Australian
Chemical Specialties
Manufacturers Association
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ACSMA

Australian Chemical Specialties Manufacturers Association

Submission on Draft Productivity Commission Report on Cost Recovery Arrangements by Commonwealth Government regulatory, administrative and information agencies

June 2001

1. Executive Summary

The Australian Chemical Specialties Manufacturers Association (ACSMA) welcomes the opportunity to comment on the Productivity Commission's draft report on cost recovery by Commonwealth regulatory agencies.

As outlined in our initial submission to the inquiry, ACSMA is one of the many users of the cost recovery system who are dissatisfied with current arrangements.

We concur with many of the report's Key Messages[1], in particular the findings that cost recovery arrangements "generally lack the attributes of good policy" and are "inconsistent with sound economic principles."

In particular, we support the finding that most arrangements "lack transparency (and) have poor accountability and review mechanisms." This was a key contention in our original submission to the inquiry.

As stated in our original submission and the evidence ACSMA presented to the inquiry hearings, our organisation does not oppose the principle of cost recovery.

However, we are strongly opposed to the inconsistent, inefficient and unaccountable systems which have grown in scale and scope in recent years as cost recovery principles are put into practice.

ACSMA is pleased that the Commission's investigations have vindicated the serious concerns of our members regarding the cost and complexity of compliance with regulators subject to cost recovery, including the Therapeutic Goods Administration (TGA), the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and the National Registration Authority (NRA).

We strongly endorse the Key Message that current arrangements "…can reduce innovation and competition, and are on occasions incompatible with overarching government objectives."[2]

The Commission's proposal of a detailed and integrated set of cost recovery guidelines with which to review existing arrangements and test new proposals, if implemented, would provide a vital benchmark to measure the effectiveness and reasonableness of existing cost recovery arrangements while ensuring that new arrangements are not beset by the inconsistencies that have dogged agencies to date.

ACSMA agrees that some sort of national framework is necessary to overcome these inconsistencies, provide a formal structure for consultation and review of overlapping

[1] Draft Report on Cost Recovery, p. XXVI
[2] Ibid., dot point 5

regulations and increase the understanding and the confidence of regulators working in the industry. In our original proposal, we outlined a proposed national chemical regulatory system which we believe could be integrated with more general cost recovery guidelines.

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

Overall, ACSMA believes that the tenor and intensity of views expressed by industry to the Commission send a signal that there is significant dissatisfaction with the current system.

In particular, the lack of competition in providing the functions performed by cost-recovered agencies and the recovery of 100% of costs from the private sector for functions which provide at least some public benefit are areas where urgent action is required.

ACSMA members have supplied additional case study material to illustrate industry's concerns at the current operations of cost-recovered agencies (in these instances, the TGA and NICNAS). In particular, these concerns relate to the non-acceptance by Australian regulatory authorities of overseas approvals of safety data and other information, and how this increases the cost and complexity of doing business for Australian firms.

2. Operational principles for cost recovery

ACSMA is gratified that the Commission has set out several operational principles for cost recovery, as many cost recovery systems have thus far developed in a haphazard manner without reference to an overall framework.

In the case of regulatory agencies, we agree with the recommendation that "cost recovered activities should not include activities undertaken for the Government such as policy development, ministerial or parliamentary services, and complying with international obligations."

In our original submission, we recommended that the recovery of costs from industry should be proportionally assigned according to the major beneficiary of the regulation.

In reference to the provision of policy advice to the Government and the attendance and participation by agencies at international negotiations, ACSMA said that it was unclear whether these activities were being paid for by companies through the cost recovery process, but that in any case these areas were "public goods" and should only be subject to partial cost recovery.

In light of this recommendation, we believe it would be appropriate to establish a working party with government, industry and consumer representatives so the extent of such activities could be defined and an equitable cost-sharing formula devised.

For example, when only 50% of the Therapeutic Goods Administration's costs were recovered from industry, there was a much clearer delineation between industry-related activities and public interest-related activities.

Under that agreement, industry fully funded the activities which were primarily industry-related; government fully funded the activities which were undertaken primarily in the public interest, and those activities with a perceived benefit to both industry and the public would be jointly funded in the agreed proportions by both industry and the government.

However, the movement to 100% cost recovery policy has greatly enlarged the range of activities that industry pays for – beyond 'industry service' activities into the realm of government and public interest activities.

