Australian
Chemical Specialties
Manufacturers Association
ABN 83 205 141 267

ACSMA

Australian Chemical Specialties Manufacturers Association

Submission to Productivity Commission Inquiry into Cost Recovery Arrangements by Commonwealth Government regulatory, administrative and information agencies

November 2000

1 Executive Summary

The Australian Chemical Specialties Manufacturers Association (ACSMA) and its members are vitally interested in the issue of cost recovery arrangements by the Commonwealth's regulatory agencies.

Chemical specialty products manufactured and formulated by ACSMA's members are regulated by several agencies, detailed in part 3, all of which operate on a basis of 100% cost recovery.

ACSMA's members have serious concerns with the cost and complexity of compliance with these regulators. These concerns include discrepancies between fees charged; a lack of regulatory consistency; differing levels of industry input into decision-making processes, and overlaps between regulators.

While ACSMA is not in favour of a product registration system, it strongly contends that a national chemical regulatory framework is necessary to overcome these inconsistencies, provide a formal structure for consultation and review of overlapping regulations and increase the understanding and the confidence of regulators working in the industry.

This framework should follow the principles of good regulation identified by the Council of Australian Governments (COAG), including minimal impact, regular review and flexibility.

ACSMA's members do not oppose the principle of cost recovery but are not prepared to fund a system which is inefficient or unaccountable. If industry is to pay an agency's costs, it should be able to influence that agency's priorities and where funds are spent.

More fundamentally, the chemical specialties industry does not believe it appropriate or fair for industry to pay entirely for activities which provide substantial public benefits, such as the provision of policy advice, agency legal and accounting fees, staff recruitment and training costs.

A more accurate and improved activity-based costing system should be introduced in all agencies along with agreed key performance indicators and an independent assessment of agency productivity.

The refusal by Australian regulators to recognise the approval of products and/or chemicals overseas has led to higher costs, substantial delays or products being prevented from reaching the market.

Improved recognition of chemical approvals by foreign regulatory authorities would be a major step in reducing regulatory agency costs, and therefore the amount recovered by industry and/or passed on to the consumer.

There is also major potential for cost savings and increases in efficiency from the introduction of competition in chemical assessments. While the restriction of approvals to public sector regulators ensures that health, safety and the environment are protected, it would be possible to open the assessment process to competition with appropriate performance standards in place.

A number of case studies have been provided in Appendix 1 to illustrate the problems associated with the Australian regulatory system and how these increase the cost of compliance for business.

2 Introduction to ACSMA

ACSMA is the national peak body and advocate for manufacturers, formulators and marketers of chemical specialty products. Its mission is to promote the interests of the chemical specialties industry by speaking with a common voice on behalf of its members on issues such as regulatory matters including occupational health, safety and environment, commercial trade matters, taxation and other public affairs and policy areas.

Chemical specialties such as soaps, detergents and other formulated chemicals play an important part in the everyday life of consumers and major industries such as manufacturing, mining, medical institutions, schools and hotels.

ACSMA's membership includes manufacturers, formulators and companies that process, package, market or service the chemical specialty industry. This includes any chemical raw material or specialty product used in the household, industrial or institutional setting, such as cleaning agents, personal care products, protectants, disinfectants, hygiene products, water treatment products and metal treatment products.

Current membership includes well-known companies such as Colgate-Palmolive, Cussons, Campbell Brothers, Lever Rexona, Reckitt Benckiser, Ecolab and Henkel as well as many small to medium enterprises which play an integral role in the chemical specialties industry. The estimated sales turnover of this industry is approximately $2.7 billion per annum.

The industry operates in a very competitive climate where the highest value is placed upon product innovation, continuing improvement in product performance, and regard for human and environmental safety.

3 Interaction with regulatory agencies

Products manufactured by the chemical specialties industry are regulated by several different agencies - the National Registration Authority (NRA), Therapeutic Goods Administration (TGA), the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and the Australian Quarantine and Inspection Service (AQIS). These agencies all operate on a basis of 100% cost recovery from industry through a mix of company levies and new chemical or product assessment fees.

