ACCORD

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

Mr Gary Banks
Chair
Regulation Taskforce
PO Box 282
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Dear Mr Banks

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

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

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

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

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

Yours sincerely

Unsigned for electronic transmission

Bronwyn Capanna
Executive Director

28 November 2005

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

Reducing the regulatory burden on business

28 November 2005

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Foreword

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

Our industry's products play a vital role in:

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

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

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

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

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

Bronwyn Capanna
Executive Director

Executive Summary

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

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

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

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

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

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

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

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

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

ACCORD Recommendations

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

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

Recommendation 3
ACCORD recommends that the:

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

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

Recommendation 5

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

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

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

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

Recommendations 8

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

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

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

Recommendation 9

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

Recommendation 10

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

Introduction

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

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

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

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

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

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

1. A principled approach - efficient risk resource management

1.1 Regulatory principles

ACCORD supports the Australian Government's approach to regulatory best practice and has always recommended that the Council of Australian Government's (COAG) Principles and Guidelines for National Standard Setting and Regulatory Action by

Ministerial Councils and Standard Setting Bodies (COAG Principles) should be rigorously applied to any regulatory decisions proposed by government agencies. In addition, ACCORD supports the following as good regulatory practice principles.

Regulatory solutions should:

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

1.2 Risk Management

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

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

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

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

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

The benefits of prudent risk management are:

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

1.3 ACCI's & the BCA's reform proposals

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

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

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

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

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

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

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

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

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

1.4 Urgent need for cultural change by regulatory agencies

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

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

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

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

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

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

as well as monitoring regulatory performance including compliance with:

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

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

Recommendation 1

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

1.5 Governance Issues

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

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

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

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

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

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

1.6 Cost recovery

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Recommendation 2

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

1.7 Chemicals and Plastics Industry Action Agenda – regulatory reform priorities

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

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

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

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

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

Recommendation 3

ACCORD recommends that the

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

2. *Specific reform proposals for the chemicals industry*

2.1 Development of an integrated chemical management framework

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

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

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

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

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

Recommendation 4

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

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

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

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

2.2.1 Reform to the system for interface products is urgently required

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

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

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

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

2.2.2 Reform of the agricultural active constituent scheme is urgently required

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

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

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

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

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

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

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

Listed registration and reservation

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

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

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

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

Case Study 2: Regulation of interface products - dairy cleansers and sanitisers

For a single identical formulation for a dairy sanitiser that is used to clean the milk vat on a dairy farm and the same formulation used to clean the milk tanker that picks up the milk from the farm and also used throughout the rest of the milk handling, processing and production chain there is totally separate regulation.

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

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

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

Recommendation 5

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

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

2.3 The burden of therapeutic goods regulation

2.3.1 The regulation of products at the cosmetic/therapeutic interface

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

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

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

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

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

undertake a detailed assessment of the safety data.

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

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

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

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

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

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

2.3.2 Australian regulatory agencies have mutual acceptance of assessment

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

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

Recommendation 6

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

2.3.3 The urgent need to streamline regulatory requirements for common disinfectants

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

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

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

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

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

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

Recommendation 7

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

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

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

- introduction of civil penalties;

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

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

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

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

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

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

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

2.4 The burden of environmental regulation

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Recommendation 8

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

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

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

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

2.5 The burden of unique Australian requirements

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

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

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

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

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

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

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

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

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

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

All the issues listed above require us to either go to the lengths of having our own packaging artwork for Australia, which is not a very large market and therefore the costs are high for us, or overlabel our products often with two or more overlabels per product. To have our own packaging, we need to order large quantities of stock to justify the dedicated production run and this can results in high overstocks in our warehouse as well. The overlabelling of products results in double-handling which poses a logistical obstacle which is time-consuming and expensive.'

Recommendation 9

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

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

2.6.1 National security issues – control of chemicals of interest

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

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

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

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

Recommendation 10

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

2.6.2 Development of a chemicals adverse reporting system

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

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

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

3. Concluding Comments

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

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

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

Attachment 1

ACCORD Australasia Membership

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

Associate Members:

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

Attachment 2

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

1 Treatment of interest

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

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

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

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

Recommendation 1

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

2 Treatment of reserves

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

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

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

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

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

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

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

Recommendation 2

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

3 Funding of appeals

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

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

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

4 Funding of services performed for Government

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

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

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

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

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

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

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

5 Activity based costing

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

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

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

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

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

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

ACCORD supports a levy design that:

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

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

Recommendation 6

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

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

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

7 Performance measures to demonstrate efficiency and effectiveness

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

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

Recommendation 7

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