ACCORD

Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry

Submission to the Productivity Commission Annual Review of Regulatory Burdens on Business – *Manufacturing & Distributive Trades*

8 April 2008

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Foreword

ACCORD Australasia is the peak national industry association representing the manufacturers, importers and suppliers of formulated consumer, cosmetic, hygiene and specialty products including the suppliers of raw materials used in these products.

Products supplied by our sector include all types of cleaning agents, personal care products, cosmetics, fragrances, hygiene products, disinfectants, adhesives, sealants, protectants and other treatment products used in households, industry, agriculture and institutions.

These products play an important role in:

- keeping Australia's households, workplaces, schools and institutions clean, hygienic and comfortable;
- personal hygiene, grooming and beauty treatments to help Australians look and feel their best;
- specialised uses that assist production and manufacturing to keep the wheels of commerce and industry turning; and,
- maintaining the hygienic and sanitary conditions essential for our food and hospitality industries and our hospitals, medical institutions and public places.

These benefits are essential to safe, healthy living and maintaining the quality lifestyle we all too often take for granted.

With estimated annual retail-level product sales in the vicinity of $10 billion, the formulated consumer, cosmetic, hygiene and specialty products industry is a significant part of a prosperous Australian economy.

We are a dynamic and growing industry, employing Australians and - through our industrial and institutional sector - supplying products essential for Australian businesses, manufacturing firms, government enterprises, public institutions, farmers and consumers.

Our industry has more than 50 manufacturing operations throughout Australia and member companies cover the full spectrum of company size from large global consumer product manufacturers to small and dynamic Australian-owned businesses.

A list of ACCORD member companies is provided at *Attachment 1.*

Craig Brock
Director, Policy & Public Affairs

8 April 2008

1. Overview on regulation and pressures on our sector

The products manufactured and marketed by the Australian formulated products industry are – for the most part – downstream products of the chemical raw materials industry. Our industry's products, and the ingredients which comprise them, are subject to significant and specific regulatory regimes and requirements within Australia.

This regulation extends also to products within the sector that Australian consumers would consider outside of the 'chemicals industry' because they are marketed as 'natural' products and comprised of 'natural' or 'plant-derived' ingredients.

The primary thrust of chemicals regulation is the protection of public health and the environment. ACCORD supports these important objectives. We endorse the need for efficient regulation that is set at the minimum effective level of intervention necessary to manage risks while at the same time promoting innovation and business activity.

While the principal national regulator for our sector and the ingredients in industry products is currently NICNAS (National Industrial Chemicals Notification and Assessment Scheme), the industry is still subject to intervention from an array of state and territory agencies and their regulatory requirements as well as other Commonwealth agencies, including TGA, APVMA, ACCC and possible, in the near future, A-G's for chemicals (and chemical products) of security concern.

The existing regulatory regimes and frameworks, as they impact on our sector and the broader chemicals industry, are:

- complex and confusing,
- fragmented and inconsistent;

  and as a result are,
- costly to:
  - businesses (in terms of the direct costs of red-tape compliance burdens plus the indirect costs of lost investment and innovation opportunities),
  - governments (in terms of their administration and duplication); and,
  - consumers (in terms of increased prices due to the passing on of these cost burdens).

These specific problems, and the opportunities they present for reform, have been recognised as requiring action by Australia's governments.

COAG has targeted chemicals and plastic regulation as a regulatory hotspot for which a Productivity Commission research study has commenced and a special ministerial taskforce established.

While ACCORD remains hopeful that these national initiatives will restart stalled reforms to simplify chemicals regulation and eliminate inconsistencies across Australia's jurisdictions, companies operating in our sector are also subject to the 'standard' regulatory burdens which currently impact on all Australian-based business operations.

This is particularly the case for our industry's manufacturing members, who continue to face challenging business operating pressures, including;

- a high Australian dollar, which impacts on the export competitiveness of Australian manufacturers
- high crude oil prices, which have the direct impacts of increasing the price of many chemical raw materials, as many of these are derived from petro-chemical supply chains
- high global demand for many raw materials from the booming manufacturing economies of China and India, which also increases global prices of raw materials used by local manufacturers (e.g. palm oil and derivatives used for soap and cosmetic manufacturing)
- direct competition from imported manufactured goods and in particular the growth in imports from China and India,
- difficulties with recruiting skilled staff, especially with necessary experience in chemistry or formulation technology.

These pressures are listed here – not to suggest that they may require specific interventionist or protectionist policies[1], as for the most part they simply reflect the normal operation of global or local markets – but to highlight the important role Australia's governments can play in removing unnecessary regulatory burdens on affected manufacturing businesses.

As is the case with other Australian manufacturing businesses, many of our industry's manufacturers face the following areas of regulatory burden[2], additional to specific chemicals-related regulation already mentioned above:

- OHS legislation and regulation
- Consumer protection legislation and regulation
- Environmental laws and regulation
- Employment-related regulations
- Workers' compensation
- Customs and excise requirements
- Payroll tax requirements
- FBT requirements
- Road transport requirements
- Environmental approvals processes
- Contaminated sites legislation
- Waste laws
- Water, sewage and trade waste regulation by water utilities
- Greenhouse gas and emissions reporting
- State gas safety regulations
- Privacy Act and workplace surveillance

[1] Issues like the shortage of skilled staff require capacity and capability building policies from Australia's Governments.

[2] This list is derived from a list of 'Regulatory Overlaps in Australia' presented in the Business Council of Australia publication "*Towards a Seamless Economy" Modernising the Regulation of Australian Business*". It is not comprehensive but is provided to highlight the array of regulation across the jurisdictions with impact on maufacturers.

- Food laws and regulation
- Energy efficiency regulation

The key issues with these regulations are their complexity and the level of inconsistency in rules and requirements across Australia's nine jurisdictions. There is also a direct link for the above to current reform initiatives for chemicals regulation due to the following fact highlighted by the Commission in its March 2008 draft research report on Chemicals and Plastics Regulation:

"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." pg xxiv

2. Chemicals and plastics regulation reform

The two tables[3] presented in Attachment 2 illustrate the complex and fragmented system of multi-jurisdictional legislation and responsible authorities regulating the industry in Australia.

On behalf of our industry sector, ACCORD has long advocated the need for reforms to simplify and streamline the current Australian system of chemicals regulation.

As background for this Review on key issues relating to chemicals regulation and therefore manufacturers in our sector, attached to this submission are the following key ACCORD submissions on the need for regulatory reform:

- Submission to the Bank's Regulation Taskforce, "*Reducing the Regulatory Burden on Business, 28 Nov 2005*" (Attachment 3)
- Submission to the PC study of chemicals and plastics regulation, "*Productivity Commission Study into Chemicals and Plastics Regulation, 24 October 2007*" (Attachment 4)
- Supplementary submission to PC study of chemicals and plastics regulation, 21 January 2008, including "*Report of ACCORD Survey on the impacts and costs of regulation*" (Attachment 5)

Late last year ACCORD conducted a survey of member companies to better quantify the impacts of NICNAS regulation on the industry.

The findings of this survey were as follows:

- Eighty-nine percent (89%) of ACCORD industry and regulatory consultant members responded to the ACCORD Industry Survey.
- Ninety-two percent (92%) of survey participants having experience with NICNAS reported negative impacts from this association.
- Ninety-three percent (93%) 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.

[3] These tables are part of a Deloitte Economics presentation given by the Chemicals and Plastics Leadership Group (CPLG) to the Commission for the Chemicals and Plastics Regulation Study as well as the ministerial taskforce on chemicals and plastics regulation.

- 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 fifty percent (50%) 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 (companies with a turnover of less than $10 million)
- Thirty-six percent (36%) 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 five percent (5%) of SMEs
- Sixteen percent (16%) 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 fifty percent (50%) of cases where a company has the opportunity to self assess through the LRCC initiative, they choose not to do so, for reasons such as onerous auditing requirements.
- 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 thirty-eight percent (38%) 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.

While these findings illustrate the opportunities for reform of NICNAS requirements, and are therefore more applicable to the PC study of chemicals and plastics regulation it is ACCORD's opinion that, on the basis of anecdotal information from within the industry, similar findings would be uncovered for surveys on other aspects of regulation impacting more broadly on the manufacturing sector.

The key finding to note from this survey, which would be broadly applicable to other areas of regulation impacting manufacturing, is the negative impact on smaller enterprises.

The volume and complexity of regulation often requires commitment of dedicated resources within companies. For larger companies this often takes the form of in-house regulatory compliance experts. Smaller companies are often at a disadvantage dealing with this complexity because their finances do not allow for the recruitment of the in-house experts employed by larger companies.

3. The burdens on Australian manufacturers within our sector

3.1 The scope of the regulatory burden

To better understand the full scope of regulation applying to Australian manufacturing businesses it is helpful to remember that these businesses take **raw material inputs** and subject them to a **manufacturing process** to **fabricate a product for sale**. Regulation is applied at all stages on the inputs, the process itself and the outputs or finished products.

For our sector, regulation applying to **manufacturing inputs** includes:

- raw material regulatory approvals, via NICNAS, for ingredients not already on the Australian Inventory of Chemical Substances (AICS)
- transport of raw materials
- storage of raw materials
- placarding and hazard communication
- packaging specifications (for both the packaging of the raw materials and the packaging that will be used for the finished product)
- water use restrictions/conditions, for the use of water in products and manufacturing (e.g. state water savings plans, if applicable)
- energy use conditions, for the use of energy in manufacturing
- record keeping and control measures for specific ingredients covered by regulation as either chemical weapons pre-cursors or illicit drug pre-cursors
- customs and excise requirements, e.g. fuel tax application, credits and record-keeping for raw materials deemed to be 'fuels'
- any additional raw material requirements if ingredients are for use in TGA-regulated products

Regulation applying to operation of the actual **manufacturing process/plant** includes:

- fire safety requirements and compliance
- OHS requirements and compliance, including,
    - training requirements for hazardous operations, e.g. confined space entry, working from heights, forklift safety, manual handling, heavy machinery use, chemical handling…
    - health testing/monitoring of employees using certain chemicals
    - workplace air quality monitoring
    - building/process standards for operations
    - personal protective equipment
    - occupational noise control
    - workers' compensation
    - accident reporting/investigation
    - first-aid service provision
- employee and industrial relations requirements and compliance
- environmental requirements and compliance, including:
    - environmental licensing for operations
    - environmental planning requirements

- air and water emissions requirements
- noise requirements
- waste requirements/licences
- hazardous materials requirements
- annual reporting for the National Pollutant Inventory
- reporting for greenhouse (Greenhouse Challenge)
- emergency preparedness

- Dangerous Goods requirements and compliance
- Hazardous Substances requirements and compliance
- if applicable, Major Hazard Facility requirements and compliance
- if applicable, Good Manufacturing Practice rules, requirements and auditing for products regulated by the TGA (e.g. medical disinfectants)
- general Australian business, corporations, taxation and insurance law relating to the manufacturers' Australian business operations

Regulation applying to the **manufactured product/s** includes:

- trade practices law
- consumer product safety requirements
- trade measurement requirements
- if for export, specific requirements of the export destination
- Dangerous Goods requirements for labelling, packaging, transport and storage, if applicable
- Poison scheduling requirements for labelling and packaging, if applicable
- ACCC labelling requirements, if a cosmetic/personal care product, including full ingredients disclosure
- product regulation requirements, if the product is covered under the scope of either the Therapeutic Goods Act (because it makes therapeutic claims or is deemed to do so, in the case of some disinfectants) or the Agvet Chemicals legislation (because it controls or repels pests or is deemed to be an agvet product, eg. dairy sanitisers)

This list is meant to illustrate the range, volume and complexity of regulation, rather than being comprehensive list of all applicable regulation. The issue here is not that this regulation exists in these particular areas. Much of this regulation is essential. It aims to protect health, safety and the environment and these objectives are fully supported by industry. However, what greatly concerns industry are the following aspects of the current regulatory system:

- the poor design of much of this regulation, with either:
  - a higher level of intervention than is commensurate for the actual level of risk that the regulation seeks to manage,
  - overly prescriptive requirements and interventions that impact negatively on business flexibility, or;
  - application of unjustified, unique Australian requirements that impact two-way trade in manufactured goods (both of products and raw materials) and create inconsistency with other major economies
- the high level of inefficient duplication across Australia's jurisdictions
- the high level of inconsistency of requirements between Australia's jurisdictions

3.2 Regulatory fragmentation and national inconsistency

The fragmentation and inconsistency inherent in Australia's current system of regulation impacting on manufacturers has again been highlighted as a critical issue by the Business Council of Australia[4]:

> *"The result is an economy that is subject to nine regulatory regimes, with eight states and territories each seeking to regulate in their own way, overlaid and in some cases duplicated by national regulation imposed at the Commonwealth level. From a business perspective, Australia is not one market, it is nine."*

Manufacturers operating multiple sites across Australia experience understandable frustration at the inefficiency of needing to understand and comply with different rules and requirements that are meant to achieve the same outcome.

Here are three examples of this lack of uniformity:

a) Australian State and Territory Government controls on schedule 7 poisons

The Australian National Drug and Poison Scheduling Committee (NDPSC) has published a table documenting differences in the state and territory governments' application of controls on schedule 7 poisons on the TGA website: http://www.tga.gov.au/ndpsc/s7juris.htm#table.

The table is attached at Attachment 6 and highlights the lack of national uniformity between states for the important objective of control of dangerous poisons for health and safety. Businesses handling, using, storing and distributing these substances across state boundaries can therefore face different requirements.

b) OHS requirements, NSW vs Victoria Requirements Example

Of the multitude of regulation that impacts on manufacturers, perhaps the most significant, in terms of its fundamental impacts on operations, is OHS regulation.

Protection of Australian workers from occupational hazards is a number one priority for all responsible businesses. To best achieve this businesses need clear, consistent guidance in the form of sensible, risk-based OHS regulation.

Despite ongoing recognition of the need for national uniformity in this important area, manufacturers still encounter significant differences in state-based approaches. This not only imposes an additional compliance burden on businesses, especially those operating sites in a number of states, but presents a barrier to clear understanding of requirements, thereby running counter to the overarching policy goal of strengthening compliance to make Australian workplaces safer.

Differences in the currently in-force regulatory instruments for NSW and Victoria provide an example of this:

- Victorian *Occupational Health and Safety Regulations 2007*
- NSW *Occupational Health and Safety Regulation 2001*

[4] The Business Council of Australia, "*Towards a Seamless Economy: Modernising the Regulation of Australian Business*", March 2008

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Attachment 7 provides a comparison of the content of each of these regulations.

Even at the potentially superficial level of information presentation, there are major differences in these two regulations that make it very difficult for businesses to even cross-check that the requirements for their plant or operations in NSW would be the same as in Victoria.

Looking further into these two regulations and choosing an example that should not in any way be subject to geographical region variability, namely the important issue of managing manually handling hazards, risks and incidents; there are differences in approaches and requirements that would cause confusion for businesses trying to interpret these requirements and develop a management regime that they could apply uniformly across their operations. The two sets of regulation on manual handling are presented n Attachment 8.

Manual handling occurs in virtually all Australian manufacturing businesses. If this level of difference is extrapolated across all Australian jurisdictions (and also occurring for other OHS aspects) then clearly manufacturers operating in a number of state locations are facing a compliance burden that needs to be addressed.

c) Security sensitive ammonium nitrate controls

It would be expected that more recent regulatory initiatives and interventions by Australia's governments would take greater account of the national policy imperative for national consistency. Unfortunately, this has not been the case with the high-profile example of state responses to controls on security sensitive ammonium nitrate.

As the Productivity Commission stated in its recent Draft Report on Chemicals and Plastics Regulation:

> *"The current arrangements for controlling security sensitive ammonium nitrate (SSAN) are also resulting in unnecessary administrative and compliance burdens…The regulations vary across jurisdictions because of fundamental differences in state and territory government attitudes to the appropriate legislation to use, licence coverage, and approaches to assessing the probity of applicants"*

The above examples are illustrative of the fragmentation of regulatory requirements across Australia's jurisdictions, which have direct impacts on Australian manufacturers. It can also be expected that this fragmentation of regulatory regimes would act as a disincentive to overseas investment in new manufacturing operations in Australia, with foreign firms seeing the nation as whole, rather than as a commonwealth of states and territories.

In terms of addressing the current level of regulatory fragmentation, ACCORD strongly endorses the following statements by the Business Council of Australia:

> *"Regulation has an essential role to play in achieving social objectives and correcting market failures. However, where regulation with similar objectives is imposed inconsistently or in duplicate, it creates distortions and barriers to resource flows that result in a materially detrimental effect on the nation's economic performance.*
>
> *Businesses should be able to go about their day-to-day operations without being diverted by unnecessary red tape and administration, most of which has no benefit to business, consumers or the economy as a whole.*

The BCA is calling on all governments to consign these anomalies to history and create a seamless economy – one where a business can operate within a single set of rules anywhere within Australia.

A seamless economy should not be seen as a back-door way to eliminating the states or transferring all substantive power to the Commonwealth. There is a range of alternative models for ensuring shared responsibility that could be accommodated within a seamless economy. The states in particular have a responsibility to harmonise business regulation in areas that are clearly state responsibilities. Australia has already achieved this principle in some areas, for example, within corporations law.

It is now time to target other major areas of business regulation, including occupational health and safety, product standards, trade and professional licensing, securities and environmental laws."

3.3 Unique Australian requirements

With business supply chains becoming more global, issues of unjustified unique Australian regulatory requirements need to be addressed. These act against the integration of Australian businesses into these global supply chains and have negative implications for Australian export manufacturers as well as importers of new technologies that could be of use to Australian business and manufacturing.

ACCORD's member survey of impacts of NICNAS regulation, highlighted that an estimated 38 percent of assessments required unique Australian data for chemicals and ingredients already in commerce in other major economies.

Another example, which will impact many Australian manufacturers, relates to Australia's unique classification of Combustible Liquids under Australian Standard 1940, which will be referenced and thereby enforced through Australian Dangerous Goods Code 7 once this is adopted by the states in the near future.

Combustible Liquids are regulated in Australia for storage and handling as well as road and rail transport by bulk. Globally, Combustible Liquids are not routinely regulated. In Australia, regulation extends to Combustible Liquids Class C1 (flashpoint up to 150°C) and the open-ended Class C2 (flashpoint greater than 150°C).

This unique treatment of combustible liquids imposes an additional compliance burden on Australian manufacturing and distribution operations.

3.4 Lack of information and guidance

In representing our member companies and fielding inquiries from them on regulation, ACCORD is aware of information gaps that are not being adequately addressed by many regulators.

While we have a good relationship with key national regulators for our sector such as NICNAS and at times jointly coordinate industry training on regulatory compliance, we are aware of member concerns about lack of information and guidance in other key areas of state regulatory compliance. This covers general OHS and environmental requirements that would also apply to other sectors beyond our industry.

This issue is taken up in the NSW Business Chamber's submission to this Review and ACCORD endorses the Chamber's recommendations on 'Information Disclosure and Transparency' that business's need:

- *"Simpler language from regulatory bodies*
- *Continual improvement of the design of forms to make them easier to understand and complete*
- *Greater access to government resources and assistance in complying with regulations, especially in rural and provincial Australia*
- *Early and clear notice of new regulatory requirements*
- *Better explanations of the purpose of specific regulations and the agency(-ies) responsible for administering them."*

4. Conclusions

ACCORD welcomes this opportunity to provide information to the Commission's Annual Review of Regulatory Burdens on Business – Manufacturing & Distributive Trades on issues relating to our member companies and industry sector.

Manufacturers in our sector face a range of regulatory burdens. Additional to the routine regulatory burdens on Australian manufacturing business, they also face specific requirements relating to chemicals and plastics regulation which have been recognised by the Commission's draft report on chemicals and plastics regulation as "fragmented and inconsistent".

It is noted that a number of areas of specific concern in terms of the complexity, national inconsistency and compliance burden of regulation have been identified by COAG as 'hotspots' for action.

These include: trade measurement, OHS, environmental assessment and approval processes, consumer policy framework, chemicals and plastics regulatory reform, building regulation, rail safety regulation, product safety, trade licensing, further payroll tax harmonisation, standard business reporting, food regulation, mine safety, upstream petroleum (oil and gas) regulation, maritime safety and directors' liabilities.

Action to reform and harmonise these will assist Australian manufacturers.

Attachment 1

List of ACCORD Member Companies

March 2008

ACCORD
Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry

Members

Consumer, Cosmetic and Personal Care:

Advanced Skin Technology Pty Ltd
Alberto Culver Australia
Amway of Australia Pty Ltd
Apisant Pty Ltd
Aroma Science
AVON Products Pty Limited
Baylor Limited
Beiersdorf Australia Ltd
Chanel Australia
Clorox Australia Pty Ltd
Colgate-Palmolive Pty Ltd
Combe International Ltd
Cosmax Prestige Brands Australia Pty Ltd
Coty Australia Pty Limited
Creative Brands Pty Ltd
De Lorenzo Hair & Cosmetic Research Pty Ltd
Dermalogica Pty Ltd
Elizabeth Arden Australia
Emeis Cosmetics Pty Ltd
Estée Lauder Australia
Frostbland Pty Ltd
GlaxoSmithKline Consumer Healthcare
Helios Health & Beauty Pty Ltd
Incolabs Pty Ltd
Johnson & Johnson Pacific
Kao (Australia) Marketing Pty Ltd
Keune Australia
KPSS Australia Pty Ltd
Kimberly Clark Australia
La Biosthetique Australia
La Prairie Group
L'Oreal Australia Pty Ltd
LVMH Perfumes and Cosmetics
Mary Kay Australia Pty Ltd
Nutrimetics Australia
NYX Pty Ltd
Procter & Gamble Australia Pty Ltd
PZ Cussons Pty Ltd
Reckitt Benckiser
Revlon Australia
Scental Pacific Pty Ltd
Schwarzkopf
Shiseido (Australia) Pty Ltd
Thalgo Australia
The Heat Group Pty Ltd
The Purist Company Pty Ltd
Tigi Australia Pty Ltd
Trilogy Products
Trimex Pty Ltd
Ultraceuticals
Unilever Australasia
YSL Beaute

Hygiene and Specialty Products

Albright & Wilson (Aust) Ltd
Applied Australia Pty Ltd
BP Castrol Australia Pty Ltd
Callington Haven Pty Ltd
Campbell Brothers Limited
Castle Chemicals Pty Ltd
Chemetall (Australasia) Pty Ltd
Chemform
Ciba Specialty Chemicals
Clariant (Australia) Pty Ltd
Cleveland Chemical Co Pty Ltd
Deb Australia Pty Ltd
Dominant (Australia) Pty Ltd
E Sime & Company Australia Pty Ltd
Ecolab Pty Limited
Henkel Australia Pty Limited
Huntsman Corporation Australia Pty Ltd
Jalco Group Pty Limited
Lab 6 Pty Ltd
Milestone Chemicals Pty Ltd
Novozymes Australia Pty Ltd
Nowra Chemical Manufacturers Pty Ltd
Peerless JAL
Recochem Inc
Rohm and Haas Australia Pty Ltd
Solvay Interox Pty Ltd
Sonitron Australasia Pty Ltd
Sopura Australia Pty Ltd
Tasman Chemicals Pty Ltd
Thor Specialties Pty Limited
True Blue Chemicals Pty Ltd
Whiteley Corporation Pty Ltd

ACCORD

Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry

Associate Members

Specialist Laboratories and Testing

ams Laboratories

Dermatest Pty Ltd

Silliker Microtech Laboratories Pty Ltd

Equipment and Packaging Suppliers

EquipNet Inc.

HydroNova Australia NZ Pty Ltd

SCHÜTZ DSL Group Pty Ltd

Logistics

Star Track Express Pty Ltd

Legal and Business Management

FCB Lawyers

Middletons Lawyers

PricewaterhouseCoopers

TressCox Lawyers

Recruitment

Chemskill

Regulatory and Technical Consultants

Archer Emery & Associates

Cintox Australia Pty Ltd

Competitive Advantage

Engel Hellyer & Partners Pty Ltd

Robert Forbes & Associates

Sue Akeroyd & Associates

Toxikos Pty Ltd

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Legislation regulating the sector: complex, fragmented, & leading to inconsistency

Federal Government

Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994
Agricultural and Veterinary Chemicals (Administration) Act 1992
Agricultural and Veterinary Chemicals Act 1994
Agricultural and Veterinary Chemicals Code Act 1994
Charter of the United Nations Act 1945
Chemical Weapons (Prohibition) Act 1994
Comprehensive Nuclear Test-Ban Treaty Act 1998
Customs Act 1901
Environment Protection (Sea Dumping) Act 1981
Hazardous Waste (Regulation of Exports and Imports) Act 1989
Industrial Chemicals (Notification & Assessment) Act 1989
Maritime Transport and Offshore Facilities Security Act 2003
National Environment Protection Council Act 1994
National Environment Protection Measures (Implementation) Act 1998
National Transport Commission Act 2003
National Water Commission Act 2004
Occupational Health and Safety Act 1991
OHS (Safety Standards) Regulation 1994
Product Stewardship (Oil) Act 2000
Road Transport Reform (Dangerous Goods) Act 1995
Therapeutic Goods Act 1989
Water Efficiency Labelling and Standards Act 2005

ACT

Criminal Code 2002,
Dangerous Substances Act 2004
Drugs of Dependence Act 1989
Environment Protection Act 1997
Occupational Health and Safety Act 1989
Poisons and Drugs Act 1978

Northern Territory

Dangerous Goods Act
Environment Protection and Biodiversity Conservation Act 1999
Hazardous Waste Act
Poisons and Dangerous Drugs Act
Work Health Act
Agricultural and vet chemicals (control of use) Act (NT) 2004

NSW

Agricultural and Vet Chemicals (NSW) Act 1994
Contaminated Land Management Act 1997
Drug Misuse and Trafficking Act 1985
Drug Misuse and Trafficking Regulation 2006
Environmentally Hazardous Chemicals Act 1985
Explosives Act 2003
Explosives Regulation 2005
National Environment Protection Council (NSW) Act 1995
Occupational Health and Safety Act 2000
Occupational Health and Safety Regulation 2001
Pesticides Act 1999
Poisons and Therapeutic Goods Act 1966
Poisons and Therapeutic Goods Regulation 2002
Road and Rail Transport (Dangerous Goods) Act 1997
Road and Rail Transport (DG) Regulation 1998, 1999
Waste Avoidance and Resource Recovery Act 2001
Waste Recycling and Processing Corporation Act 2001

Queensland

Agricultural and Veterinary Chemicals (QLD) Act 1994
Dangerous Goods Safety Management Act 2001
Dangerous Goods Safety Management Regulation 2001
Environmental Protection (Waste Management) Act 1994
Drugs Misuse Act 1986
Environmental Protection Act 1994
Environmental Protection Regulation 1998
Explosives Act 1999
Health Act 1937
Health (Drugs and Poisons) Regulation 1996
Transport Operation (Road Use Management—Dangerous Goods) Act 1995
Workplace Health and Safety Act and Regulation 1997

South Australia

OHS and Welfare Act 1986 and Regulation 1998
Dangerous Substances Act 1979 and Regulation 2002
Explosives Act 1936 and Regulation 1996
Explosives (Security Sensitive Substances) Regulation 2006
Dangerous Substances and Major Hazard Facilities Bill 2006
Environment Protection Act 1993
Explosives Act 1999
Health (Drugs and Poisons) Regulation 1996
Health Act 1937
Transport Operation (Road Use Management—Dangerous Goods) Act 1995
Workplace Health and Safety Act and Regulation 1997
Agricultural and Vet Products (Control of Use) Act 2002 and Regulation 2004
Controlled Substances Regulation 1996
Environment Protection (Waste Management) Policy 1994
EPA (National Pollutant Inventory) Measure

Tasmania

Agricultural and Vet Chemicals (Control of Use) Act 1995
Environment Management and Pollution Control Act 1994
Dangerous Goods Act 1998
Poisons Act 1971
Security-Sensitive Dangerous Substances Act 2005
Workplace Health and Safety Act 1998

Victoria

Agricultural and Vet Chemicals (Control of Use) Act 1992
Dangerous Goods (Explosives) Regulation 2000
Dangerous Goods (HCDG) Regulation 2005
Dangerous Goods Act 1985
DG (Storage and Handling) Regulation 2000
Drugs, Poisons and Controlled Substances Act 1981 and Regulation 2006
Environment Protection Act 1970
Health Act1958
Drugs, Poisons and Controlled Substances Act 1981 and Regulation 2006
National Environment Protection Council (Vic) Act 1995
Other policies regarding Air/Water e.g. SEPPs
Occupational Health and Safety Act 2004
Occupational Health and Safety Regulation 2007
Pollution of Waters by Oils and Noxious Substances Act 1986

Western Australia

Dangerous Goods (Transport) Act 1998
Dangerous Goods Safety Act 1961
Environment Protection Act 1986
Explosives and Dangerous Goods (Dangerous Goods Handling and Storage) Regulation 1992
Explosives and Dangerous Goods Regulation 1963
Health (Pesticides) Regulation 1956
Misuse of Drugs Act 1981 and
Occupational Health and Safety Regulation 2007
Occupational Safety and Health Act 1984
Occupational Safety and Health Regulation 1996
Poisons Act 1964
Pollution of Waters by Oils and Noxious Substances Act 1986
Road Transport Reform (DG) Regs 1997

Agencies regulating the sector: a multitude of roles and responsibilities leading to inconsistency

Federal Government

Department of Health and Ageing
Food Standards Australia New Zealand
Gene Technology Regulator
National Drugs and Poisons Scheduling Committee (NDPSC)
National Industrial Chemicals Notification and Assessment Scheme
Office of Chemical Safety
Therapeutic Goods Administration
Department of Agriculture, Fisheries and Forestry
AQIS
Australian Pesticides & Veterinary Medicines Authority
Attorney General's Department
Department of Education, Employment and Workplace Relations
Office of Australian Safety and Compensation Council
Australian Customs Service
Comcare
Department of Foreign Affairs and Trade (ASNO)
Department of Infrastructure, Transport, Regional Development and Local Government
Department of the Environment, Water, Heritage and the Arts
National Transport Commission

ACT

ACT Police
Department of Health
Department of Territory and Municipal Services
Workcover ACT

Northern Territory

Department of the Environment and Water Resources
Department of Health
Department of Primary Industry, Fisheries and Mines
NT WorkSafe

NSW

WorkCover NSW
Department of Environment and Climate Change (DECC)
Environmental Protection Agency
Department of Health
Department of Primary Industries
NSW Police

Queensland

Department of Emergency Services (Chemical Hazards and Emergency Management Services)
Department of Employment and Industrial Relations (Workplace Health and Safety)
Department of Health
Department of Natural Resources, Mines and Energy
Department of Primary Industries and Fisheries
Environmental Protection Agency
Local Government
Queensland Police
Queensland Transport

South Australia

Department of Health
Environment Protection Authority
Primary Industries and Resources SA
SA Police
SafeWork South Australia

Tasmania

The Department of Tourism, Arts and the Environment (DTAE)
Department of Justice (Workplace Standards Tasmania)
Department of Human Services
Department of Primary Industries and Water

Western Australia

Department of Consumer and Employment Protection
Department of Environment and Conservation
WA Police
Department of Agriculture
Department of Health

Victoria

Department of Human Services (Health)
Department of Primary Industries
Department of Sustainability and Environment
Environment Protection Authority
Victoria Police
WorkSafe Victoria

COAG Ministerial Councils

Australia and New Zealand Food Regulation Ministerial Council
Australian Health Ministers' Conference
Australian Transport Council
Ministerial Council on Consumer Affairs
Ministerial Council on Drug Strategy
Primary Industries Ministerial Council

Attachment 3

ACCORD Submission to the Banks' Regulation taskforce

November 2005

ACCORD

Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry

Mr Gary Banks
Chair
Regulation Taskforce
PO Box 282
BELCONNEN ACT 2616

Dear Mr Banks

ACCORD Australasia is the peak national industry association that represents the manufacturers and marketers of formulated consumer, cosmetic, hygiene and specialty products, their raw material suppliers, and service providers.

With $3 billion plus in annual product sales (ex-factory), the formulated consumer, cosmetic, hygiene and specialty products industry is a significant part of a prosperous Australian economy. We are a dynamic and growing industry, employing Australians and - through our industrial and institutional sector - supplying products essential for Australian businesses, manufacturing firms, government enterprises, public institutions, farmers and consumers. Our industry has more than 50 manufacturing operations throughout Australia and member companies include large global consumer product manufacturers to small dynamic Australian-owned businesses.

ACCORD, welcomes the opportunity to provide the attached submission for the Regulation Taskforce's consideration.

The annual growth in regulation for all Australian jurisdictions has been estimated by industry to be 10%. This is more than twice the rate of Australia's economic growth. This regulatory growth comes at a cost, much of which is passed directly onto business, which in turn is passed onto the consumer. A more efficient regulatory system will deliver benefits to the entire community though lower costs creating a business operating environment which will stimulate growth, create better employment opportunities and foster enhanced competitiveness and innovation.

ACCORD, on behalf of its member companies, has a specific and direct interest in regulation reform processes which will deliver real and meaningful outcomes for our members resulting in reduced compliance costs and red tape reduction. ACCORD will continue to work collaboratively with the Regulation Taskforce and the Australian Government to improve the regulatory environment for our members.

Yours sincerely

Unsigned for electronic transmission

Bronwyn Capanna
Executive Director

28 November 2005

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ACCORD

Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry

Reducing the regulatory burden on business

28 November 2005

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Foreword

ACCORD Australasia (formerly the Australian Consumer & Specialty Products Association) is the peak national industry association that represents the manufacturers and marketers of formulated consumer, cosmetic, hygiene and specialty products, their raw material suppliers, and service providers.

Our industry's products play a vital role in:

- keeping our households, workplaces, schools and institutions clean, hygienic and comfortable;
- personal hygiene, grooming and beauty treatments to help us look and feel our best;
- specialised uses that assist production and manufacturing to keep the wheels of commerce and industry turning; and
- maintaining the hygienic and sanitary conditions essential for our food and hospitality industries and our hospitals, medical institutions and public places.

These benefits are essential to safe, healthy living and maintaining the quality lifestyle we all too often take for granted.

With an estimated $3 billion plus in annual product sales (ex-factory), the formulated consumer, cosmetic, hygiene and specialty products industry is a significant part of a prosperous Australian economy. We are a dynamic and growing industry, employing Australians and - through our industrial and institutional sector - supplying products essential for Australian businesses, manufacturing firms, government enterprises, public institutions, farmers and consumers.

Our industry has more than 50 manufacturing operations throughout Australia and member companies include large global consumer product manufacturers to small dynamic Australian-owned businesses. A list of ACCORD's membership is at **Attachment 1.**

ACCORD, on behalf of its member companies, has a specific and direct interest in reform processes which improve the business operating environment for our members. Industry's competitiveness and capacity to maintain local production now and into the future is heavily dependent on reducing the regulatory burden Australian businesses face. ACCORD welcomes the opportunity to provide this submission and recommendations for consideration as a basis for further consultation and dialogue.

Bronwyn Capanna
Executive Director

Executive Summary

The annual growth in regulation for all Australian jurisdictions has been estimated by industry to be 10%. This is more than twice the rate of Australia's economic growth. This regulatory growth comes at a cost, much of which is passed directly onto business, which in turn is passed onto the consumer. A more efficient regulatory system will deliver benefits to the entire community though lower costs creating a business operating environment which will stimulate growth, create better employment opportunities and foster enhanced competitiveness and innovation.

Industry's competitiveness and capacity to maintain local production now and into the future is heavily dependent on reducing the regulatory burden on Australian businesses. Of particular importance is the need to significantly reduce *Australian - specific* regulatory requirements imposed by regulatory agencies on those seeking to do business in Australia.

ACCORD's submission is in two parts. The first part outlines ACCORD's principles and approaches to regulatory efficiency and the second part provides to the Regulation Taskforce a range of reforms to recommend to the Australian Government for immediate implementation.

ACCORD believes that regulatory agencies can improve their regulatory efficiency through the appropriate application of risk management. ACCORD's members must comply with more than 144 pieces of legislation which control chemicals throughout Australia. .

It is evident that drastic measures are required and that all governments need to give a long term commitment to addressing the problem. Short term solutions can provide short term relief, but a sustained effort is required if there is to be a significant improvement in the regulatory burden faced by business over the longer term.

ACCORD believes that significant Government effort must go into improving the culture of regulatory agencies. Without this focus on improved regulatory culture, the other reform processes will fail to deliver the Government's objective for an improved business operating environment through measurable red tape and compliance cost reduction.

Specific areas of reform to assist the chemicals industry include, inter alia:

- a Productivity Commission review to identify opportunities for efficiency improvements, productivity dividends and the adoption of best practice for the chemicals sector;
- an integrated chemical management framework;
- a national control system for security sensitive chemicals; and
- the reduction of unique Australian specific regulatory requirements.

ACCORD makes a number of recommendations which it believes, if implemented, will make a significant difference to our sector.

ACCORD Recommendations

Recommendation 1
ACCORD recommends that the Government provides independent oversight of regulatory agencies as part of its wider regulatory reform agenda.

Recommendation 2
ACCORD recommends that the Minister for Finance together with the respective Ministers, ensure that all regulatory agencies fully comply with the Government's cost recovery policy.

Recommendation 3
ACCORD recommends that the:

- *Australian Government immediately releases its response to the Chemicals and Plastics Leadership Group's Final Report; and*
- *recommendation for a Productivity Commission review into the chemicals sector be accepted and implemented as soon as possible.*

Recommendation 4
ACCORD recommends that the Government agrees to the establishment of an integrated chemical management framework through the establishment of a National Office of Chemical Safety under the auspices of the Australian Government Department of Health and Ageing.