Industrial chemicals are regulated by NICNAS, AQIS is responsible for certification of sanitisers used in the export meat industry, the NRA covers on-farm dairy cleansers/sanitisers and household pesticides and the TGA regulates the range of disinfectants and antibacterial handwashes. ACSMA members also deal extensively with the National Drugs and Poisons Schedule Committee (NDPSC) who under the TGA are responsible for the scheduling of household chemicals and therefore their labelling and packaging requirements.

The issues regarding these agencies include discrepancies between fees charged; a lack of regulatory consistency; differing levels of industry input into decision-making processes; and overlaps between regulators. All of these issues have serious consequences for the cost and complexity of compliance by ACSMA members, however the impact of each issue varies between agencies.

NICNAS is a small agency which is overseen by a joint Industry/Government Consultative Committee (IGCC) set up in 1997 by the Department of Workplace Relations and Small Business. ACSMA is a member of the IGCC. Recent comments by ACSMA members in the context of an evaluation of the Company Registration Program revealed considerable dissatisfaction about the way NICNAS operates, including innovation being stifled by excessive fees, a lack of commitment to the timeliness of processing of applications and the imposition of upfront fees placing a major burden on small companies. NICNAS was also cited by manufacturers of chemical products in Australia and New Zealand as being a "major obstacle" to the introduction of new products into those markets.

ACSMA is also disappointed that some suggested improvements to NICNAS to reduce the regulatory burden on chemical manufacturers and importers have taken far too long to resolve.

In regard to the TGA, because of its very large size it has been very difficult for ACSMA members who are not mainstream producers of therapeutic products to gain adequate representation on the various committees that review and/or draft regulations. This obviously creates problems when the TGA develops regulations covering the chemical specialties industry - for example, the disinfectants standards introduced in 1997 were very costly and restrictive on the industry and were developed without a regulatory impact assessment, as required under Council of Australian Government (COAG) requirements.

While ACSMA is gradually gaining a seat at the necessary consultative forums, we are concerned that the TGA should not become an overarching authority for the review of public health and safety.

The NRA is focussed on agricultural and veterinary chemicals. ACSMA is a member of the NRA's Industry Liaison and Industry Technical Committees, and therefore has opportunities to consult with the NRA. However, a number of issues that have been

debated for some years are only now being appropriately considered by the NRA, including a fairer fee structure and low level registration of low risk products.

4 The need for a national chemical regulatory framework

While relationships differ with each individual agency, ACSMA is concerned in a more general context at the lack of consistency between agencies in the areas of regulatory control, industry input into the decision-making process and regulatory overlap.

In particular, the charging of different rates by different agencies on a cost-recovered basis does not permit adequate comparison of charges between agencies.

Many products manufactured by the chemical specialties industry are increasingly regarded as "gap chemicals" because they do not fall under the purview of one agency. Those that are regulated as products occupy the periphery of the TGA and NRA's regulatory structure. It should be stressed that all other products are already regulated by NICNAS on an ingredient basis and through post-market monitoring.

ACSMA is not in favour of any expanded product registration system as it is not convinced that such a system provides a public benefit equal to the increased cost. However, we believe that a national chemical regulatory framework should be adopted to overcome the inconsistencies and differing standards inherent in the current structures of the regulatory agencies.

This framework would adopt a whole of government approach to regulations to ensure consistent adoption across all States and agencies. It would prevent, or at least minimise, the development of new regulations on an ad-hoc basis which impacted on or overlapped with similar legislation already in place. In addition, it would increase the understanding and therefore the confidence in the system across the range of regulators working in the chemical specialties industry.

This framework is not put forward as a support mechanism for an all-powerful central agency for chemical regulation, but to provide a formal structure for consultation and review of overlapping regulations. It would be efficient and transparent; cover legislative, policy and regulatory issues, and acknowledge and recognise the need for a viable Australian chemical industry.

In particular, the framework would follow the principles of good regulation identified by COAG:

- Minimising the impact of regulation, including a scientifically rigorous risk assessment process taking into account public health and safety and environmental protection;

- Minimising the impact on competition, especially entry, exit or innovation;

- Predictability of outcomes, including a focus on performance-based outcomes;
- Compatibility with internationally accepted standards or practices and consistency with international obligations;
- Removal of unnecessary obstacles to international trade;
- Review of regulations at least once every ten years;
- Flexibility of regulatory measures to enable adjustment as circumstances change, and
- Minimal potential for bureaucratic interpretation to reduce the potential for uncertainty and increased compliance costs.

