ACCORD

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

Productivity Commission Study into Chemicals and Plastics Regulation

24 October 2007

Contents

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

Risk Analysis:

Risk Assessment:

- **hazard identification**
- **hazard characterization**

} **GHS hazard classifcation**

- **exposure assessment**
- **risk characterisation**

Risk Management

Risk Communication: **may include appropriate hazard elements**

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)

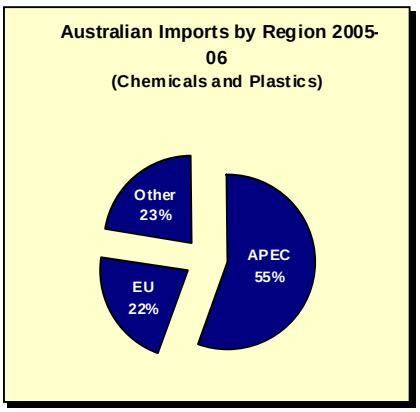
	Source of Imports	$m	%	Exports Destination	$m	%
1	United States	3,088	21.02	New Zealand	804	21.72
2	China	1,553	10.57	China	307	8.30
3	Japan	1,020	6.95	United States	295	7.97
4	Germany	810	5.51	Indonesia	166	4.50
5	United Kingdom	698	4.75	Japan	143	3.87
6	New Zealand	513	3.49	Korea, Republic of	136	3.68
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**

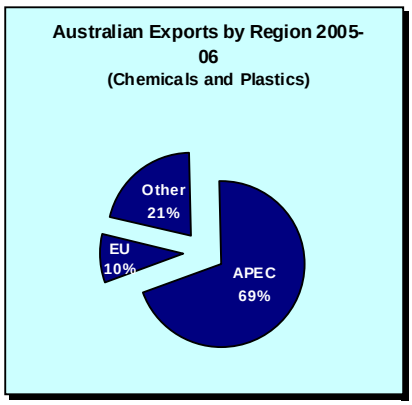
The United States is Australia's largest single country sources of imports at 21.02% and accepts 7.97% of Australia's exports. New Zealand accounts for 3.49% of imports but is Australia's largest export destination at 21.72%

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

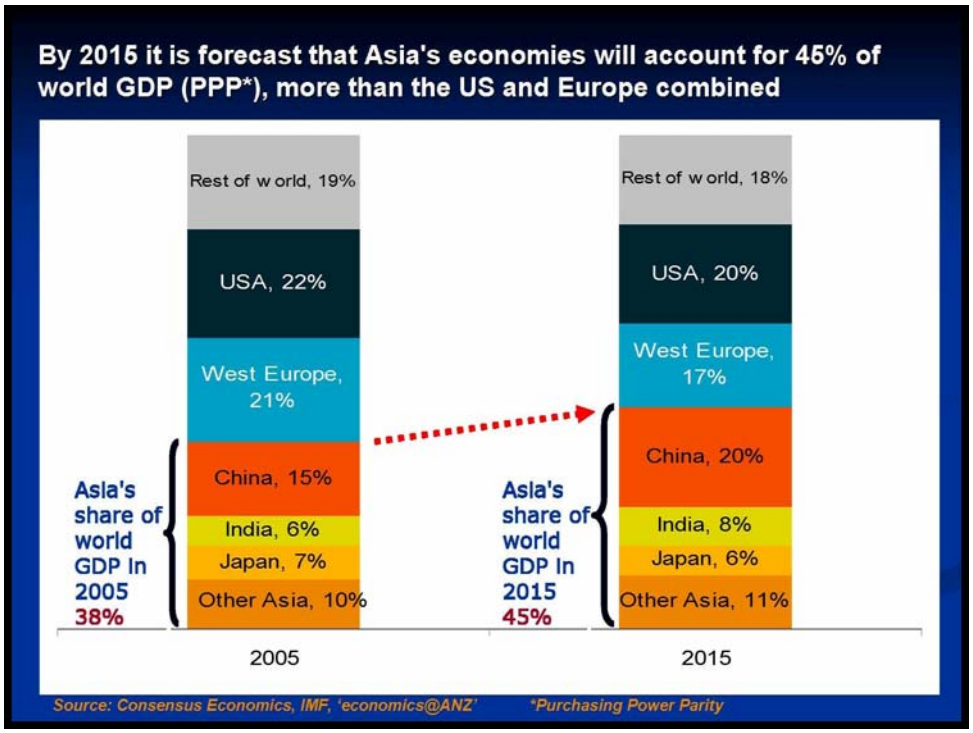
Diagram 1. Australian Imports and Exports by Region 2005-2006





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

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).

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