Recommendation 5

ACCORD recommends that the Regulation Taskforce recommends that the Department of Agriculture, Fisheries and Forestry (DAFF) and the Australian Pesticides and Veterinary Medicines Authority (APVMA) implement clear and accountable mechanisms for the earliest possible introduction of reforms to:

- *the system for interface products;*
- *the agricultural active constituent scheme;*
- *the system for the requirements and approval of labels; and*
- *introduce of a workable scheme for low regulatory concern products*

Recommendation 6
ACCORD recommends that Australian Government regulatory agencies commit to examining ways and implementing systems in which assessment requirements can be streamlined to enable mutual acceptance by June 2006.

Recommendation 7
ACCORD recommends that the reform program for the control of hospital, household and commercial grade disinfectants be resolved with industry immediately.

Recommendations 8

8.1 ACCORD recommends that the Regulation Taskforce reminds key environmental policy and regulatory bodies, including the Environment Protection Heritage Council (EPHC), of their obligations to regulatory policy best practices under the COAG Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard-Setting Bodies.

8.2 Further, ACCORD recommends that, in addition to these, the Regulation Taskforce recommends that consultation with industry on new areas of environment policy occur as early as possible in the scoping and problem identification stage as this will improve the technical and administrative feasibility as well as cost-effectiveness of the options to address the problem.

8.3 ACCORD recommends that the Regulation Taskforce notes ACCORD's WashRight proposal to address the impact of laundry detergent use on urban wastewater recycling as a cost-effective alternative to regulatory proposals and as the option that EPHC should support in the first instance, in accordance with COAG Principles.

Recommendation 9

ACCORD recommends that where imported products already meet the regulatory requirements of Australia's comparable trading partners then no further Australian specific requirements should be applied.

Recommendation 10

ACCORD recommends that the Australian Government in collaboration with industry provides leadership though COAG to ensure that a national system for the control of security sensitive chemicals is implemented with minimal costs and regulatory burden on industry.

Introduction

ACCORD, on behalf of its member companies, has a specific and direct interest in reform processes which improve the business operating environment for our members. The annual growth in regulation for all Australian jurisdictions has been estimated by the Business Council of Australia (BCA) to be 10% which is more than twice the rate of Australia's economic growth. This regulatory growth comes at a cost, much of which is passed directly onto business, which in turn is passed onto the consumer. A more efficient regulatory system will deliver benefits to the entire community though lower costs creating a business operating environment which will stimulate growth, create better employment opportunities and foster enhanced competitiveness and innovation.

Industry's competitiveness and capacity to maintain local production now and into the future is heavily dependent on reducing the regulatory burden on Australian businesses. Of particular importance is the need to significantly reduce *Australian - specific* regulatory requirements imposed by regulatory agencies on those seeking to do business in Australia.

In its report to the Government in 2001, the chemicals and plastics industry found that a number of companies dedicated the equivalent of at least four full time staff to meeting various regulatory requirements of all the jurisdictions. In addition, many companies also used the services of intermediaries to assist with compliance. It is estimated that the use of these intermediaries ranged from the equivalent of 20 days per year to the equivalent of 2-3 full time staff (*Underpinning Australia's Industrial Growth* March 2001, p29).

The Regulation Taskforce's review into reducing the regulatory burden is an extremely important initiative which recognises the value of Australian industry to the economy and is prepared to provide positive steps to remove the regulatory obstacles which impede the effectiveness of their day to day operations.

ACCORD notes that there have been a number of recent industry reports which outline the problems faced by business, in particular the problems faced by the burden of regulatory creep. The Australian Chamber of Commerce and Industry's (ACCI) Position Paper, *Holding Back the Red Tape Avalanche, A Regulatory Reform Agenda for Australia* and the BCA's, *Business Regulation Action Plan*, provide all Australian governments with an excellent way forward to reducing the regulatory burden on Australian business. ACCORD's submission will not repeat the work of these two major contributors, rather, ACCORD will focus on providing examples of specific reforms which will make a significant difference to our sector once implemented.

ACCORD's submission is in two parts. The first part outlines ACCORD's principles and approaches to regulatory efficiency and the second part provides to the Regulation Taskforce a range of reforms to recommend to the Australian Government for immediate implementation.

1. A principled approach - efficient risk resource management

1.1 Regulatory principles

ACCORD supports the Australian Government's approach to regulatory best practice and has always recommended that 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 Principles) should be rigorously applied to any regulatory decisions proposed by government agencies. In addition, ACCORD supports the following as good regulatory practice principles.

Regulatory solutions should:

- be the minimum required to achieve the stated objectives;
- adopt a risk management approach to forming and administering regulation;
- minimise the impact on competition;
- be compatible with international standards and practices;
- cause no restriction to international trade;
- be developed in consultation with the groups most affected and be subject to regular review;
- be flexible, not prescriptive and be compatible with the business operating environment;
- standardise the exercise of bureaucratic discretion; and
- have a clear delineation of regulatory responsibilities and effective and transparent accountability mechanisms.

1.2 Risk Management

ACCORD believes that regulatory agencies can improve their regulatory efficiency through the appropriate application of risk management. ACCORD's members are primarily regulated by the Therapeutic Goods Administration (TGA), the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and the Australian Pesticides and Veterinary Medicines Agency (APVMA). In addition, ACCORD's members must also comply with more than 144 pieces of legislation which control chemicals throughout Australia, these include state and federal environmental regulations, international treaties controlling the movement of chemicals, occupational health and safety, transport, storage and labelling requirements at the federal and state level, management of waste chemicals, food handling requirements as well as a range of self-regulatory stewardship activities. This does not cover the general business regulation requirements such as taxation, workers' compensation, industrial relations, financial services, trade practices and corporations' requirements.

While the three regulatory agencies with which ACCORD's members have their major dealings with at the Federal level would argue that they apply effective risk management strategies, ACCORD would suggest that only one of the three better understands and implements a risk based approach in the delivery of its regulatory strategy. NICNAS through adopting this approach has consistently reformed its operations resulting in improved services and lower costs for chemicals of low regulatory concern.

Effective risk resource management ensures that resources are directed to the areas of greatest need. It also ensures that regulatory agencies fully understand their business priorities through a thorough analysis of the internal and external environment. Risk management is regarded as the systematic application of

management policies, procedures and practices to the tasks of identifying, analysing, assessing, treating and monitoring risk.

Risk management is a logical and systematic process that can be used when making decisions to improve the efficiency and effectiveness of performance. It is a management tool to identify and prepare for contingencies. Managing risk involves taking action to avoid or reduce unwanted exposure to the costs or other effects of these events, or to maximise the potential of any opportunities identified.

The benefits of prudent risk management are:

- a more rigorous basis for strategic planning as a result of a structured consideration of the key elements of risk;
- no costly surprises - because undesirable risks are identified and managed;
- better outcomes in terms of program effectiveness and efficiency, e.g. improved client service and/or better use of resources;
- greater openness and transparency in decision-making and ongoing management processes; and
- a better preparedness for, and facilitation of, positive outcomes from subsequent internal/external review and audit processes.

1.3 ACCI's & the BCA's reform proposals

As mentioned, ACCORD supports the proposals for improved regulatory efficiency already put forward by ACCI and the BCA in their respective papers. In particular ACCORD supports the recommended approaches put forward by ACCI for:

- regulatory transparency and accountability;
- enforcement, stringency and consistency;
- dealing with existing regulation; and
- simplifying the system.

As these issues are discussed in detail in ACCI's position paper, ACCORD does not intend to repeat the arguments except to say that priority should be given to introducing regulatory budgeting. It is obvious that drastic measures need to be taken to reduce the regulatory burden which ACCI estimates costs the Australian economy approximately $86 billion.

Regulatory budgeting can introduce the discipline which is required to stem the flow of regulation. The Small Business Deregulation Task Force made a number of recommendations in its report *Time for Business* regarding improving the regulatory system and monitoring government performance. Many of these have been implemented, yet the annual flow of regulation is increasing with compliance costs blowing out. It is evident that drastic measures are required and that all governments need to give a long term commitment to addressing the problem. Short term solutions can provide short term relief, but a sustained effort is required if there is to be a significant improvement in the regulatory burden faced by business over the longer term.

ACCORD also strongly supports the BCA's Action Plan and believes that the ACCI and BCA proposals for future action are mutually supportive and provide the Regulation Taskforce with an excellent plan to take to the Australian Government for immediate implementation. While ACCORD supports the general thrust of the BCA Action Plan an area where ACCORD is not in agreement with the BCA is in the area of excluding small business exemptions from certain areas of regulatory burden.

ACCORD does not believe in the trickle down effect of regulatory reform, rather we support the proposal that what is good for small business is good for big business. It is well known that small business owner-operators do not have the additional resources available to them to deal with taxation, industrial relations and human resource management. These matters, along with running the day to day business operations are usually dealt with by the owners themselves. It is essential therefore when devising regulation reform reduction programs, that the benefits flow directly to this group of people. If intermediaries are required to assist in implementation of the reforms, then this only adds to the compliance costs, not decreases them, hence reducing the effectiveness of the Government's intended reform proposals.

In addition to ACCI's and the BCA's proposals to manage issues such as:

- reducing the overall stock of regulation;
- improving the gatekeeper functions; and
- introducing a proper costing model,

ACCORD believes that significant Government effort must go into **improving the culture of regulatory agencies**. Without this focus on improved regulatory culture, the other reform processes will fail to deliver the Government's objective for an improved business operating environment through measurable red tape and compliance cost reduction.

1.4 Urgent need for cultural change by regulatory agencies

Along with stemming the flow of regulation, Australia needs to address the culture of its regulatory agencies. As mentioned previously, there is little understanding of the proper use of risk resource allocation and the application of minimum effective regulation. In Australia the regulatory agencies tend to over-regulate for zero risk. This is an urgent area for action by all governments and we urge the application of the COAG Principles, in particular that legislation should be **the minimum necessary to achieve the objectives** and **should standardise the exercise of bureaucratic discretion to reduce discrepancies across regulatory agencies**.

The establishment of Small Business Commissioners by a number of Australian jurisdictions recognises the need for specialist oversight and advocacy in areas of small business concern. ACCORD supports similar independent oversight of the activities of regulatory agencies. ACCORD recommends that the Government provides independent oversight of regulatory agencies as part of its wider regulatory reform agenda. ACCORD notes that the Government did not agree with the Productivity Commission's Report No 15, *Cost Recovery by Government Agencies,* Recommendation 8.6 that an independent review body should be appointed to assess whether cost recovery impact statements (CRISs) adequately address the cost recovery guidelines. The *Review of the Corporate Governance of Statutory Authorities and Office*

Holders (the Uhrig Review) also recommended to the Government the establishment of independent oversight of regulatory agencies. In light of our experiences, ACCORD considers that these two recommendations are worth revisiting.

A good example for consideration is the system established by the Federal Government of the United States with the National Ombudsman for Fair Enforcement of Federal Regulation. The US National Ombudsman's primary mission is to assist small businesses when they experience excessive federal regulatory enforcement actions, such as repetitive audits or investigations, excessive fines, penalties, threats, retaliation or other unfair enforcement action by a federal agency.

This model could be adapted to also apply to all the activities of the Australian Government regulators including:

- governance arrangements,
- cost recovery;
- stakeholder engagement;
- accountability;
- transparency;

as well as monitoring regulatory performance including compliance with:

- regulation impact assessment and cost benefit analysis requirements;
- regulatory performance indicators;
- annual regulatory plans;
- the Timesaver Initiative; and
- service charters.

ACCORD has recommended this model to the Government on a number of occasions, but so far our recommendations for independent oversight of its regulatory agencies have been rejected.

Recommendation 1

ACCORD recommends that the Government provides independent oversight of regulatory agencies as part of its wider regulatory reform agenda.

1.5 Governance Issues

ACCORD supports the Australian Government's response to the recommendations of the independent Uhrig Review.

In particular, ACCORD supports the proposed governance arrangements for statutory authorities in achieving clarity in roles and responsibilities and believes that these findings are directly applicable to the governance arrangements of regulatory agencies. The publication of a Statement of Expectations and Intent will give industry increased transparency into the operations of the respective regulatory agencies.

ACCORD has noticed a disturbing tendency by the regulators to undertake activities outside the scope of their legislation. This is usually in the areas of policy, the provision of public information services (both of which are funded from industry cost recovered monies) and regulators' requirements for industry quality improvement programs which seek higher standards than those required in the legislation. Regulatory agencies should focus on core activities using a risk management approach to deliver a regulatory system which is efficient and effective. ACCORD believes that the development of the Statement of Expectations and Intent with the involvement and oversight of the relevant Ministers could assist regulatory agencies to refocus their activities on their core functions.

The Uhrig Review identifies the potential benefits of the Statement of Expectations and Intent for all regulatory agencies as follows:

- Improving the transparency and accountability of statutory authorities through:
  - clear and transparent lines of accountability
  - clear understanding of roles
  - clearly articulated and publicly available objectives and strategies
- Improving efficiency of statutory authorities by ensuring:
  - there is effective supervision of management
  - management is accountable for its performance
  - the effort of authorities is directed towards the achievement of well-understood objectives.
- Improving the effectiveness of statutory authorities through developing a sound understanding of what they are required to achieve resulting in:
  - higher quality services
  - **better regulation**.

These goals and outcomes of the proposed Statement are supported by industry.

1.6 Cost recovery

As mentioned previously, ACCORD's members are regulated primarily by the TGA, NICNAS and the APVMA, all of which apply 100% cost recovery on industry for the funding of their regulatory activities.

ACCORD has recently been involved in consultations regarding the development of cost recovery impact statements (CRISs) for the TGA, NICNAS and the APVMA. During these consultations, ACCORD identified areas for improvement in the application of the Government's cost recovery policy by these regulatory agencies. While some of these have been addressed in the revised Guidelines put out by the

Department of Finance and Administration (DoFA) in June 2005, concerns still remain. For example, the recent Government decision to impose 100% cost recovery on NICNAS now means that Australian chemical safety policy is currently funded by industry cost recovered monies for industrial chemicals from NICNAS.

This practice, if allowed to continue unchecked will have a huge cost impost on the chemicals industry. For example, ACCORD has estimated that to recoup a further $400,000 (NICNAS's 2005-06 Government appropriation) to fund activities currently deemed 'government business' will result in a 6.5% increase in NICNAS's fees and charges. **If you add a CPI increase of roughly 2 to 3% onto this, then industry could be looking at an 8 to 9% increase in 2006-07.**

ACCORD is of the view that cost recovery does not apply to the provision of services to the Government such as:

- advising Parliament on issues where the agency has expertise;
- answering Parliamentary questions;
- briefing Ministers and responding to their correspondence;
- financial reporting; and
- complying with international treaties.

In addition, ACCORD does not believe that cost recovery applies to those information products provided on behalf of Government in relation to matters of public interest such as the TGA's, NICNAS's and APVMA's public health responsibilities and information to the community.

As a general observation, we note that cost recovery was introduced by the Government following the 1996 election as part of its Budget deficit reduction strategy. This deficit reduction strategy has been very successful with the Government sustaining a Budget surplus for a number of years. The decisions made under more stringent economic conditions in 1998-99 regarding cost recovery are no longer relevant and the current economic climate provides an opportunity for the Government to reduce some of the costs of regulation without the stigma of 'business welfare'.

Not withstanding, ACCORD supports the Government's cost recovery policy. As an industry association, we believe we have acted responsibly in assisting the Government to bed down its policy and gain general acceptance for it by our members.

ACCORD believes that where the community or the public interest is the chief beneficiary, then it is appropriate for the taxpayer to pay for this service. ACCORD has always argued that the Government should fund the public good aspects of regulatory agencies' activities.

It has been our experience that regulatory agencies are widening their scope of cost recovered activities by interpreting the Guidelines in the widest possible sense. It has been put to ACCORD that cost recovery arrangements can be legitimately applied even though '*it may not be necessary for the industry participant to benefit*'. ACCORD believes that the Guidelines make it clear that the key issue in determining the scope of cost recovered activities is whether there is an 'identifiable beneficiary' of the

activity. Clearly this is an area where independent oversight would have a role in ensuring adherence to the Government's policy.

One of COAG's principles of good regulation is to minimise the exercise of bureaucratic discretion to reduce discrepancies between government regulators. It has been ACCORD's experience that the lack of clarity in the Guidelines has resulted in the cost recovery arrangements being interpreted and applied differently by the regulatory agencies with which our members have dealings. We believe that the Guidelines need to be more clearly spelt out in certain areas to avoid being open to misinterpretation.

ACCORD has identified a number of areas where improvement and/or clarification is urgently required. These are explained in more detail in **Attachment 2** and include recommended actions to improve the situation. The following issues require attention:

1. treatment of interest;
2. treatment of reserves;
3. funding of appeals;
4. funding of services performed for Government;
5. activity based costing;
6. using levies as a sales tax on goods for cost recovery purposes; and
7. performance measures to demonstrate efficiency and effectiveness.

Recommendation 2

ACCORD recommends that the Minister for Finance together with the respective Ministers, ensure that all regulatory agencies fully comply with the Government's cost recovery policy.

1.7 Chemicals and Plastics Industry Action Agenda – regulatory reform priorities

In August 2004, the Chemicals and Plastics Leadership Group appointed by the Australian Government's Industry Minister, the Hon Ian Macfarlane, MP, presented its final report to the Commonwealth Government regarding priorities for action in the areas of regulation reform, investment, innovation, education and training. Industry's priorities for regulation reform are outlined in the following points:

- Future regulatory reform action should focus on developing a program to systematically review regulations impacting on the chemicals and plastics industry i.e. the 144 pieces of Commonwealth, State and Territory legislation which currently regulates the chemical industry.
- That there be further expansion of the COAG Principles to cover all regulatory standards including quasi-regulation.
- Compliance with COAG principles should be matched by compliance with principles of good governance and administration such as those promoted in

the Australian National Audit Office's (ANAO) Public Sector Governance Better Practice Guide.

- All agencies should continue to investigate opportunities for introducing low regulatory concern reforms as well as enhancing the reform processes currently in place.
- That the Productivity Commission (PC) conducts a review to identify opportunities for efficiency improvements, productivity dividends and the adoption of best practice within the regulatory system.

It is disappointing that the Australian Government has not as yet released its response to the CPLG's report. The anticipated review of the chemicals industry with a view to identifying opportunities for efficiency improvements on an industry wide basis is eagerly awaited by industry.

Recommendation 3

ACCORD recommends that the

- **Australian Government immediately releases its response to the Chemicals and Plastics Leadership Group's Final Report; and**
- **recommendation for a Productivity Commission review into the chemicals sector be accepted and implemented as soon as possible.**

2. *Specific reform proposals for the chemicals industry*

2.1 Development of an integrated chemical management framework

ACCORD has been arguing for a considerable period for an integrated control framework for chemicals. The state, territory and Australian governments commissioned a national competition review to examine the legislation and regulation imposing controls over access to, and supply of, drugs, poisons and controlled substances. In 1999, an independent Chair, Ms Rhonda Galbally commenced the review with advice from a steering committee representing all jurisdictions.

The Galbally Review's final report was presented to the Australian Health Ministers' Conference (AHMC) in December 2000. The Government response to the Galbally Review was released to the public on 1 July 2005 by the AHMAC Working Party. The Government agreement to implement Galbally Recommendation 7 regarding the separation of scheduling of medicines and chemicals provides an excellent opportunity to reform the current chemical control framework. The impetus for the Government response to the 1999 review was the proposed development of a joint therapeutic medicines agency between the TGA and Medsafe, New Zealand. The separation of the two committees makes practical sense in the context of the proposed developments, although industry can see no reason why the Government did not act sooner to implement this common sense recommendation.

From an industry perspective, this reform to the scheduling committees provides an opportunity for the Government to look more broadly at the way chemicals are managed in

Australia. Industry has argued for a more integrated chemical control framework within the Department of Health and Ageing (DOHA) but separate from the joint therapeutic medicines agency. We believe that this will deliver a streamlined approach for the assessment and scheduling of chemicals in Australia but could also provide for an improved approach to the national management of chemicals including chemicals of interest from a security or illicit drug manufacture perspective reducing the cost to industry but maintaining the current high standard of public health and safety.

We believe that this approach would deliver at a national and strategic level, enhanced policy development, and more efficient, effective and streamlined regulatory controls. A copy of ACCORD's submission to the TGA on *A new scheduling model for chemicals and medicines* is at **Attachment 3**.

Recommendation 4

ACCORD recommends that the Government agrees to the establishment of an integrated chemical management framework through the establishment of a National Office of Chemical Safety under the auspices of the Australian Government Department of Health and Ageing.

2.2 The burden of agricultural and veterinary (agvet) chemicals regulation

The industry works with the APVMA through its Industry Liaison Committee (ILC) to identify and address regulatory issues. Industry's concern is that while issues are brought to the attention of the APVMA, it takes a very long time for any tangible changes to the agvet regulatory scheme. In some cases, the APVMA makes decisions, contrary to the advice of industry, which can be clearly demonstrated through experience over time as being inappropriate.

The APVMA and the Agvet Code attempts to bring together the regulations of all the jurisdictions as well as involving them at different levels in the decision making process. This causes significant delays and there is no guarantee that Australia then has a unified national set of regulatory controls for the agvet sector as the states and territories can still impose additional requirements. Laws relating to the '*control of use'* of agricultural and veterinary chemicals are not uniform throughout Australia.

2.2.1 Reform to the system for interface products is urgently required

A number of minor and non-contentious legislative amendments remain outstanding to address inadequacies with the current system. The APVMA has recently identified a range of products that need to be subject to regulatory reform. Industry supports these reforms and encourages early implementation of the proposed approach as outlined in a recent discussion paper circulated by the APVMA to the ILC in October 2005.

These matters are brought to the attention of the Regulation Taskforce because even though the APVMA recognises that action is required, from past experience industry knows that achieving the reforms in a timely manner may not happen due to the complexity and uncertainty of the decision making processes. Changed regulatory controls have been suggested for:

- substances used in conjunction with an agricultural chemical product to identify areas treated with that product;
- stockfeed non-active constituents;
- antimicrobial treatments for domestic uses – mattresses and pillows;
- sheep branding substances; products containing natural ingredients such as garlic, neem, and citronella;
- water treatments for control of micro-organisms such as swimming pool and spa sanitising products;
- dairy and other primary producer sanitisers;
- biocides for building materials and household chemicals; and
- a range of low risk veterinary products.

From this list it is obvious that a range of products should never have been included within the APVMA's regulatory controls. However, the issues have been identified with recommended actions. Industry can only support this approach and recommends that all governments agree to the APVMA's recommendations and that implementation proceeds as a matter of priority.

2.2.2 Reform of the agricultural active constituent scheme is urgently required

Industry has identified an anomaly in the coverage of the Agvet Code which requires immediate attention. The problem arises as the Agvet Code contains no offence provisions for the sale and/or supply by a manufacturer/supplier (approval holder) of an approved active constituent that does not comply with approval particulars. Under the current provisions of the Agvet Code only the registrant of a product can be made accountable for the quality of an active constituent and *not* the active constituent manufacturer or approval holder. Current regulatory intervention is at an inappropriate point in the supply chain. Despite industry's attempts for reform in this area as well as the ANAO 1997 review of the then National Registration Authority (NRA) pointing this out as a problem, industry is still waiting for action in this area.

2.2.3 Reform to the system for approval of label changes is urgently required

Industry has raised with the APVMA on numerous occasions the need to revise and streamline its approval process for changes to the labelling of agvet products. Currently the APVMA processes hamper rather than facilitate the timely introduction of the requirements of other legislation such as updating:

- changes arising from decisions of the National Drugs and Poisons Schedule Committee,
- Poison's Information Centre Numbers and other information.

Industry requires greater flexibility in label layout and design. For example, the APVMA's regulatory requirements for matters of no significant consequences to public health and safety such as the removal of a value-pack promotion on an aerosol product are an inefficient and unwarranted use of resources for both industry and the regulator. Also, the requirement to seek APVMA approval for a label change when only the shade of the label has changed is unacceptable to industry. Many of the current requirements in this area of labelling for agricultural and veterinary products

exceed those of '*over the counter medicines'* administered by the TGA. These facts have been presented to the APVMA, the Department of Agriculture, Fisheries and Forestry (DAFF) and states and territories on numerous occasions but there is little will by these agencies to address the concerns of industry.

Case Study 1: Introduction of a control system for low regulatory concern agvet products with no regulatory outcomes

Listed registration and reservation
Since October 2003 the Agvet Code has provided for listed registration and reservation of products which conform to a pre-determined Standard. The process of registration is for products whose:

* Risk characteristics are low and well known; and
* Efficacy claims are relatively modest and conform to the Standard.

Despite some 80 pages of legislative amendments not one approval has been made under these provisions. Indeed, Industry clearly advised APVMA and DAFF that the changes, together with the processes that have been defined either have little or no practical application, or are excessively cumbersome. The activity-based costs of the processes are also likely to be very high, making it unattractive to regulatory process.

Currently, the lack of an adequate resolution remains an on-going inefficient cost to industry, and the APVMA. There is critical need for the establishment of a process to develop a workable efficient and cost-efficient scheme for products of low regulatory concern that embodies appropriate risk management and risk-resource allocation resulting in appropriate levels of regulatory intervention for these products.

Case Study 2: Regulation of interface products - dairy cleansers and sanitisers
For a single identical formulation for a dairy sanitiser that is used to clean the milk vat on a dairy farm and the same formulation used to clean the milk tanker that picks up the milk from the farm and also used throughout the rest of the milk handling, processing and production chain there is totally separate regulation.

The product used on the dairy farm is required to be specifically registered by the APVMA, have unique labeling, and pay levies on every dollar of sales to the APVMA.

For companies marketing products to the two '*artificially'* regulated markets there is no incentive to bring improvements or innovation to the farm sector. The regulation also creates unnecessary increased costs to industry through requirements for separate inventories, separate labeling, additional APVMA costs for applications and label changes, payment of annual levies and other costs.

The same anomalies exist for products used as dairy cleansers. The APVMA has noted that it is '*incongruous that the APVMA regulates in isolation one small segment of dairy food hygiene i.e. on-farm dairy cleansers*.' Industry has sought action in this area for a number of years and would urge that immediate that action is required – not to review the situation for as yet an indeterminate amount of time.

Recommendation 5

ACCORD recommends that the Regulation Taskforce recommends that the Department of Agriculture, Fisheries and Forestry (DAFF) and the Australian Pesticides and Veterinary Medicines Authority (APVMA) implement clear and accountable mechanisms for the earliest possible introduction of reforms to:

- **the system for interface products;**
- **the agricultural active constituent scheme;**
- **the system for the requirements and approval of labels; and**
- **introduce a workable scheme for low regulatory concern products.**

2.3 The burden of therapeutic goods regulation

2.3.1 The regulation of products at the cosmetic/therapeutic interface

Many of ACCORD's members are regulated by a number of Australian regulatory agencies where the boundaries between the different schemes overlap. This can result in overregulation of products at the interface, many of which are low risk. A particular area of concern for the majority of ACCORD's cosmetic and personal care companies has been the resolution of the regulation of products at the cosmetic and therapeutic interface. ACCORD has been arguing for changes to this area of regulation since 2001. In November 2005, the Government finally released its response and agreed to implement a number of recommendations which will address many of industry's long held concerns. While industry is pleased with this outcome, it took the TGA five years to take industry's concerns seriously and only as a result of intensive industry lobbying as part of the broader reform process from the Chemicals and Plastics Action Agenda.

While this reform is welcomed by industry, it has exacerbated the difference in approaches to risk management by the regulatory agencies resulting in different assessment requirements and treatment of assessment data, in particular by the TGA and NICNAS, both of which are within the same department.

Case study 3: Over-regulation of excipients by the TGA

An ACCORD member has identified a problem with the TGA's assessment process for 'new' excipients. An excipient is an inactive or inert substance which is added to a formulation, usually to provide stability or bulk. For those sunscreens that are still regulated by the TGA (primary sunscreens or moisturiser/sunscreen with SPF >15), the way that "new" excipients are evaluated cannot be justified.

The regulatory requirements for listing new sunscreen excipients are found in the Australian Regulatory Guidelines for OTC Medicines - Chapter 10. The relevant section is provided below. In summary, it is necessary to obtain a provisional listing of the excipient by submitting appropriate information according to points 1, 2, 3 and 4 below. The TGA will assess this request for provisional listing and respond within a few weeks. It is then possible to list and sell a sunscreen product with this excipient. Information relating to points 5, 6 and 7 below, together with an evaluation fee of $5,000, must be sent to the TGA within 6 months of the date of listing the product. The TGA then

undertake a detailed assessment of the safety data.

This member argues that such a detailed assessment of provisionally listed excipients should not be required:

- Historically, TGA take a number of years to complete their assessment, during which time the product is on the market. If there is a significant health or safety issue, some damage may already have been done.
- For several years it was TGA policy that detailed assessment of new sunscreen excipients was not required. Information on points 1 to 4 were generally sufficient to demonstrate safety of the excipient. To their knowledge, no safety issues occurred when this policy was in place.
- Most new excipients used in sunscreens are at very low concentrations (<1%). so it is most unlikely that they would pose significant risks in the formulated product, especially if conditions in points 1 to 4 were met.

The regulatory system would be much more timely and cost effective if sponsors could list new excipients by providing information according to points 1 to 4 and at the same time self certify the safety.

New excipients in sunscreens
Where a sunscreen contains an excipient ingredient which is not in any product currently included in the Australian Register of Therapeutic Goods (ARTG) for supply in Australia, the excipient must be cleared for use by the TGA. The following information is required:

1. *Identification of the excipient as a substance included in the CTFA International Cosmetic Ingredient Dictionary (the page number and reference should be quoted); and*
2. *Assurance that it does not appear in Annex II to the EEC Directive 76/768 List of substances which must not form part of the composition of cosmetic products; and*
3. *Assurance that the excipient has been approved by the appropriate regulatory agency in Sweden, Canada, USA, UK or The Netherlands; or (less desirably)*
4. *Assurance by the applicant that there have been market-place sales of comparable products containing the excipient in one of those five countries for at least two years; and*
5. *Acute oral toxicity: LD50 . animal or alternative method; and*
6. *Irritation study .skin; animal or alternative method; and*
7. *Sensitisation study .skin; animal or alternative method. The following additional studies may be requested in individual cases where concerns become evident at the time of evaluation.*
8. *Eye irritation study; and*
9. *In vitro mutagenicity (Ames) test; and*
10. *Invitro percutaneous absorption test. All of the above information can be submitted prior to listing together with the New substance application form1 (available from the TGA website). If the substance is cleared it will be given an .Australian Approved Name. (AAN) and will thereafter be able to be used in other topical non-prescription medicines (subject to any conditions or limitations) without the need for further evaluation. The sponsor will be advised of the AAN and will then be able to submit an application to list/register the sunscreen product. Alternative sources of data on the safety of the excipient will be considered. For instance, if the excipient has been cleared by NICNAS or by the US Cosmetic Ingredient Review (CIR) group the review document may be sufficient in itself.*

Copies of CIR reviews are available on the Internet2. Copies of NICNAS reviews may be available from the supplier of the excipient. Alternatively, the information in the first four points above can be submitted as part of a .Listing. application for a sunscreen together with an assurance that the data specified in points 5 to 7 will be provided to the TGA within 6 months of the date of listing of the product. The new excipient will be given a .provisional AAN. (known as a .PRV.) and the product listed with a condition that the data must be provided within 6 months of listing. Failure to submit the specified data within this time may result in cancellation of the product from the ARTG and recall. The data will be evaluated by the TGA and, if cleared, the excipient will be given an AAN and will thereafter be able to be used in other topical non-prescription medicines (subject to any conditions or limitations) without the need for further evaluation. If there are concerns about the safety of the excipient or if the data provided by the sponsor are incomplete or otherwise unacceptable, the product may be cancelled from the register and/or recalled. Fees will apply to the evaluation of the data and the listing of the product as specified in the Summary of fees and charges1.

2.3.2 Australian regulatory agencies have mutual acceptance of assessment

Industry has for a number of years raised its concerns about the need for the APVMA, TGA, NICNAS and the Australian Government Department of the Environment and Heritage (DEH) to streamline their assessment processes and data requirements so that relevant information can be more freely exchanged between regulatory agencies, hence reducing the reporting and cost burden on industry seeking approval for the same chemical for different purposes from different regulatory agencies.

While these regulatory agencies have agreements in place with comparable international agencies, no such process exists for inter-agency mutual acceptance. While the Government in its response to the Chemicals and Plastics Industry Action Agenda indicates that this is an area for reform, industry has seen little effort to date to achieve this outcome. ACCORD would recommend that this be a priority for the regulatory agencies.

Recommendation 6

ACCORD recommends that Australian Government regulatory agencies commit to examining ways and implementing systems in which assessment requirements can be streamlined to enable mutual acceptance by June 2006.

2.3.3 The urgent need to streamline regulatory requirements for common disinfectants

Urgent reform is required for the existing controls on hospital, household and commercial grade disinfectants. The TGA commenced this reform process with industry in 1997 and has recently recommenced these discussions to conclude the process as part of the reform to the joint therapeutic medicines agency. ACCORD does not support the Government's decision that the joint therapeutic medicines agency should create a category of Australia only related therapeutic products (RTP) which includes amongst other things, the regulation of disinfectants. New Zealand does not regulate disinfectants as therapeutic products. Industry is yet to see the justification for Australia continuing to regulate these products as RTP's, particularly given the COAG Principles for minimum effective regulation, the commitment to Closer Economic Relations between Australia and New Zealand and the Trans-Tasman

Mutual Recognition Agreement to reduce barriers to the movement of goods between Australia and New Zealand.

By applying a higher, or Australian only regulatory standard to this group of products, Australia is possibly eliminating from competition comparable New Zealand products. Conversely, higher compliance costs faced by Australian industry means that these products are less competitive on a cost basis than comparable products in New Zealand. Either way, Australian industry is being disadvantaged by the Australia only regulatory requirements for disinfectants. It is therefore important for the TGA to establish a case for the additional regulatory requirements, something which as yet, has not happened. The development of RTP's is the adoption of the status quo by the TGA. There is no analysis or justification for this decision as required by the COAG Principles.

ACCORD has identified that reform is required for the following product categories not making specific claims:

- Hospital grade disinfectants without specific claims;
- Household/commercial grade disinfectants without specific claims (including new chemical entities);
- Household/commercial grade disinfectants without specific claims;
- Sanitisers;
- Sanitary fluid; and
- Antibacterial clothes preparations.

This example is brought to the Regulation Taskforce's attention as an area where the regulator and industry had identified a need for reform as early as 1997, but the reform process has been hindered from progressing. This example is similar to the resolution of cosmetic/therapeutic products interface issues which also took a long time before industry saw any positive outcomes. This is because the regulation of these products is not the core business of the TGA which is primarily focused on medicines. For this reason ACCORD believes that if the TGA used proper risk management and risk resource allocation then these issues would have been correctly identified as low risk and excluded from the therapeutic products regime and regulated by more appropriate controls.

Recommendation 7

ACCORD recommends that the reform program for the control of hospital, household and commercial grade disinfectants be resolved with industry immediately.

2.3.4 Impact of proposed amendments to therapeutic goods legislation and flow on effect to other sectors

The TGA recently introduced a range of amendments to its Therapeutic Goods legislation which includes a number of changes such as the:

- introduction of civil penalties;

- introduction of infringement notices;
- substantial increase in penalties;
- introduction of enforceable undertakings;
- introduction of search warrants for civil penalties; and
- introduction of employees' and directors' liability.

ACCORD raised with the TGA a number of reservations about the way the proposed changes were brought to industry's attention and in particular the lack of regulatory impact analysis to substantiate the TGA's claims that the proposed changes were warranted. In particular we raised with the TGA the:

- lack of transparency in the development of policy proposals;
- lack of consultation and stakeholder engagement processes; and
- nature of the proposed changes.

ACCORD believed that the proposed amendments in the Draft Bill were significant and warranted a high degree of policy development and engagement with a broad range of stakeholders, prior to its development and release for limited and selective stakeholder consultation. By contrast, recent discussions by the Ministerial Council of Consumer Affairs to review the product safety provisions of the TPA has resulted in extensive consultation including a reference to the Productivity Commission to look at the costs and benefits of the various proposals included in the Ministerial Council's discussion paper. This is an example of the adoption of open and transparent stakeholder engagement based on identification of the issues which need to be addressed.

ACCORD is at a loss to understand why the proposed amendments are required in light of the recommendations arising from the Australian National Audit Office (ANAO) review of the Regulation of Non-prescription and Medicinal Products. Of the 26 recommendations, not one indicated a need to strengthen the *Therapeutic Goods Administration Act 1989* (TGA Act). The ANAO found that '*where a manufacturer or product is not compliant with regulatory requirements, the TGA has a range of actions available to reduce possible risks to public health and safety*' (p13). The focus of the ANAO's recommendations found that the TGA did not have systematic monitoring arrangements in place to ensure action to manage non-compliance was taken, nor that there was consistency in application of operational procedures.

This example is drawn to the attention of the Regulation Taskforce because it highlights the problems faced by industry. If industry had an effective working relationship with the regulator then it could have looked at alternatives and developed a range of suitable options for implementation to address problems in the regulatory framework, rather than having an onerous regulatory scheme placed upon them. Industry was advised that there would be no additional burden faced by complying businesses. This is a naive statement from a regulatory agency implementing such significant changes. No regulatory change comes without a cost.

The problem industry now faces are that other regulatory agencies are seeking the same level of penalties and provisions as those proposed in the TGA's Amendment Bill. This is regulatory creep at its best, where standards become adopted without the necessary rigour of an impact assessment.

2.4 The burden of environmental regulation

ACCORD members are also concerned with the increased amount of environmental regulation, much of which is being developed in the absence of direct input from industry.