In the same context, agency overheads such as accommodation costs, legal and accounting fees, staff recruitment costs, training and staff replacement costs should not be included in the costs recovered from industry.

3. Impact on agencies

ACSMA strongly endorses the finding by the Commission that while cost recovery has the potential to increase agency efficiency, "it can also weaken government scrutiny through normal budget processes" and "to the extent that agencies become in effect self-funding (under cost recovery), there is less incentive for their respective portfolios and expenditure review processes to subject them to closer scrutiny."

We believe the current system provides few incentives to agencies to contain costs because they are not subject to the discipline of the Budget and Estimates Committee process. This lack of transparency also means that it is very hard for industry to accurately gauge whether agencies are operating efficiently.

It is highly inappropriate for agencies to have automatic access to cost recovered revenues without proper scrutiny through the normal budgetary and parliamentary mechanisms. It is totally appropriate for cost recovered funding to be subject to the same level and intensity of oversight as budget funded government activities.[3]

We agree that there are grounds for including a "community pays" component for activities with benefits which accrue to the wider community and not specifically to the regulated firm or its customers.[4]

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[3] Draft Recommendation 5.1

[4] Draft Report on Cost Recovery, p. 26, final paragraph

In the same vein, we support the Commission's statement that "it is imperative that external systems are implemented to shore up accountability and to encourage agency efficiency."

ACSMA believes that the implementation of these systems would go beyond "shoring up" accountability and "encouraging" efficiency – in fact, it would provide an inescapable obligation for agencies to improve their accountability to the Australian public through such mechanisms.

The current Commonwealth Government, and the current Opposition, share the objective of reducing the burden of regulation and red tape on business.

Yet since the introduction of cost recovery (under the former Government), agencies have used cost recovery as the basis for "empire building" – the construction of bureaucratic structures bankrolled by industry but not accountable to industry.

We have already suggested that the introduction of key performance indicators and benchmarks would permit industry and agencies to monitor performance and efficiency improvements over time. In addition, we suggested that monitoring or audit systems should be introduced to measure productivity on an ongoing basis and suitable cost reduction targets put in place.

ACSMA wishes to reiterate those suggestions in light of the Commission's finding that external systems of assessment be introduced without delay and the apparent inattention paid by other studies to this crucial area

For example, the current Review (by the Commonwealth's Regulatory Reform Taskforce) of Administrative Arrangements of Public Health and Safety Regulation for Chemical Safety Assessment, Medicines, Medical Devices, Gene Technology and Food proposes a single statutory authority to regulate public health in the areas of medicines, medical devices, services for gene technology and chemical safety evaluation.

Disappointingly, however, the Review's discussion paper only highlighted potential cost savings and opportunities. We believe the review should have further examined the extent of those likely cost savings and provided real incentives in terms of costs or other benefits which would be passed on to stakeholders, in particular industry.

While it is assumed that the single statutory authority would operate on the same cost-recovered basis as the organisations it replaces, there is no reference in the Taskforce's report to performance criteria by which the performance of the authority can be measured.

ACSMA believes that it is inexcusable for a proposed new organisation, whose proponents should have learnt from the mistakes made by other organisations, not to embrace such criteria. Indeed, the Taskforce recommends that the proposed administrative arrangements for the authority be reviewed in four years' time. What

criteria would such a review be based on, given the absence of key performance indicators?

We strongly endorse the Commission's finding that harmonisation of standards and mutual recognition can also encourage regulatory agency efficiency by improving contestability of assessment and approval processes. We believe that there is great potential for reducing costs to companies by improving recognition of product approvals by foreign regulators.

Overall, the lack of international harmonisation of our regulatory system, for example in definitions and classifications makes provision of data and compliance more difficult and costly. There are a number of examples – outlined in Appendix 1(d) to our original submission – where the refusal by Australian regulatory agencies to recognise the approval of products or chemicals overseas has led to high costs, substantial delays or products being prevented from reaching the market.

Further detail on these areas is provided in the case studies detailed in the appendix to this submission.

ACSMA also believes that there is considerable potential for cost reduction and efficiency improvements through the introduction of competition in chemical assessments.

Such assessments are currently the province of Government agencies only, and there is no competitive pressure on these agencies to provide services in a timely or cost effective manner – thereby increasing costs for assessments.

The acceptance by the NRA of alternative provision of assessment services has already been recommended by separate reviews by the Australian National Audit Office and the National Competition Policy Review.

