accordance with draft ASCC Code unless a cosmetic or consumer product. Environmental labelling not mandatory but optional.	Recognition of agvet labels have been removed. Possible overlap should be examined by regulatory impact analysis.
Consumer products that are hazardous chemicals (scheduled poisons are not distinct from consumer products under the draft ASCC Code)	If use is incidental to the workplace or consistent with household use, exempt from draft ASCC Code. For workplace use, labelled in accordance with draft ASCC Code and exempt from SUSDP (if it is a poison).[b]	..
Dangerous goods	Labelled in accordance with the Australian Dangerous Goods Code which is consistent with the draft ASCC Code.	Label approved by the APVMA, including dangerous goods information. APVMA approval will not be required for changes to dangerous goods information.
Cosmetics (when not packed and sold as end use products or use is related to work activity)	Labelled under OHS requirements when related to work activity and the Australian Competition and Consumer Commission (ACCC) Information Standard when sold to consumers.	..

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Table G.4 continued

Type of chemical	*Industrial chemicals*	*Agvet chemicals*
Used in the domestic situation or household		
Hazardous substances	Not subject to ingredient labelling (unless a cosmetic).	
	Not subject to hazard classification regulation (unless a scheduled poison) if targeted directly at households.	
Scheduled poisons	Labelled in accordance with SUSDP.	
Hazardous chemicals	Not subject to ingredient labelling (unless a cosmetic).	Domestic/household use of pesticides is covered by the Agvet Code
	Not subject to hazard classification regulation (unless a scheduled poison) if targeted directly at households.	
Consumer products that are not scheduled poisons or cosmetics	Not subject to ingredient labelling.	
	Not subject to hazard classification regulation.	
Dangerous goods	Not subject to hazard classification regulation (unless a scheduled poison).	
Cosmetics	Labelled under the Cosmetic Information Standard. The ACCC should review the Information Standard and scope for deemed-to-comply arrangements (section 5.3)	

a The current ASCC Code may be replaced by the draft GHS-based ASCC workplace hazardous chemicals Code. 'Hazardous substances' and 'scheduled poisons' is terminology used under the current ASCC Code; 'Hazardous chemicals' and 'consumer products' is terminology used under the draft ASCC Code; 'Dangerous goods' and 'cosmetics' is terminology used for both Codes. **b** The Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) (no. 21, June 2006) in sections 13 and 26, Part 2, states that the labelling and container provisions do not apply to a poison that is packed and sold solely for dispensary, industrial, laboratory or manufacturing purposes. Labelling provisions also do not apply where a poison is labelled in accordance with the ASCC National Code of Practice for the Labelling of Workplace Substances. .. Not applicable.

General principles for reform

The Commission offers some general principles to apply to labelling regulation arising from the issues discussed in this appendix:

- New labelling regulations should only be introduced where a net benefit to the community can be demonstrated. A cost–benefit analysis should be conducted of any labelling reforms in line with Best Practice Regulation Guidelines (COAG 2007a).

- Where the need for new labelling regulations can be demonstrated, they should be:
  - incorporated into existing labelling schemes, where possible, to avoid administrative burdens or uncertainties arising from compliance with multiple schemes and inconsistencies between schemes
  - implemented uniformly across jurisdictions with any deviations being required to be publically reported and explained to the overseeing ministerial council
  - aligned with the schemes of Australia's major trading partners where there are net benefits to Australia from doing so, with any variations subject to cost–benefit analysis to demonstrate the net benefit to the Australia.
- Opportunities to rationalise and simplify labelling schemes should be examined in the context of ongoing reforms and reviews of regulation. This includes options to streamline approval processes (in the case of agvet chemical products) and introduce performance-based labelling where possible.

References

AATSE (Australian Academy of Technological Sciences and Engineering) 2001, *Technology in Australia 1788-1988* (online version), <www.austehc .unimelb.edu.au/tia> (accessed 3 August 2007).

—— 2002, *Pesticide Use in Australia*, Ian McLennan House, Parkville.

ABS (Australian Bureau of Statistics) 2002, *Agricultural Census 2001*, Cat. no. 7121.0, ABS Canberra.

—— 2006a, *Australia and New Zealand Standard Industrial Classification 2006*, Canberra.

—— 2006b, *Australian National Accounts: Input-Output Tables – Electronic Publication 2001-02*, Cat. no. 5209.0.55.001, Canberra.

—— 2007a, *Australian System of National Accounts, 2006-07*, Cat. no. 5204.0, Canberra.

—— 2007b, *Manufacturing Industry Australia 2005-06*, Cat. no. 8221.0, Canberra.

ACA (Australian Consumers' Association) 2008, Strawberries: About our test, Sydney, <www.choice.com.au/viewArticle.aspx?id=106157&catId=100286&tid =100008&p=2&title=Strawberries> (accessed 1 February 2008).

ACCC (Australian Competition and Consumer Commission) 1998, *Cosmetics — June 1998: Regulation Impact Statement*, <www.accc.gov.au/content/index .phtml/itemId/614088?url=%2Fcontent%2Findex.phtml%2FitemId%2F614088 &rewriteMember=116&pageDefinitionItemId=86167> (accessed 3 January 2007).

—— 2004, *2003-04 Annual Report* [performance section], <www.accc.gov.au /content/item.phtml?itemId=710675&nodeId=2f18520ba8493955971e8154bc57 6b5c&fn=ACCC%20AR2004-2005%20part%20two%20-%20performance.pdf> (accessed 3 January 2008).

—— 2005, *2004-05 Annual Report* [performance section], <www.accc.gov.au/ content/item.phtml?itemId=710675&nodeId=2f18520ba8493955971e8154bc576 b5c&fn=ACCC%20AR2004-2005%20part%20two%20-%20performance.pdf> (accessed 3 January 2008).

—— 2006, *2005-06 Annual Report*, <www.accc.gov.au/content/item.phtml ?itemId=764868&nodeId=ed40d21da9996d4c556e36d1572c7298&fn=ACCC% 20annual%20report%202005-06,%20pages%20i-148.pdf> (accessed 3 January 2008).

—— 2007, *No formaldehyde found in clothing*, Media release 277/07, 17October, <www.accc.gov.au/content/index.phtml/itemId/801314/fromItemId /776481> (accessed 7 March 2008).