5 Industry's requirement for more accountability and greater influence

While ACSMA is not opposed to the principle of cost recovery, its members are not prepared to pay for a system which is inefficient or unaccountable. In addition, if industry is required to pay an agency's costs, it should have the ability to influence the allocation of funds and prioritisation of activities.

The current cost recovery system passes costs onto industry (and therefore consumers) without adequate consideration of efficiency improvements. A lack of transparency means it is very difficult for industry to accurately gauge whether agencies are operating efficiently.

Because the regulatory agencies are not subject to the discipline of the Budget and Estimates Committee process, there are few incentives to contain costs. ACSMA believes that the introduction of key performance indicators and benchmarks would permit both industry and agencies to monitor performance and efficiency improvements over time.

It would also be appropriate to independently assess the productivity of regulatory agencies to ensure that they are operating according to best practice principles. Subsequently, monitoring or audit systems would be introduced to measure productivity on an ongoing basis and suitable cost reduction targets put in place.

There is also a need to formulate an improved activity-based costing system to replace the current revenue-based system with its inherent lack of accountability. Fixed costs such as company and/or product annual fees should be minimised and replaced with fees based on the output of activities or services provided. In addition, there should be an equitable formula applied to the funding of post-market monitoring to ensure companies are not paying for the monitoring of products which it does not supply.

For example, while ACSMA supports the NRA's Existing Chemical Review Process (ECRP), our members resent having to pay for an assessment process which involves the

review of Technical Grade Active Constituents (TGACs) and the products which contain them, because ACSMA member products contain chemicals which are exempt TGACs.

It is highly unreasonable to expect industry to pay the entire costs of a particular agency but not permit sufficient accountability to allow industry to determine whether that agency is run in an efficient manner with a full appreciation of potential efficiency improvements.

ACSMA contends that the recovery of costs from industry should be proportionally assigned depending on the major beneficiary of the regulation.

In the context of the assessment of new chemicals and chemical products, industry gains from a high level of consumer confidence in products and the industry (a "private good"), but the assurance that is provided of protection of public health and safety and the environment provides a "public good" to the wider community.

The resources expended by regulatory agencies on compliance monitoring and administration are subject to cost recovery, yet it is highly unfair for companies in compliance to subsidise the monitoring of non-complying companies or to expect firms to cover the costs of administering the cost recovery process.

It is not clear whether the provision of policy advice to the Government and the attendance and participation by agencies at international negotiations is being paid for by companies through the cost recovery process. ACSMA believes that these areas are clearly "public goods" and should only be subject to partial cost recovery.

Agency overheads such as accommodation costs, legal and accounting fees should not be included in the costs recovered from industry. In addition, ACSMA does not believe that industry should be responsible for costs incurred through staff recruitment and training and staff replacement.

In particular, where products are sold in low volume and the small size of a market limits opportunities for the industry to pass on costs, alternatives to full cost recovery should be considered.

6 Potential cost reductions from international standardisation

One area with the potential for regulators to decrease their costs significantly, and therefore the amount recovered from industry, is the improved recognition of chemical approvals by foreign regulatory authorities. This would also significantly reduce the costs of companies providing information to regulators.

Regulators should be working to ensure internationally consistent - and where appropriate harmonised - systems in the areas of chemical assessment and notification, packaging, labelling, chemical hazard and risk information provision and modal transportation.

Currently, the lack of international harmonisation of definitions and classifications makes provision of data and compliance more difficult and costly.

There are a number of examples where the refusal by Australian regulatory agencies to recognise the approval of products and/or chemicals overseas has led to higher costs, substantial delays or products being prevented from reaching the market. These are discussed in Appendix 1(d).

Some progress is being made, for example the current Chemicals Case Study under the Trans-Tasman Mutual Recognition Arrangement Chemicals Cooperation Program, which may form the basis of recommendations to Ministers on the possible mutual recognition of laws. However, overall progress on this issue is frustratingly slow with industry only recently brought into the consultation process.