We are therefore concerned about the Regulatory Reform Review's lack of consideration of alternative and possibly more efficient (and cost competitive) models when it comes to the retention of the Australian chemicals public health evaluation unit within the proposed single statutory authority.

ACSMA is also taking a particular interest in feedback from the working party of Commonwealth officials which is currently examining the issue of contestability in regulatory toxicology and considering whether it is appropriate to contract toxicology work to outside bodies.

As a potential beneficiary of any increase in contestability, industry should be included in these discussions.

4. Impacts on users

ACSMA was among the participants in the Commission's inquiry to express concern about the effects of cost recovery on industries, firms and consumers.

In particular, we made the point that in some cases the costs of new chemical assessment put up a significant barrier to the introduction of new chemicals. This is especially important because with only one per cent share of world production, Australian firms frequently rely on the availability of the latest information and technology from overseas.

These high costs are preventing the introduction of products that are approved overseas and are potentially more effective and safer. For example, with up to three new ingredients involved, it is simply not worth it for companies to invest the money required to get such products approved for the relatively small Australian market.

Yet if regulatory agencies were subject to greater accountability, scrutiny and external assessment – as well as competition from other service providers – there is little doubt that the costs of assessment would fall.

This would make it more viable for companies to introduce products onto the Australian market which provided potential improvements in product performance, environmental quality or health and safety.

The lack of accountability and competition in the assessment process is therefore having a direct effect on costs recovered from companies and the prospects of successfully introducing a new, and perhaps more effective, product onto the Australian market.

This is related to the last finding on page LII, which states that Australian consumers may be affected by cost recovery directly, in that they may pay higher prices or have a smaller range of choice for some regulated products.

ACSMA submits that consumers are being denied the option of choosing a more effective or cheaper product because the inefficiency and lack of competition inherent in the current system are making new products prohibitively expensive.

In that context, it was gratifying to read a recent media interview with Commissioner Helen Owens in which she stated that following the release of the Commission's final report: "Ultimately, firms will pay less and consumer prices will come down."[5]

5. Guidelines for cost recovery

The Commission has pointed out that there are "currently no Government endorsed guidelines available to Commonwealth agencies that have, or are considering introducing, cost recovery."[6]

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[5] "Taxpayers hit twice - illegal fees exposed," Sunday Telegraph 06/05/01

This in itself is a key indicator of the ad hoc way in which these arrangements have developed. In addition, it is indicative of the negligent attitude by agencies that no guidelines have yet been developed for cost recovery, despite the entrenched and long-standing nature of such arrangements.

In ACSMA's view it is essential to integrate cost recovery arrangements with an overall policy framework. In that context, the policy process outlined in Chapter 9.1 of the Commission's draft report is extremely useful.

However, we feel that such guidelines may be open to manipulation by the Commonwealth's economic agencies (the Department of Treasury and the Department of Finance and Administration) and would therefore recommend that the guidelines be put into some kind of legislative form – either a disallowable Order or Regulation.

In addition, we recommend that the guidelines be subject to appeal on both their merits (via the Administrative Appeals Tribunal) or in relation to due process (via the Administrative Decisions Judicial Review process).

This would avoid the situation where guidelines are introduced that are initially acceptable to industry but become less so over time because of self-serving interpretations by the aforementioned economic agencies.

The initial policy review adopts a "first principles" approach in assessing whether or not a particular regulation or service is consistent with agency objectives, who should pay and how payments should be recovered.

ACSMA contends that such a fundamental examination of cost recovery arrangements will be necessary if adequate demarcation between "public good" and "private good" functions is to occur. It would also be useful to move agencies away from the automatic assumption that cost recovery is the only suitable avenue for agency funding towards an understanding that cost recovery has to be properly justified.

Overall, ACSMA is pleased that the fundamental policy principle of funding activities – not agencies – has been adopted under the guidelines. In addition, we are pleased that the Commission has recommended that specific "public" services such as policy development and advice, international relations and Ministerial and Parliamentary processes be taxpayer funded.

We also endorse the recommendation that product recalls under the TGA be publicly funded.

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[6] Chapter 9.1, p 195, first paragraph.

Appendix A: Additional Case Studies

ACSMA's Member companies have provided the following case studies with details which would identify the company removed for the purposes of this submission. However, should the Commission require more details, the Association would be happy to facilitate discussions and the provision of more information by the specific companies involved.