For example, as part of its consideration of the National Water Initiative at its 1 July 2005 meeting, the Environment Protection & Heritage Council (EPHC) *'…discussed a national strategy to reduce the salts and fillers that provide the bulk[1] in many* ***washing detergents*** *but make recycled water difficult to reuse. It will undertake work to investigate options for a national product standard for detergents that reduces salts and other chemicals that inhibit water recycling[2].'.*

This meeting considered potentially burdensome regulatory actions such as mandatory reformulation of all products on the Australian laundry detergents market or the mandatory labelling of all products for salt content. However, in the lead up to this meeting and the subsequent consideration by the nation's peak environmental policy body of a matter of great significance to the laundry products' industry, no industry input was sought[3] nor any information provided to industry to support the need for regulation over other alternatives.

Industry, through ACCORD, has put forward a self-regulatory scheme which addresses the concerns raised by governments and will support the overriding policy goal of better utilisation of Australia's scarce water resources.

As an effective and flexible alternative to regulation, ACCORD's *WashRight* proposal will educate consumers and change behaviors by promoting household laundry practices that reduce water usage, are energy efficient, and, reduce 'salt' discharge, where needed.

As part of this proposal industry will also publish lists of '*low salt'* products that are currently readily available on the Australian retail market so that consumers may purchase these in a targeted manner. This means that if you live in a water supply area in which your household wastewater is recycled by your water utility then you should use a lower salt product to reduce the burden on the local treatment plants. However, if you live in an area where your wastewater goes straight to ocean outfall or is not recycled, then the salt content is not environmentally relevant and you do not need to change your product purchase.

ACCORD's approach offers tangible benefits which can be achieved without regulation and unnecessary costs to both industry and consumers. ACCORD's proposal can be implemented immediately. National regulation for reformulation of all products or for mandatory product labelling could takes years to implement and even then there is no guarantee of national uniformity, **yet the EPHC has been unable to make a decision**

[1] This statement is not correct. For the most part sodium salts are used in laundry detergents to provide the chemical washing activity needed to clean dirty laundry.
[2] EPHC Communiqué, 1 July 2005, '*Ministers Act on Pollution, Waste and Water*'
[3] This has since been corrected to some extent through the appointment of the Victorian EPA as lead agency for this matter and efforts by this agency to seek input from ACCORD on behalf of the laundry products industry. For example, ACCORD's WashRight proposal was summarised by the Vic EPA as part of an Options Paper considered by EPHC at its 26 October 2005 meeting.

on whether it wants an immediate low-cost solution or a high-cost, imposed solution to the salts issue.

ACCORD has previously been active in implementing a number of product stewardship initiatives aimed at addressing health, environment and/or consumer issues of significance. An example is the *Scheme for Phosphorus Content and Labelling of Detergents*. This illustrates industry's willingness to initiate measures to solve environmental problems. Our members have demonstrated their industry responsiveness through the pro-active establishment of self-regulation to address distortions in the marketplace rather than wait for government intervention through regulation.

The recent EPHC Industry Discussion paper on Co-Regulatory Frameworks for Product Stewardship again illustrates the point that governments appear to be keen to intervene even when there is little evidence to support their case, rather than let industry self regulate.

ACCORD does not support the EPHC's proposed co-regulatory approach for product stewardship. ACCORD recommended that the EPHC should commit to best practice environmental regulation and encouragement of sustainable development by allowing industry to self-regulate. Where self-regulation has clearly failed and this can be objectively demonstrated, then alternatives to self-regulation should be considered.

The EPHC Co-Regulatory Framework has provided no data to demonstrate that self-regulation has failed to deliver the desired objectives. Nor has it provided a justification for government intervention in the market place. The Framework does not clearly articulate the problem that is to be solved through the proposed co-regulatory approach. There is no justification for Government intervention in the market place, no exploration of alternative options and no data to support any claims of 'competitive advantage' to those companies not participating in the voluntary scheme. Until this information is provided, ACCORD believes that further government intervention in this area is unwarranted.

Environmental protection is an important responsibility for governments, industry and the community and, more often than not, requires effective collaborative solutions rather than prescriptive regulation. It should be the primary role of the state and federal environment agencies to encourage and generate these solutions rather than continually seeking to enact statutes and rules.

Recommendation 8

8.1 ACCORD recommends that the Regulation Taskforce reminds key environmental policy and regulatory bodies, including the Environmental Protection and Heritage Council (EPHC), of their obligations to regulatory policy best practices under the COAG Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard-Setting Bodies.

8.2 Further, ACCORD recommends that, in addition to these, the Regulation Taskforce recommends that consultation with industry on new areas of environment policy occur as early as possible in the scoping and problem

identification stage as this will improve the technical and administrative feasibility as well as cost-effectiveness of the options to address the problem.

8.3 ACCORD recommends that the Regulation Taskforce notes ACCORD's WashRight proposal to address the impact of laundry detergent use on urban wastewater recycling as a cost-effective alternative to regulatory proposals and as the option that EPHC should support in the first instance, in accordance with COAG Principles.

2.5 The burden of unique Australian requirements

As noted previously, ACCORD's members are regulated by a number of key Australian Government regulatory agencies and a common complaint is the high number of regulatory requirement unique to Australia. Many of these products, particularly in the cosmetic, personal care and devices area are imported from Europe, the USA, the UK, Japan and Canada and have already been assessed for public health and safety outcomes. Australian regulatory agencies still require additional controls, many of which do not contribute to safety or improved consumer knowledge but add costs and barriers to the importation of innovative products into the Australian marketplace.

Case study 4: '*burdensome*' unique Australian regulatory requirements
There are a number of '*burdensome*' unique Australian regulatory requirements which ACCORD's members are required to deal with, and are typical for the cosmetics and personal care sector. This case study provides the Regulation Taskforce with a good idea of the additional requirements and complexity faced by the one ACCORD member company in the cosmetics sector on a day to day basis.

'The Australian industry is required to incorporate these requirements specifically into dedicated packaging for the Australian market for products which are of low risk.

- ***Weights & Measures Regulations:***
  - *the need to have the measurement marking on the front panel of the article where the back or side alone is not sufficient.-. this requires overlabelling for products from the EU;*
  - *the need to have the measurement marking of aerosol products in grams where mls alone is not sufficient - this requires overlabelling for products from the EU and the USA;*
- ***Dangerous Goods:***
  - *primary and secondary package marking requirements that do coincide with the UN requirements. In particular we are concerned with the recognition of the EU Flame Symbol and symbols used in the USA as well as the repacking of shipper quantities into cartons that are marked in accordance with unique Australian requirements;*
- ***Schedule 5 and 6 poisons:***
  - *labelling requirements for Schedule 5 and 6 single-application hair dyes and bleaching powder kits;*

- *retail storage requirements for Schedule 5 and 6 single-application hair dyes and bleaching powder kits;*

- ***NOHSC Workplace Health & Safety labelling requirements** for professional use only products (over and above the safe handling and usage instructions that are already included for professional use only products in the EU and the USA);*

- ***Cosmetic claim guidelines** for packaging claims and advertising that do not match international guidelines (we don't want specific claims for the Australia only market);*

- ***TGO69 drug standard labelling requirements** for Exempt and Listable Therapeutic Goods (particularly Exempt);*

- ***the ASMI approval mechanism** for Exempt and Listable Therapeutic Goods advertising (particularly Exempt);*

- ***the Australian/New Zealand Standard for SPF**, Broad Spectrum and Water-Resistancy testing that does not recognise the Colipa and FDA methods and test results.*

All the issues listed above require 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 results 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.'

Recommendation 9

ACCORD recommends that where imported products already meet the regulatory requirements of Australia's comparable trading partners then no further specific requirements should be applied.

2.6 Emerging issues –increased regulatory burden and costs on the horizon

2.6.1 National security issues – control of chemicals of interest

All governments through the COAG process have been working with industry on the matter of national security and the identification of a process for the control of chemicals of interest. While ACCORD supports work in this important area, it is important for governments to adopt a national approach to the problem.

The need for a national approach was highlighted recently by the failure of governments to introduce regulations for the control of ammonium nitrate. In June 2004, COAG agreed to implement controls for these security sensitive chemicals, yet

12 months down the track, only Queensland and the Northern Territory have controls in place. The controls for ammonium nitrate are not nationally uniform which will result in unnecessary costs to industry by the failure all government's to implement the decision they reached in June 2004 regarding the control of this substance.

From industry's perspective it is important that a nationally uniform approach be adopted by all governments and that excessive costs arising from the implementation of any national scheme are not passed onto the chemicals industry. As this is a matter of significant national interest it is an area where industry would expect governments to contribute to the costs. We draw this matter to the attention of the Regulation Taskforce as we regard it an important issue but one which industry should not be asked to meet the entire cost.

Recommendation 10

ACCORD recommends that the Australian Government in collaboration with industry provides leadership though COAG to ensure that a national system for the control of security sensitive chemicals is implemented with minimal costs and regulatory burden on industry.

2.6.2 Development of a chemicals adverse reporting system

As part of the recent reforms to low regulatory concern chemicals, the community has sought more information on chemical safety matters and community right to know issues in relation to the control and use of industrial chemicals. Industry has supported this approach and currently funds though its cost recovered monies a Community Engagement Forum which provides advice to the Director, NICNAS on strategies to improve the public's knowledge in these areas.

While ACCORD is not opposed to a reporting scheme in-principle, there are already in place a number of national systems which provide data on accidental poisonings. Industry itself has taken a responsible position and provides information through its consumer information lines. By way of example, the agvet adverse reporting scheme, a poorly designed system does little to provide information of significance and is borne at great cost to industry.

We draw this to the attention of the Regulation Taskforce because we understand that the Government is giving consideration to implementing an adverse chemical reporting system. We regard this as an area of public interest and believe that this should be taxpayer funded. We believe that the costs of a system would be an additional burden on the chemicals industry with little benefit to be gained by the public.

3. Concluding Comments

Throughout our submission ACCORD has attempted to draw to the Regulation Taskforce's attention areas of significant burden to the chemicals industry. ACCORD believes that much of this burden could be reduced through appropriate risk resource

management by Australian Government regulators and urge that the Government to focus on improving this aspect of regulatory activity along with the recommendations put forward by ACCI and the BCA in stemming the flow of regulations.

We urge the Taskforce to consider our recommendations as worthy of immediate Government action. We believe that if these recommendations are implemented, the flow on effects to our sector will be significant.

Attachment 1

ACCORD Australasia Membership

Advance Chemicals Pty Ltd
Albright & Wilson (Aust) Ltd
Amway of Australia Pty Ltd
Applied Australia Pty Ltd
Auto Klene Solutions Pty Ltd
Beiersdorf Australia Ltd
Callington Haven Pty Ltd
Campbell Brothers Limited
Canpoint International Pty Ltd
Castle Chemicals Pty Ltd
Castrol Australia Pty Ltd
Chemetall (Australasia) Pty Ltd
Ciba Specialty Chemicals
Clariant (Australia) Pty Ltd
Cleveland Chemical Co Pty Ltd
Clorox Australia Pty Ltd
Colgate Palmolive Pty Ltd
Creative Brands Pty Ltd
Deb Australia Pty Ltd
Dominant (Australia) Pty Ltd
DuPont Chemical Solutions Enterprise
Ecolab Pty Limited
GlaxoSmithKlineConsumer Healthcare
G S B Chemical Co Pty Ltd
Henkel Australia Pty Limited
Huntsman Corporation Australia Pty Ltd
Jalco Group Pty Limited
Jasol Australia
Johnson & Johnson Pacific Pty Ltd
Kao (Australia) Marketing Pty Ltd
Lab 6 Pty Ltd
L'Oreal Australia Pty Ltd
Milestone Chemicals Pty Ltd
Northern Chemicals Pty Ltd
Novozymes Australia Pty Ltd
Nowra Chemical Manufacturers Pty Ltd
Peerless JAL
Procter & Gamble Australia Pty Ltd
PZ Cussons Pty Ltd
Reckitt Benckiser
Recochem Inc
Rohm and Haas Australia Pty Ltd
Scental Pacific Pty Ltd
Selkirk Laboratories Pty Ltd
Solvay Interox Pty Ltd
Sonitron Australasia Pty Ltd
Sopura Australia Pty Ltd
Steric Trading Ltd
Tasman Chemicals Pty Ltd
Thor Specialties Pty Limited
True Blue Chemicals Pty Ltd
Unilever Australasia
Whiteley Industries Pty Ltd

Associate Members:

AMS Laboratories Pty Ltd
Cintox Pty Ltd
Competitive Advantage
Dermatest Pty Ltd
DSL Packaging
Engel, Hellyer & Partners Pty. Ltd
E-Three & Associates Pty Ltd
Hydro Nova Controls
Middletons Lawyers
Robert Forbes & Associates
Silliker Microtech Laboratories Pty Ltd
Sue Akeroyd & Associates
Tonic Creative
Visy Industrial Packaging

Attachment 2

AREAS FOR IMPROVEMENT IN THE APPLICATION OF THE GOVERNMENT'S COST RECOVERY POLICY BY FEDERAL REGULATORY AGENCIES

1 Treatment of interest

ACCORD has noticed that interest accrued on industry cost recovered monies is shown as total revenue from Government appropriation. The Government response to the Productivity Commission's Recommendation 3.2 regarding identification of cost recovery arrangements, states that 'the Government agrees to the separate identification of cost recovery receipts in order to increase transparency of revenue obtained in cost recovery arrangements. Cost recovery revenue should be clearly identified in agency financial statements in both annual reporting and portfolio budget documentation'.

ACCORD does not believe that the aggregation of interest accrued on cost recovered monies with Government appropriation is transparent and we would ask that the Government reconsiders this approach. For example, in the Portfolio Budget Statement (PBS) for the Department of Health and Ageing (DoHA) the Budget Estimate for 2005-06 to the TGA Special Account is shown as zero. Receipts for 2005-06 are estimated to be approximately $69M which is significant and would be expected to accrue some interest over the year. ACCORD is under the impression that interest accrued from the TGA's cost recovered activities would be shown in this part of the PBS.

In the establishment of the Trans Tasman Joint Agency, the TGA was provided with Government appropriation of approximately $7M over two years to assist with the Agency's implementation. In the Regulation Impact Statement for the Agency, it was indicated that this money would be paid back from industry cost recovered monies, presumably commencing in 2005-06. If this is the case, the Budget figures do not make it readily identifiable as to how much money is being paid back in 2005-06. Also, if this is the case, then the PBS should be showing a negative amount for the Government appropriation, not a zero. Presumably the interest accrued on the cost recovered money is being used to pay back the Government loan to establish the Agency, however, this is not apparent from the PBS.

As you can see, since the PBS is industry's only source of public advice on the accountability of cost recovered monies, there is some confusion as to how these statements are to be read.

Recommendation 1

To improve transparency of industry cost recovered monies, ACCORD recommends that the Government agrees to disaggregate the amount of interest accrued from cost recovered money from the Government appropriation in the PBS.

2 Treatment of reserves

ACCORD has noticed an inconsistent treatment of reserves by the three regulatory agencies with which our members have dealings. The running down of reserves has resulted in significant increases in fees, charges and levies which ACCORD members have been subjected to in recent times. For example, the APVMA recently put out a Draft CRIS on its proposed revised cost recovery framework. The CRIS identified that the APVMA had used its reserves to compensate for the decline in revenue which resulted largely from the drought and the reduction in the levy rate in 2000. However,

the key impact of the drought on the APVMA's revenue was in 2003-04 and 2004-05, not in 2000. Further, the APVMA had accumulated reserves of approximately $9m in 2000-01. During 2000-01 the APVMA began an expanded program of activities, taking on more staff. Expenses for the period from 1989-99 to 2003-04 had risen by 48% with staff increases of 20% and large increases in non-discretionary expenditure items such as insurance and superannuation. The APVMA over this period was not matching its level of services with revenue, which is the basis of an effective cost recovery scheme using an activity based costing model.

While ACCORD supports the operation of a reserve as prudent financial management, it notes that the APVMA's reserve had been allowed to erode by more than $6M over a very short period. To compensate for the poor judgement in allowing the reserves to fall over a number of years, the APVMA proposed to increase fees by 33% in 2005-06 to balance its budget and re-establish the APVMA's financial reserves.

We believe that guidance to regulatory agencies on the management of reserves is required. This is a sensitive issue as it could be misinterpreted by industry as over-recovery. To overcome this problem, for example, NICNAS had agreed to a Budget strategy to establish an operational reserve capped at 10% of revenue, with revenue accrued over this amount to be placed in the reserves set aside for funding reform activities. This reserve is to be capped at $400,000. Any additional reserve would be set aside to reduce fees. This policy was developed in consultation with industry and it was done in the hope that it will avoid significant price increases in any one year. If managed appropriately, NICNAS's cost recovery arrangements should only lead to price increases which reflect the CPI.

A key principle that industry expects from regulatory agencies is to adhere to the 'no surprises' principle.

When it comes to regulatory fees and charges, for its business planning, industry expects predictability in assessing and determining its likely liability for the coming financial year. This means knowing the level of fees and charges at least 18 months out and not being hit with unexpected increases without sufficient warning and justification in terms of program activities.

All businesses and small businesses in particular, are adversely affected by unplanned costs. Some, like currency fluctuations and petrol price increases, are naturally volatile and part of the risks to which businesses are exposed. Others, like regulatory costs, are entirely within the control of agency management and should be predictable up to three years out. It is not unreasonable for business to have the same expectations that governments have of their departments when it comes to regulatory agency cost recovery demands.

Recommendation 2
ACCORD recommends that the Government provides guidance to regulatory agencies on the management of operational reserves. In addition, ACCORD recommends that as good practice, regulatory agencies should advise industry of proposed fee increases at least 18 months in advance of the proposed commencement date.

3 Funding of appeals

ACCORD has identified the need for a policy on the funding of appeals as there is a discrepancy by agencies as to whether they are funded from Departmental appropriation or by cost recovered monies. ACCORD does not accept that there should

be any industry funding for the cost of appeals against the decision of a Government regulator. We believe that this is a role for Government funding.

Recommendation 3
ACCORD recommends that the Government advises regulatory agencies that the funding of appeals must be met from Government appropriation.

4 Funding of services performed for Government

While it is ACCORD's view that the Guidelines and policy are quite clear about excluding activities undertaken on behalf of Government, from our experiences, we believe that this is the area which requires urgent clarification. The Guidelines provide examples of Government business activities such as:

- advising Parliament on issues where the agency has expertise;
- answering Parliamentary questions;
- briefing Ministers and responding to their correspondence;
- financial reporting; and
- complying with international treaties.

It is in this area that ACCORD has noticed regulatory agencies are seeking to extend the scope of cost recovered activities to include services to Government through a liberal interpretation of services which are 'integral' to the regulatory activity or the identification of an 'identifiable beneficiary' of the activity, no matter how tenuous that benefit is to industry. There appears to be no consideration of the public as an 'identifiable beneficiary' given that the objects of the respective Acts for the TGA, NICNAS and APVMA make it very clear that protection of public health and safety are one of the main purposes for the regulation.

The TGA recently engaged ACUMEN Alliance to undertake an independent review of the TGA's and NICNAS's cost recovery arrangements. ACUMEN Alliance's independent review noted that the Government's policy on what constituted government business was open to interpretation stating that '…the argument for cost recovery versus Government funding is subjective, given the lack of clarity in the Guidelines'. The ACUMEN Alliance report also stated that 'the Guidelines are not sufficiently prescriptive to provide definitive guidance on this matter, (i.e. what activities constitute government business). Further, DoFA were not willing to provide advice on specific examples cited. Rather, they advised that it was the responsibility of agencies and the responsible Minister to interpret the Guidelines as they see fit.'

Given this lack of clarity, ACCORD is of the view that there needs to be consistency from the Department of Finance and Administration with regard to advice on the funding of services to Government to minimise the impact of bureaucratic discretion. ACCORD has experienced that activities which were seen as government business for a number of years by one portfolio, are now regarded differently in another department. The recent decision in May 2005 by the Parliamentary Secretary to the Minister for Health and Ageing to extend the scope of NICNAS's cost recovery activities to include those previously considered as Government Business could mean that industry is required to pay for all policy related matters dealing with industrial chemicals as there is no policy unit with DoHA dealing with industrial chemicals policy matters more generally. While industry deeply regrets this decision and will request the Parliamentary Secretary to reconsider the matter, we expect that the current

Government appropriation for 2005-06 of $494K will be returned to consolidated revenue minus the interest accrued from NICNAS's cost recovered funds.

Recommendation 4
ACCORD recommends that the Government provides greater clarity to departments and regulatory agencies on services to Government to remove the subjective nature of the bureaucratic decision-making. As a standard practice, an annual service level agreement between the Department and regulatory agencies regarding the level of services to be provided should be published as part of the PBS.

5 Activity based costing

While the Government's policy is quite clear that the cost of regulatory charges should be as closely linked to the cost of products or services, ACCORD notes that not all agencies have developed robust activity based costing models. Transparent activity-based costing and budget details are still not available from all regulatory agencies which is inconsistent with the Government's policy.

This lack of transparency is impeding effective scrutiny of regulatory agencies with regard to fees and charges and inhibits the identification of possible productivity improvements and cost savings.

Recommendation 5
ACCORD recommends that the Government together with industry, provides guidance on best practice activity based costing and that all regulatory agencies have robust activity based costing models in place by 30 June 2006.

6 Using levies as a sales tax on goods for cost recovery purposes

ACCORD is concerned that the recent example by the APVMA in using sales tax on goods sold as a general levy is not consistent with the principles of the Government's cost recovery arrangements, particularly in aligning costs as closely as possible to the services provided. In ACCORD's view, the APVMA example demonstrates that there had not been sufficient rigor in applying the principles of levy design.

An example is the support given for hormone growth promotants (HGPs) through the levy. This is a tightly defined group of specific products, with specific uses, and with known registrants. The audit function for HGPs has a nominated and directly defined cost of $464,140. The use of HGPs are not a health, occupational health, environment or food residue concern for produce for local consumption nor to many major export markets. The HGP program is a specific market-access scheme and it is inappropriate for the general levy to subsidise this market-access activity. Indeed, there seems to be significant reasons to question whether these activities should be funded by APVMA at all. The same concerns arise with the allocation of costs the AERP (separation for agricultural and veterinary), Manufacturer Licensing Scheme (veterinary), Ag actives and quality assurance schemes. There is opportunity for these costs to be directly attributed to the parties who use these activities, rather than a general levy on the sales of goods which amounts to a sales tax for agricultural and veterinary products.

ACCORD supports a levy design that:

- is consistent with policy objectives;
- is efficient and cost-effective; and
- avoids unnecessary cross-subsidisation.

It is inherent in a best-practice approach that all directly attributable efficient costs are assigned to parties accessing and using the regulatory functions. The levy design utilised by the APVMA does not achieve this. ACCORD believes that this is an area where greater advice and consistency in Government policy could apply.

Recommendation 6

ACCORD notes that the Australian National Audit Office (ANAO) has on its provisional work plan for 2005-06 an audit of the APVMA which will asses the effectiveness of the APVMA's regulatory role. In particular, the audit is proposed to look at systems and management processes used to:

- recover regulatory costs,
- ensure industry compliance and product integrity; and
- manage stakeholder relationships.

ACCORD recommends that the proposed ANAO audit of the APVMA be given high priority.

7 Performance measures to demonstrate efficiency and effectiveness

ACCORD notes that a number of the Draft CRISs for the specified regulatory agencies claim that the cost recovery arrangements are efficient and consistent with the Government's cost recovery guidelines. The Draft CRISs do not provide any performance data to indicate that the regulatory agencies are delivering their services in a timely manner without any undue impact on the competitiveness of the particular industry sector. ACCORD understands that this information is readily available as regulatory agencies are required to meet statutory time frames in the delivery of their services as well as undertake annual customer satisfaction surveys. Performance data of this kind can be a valuable indictor to demonstrate that regulatory agencies are efficient and effective and that industry's money is being put to good use.

ACCORD supports the inclusion of performance data in CRISs as a way of demonstrating in a transparent manner, that the cost recovery arrangements are not only compliant with Government policy but are efficient. We believe that performance measures would greatly improve the value of CRISs. As a general observation, ACCORD would support more use of quantitative data to support the effectiveness of Government policies. While qualitative data has its place, efforts should be made to improve the collection of data to demonstrate in measurable ways that real achievements have been delivered.

Recommendation 7

ACCORD recommends that all regulatory agencies include performance data in their CRISs to demonstrate efficiency and effectiveness of their cost recovery arrangements. We note that this proposal was put to the TGA in our comments on the draft CRIS and has been accepted as good practice. Wider application of this across all Federal regulatory agencies would be a positive step forward.

Attachment 4

ACCORD Submission to the PC study on chemicals and plastics regulation

October 2007

ACCORD

Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry

Mr. Mike Woods
Commissioner
Chemicals and Plastics Regulation Study
Productivity Commission
Locked Bag 2
Collins St
EAST MELBOURNE VIC 8003

Dear Mr Woods

Productivity Commission Study into Chemicals and Plastics Regulation

ACCORD Australasia is the peak national industry association that represents the manufacturers and marketers of formulated consumer, cosmetic, hygiene and specialty products, their raw material suppliers, and service providers.

With an estimated $10 billion plus in annual product sales, the formulated consumer, cosmetic, hygiene and specialty products industry is a significant part of a prosperous Australian economy. We are a dynamic and growing industry, employing Australians and - through our industrial and institutional sector - supplying products essential for Australian businesses, manufacturing firms, government enterprises, public institutions, farmers and consumers. Our industry has more than 50 manufacturing operations throughout Australia and Member companies include large global consumer product manufacturers to small dynamic Australian-owned businesses.

The chemical industry is a diverse grouping. Its products and services are fundamental to the economic and social well being of all Australians. The global chemicals industry is intensely competitive. The chemical industry is seeking a level playing field to enable it to compete effectively in the global economy. A more efficient and effective regulatory system will deliver benefits to the entire community through lower costs creating a business operating environment which will stimulate growth, create better employment opportunities and foster enhanced competitiveness and innovation.

ACCORD, on behalf of our Member companies, has a specific and direct interest in the Productivity Commission's (PC) study. In particular we look forward to the recommendations for reform for the establishment of a best practice governance framework for the chemicals sector. ACCORD has been promoting the need for a fully integrated national framework for chemical policy and management for a considerable period and regards this as a high priority.

ACCORD will continue to work collaboratively with the PC, the Council of Australian Governments (COAG) and its Ministerial Taskforce on chemicals and plastics to improve the regulatory environment for our Members.

Yours sincerely

Authorised for electronic signature

Bronwyn Capanna
Executive Director

24 October 2007

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ACCORD

Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry

Productivity Commission Study into Chemicals and Plastics Regulation

24 October 2007

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Foreword

ACCORD Australasia (formerly the Australian Consumer & Specialty Products Association) is the peak national industry association that represents the manufacturers and marketers of formulated consumer, cosmetic, hygiene and specialty products, their raw material suppliers, and service providers.

Our industry's products play a vital role in:

- keeping our households, workplaces, schools and institutions clean, hygienic and comfortable
- personal hygiene, grooming and beauty treatments to help us look and feel our best
- specialised uses that assist production and manufacturing to keep the wheels of commerce and industry turning; and
- maintaining the hygienic and sanitary conditions essential for our food and hospitality industries and our hospitals, medical institutions and public places.

These benefits are essential to safe, healthy living and maintaining the quality lifestyle we all too often take for granted.

With an estimated $10 billion plus in annual product sales, the formulated consumer, cosmetic, hygiene and specialty products industry is a significant part of a prosperous Australian economy. We are a dynamic and growing industry, employing Australians and - through our industrial and institutional sector - supplying products essential for Australian businesses, manufacturing firms, government enterprises, public institutions, farmers and consumers.

Our industry has more than 50 manufacturing operations throughout Australia and Member companies include large global consumer product manufacturers to small dynamic Australian-owned businesses. A list of ACCORD's membership is at Attachment 1.

ACCORD, on behalf of its Member companies, has a specific and direct interest in reform processes which improve the business operating environment for our Members. Industry's competitiveness and capacity to maintain local production now and into the future is heavily dependent on reducing the regulatory burden faced by the chemicals sector on a daily basis. ACCORD welcomes the opportunity to provide this submission in response to the PC Issues Paper for consideration as a basis for further consultation and dialogue.

Bronwyn Capanna
Executive Director

24 October 2007

1. Introduction

ACCORD, on behalf of its Member companies, has a specific and direct interest in the Productivity Commission (PC) Study into chemicals and plastics regulation (the PC Study). The PC Study provides an opportunity to rethink Australia's chemical management infrastructure with a view to providing an innovative framework to enable Australian industry to compete on an equal footing with our most important trading partners in the Asia Pacific region.

The Asia Pacific region can now be regarded as the engine room of the global economy due to its dynamic and sustained growth. To capitalize on this unprecedented growth in our region, Australia must rethink its control and management strategies for chemicals to ensure that Australian companies, and in particular Australian small and medium enterprises, are able to take advantage of the opportunities for growth and trade which now present themselves in the Asia Pacific region.

A more efficient regulatory system will deliver benefits to the entire community through lower costs creating a business operating environment which will stimulate growth, create better employment opportunities and foster enhanced competitiveness and innovation.

Industry's competitiveness and capacity to maintain local production now and into the future is heavily dependent on reducing the regulatory burden on Australian businesses. Of particular importance is the need to significantly reduce *Australian -specific* regulatory requirements imposed by regulatory agencies on those seeking to do business in Australia and to harmonise and/or mutually recognise regulatory controls with those of our major trading partners to minimise barriers to trade and enable the free flow of goods.

In its report to the Government in 2001, the chemicals and plastics industry found that a number of companies dedicated the equivalent of at least four full time staff to meeting the various regulatory requirements of all the jurisdictions. In addition, many companies also used the services of intermediaries to assist with compliance. It is estimated that the use of these intermediaries ranged from the equivalent of 20 days per year to the equivalent of 2-3 full time staff (*Underpinning Australia's Industrial Growth* March 2001, p29).

Anecdotal evidence suggests that the cost of notifying a new chemical in Australia appears to be higher than anywhere else in the world – yet Australia is estimated to be only 1% of the global trade. Table 2 at Attachment 2 provides some cost data for the assessment of non polymer new chemicals which indicates that in comparison to other jurisdictions, Australia is the most expensive jurisdiction in which to notify these new chemicals.

The PC Study into the regulatory burden of the chemicals and plastics industry is an extremely important initiative which recognises the value of the Australian chemical industry to the economy. The terms of reference provide hope to our sector in that it will make long awaited recommendations for reform on a whole-of-government basis rather than the piece meal ad hoc approach which has been government practice to date.

ACCORD's submission to the PC Study provides additional examples of the problems faced by our sector in addition to the work we have already provided to the PC Study for its consideration resulting from our earlier consultation. ACCORD has responded to a significant number of government enquiries regarding reform proposals over the last few years ranging from the Banks Review to trade measurement, the operation of Standards Australia, consumer

policy and product safety matters, poisons' scheduling, the joint agency for therapeutic products and environmental issues.

ACCORD notes that there have been a significant number of industry reports going back as far as the 1980s when the Australian Government put forward its proposal for the social regulation of the chemical industry. The issues identified by the Business Regulation Review Unit (BRRU) in 1986 are still relevant today in terms of the excessive costs of over-regulation and the need to undertake cost benefit analysis to determine the most effective form of regulation required to meet the industry's needs, while maintaining public health and safety interests. The BRRU found that:

> *There is no Australia-wide quantitative or factual evidence about problems involving chemicals which may have been prevented or are likely to be prevented by a chemicals notification and assessment scheme. Unless the benefits can be quantified and determined it is not possible to judge whether the envisaged program is the best use of our national resources (page 1).*

The current levels of regulatory intervention need to be justified through proper cost benefit analysis. This quantitative data should be available to justify the existing levels of control and should be shared with industry.

1.1 Adoption of COAG regulatory principles

As identified above, ACCORD believes that Australia's control framework for the management of chemicals has exceeded its use-by date and that Australia is in danger of regulating the chemical industry out of existence if it continues to follow the current trajectory of over-regulation.

ACCORD supports the federal government's approach to regulatory best practice and has always recommended that the COAG Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard Setting Bodies (COAG Principles) be applied in the consideration of regulatory decision making for cross jurisdictional matters. These COAG Principles should be rigorously applied to any regulatory decisions proposed by government agencies with responsibility for regulating chemicals as chemicals management is not restricted to the federal sphere but is intersected by a number of jurisdictions. Chemicals management in Australia requires a whole-of-government approach by all tiers of government.

ACCORD has promoted the COAG principles as the basis for the Principles for Best Practice Chemical Regulation for the APEC Chemical Dialogue. These Principles are currently being finalised by the Chemical Dialogue Working Group under Australia's leadership through ACCORD and the Office of Chemical Safety (OCS).

ACCORD has always argued that if proper processes were maintained with a commitment from the top to regulatory efficiency and effectiveness then the chemical industry would not be overwhelmed by the plethora or regulatory requirements it faces today.

ACCORD supports the following as good regulatory practice principles and believes that regulatory solutions should:

- be the minimum required to achieve the stated objectives
- adopt a risk management approach to forming and administering regulation
- minimise the impact on competition
- be compatible with international standards and practices

- cause no restriction to international trade
- be developed in consultation with the groups most affected and be subject to regular review
- be flexible, not prescriptive and be compatible with the business operating environment
- standardise the exercise of bureaucratic discretion; and
- have a clear delineation of regulatory responsibilities and effective and transparent accountability mechanisms.

2. The case for change

Despite the many reviews and good intentions for reform over the past decade, industry criticism has been that the reforms achieved have been ad hoc and piece meal. It is much easier to achieve a few modest reforms within a particular regulatory regime rather than address the underlying structural problems. This is evident from the success of the Low Regulatory Concern Chemicals (LRCC) reform program which produced some identifiable and significant short term gains for industry without changing the fundamental structure of the regulatory regime.

Contrast this to the lack of success of the Bell Task Force Report's (1996) recommendation which was largely ignored by governments and was managed through internal departmental review, and a review of the Agricultural and Veterinary Chemicals Act 199 under the Competition Principles Agreement. The Bell Report in 1996 made the following recommendation:

> *Recommendation 34*
>
> *That the Commonwealth Government send a reference to the Productivity Commission to inquire into and report by 31 December 1997 on the most efficient and effective institutional and regulatory arrangements for industrial, agricultural and veterinary chemicals (page 84).*

Unfortunately, this recommendation was never implemented. Had it been undertaken, we would now be at the end of implementation of the PC recommendations rather than at the beginning of the process some 11 years later. This is indeed a lost opportunity arising from the lack of will by key Australian Government regulatory agencies to be subjected to independent scrutiny.

At that time in 1996, the industrial chemicals regulator, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) claimed to be focusing on reducing assessment times and overcoming unnecessary assessment requirements for low risk chemicals. In addition, it claimed that it was pursuing electronic lodgement of notifications. Even in the post LRCC phase and some 11 years later, NICNAS is still grappling with concepts of low hazard and/or low risk. NICNAS is not alone, as the majority of their Australian counterparts are also struggling with these principles

Recent Australian Government reviews into trade measurement and consumer product safety have recommended national control through a Commonwealth agency rather than the current fragmented approach through state and territory enforcement and administration. The move back to central agency control for not only policy but implementation and administration appears to be the most effective form of reform measure and one which the PC Study should consider as a possible model for the control of chemicals.

It is obvious that to achieve sustained and measurable reform the chemical industry requires not only the political will for change but also a champion for reform. We hope that the COAG ministerial task force for chemicals and plastics will fulfil these roles.

3. The need for effectiveness

3.1 Utilisation of effective risk management in regulatory decision making

ACCORD believes that all regulatory agencies whether they be state or federal can improve their effectiveness through the appropriate application of risk management. ACCORD's Members are primarily regulated at the federal level by the Therapeutic Goods Administration (TGA), NICNAS and the Australian Pesticides and Veterinary Medicines Agency (APVMA). In addition, the Australian Safety and Compensation Commission (ASCC) the Food Standards Australia and New Zealand (FSANZ) and the National Transport Commission (NTC) also set standards for Member products. All these regulators have formal relationships with respective state health, environmental, occupational health and safety and as necessary agricultural agencies.

This intersection of jurisdictional responsibility for chemicals management in Australia means that ACCORD's Members must also comply with more than 144 pieces of legislation which control chemicals throughout Australia. These include state and federal environmental regulations, international treaties controlling the movement of chemicals, occupational health and safety, transport, storage and labelling requirements at the federal and state level, management of waste chemicals, food handling, dairy sanitation and water usage requirements as well as a range of self-regulatory stewardship activities. This does not cover the general business regulation requirements such as taxation, workers' compensation, industrial relations, financial services, trade practices and corporations' requirements.

While the three regulatory agencies with which ACCORD's Members have their major dealings at the federal level would argue that they apply effective risk management strategies, ACCORD would suggest that none of these agencies currently understand or apply an effective risk management strategy.

Anecdotal evidence from Member companies indicates excessive time is now spent by NICNAS staff on low risk chemicals through assessment processes to the point that it is no longer feasible in terms of time and money to utilise the benefits of the self assessment processes established as part of the LRCC reform process. One could argue that if proper risk management was in place, would Australia not need a unique assessment processes for all new chemicals? For example, Australia is one of the few jurisdictions in the world which has pre-market approval requirements for all new cosmetic ingredients.

ACCORD has argued that for fast moving low risk consumer goods such as cosmetic products – Australia should not impose any additional market entry barriers such as unique notification and assessment requirements, trade measurement or ingredient labelling if these products already comply with the regulatory requirements of our comparable trading partners such as the European Union (EU), the United States of America (USA), Japan, Canada or New Zealand.

Effective risk resource management ensures that resources are directed to the areas of greatest need. It also ensures that regulatory agencies fully understand their business priorities through a thorough analysis of the internal and external environment. Risk management is regarded as the systematic application of management policies, procedures

and practices to the tasks of identifying, analysing, assessing, treating and monitoring risk.