ACSMA contends that separate regulatory controls should only be necessary if risks are identified which are unique to Australia. We simply cannot afford to have different requirements to those applying in recognised overseas jurisdictions where there is little or no difference in applications.

Australian chemical production is only 1% of the world market and therefore relies heavily on input chemicals from overseas. There are a number of cases where chemicals in use overseas have not been introduced in Australia because of the onerous costs and complexity of the approval process.

Compatibility with internationally accepted standards or practices and consistency with international obligations is one of the COAG principles of good regulation which ACSMA believes should be included in a national framework for regulation of chemicals.

ACSMA proposes that chemical approvals from overseas countries be unilaterally recognised as a prelude to mutual recognition; data from overseas sources that tests to accepted international standards be recognised, and definitions of products and classifications be harmonised according to recognised overseas classifications.

7 More competition needed in chemical assessment

There is considerable potential for cost reduction and efficiency improvements through the introduction of competition in chemical assessments.

Currently, these assessments are entirely the province of Government agencies, and there is therefore no competitive pressure on these agencies to provide services in a timely or cost effective fashion - thereby increasing costs for assessments.

While the restriction of approvals to Government agencies ensures a high protection for health, safety and the environment, it is feasible that the assessment process could be

opened to competition while final approval would still be the province of the relevant agency.

If this was to occur, agencies responsible for approval would need to clearly communicate the performance standards for assessments - which would improve the transparency of the regulatory process and reduce opportunities for bureaucratic discretion, bringing regulatory practice more into line with the COAG principles already outlined.

Reviews by the Australian National Audit Office and the National Competition Policy Review have already recommended that the NRA accept alternative provision of assessment services.

8 Recommendations

- More effort should be expended on the improved recognition of chemical approvals by foreign regulatory authorities to ensure internationally consistent - and where appropriate harmonised - systems in the areas of chemical assessment and notification, packaging, labelling, chemical hazard and risk information provision and modal transportation.

- Chemical approvals from overseas countries should be unilaterally recognised as a prelude to mutual recognition; data from overseas sources that tests to accepted international standards should be recognised, and definitions of products and classifications should be harmonised according to recognised overseas classifications.

- Other standards relating to efficacy and testing should also be harmonised with international regulations.

- The recovery of costs from the chemical specialties industry by regulatory agencies should be proportionally assigned depending on the major beneficiary of the regulation.

- Services such as compliance monitoring and administration, policy formulation, staff training and recruitment and participation by agencies in international negotiations should not be subject to full cost recovery.

- Key performance indicators and performance benchmarks for regulatory agencies should be introduced to improve transparency and accountability to industry.

- An improved activity-based costing system should replace the current revenue-based system. Fees should be levied on the basis of the output of activities or services provided.

- A national chemical framework should be put in place to address the lack of consistency between regulatory agencies, improve industry input into the decision-making process and address problems caused by regulatory overlap.

- This framework should ensure consistent adoption of regulation across all States and agencies; be efficient and transparent; cover legislative, policy and regulatory issues, and acknowledge the need for a viable Australian chemical industry.

- The framework should comply with the COAG principles of good regulation including minimal impact, predictability of outcomes, regular review, flexibility and minimal potential for bureaucratic intervention.

- The chemical assessment process should be opened to competition by private bodies, but final approval should remain the province of the relevant government agency.

- Regulations should be equitably applied to companies so as not to disadvantage small to medium companies or favour one segment of the market over another.

Appendix 1: some examples from companies of the cost and regulatory burden

(a) Lack of national uniformity

(i) The implementation of the revised Criteria and Designated List of Hazardous Substances 1999 is an example of the serious negative effect of a lack of nationally uniform standards on chemical specialty companies.

The revised List contained errors and was less than user-friendly (because of the lack of cross-referencing) as industry was not consulted. There was a lack of uniformity in the adoption of the standard and therefore its implementation.

There was no regard to a nationally uniform transition period; existing finished product and/or labelling and packaging stocks were potentially lost, and there was no time for the training of personnel or the redrafting and printing of labels and Material Safety Data Sheets (MSDSs).