—— 2008, Regulation Impact Statement (RIS), Review of Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991 (Cosmetic Regulations), February 2008 <www.accc.gov.au/content/index.phtml/itemId/614088> (accessed 15 July 2008).

ACCORD Australasia Ltd 2007, *ACCORD Submission on the ASCC Workplace Hazardous Chemicals Public Comment*, <www.ascc.gov.au/NR/ rdonlyres /9A08B9C2-8BAB-481C-80FA- D40E58C8D41D/0/ChemComment_Accord _2007.pdf> (accessed 10 January 2007).

—— nd, *Scheme for Phosphorus Content and Labelling of Detergents*, </www.accord.asn.au/my/429/1331/1328> (accessed 17 January 2008).

AFER 2008, *Draft Consultation Regulatory Impact Statement, Australian Code for the Transport of Explosives by Road and Rail — 3rd Edition*, February.

Affleck Consulting and Meyrick and Associates 2002, *Review of National Road Transport Commission Act 1991*, July.

AG (Attorney-General's Department) 2004a, *Ammonium nitrate guidance note no. 1 — Transport*, <www.nationalsecurity.gov.au/agd/WWW/ rwpattach.nsf/VAP/ (5738DF09EBC4B7EAE52BF217B46ED3DA)~GUIDANCE+NOTE+No+1+T RANSPORT+5+NOV.doc/$file/GUIDANCE+NOTE+No+1+TRANSPORT+5+ NOV.doc> (accessed 19 March 2007).

—— 2004b, *Ammonium nitrate guidance note no. 2 — Storage*, <www.nationalsecurity.gov.au/agd/WWW/rwpattach.nsf/VAP/(5738DF09E BC4B7EAE52BF217B46ED3DA)~GUIDANCE+NOTE+No+2+STORAGE+8 +NOV.doc/$file/GUIDANCE+NOTE+No+2+STORAGE+8+NOV.doc> (accessed 19 March 2007).

—— 2004c, *Ammonium nitrate guidance note no. 3 — Agricultural use*, <www.nationalsecurity.gov.au/agd/WWW/rwpattach.nsf/VAP/(5738DF09E BC4B7EAE52BF217B46ED3DA)~GUIDANCE+NOTE+No+3+AG+USE +NOV+8.doc/$file/GUIDANCE+NOTE+No+3+AG+USE+NOV+8.doc> (accessed 19 March 2007).

—— 2004d, *Ammonium nitrate guidance note no. 4 — Siting new facilities*, <www.nationalsecurity.gov.au/agd/WWW/rwpattach.nsf/VAP/(5738DF09E BC 4B7EAE52BF217B46ED3DA)~GUIDANCE+NOTE+NO+4+SITING+5+NOV EMBER.doc/$file/GUIDANCE+NOTE+NO+4+SITING+5+NOVEMBER.doc> (accessed 19 March 2007).

——2006, 'What is the Government doing? AN — Frequently asked questions' <www.nationalsecurity.gov.au/agd/www/nationalsecurity.nsf/AllDocs/8FCA7A 705B40263ACA25701B00155D7A?OpenDocument> (accessed 19 March 2007).

Agriculture and Agri-Food Canada 2006, *A Review of Agricultural Pesticide Pricing and Availability in Canada*, <www.agr.gc.ca/pol/index_e.php?s1= pub&s2=pesticide&page=pest5b#5.1> (accessed 5 March 2008).

AHMAC (Australian Health Minister's Advisory Council) 2005, *Working Party Response to the Review of Drugs, Poisons and Controlled Substances Legislation (the Galbally Review)*, <www.tga.gov.au/docs/pdf/rdpahmac.pdf> (accessed October 2007).

AIG (Australian Industry Group) 2007, Workplace Hazardous Chemicals Public Comment, <www.ascc.gov.au/NR/rdonlyres/EDBAED02-BD39-4877-81F9-481922B945CA/0/ChemComment_AIG_2007.pdf> (accessed 30 January 2007).

AIHW (Australian Institute of Health and Welfare) 2006, *Australia's Health 2006*, the Tenth Biennial Health Report of the Australian Institute of Health and Welfare, Canberra, Cat. no. AUS 73, <www.aihw.gov.au/publica tions/aus/ah06/ah06.pdf> (accessed 16 December 2007).

Allen Consulting Group 2002, A National Risk Management System for Agricultural & Veterinary Chemicals. Positioning for the Future. A strategic review for the NRA. Canberra.

——2003, *Alternative Models for Regulation of the Chemicals and Plastics Industry*, Report prepared for the Plastics and Chemicals Industry Association, Australian Consumer Specialty Products Association, Australian Paint Manufacturers Federation and Australian Chamber of Commerce and Industry, Canberra.

ANAO (Australian National Audit Office) 2006, *Regulation of Pesticides and Veterinary Medicines, Australian Pesticides and Veterinary Medicines Authority*, Audit report no. 14, Canberra.

APVMA (Australian Pesticides and Veterinary Medicines Authority) 2004a, *Chemicals and Food Safety*, Information sheet, Canberra, <www.apvma.gov.au/publications/downloads/information_sheet_food.pdf> (accessed 25 October 2007).

—— 2004b, *Registering Agricultural Products – Manual of Requirements and Guidelines*, Canberra.

—— 2005, *New Cost Recovery Arrangements for the APVMA*, Canberra.

—— 2006, *Report of Adverse Experiences for Agricultural Chemicals – Calendar Year 2005*, Canberra.

—— 2007a, *Annual Report 2006-07*, Canberra.

——2007b, *Australian Pesticides and Veterinary Medicines Authority Comments*, <www.ascc.gov.au/NR/rdonlyres/CA996623-464F-4BE7-90D3-EF137FB17AB /0/ChemComment_APVMA_2007.pdf> (accessed 17 January 2008).

—— 2007c, *Report of Adverse Experiences for Veterinary Medicines and Agricultural Chemicals – Calendar Year 2006*, Canberra.

—— 2008, *Progress on Implementation of Recommendations and Addressing Suggestions of The Anao Performance Audit 2006*, <www.apvma. gov.au/about_us/pdf/ANAOprogressreportFeb%2008.pdf> (accessed 3 March 2008).

—— nd, *Advisory Board, Canberra*, <www.apvma.gov.au/about_us/ advisory_bo ard.shtml> (accessed 18 January 2008).

ARA (Australian Retailers' Association) 2003, *Code of Practice for the Management of Plastic Bags*, Sydney.