Risk management is a logical and systematic process that can be used when making decisions to improve the efficiency and effectiveness of performance. It is a management tool to identify and prepare for contingencies. Managing risk involves taking action to avoid or reduce unwanted exposure to the costs or other effects of these events, or to maximise the potential of any opportunities identified.

The benefits of prudent risk management are:

- a more rigorous basis for strategic planning as a result of a structured consideration of the key elements of risk;
- no costly surprises - because undesirable risks are identified and managed
- better outcomes in terms of program effectiveness and efficiency, e.g. improved client service and/or better use of resources
- greater openness and transparency in decision-making and ongoing management processes; and
- a better preparedness for, and facilitation of, positive outcomes from subsequent internal/external review and audit processes.

3.2 Urgent need for cultural change by regulatory agencies

ACCORD believes that significant government effort must go into improving the culture of regulatory agencies. Without this focus on improved regulatory culture, any other reform processes will fail to deliver objectives for an improved business operating environment through measurable red tape and compliance cost reduction.

Along with stemming the flow of regulation, the culture of regulatory agencies needs to be an integral part of the reform process. As mentioned previously, there is little understanding of the proper use of risk resource allocation to achieve minimum effective regulation. ACCORD's experience is that Australian regulatory agencies tend to over-regulate for zero risk. This is an urgent area for action by all governments and we urge the application of the COAG Principles, in particular that legislation should be the minimum necessary to achieve the objectives and should standardise the exercise of bureaucratic discretion to reduce discrepancies across regulatory agencies.

The establishment of Small Business Commissioners by a number of Australian jurisdictions recognises the need for specialist oversight and advocacy in the area of small business concern. ACCORD supports similar independent oversight of the activities of regulatory agencies.

ACCORD notes that the Government did not agree with the PC's Report No 15, *Cost Recovery by Government Agencies,* Recommendation 8.6 that an independent review body should be appointed to assess whether cost recovery impact statements (CRISs) adequately address the cost recovery guidelines. The *Review of the Corporate Governance of Statutory Authorities and Office Holders* (the Uhrig Review) also recommended to the Government the establishment of independent oversight of regulatory agencies. In light of our experiences, ACCORD considers that these two recommendations are worth revisiting and recommends that the Australian Government provides independent oversight of its regulatory agencies as part of its wider regulatory reform agenda.

A good example for consideration is the system established by the Federal Government of the

United States with the National Ombudsman for Fair Enforcement of Federal Regulation. The US National Ombudsman's primary mission is to assist small businesses when they experience excessive federal regulatory enforcement actions, such as repetitive audits or investigations, excessive fines, penalties, threats, retaliation or other unfair enforcement action by a federal agency.

This model could be adapted to also apply to all the activities of the regulatory agencies, including:

- governance arrangements
- cost recovery
- stakeholder engagement
- accountability
- transparency

as well as monitoring regulatory performance including compliance with:

- gatekeeper requirements
- regulation impact assessment and cost benefit analysis requirements
- benchmarking and regulatory performance indicators
- annual regulatory plans; and
- annual reviews.

3.3 Governance arrangements

ACCORD supports transparent and accountable governance arrangements for regulatory agencies and statutory authorities. The issue was of significant concern to the federal government which commissioned an independent review by John Uhrig. The federal government accepted the majority of the recommendations contained in the Uhrig Review and more than 160 federal government bodies are being assessed against the governance principles and templates developed by John Uhrig. This has resulted in changes to the accountability and management arrangements for some statutory authorities, such as the changed arrangements to the Australian Pesticides and Veterinary Medicines Authority (APVMA).

ACCORD supports the Uhrig governance arrangements for statutory authorities as it improves clarity in roles and responsibilities and believes that these findings are directly applicable to the governance arrangements of all regulatory agencies. The publication of a Statement of Expectations and Intent will provide industry with increased transparency into the operations of the respective regulatory agencies.

ACCORD has noticed a disturbing tendency by the regulators to undertake activities outside the scope of their legislation, for example in the provision of policy advice or increasing compliance requirements beyond legislative requirements. These issues will addressed further in this submission. This is usually in the areas of policy, the provision of public information services (both of which are generally funded from industry cost recovered monies) and regulators' requirements for industry quality improvement programs which seek higher standards than those required in the legislation. Regulatory agencies should focus on core activities using a risk management approach to deliver a regulatory system which is efficient and effective.

ACCORD believes that the development of the Statement of Expectations and Intent with the involvement and oversight of the relevant Ministers could assist regulatory agencies to refocus their activities on their core functions.

The Uhrig Review identifies the potential benefits of the Statement of Expectations and Intent for all regulatory agencies as follows:

- Improving the transparency and accountability of statutory authorities through:
    - clear and transparent lines of accountability
    - clear understanding of roles
    - clearly articulated and publicly available objectives and strategies
- Improving efficiency of statutory authorities by ensuring:
    - there is effective supervision of management
    - management is accountable for its performance
    - the effort of authorities is directed towards the achievement of well-understood objectives.
- Improving the effectiveness of statutory authorities through developing a sound understanding of what they are required to achieve resulting in:
    - higher quality services
    - better regulation.

These goals and outcomes of the proposed Statement are supported by industry.

Following the recent announcement by the Secretary of the Department of Health and Ageing about the restructuring of the Department, specifically the movement of the Office of Chemical Safety (OCS) into the Office of Health Protection (OHP), ACCORD sought clarification as to which group within the OHP will have responsibility for chemical policy.

ACCORD shares the view of the Government that the roles and responsibilities for policy development and the implementation thereof, should be clearly separated and defined i.e. policy development should not be the responsibility of the implementing regulatory agency. Further, the reform priority for efficient and effective chemicals management should be the establishment of a nationally integrated chemical policy and control framework.

It is three years since the Government response to Uhrig and yet industry is still waiting to see statements of intent and expectations between the Minster and NICNAS. We believe that such a statement is critical to providing transparency to industry on the respective roles of NICNAS, OCS and OPH within the Health portfolio.

ACCORD understood that since the Department of Health had responsibility for OCS and NICNAS it would play a strong leadership role in the development of a framework for an integrated control framework for chemicals. To date however, ACCORD is concerned with what appears to be the fragmentation of chemical policy oversight, and the possible duplication of chemical policy development between the various offices and agencies within the Department of Health. We have not as yet received a response or clarification to our request.

3.4 Regulatory overlap – a case study

Recently, the Australian Competition and Consumer Commission (ACCC) invited ACCORD to submit proposals for reform to the Trade Practices (Consumer Products Information Standards) (Cosmetics) Regulations 1991 (Cosmetic Regulations). This followed earlier

discussions with industry where it was agreed that a number of issues with the existing Cosmetic Regulations required change as a result of national or international developments.

There are two issues for ACCORD Members regarding the labelling of low risk, fast moving consumer goods such as cosmetic products.

ACCORD has continually argued that the Australian and New Zealand markets are too small to create and sustain a unique regulatory regime which is out of step with our major trading partners. Australia should accept pre-packed consumer goods which comply with the relevant labelling requirements of Australia's comparable trading partners without any additional labelling requirements and should accept these either through deemed to comply provisions or alternate compliance measures. While these regulatory tools are not readily used in Australia, they are not without precedent and we believe that the New Zealand Cosmetic Products Group Standard provides a good model for adoption in Australia regarding labelling of certain imported cosmetic products.

3.4.1 No unique Australian trade measurement requirements

ACCORD has promoted this idea to the Ministerial Council on Consumer Affairs (MCCA) review on trade measurement as well as the ACCC since both bodies have responsibility for consumer product labelling either through trade measurement or ingredient labelling. We have argued that the insistence of the Australia unique trade measurement requirement on the front of the pack for cosmetic products is outdated and should be changed so as not to specify where the unit measure must appear but simply to require it as is the practice in other jurisdictions.

We welcome the COAG decision to implement a national trade measurement framework and hope that as part of the reform process that trade measurement practices will be harmonized and/or mutually recognise those of our major trading partners.

Example 1 - 'burdensome' unique Australian regulatory requirements

'The Australian industry is required to incorporate these requirements specifically into dedicated packaging for the Australian market for products which are of low risk.

Weights & Measures Regulations:

- *the need to have the measurement marking on the front panel of the article where the back or side alone is not sufficient.-. this requires overlabelling for products from the EU;*
- *the need to have the measurement marking of aerosol products in grams where mL alone is not sufficient - this requires overlabelling for products from the EU and the USA;*

All the issues listed above require 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 results 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.'

One ACCORD member estimates the cost to over label a product because of a unique Australian requirement costs approximately 50cents/unit. Based on the number of units sold in Australia in 2006, i.e. 130M the additional costs to industry in any one year, could be as high as $65M.

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, 7,300 units ordered requiring local over labelling where the cost of compliance affected the profit margin by a 9% loss on the net profit for this product.

Labelling changes can be costed - it ranges from $25k to $75k depending on the type/quality/extend of packaging.

We are hopeful that the move towards a national control framework for trade measurement will bring an opportunity for reform to unit measurement requirements along the lines proposed by industry. The main aim is to be fully harmonised and/or mutually recognise those products which present low risk to the Australian consumer and are fully compliant with equivalent regulatory regimes of Australia's comparable trading partners.

3.4.2 Cosmetic ingredient labelling

ACCORD supports the principle of cosmetic ingredient labelling. This is now a recognised international practice to provide consumers with information regarding the products' ingredients and allows consumers to make informed choice about a products' safety for use on skin, particularly with regard to possible allergens.

3.4.2a Acceptance of deemed to comply provisions

Given Australia's new trade agreements such as the American Free Trade Agreement, unique Australian labelling requirements for imported products may not be consistent with the aims of such trade agreements. This is particularly the case since there would be no threat to consumer product safety and/or information.

The New Zealand Government recently introduced a range of reforms for the classification and approval of hazardous chemicals under Part 6A of the Hazardous Substances and New Organisms Act 1996 (HSNO). A group standard is an approval under HSNO for a group of hazardous substances of a similar nature, or type or having similar circumstances of use and is risk based rather than solely hazard based. The risk of substances in the group standard will be managed by a single set of conditions rather than by the controls set out in the HSNO regulations. Within the Group Standard acceptance of other regulatory decisions has been made possible through the use of alternate compliance measures for labelling which accepts products that meet the labelling requirements of Australia, the USA, Canada, the EU or any other country approved by the Authority. The following provision is as it appears in the Cosmetic Products Group Standard:

General requirements for labelling

(2) The labelling on a substance must comply with one of the following:

(a) the labelling provisions in the Hazardous Substances (Identification) Regulations 2001, the Hazardous Substances (Emergency Management) Regulations 2001 and the Hazardous Substances (Disposal) Regulations 2001; or

(b) the current labelling requirements for cosmetic products of Australia, USA or the European Union, as if the substance were for sale or supply in those countries.

3.4.2b Amendment to exempt cosmetic products provisions

ACCORD proposed an amendment to the ACCC to accept products intended for use as cosmetic products in Australia but which meet the labelling requirements of the EU, USA,

Canada or New Zealand as not requiring additional unique Australian requirements and that the ACCC would deem these labels as complying with the requirements of the Cosmetic Regulations. The suggested amendment could be as simple as follows:

Under Part 4 Exempt cosmetic products,

These regulations do not apply to:

(a) therapeutic goods within the meaning of the Therapeutic Goods Act 1989; or

(b) free samples of a cosmetic product; or

(c) testers of a cosmetic product; or

(d) fully imported products intended for use as cosmetics which meet the labelling requirements of the European Union, the United States of America, Canada and/or New Zealand.

This would be quite a significant improvement because 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. This comes at a cost which ultimately the consumer must bear.

3.4.3 Overlap between OHS and ingredient labelling requirements

As part of the review process, ACCORD Members identified a regulatory overlap of the Cosmetic Regulations with current requirements for the management of industrial products under occupational health and safety legislation.

Industrial hand cleaners for specific use in workplaces are not consumer products and need to meet the labelling requirements under the Australian governments' hazardous chemicals framework. Within the workplace, safety information regarding chemical use is disseminated through Safety Data Sheets (SDS). The SDS is a document that describes the chemical and physical properties of a material and provides advice on safe handling and use of the material.

The SDS is a recognised information source which underpins the overall risk management program to control exposure to hazardous and dangerous materials. The advice contained on the SDS includes information on health effects, exposure control, safe handling and storage, emergency procedures, and disposal. For most workplace risk assessments required by Commonwealth, State and Territory legislation, the SDS and the label are the main information sources and may also be used as an integral component for workplace training. SDSs are required by law to provide sufficient information on the product to enable employers and employees to make risk assessments about these products in the workplace to ensure the safe use and limit the risk to health and safety.

We are unsure as to why the ACCC requires cosmetic ingredient labelling information when industrial hand cleaners are covered under well established occupation 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.

We cannot accept the ACCC argument that there would be increased complexity of the Cosmetic Regulations by removing industrial hand cleaners from its scope. We believe that it would be the reverse. To ensure compliance with the Cosmetic Regulations would require ACCC compliance officers to inspect workplaces. There is no ambiguity – industrial hand

cleaners used in the workplace are covered by occupational health and safety legislation. Industrial hand cleaners are not purchased for personal, domestic or household consumption, they are for use in the workplace. Hand cleansers used as cosmetic products are covered by the Cosmetic Regulations and have ingredient labelling. Where products are intended for use as cosmetic products then they should be labelled appropriately.

We consider that the imposition of additional labelling requirements is an unnecessary burden and a unique Australian requirement. This imposition of a unique Australian requirement is perpetuating a technical barrier to trade without any justification regarding identification of the market failure which requires this additional level of intervention, the cost and/or impact assessment. We fail to see the enhanced consumer benefit as argued by the ACCC since these products are encased in dispensers where the ingredient label is not visible. There is no enhanced transparency through ingredient disclosure. This could only happen if the user removes the pack from the dispenser prior to use.

These three examples are provided to the PC Study to highlight inappropriate regulatory burdens which industry face but could be easily rectified. These are requirements which are extraneous to the real costs of doing business and are borne by business because it is often easier to comply than to try and change the regulators' attitude. As can be seen, minor progressive changes to existing legislation can have a significant impact without undermining current levels of public health and safety. Despite this, we do not see regulators responding with these kinds of simple innovative suggestions.

3.5 Responses to consumer enquiries and 'scares'

The recent incident with the importation of toothpaste from China which contained levels of Diethylene Glycol (DEG) demonstrated again the clear need for better integration in the chemical control system.

While it is acknowledged the system is in need of considerable overhaul and streamlining, there is neither public health and safety deficiency nor 'gap' in the system. Notwithstanding, industry is extremely concerned that the respective 'players' i.e. respective regulators, particularly within the jurisdictions, have little knowledge of their specific role or indeed the role and responsibilities other regulatory control mechanisms play, and how the whole system fits together.

Australia has in place more than adequate consumer product safety regulation. Indeed, a recent PC Study into consumer product safety found that there were no significant deficiencies in the current system but it did recommend that to overcome the current system of duplication that one national law and one national regulator be established.

When faced with the DEG issue, the mix of regulatory agencies appeared not to know what to do. ACCORD and its Members were inundated with requests for information from a number of agencies regarding levels of DEG in products. State departments of health appeared to be acting on their own with no regard to national processes for consumer product safety and product recalls. But while there was a flurry of activity, the public were not provided with the necessary and timely information.

The ACCC issued a product recall notice, and in our view, the ACCC was the correct agency to deal with this issue, coordinating relevant input from NICNAS and the state health and consumer affairs departments, since it was a consumer product safety matter.

However there needs to be a greater level of effective communication and co-ordination. This example highlights that even though we may have a more than adequate level of

control for chemical and consumer safety protection – if key stakeholders including government agencies are not familiar with these processes, then the controls are of little use. It is usually at this point in time that there is a call for more legislation as a reaction to the perceived failure of authorities to respond properly rather than utilise the more than adequate systems already in place. This was not a failure of the system – but a failure of the respective agencies and departments to understand their place within the current regulatory control framework.

"Crisis management" in the face of consumer scares or emergencies is the is about communication co-ordination – this needs leadership and co-ordination from within one agency that understands the roles and respective legislative controls of the other agencies both across the federal and the state systems but also across portfolios, and a communication strategy that keeps all the relevant stakeholders informed in a timely manner.

Other such examples where a lack of understanding and/or trust in the role of the various regulatory components has resulted in duplication and/or referral to an inappropriate part of the system include:

- The continued referral of cosmetic regulatory inquires from junior staff within the TGA to ACCORD, rather than NICNAS as the cosmetic regulator. (At one time, there was a perception that ACCORD was a regulatory body.)
- The increasing propensity for NICNAS to recommend annotation of the AICS in lieu of scheduling controls imposed on domestic chemicals by the National Drugs and Poisons Schedule Committee.

3.6 Industry concerns with (NChEM)

ACCORD strongly supports the best practice principle, that any proposals for new or increased regulatory intervention must have a firm evidence-based justification.

It is agreed that there is room for significant improvement for the better administration of existing processes for the environmental regulation of chemicals. For example, 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.

However, 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.

ACCORD's submission to the NEPC on NChEM of 6 October 2006, addressed this issue in detail.

We highlighted that much of the background evidence and specific examples put forward in support of NChEM interventions were:

1. irrelevant to the present environmental safety practices that characterise the operations of the Australian chemicals industry,
2. generally irrelevant to the nature of the vast majority of chemicals now in trade especially

since highly persistent and toxic chemicals – such as DDT and other persistent organic pollutants – have been removed from the market,

3. more than readily capable of being addressed through more rigorous use of existing powers and punitive penalties by the states and territories.

Our submission to the NEPC presented the facts on this as follows:

> "ACCORD recognises there is significant room for improvement within the current system of chemicals regulation, including a better linking of environmental considerations into national agency processes as well as the establishment of a simpler, more uniform system for control of the limited number of chemicals shown to result in significant environmental problems.
>
> However, before presenting our views on how this can be best progressed, a number of the examples presented in the discussion paper must be put into proper perspective in terms of the 'evidence' they provide as "Examples of Chemicals Impacts" that would warrant creation of a new NChEM system. It needs to be recognised that many of these examples have been (or can be) effectively addressed through existing regulatory measures.
>
> • Pesticides and 'fish kills'/'bird kills' (pg 9) – to support the general comment that "Queensland and New South Wales have both experienced significant fish kills caused by pesticides" the discussion paper recounts a serious incident at a golf course resulting in "4 tonnes of dead fish, ducks and geese". Such an incident would clearly indicate misuse and would certainly warrant investigation by the responsible state environment agency with a view to initiating a prosecution.
>
> Industry fully supports – and the Australian public rightly expects – state environment agencies taking strong and decisive action under their existing pesticides, pollution control or environmental offences and penalties legislation to stamp out cases of product misuse and to send a message that environmentally negligent product use and behaviour is unacceptable.
>
> Hopefully this is exactly what occurred in terms of responding to this incident. ACCORD notes that the NSW Department of Environment & Conservation (DEC), for example, publishes details about how to report pesticide misuse on its website. However, the fact that the discussion paper raises this incident in the context of the need for a new policy framework leaves ACCORD concerned that more may need to be done to ensure that best use is being presently made of the existing state and federal regulatory controls to address environmental problems that arise before policymakers jump to the conclusion that a new regulatory model like NChEM is a panacea.
>
> In the example above we have highlighted the need for state agencies to use their punitive powers under the penalty provisions of their legislation. Without knowing the actual detail for the golf course incident, let's assume instead the less likely scenario that the wildlife deaths in this case were not the result of misuse but rather that the product was used as per APVMA-approved label directions. In this case, the state agency still has a range of options available to correct the situation through the existing national Agvet system. Under s161 of the nationally consistent *Agricultural and Veterinary Chemicals Code Act 1994*, the product registrant is obliged to notify the APVMA if it "*becomes aware of any relevant information" that "shows the use of…the chemical product in accordance with the instructions for its use…may be likely to have an unintended effect that is harmful to animals, plants or things or to the environment*." Quite simply, the state agency can remind the product manufacturer to comply with s161 and also alert the APVMA itself to ensure this happens. Additionally, the state agency can also alert the APVMA to an incident of this type through the Adverse Experience Reporting Program for Agricultural Chemicals.
>
> These comments are provided as a reminder that the regulatory system offers many remedies to address serious environment impacts arising from chemicals, especially the misuse of chemical products.

- US CDC & P chemical exposure study (pg 10) – this public health agency survey (*National Report on Human Exposure to Environmental Chemicals*) is now in its third report and is cited in the discussion paper as providing evidence that "*control strategies do w*ork". ACCORD is interested that this conclusion has been reached when the CDC&P report itself states that:

  > *"We have **not performed statistical tests for trends over time** given that data are available only for the 1999-2000 and 2001-2002 survey periods. New data will be released for the U.S. population every 2 years, with the next release covering the survey period 2003-2004. **With additional data points it will be possible to describe patterns over time and in some cases test for trends**. We plan to investigate trends in future Reports for chemicals that have at least 3 survey periods." (page 4, our bolding)*

  It is also noted that this report makes the following conclusions:

  > *"**Just because people have an environmental chemical in their blood or urine does not mean that the chemical causes disease. The toxicity of a chemical is related to its dose or concentration in addition to a person's individual susceptibility. Small amounts may be of no health consequence, whereas larger amounts may cause adverse health effects**. Research studies, separate from the Report, are required to determine which levels of a chemical may cause health effects and which levels are not a significant health concern."(page 4, our bolding)*

  Assessing the significance or otherwise of population bio-monitoring data, and acting on this assessment, is primarily a public health agency responsibility and therefore any link to the NChEM proposal has to be considered tenuous.

  It cannot be suggested that Australia does not presently have the regulatory capacity to address potential public health concerns arising from chemicals. Through the priority review programs of both the APVMA and NICNAS, specific chemicals for which a concern exists can be reviewed and, if necessary, subject to tighter regulatory controls. The National Drugs & Poisons Scheduling Committee process, conducted within the Australian Department of Health & Ageing, and involving the health departments of all states and territories, also allows for ongoing reviews of domestic and agvet chemicals for both acute and chronic health impacts.

  The discussion paper also makes mention of phthalates and ACCORD notes that this class of chemicals is currently undergoing a comprehensive Priority Existing Chemical review by NICNAS.

- Economic legacies (pg 10) – it is a matter of regret that legacies of past industrial, mining and agricultural practices have created problems that still impact within Australia today. And, as highlighted in the discussion paper, one of these has been chemicals contamination and the associated costs of either clean up or negative impacts on resources such as fisheries.

  It must, however, be remembered that these legacies mainly resulted from the distinct fusion of two factors characterising manufacturing in the past – 1) inadequate environmental management within manufacturing facilities, and; 2) the highly persistent nature of some chemicals in use at the time.

  These causative factors are no longer relevant and are certainly not characteristic of the contemporary chemicals industry within Australia.

  Facilities now operate in an environment of utmost scrutiny with company directors and officers able to be held directly accountable for any environmentally damaging actions under legislation such as the NSW Protection of the Environment Operations Act[1]. Industry has also committed itself to voluntarily doing the right thing through such measures as the chemical industry's Responsible Care program.

Action has also been taken to address the environmental persistence of chemicals. Persistent chemicals such as organochlorine pesticides like DDT have been banned from use for many years now. And Australia has been at the forefront of international treaty (Stockholm Convention) processes to limit persistent organic pollutants (POPs) in the environment. Persistence is considered in the NICNAS and APVMA chemicals assessment processes. For example, the following statement is from the NICNAS website:

> *"During assessment of industrial chemicals, both new and existing, NICNAS will take into consideration the POPs criteria in Annex D of the Convention. For new industrial chemicals screening to identify potential POPs characteristics will be undertaken and additional data in accordance with the Information Requirements and Screening Criteria of Annex D of the Convention may be requested, in particular, information relating to persistence, bioaccumulation and toxicity (PBT)."*
> *See http://www.nicnas.gov.au/Treaties/Stockholm_Convention.asp*

This is in no way an attempt to diminish the impacts of these legacies of poor past practices. What we are saying, though, is that it is misleading to present these as problems justifying a contemporary policy prescription, such the proposed NChEM model, if corrective regulatory and self-regulatory actions addressing the actual origins of these problems have already been implemented.

- Waste (pgs 10-11) – the discussion paper raises important issues relating to chemical waste issues, unwanted/unused chemical products and the need for life-cycle management of consumer products. ACCORD notes however that state agencies are already implementing a range of measures directly targeting these issues, making it unclear how these are (or would be) linked to the NChEM proposal. For example, NSW DEC has only just released its 2006 Waste Avoidance & Resource Recovery Strategy. This policy refers to the following chemicals-related objective:

  > "*Waste Strategy 2003 identified a goal of phasing out priority substances in identified products by 2014 or earlier as a first choice or, if not possible, of achieving maximum recovery for re-use."* (pg 10)

  ACCORD also notes that in NSW, Extended Producer Responsibility measures have been introduced to achieve this goal:

  > *"The Extended Producer Responsibility (EPR) Expert Reference Group that was formed to monitor sectors identified in the EPR Priority Statement has been encouraging and monitoring industry efforts to reduce toxicity through a focus on the products nominated in the current Priority Statement. In its 2004 Report to the Minister and DEC, the Expert Reference Group specifically raised the issue of potentially hazardous substances in relation to computers, televisions, other consumer electronics, PVC, batteries, fluorescent tubes and shredder floc." (pg 11)*
  >
  > *"DEC is negotiating extended producer responsibility (EPR) outcomes for specific products identified in the (annual) NSW Extended Producer Responsibility Priority Statement and via the Environment Protection and Heritage Council (EPHC) to ensure that producers take physical or financial responsibility for the environmental impacts of their products throughout the products' life cycle. The first Priority Statement was published in March 2004. It listed 16 'wastes of concern', namely, TVs, computers, tyres, mobile phones, NiCad batteries, agricultural and veterinary chemicals and chemical containers, packaging, plastic bags, cigarette butts, polyvinyl chloride, treated timber, office paper, used oil/lubricants, end-of-life vehicle residuals and other electrical equipment. This list has been maintained in the EPR Priority Statement 05/06.*
  >
  > *DEC has been working nationally with industry sectors such as TVs, computers, packaging, tyres, mobile phones and plastic bags to develop effective national product stewardship schemes to increase recycling, or in the case of plastic bags, phase out the use of these products."* (pg 48)

It is interesting to note that instead of referring to local measures like this, the discussion paper states that the issue of "heavy metals and brominated flame retardants used in electronic equipment" and the waste problems these can cause are "now being addressed through product stewardship programs around the world such as the European Union's Restriction of Hazardous Substances Directive." This may unfortunately be taken by some readers of the discussion paper to imply that local waste policy action of the type described above is not being undertaken.

- *Nonyl phenol ethoxylates (pg 9) and perfluoro octanoic acid* (pg 10) - it is noted that both of these chemicals have been subject to 'watch' action by NICNAS, with nonyl phenol ethoxylates on the candidate list for Priority Existing Chemical Review and NICNAS issuing the following statement related to PFOA and Teflon in January 2006:

> *"Information on use of Teflon in non-stick cookware*
> *27 January 2006*
>
> *In general, non-stick cookware contains a surface chemical coating. One such coating is Teflon™, a DuPont trademark brand. Teflon or polytetrafluoroethylene is the homopolymer of tetrafluoroethylene, and is used as an ingredient in the coating on non-stick cookware. However, not all Teflon™ products are based on polytetrafluoroethylene (PTFE) or contain perfluorooctanoic acid (PFOA).*
>
> *There has been considerable interest in the possibility of adverse health effects following exposure to fumes released when Teflon coated cookware is used for cooking. However, fumes are released only when cookware is heated to extremely high temperatures (between 340°C to 650°C), that is, temperatures which in fact would incinerate food. There are claims that Teflon™ contains PFOA which is released when Teflon coated cookware is heated to 340°C. Available evidence indicates that no PFOA would be released from cookware at or below normal cooking temperatures. It is advised that consumers do not overheat an empty non-stick pan or leave it unattended on the stovetop (especially at high settings as general good practice).*
>
> *Based on information currently available, there is no risk to the health of consumers using non-stick cookware under normal cooking conditions."*
> See http://www.nicnas.gov.au/Media/Latest_News/Teflon_270106.asp "

Protecting the nation's environment is a top ranking priority for all Australian governments. To assist in the process of determining where efforts should be placed in this endeavour, most governments undertake comprehensive, regular independent and science-based State of the Environment assessments and reports.

For the most part, these reports rank the impacts of development activities and resulting problems such as habitat destruction as of greater significance in terms of damage to the environment than the use or possible mis-use of chemicals. These activities include amongst others - land clearing, urbanisation, mining and water extraction for agriculture and population centres.

ACCORD notes that at its most recent meeting in June 2007, the EPHC signed a new Ministerial Agreement, "Principles for Better Environmental Management of Chemicals", which will give effect to a staged NChEM implementation in accordance with the following principles:

> *i improve information and consultation links with national chemical regulators (industrial chemical and agvet) so that environmental considerations are clearly, consistently and comprehensively articulated*
>
> *ii. improve coordination with national chemical regulators (industrial chemical and agvet) so that environmental considerations are integrated in decision making on the*

management of chemicals

iii. improve coordination and enhance synergies with State, Territory and Australian Government counterparts with chemicals management responsibilities

iv. use best practice approaches when undertaking environmental risk assessments of chemicals and make the methodology transparent to the community and industry

v. raise industry and community confidence in the effective and efficient environmental management of chemicals

vi. improve and target mechanisms to collect information on the environmental impacts of chemicals so that governments, industries and the community can make more informed decisions about chemicals and the environment, noting any linkages with health and trade issues

vii. prioritise using a transparent and inclusive process, environmental chemical issues that require consistent national action

viii. streamline the environmental regulation of higher risk chemicals to deliver sound and effective outcomes for the environment, industry and the public without unnecessary red tape.

These are sound principles in that they place NChEM as a policy and administrative initiative with a primary goal of making better use of existing arrangements and improving the agency collaboration that both industry and the Australian public had reasonable expected would have already been in place anyway. Likewise, we note that EPHC ministers have placed NChEM in the context of the broader regulatory reform agenda being directed by the COAG ministerial taskforce for chemicals and plastics regulation and this Productivity Commission study:

> *"Environment Ministers support COAG's National Reform Agenda and commit to working with COAG to bring system reforms that will help to reduce unnecessary red tape while maintaining or improving protection for the environment".*

On this basis NChEM may have a positive role to play in helping to advance the reform agenda to simplify existing regulatory arrangements. However, a concern still exists that regarding the piecemeal nature of such an approach plus the fact that it would most likely perpetuate the inefficiencies and duplication that characterises the existing federal/state arrangements for environmental regulations for chemicals.

3.7 Streamline data requirements and assessment processes

Industry has for a number of years raised its concerns about the need for the APVMA, TGA, NICNAS and the Australian Government Department of the Environment and Heritage (DEH) to streamline their assessment processes and data requirements so that relevant information can be more freely exchanged between regulatory agencies, hence reducing the reporting and cost burden on industry seeking approval for the same chemical for different purposes from different regulatory agencies.

While these regulatory agencies have agreements in place with comparable international agencies, no such process exists for inter-agency mutual acceptance.

While the Government in its response to the Chemicals and Plastics Industry Action Agenda indicates that this is an area for reform, industry has seen little effort to date to achieve this

outcome. ACCORD would recommend that this be a priority for the regulatory agencies. Recognising that the APVMA and TGA regulate products, nevertheless data on individual ingredients is generated and this could be usefully exchanged in some instances. In other instances, the regulator's decision on particular ingredients, if listed on an inventory or in the public domain, should be accepted by other regulatory agencies, particularly in instances related to low risk products and when the practice is unique to Australia.

Example 2 - Inequality of requirements compared to the TGA and other regulatory agencies

Fragrance Ingredients

"*NICNAS requires Companies to assess the ingredients in the fragrances that are used for most cosmetics. These fragrances are used at typically 0.3-0.6% for wash off products and 0.1-0.4 in leave on products. They consist of many ingredients usually and most are on AICS. Many Companies that are importers particularly those that are also distributors for a number of brands are unable to obtain formulations for products and even if they can the formulations will not even state the name of the fragrance let alone who the supplier is. I would prefer a system that exempts fragrance ingredients if used at less than 1% in a product provided all the ingredients are on the International Fragrance Research Association's data base. IFRA self regulate this list and investigate new component toxicity. The current system is simply ignoring the difficulties of compliance for what is a very low risk and expecting Industry to comply. Many companies are unable to comply. TGA do not evaluate fragrance ingredients although they do require the ingredients to be advised to them and they give an approval based on the list of ingredients*."

Overseas Suppliers/ Local agent combined Certificates

"*On certificates why cannot the overseas raw material supplier also be a co applicant? This would allow imported fully formulated products that use an ingredient that has a certificate held by the overseas raw material supplier as well as Australian distributor to allow import of finished products that contain the parent's ingredient. This would still exclude products that use a competitor's identical raw material until the 5 year confidentiality expires. It stops duplication of notification and it also reduces extensions to an original certificates by finished product importers*."

Unique Australian requirement – data for excipients

"*In other cases we pay the high compliance costs to introduce new products even though we do not agree with the particular regulatory approach. An example is the data requirements and review cost of submitting "new" sunscreen excipients to TGA before they can be used in listed products. It seems incongruous that an ingredient that has been used for many years in cosmetics in Australia must undergo costly reviews before it can be used in listed sunscreens*."

Quoted from Member consultations.

3.8 The need for effective stakeholder engagement

Effective consultation requires regulatory agencies to have an open and transparent stakeholder consultation process to allow all parties to engage in the process effectively. ACCORD has raised with a number of regulatory agencies, the need to develop principles for effective consultation consistent with government policy for their processes to be open and transparent.

Most Australian governments are committed to community consultation and recognise that effective industry and community engagement enables them to tap into diverse perspectives and develop solutions in partnership with its stakeholders which improves decision making.

This process will result in improved decision making and consensus building amongst all parties. We note that as a result of the Banks Review the Australian Government has endorsed a whole-of-government approach to consultation. While this is a good start, the principles outlined in the Best Practice Regulation Handbook could be improved upon.

ACCORD supports the development of an official Stakeholder Engagement Strategy by individual regulatory agencies as a means of improving processes for meaningful and timely dialogue with their respective stakeholders. A Stakeholder Strategy also introduces transparency into the process as key stakeholder groups are identified and processes for nominating participants onto committees are clearly outlined. Engagement covers a wide variety of government-industry connections, ranging from information sharing to consultation and, in some instances, active participation in government policy development and decision-making processes.

The COAG Principles also recognise that for regulatory agencies public consultation is an important part of any regulatory development process. In addition, the Uhrig Review of the Corporate Governance of Statutory Authorities and Office Holders (Uhrig Review) also noted that effective consultation is a key to success for regulatory bodies.

ACCORD believes that there is a critical need to consider consistent mechanisms for stakeholder engagement across all regulatory agencies to ensure a fully integrated and transparent approach when undertaking consultation.

From a first-principles basis we believe there is need to:

- identify stakeholder engagement objectives
- identify the right target audiences; and
- develop the right strategies for stakeholder engagement.

Commonwealth, State and Territory Small Business Ministers have endorsed, *Giving small business a voice – Achieving best practice consultation with small business (2000).* This publication identifies 10 key principles of consultation that are useful when considering the development of an engagement model, as follows:

- flexibility
- appropriate targeting
- timeliness
- accessibility
- appropriate medium
- transparency
- responsiveness
- appropriate resources
- evaluation; and
- continuity.

The principles are closely linked and need to be considered in their entirety for designing stakeholder engagement strategies. We believe that these are an enhancement on those currently adopted by the Australian Government but must be developed in full consultation with industry.

4. The need for efficiency

Anecdotal evidence from industry is that the costs of the regulatory system for chemicals in Australia are too high and that with full cost recovery it is much higher than the cost of introducing new chemicals in the EU, USA or Canada. Given the complexity of the issues surrounding efficiency in the regulatory system ACCORD is undertaking a Member Survey to quantify the costs of regulation. The survey is expected to provide data in the following three areas of Member concern:

1. Lost opportunities - the impact of the current regulatory system on the realization of commercial opportunities.
2. Rating of the success of the LRCC Regulatory Reforms
3. Operational Performance of the Regulator

ACCORD expects to provide the results of our survey to the PC Study towards the end of the year.

5. The need for coordination within and across jurisdictions

5.1 Problem with poisons scheduling

ACCORD has been arguing for a considerable period for an integrated control framework for chemicals. An important element of the chemical control which requires significant improvement is the process for the scheduling of chemicals.

Scheduling is a vital risk management component that enables labelling and packaging controls to be imposed on chemicals, particularly those in the domestic setting. Through its hierarchy of risk management, the system can include substances into Schedule 5, 6 or 7 in a range of concentrations and/or presentations or even ban certain uses through other schedules and/or appendices.

We have argued that all jurisdictions should commit to separate the scheduling of chemicals from that of medicines, implement the decisions of the National Drugs and Poisons Schedule Committee (NDPSC) without variation and nationally harmonise those consequences that are linked to scheduling e.g. storage requirements, licensing arrangements.

The state, territory and federal governments commissioned a national competition review to examine the legislation and regulation imposing controls over access to, and supply of, drugs, poisons and controlled substances. In 1999, an independent Chair, Ms Rhonda Galbally commenced the review with advice from a steering committee representing all jurisdictions.

The Galbally Review's final report was presented to the Australian Health Ministers' Conference (AHMC) in December 2000. The federal government response to the Galbally Review was released to the public on 1 July 2005 by the AHMAC Working Party. The federal government's agreement to implement Galbally Recommendation 7 regarding the separation of scheduling of medicines and chemicals by establishing 2 committees, provides an excellent opportunity to reform the current chemical control framework at the national level.

The impetus for the government response to the 1999 review was the proposed development of a joint therapeutic products agency between the TGA and Medsafe, New

Zealand. The separation into two committees makes practical sense in the context of the proposed developments, although industry can see no reason why the federal government along with the state and territory health agencies did not act sooner to implement this common sense recommendation regarding the separation of the scheduling of medicines and chemicals decision making committees. It had been a recommendation from several previous reviews.