(i) The TGA and disinfectant regulation

This first case study shows how costs to industry can grow alarmingly when regulations are introduced without meaningful consultation with industry and Australian regulators attempt to experiment and tinker with international approaches.

In 1995, the TGA met with industry to flag their intention to regulate the disinfectant market after concerns were raised regarding the claims and marketing associated with product with medical applications (so-called High Level Disinfectants and Sterilants) and claims linked with products marked as Hospital Grade Disinfectants for consumer usage.

Industry generally supported a level playing field, particularly for pre-market product assessment for High Level Disinfectants and Sterilants. Prior to the TGA's intervention, fees attached to the sector (generally below $500 per annum for even the High Level Disinfectants and Sterilants) were occasionally levied by State Governments under a range of Public Health Acts and regulations.

The TGA's agenda – particularly that of their microbiologists – became quickly apparent in 1996 when the TGA invited industry to participate in a Disinfectant Working Group convened specifically to shape regulations which would cover the sector.

At that meeting the TGA presented a weighty draft "Guidelines" document, based on the "510k" document from the US Food and Drug Administration (FDA) and the result of considerable international travel by TGA officers.

However, the TGA document included three changes from the FDA's 510k document.

First, the Australian standard bactericidal test (known as "the TGA test") was made mandatory (at a cost of $500 per product test).

Second, the equivalent standard US test (the AOAC Surface Carrier Test) was altered to suit the TGA, with no international standard reference for their changes, and was also made mandatory for higher-level products (at a cost of $1350 per product test).

Third, the TGA introduced a new test – without any published supporting peer review paper – which applied the concept of D-values to sporicidal testing requirements for High Level Disinfectants and Sterilants.

At that time, there was no Australian laboratory which could run this new protocol and no Australian manufacturers had ever tested their product to this standard. How, then, could the TGA make even an educated guess at the impact on Australian manufacturers of this regulation?

This headlong rush to implement a new test was done without any consultation with the Disinfectant Working Group, which as noted earlier was set up to shape the regulations covering this sector.

The Working Group held three meetings in Canberra while the review process of 1996 was underway. At its final meeting in September, the Working Group outlined its objections to the proposed changes, including being opposed to:

- The unreferenced changes in the AOAC test;
- The lack of a regulatory impact statement as required under COAG guidelines, and
- The lack of several other specific and uniquely Australian requirements within the draft document.

Importantly, the Working Group was not told of the introduction of the D-Value methodology until a letter was sent after its third meeting in September 1996. The following month, the TGA gazetted the regulation without notifying the Working Group. It then sent out a totally revised draft Guidelines document, which was finalised following the receipt of several never-disclosed petitions and sent to industry as a "fait accompli" in November.

The D-Value methodology was then introduced and finalised without any review by the Working Group. Manufacturers of High Level Disinfectants and Sterilants were then given until February 1997 (three months) to obtain a "pending" registration status under the new legal framework.

The manufacturers most affected were therefore given minimal opportunity to comment and no chance to develop data on the new proposal prior to its implementation. No other country has shown any real intention of following the Australian proposal which is seen by industry as an experimental system imposed on Australian manufacturers.

The cost of each test under this system is around $2200 per product, per test. Companies doing multiple tests face the very real risk of a significant cost blowout and the fact that the data obtained is meaningless in all other global jurisdictions, with the FDA sporicidal test remaining the global benchmark.

Initially, the registration fee for High Level Disinfectants was set at $2700; the new fee is $10,000, with full cost recovery used to justify this increase.

Now, industry is facing a situation where the latest TGA guidelines resemble the FDA 510K guidelines; the contentious D-Value requirement is up for review, and it appears

the FDA sporicidal testing system is now the TGA's preferred method. The TGA's insistence on using "experimental" methodologies meant that the only Australian product ever to be approved under 510k had its sporicidal time doubled in the US – entirely due to the requirements of the TGA. If not for the TGA input, the product's sporicidal time would have been 53% less.

As a result, this product was forced to make less commercially competitive claims, meaning an Australian competitor faces more onerous conditions than an equivalent US product.

It is also lamentable that the only review mechanism available for industry facing the plethora of technical details inherent in the TGA approval process is a protracted and expensive review process under section 60 of the Therapeutic Goods Act. Thereafter, legal appeals go to the Administrative Appeals Tribunal.

There is no review mechanism which covers TGA fees.