Argy, S. and Johnson, M. 2003, *Mechanisms for Improving the Quality of Regulations: Australia in an International Context*, Productivity Commission Staff working paper, Canberra.

ASCC (Australian Safety and Compensation Council) 2004a, *Approved Criteria for Classifying Hazardous Substances*, Canberra.

—— 2004b, *Major Hazard Facilities Annual Situation Report*, Australian Government, Canberra, <www.ascc.gov.au/NR/rdonlyres/F823A783-7EE9-4E31-B2CD-B663905BBAB8/0/MajorHazardFacilities2004ASR.pdf> (accessed 8 November 2007)

—— 2005, *National OHS Strategy 2002-2012*, Canberra.

—— 2006a, *Barriers and Enablers to Control of Hazardous Chemicals in SMEs*, Canberra.

—— 2006b, *Draft National Code of Practice for the Control of Workplace Hazardous Chemicals*, Canberra.

—— 2006c, *Draft National Code of Practice for the Labelling of Workplace Hazardous Chemicals*, Canberra.

—— 2006d, *Draft National Code of Practice for the Preparation of Safety Data Sheets*, Canberra.

—— 2006e, Draft National Standard for the Control of Workplace Hazardous Chemicals, Canberra.

—— 2006f, *Draft Regulation Impact Statement Proposed Revisions to the National OHS Framework for the Control of Workplace Hazardous Substances and Dangerous Goods*, Canberra.

—— 2006g, *Occupational Cancer in Australia*, Canberra.

—— 2006h, *Public Discussion Paper, Draft National Code of Practice for the Labelling of Workplace Hazardous Chemicals, and the Draft National Code of Practice for the Preparation of Safety Data Sheets*, Canberra.

—— 2007, *Compendium of Workers' Compensation Statistics Australia 2004-2005*, <www.ascc.gov.au/NR/rdonlyres/E0C9B5C7-9C4E-45A6-A733-475E90F2DA25/0/Completeversion_WorkCompStats0405.pdf> (accessed 7 January 2007).

—— nd1, *Hazardous Substances Information System*, Canberra, <www.hsis.ascc.gov.au/Default.aspx> (accessed 9 January 2008).

—— nd2, *National Online Statistics Interactive*, Canberra <www.nosi.ascc.gov.au/Default.aspx> (accessed 10 January 2008).

ATA (Australian Trucking Association) 2005, *Submission on the National Transport Commission Draft of the 7th Australian Dangerous Goods Code*, August. Canberra.

—— nd, *About TruckSafe*, <www.atatruck.net.au/trucksafe_about_us.html> (accessed 4 October 2007).

ATSB (Australian Transport Safety Bureau) 2007, *Fatal Heavy Vehicle Crashes Australia*, April-June. Canberra.

AusCheck 2006, AusCheck homepage, <www.ag.gov.au/www/agd/agd.nsf/Page/Organisational_StructureNational_Security_and_Criminal_Justice AusCheck> (accessed 10 January 2008).

Australian Government 1992, *Intergovernmental Agreement on the Environment*, <www.environment.gov.au/esd/national/igae> (accessed 12 January 2008).

—— 2002, *Underpinning Australia's Industrial Growth: Government Response*, Canberra, <www.industry.gov.au/assets/documents/itrinternet/cpaa_govt_response20050405101309.pdf> (accessed 24 November 2006).

—— 2006, *Rethinking Regulation: Report of the Taskforce on Reducing Regulatory Burdens on Business - Final Government Response*, August. Canberra.

—— 2007, *Best Practice Regulation Handbook*, Canberra.

Australian Toy Association nd, *Australian Toy Association* <www.austoy.com.au/> (accessed 19 February 2008).

Boyd, J. 2001, *Financial Responsibility for Environmental Obligations: Are Bonding and Assurance Rules Fulfilling their Promise?*, Discussion paper 01-42, Resources for the Future, Washington DC.

Burke, K. 2008, 'Residue find leads to tougher berry tests', *Sydney Morning Herald*, 4 February, p. 5.

Business Decisions Limited 2007, *Benchmarking the Competitiveness of the Australian Animal Health Industry*, <www.animalhealthalliance.org.au/files/benchmarking/IFAH%20Final%20Report%20Australia%20_March%202007_pdf> (accessed 3 March 2008).

CEPR (Centre for Economic Policy Research) 1993, *Making Sense of Subsidiarity: How Much Centralisation for Europe*, London.

COAG (Council of Australian Governments) 2001, *Guidelines for the creation of new ministerial councils*, <www.coag.gov.au/compendium/guidelines.pdf> (accessed 15 February 2007).

—— 2002, Communiqué, 6 December 2002.

—— 2004a, Communiqué, 25 June 2004, <http://www.coag.gov.au/meetings/250604/index.htm> (accessed 1 May 2007)

—— 2004b, *Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard Setting Bodies*, <www.coag.gov.au/meetings/250604/coagpg04.pdf> (accessed 21 June 2007).

—— 2004c, *Regulatory Impact Statement in Relation to the Regulation and Control of Ammonium Nitrate*, Canberra.

—— 2006a, Communiqué, 14 July 2006, <www.coag.gov.au/meetings/140706/docs/attachment_e_reform_regulatory_burden.pdf> (accessed September 2008).

—— 2006b, Meeting Outcomes 10 February, Attachment B, Canberra, <www.coag.gov.au/meetings/100206/attachment_b_ncp_review.rtf> (accessed 3 March 2008)

—— 2007a, Best Practice Regulation: A Guide for Ministerial Councils and National Standard Setting Bodies, October

—— 2007b, *COAG National Reform Agenda*, COAG Regulatory Reform Plan, Meeting 13 April 2007. Canberra.

—— 2008a, Communiqué, 26 March 2008, <www.coag.gov.au/meetings/260308/docs/communique20080326.rtf> (accessed 28 March 2008)

——2008b, Communiqué, 3 July 2008, <www.coag.gov.au/meetings/030708/index.htm#economy> (accessed 11 July 2008)

—— 2008c, Inter-Governmental Agreement for Regulatory and Operational Reform in Occupational Health and Safety, <www.coag.gov.au/meetings/030708/docs/OHS_IGA.rtf> (accessed 17 July 2008).