Because of the nature of their business, formulating chemical specialty companies market many products. For example, one company has more than 700 different formulated products for the industrial and institutional market.

The extensive changes and additions to the Designated List included very common chemicals used in formulated products, resulting in a very lengthy review of the company's entire product range.

For one company, the review of the formulations and flagging of required changes took one regulatory affairs chemist three months full-time to complete, equating to $15,000 in labour costs.

The company uses both preprinted labels and computer-generated labels for products. While computer-generated labels are altered in house with little cost, preprinted labels cost on average $250 per printing plate change. As the company currently have 300 different preprinted labels, changes had to be made to 50 labels at a cost of $12,000.

There was no transition period given to manufacturers to adopt the new standard because of the way the regulations called up the National Occupational Health and Safety Commission (NOHSC) standards. While ACSMA successfully lobbied the Queensland division of Workplace Health and Safety to provide for a transition period, there was no amendment made by other State agencies.

This meant that to run out existing preprinted label stock (usually held for about 12 months supply), the company would be in breach of Occupational Health and Safety regulations in other States.

MSDSs also had to be reviewed and resent to all existing customers. It took an administration officer one month to send out the updated versions to existing customers at a cost of $3,500.

If the current draft Code of Practice for the preparation of MSDSs obtains NOHSC approval, the change to the new 16 header format would take the company approximately 12 months. Labour costs alone will be $60,000, and all MSDSs will need to be reissued to existing customers, taking a further 2 months at a cost of $7000.

(ii) In addition, the product classifications used by Australian regulatory agencies also increase costs for industry and consumers.

For example, marine anti-fouling paints are regulated by the NRA. The regulations covering these products are different in each state and territory. This increases the cost of compliance for companies to make products that meet the requirements for each jurisdiction.

(b) Failure to observe sound regulatory practice

A failure by agencies to follow good regulatory practice has incurred significant extra costs for companies.

In 1995 it was decided that disinfectants would no longer be exempt under the Therapeutic Goods Act 1989. The Conformity Assessment Branch of the TGA took on the task of developing Therapeutic Goods Order (TGO) Number 54.

The TGA decided that the range of products to be regulated should include sterilants, instrument grade, hospital grade and household and commercial disinfectants. However, despite industry's protestations, these requirements were developed without first determining the size of the Australian market for each category of disinfectant and without determining the key efficacy and stability testing requirements and likely compliance costs.

This meant that no regulatory impact statement was prepared as required by COAG's regulatory principles. At the time, the TGA argued that the requirement to regulate disinfectants predated the need for an RIS in accordance with COAG principles.

The real objective of the regulations for each disinfectant category was never provided, and the overall range of products to be regulated was never defined. This led to grey areas in the regulation, e.g. sanitisers used in the manufactured foods industry were required to comply with TGO 54, although they were clearly not Therapeutic Goods.

A number of requirements (based on overseas test methods still in development) for efficacy, stability and Good Manufacturing Practice (GMP) were prescribed as standards for Australia despite the market here being quite small.

This process has been extremely costly, particularly to small industry players.

(c) Failure to determine appropriate risk/resource allocation

Companies face high compliance costs when the system remains inflexible despite a low risk being established.

One company is currently trying to register an antibacterial liquid hand soap with the TGA - a process which has taken more than 16 months to date because of a lack of clear guidelines and assistance.

The product is currently being sold in the hospitality/healthcare field as a plain liquid hand soap, and is not able to compete with other products that are making antibacterial claims. The cost to date for compiling a data package with suitable stability and efficacy data has been $30,000. A significant amount of time and effort has been spent by the regulatory affairs chemist, discussing and interpreting TGA requirements. A log of the time involved now totals 160 hours.

(d) Inconsistency with international regulations

There are a number of examples where chemicals in use overseas have not been introduced in Australia despite potential improvements in product performance, environmental quality or health and safety.

With only one per cent share of world production, Australian firms rely heavily on the availability of the latest information and technology from overseas, yet the costs involved in new chemical assessment put up a significant barrier to the introduction of new chemicals.

NICNAS requirements prevent the introduction of products available overseas as they include chemicals regarded as "new" in Australia.