Industry became aware that the scheduling reforms might be proceeding with the publication of the proposed legislative timetable, which indicated that the Department of Health and Ageing intended to introduce a Commonwealth Poisons Bill as a consequential amendment to the joint agency implementation legislation.

However in July this year, it was announced that the New Zealand Government would not be proceeding with the legislation to establish a joint agency with Australia for the regulation of therapeutic products and that the Australian Government has postponed its plans for the time being to establish the joint agency

Without further clarification of the ramifications, the TGA decided to proceed with another round of consultation regarding proposed changes to the scheduling of medicines and chemicals.

Much earlier, in September 2005, ACCORD responded to the TGA's original proposals for changes and made 11 recommendations for change. (ACCORD has already provided the PC Study with a copy of this submission.) The TGA had not consulted in the interim nor advised stakeholders on the outcomes of the original consultation even though it was made clear that industry wanted to be involved in the further development of the proposed Scheduling Framework and model.

At one stage, industry would have supported the introduction of the Poisons Bill regardless of progress with the joint agency. However, given the lack of responsiveness by the National Coordinating Committee on Therapeutic Goods (NCCTG) to industry's initial concerns with the Scheduling Framework, we would not support any changes to the current system until it has been considered by the PC Study and referred to the COAG Ministerial Taskforce for Chemicals and Plastics.

Industry sees little to be gained from the approach suggested by the NCCTG which represents the jurisdictions limited view for minimal change and is not a broad vision for national chemicals reform and the opportunities which this might present for better integration and co-ordination.

ACCORD questions the role of NCCTG with regard to chemicals scheduling and chemicals policy. The NCCTG is a working group of health officials with a mandate for medicines policy. We continue to have reservations regarding the administrative arrangements and the priority given to these process issues such as convenience of meeting attendance e.g. the Medicines Committee will meet prior to the Chemicals Committee. The convenience of meeting times appears to be driving the Scheduling Framework and Policy, not the recognition that reform is required and the separation of the work into two committees presents such an opportunity.

5.1.1 Automatic default to Schedule 7

Despite earlier concerns being expressed, by far one of the most problematic of the NCCTG's recommendations regarding future scheduling processes, is the recommendation for the automatic default to Schedule 7 for all chemicals. We are yet to see an impact

assessment to justify the reversal of the current scheduling process. Industry is not aware of any demonstrated market failure or risks to public health from the current approach.

The NCCTG is recommending a significant ramping up of regulatory intervention with no justification that that new approach is required or what benefits it will deliver in terms of public health and safety outcomes, improved consumer information or reduced costs to industry.

Schedule 7 substances are described generally as **Dangerous Substance** – substances with a high potential for causing harm at low exposure and which requires special precautions during manufacture, handling or use. The poisons should be available only to specialised or authorised users who have skills necessary to handle them safely. Special regulations restricting their availability, possession, storage or use may apply.

This principle of starting at the highest scheduling level is contrary to the COAG Principle to minimise the impact of regulation:

> *'Working from an initial presumption against new of increased regulation, the overall goal is the effective enforcement of stated objectives. Regulatory measures and instruments should be the minimum required to achieve the pre-determined and desirable outcomes.' (COAG Principles page 6)*

On the basis of the COAG Principles, the starting point for consideration of a scheduling classification should be 'unscheduled' and if proven that scheduling is required the first consideration should be classification against Schedule 5 criteria and then Schedule 6 and so on. To adopt the NCCTG approach would in effect result in the banning of all chemicals including excipients for use in domestic products. Further, it disregards the existing NICNAS process for public health assessment of new chemicals and referral to the NDPSC for scheduling decisions where appropriate.

In considering harmonisation of scheduling decisions, the NCCTG has already adopted the following practice for trans-Tasman harmonisation of scheduling that 'where differences in scheduling exist between Australia and New Zealand that the underlying principle is to harmonise on the less restrictive schedule while giving due consideration to public health and safety issues and/or specific jurisdictional needs'. Given the current practice by the NDPSC to harmonise on the less restrictive schedule, we do not understand why the Chemicals Scheduling Committee would automatically default to the effectively the highest schedule i.e. Schedule 7. This is a backward step and cannot be supported.

5.1.2 Single Scheduling policy framework

Another example of the failure of the NCCTG to embrace the reform opportunity presented by the separation of the two committees is for the insistence of an overarching unified scheduling policy framework. 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.

Industry does not oppose closer alignment of committee meeting dates to assist the states and territories utilise representational resources more efficiently, but this is a process matter, not a decision which is integral to the decision making processes of the two scheduling committees. These administrative decisions should not hinder the development of the best regulatory model to deliver a chemicals scheduling model for Australia.

Further, there has been no demonstrated commitment by the jurisdictions to national uniformity i.e. to address large number of inconsistencies that exist between the State & territory legislation in relation to the control of scheduled chemicals across Australia, requiring businesses operating nationally to implement possibly up to 7 different processes to accommodate the varying controls for a particular scheduled poison.

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.

Example 3 - Schedule 7 Poisons for industrial uses.

In September 2004, ACCORD raised its concerns regarding the draft replacement regulations for the Drugs, Poisons and Controlled Substances Regulations 1995. These concerns were illustrated through the practical example of hydrofluoric acid (HF). In its reconsideration of the scheduling of HF, NDPSC rescheduled concentrations above 1.0% HF to Schedule 7. This action was apparently precipitated by an incident involving a householder in Tasmania using a product marketed to household consumers. The intention was to ensure that products containing a concentration of more than 1.0% HF were not available for domestic use.

The implications of this change have varied from state to state, but in general had the unintended consequence of requiring bone-fide industrial users (e.g. welders, stainless steel fabricators and others) to seek certain authorities/licenses to supply and/or possess and/or use the substance. This particular example has been the subject of discussions at both the federal, state and territory levels. It has highlighted that certain scheduling decisions at NDPSC may trigger requirements at the state level that produce unintended consequences for industrial users of substances in the course of their respective businesses. There appears recognition, at all levels, that appropriate amendments to regulations are required to address this anomaly.

Another example, **Methylcyclopentadienyl Manganese Tricarbonyl (MMT),** also under consideration by NDPSC in 2004 and the same in-principle issues arise. This is an important matter to be resolved for industrial users of substances in the conduct of their businesses, also recognizing the substantial controls that apply under the industrial chemicals and workplace substances regimes.

The NSW Poisons and Therapeutic Goods Regulation 2002 has dealt with this matter with a specific exemption for supply, obtaining or use or a Schedule 7 substance for “non-domestic purpose” [cl 19(8)(d)]3

It has therefore been industry’s strong recommendation that appropriate amendments be included in the regulations to address this matter. Still no action has been taken.

Given our disappointment with the lack of progress over the past two years and lack of responsiveness to industry’s request for meaningful reform, ACCORD does not support any immediate change to the scheduling framework and has been forced to recommend that no decision about changes to Commonwealth/State scheduling decisions regarding chemicals is made until the PC Study into chemicals and plastics has been considered by the COAG Ministerial Task Force into Chemicals and Plastics.

While ACCORD’s position may be frustrating to those that wish to act now, we have already been waiting more than 7 years to make a decision, and the proposed changes are of no benefit to industry and do not guarantee a more efficient and effective decision making process for the scheduling of chemicals.

The poor management of the chemical scheduling reform process, the disregard of concerns repeatedly raised, the obvious preference for the jurisdictions to essentially maintain status quo, and the failure to implement improvements that are based on COAG principles and relevant specifically to chemicals scheduling as part of an integrated chemicals control system are the basis for our conclusion to await more substantive reform.

6. Implementation and administration of regulation

6.1 Cost recovery

ACCORD has on previous occasions raised its concerns with the 100% cost recovery of NICNAS. ACCORD notes that given the objectives of the *Industrial Chemicals (Notification and Assessment) (ICNA) Act 1989* in that it is fulfilling a social function regarding public health and safety and environmental concerns, industry should not be required to meet the full cost of this regulation which has a significant element of public interest. ACCORD has always argued that the Australian Government should fund the public good elements of regulatory agencies activities.

In August 2005, the Australian Government made a decision to extend the scope of NICNAS's cost recovery arrangements to include activities previously funded by Government appropriation for NICNAS's government business activities. The effect of this decision was that NICNAS was now 100% cost recovered. ACCORD was opposed to this Government decision and still believes that it was inappropriate.

We remain concerned that despite the Guidelines, regulatory agencies and/or departments regard industry cost recovered monies as a somewhat 'a never ending' source of revenue. Specifically ACCORD is concerned with the failure of government agencies to abide by the Government's own requirements for cost recovery of Government business includes activities such as:

- advising Parliament on issues where the agency has expertise
- answering Parliamentary questions
- briefing Ministers and responding to their correspondence
- financial reporting; and
- complying with international treaties.

Example 4 – NICNAS's cost recovery arrangements

An Independent Review of NICNAS's cost recovery arrangements undertaken by ACUMEN Alliance found that NICNAS was broadly complying with the Government's cost recovery arrangements. The Independent Review also noted that the Government's policy on what constituted government business was open to interpretation stating that *'…the argument for cost recovery versus Government funding is subjective, given the lack of clarity in the Guidelines'.*

The ACUMEN Alliance report estimated that for 2004-05 NICNAS's Government business activities cost $327,000. The independent consultant using the guidelines estimated that $155,000 of these activities could be interpreted as Government business.

Some of the examples cited by ACUMEN Alliance are:

> the Act requires NICNAS to prepare an annual report. It has been argued that industry is the beneficiary of the annual report and therefore should pay. However, NICNAS also reports on its governance arrangements in the departmental annual report. The

requirement in the Act to produce an annual report of which 450 copies must be tabled is duplication and an unnecessary cost on industry. Industry would be quite willing to see the Act amended to remove this requirement for duplicate annual reporting rather than being asked to pay $36,000.'

NICNAS's represents the Australian Government at an OECD meeting which deals with amongst other matters, pesticides and agricultural chemicals. The industrial chemicals sector is not the main beneficiary yet is expected to foot the bill for this Government policy activity estimated to be around $34,000.

The ACUMEN Alliance report stated that ' *the Guidelines are not sufficiently prescriptive to provide definitive guidance on this matter, (i.e. what activities constitute government business). Further, DoFA were not willing to provide advice on specific examples cited. Rather, they advised that it was the responsibility of agencies and the responsible Minister to interpret the Guidelines as they see fit.'*

Given that NICNAS had undertaken government business since 1997 and these arrangements had been in place with various Ministers, ACCORD was not aware of any justification to change the arrangements regarding the funding of government business.

To enhance transparency, the ACUMEN Alliance report did suggest that a Service Level Agreement be established between NICNAS and the Department for the services which NICNAS is to provide from Government appropriation. Industry supports this as an open and transparent way of operating.

As a result of the changed nature of NICNAS's cost recovery arrangements, ACCORD took the issue up with the Department of Finance and Administration (DOFA). DOFA revised its Guidelines in mid 2005 to assist agency understanding with the Government's policy requirements. The update Guidelines partially addressed some of industry's concerns. ACCORD however remains concerned with the application of 100% cost recovery on NICNAS's activities and indeed and regulatory agency which has as its objectives to maintain public health and safety. Industry believes that this should be a shared cost not an industry burden.

6.2 Industry concerns with the administration of the ICNA Act

ACCORD Members have raised their concerns with the operation of NICNAS. As part of ACCORD's work in gathering data for the PC Study, ACCORD together with PACIA held an industry roundtable to gauge the current level of industry dissatisfaction with the current operations. Industry has identified a number of issues under the following headings:

- Administrative: particular issues identified have been with pre-screening and stopping of the clock
- Inventory: the new process of annotation is not transparent and is therefore failing its prime objective of providing information
- Costs: the cost to industry to obtain exempt information status is excessive, industry believes that this should be free
- Assessments: data requirements are more extensive than in the EU and USA, and industry believes that physiochemical data requirements are not commensurate with the end goal. There appears to be no use of risk assessment anymore and the industry perception is that NICNAS has moved away from ingredient based evaluation to product based evaluation
- Over-reporting since LRCC: industry is concerned with the excessive amount of time

spent on annual reporting requirements for minute amounts of exempt ingredients

- Failure of LRCC to deliver appropriate reforms: increased complexity, the lack of risk assessment, and the burdensome annual reporting requirements for no perceived gain
- Consultation processes: the constant calls for information on existing chemicals are time consuming with no real benefit identified. The process appears to be reactive and not based on any real planning regarding pre-existing priorities based on identified risks

6.2.1 Unique Australian treatment of polymers

As mentioned previously, NICNAS along with other government regulators have been grappling with the concept of low hazard and/or low risk for a considerable period. It was an important part of the LRCC process which held great promise of real reform to industry. For industry, finalisation of these criteria would enable the introduction of additional low risk products through an easier assessment route with the added benefit of decreased time to market and lower introduction costs. In particular, industry has for a considerable period expressed its concern with the assessment process for polymers in Australia under its unique assessment processes compared to a more pragmatic entry pathway in the EU or USA.

For example in the US, polymers in general are exempt from assessment and introduction fees. Similarly in the EU polymers which are derivatives of certain monomers are exempt. Decisions by EU and US regulators to treat this group of chemicals in this way is based on a history of use and a risk based approach to the inherent hazards posed by this group of chemicals. We would recommend that Australian regulatory agencies also adopt this pragmatic approach.

Example 5 - Treatment of polymers by the US EPA

The US polymer exemption encompasses three categories:

- those with Mn > 10,000 - no cost

- those with Mn > 1,000 and strictly limited functional groups - no cost

- polyesters made from an "approved" list of ~ 100 monomers - no cost

Where a polymer does not meet these criteria, a regular pre-manufacturing notice must be filed at a cost of $2,500. In the US the submitter must report any physical, chemical or toxicological data in his possession. But he is not obligated to conduct any specific menu of tests. The US EPA has great confidence in a suite of models (publicly available) that predict hazards from chemical structure considerations, obviating the need for much testing. Most polymer PMNs contain a GPC but little else.

Given the extent of issues raised and the need to quantify the impact of the regulatory scheme on the chemical sector, as indicated previously, ACCORD is undertaking a Member Survey to identify in more detail issues raised and the significance of these to the industry.

Example 6 – Member dissatisfaction with NICNAS operations

Implementation of pre-screening for assessment process
"*In the past NICNAS had for, say, a Limited Notification 90 days to complete their assessment. The clock started on day 1 when the notification was received and if the notification was incomplete the clock was stopped while information was obtained. This meant that some of the assessment time of 90 days was used while new information was being obtained. Under the original arrangement there was a sense of urgency to get on, get data if required and finish the assessment by both parties. About 12 months ago NICNAS began or introduced what they call a Screening Outcome where the clock does not start until they have reviewed the notification, requested any missing information, assessed any new requested information and if they then thought they had everything then they started the clock for the 90 day period. This system imposed no urgency on NICNAS as the Screening Outcome has no statutory time limit. NICNAS liaise with the Department of Environment and Heritage during the Screening Outcome time, before this was in the 90 day clock period. The end result is longer assessment times and easy achievement of KPIs for assessors*. "

Failure of risk management
"*NICNAS now say that a Limited or Standard Notification must be submitted for UV filters for hair because that is required for UV filters for skin. The risk is completely different as is the usage. Previously Companies could do a Low Volume Chemical Permit cost $3204 time maybe 6 weeks. Now they will need to do a Limited notification cost $12076 and time about 5-6 months if there is a good data package*."

Concerns with AICS annotation
"*This process of annotation was poorly discussed with Industry during LRCC 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 but without the ability of Industry to comment.There is no mechanism to complaint without paying a fee of $633 and further delays to the approval*."

Extensions to an Original Certificate
"*If one company has a Certificate for an ingredient it may grant an extension to that original certificate to another company for the same ingredient via NICNAS. NICNAS charge a fee of $2588 for checking and approving this assessment. The problem is that NICNAS are defining an extension as simply a reallocation of the original company's volume. For example for a Limited Notification Company A apply for and receives 1000kg pa approval for ingredient X. Company B comes along and wants to use 500kg and receives permission from Company A for an extension to their original certificate. NICNAS is now saying that Company A is limited to only 500kg. That is the difference between the original amount requested and granted and the quantity that Company B wants to use. This does not seem to be an extension to the original certificate at all. Since the environment, OHS and public exposure has not changed then why is NICNAS charging $2588 for what is only a bureaucratic process on their definition. The regulations are ambiguous but to me an extension is an increase of existing and hence an Extension to an Original Certificate in the example above should be Company A 1000kg plus Company B 500kg and the NICNAS fee is for NICNAS to assess the extra risk of the increased volume. It should be possible for Company B to get an extension up to 1000kg without affecting Company A's allocation*."

Quoted from Member consultations.

6.3 The Cost of doing business with the TGA

Industry has argued for a long time that the TGA's regulation of certain skin disinfectant products, commercial grade disinfectants and sanitisers is too costly and anti-competitive to local manufacturers. Assessment times for some locally developed products can take years by which time international competitors have been able to introduce their products and develop well established markets for their particular niche products.

The Australian Government has announced a review of household and commercial grade disinfectants with a view to reforming the process along the lines of the recent reform to cosmetics at the therapeutic interface. This reform proposal was first suggested some 7 years ago when industry and the TGA established a working group to examine the issue. Industry is still yet to see anything concrete.

For skin disinfectant products, many of which will be excluded from this anticipated review and regulated as medicines, the chemistry is already well defined. Products are generally relatively simple blends of existing known active materials and there are a known number of approved testing methods for product assessment.

For a person wishing to bring a new skin disinfectant product into the market which falls under the TGA there is currently no publicly available advice as to either the categories of registration, tests that should be performed, or labeling indications commensurate with the tests and assessments to be conducted by the TGA.

The current system to bring new products to market in this category has been described by one of our members as “doing hopscotch in a maze whilst wearing a blindfold”. No advice is available in advance, guidance on the tests chosen is only available after submission and assessment of the data submitted, and the time and cost of the process is unnecessarily long and costly.

One Member has advised that a manufacturer can easily spend more than $200,000 in pre-market costs, only to find that the tests chosen by the independent testing laboratory have some minor flaw that causes the TGA assessor to exclude the test from consideration in the filing of the submission. This product category could be easily controlled through a clear and transparent set of guidelines that could be introduced as a Therapeutic Goods Order similar to that for Disinfectants (TGO No. 54, 1996).

There are four primary segments for products under this general category. These are:

1. Wound Antiseptics;

2. Intact skin Disinfectants;

3. Surgical Scrubs;

4. General Purpose Antibacterial Washes and Rubs (those not now controlled by NICNAS following the cosmetic therapeutic goods interface review).

Industry requires certainty from the regulator as to what tests are acceptable prior to lodgement of an application, not at then end of the process. This could be in the form of guidelines that attached testing methods and pre-market assessment requirements to the risk of the different categories of product. Each category has it own unique issues that could easily be documented and appropriate testing and assessment systems documented and adopted with all stakeholders involved.

Such a system would improve transparency and clarity for formulators and sponsors, would define the terms and requirements concordant with risk, would increase the efficiency of the process (TGA would require less effort in approval as a systems approach could be adopted similar to that which currently applies disinfectants), would decrease the time taken and the pre-market costs for this important infection control product grouping, public health would be protected and the integrity of the process would be maintained, and competition would be enabled in the market.

Table 3, Attachment 3 provides the pre-market costs for the same products in different TGA categories, i.e. sanitisers, disinfectants and anti-bacterial hand washes.

Example 7 – difficulty registering products with the TGA

"Difficulty in registering alcohol hand gels / soaps for hospitals is a barrier to trade – extreme cost to market. The cost of $35 000 to register an antibacterial hand wash at $10/L is not justified.

The requirements are too difficult to meet. After two years in assessment I know of four products that can't get registration with the TGA. The efficacy requirements are two stringent. The expectations for such low risk topical products are unrealistic. There is also a barrier to innovation and improvement. Applications to update packaging for products that are both listed and registered are being met with requests for new data that is difficult to provide. The problem also exists for another topical product, head lice treatment."

"Our company has sold an antibacterial hand wash in New Zealand for many years, but because of the high cost of obtaining test data to satisfy TGA requirements, we have not sold this product in Australia. In another instance we omitted an antibacterial claim from a bar soap, again because of the difficulty in testing to TGA requirements. This necessitated a different label for Australia."

6.4 Charging for regulatory documents and standards

ACCORD supports the principle of transparency and accessibility of legal requirements and therefore recommends that any standard, code of conduct or other quasi-regulatory tools that are referenced in legislation should be made freely accessible through the use of appropriate publicly accessibly legal databases such as the Australian Government's Federal Register of Legislative Instruments (FRILI). There is a growing practice by regulatory agencies to charge for documents which outline mandatory requirements for industry compliance.

For example, significant costs will be incurred by industry and all users of ADG7 in training and implementation. Additionally, 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. No doubt there will remain a market for hard-copy and it would be appropriate for the government to charge accordingly for these printed versions.

ACCORD also advises that not only is the cost of accessing a standard a problem, but also obtaining the correct referenced standard, as regulatory agencies tend to reference a standard and then add the phrase – as in force or as amended from time to time.

The Australian Government's Guide to Regulation (December 1998) is quite specific about how external standards which are incorporated into regulation, including but not limited to Australian Standards, should be referenced:

> *Where a standard is used, the regulation should not allow the standard to be modified or changed, unless it can be clearly shown that modification or change is necessary. Any modifications to the standard should not be automatically incorporated into regulation.* ***Where regulation refers to a standard, it should explicitly refer to the***

type, characteristics and date the standard was made. It should not refer to a standard that could be changed or modified*. (page E21)*

These issues regarding the costs to industry of not only paying for referenced standards but ensuring that they are using the most up to date referenced Standard is time consuming and often makes compliance difficult. The development of FRILI was meant to overcome these difficulties but more needs to be done to promote this service to industry and more needs to be done to ensure that referenced standards are able to be accessed by industry at no cost.

7 Leveraging international linkages

7.1 The Globally Harmonised System for Classification and Labelling of Chemicals (GHS)

7.1.1 General

The GHS has developed on the premise of a single, globally harmonized system for classification of chemicals and hazard communication (labels and safety data sheets). The genesis of the GHS will be well known to the Commission and will not be further elaborated in this submission.

The challenge for the GHS is that it attempts to address classification and labelling for all chemical sectors (transport, industrial/workplace chemicals, industrial formulated products, agricultural chemical products, and household consumer products) under a single approach. Moreover, it attempts to do so for both developing nations, which may have limited or no schemes, and developed nations with sophisticated chemicals management regimes.

Whilst many governments are actively considering how GHS may be implemented in national schemes, no major economy has yet fully implemented the GHS across all chemical sectors. Indeed, governments and industry are now focusing attention on the practical aspects of how the GHS might be implemented at the national level, while keeping in mind the key considerations of enhancing national schemes and gaining the benefits of trade facilitation.

Hazard-based approaches to labelling in the transport sector and for bulk commodity industrial chemicals in international and national trade and in the workplace sector are non-contentious except where regulators maintain or promote unique Australian requirements such as inner package labelling. The central issues relate to timing (including transition periods and what occurs during transition periods), the scope of implementation of hazard classes and categories, and how to achieve consistency in chemical classifications. This latter point is not to be underestimated. At the 9-12 July 2007 meeting of the United National Sub-committee of Experts on the GHS (UNSCEGHS), the United States reported on its pilot program to test the classification criteria for mixtures:

> *"During the twelfth meeting of UN/SCEGHS held in December 2006, an informal group met to discuss a mixtures' pilot program. At that meeting, an exercise was provided that included information on the health hazard classifications for seven fictitious chemicals, along with the components for three mixtures of the fictitious chemicals. Group members were asked to classify the mixtures according to the provided information and the GHS mixtures' rules. The purpose of the exercise was to determine differences in approach to classification.*
>
> *Eight work group participants submitted results. All health hazards other than aspiration hazard*

were evaluated. The results show that there were, indeed, inconsistencies in the application of the classification criteria for mixtures." (underlining added)

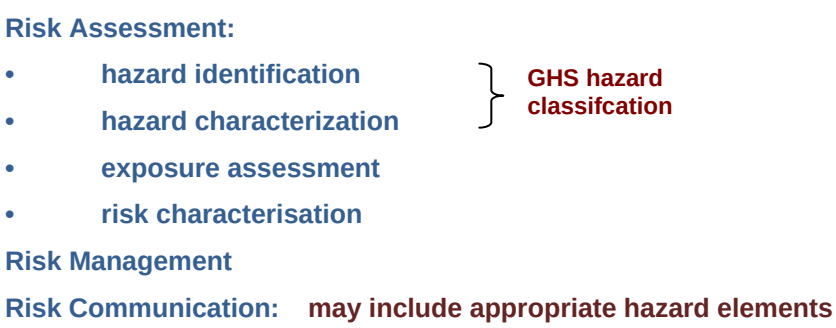
http://www.unece.org/trans/doc/2007/ac10c4/UN-SCEGHS-13-inf06e.pdf

The GHS remains a 'work-in-progress' and will need to evolve in recognition of problems that arise in both practical application, and to reflect changes that arise in the implementation that occurs in the major chemical trading nations – otherwise the official GHS text and documentation will lose relevance.

In its 27 June 2007 announcement, the European Commission proposed a hazard-based approach across all chemical sectors. In Australia and countries such as the United States, Canada, Japan and others, the contemporary regulatory approach for consumer products and agricultural chemical products (pesticides) has been for consideration product labelling within a risk analysis framework.

A simplified risk analysis framework, including potential application of the GHS, can be represented as follows.

Figure 1. Simplified risk-analysis framework identifying potential application of GHS



In such more sophisticated approaches, GHS hazard classification has a potential role in hazard identification and hazard characterisation.

Notwithstanding the pros and cons of hazard versus risk-based labelling, there is a clear divide in how regulatory philosophies approach communication with end-users in the various sectors. The current European Commission proposals are very different in approach from current practices in countries such as Australia, United States, Canada, Japan and others.

7.1.2 The emergence of 'brands' of GHS

Europe: Without debating the merits of the proposals, 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.

During a panel question time at the 24-27 April 2007 ChemCon Conference in Singapore, a representative of the European Commission responded to a question as to whether a chemical classified and labelled to all GHS endpoints (i.e. more protective than the Commission's proposals) would be acceptable in the EU – the response was that only chemicals classified and labelled to the European adoption of GHS would be acceptable.

ACCORD understands that this European Commission position is also the interpretation of Australian government representatives to the UNSCEGHS.

New Zealand: The Environmental Risk Management Authority (ERMA) 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.

Adoption of the lowest classification toxicity categories means that ERMA regulates chemicals, as hazardous substances, that may be or of similarly toxicity to common food items. For example, GHS Acute Oral Toxicity Category 5 classifies substances with LD50 values of 2000mg/kg to 5000mg/kg. This classification picks up chemicals such as sodium chloride (table salt) with an acute chloride oral LD50 in rat approximately 3000mg/kg and sodium carbonate (baking soda) with acute oral LD50 in mouse approximately 3360mg/kg. These low-end classifications are not included in the European Commission's proposals.

New Zealand's scheme is not currently harmonised with any other country and is commonly referred to as a 'GHS-based' scheme rather than a 'GHS implemented' scheme.

In 2006, ERMA pragmatically provided 'alternative compliance measures' under its Group Standards to allow the transfer of substances and mixtures to its Hazardous Substances and New Organisms Act 1996 (HSNO). The alternate compliance measures provide for acceptance of:

"the relevant current labelling requirements of Australia, USA, Canada, the European Union or any other country as approved by the Authority, as if the substances were for sale or supply in those countries"

Example of text in a Group Standard is at

http://www.ermanz.govt.nz/appfiles/orgctrl/pdf/HSR002525Con.pdf*, page 8*

These alternate compliance measures are due to expire on 31 December 2010 but in reality these will need to be extended as even the European Commission's proposals do not contain mandatory GHS labelling of mixtures until 2015. Additionally, for consumer products and others where New Zealand's major trading partners will adopt risk-based approaches to labelling there are no current provisions under HSNO for this to occur.

The New Zealand experience has highlighted the significant problems that can occur with small economies trying to implement schemes in isolation before major trading partners and not benefiting from the substantial work that is still to be done in the major chemical trading nations. This is not a model for Australia to emulate.

North America: there is no detailed information yet available on GHS implementation in North America.

The consequence of different 'brands' of GHS

The emergence of different customised brands of GHS, without mutual recognition of GHS in other economies has the potential to strongly work against a stated objective of GHS with regard to trade facilitation. This is a key issue

ACCORD would be pleased to provide additional information to the Commission on country GHS status separately.

7.1.3 What will be the costs and benefits of implementing the GHS in Australia?

United Kingdom Health and Safety Executive

In July 2007, the UK HSE commenced a consultation of GHS implementation in the United Kingdom (http://www.hse.gov.uk/consult/condocs/cd213.htm) to allow it to inform the considerations of the European Parliament and Council. The consultation closes on 2 November 2007

The HSE Initial Regulatory Impact Assessment (RAI) notes the context of GHS for the United Kingdom.

> "5. *The current EU classification and labelling system for supply and use of chemicals is mature, well developed, and widely understood. It is unlikely the EU (and therefore the UK) will experience significant benefits for human health or environmental protection from implementation of the United Nations Global Harmonised System of Classification and Labelling of Chemicals (GHS), compared with the current EU classification and labelling system. It is countries that as yet do not have a regime in place to control the supply and use of hazardous chemicals, that are expected to benefit the most from the UN GHS, and for them it will be a significant step forward in the safer management of chemicals.*
>
> *6. The principal economic benefit of the GHS for the EU, and therefore the UK, is considered to be the facilitation of international trade, over the longer term, due to the lowering of technical barriers to trade….."*
>
> *UK Initial Regulatory Impact Assessment on the Proposed European Regulation on the Classification, Labelling and Packaging of Substances and Mixtures (Based on the UN Globally Harmonised System. Consultative Document 213 - Annex B, July 2007* http://www.hse.gov.uk/consult/condocs/cd213ria.pdf

The RAI includes cost estimates for the introduction of the GHS at between £95,680,000 and £215,680,000. At current exchanges rates this equates to A$218 million to A$492 million.

Australia has a developed and mature regulatory regime for chemicals management that is comparable to other developed countries.

The contribution of the GHS to Australia's National Interest will be best served through trade facilitation and efficiencies that may be achieved through harmonized international approaches to classification, labelling and safety data sheets.

ASCC Regulatory Impact Assessment

The ASCC 2006/2007 consultation on the Draft National Standard and Codes of Practice for the Control of Workplace Hazardous Chemicals included key elements of:

- use of the Globally Harmonised System for Classification and labelling of Chemicals (GHS) as the primary tool for classification, labelling and safety data sheets in the workplace sector; and
- consolidating the requirements for workplace hazardous substances and dangerous goods into a consolidated framework

The detail of the overlapping considerations were extremely complex as recognised in government and industry submissions. Copies of the submissions to the consultation are at:

http://www.ascc.gov.au/ascc/AboutUs/PublicComment/ClosedComment/Public+Submissions/PublicSubmissions-ControlofWorkplaceHazardousChemicals.htm

The detail of some submissions is worth noting, for example WorkCover NSW (150 pages), PACIA (55 pages), ACCORD (50 pages). The complexity is also reflected in the nature of the draft Regulation Impact Statement (146 pages).

Consultation meetings for the Regulatory Impact Analysis were conducted in early 2006. This was at a time when no major economy in the world had released a detailed GHS proposal. Further, no analysis of the detail of potential GHS implementation impacts had been conducted by industry or governments at this time – indeed much of this detail continues to emerge.

It will not be possible, nor would it be appropriate, to complete an analysis of costs and benefits, even for the industrial chemicals sector; until Australia's major trading partners have released detailed proposals for GHS implementation.

Australian regulators for consumer products and agricultural chemicals

The regulators considering GHS implementation within frameworks for consumer products and agricultural chemicals (Office of Chemical Safety and Department of Agriculture Fisheries and Forestry) have taken the practical approach of allowing their considerations to be informed by international developments.

A range of significant issues with the GHS remain unresolved. The Informal Paper titled Consumer and Pesticide Chemicals - Potential Implementation Issues for the Adoption of the GHS in Australia, transmitted by the expert from Australia, to the December 2006 meeting of the United Nations Sub-Committee of Experts on the GHS has been heralded internationally as an important and timely identification of GHS implementation issues for specific sectors. The GHS is expected to evolve over a period of time as problems with implementation and other issues become apparent. Early adopters will bear the highest costs.

7.1.4 Who are Australia's major trading partners for chemicals and plastics?

Industry has recommended that regulatory agencies be informed on trade considerations by the Department of Foreign Affairs and Trade (DFAT) and Department of Industry, Resources and Tourism (DITR).

There are different trade classification systems and there is critical need for agreement on classification and data sets. For example, data can been analysed under the Australia New Zealand Standard Industrial Classification (ANZSIC) codes or by trade using a harmonised tariff system – the two are not directly comparable but appear to yield similar relativities.

Industry has undertaken an analysis using the ANZIC codes.

Table 1. Major Sources of Australian Chemicals & Plastics imports and destinations of exports (2005-06)

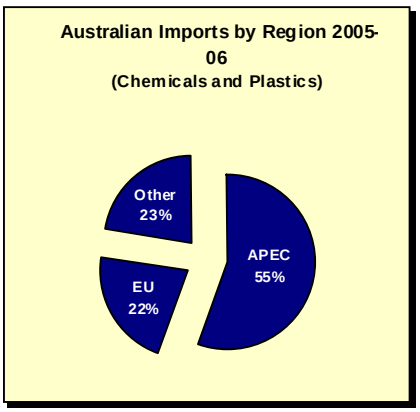
	Source of Imports	$m	%	Exports Destination	$m	%
1	United States	3,088	21.02	New Zealand	804	21.72
2	China	1,553	10.57	China	307	8.30
3	Japan	1,020	6.95	United States	295	7.97
4	Germany	810	5.51	Indonesia	166	4.50
5	United Kingdom	698	4.75	Japan	143	3.87
6	New Zealand	513	3.49	Korea, Republic of	136	3.68
7	Korea, Republic of	476	3.24	Hong Kong	135	3.67
8	Malaysia	427	2.91	India	124	3.37
9	France	419	2.85	Thailand	110	2.97
10	Taiwan	361	2.46	Finland	105	2.86
11	Thailand	325	2.22	Singapore	84	2.27
12	Singapore	302	2.06	United Kingdom	77	2.10
13	Italy	288	1.97	Malaysia	77	2.10
14	Netherlands	197	1.34	Papua New Guinea	72	1.95
15	Belgium	183	1.25	Taiwan	67	1.82
16	Qatar	170	1.16	Viet Nam	57	1.57
17	Indonesia	167	1.14	Philippines	51	1.39
18	Ireland	159	1.08	South Africa	45	1.24
19	India	153	1.05	Netherlands	41	1.11
20	Spain	151	1.03	Pakistan	39	1.06
	Other	3,225	21.95	Other	759	20.49
	Top 10	**9,370**	**63.76%**	**Top 10**	**2,330**	**62.91**
	Top 20	**11,469**	**78.05%**	**Top 20**	**2,945**	**79.51**
	Total	**14,694**	**100.00%**	**Total**	**3,704**	**100.00**

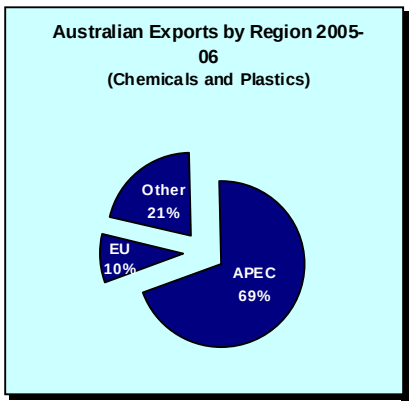
The United States is Australia's largest single country sources of imports at 21.02% and accepts 7.97% of Australia's exports. New Zealand accounts for 3.49% of imports but is Australia's largest export destination at 21.72%

Further analysis of the data identifies that:

- Australia was 0.86% of global trade in chemicals and plastics in 2005-2006
- Australia is a net chemicals importer with imports exceeding exports by a ratio of 4:1
- the 27 countries of the European Union contribute, in total, 21.88% of imports and accept 9.52% of Australia's exports
- North America (Canada, USA and Mexico) accounts for a total of 21.96% of imports and accepts 9.05% of exports (note: Australian chemicals trade with Canada and Mexico is relatively minor at this time)
- The 21 member economies of the Asia Pacific Economic Cooperation (APEC) contribute 55.36% of imports and accept 69.16% of Australia's exports

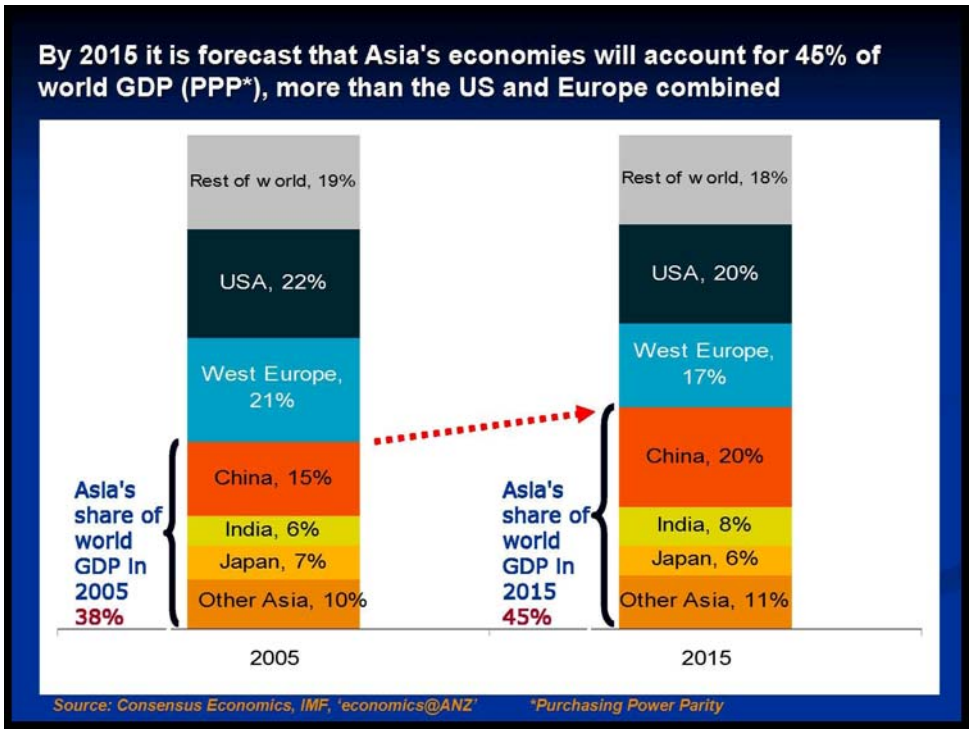
Diagram 1. Australian Imports and Exports by Region 2005-2006





There is also important need for analysis of export and import trends in the chemicals and plastics sectors to position Australia for future market opportunities and trade efficiencies.