—— 2008d Meeting 3 July 2008, COAG Ministerial Taskforce on Chemicals and Plastics Regulatory Reform — 'Early Harvest' Reforms <www.coag.gov.au/meetings/030708/docs/COAG_taskforce_regulatory_reform.rtf>(accessed 7 July 2008)

CPAASG (Chemicals and Plastics Action Agenda Steering Group) 2001, *Underpinning Australia's Industrial Growth: Report to Government*, Department of Industry, Tourism and Resources Canberra, <www.industry.gov.au/assets/documents/itrinternet/cpunderpinningp1.pdf> (accessed 25 June 2007).

CPLG (Chemicals and Plastics Leadership Group) 2004, *Underpinning Australia's Industrial Growth: Final Report to the Australian Government: The Australian Chemicals and Plastics Industry Action Agenda*, Department of Industry, Tourism and Resources, Canberra.

Cripps, R. and Steel, D. 2006, *Childhood poisoning in Australia*, NISU Briefing no. 5, October, Australian Institute of Health and Welfare National Injury Surveillance Unit, Adelaide, <www.nisu.flinders.edu.au/pubs/reports/2006/injcat90.pdf> (accessed 21 February 2008).

DAFF (Department of Agriculture, Fisheries and Forestry) 2005, *Final Cost Recovery Impact Statement on the Proposed Revised Cost Recovery Framework for the National Registration Scheme for Agricultural and Veterinary Chemicals*, March. Canberra.

—— 2007, *National Residue Survey Annual Report 2006-2007*, Canberra, <www.daff.gov.au/agriculture-food/nrs/publications/annual-reports> (accessed 30 October 2007).

DEFRA (Department for Environment, Food and Rural Affairs) 2007, *PSD Fees Charged for Individual Application Types*, <www.pesticides.gov.uk/approvals.asp?id=50> (accessed 3 March 2008).

—— 2008, *Regulation of Plant Protection Products in Europe under the Authorisation Directive 91/414/EEC*, <www.pesticides.gov.uk/ approvals.asp?id=2310> (accessed 18 July 2008) .

DEH (Department of the Environment and Heritage) 2004, *National Dioxins Program – Dioxins in Australia: a Summary of the Findings of Studies Conducted from 2001 to 2004*, Canberra.

—— 2006, *Australia State of the Environment 2006 at a Glance*, Canberra.

DEWHA (Department of the Environment, Water, Heritage and the Arts) 2007, *Legislation and Regulations: Ozone and Synthetic Greenhouse Gases*, Canberra, <www.environment.gov.au/atmosphere/ozone/legislation/index.html> (accessed 19 February 2008).

—— 2008, *Ozone and Synthetic Greenhouse Gases*, Canberra, <www.environment.gov.au/atmosphere/ozone/index.html> (accessed 19 February 2008).

DITR (Department of Innovation, Industry, Science and Research, formerly Department of Industry, Tourism and Infrastructure) 2007, *National Nanotechnology Strategy*, Canberra.

DITRDLG (Department of Infrastructure, Transport, Regional Development and Local Government) 2007, *Control of Harmful Anti-fouling Systems on Ships*, Canberra, <www.infrastructure.gov.au/maritime/environment/anti_fouling. aspx> (accessed 18 February 2008).

DOCEP (Department of Consumer and Employment Protection, Western Australia) 2007b, *Dangerous Goods Safety (Security Risk Substances) Regulations 2007 — Collation of public comments on the Dangerous Goods Safety (Security Risk Substances) Regulations 2006 and Resource Safety's responses*, <www.docep.wa.gov.au/ResourcesSafety/Sections/Dangerous_Goods/pdf/DG_ Legislation/response/ResponseCommentsSRSR.pdf> (accessed 5 April 2007).

—— nd, *Fees and Charges under the Dangerous Goods Safety Act 2004 Licensing Regime — Information Sheet*, <www.docep.wa.gov.au/ResourcesSafety /PDF/Dangerous%20Goods%20Act%20related/Consultation_package/DG_IS _FeesChargesUpd.pdf> (accessed 5 April 2007).

DOFA (Department of Finance and Administration) 2005a, *Australian Government Cost Recovery Guidelines*, <www.finance.gov.au/publications/finance-circulars/2005/docs/Cost_ Recovery_Guidelines.pdf> (accessed 18 July 2008).

—— 2005b, *Governance Arrangements for Australian Government Bodies*, Commonwealth of Australia, Canberra.

DOHA (Department of Health and Ageing) 2003a, *NICNAS Annual Report* 2002-03, Canberra.

—— 2003b, *Regulation Impact Statement for proposed amendments to the Industrial Chemicals (Notification and Assessment) Act 1989*, Canberra.

—— 2004a, *NICNAS Annual Report* 2003-04, Canberra.

—— 2004b, *NICNAS Handbook for Notifiers*, Canberra.

—— 2005a, *Guidelines for Establishing a Case for Confidential Listing of Chemicals on the Australian Inventory of Chemical Substances*, Canberra.

—— 2005b, *NICNAS Annual Report* 2004-05, Canberra.,

—— 2006a, *NICNAS Annual Report* 2005-06, Canberra.

—— 2006b, *Promoting Safer Chemical Use: Towards Better Regulation of Chemicals in Australia: Final Report and Recommendations*, Canberra.

—— 2007a, *NICNAS Annual Report* 2006-07, Canberra.

—— 2007b, *Promoting Safer Chemical Use: Towards Better Regulation of Chemicals in Australia: Implementation Strategy*, Canberra.

—— 2008, *A New Regulatory Framework for Disinfectants*, <www.nicnas.gov.au/Current_Issues/Disinfectants/Disinfectants_Final_Report_to_Stakeholders_PDF.pdf> (accessed 18 July 2008).

DPI (Department of Primary Industries) Victoria 2006, *Victorian Produce Monitoring Program 2005*, Melbourne, <www.dpi.vic.gov.au/dpi/nrenfa.nsf/93a98744f6ec41bd4a256c8e00013aa9/8b5832a7c424a49bca25726d007ed4d1/$FILE/VPMP%202005%20Report.pdf> (accessed 30 October 2007).

DPIW (Department of Primary Industries and Water, Tasmania) nd, *Ammonium nitrate factsheet*, <www.dpiw.tas.gov.au/inter.nsf/Attachments/CART-6K3VXV/$FILE/FINAL%20Ammonium%20Nitrate%20fact%20sheet_web.pdf> (accessed 10 January 2008).