(i) A company involved in the personal care, cosmetics and detergent marketing areas when using a "new" chemical ingredient in a small volume product may be able to first apply for a Commercial Evaluation Permit from NICNAS. For this, the applicant is obliged to pay around $3000 for the Permit. Should the product be successful to market, or in the case of a larger volume product, the company must apply for a Limited Notification or Standard Notification. These cost $10,000 and $11,700 respectively for each new ingredient to be assessed.

Companies often use third parties to collect and submit the data, adding consultancy fees as well as data preparation fees. This is likely to bring the costs up to $60-80,000 per ingredient to be assessed. The company then has to wait around one year for a product under Standard Notification to be fully assessed and authorised for release.

ACSMA is aware of products which are more efficacious and safer that are approved overseas which have up to three new ingredients. For the relatively small Australian market, it is not worth the investment.

The Australian chemical specialties industry is in danger of falling behind its overseas competitors because of the high assessment costs involved in importing new products.

Agencies argue that assessment costs are not significant - but it is important to note that costs charged by agencies may be only a small proportion of the total costs paid by companies for assessment. For example, while NICNAS charge $11,700 for a standard notification, companies can face costs of up to $250,000 to generate and provide the necessary data packages which are required for assessment, which is obviously a major barrier to the introduction of new technology in a small market like Australia.

(ii) Other aspects of TGA regulation push up costs and the complexity of compliance for manufacturers, such as the example of antibacterial liquid handwashes. Current TGA legislation requires that liquid handwashes claiming an antibacterial effect are regulated as therapeutic goods, whereas in Europe the same products are regulated as cosmetic products.

One company markets this product under an international brand, building on the brand's success overseas. The impact of the Australian legislation is that liquid handwashes must be made at a facility complying with the Good Manufacturing Practice (GMP) guidelines of the TGA (the purpose of GMP licensing is to ensure that medicines and medical devices meet definable standards of quality assurance and are manufactured in conditions that are clean and free of contaminants).

While the company in question owns a manufacturing facility in Australia of a high standard, it does not carry a GMP license and the product must therefore be made by a sub-contractor.

The impact of this requirement is a loss in net contribution from the brand of approximately $160,000, versus the contribution the company would expect if the liquid handwash was regulated in the same way as Europe, primarily due to the higher cost of manufacture.

In addition, the ability of the company to market this brand is severely restricted by the TGA's requirements on extended testing, registration delays and the need for all changes to be either notified or applied for through the TGA. These obligations mean that the Australian business is less able to expedite the normal commercial strategies that would be used for other personal care products, such as upgrades to artwork as part of brand

evolution, swift roll-out of formulation upgrades and the introduction of more cost-efficient technologies including packaging.

Although these restrictions are more difficult to quantify in cost impact terms, the net effect will be a loss in profitability to the Australian company.

(iii) Other case studies have more positive outcomes, and ACSMA acknowledges that some progress has been made towards reducing pre-market barriers. For example, the TGA recognised that it did not have adequate justification or resources to undertake full toxicity requirements of all excipients used in cosmetic sunscreens and subsequently identified a list of criteria where cosmetic ingredients could be introduced without requiring the assessment.

The criteria included a requirement that the chemical is used in a similar application overseas and that the company would provide further information on the product within six months of introduction.

(iv) In another example, a company markets a number of aerosol gels within its portfolio of personal care products. There is currently no manufacturing facility available in Australia for the company to make these products here and hence they have to be imported from the UK.

In order to comply with legislation covering the distribution and sale of these products, the labelling of these aerosol cans must conform with the requirements of the Australian Dangerous Goods Code, which differ from the can labelling requirements applicable in Europe. The option of producing a specific can for the Australian market in Europe is not available, because the much smaller volumes for Australia compared to Europe means that specific production runs for Australia are not feasible.

The company would therefore have to import product from the UK and overlabel in Australia. The cost of overlabelling would be approximately $200,000 per annum, and the loss of margin would be of such a scale that the distribution and sale of these products could not be justified.

In this case, the company applied for an exemption to the Dangerous Goods regulations to allow for cans marked in accordance with European regulations to be sold in Australia. The granting of this exemption allowed the company to make an innovative product available to Australian consumers.