Diagram 2. GDP Growth 2005-2015



ACCORD strongly supports industry recommendations to regulatory agencies that information be sourced from DFAT and DITR to establish the context and trends of Australia's trade in chemicals and plastics. This information must inform policy consideration such as whether Australia should align with any individual or regional trading partner(s). It may be that Australia's does not directly align with any individual trading partner but optimises benefits to consider the full range of trade considerations.

7.1.5 What should influence decisions about the timing of the implementation of the GHS? Should Australia wait until the system has been implemented by our major trading partners, or aim to be a leader in adopting the new system?

Australia represents less than 1% of the world's chemicals trade and is a net chemicals importer. Given Australia's trade profile, it is critical that any consideration of GHS implementation locally be informed by developments from our major trading partners. Ongoing dialogue and consultation with trading partners is crucial to *Australia's National Interest.*

The benefits to any country implementing the GHS will be realised only with a high level of co-ordination and harmonization within the affected sectors in major trading partners. No nation can meaningfully implement the GHS in isolation. Consistent approaches to GHS implementation among Australia's trading partners are crucial to realise the benefits of a harmonized system. For Australia, failure to recognise this key imperative could lead to much effort for no gain or negative outcomes and bring the national application of GHS into disrepute.

Australia has a unique opportunity to gain benefits of GHS classification and approaches to communication through labelling and safety data sheets if it phases GHS implementation to follow behind that adopted in major economies and trading partners such as the European Union, North America and other APEC economies. ACCORD made specific recommendations to the 2006/2007 ASCC consultation in this regard. If Australia extended the transition periods for mandatory adoption of GHS by 2 years from whatever becomes an agreed international benchmark then this would allow Australia to benefit from:

- GHS classifications that are undertaken in the major chemical trading nations
- Resolution of major GHS implementation issues
- Avoidance of duplication and inconsistencies
- Avoidance of potential significant costs of 'reworking' as the GHS evolves during implementation

7.1.6 Australian Government hosted informal GHS Roundtable prior to APEC Chemicals Dialogue Meeting, 27 June 2007

The informal GHS Roundtable was attended by participants from 17 of APEC's 21 member economies. The common issues identified at the Roundtable were:

- Timing of implementation (progress by APEC economies)
- Scope of implementation (GHS hazard classes/categories)
- Transition periods *(single substances/mixtures and whether or not co-existence of current and GHS classified/labelled chemicals during transition within national schemes)*
- Means for trade facilitation during transition periods
- GHS classifications (*measures to avoid duplication and promote consistency, concept of guidance classification lists)*
- Chemical sector issues (hazard and risk-based approaches)
- Opportunities for mutual recognition (*vs full harmonization*)
- Training, outreach and awareness raising

These issues were formally report to the APEC Chemicals Dialogue meeting of 28 June

2007 in Cairns. The Chemical Dialogue agreed to establish a small group within the Friends of the Chair process to identify implementation issues and determine a work plan for addressing these. Australia agreed to coordinate the group. New Zealand, Chinese Taipei, and the United States volunteered to join the group. Economies were asked to consult internally and contact the secretariat with their point of contact for the group. The group will operate virtually, work with the APEC Secretariat to enhance the utility of information on GHS for member economies, and prepare a report and recommendations for consideration by the CDSG at SOM I 2008 (to be held in Peru in late February 2008). Issues for consideration by the group are to include:

- Information update mechanisms;
- Ways of addressing the diversity in transitional periods, processes and phasing, with the prospect of mutual recognition of systems during the transitional process; and,
- Standardized approaches to capacity building, including how to respond to unintended differences in approach.

This was a very positive development and industry welcomes the opportunity to participate in this important process.

7.1.7 Should the GHS be implemented across all sectors of the chemicals and plastics industry, including agricultural and veterinary chemicals and scheduled drugs and poisons?

The official GHS indicates states that "pharmaceuticals, food additives, cosmetics, and pesticide residues in food will not be covered by the GHS in terms of labelling at the point of intentional intake.

The schemes for regulation of hazardous substances, agricultural/veterinary chemicals and consumer products have different approaches to who conducts the risk-assessment and to communication with end-users:

- The Hazardous Substances regulatory approach is based on hazard classification and hazard communication which is appropriate for substances which may have diverse uses. Under this scheme risk-assessments are legally required to be conducted in the workplace and based on the particular circumstances of use.
- The Agricultural and Veterinary Chemical Products regulatory approach provides a higher, and appropriate, level of regulatory intervention whereby the risk-assessment for these defined-use products is part of the registration and approval process. The agricultural and veterinary product label is the culmination of the risk-assessment, exposure assessment, risk-characterisation, risk-management and risk communication for the product.
- The Consumer Products regulatory approach provides for notification and assessment of substances by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and risk-assessment, risk management and risk communication through the regulatory intervention of the National Drugs and Poisons Schedule Committee (NDPSC) and the adoption of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) by the States and Territories

In Australia, the proponents for hazard-based approaches, such as adopted in the hazardous substances chemical regime, argue that all chemicals and chemical products should be hazard labelled i.e. one rule for all. This is neither supported by the regulators for consumer products, agricultural chemicals nor industry.

WARNING
KEEP OUT OF REACH OF CHILDREN
PLEASE READ THE LABEL COMPLETELY BEFORE USE

RIDOMIL® GOLD 2.5G

FUNGICIDE
Active Ingredient: RIDOMIL Gold 2.5G contains 25 g/kg METALAXYL-M in the form of a granule.
For the control of Phytophthora Root Rot in Avocados and Phytophthora Spear Rot in Asparagus.

Net Contents: 10 kg

Registered pursuant to the ACVM Act 1997, No. P 3160.
See www.nzfsa.govt.nz/acvm/ for registration conditions

Approved pursuant to the HSNO Act 1996, Approval Code HSR000484.

Syngenta Crop Protection Limited
Tower 2, Level 7, 110 Symonds Street, Auckland

In a transport emergency dial 111, Police or Fire Brigade.
For specialist advice in an emergency only, call 0800 734 607 (24 hours).

UN-Free

This product MUST NOT be used for any purpose or in any manner contrary to the controls and conditions of this registration.

HSNO Classification 6.4A, 6.9B, 9.1D

WARNING
May cause eye irritation.
May cause liver damage from repeated oral exposure at high doses.
Harmful to aquatic organisms.

PRECAUTIONS
Store in original container, tightly closed, away from foodstuffs.
When mixing or applying wear protective clothing, including overalls, gloves and footwear.
Avoid contact with skin and eyes, and inhalation of dust.
If clothing becomes contaminated with product, remove clothing immediately.
DO NOT eat, drink or smoke while using.
Wash hands and face before eating, drinking or smoking and after work.
Wash protective clothing daily after work.
Apply with well-maintained and calibrated spray equipment.
Application and storage should be as described in the Management of Agrichemicals NZS8409.
DO NOT carry on a passenger service vehicle.
Avoid contamination of any water supply with chemical or empty container.

Container disposal: Ensure the container is empty. If allowed under local Territorial Authority District Plans, burn if circumstances, especially wind direction permit, otherwise crush and bury in an approved local authority facility. DO NOT reuse this container for any other purpose.
Product disposal: Dispose of this product only by using according to the label, or at an approved landfill or other approved facility.

For agricultural chemical products, users would be trying to second guess the expert risk-analysis undertaken by the agricultural chemicals regulator.

Examples are known from New Zealand where hazard based approaches lead to confusing labelling. A sample label for the agricultural product Ridomil® Gold 2.5G Fungicide is provided as an Appendix to the *Product Labelling & Documentation Guide for Agricultural Compounds & Veterinary Medicines (Approved Code of Practice under HSNO Act 1996 and ACVM Act 1997 HSNO Approval Code: HSNOCOP 9-1)*
http://www.agcarm.co.nz/Document.aspx?Code=1a6372d9-9d4a-4943-8d54-7384e7ad736c

The product is a granule formulation containing 2.5% of the active ingredient.

The label contains the exploding human pictogram and the following statement under the WARNING heading: "May cause liver damage from repeated oral exposure at high doses".

The clear message from the label is not to repeatedly eat high doses of the product. But in the practical use of the product it would be unusual for any worker to contemplate such an activity. The key considerations for agricultural spray operators would be dermal and inhalation exposures. Repeated ingestion of "high doses" is not an occupational exposure.

Hazard-based labelling for products with *defined uses,* such as agricultural chemical products, - *users need to determine <u>what is irrelevant on the label</u> …rather than start from the premise that all information on the label is important.*

There is clearly the danger that users would come to regard certain pictograms (e.g. the exploding human) as irrelevant from experiences where the hazard identified had little or no relevance to the use scenarios for defined use products.

If the workplace hazardous substances model was followed for consumer products then every householder would need to conduct individual risk-assessments for every cleaning product, laundry detergent, dishwash liquid and other household products that they purchase from the supermarket. This is neither practical nor desirable. Consumer product labels need to contain clear and concise information to allow safety-in-use.

> *"It is reported that cluttered, difficult to read labels, containing superfluous warnings that are outside the experience of typical consumers reduces the likelihood of consumers' understanding of and adherence to warranted labels"*
>
> (ILO/HC6/00.13 21.09.2000)

7.1.8 Is there a need for more extensive use of a risk-based approach to regulation in parts of the system? How can such an approach be integrated with future adoption of the hazard based Globally Harmonised System

GHS labelling implications for industrial "products" need special consideration. *Products* are different from *raw materials* and bulk commodity chemicals in trade and use in manufacture as the former have *defined uses*.

An example might be a cleaning product used that is used in the workplace by janitorial staff (and requires labelling as an industrial chemical). If the product contains ethanol (ethyl alcohol – also present in all alcoholic beverages) at a concentration of >0.3% then the label, according to the GHS, may be required to bear the following information and pictogram:

Signal Word: DANGER

Pictogram: Exploding Human (Health Effects)

Label Statements: May damage fertility or the unborn child (state specific effect if known) (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)

This type of labelling for industrial 'defined-use' products presents the same types of communication problems as described in section 7.1.7 above. Once users become aware that the product contains an ethyl alcohol content of less than many brands of low-alcohol beers (beer typical 4-5% alcohol by volume and wine 10-15% alcohol by volume) then its seems likely that such label information would fall into disrepute.

The above example identifies the inadequacy of only considering hazard for *defined use* products and how this may lead to miscommunication of relevant information to users.

7.1.9 Recommendations on the Globally Harmonised System for Classification and labelling of Chemicals (GHS)

Australia has the opportunity to maximise the benefits and minimise the costs of the GHS through its implementation strategy. ACCORD strongly recommends that the Productivity Commission supports the following recommendations:

- the Department of Foreign Affairs and Trade (DFAT) and the Department of Industry Tourism and Resources (DITR) provide advice to Australian government regulators of the chemicals and plastics industry on Australia's trade profile and emerging trends
- DFAT and DITR be actively engage in the development of Australian implementation strategies for the GHS
- further considerations on Australian GHS implementation to be informed by developments in Australia's major trading partners
- acknowledgement be given that Australia's National Interest will be best served through trade facilitation and efficiencies that timely and appropriate GHS implementation may offer
- Australia maintain an active role in the APEC Chemicals Dialogue to promote trade facilitation from GHS implementation within the 21 APEC economies
- acknowledgement be given that Australia's currently developed regulatory regime for chemicals and plastics is comparable to those in other developed countries

- the Productivity Commission endorses the principle that Australia adopt GHS implementation transition periods that are beyond major chemical trading economies thereby allowing efficiencies and cost-effective benefits to be realised
- the Productivity Commission supports the development of an Australian government/ industry workplan that:
  - involves government and industry in a partnership approach
  - addresses the individual chemical sector needs and issues
  - is progressively informed by international developments
  - recognises and provides input on Australian views to international fora, such as the APEC Chemicals Dialogue and the UN Sub-committee of Experts on the GHS
  - ensures efficiency, avoids duplication, enhances trade, and promotes consistency with international progress such as in the area of GHS classifications
  - follows behind the transition timetable that becomes established as relevant by Australia's major trading parttners
  - explores opportunities for mutual recognition (vs full harmonisation)
  - provides for broad training, outreach and awareness raising

7.2 Chemical risk and hazard assessment processes

The GHS identifies hazards as properties arising from the intrinsic properties of chemical elements, compounds and mixtures thereof, whether natural or synthetic. Hazard properties are independent of factors such as geographic location.

All regulatory approaches (hazard-based or risk-based) consider the hazard properties of chemicals, compounds and mixtures.

Risk analysis is a framework for higher level consideration for identification and characteristation of hazards, exposure assessment, risk characterization, risk management and risk communication. A simplified risk-analysis framework was identified in section 7.1.1 of this submission.

Chemical hazard properties, based on accepted testing methodologies, have the potential to be universally used around the world – because the intrinsic properties do not change. Where the use of a chemical, compound or mixture is the same or similar in one location to another location then it may be valid to fully accept a risk assessment developed under with comparable standards.

National efforts need to focus on acceptance of testing methodologies from other jurisdictions. There is also need to allow free-trade of products that are considered to be of low regulatory concern, without further regulatory intervention on labelling, for products such as cosmetics and fast moving consumer goods.

There are currently other non-science factors that may impose on the ability for transmittance of information from one country to another. Such factors may include intellectual property rights, treatment of commercial-business-information, the nature of reports that may be prepared by regulatory agencies, and other factors. Despite any philosophical desire for increased sharing of information, the fundamental incentive for innovation through intellectual property rights, including as defined under the World Trade Organisation, must be respected.

7.3 Role of mutual recognition

Mutual recognition arrangements (MRA) can be extremely valuable vehicles to reducing regulatory impediments to goods and services mobility across jurisdictions. The Productivity Commission's (PC) Research Report, 8 October 2003 Evaluation of the Mutual Recognition Schemes found that the effectiveness of the MRA would be enhanced by undertaking an awareness program on the obligations and benefits of mutual recognition, aimed at regulators, policy advisers and relevant industries and professions. ACCORD supports this finding from the PC Research Report and would encourage all jurisdictions to undertake training and provide information to better inform regulators and policy makers as well as to encourage better take up of the MRA provisions by industry.

ACCORD notes that the federal government has not as yet released its response to the PC Research Report of 2003. This brings into question the Government's commitment to MRA and the Trans Tasman Mutual Recognition Arrangements (TTMRA). The chemicals sector is currently exempt from TTMRA but we believe that effort is required by regulators on both sides of the Tasman to overcome perceived obstacle regarding the trade in chemicals. Again we bring into question why Australia requires a notification and assessment scheme for all chemicals whereas New Zealand has a more pragmatic approach without any detriment to environment, or public health and safety.

Since the Australian Government finalised its reforms to cosmetic at the therapeutic interface and New Zealand introduced the Cosmetic Products Group Standard, the regulatory controls for cosmetic products are now much more closely harmonised and there is a strong case for TTMRA to apply to this class of goods. This would at least be one good outcome which could be achieved.

While we note that COAG has put out an excellent document to assist in understanding the MRA process, this was only by accident and we would be surprised if there is much benefit being realised to industry at this stage. The document needs to be promoted more effectively if it is to be of any benefit.

8 Regulation of security sensitive ammonium nitrate

All governments through the COAG process have been working with industry on the matter of national security and the identification of a process for the control of chemicals of interest. While ACCORD supports work in this important area, it is important for governments to adopt a national approach to the problem and to learn from past mistakes.

The need for a national approach was highlighted recently by the failure of governments to introduce regulations for the control of ammonium nitrate. The controls for ammonium nitrate are not nationally uniform and this will result in unnecessary costs to industry by the failure all government's to implement the decision they reached in June 2004 regarding the control of this substance. This has been identified by all stakeholders as a significant failure of the system since it now forms part of the terms of reference for the PC Study.

From industry's perspective it is important that a nationally uniform approach be adopted by all governments and that excessive costs arising from the implementation of any national scheme are not passed onto the chemicals industry. As this is a matter of significant national interest it is an area where industry would expect governments to contribute to the costs. In addition to our comments, ACCORD supports the views put forward by PACIA on this important issue.

9 Conclusion

As can be seen from ACCORD's submission, there are many examples of either poorly designed regulation or overregulation resulting from lack of risk management which our Members are subject to on a daily basis. There appears to be no will to tackle these issues on a whole-of-government basis and reforms are undertaken on an ad hoc piece meal process, some of which have lead to benefits.

The initial success of the NICNAS LRCC reforms was on the basis that industry was fully engaged in process and that the entire reform from inception to implementation took only two years. There was a real commitment for change from all stakeholders.

The fact that now many of the so called wins appear to have been lost is another matter – the important point is that to effect any real change, stakeholders must be involved in the process from the very beginning. Perhaps the failure of LRCC to deliver on it promise also lies partly with industry since we did not continue to engage with NICNAS in an ongoing dialogue.

ACCORD believes that the regulatory environment for chemicals could be addressed through the effective utilisation of existing government governance and accountability measures. If government policy makers and regulatory agencies adopted the following approaches, we could see significant improvement in the regulatory framework without a cost burden on either government, industry or the consumer.

While ACCORD has argued that it is time to revisit the fundamental structure of Australia's regulatory infrastructure for chemicals, we believe that through the rigid application of existing government processes much can also be achieved. We therefore re-iterate our earlier points regarding the need for government policy makers and regulatory agencies, regardless of their regulatory structure, to apply existing government policy in all their dealings with industry, in particular the:

- adoption and commitment to COAG Principles by all regulatory agencies from which ever jurisdiction be it federal, state or local involved in chemicals regulation
- adoption and application of risk assessment and management to regulatory decision making
- commitment to cultural change and adoption of whole-of-government reform strategies by regulatory agencies
- development of centralised policy making body
- proper understanding of respective roles and responsibilities of all decision makers within the regulatory framework; and
- mutual recognition of assessments and adoption of international risk based approaches to product labelling.

Attachment 1

List of ACCORD Member Companies

September 2007

Members

Consumer, Cosmetic and Personal Care:

Advanced Skin Technology Pty Ltd
Alberto Culver Australia
Amway of Australia Pty Ltd
Apisant Pty Ltd
Aroma Science
AVON Products Pty Limited
Baylor Limited
Beiersdorf Australia Ltd
Chanel Australia
Clorox Australia Pty Ltd
Colgate-Palmolive Pty Ltd
Combe International Ltd
Cosmax Prestige Brands Australia Pty Ltd
Coty Australia Pty Limited
Creative Brands Pty Ltd
Dermalogica Pty Ltd
Elizabeth Arden Australia
Emeis Cosmetics Pty Ltd
Estée Lauder Australia
Frostbland Pty Ltd
GlaxoSmithKline Consumer Healthcare
Helios Health & Beauty Pty Ltd
Innoxa Pty Ltd
Johnson & Johnson Pacific
Kao (Australia) Marketing Pty Ltd
Keune Australia
Kimberly Clark Australia
La Biosthetique Australia
La Prairie Group
L'Oreal Australia Pty Ltd
LVMH Perfumes and Cosmetics
Mary Kay Australia Pty Ltd
Nutrimetics Australia
NYX Pty Ltd
Procter & Gamble Australia Pty Ltd
PZ Cussons Pty Ltd
Reckitt Benckiser
Revlon Australia
Scental Pacific Pty Ltd
Schwarzkopf
Shiseido (Australia) Pty Ltd
Thalgo Australia
The Heat Group Pty Ltd
The Purist Company Pty Ltd
Tigi Australia Pty Ltd
Trilogy Products
Trimex Pty Ltd
Ultraceuticals
Unilever Australasia
YSL Beaute

Hygiene and Specialty Products

Albright & Wilson (Aust) Ltd
Applied Australia Pty Ltd
BP Castrol Australia Pty Ltd
Callington Haven Pty Ltd
Campbell Brothers Limited
Castle Chemicals Pty Ltd
Chemetall (Australasia) Pty Ltd
Chemform
Ciba Specialty Chemicals
Clariant (Australia) Pty Ltd
Cleveland Chemical Co Pty Ltd
Deb Australia Pty Ltd
Dominant (Australia) Pty Ltd
E Sime & Company Australia Pty Ltd
Ecolab Pty Limited
Henkel Australia Pty Limited
Huntsman Corporation Australia Pty Ltd
Jalco Group Pty Limited
Lab 6 Pty Ltd
Milestone Chemicals Pty Ltd
Novozymes Australia Pty Ltd
Nowra Chemical Manufacturers Pty Ltd
Peerless JAL
Recochem Inc
Rohm and Haas Australia Pty Ltd
Solvay Interox Pty Ltd
Sonitron Australasia Pty Ltd
Sopura Australia Pty Ltd
Tasman Chemicals Pty Ltd
Thor Specialties Pty Limited
True Blue Chemicals Pty Ltd
Whiteley Corporation Pty Ltd

ACCORD
Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry

Associate Members

Specialist Laboratories and Testing

ams Laboratories

Dermatest Pty Ltd

Silliker Microtech Laboratories Pty Ltd

Equipment and Packaging Suppliers

EquipNet Inc.

HydroNova Australia NZ Pty Ltd

SCHÜTZ DSL Group Pty Ltd

Logistics

Star Track Express Pty Ltd

Legal and Business Management

Fisher Cartwright Berriman

Middletons Lawyers

PricewaterhouseCoopers

Regulatory and Technical Consultants

Archer Emery & Associates

Cintox Australia Pty Ltd

Competitive Advantage

Engel Hellyer & Partners Pty Ltd

Robert Forbes & Associates

Sue Akeroyd & Associates

Attachment 2

Worldwide Registration Cost Comparisons

Table 2. Worldwide Registration Cost Comparisons

Data item	Australia	Korea	USA	Japan		EU	Canada	Philippines	China
National Inventory	AICS	KECI/ TCCL	TSCA	(Controlled under ISHL)	ENCS (Controlled under CSCL)	ELINICS (moving to REACH)	DSL	PICCS	IECSC
Volume (per year)	>1 tonne	<1 t/>1t	Unlimited	<100 kg/100 kg	<1 t / >1t	1-10 tonne	Unlimited	<1 t/>1t	<10 tonne
Government Application Fee	14418 AUD	KRW 50,000/100,000	2,500 USD	No	No	5,165 EURO (ELINCS) (REACH fees not set)	3,500 $Cdn	P 3750	Notification registration fee
Government Application Fee $AU	$14,418	$61/122	$2,797			$8,227	$4,025	$95	$?
Exempt Information Fee $AU	633 AUD	None	None	None	None	None	None	None	None
Variation of Data Requirements (if needed)	1140 AUD	None	None	None	None	None	None	None	None
Timing (mth) Consolidate / submit Government Screening, Assessment, Review	3	6	4	3 / 7	1/18 ENCS listing 18-36	10-12	2.5	3-6	4
Polymer exemptions	Not exempt	Not exempt. Reduced requirements	Exemptions	Exemption under certain conditions if covered by CSCL	No exemption. Reduced requirements	Registration not required	RRR (Recuced Regulatory Requirement)	Exempt	Reduced requirements, 1 mth review

- The timeframes indicated are based on no clock stops or concerns raised by competent authorities, i.e., EPA in US
- The EU timing and costs covers all member states incl. UK. However Switzerland is not covered and a separate notification is necessary. EU tests are sufficient. We suggest to submit after the EU approval is available, because then both fee and review in Switzerland are reduced (CHF 6'500, 30 days).

ACCORD

Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry

Attachment 3

Analysis of Pre-market Cost for Australia on Same Products in Different Existing TGA Regulations Categories

Table 3. Analysis of Pre-market Cost for Australia on Same Products in Different Existing TGA Regulations Categories

Product Category	Intact Skin Wash/ Surface Sanitiser	Hospital Grade Disinfectant	Antibacterial Handwash
Category	Medicine (Listed) or exempt good	Device (Listed)	Medicine (Registered)
Active Material	70% Ethanol (v/v)	70% Ethanol (v/v)	70% Ethanol (v/v)
Excipients	water + nil	up to five	up to five
Pre-market Microbiology	Nil	Yes	Yes
tests applicable & cost	Nil	TGA Dis Test	BS 1500
		$1,000	$6,500
		AOAC-HSCT	BS 1499
		$1,500	$6,500
			TGA Dis test Option D
			$500
# of tests req'd premarket		1 each	up to 2 of each
			Each test is independent
			No test pass in any one
			As a predictor of
			passing another
pre-mkt Cost	Nil	$2,500	$27,000
Stability data?	Nil & post mkt	3 months & post mkt	minimum 12 months
			Must be pre-market
			& includes degradation
			products as per PIC
			guidelines from TGA
Pre-mkt Cost	Nil	$1,250	$30,000
Validation of assays	only one test	Only on active	active plus all excipients
			Must be pre-market
Pre-mkt Cost			
active	$5,000	$5,000	$10,000 +$500x2
			i.e. $11,000
excipient	Nil	Nil	($7,000+$500x2)x5
			i.e. $40,000
TGA Lodgement Fee	$360	<$1000	Approx $10,000 for
			application and
			assessment fee
Consultants Assistance	Nil	Nil	Approx $7,000
Manufacturing Conditions/License	GMP	Nil	GMP
Estimated Pre-market Cost	$5,360	$9,750	$125,000
Estimated Hours for Preparation	10 Hours	25 Hours	>600 Hours

Attachment 5

ACCORD Supplementary Submission to the PC study on chemicals and plastics regulation

January 2007

ACCORD

Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry

Mr Mike Woods
Commissioner
Chemicals and Plastics Regulation Study
Productivity Commission
Locked Bag 2
Collins St
EAST MELBOURNE VIC 8003

Dear Mr Woods

Productivity Commission Study into Chemicals and Plastics Regulation

I am pleased to provide ACCORD's supplementary submission to the Productivity Commission (PC) study in response to the request for additional information following the roundtable discussions on chemicals and plastics regulation held in Canberra in December 2007.

In particular, the PC advised that it would like to receive further information that relates to any of the matters that arose from the roundtables, including:

- Data on the effectiveness and efficiency of the current chemicals and plastics regulatory system
- Institutional arrangements that could improve the efficiency and effectiveness of chemicals and plastics regulatory frameworks
- Opinions on the GHS, including the timing of Australia's implementation of the system
- The existence of 'gaps' in the chemicals and plastics regulatory system (for example, in environmental regulation)

To provide the PC study with quantitative data on the effectiveness and efficiency of the current chemicals regulatory system, ACCORD undertook a survey of our entire membership.

The survey explored issues based on previous concerns raised by members to determine the full extent of these concerns across the broad spectrum of membership and to quantify the impact on their business operations where possible. In addition, the survey built on a number of case studies to further highlight issues faced by members in their dealings with the chemical regulator, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). The full results of the Member survey and survey instruments are at Attachment 1 to this submission.

The survey consisted of two parts, the first collecting data broadly, in areas relevant to all industry members.

The second part asked targeted questions of key members in a range of supply chains to identify the:

- lost opportunities - the impact of the current regulatory system on the realisation of commercial opportunities;
- effectiveness or otherwise of NICNAS' Low Regulatory Concern Chemicals Regulatory Reforms (LRCC), and;
- operational performance of the Regulator.

Member interaction with NICNAS was chosen because for ACCORD's membership this is the one Commonwealth regulator which they have the most interaction with in their day to day operations. Therefore the results highlight the difficulties encountered by ACCORD's membership of only one element of the regulatory scheme and do not take into account the complexity and interaction of the other Commonwealth regulators and/or the intersection of other regulatory requirements such as dangerous goods, hazardous material, waste disposal nor even seemingly innocuous tasks such as packaging and labelling.

The main findings of ACCORD member survey are:

- Ninety-three percent (93%) 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/reformulated 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 fifty percent (50%) 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 (in terms of products being unavailable on the Australian market) is $400 million.
- The current regulatory system is biased towards larger companies (companies with a turnover of greater than $10 million).

While members have raised serious concerns about the impact of NICNAS processes on their day to day operations, it would be fair to say that the recent reform to products at the cosmetic/therapeutic interface are anticipated to deliver real benefits in both compliance costs and time to market. While ACCORD Members noted that the delay in passing the legislation, i.e. it was first announced in November 2005 and legislation was passed in September 2007, was estimated to have cost a $21M loss in sales per annum, it can also be argued that industry stands to gain from reduced evaluation fees, no therapeutic Good Manufacturing Practice requirements and subsequent medicinal-level auditing for certain products now regarded as cosmetic. These changes now have the potential to deliver savings and reduce complexity.

The PC also sought additional information on the GHS, including the timing of Australia's implementation of the system. This information is provided at Attachment 2. Of interest to the PC study is meeting between the Government-led GHS Roundtable Group and DFAT on 7 February 2008 to discuss a study to assist to inform GHS implementation from a trade perspective. Industry has prepared a draft briefing document for the meeting and a copy is included for the PC's information. We believe that the results of the trading partner analysis will be useful to this study, however at this stage there is not a finalisation date for this project.

ACCORD reiterates previous statements regarding implementation of the GHS. Australia should not move ahead of its major trading partners. Instead the Australian Government should take advantage of the opportunity to maximise the benefits and minimise the costs of the GHS through the development of Australia's implementation strategy. ACCORD strongly recommends that the PC supports the engagement of the Departments of Foreign Affairs and Trade (DFAT) and of Innovation, Industry, Science and Research (DIIRS) in the development of Australian implementation strategies for the GHS as discussed in Attachment 2.

Regarding the request for further information on future institutional arrangements that could improve the efficiency and effectiveness of the regulatory system, ACCORD is pleased to inform the PC that the Chemicals and Plastic Leadership Group (CPLG) has engaged the Deloitte's Insight Economics consultancy to assist it in investigating such improvements and how they can be best delivered. The CPLG is to present its suggested framework for commencing these improvements to the PC via a presentation session which will be arranged shortly.

ACCORD would like to thank the PC for the opportunity to provide this additional information which we believe will greatly assist the study with regard to demonstrating in very real terms the burden of regulation for the chemicals sector in Australia.

Should you require any additional information about the matters addressed in our supplementary submission the contact officer is Ms Dusanka Sabic on 02 9281 2322 or email dsabic@acord.asn.au.

Yours sincerely

Executive Director

21 January 2008

ATTACHMENT 1

Productivity Commission Study of the Regulatory Burden on the Chemicals Industry

Report of ACCORD Industry Survey on the impacts and costs of regulation

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Appendix 1 Member list at time of survey

Appendix 2 Survey Part 1

Appendix 3 Survey Part 2

Appendix 4 *Table 2. Worldwide Registration Cost Comparisons*, from page 49 of ACCORD's Submission to the Productivity Commission Study into Chemicals and Plastics Regulation

1 The ACCORD Survey: purpose and background

This Survey was initiated to collect impact and cost data related to the regulatory burden on the formulated chemicals industry along with illustrative case studies based on company experiences.

This Survey Report has been prepared by ACCORD as an important supplementary report to the Productivity Commission study of chemicals and plastics regulation.

Its genesis goes back to early 2007, when ACCORD members started to consistently flag specific concerns relating to the performance of our sector's key regulatory agency, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS).

It is for this reason that the Survey focuses primarily on issues relating specifically to NICNAS matters.

However, ACCORD feels that these are indicative and illustrative of many of the problems and issues encountered throughout Australia's complex and confusing system of chemicals and plastics regulation. As such the Survey findings highlight a range of key issues that could in essence be considered the tip of the iceberg.

Prior to deciding to initiate a Survey, ACCORD scoped the major concerns regarding aspects of NICNAS operations via discussions with the company specialists in our Regulatory Affairs Committee.

This culminated in a joint workshop with PACIA and ACCORD members on 4 October 2007 to further scope out the main problems being experienced by companies with NICNAS operations.

As an outcome of this workshop, ACCORD decided to develop and issue a detailed Survey to member companies to formally collect information. This was to be used both in direct discussions with NICNAS and also to provide additional data in support of the industry's submissions to the Productivity Commission study.

The survey consisted of two parts, the first collecting data broadly, in areas relevant to all industry members.

The second part asked targeted questions of key members in a range of supply chains to identify the:

- lost opportunities - the impact of the current regulatory system on the realisation of commercial opportunities;
- effectiveness or otherwise of the Low Regulatory Concern Chemicals Regulatory Reforms (LRCC), and;
- operational performance of the Regulator.

2 Key findings of the Survey

- Eighty-nine percent (89%) of ACCORD industry and regulatory consultant members responded to the ACCORD Industry Survey.
- Ninety-two percent (92%) of survey participants having experience with NICNAS reported negative impacts from this association.
- Ninety-three percent (93%) 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/reformulated 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 fifty percent (50%) 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 (in terms of products being unavailable on the Australian market) is **$400 million**.

- The current regulatory system is biased towards larger companies (companies with a turnover of greater than $10 million).

- Thirty-six percent (36%) of larger companies 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 five percent (5%) of smaller companies (turnover less than $10 million).

- Sixteen percent (16%) of larger companies were still prepared to pursue Australian market entry despite saying that regulatory costs in Australia were too high, compared to nil for smaller companies.

- In around fifty percent (50%) of cases where a company has the opportunity to self assess through the LRCC initiative, they choose not to do so, for reasons such as onerous auditing requirements.

- 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 thirty-eight percent (38%) 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.

3 Overview

The Productivity Commission (PC) has indicated that particular value would be placed on industry-wide impact and cost data related to the regulatory burden on the chemicals industry. As a representative of a significant sector of the chemicals industry, ACCORD developed a survey to collect data and costs from its members.

ACCORD Australasia is the peak national industry association that represents the manufacturers and marketers of formulated consumer, cosmetic, hygiene and specialty products, their raw material suppliers, and service providers.

With an estimated $10 billion plus in annual product sales, the formulated consumer, cosmetic, hygiene and specialty products industry is a significant part of a prosperous Australian economy. It is a dynamic and growing industry, employing Australians and - through our industrial and institutional sector - supplying products essential for Australian businesses, manufacturing firms, government enterprises, public institutions, farmers and consumers. Our industry has more than 50 manufacturing operations throughout Australia and member companies include large global consumer product manufacturers to small dynamic Australian-owned businesses.

ACCORD, on behalf of its member companies, has a specific and direct interest in the Productivity Commission's (PC) study. In particular it looks forward to recommendations for reform for the establishment of an effective and efficient governance framework for the chemicals sector.

ACCORD has been promoting the need for a fully integrated national framework for chemical policy and management for a considerable period and regards this as a high priority.

This Survey indicated that regulatory impacts were related in large part to Australia's unique regulatory system and that inefficiencies delivered cost burdens resulting in a business operating environment which stifled competitiveness and innovation.

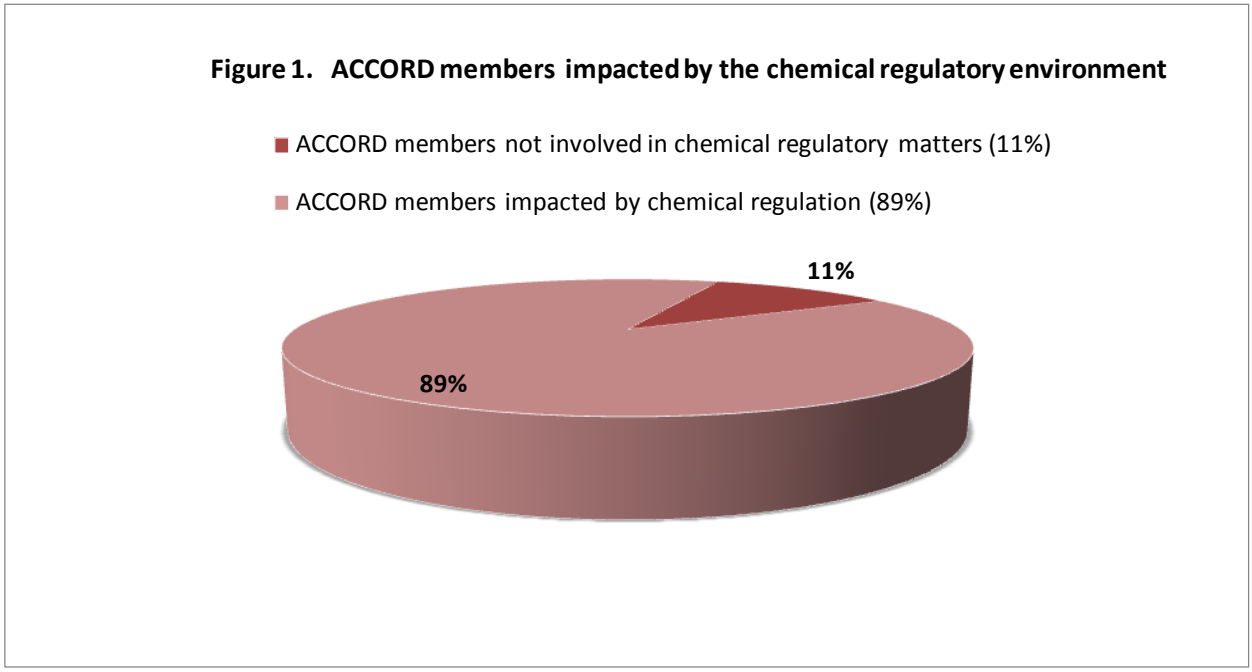
The ACCORD Industry Survey had two parts.