EC (European Commission) 2001, What is REACH? <ec.europa.eu/environment/chemicals/ reach/reach_intro.htm> (accessed 3 March 2008).

—— 2003, The cost-saving potential of QSARs, Stakeholder Workshop on Impact Assessment of REACH, Brussels, 21 November.

—— 2006, *REACH in Brief*, Brussels, <ec.europa.eu/environment/chemicals/reach/reach_in_brief04_09_15.pdf> (accessed 1 February 2007).

—— 2008, *New cosmetic regulation to strengthen product safety and to cut red tape*, IP/08/184, 5 February, Brussels, <www.europa.eu/rapid/pressReleasesAction.do?reference=IP/08/184&format=HTML&aged=0&language=EN&guiLanguage=en> (accessed 15 January 2008).

EPA NSW (Environmental Protection Agency, New South Wales) 2007, *Chemical Control Orders*, Sydney <www.epa.nsw.gov.au/pesticides/ccos.htm> (accessed 14 January 2008)

EPA QLD (Environmental Protection Agency, Queensland) 2007, *Circumstances for Requiring Financial Assurance on a Development Approval*, Brisbane, <www.epa.qld.gov.au/publications/p00625aa.pdf/Circumstances_for_requiring_financial_assurance_on_a_development_approval.pdf> (accessed 10 February 2008).

EPA Victoria (Environmental Protection Agency, Victoria) 2006, *Notifiable Chemical Orders*, Melbourne, <www.epa.vic.gov.au/about_us/legislation/nco.asp> (accessed 21 January 2008).

EPHC (Environment Protection and Heritage Council) 2002, *Polychlorinated Biphenyls Management Plan Revised Edition April 2003*, Canberra.

—— 2005, *National Dioxins Program – National Action Plan for Addressing Dioxins in Australia*, Canberra.

—— 2006a, *National Environment Protection Measures (NEPMs) Explained, EPHC Secretariat*, Adelaide, <www.ephc.gov.au/nepms/nepms.html> (accessed 18 January 2008).

—— 2006b, *NChEM: A National Framework for Chemicals Management in Australia*, Adelaide.

—— 2007a, *Environmental Risk Assessment Guidance Manual for Agricultural and Veterinary Chemicals – Draft for Public Comment*, Canberra.

—— 2007b, *Environmental Risk Assessment Guidance Manual for Industrial Chemicals – Draft for Public Comment*, Canberra.

—— 2007c, *Principles for Better Environmental Management of Chemicals: Ministerial Agreement*, Adelaide.

EPHCCWG (EPHC Chemicals Working Group) 2006, *National Framework for Chemicals Environment Management: Priority and Emerging Issues – Thought Starter Paper*, Canberra.

EPHCNCT (EPHC National Chemicals Taskforce) 2003, *Towards Ecologically Sustainable Management of Chemicals in Australia – Scoping Paper*: Report of the EPHC National Chemicals Taskforce, Adelaide.

FSANZ (Food Standards Australia New Zealand) 2003, *Limiting Chemical Residues in Food: the Role of Maximum Residue Limits*, Fact sheet, Canberra, <www.foodstandards.gov.au/newsroom/factsheets/factsheets2002/limitingchemicalresi1424.cfm> (accessed 29 January 2008).

—— 2005, *The 21st Australian Total Diet Study*, Canberra, <www.foodstandards.gov.au/_srcfiles/21st%20ATD%20Study%20report-Aug051.pdf> (accessed 30 October 2007).

—— 2007, *Initial/Draft Assessment Report: Maximum Residue Limits (January, February, March 2007)*, Application A599, Canberra, <www.foodstandards.gov.au/_srcfiles/A599%20MRLs%20_Jan,%20Feb%20March%2007_%20IADAR%20FINAL.pdf> (accessed 9 November 2007).

—— nd, *Food Regulation System: Australia New Zealand*, Canberra, <www.health.gov.au/internet/wcms/publishing.nsf/Content/C26129AB38BDF918CA2572DC0082A8CA/$File/system-brochure.pdf> (accessed 8 February 2008).

Galbally, R. 2001, *National Competition Review of Drugs, Poisons and Controlled Substances Legislation, Final Report Part B*, <www.tga.gov.au/docs/pdf/rdpfinb.pdf> (accessed September 2007).

Gretton, P. and Fisher, B. 1997, *Productivity Growth and Australian Manufacturing Industry*, Industry Commission staff research paper, AGPS, Canberra.

Haztech Environmental 2007, *Comments on the ASCC Draft Workplace Hazardous Chemicals Documents*, <www.ascc.gov.au/NR/rdonlyres/CB25CB0C-7278-4272-A921-6E9541604337/0/ChemComment_Haztech_2007.pdf> (accessed 11 January 2008).

Henley, G., Kreisfeld, K. and Harrison, J.E. 2007, *Injury deaths: Australia 2003-04*, Injury research and statistics series no. 31, AIHW Cat. no. INJCAT 89, Adelaide, <www.nisu.flinders.edu.au/pubs/reports/2007/injcat89.pdf> (accessed 21 February 2008).

Hill, J. 2005, *Response to the Social Development Committee Inquiry into Multiple Chemical Sensitivity (MCS)*, November 2005, <www.parliament.sa.gov.au/NR/rdonlyres/91D5721F-E440-4669-80C3-960E97510432/4723/22ndreportmcs.pdf> (accessed 10 December 2007).

Huntsman Chemical Company 2007, *Comments on the ASCC Draft National Standard for the Control of Workplace Hazardous Chemicals*, <www.ascc.gov.au/NR/rdonlyres/14232E45-0B41-4E81-BE06-8FE3354203EA/0/ChemComment_huntsman_2007.pdf> (accessed 30 January 2007).

IAC (Industries Assistance Commission) 1986, *The Chemicals and Plastics Industries*, Canberra.

IC (Industry Commission) 1995, *Work, Health and Safety: An Inquiry into Occupational Health and Safety*, Report no. 47, AGPS, Canberra.

—— 1996a, *Packaging and Labelling*, Inquiry Report, Canberra.

—— 1996b, *The Pharmaceutical Industry, Volume 1: The Report*, Report no. 51, 3 May 1996, Australian Government Publishing Service, Melbourne, <www.pc.gov.au/__data/assets/pdf_file/0016/31381/51drugsv1.pdf> (accessed 1 February 2008). [check style, does this really need an internet ref if its an IC report?]

—— 1997, *Role of Economic Instruments in Managing the Environment*, Staff Working Paper, Canberra

INPAA (Infant and Nursery Products Association of Australia) nd, *Infant and Nursery Products Association of Australia*, <www.inpaa.asn.au/> (accessed 19 February 2008).

Intergovernmental Forum on Chemical Safety 2006, *Toys and Chemical Safety: A Thought Starter*, FORUM V, Fifth Session of the Intergovernmental Forum on Chemical Safety, Budapest, Hungary, 25-29 September 2006, <www.who.int/ifcs/documents/forums/forum5/03_ts_en.pdf> (accessed 27 February 2008).

International Occupational Safety and Health Information Centre nd, *Yearly Statistics*, <laborsta.ilo.org/> (accessed 10 January 2007).

IP Australia 2006, *Patent Applications and Grants by Subject Matter*, <www.ipaustralia.gov.au/about/statistics.shtml#patents> (accessed 3 March 2008).

IPCC/TEAP (Intergovernmental Panel on Climate Change/Technology and Economic Assessment Panel) 2005, *Special Report on Safekeeping the Ozone Layer and the Global Climate Change System: Issues Related to Hydro-fluro Carbons and Perfluorocarbons – Summary for Policymakers*, Cambridge.

Kasper, W. 1995, *Competitive Federalism: Promoting Freedom and Prosperity*, States' Policy Unit, Institute of Public Affairs, Perth.

—— 1996, *Competitive Federalism Revisited: Bidding Wars or Getting the Fundamentals Right?*, States' Policy Unit, Institute of Public Affairs, Perth.

Knott, M. 2007, 'Silent suffering of the new lepers', *The Sun Herald*, 18 November 2007, p. 54.

Longford Royal Commission 1999, *The Esso Longford Gas Plant Accident – Report of the Longford Royal Commission*, Melbourne.

Mahdi S., Nightingale P., Berkhout F. 2002, *A Review of the Impact of Regulation on the Chemical Industry – Final Report to the Royal Commission on Environmental Pollution*, SPRU, University of Sussex, accessed on 1 July 2008 at http://www.rcep.org.uk/pdf/chin-txt.pdf.

McIntyre, K. and Moore, B. 2001, *The National Road Transport Commission: An Experiment in Cooperative Federalism*, Paper presented to the Public Law Discussion Group, Faculty of Law, ANU.

MCCA (Ministerial Council on Consumer Affairs) 2007, *Joint Communiqué: Ministerial Council on Consumer Affairs Meeting*, Friday 18 May 2007, <www.consumer.gov.au/html/download/Final_Communique_May_2007.pdf> (accessed September 2007).

——2008, *Joint Communique: Ministerial Council on Consumer Affairs Meeting*, Friday 23 May 2007, <www.consumer.gov.au/html/download/MCCA_Meetings /Meeting_19_23_May_08.rtf)> (accessed 11 July 2008)

Miller 2007, *National Economic Impact of the IR-4 Project*, Center for Economic Analysis, Michigan State University, www.ir4.rutgers.edu/Other/ IR4EconomicImpact.pdf (accessed 18 July 2008)

MULO (Minor Use Liaison Office) 2007, *Discussion Paper*, <www.daff.gov.au/__data/assets/pdf_file/0006/374721/discussion-paper.pdf> (accessed 3 March 2008).

NABSW/SWMG (National Advisory Body on Scheduled Wastes/Scheduled Wastes Management Group) 2001, *Review of the PCB Management Plan: Discussion Paper*, Canberra.

NaCTSO (National Counter Terrorism Security Office) 2007, *'Secure your fertiliser'* <www.secureyourfertiliser.gov.uk/index.html> (accessed 1 May 2007).

NCC (National Competition Council) 2000, *Road Transport Reform*, Community Information paper, September.

NCCTG (National Coordinating Committee on Therapeutic Goods) 2007, *Scheduling Policy Framework for Medicines and Poisons*, Draft for Consultation, <www.anztpa.org/consult/dr-schpolicy.pdf> (accessed 23 October 2007).

NFF (National Farmers Federation 2007), Submission to the Council of Australian Government Review of Hazardous Materials, <www.nff.org.au/policy/ submissions.html?hilite=chemical+security> (accessed 12 December 2007).

NICNAS (National Industrial Chemicals Notification and Assessment Scheme) 2008, *National Industrial Chemicals Notification and Assessment Scheme* <www.nicnas.gov.au/> (accessed 20 February 2008).

—— nd, *What is Nanotechnology*, <www.nicnas.gov.au/Current_Issues/ Nanotechnology.asp> (accessed 3 March 2008).

—— and TGA (the Australian Government Therapeutic Goods Administration) 2005, *Regulation of Cosmetic Chemicals: Final Report and Recommendations*, November, <www.nicnas.gov.au/Current_Issues/Cosmetics/Regulation_Cosmetic_Chemicals_Final_Report_PDF.pdf> (accessed 20 February 2008).

NOHSC (National Occupational Health and Safety Commission) 1994a, *National Code of Practice for the Control of Workplace Hazardous Substances*, Canberra.

—— 1994b, *National Code of Practice for the Labelling of Workplace Substances*, Canberra.

—— 2001a, *National Standard for the Storage and Handling of Dangerous Goods*, Canberra.

—— 2001b, *Storage and Handling of Workplace Dangerous Goods – National Code of Practice*, Canberra.

—— 2002a *Control of Major Hazard Facilities: National Standard [NOHSC:1012(2002)] National Code of Practice [NOHSC:2016(1996)]* Australian Government, Canberra, <www.ascc.gov.au/NR/rdonlyres/C4246822-C5C6-4AEF-9E09-C8F6D1874413/0/MajorHazardFacilities_2ed_2002.pdf> (accessed 4 March 2008).

—— 2002b, *Major Hazard Facilities — Annual Situation Report 2002*, <www.ascc.gov.au/NR/rdonlyres/CC8A9DE8-5B8B-44AF-83FB-B90205A24C82/0/MajorHazardFacilities2002ASR.pdf> (accessed 8 November 2007).

—— 2003, *National Code of Practice for the Preparation of Material Safety Data Sheets 2nd Edition*, Canberra.

NPCC (National Packaging Covenant Council) 2005, *The National Packaging Covenant*, <www.deh.gov.au/settlements/publications/waste/covenant/pubs/covenant.pdf> (accessed 11 February 2008).