In the first part a general, broad ranging survey was made of the membership body to ascertain NICNAS regulatory burdens and consequences.

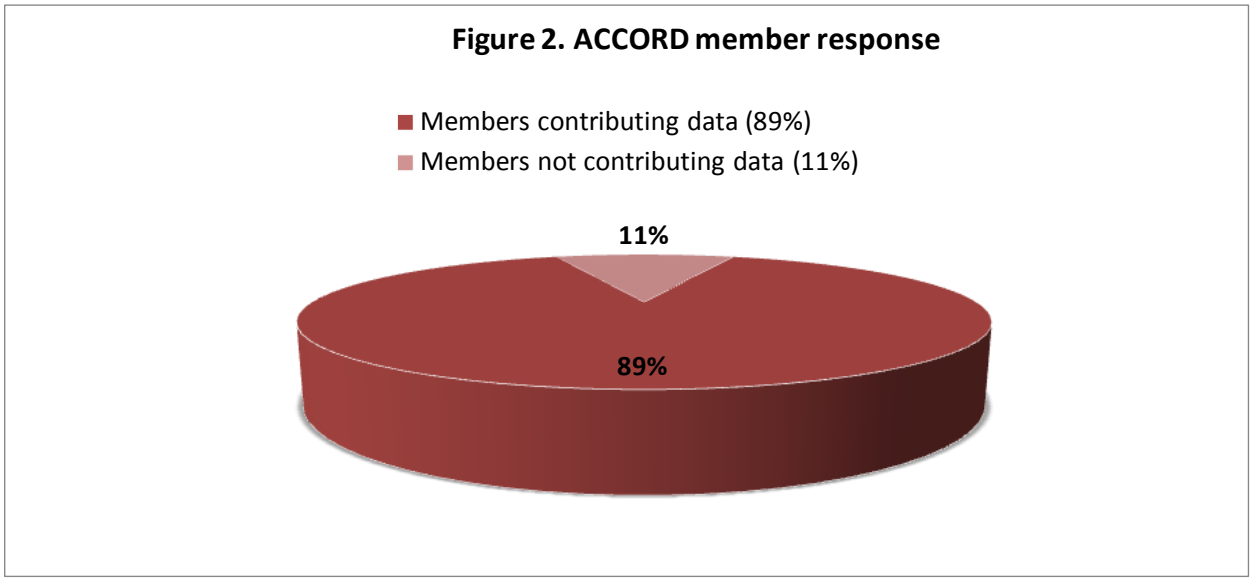
In the second part of the survey more detailed questions were put forward. A smaller number of targeted member companies participated in this part and considered issues of lost opportunities, the effectiveness or otherwise of LRCC Regulatory Reforms and the operational performance of the regulator.

4 Survey participation

At the time of this survey (November 2007) ACCORD had 99 members. Of these, 11 are not involved in chemical regulatory matters and therefore were not invited to participate in data collection. These are associate members operating in the areas of: specialist laboratories and testing; equipment and packaging supply; logistics and; legal and business management. The 88 members asked to contribute to the survey are from: the Consumer, Cosmetic and Personal Care industries (50 members); the Hygiene and Specialty Products industries (32 members) and; the Regulatory and Technical Consultant sector (six associate members). Figure 1 represents the proportion of members impacted / not impacted by chemical regulatory matters.



Of the members asked to contribute to Part 1 of the industry survey, 78 of the 88 responded (see Figure 2). The findings are therefore considered to be highly representative of the complete ACCORD membership.

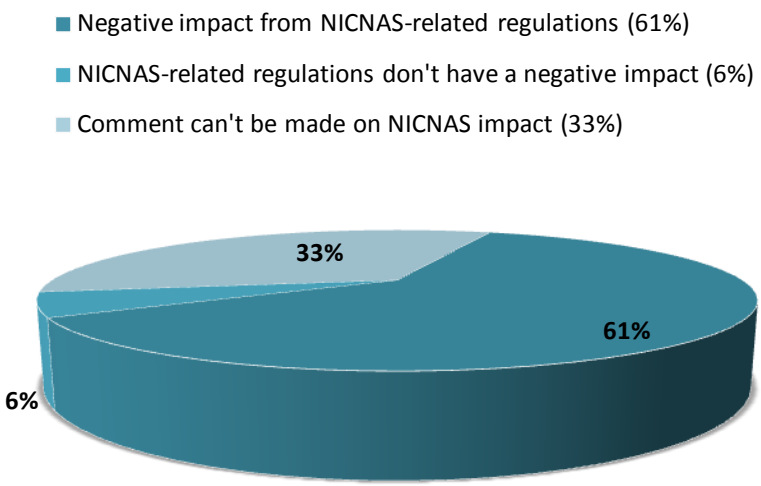


Part 2 of the survey was targeted to a smaller subset of companies and represented a good cross section of the ACCORD membership base.

5 Part 1: Survey of broad ACCORD membership on regulatory burden

Of the 72 chemical industry members contributing data, 44 reported a negative impact from NICNAS-related regulation, four reported no negative impact and 24 reported that they couldn't comment on NICNAS current activities (see Figure 3).

Figure 3. NICNAS regulatory impact



The main reasons members gave for being unable to comment on NICNAS were that their company formulates and/or distributes products with materials already listed on the Australian Inventory of Chemical Substances (AICS) and/or that they consider raw material suppliers responsible for listings.

It is considered very likely that some of these companies only market products with ingredients currently listed in the Australian Inventory of Chemical Substances as a way of avoiding the regulatory burden associated with listing and that therefore the negative findings expressed in this Survey underestimate the overall level of negative impact across the industry.

Four charts follow, showing the consequences of the regulatory burden, and the causes and factors involved, as given by respondents. Respondents may have reported multiple causes and consequences. The data is reported in the charts as a proportion of the overall 44 negative findings.

Three members reported that their company policy not to get involved with NICNAS applications was due to a perception that the process was too difficult and expensive. These companies had not completed any NICNAS applications but made their decision following attendance at NICNAS seminars and from discussions they had with other industry people. This indicates a need for greater and clearer guidance from NICNAS, a factor mentioned in 14 percent of cases.

ACCORD has continually argued that the Australian and New Zealand markets are too small to create and sustain a unique regulatory regime which is out of step with our major trading partners.

An overwhelming 93% 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.

The regulatory system was also seen as a barrier to innovation by 59%.

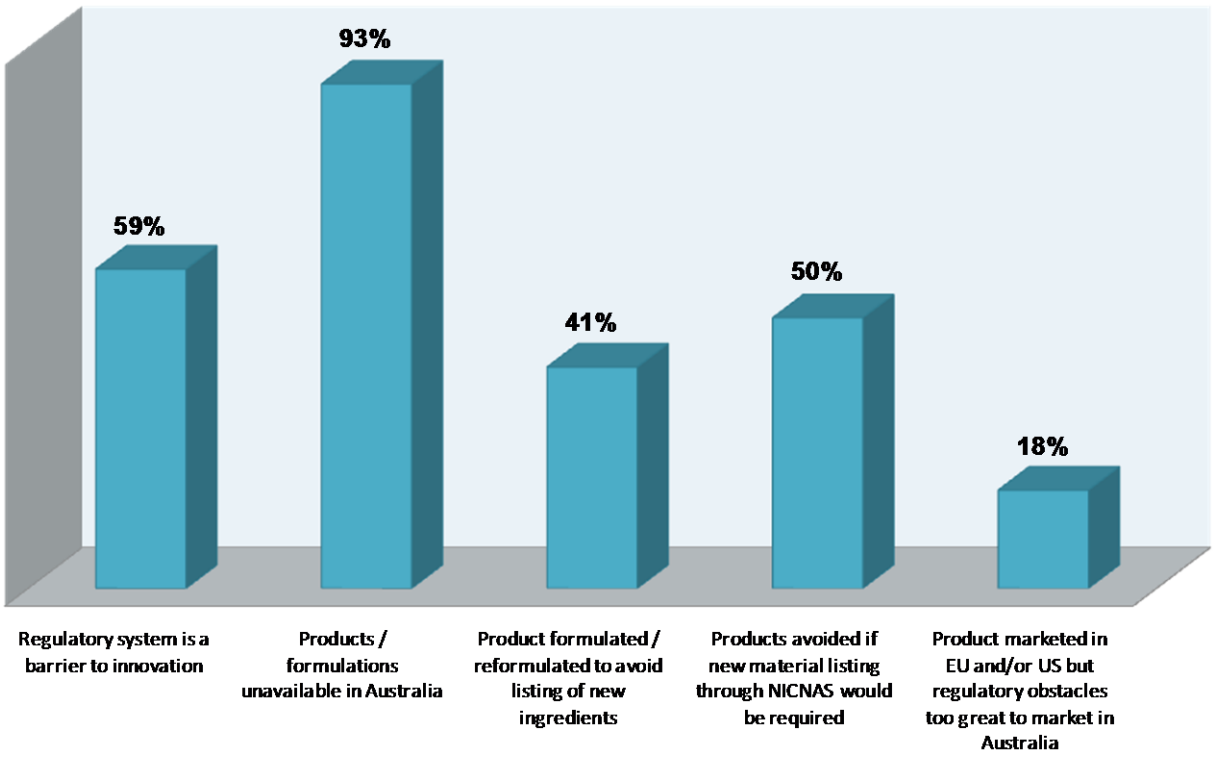
Additonally, 41% reported that products were formulated/re-formulated to avoid listing material on the Australian Inventory of Chemical Substances through NICNAS and 50 percent avoided products that would require listing through NICNAS.

Further to this, 18 percent reported that their companies marketed products in the EU and/or US but that the regulatory obstacles were too great to market these same products in Australia.

All consequences of regulatory burden reported by members (see Figure 4) show that Australia is placed at a disadvantage with regard to commercial opportunities and, more importantly, innovation.

It is also apparent that Australian industry faces an additional resource burden - when companies persist with introductions, they are often incurring additional costs associated with formulating or re-formulating to avoid the difficulties of dealing with the regulatory system.

Figure 4. Consequences of regulatory burden



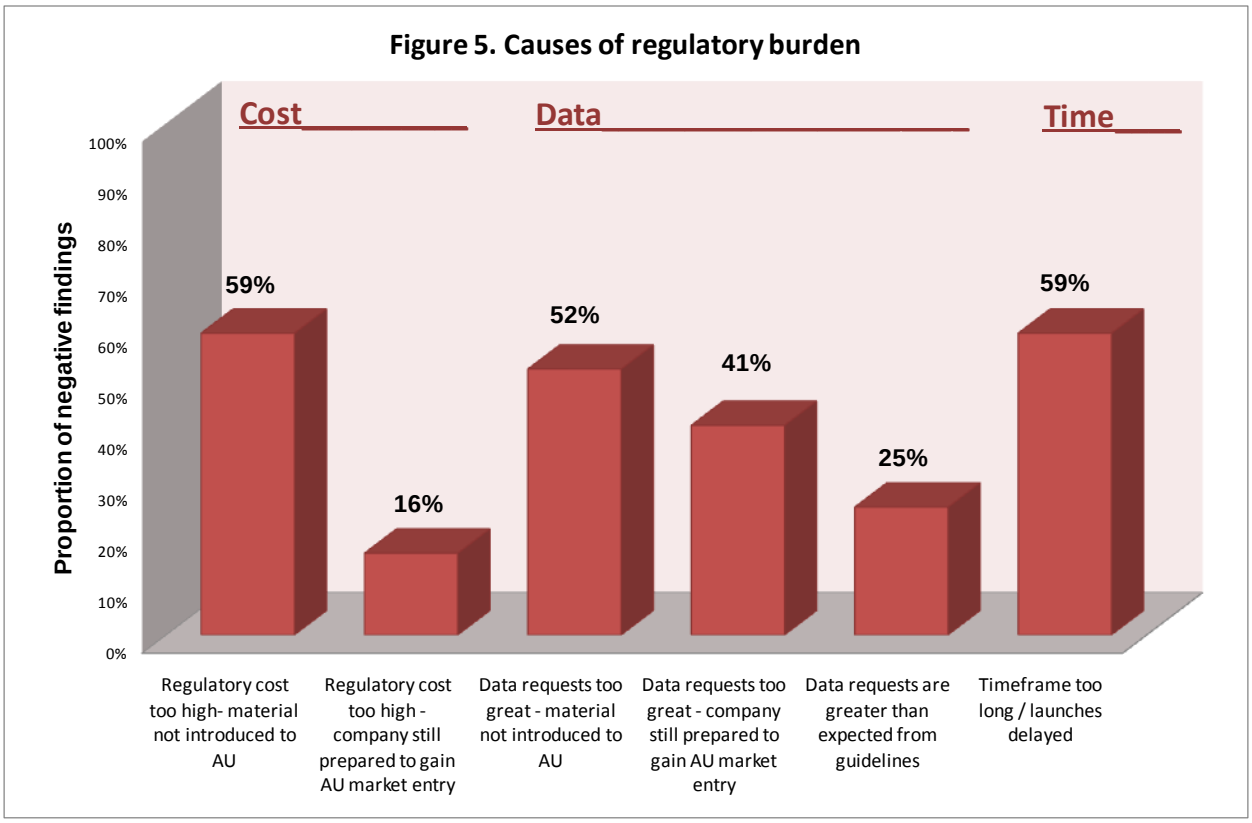
Costs, data and time factors are individually cited in over 50 percent of cases as causes of regulatory burden.

For businesses introducing new innovations and products, launch delays are of great commercial significance. To miss a launch date can mean missing an entire year of sales and ultimately compromise the commercial return associated with undertaking development work for innovation. A problem with the existing regulatory system relates to uncertainty in achieving 'approval' within the published statutory timeframes. While it is not incumbent on regulators to work to a company's desired launch date, it is essential that the process for consideration of applications is efficient and provides certainty in terms of meeting agreed timeframes.

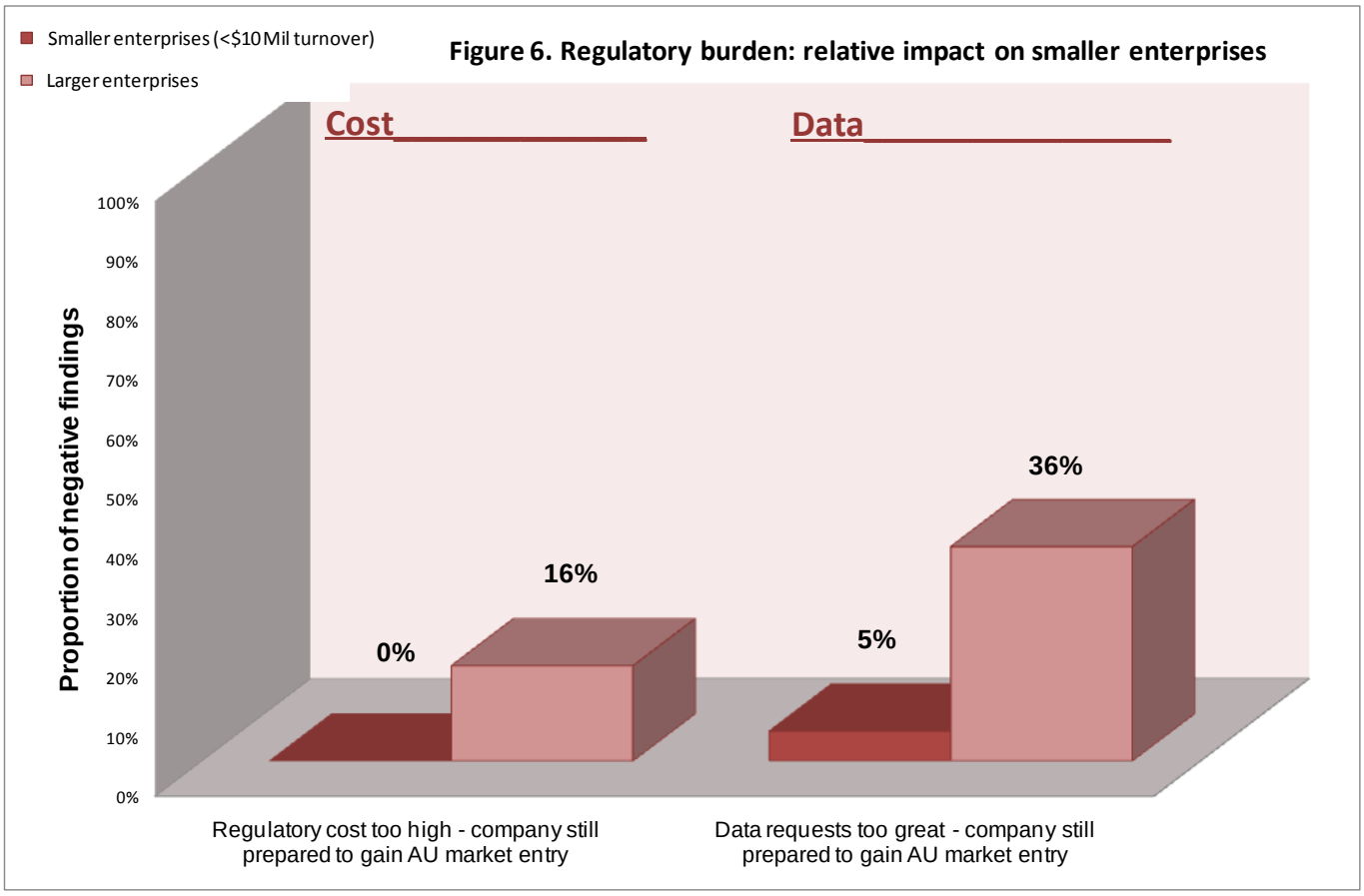
The impact of cost and time on introduction of a product to Australia should also be noted.

For example, in 59 percent of cases the high regulatory cost[1] results in non-introduction to Australia and in only 16 percent of cases the company was still prepared to do the work to gain entry to the Australian market. Cost and time impacts are shown in Figure 5.

[1] *Table 2 – Worldwide Registration Costs Comparisons* on page 49 of ACCORD's 24-10-07 submission to the Productivity Commission showed that Australia has the costliest system in terms of government application fees ($14,418). This compares to $2,797 for the USA and $122 for Korea. The cost differential also needs to be put into perspective in comparison to the major market size difference between, say, Australia and the USA. This factor acts as a barrier to the introduction of chemicals/products.

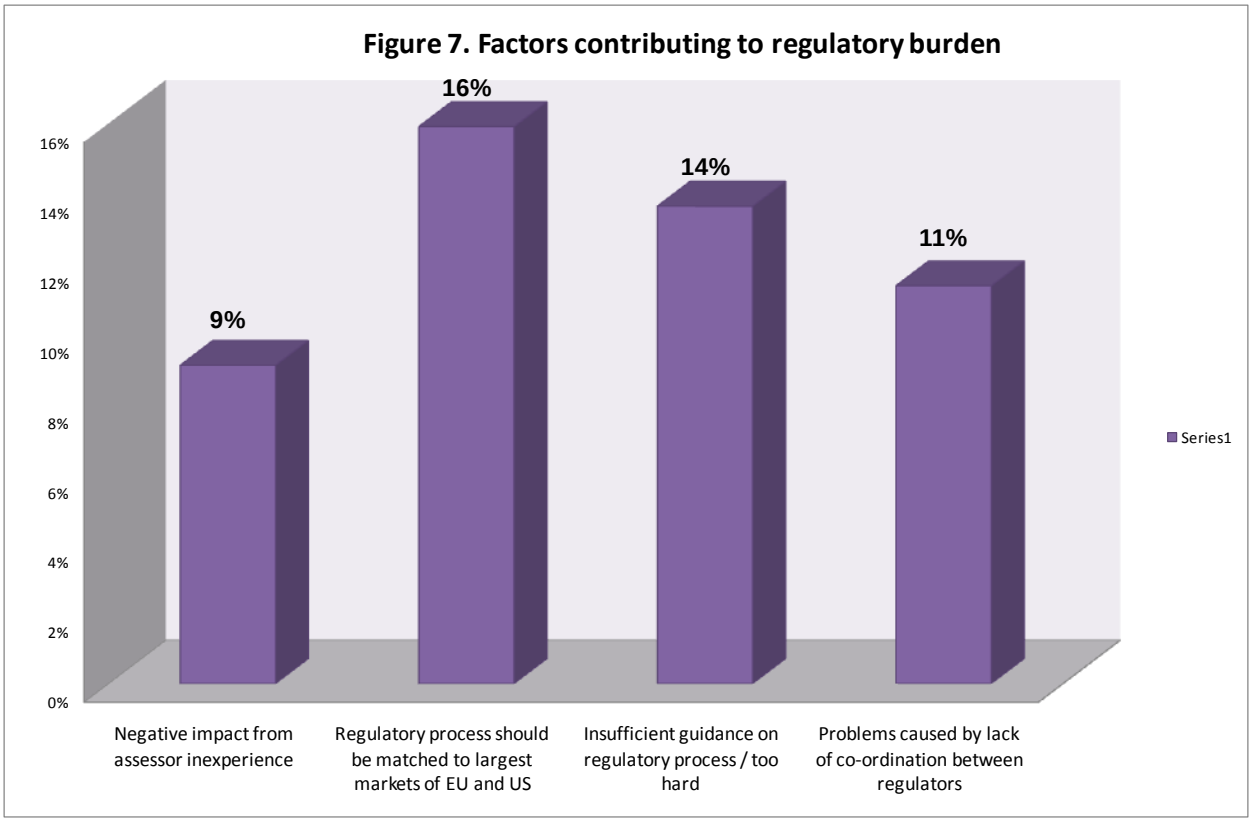


The impact of cost and data requirements on the ability of smaller enterprises[2] to introduce new chemistry to Australia can be seen in Figure 6. This compares the number of smaller versus larger companies prepared to gain Australian market entry under cost and data conditions they consider onerous.



[2] $10 Mil turnover

A number of other factors (see Figure 7) indicate that there would be great advantage in streamlining and co-ordinating the activities of the different regulatory agencies. The resource savings in such an approach could be channelled into training of assessors and applicants. In addition, harmonisation and mutual recognition of Australian regulatory processes with those of the larger EU and US markets could reduce the regulatory workload for industry.



ACCORD Members made a number of comments in responding to the Survey, describing, for example, their experiences or company policy surrounding regulatory burden. Examples of those of importance to Productivity Commission deliberations are listed below. Case studies submitted by members are in a latter part of this report.

- "We try and do the right thing but the regulations are too complicated".
- "We believe there should be guidelines and lists that everyone can follow, and that are updated regularly."
- "We avoid choosing products that would require listing of new ingredients on the Australian Inventory of Chemical Substances (AICS)."
- "The only interaction that we have had with NICNAS over the last two years is with low volume/percentage ingredients for cosmetics. The changes in this area have been very beneficial to our business because the new regulations mean that there are no regulatory delays in getting our products to market."
- "We develop new products but restrict ourselves to materials already listed on the Australian Inventory of Chemical Substances (AICS). We have the perception from seminars with NICNAS and from what we have heard that it would be too hard and expensive."
- "Our policy is to not go ahead with any products that would require notification through NICNAS - the cost wouldn't be justified and it is too hard to get data on innovative chemistry."
- "Bringing materials in through NICNAS is an onerous task and introducing something new is always questioned because of the burden. On rare occasions we have gone through the process ourselves but it is very hard to get all the data."
- "It is straight-forward preparing the data for EU but there are constant issues with NICNAS."

- “Our company automatically doubles the indicated time to allow for a slow process at NICNAS.”
- “Products are re-formulated if the ingredients aren't on the Australian Inventory of Chemical Substances (AICS).”
- “Suppliers used to promote innovate materials but then would get into difficulty when they had orders and couldn't get through NICNAS. Now suppliers are much more cautious and only promote materials already listed on the Australian Inventory of Chemical Substances (AICS).”
- “Inexperienced assessors ask for more data than the experienced assessors because they don't have the experience with risk assessment to know what is reasonable.”
- “The process is too expensive, especially when some data is Australia-specific.”
- “We have given up on trying to introduce new materials because the data requirements, cost and time are too great. This is not good for innovation.”
- “We would like to use innovative materials from overseas but see NICNAS as obstructive.”
- “If a raw material in a formulation proposed for Australia is not on the Australian Inventory of Chemical Substances (AICS) we either reformulate or drop the product. This is because we do not see a good payoff equation for a market that has such short product life cycles.”
- “We are prepared to spend money to get accreditation marks for the UK and US because the process is defined. We are not prepared to go through NICNAS because the time and cost is open-ended.”
- “The material was commercial in the US, without the same requirements as in Australia. This stifled commercial opportunity.”
- “We make no Standard Notifications (STD) because of the prohibitive cost of doing so. Hence we get away with a Limited Notification (LTD) and let them run out in five years (i.e. become standard by default).”
- “The burden is not in cost of making applications because many, if not most applications don’t get made because of the time and cost. So the cost is in not making applications.”
- “One of the strongest marketing cases for new chemicals is that they are safer to humans and the environment. Why would a company use a harmful chemical when it can be substituted by a safer one? Only one reason in Australia, you can’t get access to new chemicals without a lot of cost, time and effort.”

6 Part 2: Targeted, in-depth survey on regulatory burden

ACCORD prepared a more detailed survey to identify failures of the regulatory system, with particular reference to barriers to trade and innovation for consumer, cosmetic, hygiene and specialty products. Questions focused on NICNAS but responses on TGA and the APVMA were invited to be submitted separately, along with instances where conflicting Federal, State and Local requirements have caused problems.

The survey was divided into three sections:

SECTION 1: Lost opportunities - the impact of the current regulatory system on the realization of commercial opportunities.

SECTION 2: Rating of the success of the, already implemented, LRCC Regulatory Reforms

SECTION 3: Operational performance of the Regulator

Eleven members participated in this section of the study. Two of the participants were regulatory consultants. The consultants’ experience is drawn from representation of a range of large and small companies, both within and outside the ACCORD membership.

6.1 Failure of the regulatory system: lost opportunity

All industry participants reported that some of their company's worldwide product portfolio is unavailable in Australia due to Australian regulatory factors.

On average, 14 percent of a portfolio was not introduced to Australia in the last two years, for regulatory reasons. Smaller companies are likely to be at a disadvantage in this area.

As can be seen in Table 1, costs, specifically: the regulatory cost compared to expected revenue; the fees for an application; the cost of application preparation, and; the cost and difficulty in obtaining Australia-specific data requirements, were the largest regulatory contributors to product unavailability in Australia.

This section of the survey sought to give more detailed information on the elements of cost, data and time than was collected in the general survey.

In particular, data was sought for cases of lost opportunity (as opposed to the experience reported in the first section for all cases, whether the product came to market or not). It is important to see that the results highlight data and cost, already identified by the wider body of members, as regulatory burdens.

The two most common cost contributors to non-introduction can be linked directly to Australia's unique regulatory system.

These factors are the regulatory cost compared to expected revenue and the cost of obtaining Australia-specific data. It is then not surprising that the difficulty and time involved in obtaining Australia-specific data were frequently cited.

The identification of Australia-specific data requirements as a contributor to lost opportunity indicates the need for an internationally harmonised system here.

The results support ACCORD's argument that for fast moving consumer goods Australia should not impose any additional market entry barriers such as unique notification and assessment requirements[3], if these products already comply with the regulatory requirements of our comparable trading partners such as the European Union (EU), the United States of America (USA), Japan, Canada or New Zealand.

Annual reporting requirements were not a large cause of non-introduction of products to the Australian market, although members do see this as a considerable contributor to regulatory burden (as discussed in the following section of this report).

Specific data on the $AUD cost of lost opportunities in terms of products not made available in Australia because of regulatory barriers was provided by six companies.

On the basis of the known share of the Australian market of these six companies (which are collectively broadly representative of the overall market), ACCORD is able to estimate that the total lost opportunity cost for the sector we represent is in the vicinity of $400 million.

In terms of the overall chemicals industry, including other key sectors in plastics, polymers and paints, this figure would be anticipated to be much higher.

[3] This also applies to trade measurement and ingredient labelling

Table 1. Identification of cost, data and time elements acting as barriers to introduction of products to the Australian market

Factor acting as a barrier to availability on the Australian market	Average occurrence, percent (there may be more than one causal factor reported)
Costs	
Regulatory cost compared to expected revenue	**45**
Obtaining Australia-specific data	**43**
Application preparation	**17**
Application fees	**19**
Data	
Difficulty in obtaining Australia-specific data	**41**
Time	
Obtaining Australia-specific data	**12**
Assessment timeframe	**5**
Unpredictability of assessment timeframes	**2**
Application preparation	**1**
Reporting	
Annual reporting requirements	**1**

6.2 Success of regulatory reforms

This section of the survey sought to rate the success of the, already implemented, LRCC Regulatory Reforms.

Participants were asked to report on the proportion of cases where self assessment has been an option for their company, but that the decision was to not to self assess. (See Table 2).

Table 2. Proportion of cases where self assessment has been an option but the decision was to not to self assess.

Category	Proportion, Average, %
Non hazardous chemicals	46
Non hazardous polymers	57
Polymers of low concern	43

Reasons given for the decision not to self assess were:

Auditing requirements: Complicated protocol: Joint company applications

Participants were asked to assess whether the range of LRCC reforms implemented to date had been beneficial in reducing the regulatory burden. Respondents indicated that at the time of introduction of the chemical the regulatory burden is reduced, but that annual reporting has significantly increased the ongoing regulatory burden.

6.3 Operational performance

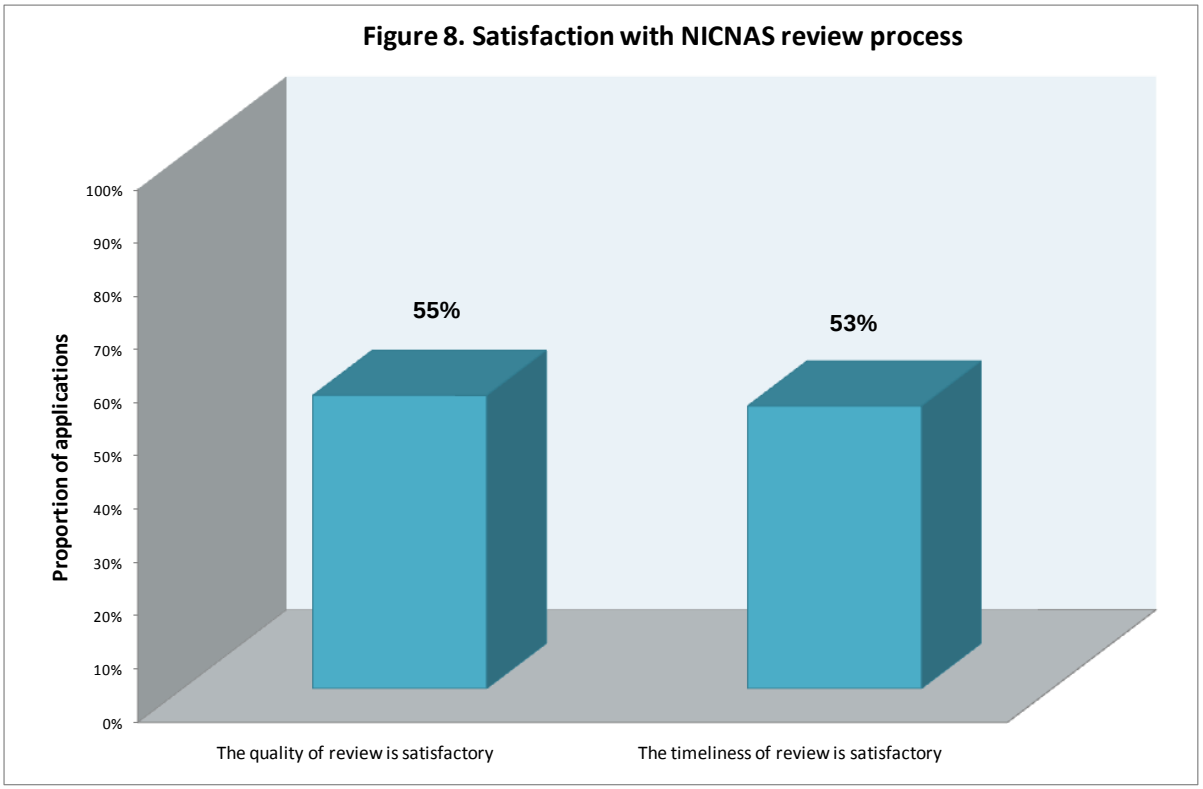
A number of survey questions were designed to elicit member opinion on NICNAS operational performance. Responses ranged from approval to disapproval of operational performance. This variation is not surprising when the response to questions on assessment consistency is considered.

Respondents rated consistency from one application to another with regard to assessment process and assessor performance. The responses varied considerably. On average, respondents did not agree that there was consistency. Some comments follow:

- "The amount of information required depends significantly on the assessor."
- "I can model an application on a previous assessment report and still get a different range of questions and amendments even for similar substances."
- "Inexperience generally causes conservative assessments."

A number of questions were put to participants to assess areas of concern within the review process. The quality and timeliness of the review was considered satisfactory in only about 55 percent of cases (see Figure 8). Whether the responses were due to actuality or perception is not known. However, it is clear that there is considerable room for improvement in the assessments themselves and / or the communication with applicants on the process and requirements.

Figure 8. Satisfaction with NICNAS review process

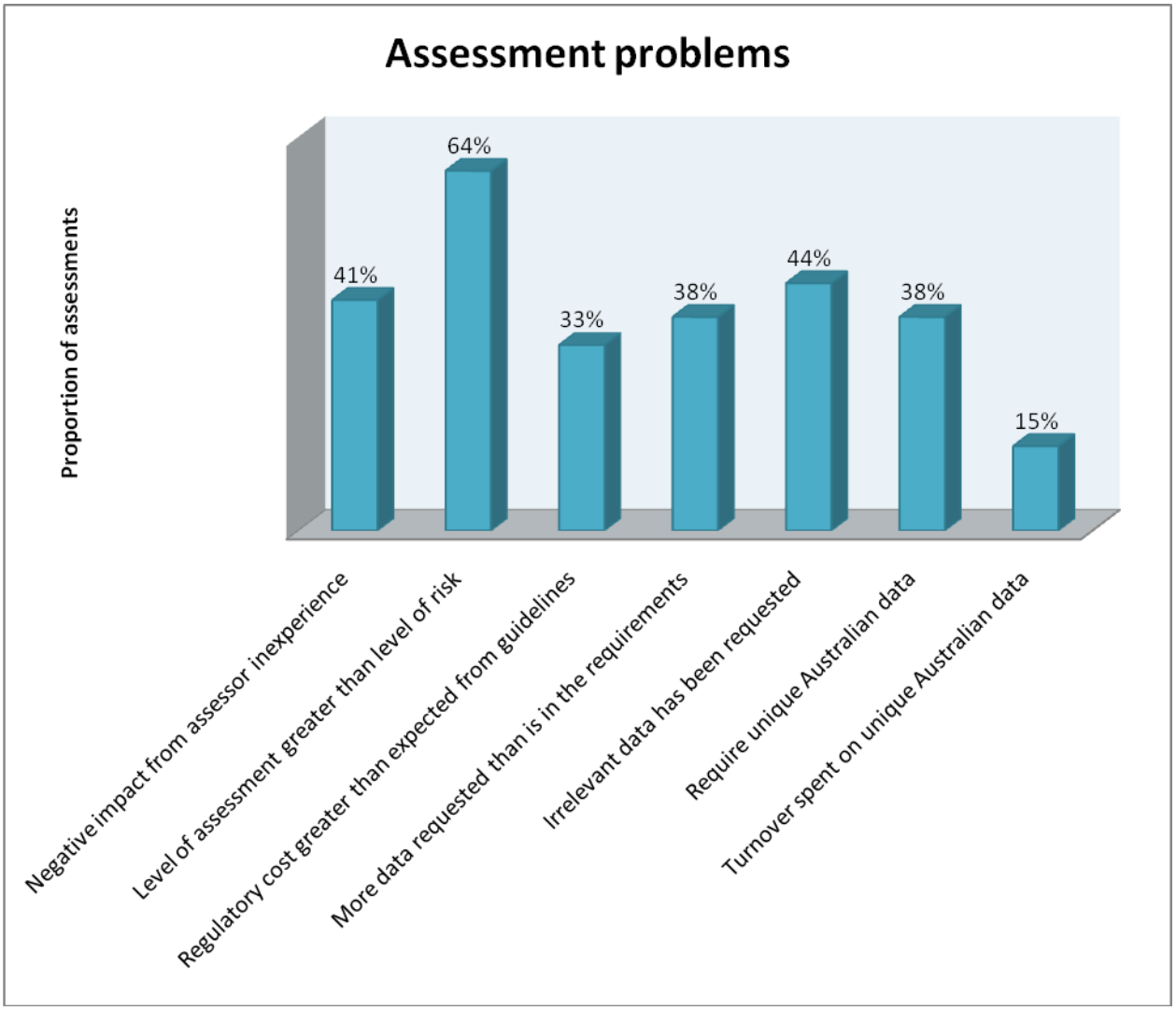


Survey participants were asked to report on the proportion of assessments for which a range of problems occurred (see Figure 9). The results, averaged across responses, are reported in the following chart. A negative impact from assessor inexperience was reported in 41 percent of cases. Comments were made that:

- "Assessors have become more pedantic and less helpful in assisting to overcome issues in each assessment."

- “There has been an increase in assessors using their discretion in asking for additional data that are outside the data requirements in the criteria”.