NRCan (Natural Resources Canada) 2006, *Regulatory Impact State — Explosives Act*, <www.nrcan-rncan.gc.ca/mms/explosif/pdf/RestrictedComp_e.pdf> (accessed 12 December 2007).

NRTC (National Road Transport Commission) 2002, *Submission to the 2nd Review of the National Road Transport Commission*, March. Melbourne.

NSW DEC (New South Wales Department of Environment and Conservation) 2006, *NSW Extended Producer Responsibility Priority Statement 2005-06*, Parramatta.

NTC (National Transport Commission) 2005, *Development of the 7th Edition of the Australian Dangerous Goods Code. Draft Regulatory Impact Statement*, July. Melbourne.

—— 2006a, *Australian Dangerous Goods Code 7th Edition Legislative Package: Summary Response to Public Submissions*, August. Melbourne.

—— 2006b, *Development of the 7th Edition of the Australian Dangerous Goods Code. Draft Regulatory Impact Statement*, November. Melbourne.

—— 2007, *Australian Code for the Transport of Dangerous Goods by Road & Rail Seventh Edition*, two volumes, October. Melbourne.

—— 2008, *National Transport Policy Framework A New Beginning*, February. Melbourne.

Nufarm Limited 2007, *Proposed Revision of the National OHS Framework for Hazardous Substances and Dangerous Goods – Nufarm's Submissions*, <www.ascc.gov.au/NR/rdonlyres/9B271162-D904-4190-8DD8-39FF8847950A/0/ChemComment_nufarm_2007.pdf> (accessed 11 January 2008).

OCS and NICNAS (Office of Chemical Safety and National Industrial Chemical Notification and Assessment Scheme) 2007, *Current Activity on Multiple Chemical Sensitivity*, December, <www.nicnas.gov.au/Publications/Information_Sheets/MCS_I_S_122007.pdf> (accessed January 2008).

OECD (Organisation for Economic Cooperation and Development) 2001a, *Environmental Outlook*, Paris.

—— 2001b, *Environmental Outlook for the Chemicals Industry*, Paris. <www.oecd.org/dataoecd/7/45/2375538.pdf> (accessed 3 March 2008).

Orica 2007, Security Sensitive Ammonium Nitrate (SSAN) — Australia Only <www.oricaminingservices.com/default.asp?RegionID=1&LangID=1&id=913> (accessed 13 April 2007).

PACIA (Plastics and Chemicals Industry Association) 2005, *A new scheduling model for chemicals and medicines, Submission to the National Coordinating Committee on Therapeutic Goods as part of consultation on proposed changes to drugs and poisons scheduling arrangements*, <www.pacia.org.au/_uploaditems/docs/2.sub_schedtga_sept2005.pdf> (accessed September 2007).

—— 2006a, *Issues for Australia's Chemical Industry in Dealing with Regulations of Security Sensitive Ammonium Nitrate (SSAN)*, <www.pacia.org.au/_uploaditems/docs/2.paciasub_regs_ssan_%20sept06.pdf> (accessed 22 October 2007).

—— 2006b, *Submission on NTC Draft Edition of 7th Australian Dangerous Goods Code (ADG7) Package*, October. Melbourne.

—— 2007a, *COAG Review of Hazardous Materials – A Discussion Paper on the Control of Chemicals of Security Concern PACIA Submission*, <www.pacia.org.au/_uploaditems/docs/2.paciasub_chemicals_securityconcern_1mar07.pdf> (accessed 22 October 2007).

—— 2007b, *Draft Standard for the uniform Scheduling of Medicines and Poisons and Draft Scheduling Policy Framework*, Submission to the National Coordinating Committee on Therapeutic Goods as part of consultation on proposed changes to drugs and poisons scheduling arrangements, <www.pacia.org.au/_uploaditems/docs/2.paciasub_chemicals_scheduling_24aug07.pdf> (accessed September 2007).

——2007c, *Proposed Workplace Hazardous Chemicals Framework Public Comment*, <www.ascc.gov.au/NR/rdonlyres/CD293E08-225D-4D1D-B070-8CE9B0B3BF4D/0/ChemComment_PACIA_2007.pdf> (accessed 30 January 2008).

—— nd, *PACIA Carrier Accreditation Scheme*, Brochure.

—— and SIA (Science Industries Australia) 2007, *Code of Practice for Supply Diversion into Illicit Drug Manufacture*, <www.pacia.org.au/_uploaditems/docs/drugsCOP2007.pdf> (accessed 5 November 2007).

PC (Productivity Commission) 2001, *Cost Recovery by Government Agencies*, Report no. 15, Ausinfo, Canberra.

—— 2004a, *National Workers' Compensation and Occupational Health and Safety Frameworks*, Report no. 27, Canberra.

—— 2004b, *Reform of Building Regulation*, Research report, Canberra, November.

—— 2005, *Annual Report 2004-05*, Canberra.

——2006a, Potential Benefits of the National Reform Agenda, Report to the Council of Australian Governments, Canberra.

—— 2006b, *Review of the Australian Consumer Product Safety System*, Research report, Canberra.

—— 2006c, S*tandard Setting and Laboratory Accreditation*, Research report, Canberra, November.

—— 2006d, *Waste Management*, Inquiry report no. 38, Canberra.

—— 2007a, *Annual Review of Regulatory Burdens on Business: Primary Sector*, Research report, Canberra.

—— 2007b, *Performance Benchmarking of Australian Business Regulation*, Research report, Canberra.

—— 2008, *Review of Australia's Consumer Policy Framework*, Inquiry Report, Canberra

Parliament of South Australia 2005, *Inquiry into Multiple Chemical Sensitivity*, Twenty Second Report of the Social Development Committee, Parliament of South Australia, <www.parliament.sa.gov.au/NR/rdonlyres/2C73AADA-0FFD

-404A--BA06-EFF16BB533A9/4710/22ndreportmultiplechemicalsensitivity .pdf> (accessed 9 November 2007).

Price, N.R. and Watkins, R.W. 2003, 'Quantitative structure-activity relationships (qsar) in predicting the environmental safety of pesticides', *The Royal Society of Chemistry*, June.

PSIC (Product Safety Integrity Committee) nd, *An Overview of Australia's National System for Managing Agricultural and Veterinary Chemicals*, Primary Industries Ministerial Council Canberra, <www.apvma.gov.au/about_us/pdf/overview _agvet_national_system.pdf> (accessed 30 October 2007).