Respondents felt that irrelevant data was requested for nearly half the assessments and, it is significant that in 64 percent of cases, it was considered that the level of assessment was greater than warranted for the level of risk. It was commented that the excessive amount of information required is not related to the nature of the potential hazards a chemical may pose to the Australian environment or to the public. Data requirements are not commensurate with notification category and do not relate to the level of risk a chemical poses. Thirty eight percent of assessments required Australian data.



Data requests during screening have a particular impact on assessment timeframes as the regulator is not subject to statutory time constraints in this period. The following comments were made on screening data requests:

- “Environmental data can be the most problematic in screening.”
- “Inexperience of assessors contributes to the screening period being extended significantly. Sometimes this is a case of not reading the data properly, other times it is a lack of understanding of basic chemistry, for example in asking for the solubility of insoluble materials.”

7 Regulatory agency coordination

Industry has for a number of years raised its concerns about the need for the APVMA, TGA, NICNAS and the Australian Government Department of the Environment, Water, Heritage and the Arts (DEWHA) to streamline their assessment processes and data requirements so that relevant information can be more freely exchanged between regulatory agencies, hence reducing the reporting and cost burden on industry seeking approval for the same chemical for different purposes from different regulatory agencies.

As mentioned in a preceding section, members reported problems from a lack of co-ordination between regulators. An example is that a chemical can be imported for use in a therapeutic product, having gone through the TGA process, but cannot then be used in a cosmetic or household product without re-review by NICNAS.

8 Case studies

A number of case studies were put forward by members to highlight their survey responses:

Case study 1

This company deals with an agency where the overseas Principal has developed some new chemicals particularly geared towards use in personal care products. The chemicals are covered by patents, and use renewable resources. Simple skin irritancy trials show that they are significantly milder on the skin than some of the products they are designed to replace. Other tests carried out include the Het-Cam test which is a replacement test for the Draize test to determine eye irritancy, mutagenicity testing and LD50 test (which shows the product is completely harmless).

In one case the product is apparently now listed on the US Toxic Substances Control Act (TSCA) Inventory (which cost the company $100), without a lot of extra testing. NICNAS will require significantly more testing, such as biodegradability, to be carried out for a Standard Notification. The cost estimate for NICNAS approval would be in excess of $100,000 and the company is still to decide whether to proceed with the product.

Case study 2

When this company wants to introduce a new formulation to Australia they first check if all ingredients have been notified with NICNAS. If new non-polymer materials haven't been notified the company will usually re-formulate because of the expense, time delay and uncertain outcome of going through the NICNAS process. The cost to the company in reformulation is additional development and research expense and lost time. Major retailers, Woolworths and Coles only allow introduction of new laundry products once a year. If there is delay of even one month, the product is then pushed back a year, which means one year of lost sales.

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). The company wasn't sufficiently large in Australia to justify this cost. The formulants not listed on the Australian Inventory of Chemical Substances (AICS) were replaced. The delay was four months, which converts to a year's delay to market

Case study 3

This company reports that the consumer care market is asking for additional benefits in its products. As listing of ingredients on the Australian Inventory of Chemical Substances (AICS) is too difficult commercial opportunities are lost to the company and innovative or beneficial products are not available to consumers. Various marketing ingredients, such as green tea extracts are left out of personal care products and fabric softeners, fungicides, bactericides and optical brighteners are left out of laundry products.

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.

The supplier investigated alternate data availability but some testing would still be required. The 1000 kg "low volume" approval was not an option. A standard application was required which meant EU 125K + (about $210k AUD) to generate the required data. It was not considered commercially viable for the supplier to support the generation of the data. In addition, it was not certain that, once generated, the data would be sufficient for certification.

The company decision was to abandon the idea to list the material on the Australian Inventory of Chemical Substances (AICS) and instead to investigate an alternate technology.

Costs:

Six months development lost + lengthy discussion with suppliers	$35K
Six month development of an alternate technology	$25K
Investment to handle the alternate technology in plant (now a powder)	$250K
Estimated lost business opportunity (one year delay on market)	$300K

Case study 4

This company finds the cost of maintaining their product portfolio a huge regulatory burden. The main burden is the continuing monitoring and evaluation of the volume introduced. For each ingredient it is necessary to establish proportion of the product, then continually monitor that the volume imported does not breach the level applied for. Data requirements from one volume threshold to the next are greatly increased and the company can see no benefit to the consumers or the environment or their staff.

The company considers the information required to introduce a polymer of low concern (PLC) excessive, in particular when the material is already on the Australian Register of Therapeutic Goods (ARTG) for use in therapeutics. The lack of cooperation between the agencies confounds the situation.

This company spends about $100 000 a year in staff and consultancy costs, over and above fees to NICNAS, on gathering data and reporting requirements for its portfolio of approximately 7,500 formulas, made up of 3,000 different ingredients.

Case study 5

A recent issue for this company was their warehouses' ability to handle a cleansing agent used at less than 10 percent of a facial cleaner. As part of an LTD (limited notification category) application they had to provide details on handling, storage, and environmental protection within the warehouse for the ingredient in its raw form. As it is in a compound the information was totally inappropriate and superfluous, however the company had to put resources into gathering the data and proving the capacity for safe handling in the event of a spill. The company reports that, at the end of the day, if there was a spill, they would have a very clean floor and hands.

Case study 6

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.

Case study 7

This company is a contract manufacturer. While much production has been lost to Asia over the last 10 years the economics of local manufacture have significantly improved and as a result they have just won back a significant amount of business from China. Looking forward the opportunities to supply regionally are very real. However, there are considerable concerns as problems with certification of new chemicals will seriously impact on these opportunities. If a potential tender uses chemicals not registered in Australia, then any economic advantage of local production will be lost.

Case study 8

This company develops new products and formulates. They believe the guidelines are too tough but will usually go through the NICNAS process because, being fairly large, have the money to generate the

data. However they do a cost benefit analysis and, in three years, with three potential notifications, one had added cost and delay with data requests and one didn't go ahead: the company considered that the cost and time of up to 12 months wasn't justified when the product may be re-formulated in eight months for market reasons anyway.

Case study 9

This company has about 55 employees. They have submitted eight to ten notifications in the last two years. This company finds there are problems when the assessors are inexperienced and have little commercial knowledge or experience. These assessors ask for more data than experienced assessors because they don't have the experience with risk assessment to know what is reasonable. The process is too expensive, especially when some data is Australia-specific. Two submissions didn't go ahead in the last two years because of cost. Two didn't go ahead because of difficulty - fluoro-polymer submissions have got harder to do with the data requirements. Sometimes alternate materials are substitutes in formulations but are not as good technically.

Case study 10

This company is a Specialty Chemical manufacturer. It is a small company with approximately 20 employees. They no longer go through the NICNAS process because of the cost and resources required. They had gone through the process of listing a material on the Australian Inventory of Chemical Substances (AICS): it cost $30,000 and took 18 months. It was a long and tedious process because data was not available. The material was commercial in the US, without the same requirements as in Australia. This stifled commercial opportunity as by the time it was cleared for use the company had missed the timing for a commercial advantage. Now, applications to NICNAS are outside the company's budget and it will usually be put back on suppliers.

On one occasion the company was purchasing a material through an agent. A review showed that it wasn't listed on the Australian Inventory of Chemical Substances (AICS) so they reformulated while waiting for the supplier to go through the listing process. The supplier has spent the last two years dealing with NICNAS on this material, and it is still not finalised.

Case study 11

A company was recently pulled up by the TGA - $500 000 of product was seized by customs for having an unapproved ingredient and having claims that hadn't been approved. They had been using the ingredient for years. On two occasions they went through NICNAS and had approval but then the TGA confiscated the product. They asked the TGA why this could happen and the TGA said NICNAS had nothing to do with them.

Case study 12

This company formulates and develops formulations. They had a situation where there were two suppliers and difficulties with making an application. So the company decided to do the work themselves. The material was a sanitising active and they approached NICNAS. NICNAS said they would only look at it after the TGA and APVMA but there was no progress. The company eventually got the TGA and the APVMA to put it in writing that they had no interest in the active, for reasons of concentration and use situation. Only then was the company able to get NICNAS to look at their application. This process took three years!

APPENDIX 1

Members

Consumer, Cosmetic and Personal Care:

Advanced Skin Technology Pty Ltd
Alberto Culver Australia
Amway of Australia Pty Ltd
Apisant Pty Ltd
Aroma Science
AVON Products Pty Limited
Baylor Limited
Beiersdorf Australia Ltd
Chanel Australia
Clorox Australia Pty Ltd
Colgate-Palmolive Pty Ltd
Combe International Ltd
Cosmax Prestige Brands Australia Pty Ltd
Coty Australia Pty Limited
Creative Brands Pty Ltd
Dermalogica Pty Ltd
Elizabeth Arden Australia
Emeis Cosmetics Pty Ltd
Estée Lauder Australia
Frostbland Pty Ltd
GlaxoSmithKline Consumer Healthcare
Helios Health & Beauty Pty Ltd
Innoxa Pty Ltd
Johnson & Johnson Pacific
Kao (Australia) Marketing Pty Ltd
Keune Australia
Kimberly Clark Australia
La Biosthetique Australia
La Prairie Group
L'Oreal Australia Pty Ltd
LVMH Perfumes and Cosmetics
Mary Kay Australia Pty Ltd
Nutrimetics Australia
NYX Pty Ltd
Procter & Gamble Australia Pty Ltd
PZ Cussons Pty Ltd
Reckitt Benckiser
Revlon Australia
Scental Pacific Pty Ltd
Schwarzkopf
Shiseido (Australia) Pty Ltd
Thalgo Australia
The Heat Group Pty Ltd
The Purist Company Pty Ltd
Tigi Australia Pty Ltd
Trilogy Products
Trimex Pty Ltd
Ultraceuticals
Unilever Australasia
YSL Beaute

Hygiene and Specialty Products

Albright & Wilson (Aust) Ltd
Applied Australia Pty Ltd
BP Castrol Australia Pty Ltd
Callington Haven Pty Ltd
Campbell Brothers Limited
Castle Chemicals Pty Ltd
Chemetall (Australasia) Pty Ltd
Chemform
Ciba Specialty Chemicals
Clariant (Australia) Pty Ltd
Cleveland Chemical Co Pty Ltd
Deb Australia Pty Ltd
Dominant (Australia) Pty Ltd
E Sime & Company Australia Pty Ltd
Ecolab Pty Limited
Henkel Australia Pty Limited
Huntsman Corporation Australia Pty Ltd
Jalco Group Pty Limited
Lab 6 Pty Ltd
Milestone Chemicals Pty Ltd
Novozymes Australia Pty Ltd
Nowra Chemical Manufacturers Pty Ltd
Peerless JAL
Recochem Inc
Rohm and Haas Australia Pty Ltd
Solvay Interox Pty Ltd
Sonitron Australasia Pty Ltd
Sopura Australia Pty Ltd
Tasman Chemicals Pty Ltd
Thor Specialties Pty Limited

Associate Members

Specialist Laboratories and Testing

ams Laboratories

Dermatest Pty Ltd

Silliker Microtech Laboratories Pty Ltd

Equipment and Packaging Suppliers

EquipNet Inc.

HydroNova Australia NZ Pty Ltd

SCHÜTZ DSL Group Pty Ltd

Logistics

Star Track Express Pty Ltd

Legal and Business Management

Fisher Cartwright Berriman

Middletons Lawyers

PricewaterhouseCoopers

TressCox Lawyers

Regulatory and Technical Consultants

Archer Emery & Associates

Cintox Australia Pty Ltd

Competitive Advantage

Engel Hellyer & Partners Pty Ltd

Robert Forbes & Associates

Sue Akeroyd & Associates

November 2007

APPENDIX 2

ACCORD
Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry

Productivity Commission Study of the Regulatory Burden on the Chemicals and Plastics Industry

ACCORD Industry Survey (Part 1)

This survey to identify in broad terms, the impacts and costs related to the regulatory burden on the chemicals industry, with particular reference to barriers to trade and innovation for consumer, cosmetic, hygiene and specialty products.

Questions focus on NICNAS but responses on the TGA and the APVMA will also be collated.

Responses are sought on NICNAS activities over the last **2 years**.

Responses will be collated without identification of company, product or chemical.

The survey is divided into two sections:

SECTION 1: Identification of the company size, type of organization and overall interaction with the regulator.

SECTION 2: Identification of causes and consequences of regulatory burden

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SECTION 1: Identification of survey participant

1.1) Company name and size

Company Name	
Size of organization (≤20 / 20-100 / ≥100 employees)*	
Date	

* Size of organization in terms of turnover will be identified separately from ACCORD records and not recorded with the rest of the survey responses.

1.2) Member business category

Tick the member business category		
Industry members	1: Consumer, cosmetic and personal care products	
	2: Hygiene and specialty products	
Associate members	3: Specialist laboratories and testing	
	4: Equipment and packaging suppliers	
	5: Logistics	
	6: Legal and business management	
	7: Regulatory and technical consultants	

SECTION 2: Identification of regulatory burden

2.1) Impact of NICNAS-related regulations

What impact do NICNAS-related regulations have on your business? (positive / negative / neutral / can't comment)	
Please note the reasons, if you are unable to comment on NICNAS	

The remainder of the survey is to be completed where participants reported a negative impact from NICNAS-related regulations

2.2) Consequences and causes of regulatory burden

Please tick any of the following consequences of regulatory burden which apply to your product portfolio:	
There is a barrier to innovation	
Product / formulations are unavailable in the Australian market	
Product marketed in EU and/or US but regulatory obstacles too great to market in Australia	
Product formulated / reformulated to avoid AICS listing of new ingredients	
Products avoided if new material listing through NICNAS would be required	
Regulatory cost too high - material not introduced to Australia	
Regulatory cost too high - company prepared to bear the cost to gain Australia market entry	
Data requests too great - material not introduced to Australia	
Data requests too great but company in position to obtain data to gain Australia market entry	
Timeframe too long / launches delayed	
What aspects of the regulations or process cause the regulatory burden?	
Data requests are greater than expected from guidelines	
Assessor inexperience	
Lack of harmonization with major trading partners (EU / US)	
Lack of coordination between regulators	
Other (please comment)	
Comments	
Case studies	

APPENDIX 3

ACCORD
Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry

Productivity Commission Study of the Regulatory Burden on the Chemicals and Plastics Industry

ACCORD Industry Survey

This survey is to identify failures of the regulatory system, with particular reference to barriers to trade and innovation, for consumer, cosmetic, hygiene and specialty products.

Questions focus on NICNAS but responses on TGA and the APVMA would be welcome *separately*, along with instances where conflicting Federal, State and Local requirements have caused problems.

The survey is divided into three sections:

SECTION 1: Lost opportunities - the impact of the current regulatory system on the realization of commercial opportunities.

SECTION 2: Rating of the success of the, already implemented, LRCC Regulatory Reforms

SECTION 3: Operational Performance of the Regulator

Responses will be collated without identification of company, product or chemical.

Instructions for completing the form:

Type your answers in the blank fields in the tables

or

Print the form and handwrite your responses.

Please answer the questions for your experience with NICNAS over the last **2 years.**

If you don't have experience in any of the areas under investigation, please make a note to that effect in the response field.

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Company Name	
Size of organization (≤20 / 20-100 / ≥100 employees)	
Date	

SECTION 1: LOST OPPORTUNITY

1.1) Product availability in the Australian market

Of your company's worldwide product/substance portfolio, what **percentage** is **unavailable** in Australia due to **Australian regulatory factors**?	

1.2) Causes of unavailability of products to the Australian market

For the products/substances unavailable due to regulatory factors, in what proportion of cases were the following contributing factors? (there may be more than one causal factor for a product)	%
Regulatory cost compared to expected revenue	
Regulatory data requirements (difficulty in obtaining Australia-specific data)	
Regulatory data requirements (cost of obtaining Australia-specific data)	
Regulatory data requirements (timeframe for obtaining Australia-specific data)	
Regulatory assessment timeframe	
Unpredictability of regulatory assessment timeframes	
Time required for application preparation	
Cost of application preparation	
Regulatory application fees	
Annual reporting requirements	
Comments	

1.3) Value of lost opportunity

For the products/substances not introduced to Australia in the last 2 years, for regulatory reasons, what was the expected turnover ex manufacture?	

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SECTION 2: SUCCESS OF REGULATORY REFORMS

2.1) How many notifications has your company made to NICNAS?

Exemption low volume (<100kg)	Letter of Consent	
Commercial Evaluation Chemical (CEC)	Permit	
Low Volume Chemical (LVC)	Permit	
Polymers of Low Concern (PLC)	Certificate	
Limited notification (LTD)	Certificate	
Standard Notification (STD)	Certificate	
Extension of Original Assessment Certificate	Certificate	

2.2) Uptake of the LRCC reforms

For the following questions, please give your answer as a percentage	%
Where you have had the option of self assessment, in what proportion of cases have you **chosen not to self assess?**	
Non hazardous chemicals	
Non hazardous polymers	
Polymers of low concern	
Where you have had the option of self assessment, in what proportion of cases have you **chosen not to self assess because of the level of auditing required?**	
Non hazardous chemicals	
Non hazardous polymers	
Polymers of low concern	

Comment on reasons for not taking up self assessment	

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2.3) Rate the success of the LRCC reforms

Assign the following statements a rating from 1 to 5 1=Strongly agree 2=Agree 3=Neutral 4 =Disagree 5=Strongly Disagree N/A= Not Applicable						
Overall, the LRCC reforms implemented to date have been beneficial in reducing the regulatory burden						
The speed of introduction of LRCC **reforms that didn't take immediate effect in 2004** is satisfactory						
The following reforms, introduced in 2004, have been successful in reducing the regulatory burden associated with assessment timeframe, fees, data requirements, resourcing of application preparation, post notification requirements (auditing etc): **(1-5 rating)**	Overall reduction in regulatory burden	Timeframe	Fees	Data requirements	Application preparation	Post-notification regulatory requirements
Exemption category changes and additions:						
Transhipment exemption (new)						
Increase in the volume restriction for the exemption for chemicals introduced solely for the purpose of research, development and analysis from 50 to 100kg/annum						
Increase in the volume restriction for the exemption of low-risk non-cosmetic chemicals from 10 to 100kg/annum						
Introducers of low risk cosmetic chemicals, in quantities of less than 10kg/annum, are no longer required to notify NICNAS prior to introduction						
Increase in the volume restriction for the exemption of low risk non-cosmetic chemicals from 10 to 100kg/annum						
Non-hazardous chemicals introduced in cosmetics at a concentration at 1% or less do not need to be notified to NICNAS prior to introduction						
New range of permits						
Renewal of CEC and LVC Permits						
Removal of national volume restriction for LVC Permits						
Self assessment						
Non hazardous chemicals						
Non hazardous polymers						
Polymers of low concern						

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SECTION 3: OPERATIONAL PERFORMANCE OF THE REGULATOR

3.1) Director's power of discretion

For secondary notifications the Director may put forward that assessment is only required for matters of particular significance , i.e. not all matters Assign the following statements a rating from 1 to 5 1=Strongly agree 2=Agree 3=Neutral 4 =Disagree 5=Strongly Disagree N/A= Not Applicable	
The Director's use of her powers of discretion in relation to secondary notifications has **remained constant** over the last 2 years	
The Director's use of her powers of discretion in relation to secondary notifications has **increased** over the last 2 years	
The Director's use of her powers of discretion in relation to secondary notifications has **decreased** over the last 2 years	
Comment	

3.2) Consistency

Assign the following statements a rating from 1 to 5 1=Strongly agree 2=Agree 3=Neutral 4 =Disagree 5=Strongly Disagree N/A= Not Applicable	
There is consistency from one application to another with regard to assessment process	
There is consistency from one application to another with regard to assessor performance	
Comment	

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3.3) Impact of operational performance

For the following questions, please give your answer as a percentage	%
In what proportion of applications are you satisfied with the **quality of review?**	
What proportion of assessments have been negatively impacted by **assessor inexperience?**	
In what proportion of applications is the **regulatory cost** greater than expected from guidelines?	
In what proportion of applications are you satisfied with the **timeliness** of review?	
In what proportion of assessments is the **level of assessment greater than the level of risk**?	
Polymers of Low Concern (PLC) notification	
Limited notification (LTD)	
Standard Notification (STD)	
In what proportion of your applications have you been asked to provide **more data than is in the requirements**?	
Polymers of Low Concern (PLC) notification	
Limited notification (LTD)	
Standard Notification (STD)	
What proportion of products/substances require **unique Australian data?**	
What proportion of a product/substances's turnover is spent on **unique Australian data?**	
In what proportion of your applications have you been asked to provide **irrelevant data** (eg solubility data for an insoluble substance?	
Polymers of Low Concern (PLC) notification	
Limited notification (LTD)	
Standard Notification (STD)	

Details of irrelevant data required (see also section 3.7 following)	
Additional comments	

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3.4) Additional data requirement details

If you have been asked to provide more data than is set out in the guidelines complete the following for as many of these applications as you can:

Category	Example						
	1	2	3	4	5	6	7
Data was already available to your company (Y/N)							
Data generation required (Y/N)							
Type of data (eg Chem, Env)							
Time to collect, compile and submit additional data (check corresponding box)							
1-2 weeks							
2-4 weeks							
1-3 months							
3-6 months							
>6 months							
Comment on NICNAS justification for the additional requirements (for the examples above)							
Example 1							
Example 2							
Example 3							
Example 4							
Example 5							
Example 6							
Example 7							

3.5) Time in screening

Please identify the time in screening for all applications and for low and non-hazardous materials

Category	Time (days) in screening (**total** number of products)						
	0	0-7	8-14	15-21	22-28	29-90	>90
STD							
LTD							

Category	Time (days) in screening (number of **low-hazard** products)						
	0	0-7	8-14	15-21	22-28	29-90	>90
STD							
LTD							

Category	Time (days) in screening (number of **non-hazardous** products)						
	0	0-7	8-14	15-21	22-28	29-90	>90
STD							
LTD							

LTD= Limited Notification

STD= Standard Notification

Comment	

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3.8) Change of category requirement

If you have you experienced a shift in category requirement overtime (eg a material type previously notified as a PLC now must be assessed as a STD or LTD Notification) complete the following	
Example 1	
Describe the change	
What justification was given by NICNAS?	
Example 2	
Describe the change	
What justification was given by NICNAS?	
Example 3	
Describe the change	
What justification was given by NICNAS?	

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3.9) Annotation of AICS

Is AICS annotation being used beyond the scope of the original intent? (Yes / No)	

	Describe the annotation	Why do you think this annotation is inappropriate?
Example 1		
Example 2		
Example 3		
Example 4		
Example 5		
Example 6		
Example 7		

3.10) Cost of delays

Delayed assessments impose a cost burden. Please show worked examples of the cost of delay in getting to the market

EXAMPLE 1	
Type of material	
Time delay (eg 3 months)	
Cause of delay	
Cost element and value (eg x hours on additional negotiations and data provision at cost of $y)	
Data generation costs	
Loss in turnover	
Other costs, eg storage	
Comments	

EXAMPLE 2	
Type of material	
Time delay (eg 3 months)	
Cause of delay	
Cost element and value (eg x hours on additional negotiations and data provision at cost of $y)	
Data generation costs	
Loss in turnover	
Other costs, eg storage	
Comments	

EXAMPLE 3	
Type of material	
Time delay (eg 3 months)	
Cause of delay	
Cost element and value (eg x hours on additional negotiations and data provision at cost of $y)	
Data generation costs	
Loss in turnover	
Other costs, eg storage	
Comments	

APPENDIX 4

Table 2 – Worldwide Registration Costs Comparisons from page 49 of ACCORD's 24-10-07 submission to the Productivity Commission showed that Australia has the costliest system in terms of government application fees ($14,418). This compares to $2,797 for the USA and $122 for Korea. The cost differential also needs to be put into perspective in comparison to the major market size difference between, say, Australia and the USA. This factor acts as a barrier to the introduction of chemicals/products.

Table 2. Worldwide Registration Cost Comparisons

Data item	Australia	Korea	USA	Japan		EU	Canada	Philippines	China
National Inventory	AICS	KECI/ TCCL	TSCA	(Controlled under ISHL)	ENCS (Controlled under CSCL)	ELINICS (moving to REACH)	DSL	PICCS	IECSC
Volume (per year)	>1 tonne	<1 t/>1t	Unlimited	<100 kg/100 kg	<1 t / >1t	1-10 tonne	Unlimited	<1 t/>1t	<10 tonne
Government Application Fee	14418 AUD	KRW 50,000/100, 000	2,500 USD	No	No	5,165 EURO (ELINCS) (REACH fees not set)	3,500 $Cdn	P 3750	Notification registration fee
Government Application Fee $AU	$14,418	$61/122	$2,797			$8,227	$4,025	$95	$?
Exempt Information Fee $AU	633 AUD	None	None	None	None	None	None	None	None
Variation of Data Requirements (if needed)	1140 AUD	None	None	None	None	None	None	None	None
Timing (mth) Consolidate / submit Government Screening, Assessment, Review	3	6	4	3 / 7	1/18 ENCS listing 18-36	10-12	2.5	3-6	4
Polymer exemptions	Not exempt	Not exempt. Reduced requirements	Exemptions	Exemption under certain conditions if covered by CSCL	No exemption. Reduced requirements	Registration not required	RRR (Recuced Regulatory Requirement)	Exempt	Reduced requirements, 1 mth review

- The timeframes indicated are based on no clock stops or concerns raised by competent authorities, i.e., EPA in US
- The EU timing and costs covers all member states incl. UK. However Switzerland is not covered and a separate notification is necessary. EU tests are sufficient. We suggest to submit after the EU approval is available, because then both fee and review in Switzerland are reduced (CHF 6'500, 30 days).

Attachment 6

Australian State and Territory Government controls on schedule 7 poisons

State or Territory	Permit, licence, authority required for person, business, institution to:			Licence Premises	Domestic can:		Charges	Exemptions	Appendix J - Implementation	notes
	Obtain	Use	Sell	Storage	Obtain	Use				
QLD	Yes, App 7 of the HDPR	Yes, App 7 of the HDPR	Yes	Secured or specified by Chief Executive	Yes, provided not listed in App 7 of the Health Regs 1996	Authorised only	Yes, except strychnine and cyanide permits	Certain exemptions for industrial, manufacturing uses and use in research	Not by reference, however, App J provisions are largely mirrored in Appendix 7 of the Health (Drugs and Poisons) Regulation 1996	Intent of Queensland legislation is not to impose restrictions on the use of S7s in the industrial, manufacturing or research areas
NSW	Yes	Yes			No	No	No	Registered Pesticides; scientific research; use for non-domestic purposes (other than highly dangerous substances)	No	
VIC	LR Yes	LR Yes	Wholesale for all S7		Could Not LR	Could Not LR	Yes	Non LR products have no controls other than Ag chem regs	No	
TAS	Yes (App J)	Yes (App J)	Yes (App J)	Yes (App J)	No	No	Wholesaler- Yes User- No (App J)	If Dangerous Goods or pesticides permit issued	Yes	Restrictions only apply to Appendix J substances. Non App. J S7 not for domestic use.
ACT	Yes	Yes	Yes	Specified by Minister	No	No	No	Registered Pesticides	No	N/A
NT	Yes	Yes	Yes	Yes	No	No	$20 per annum for retail licence, $50 per annum for manufacturer or wholesaler, User Nil		Yes	
SA	No*	No*	Yes	Locked cage denying access to public	No	No	Yes	Yes **	Not by reference, however App J provisions are largely mirrored in Section 22 of the Controlled Substances Act 1984.	
WA		Yes	Yes				Yes	Specified groups eg Primary Producers	Implemented where appropriate	

Attachment 7

Comparison on content of NSW & Victorian OHS regulations

NSW Regulation – Occupational Health and Safety Regulation 2001 (last update 2 November 2007)

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2 Commencement

3 Definitions

4 Application of Regulation

5 Meaning of "control" of risks

6 Application of provisions providing for alternative duties if primary duty not reasonably practicable

7 Application of provisions of Part 2 of the Act (relating to general duties of certain persons) to persons having duties under this Regulation

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Vic Regulation – Occupational Health and Safety Regulations 2007

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3 Intermediate scaffolding licence
4 Advanced scaffolding licence
5 Dogging licence
6 Basic rigging licence
7 Intermediate rigging licence
8 Advanced rigging licence

PART 2—LICENCE CLASSES FOR CRANE, HOIST AND
FORK LIFT TRUCK OPERATION

9 Definitions
10 Tower crane operation licence
11 Self-erecting tower crane operation licence
12 Derrick crane operation licence
13 Portal boom crane operation licence
14 Bridge and gantry crane operation licence
15 Vehicle loading crane operation licence
16 Non-slewing mobile crane operation licence
17 Slewing mobile crane operation licence (up to 20 tonnes)
18 Slewing mobile crane operation licence (up to 60 tonnes)
19 Slewing mobile crane operation licence (up to 100 tonnes)
20 Slewing mobile crane operation licence (open/over 100 tonnes)
21 Boom-type elevating work platform operation licence
22 Materials hoist (cantilever platform) operation licence
23 Hoist (personnel and materials) operation licence
24 Winder operation licence
25 Concrete placing boom operation licence
26 Fork-lift truck operation licence
27 Order-picking fork-lift truck operation licence

PART 3—LICENCE CLASSES FOR PRESSURE EQUIPMENT OPERATION

28 Definitions
29 Basic boiler operation licence
30 Intermediate boiler operation licence
31 Advanced boiler operation licence
32 Turbine operation licence
33 Reciprocating steam engine operation licence

SCHEDULE 4—High Risk Work

Pressure Equipment For Which Licence is not Required

1 Definitions
2 Pressure equipment for which high risk work licence is not required

SCHEDULE 5—Hazardous Substances

Substances Prohibited for Specified Uses

SCHEDULE 6—Asbestos

Categories of Asbestos-Containing Material Containing Chrysotile Asbestos and their Uses

SCHEDULE 7—Asbestos

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352 Definitions

353 Penalty notice offences and penalties

354 Authorised officers

355 (Repealed)

Part 12.7 Other miscellaneous provisions

356 False or misleading information in applications

357 Additional officers authorised to consent to the institution of proceedings for offences

358 Application of Act to mines and coal workplaces: references to WorkCover

358A Sharing of information between WorkCover and Department of Primary Industries

359 Continuation of former OHS shop provisions

360 Notes

361 Transitional application of sentencing guideline provisions

362 Savings and transitional provisions

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Schedule 4 Application of Regulation to mines

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Schedule 5 Quantities of dangerous goods

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Schedule 7 Information to be contained in a manifest

SCHEDULE 8—Asbestos

Information Required to be Included in a Notification of Asbestos Removal Work

SCHEDULE 9—Major Hazard Facilities

Materials at Major Hazard Facilities (and their Threshold Quantity)

1 Definitions
2 Relevant materials
3 Threshold quantity of one material
4 Threshold quantity of more than one material

SCHEDULE 10—Major Hazard Facilities

Additional Matters to be Included in Safety Management System

1 Safety policy and safety objectives
2 Organisation and personnel
3 Operational controls
4 Duties of operators
5 Management of change
6 Principles and standards
7 Performance monitoring
8 Audit

SCHEDULE 11—Major Hazard Facilities

Matters to be Included in Emergency Plan

1 Site and hazard detail
2 Command structure and site personnel
3 Notifications
4 Resources
5 Procedures

SCHEDULE 12—Major Hazard Facilities

Additional Matters to be Included in Safety Case

A FACILITY DESCRIPTION
1 The facility
2 The surrounding area
B SAFETY INFORMATION
3 Risk control measures to limit the consequences of major incidents
4 Performance Monitoring
5 Safety Management System
6 Unauthorised persons and control of access
7 Safety and reliability of plant
8 Major incident history

SCHEDULE 13—Entry Permit Statement

ENDNOTES

1. General Information

2. Table of Amendments

3. Explanatory Details

Attachment 8

Comparison on content of NSW & Victorian OHS regulations in relation to manual handling control

NSW manual handling regs:-

r. 3.1.1

Part 4.4 Manual handling

Note. ***Employer***, for the purposes of this Part, includes self-employed persons (see clause 3).

79 Definition

In this Part:

manual handling means any activity requiring the use of force exerted by a person to lift, lower, push, pull, carry or otherwise move, hold or restrain any animate or inanimate object.

80 Employer to control risks

(1) An employer must ensure that:
(a) all objects are, where appropriate and as far as reasonably practicable, designed, constructed and maintained so as to eliminate risks arising from the manual handling of the objects, and
(b) work practices used in a place of work are designed so as to eliminate risks arising from manual handling, and
(c) the working environment is designed to be, as far as reasonably practicable and to the extent that it is within the employer's control, consistent with the safe handling of objects.
(2) If it is not reasonably practicable to eliminate a risk arising from manual handling, an employer must design the work activity involving manual handling to control the risk and, if necessary, must:
(a) modify the design of the objects to be handled or the work environment (to the extent that it is under the employer's control), taking into account work design and work practices, and
(b) provide mechanical aids or, subject to subclause (3), make arrangements for team lifting, or both, and
(c) ensure that the persons carrying out the activity are trained in manual handling techniques, correct use of mechanical aids and team lifting procedures appropriate to the activity.
(3) An employer must, as far as reasonably practicable, achieve risk control by means other than team lifting.

Maximum penalty: Level 4.

81 Assessment of risks

An employer, in carrying out a risk assessment in accordance with Chapter 2 in relation to manual handling, must take into consideration (where relevant) the following factors:
(a) actions and movements (including repetitive actions and movements),
(b) workplace and workstation layout,
(c) working posture and position,
(d) duration and frequency of manual handling,
(e) location of loads and distances moved,
(f) weights and forces,
(g) characteristics of loads and equipment,
(h) work organisation,
(i) work environment,
(j) skills and experience,
(k) age,
(l) clothing,
(m) special needs (temporary or permanent),
(n) any other factors considered relevant by the employer, the employees or their representatives on health and safety issues.

Victorian manual handling regs:-

PART 3.1—MANUAL HANDLING

3.1.1 Hazard identification

(1) An employer must, so far as is reasonably practicable, identify any task undertaken, or to be undertaken, by an employee involving hazardous manual handling.

Notes

1 Act compliance—section 21 (see regulation 1.1.7).

2 Hazardous manual handling is defined in regulation 1.1.5).

(2) An employer may carry out a hazard identification under subregulation (1) for a class of tasks rather than for individual tasks if—

(a) all the tasks in the class are similar; and

(b) the identification carried out for the class of tasks does not result in any person being subject to any greater, additional or different risk to health and safety than if the identification were carried out for each individual task.

r. 3.1.2

3.1.2 Control of risk

(1) An employer must ensure that the risk of a musculoskeletal disorder associated with a hazardous manual handling task affecting an employee is eliminated so far as is reasonably practicable.

Note

Act compliance—section 21 (see regulation 1.1.7).

(2) If it is not reasonably practicable to eliminate the risk of a musculoskeletal disorder associated with a hazardous manual handling task affecting an employee, an employer must reduce that risk so far as is reasonably practicable by—

(a) altering—

(i) the workplace layout; or

(ii) the workplace environment, including heat, cold and vibration, where the task involving manual handling is undertaken; or

(iii) the systems of work used to undertake the task; or

(b) changing the objects used in the task involving manual handling; or

(c) using mechanical aids; or

(d) any combination of paragraphs (a) to (c).

Notes

1 Act compliance—section 21 (see regulation 1.1.7).

2 Under sections 27 to 30 of the Act, designers of plant, buildings or structures (or parts of buildings or structures) and manufacturers and suppliers of plant or substances must ensure, so far as is reasonably practicable, that the plant, substance, building or structure (or part) is designed, manufactured or supplied (as the case may be) to be safe and without risks to health, including the risk of musculoskeletal disorder.

(3) If it is not reasonably practicable for an employer to reduce the risk of a musculoskeletal disorder associated with a hazardous manual handling task in accordance with subregulation (2), the employer may control that risk by the use of information, instruction or training.

Notes

1 Act compliance—section 21 (see regulation 1.1.7).

2 An employer may only rely solely or primarily on the use of information, instruction or training to control a risk if none of the measures set out in subregulation (2) is reasonably practicable.

(4) Without affecting the generality of subregulations (1), (2) and (3), an employer, when determining any measure to control any risk of musculoskeletal disorder, must address the following factors—

(a) postures; and

(b) movements; and

(c) forces; and

(d) duration and frequency of the task; and

(e) environmental conditions including heat, cold and vibration that act directly on a person undertaking the task.

Notes

1 Act compliance—section 21 (see regulation 1.1.7).

2 Sections 35 and 36 of the Act set out the duty of the employer to consult with employees, including involving the health and safety representative (if any). (See also regulation 2.1.5).

3.1.3 Review of risk control measures

(1) An employer must ensure that any measures implemented to control risks in relation to musculoskeletal disorders are reviewed and, if necessary, revised—

(a) before any alteration is made to objects used in a workplace or to systems of work that include a task involving hazardous manual handling, including a change in the place where that task is undertaken; or

(b) before an object is used for another purpose than that for which it was designed if that other purpose may result in an employee carrying out hazardous manual handling; or

(c) if new or additional information about hazardous manual handling being associated with a task becomes available to the employer; or

(d) if an occurrence of a musculoskeletal disorder in a workplace is reported by or on behalf of an employee; or

(e) after any incident occurs to which Part 5 of the Act applies that involves hazardous manual handling; or

(f) if, for any other reason, the risk control measures do not adequately control the risks; or

(g) after receiving a request from a health and safety representative.

Note

Act compliance—section 21 (see regulation 1.1.7).

(2) A health and safety representative may make a request under subregulation (1)(g) if the health and safety representative believes on reasonable grounds that—

(a) any of the circumstances referred to in subregulations (1)(a) to (1)(f) exists; or

(b) the employer has failed—

(i) to properly review the risk control measures; or

(ii) to take account of any of the circumstances referred to in subregulations (1)(a) to (1)(f) in conducting a review of, or revising, the risk control measures.