—— nd, *An Overview of Australia's National System for Managing Agricultural and Veterinary Chemicals*, <www.apvma.gov.au/about_us/pdf/overview_agvet _national_system.pdf> (accessed 5 March 2008).

Queensland Government and Caboolture Shire Council 2007, *Narangba Industrial Estate: Multi-Agency Fire and Firewater Risk Minimisation Program* <www.emergency.qld.gov.au/publications/pdf/Inter_Agency_Report.pdf> (accessed 23 January 2008).

Rae, I. 2006, 'Chemicals in the environment', Paper prepared for the 2006 Australian State of the Environment Committee, Department of Environment, Water, Heritage and the Arts, Canberra, <www.deh.gov.au/soe/2006/emerging/ chemicals/index.html> (accessed 17 January 2008).

Regulation Taskforce 2006, *Rethinking Regulation: Report of the Taskforce on Reducing Regulatory Burdens on Business*, Report to the Prime Minister and the Treasurer, Canberra, January.

Samuel, G. 2007, 'Blowing the whistle on product safety', *The Age*, 13 September 2007, p. 10.

SBDT (Small Business Deregulation Taskforce) 1996, *Time For Business*, Canberra, <www.daf.gov.au/reports/time_for_business.pdf> (accessed 22 January 2007).

SCCRHM (Steering committee for the COAG Review of Hazardous Materials) 2004, *Report on the Regulation and Control of Ammonium Nitrate*, Canberra.

—— 2006, *A Discussion Paper on the Control of Chemicals of Security Concern*, Office of National Security, Canberra.

—— 2008, *Draft Report on the Control of Chemicals of Security Concern*, Office of National Security, Canberra.

Shepherd, I. 1999, *Dangerous Goods Transport Reform in Australia: Putting the Acid on Those Responsible*. Melbourne.

Standards Australia 2004, *Risk Management*, AS/NZS 4360:2004, Sydney.

TGA (Therapeutic Goods Administration) 2007a, *Australian State and Territory Regulatory Controls on Schedule 7 Poisons*, June, <www.tga.gov.au /ndpsc/s7juris.htm> (14 January 2008).

—— 2007b, *Interim Guidelines for the National Drugs and Poisons Scheduling Committee*, <www.tga.gov.au/ndpsc/ndpscg.pdf> (accessed 2 November 2007).

—— 2007c, *National Coordinating Committee on Therapeutic Goods (NCCTG)*, <www.tga.gov.au/docs/html/ncctg.htm> (accessed 29 February 2008).

Uhrig, J. 2003, *Review of the Corporate Governance of Statutory Authorities and Office Holders*, Commonwealth of Australia, Canberra.

UN (United Nations) 2005, *Globally Harmonised System of Classification and Labelling of Chemicals*, New York.

United Nations Economic Commission for Europe 2008, GHS: Status of Implementation, <www.unece.org/trans/danger/publi/ghs/implementation _e.html#European%20Union%20and%20European%20Economic%20Area> (accessed 7 July 2008).

Underwood, R. and Hunt, W.V.P. 2007, *NSW Dangerous Goods Legislative Regime — Experience and Insights*, Paper presented to Hazmat conference, May. Sydney.

UNEPOS (United Nations Environment Programme Ozone Secretariat) 2005, *Production and consumption of Ozone Depleting Substances under the Montreal Protocol: 1986–2004*, Nairobi.

US EPA (United States Environment Protection Agency) 2007a, *Assessing Pesticide Cumulative Risk*, <www.epa.gov/pesticides/cumulative> (accessed 3 March 2008).

—— 2007b, *Fee Determination Decision Tree Logic and Fees for Fiscal Year 2008*, <www.epa.gov/pesticides/regulating/fees/tool/resources/dt_logic_and_fee _category_list_1.pdf> (accessed 3 March 2008).

VCA (Vinyl Council of Australia) 2002, *Product Stewardship Commitment*, Melbourne, <www.vinyl.org.au/product/overview.cfm> (accessed 17 January 2008).

Victorian Workcover Authority 2005, *Comment on Public Review Draft of Australian Dangerous Goods Code 7 and Supporting Legislation.* Melbourne.

Western Australia Commission for Occupational Safety and Health 2007, Provision of information on hazardous substances at workplaces — Material Safety Data Sheets (MSDS), <www.docep.wa.gov.au/WorkSafe/PDF/Guidance_notes /MSDS_Dec_07.pdf> (accessed 1 July 2008).

Western Australia Department of Health 2006, *Review of Pesticide Legislation and Policies in Western Australia*, Perth.

WHO (World Health Organisation) 2007, *Aggregate/cumulative Risk Assessment*, <www.who.int/ipcs/methods/harmonization/areas/aggregate/en> (accessed 3 March 2008).

Wilson, T. and Moore, B. 2006, *Regulatory Reform in Land Transport*, in Productivity Commission, Productive Reform in a Federal System, Roundtable proceedings. Canberra.

Workcover NSW 2007, *Proposed Workplace Hazardous Chemicals framework — Workcover NSW Response*, <www.ascc.gov.au/NR/rdonlyres/58074EC8-FA3F-42AC-92D4-FFDCD39C4569/0/ChemComment_NSWworkcover_2007.pdf> (accessed 30 January 2008).

WorkSafe Victoria 2005, MSDS database systems, <www.worksafe.vic.gov.au/wps/wcm/connect/WorkSafe/Home/Forms+and+Publications/Guidance+Notes/import_MSDS+database+systems> (accessed 1 July 2008).

World Bank 2008, *2005 International Comparison Program - Tables of Final Results*, <www.siteresources.worldbank.org/ICPINT/Resources/ICP_final-results.pdf> (accessed 3 March 2008).

WRMC (Workplace Relations Ministers' Council) 2008, *Communiqué from Australian, State, Territory and New Zealand Workplace Relations Ministers*, <mediacentre.dewr.gov.au/NR/rdonlyres/31BED76B-2655-4CDF-952F-E84FE0CD3469/0/WRMC75AgreedCommunique.pdf> (accessed 5 February 2008).

WST (Workplace Standards Tasmania) 2007, *Workplace Standards: Frequently asked questions regarding security-sensitive dangerous substances*, <www.wst.tas.gov.au/safety_comply/dang_subs/ssds/faq> (accessed 10 January 2008).