(ii) NICNAS fees and data rules affecting competitiveness of Australian firms

Product safety data which is accepted by our major trading partners is not accepted in Australia. This means that firms here are forced to provide duplicative and/or unique safety data for Australian regulators, increasing costs and the regulatory burden.

In addition, fees requested by regulators do not realistically reflect the small size of the Australian market. Overall, this makes it much more difficult for Australian firms to compete, and jobs that could go to Australians are therefore exported overseas.

For example, a uniquely Australian product with specialised household cleaning applications is sold into the consumer market. The product uses an essential raw material (ERM) at a concentration of less than 1% volume, without which the product does not work.

The ERM is sold in Australia by a subsidiary of a US corporation in foreign packaging at around 10% concentration (technical chemistry reasons prevent the ERM being made available in a more concentrated form). Under US law, the ERM intellectual property (a key aspect of the proprietary formulation) is protected, but if it is sold in Australia, no such protection is available.

At around 5% concentration, the toxic profile of the ERM requires certain declarations to be made under Australian law. There are two problems which face the US corporation:

- First, the costs of the NICNAS applications and unique data provision requirements are high, especially relative to the size of the market;

- Second, there is only one Australian manufacturer using the ERM as an essential component, with the total Australian market size (because of the 1% concentration) being less than 1000 kg annually.

At 1% concentration, the product only has a moderate safety profile, with consumer risk issues dealt with under the provisions of other regulatory requirements relating to chemical product safety.

However, for the US corporation the costs associated with these applications and the implication that their intellectual property would inevitably be compromised forces the company to discontinue with sales of the product in Australia.

Following inquiries, the Australian manufacturer finds out the substance can still be sourced directly from the US. But the cost is now greater and the minimum buying volumes have changed (there is no allowance for the small Australian market).

The Australian manufacturer finds a way to legally import the substance (via external dilution by a third party in the US prior to import), but the cost is now even greater. Profit margin on the product is now greatly diminished, but the Australian company pushes on in an effort to remain competitive – repositioning and continuing with sales.

After a short period a so-called "new generation" ERM (ngERM) is released. The US corporation releasing this product has a global release platform, and therefore at around the same time that the Australian company finds out about the ngERM, their importing competitors are releasing this new generation product into the Australian consumer market.

Sales for the Australian firm plummet, and the firm must decided to either cease sales of the line or faced by lower capitalisation, try to formulate their own version of the ngERM. A decision is reluctantly made to withdraw from sales until the ngERM becomes available in Australia.

The US corporation who make both the ERM and the ngERM decide that because of the difficulties involved and the small size of the market, the corporation will not sell the ngERM into the Australian market.

In this example, which is a real-life one drawn from the annals of ACSMA's members, the Australian firm is currently investigating ways of clawing back its competitive advantage and finding a way around the NICNAS minefield.

(iii) International harmonisation in chemical regulation a vital step

The need to obtain NICNAS approval for ingredients that are widely used overseas but cannot be used here without that approval is a major and growing concern for ACSMA members. This concern extends to products manufactured both here and overseas.

In some cases, formulators deliberately avoid ingredients that are not listed on the AICS, but this can limit competitiveness and product performance – not only in Australia but in all other countries where the product is sold when globally identical formulations are pursued.

In other cases, member companies can either forgo the introduction of the product in Australia (as has happened with, for example, a fabric soil repellent) or apply to obtain NICNAS approval.

Member companies have often used the less than 10 kg per annum exemption for cosmetic and personal care products offered by NICNAS, but in other instances it has been necessary for companies or their ingredient suppliers to obtain a Low Volume Chemical permit or Full Notification.

In the experience of ACSMA members, overseas ingredient suppliers are sometimes reluctant and quite often very slow to co-operate because of a lack of familiarity with NICNAS requirements as well as the very small market which Australia represents to overseas firms.

One major concern to members in terms of setting reasonable cost recovery arrangements is the fee of $2600 levied by NICNAS for a Low Volume Chemical permit to import less than 100 kg per annum of a new ingredient for three years. Many chemicals assessed in this category are present as a small percentage in imported finished products, so for the fee NICNAS has to complete the following modest list of tasks:

- Evaluate an MSDS (Material Safety Data Sheet) for the new chemical;
- Evaluate an MSDS for the finished product;
- Review a simple one-page application form;
- Review the applicant's summary of OH&S environmental impact and public health statements, normally no longer than three to four pages;
- Review a checklist to ensure the applicant has submitted the required data.

This process should take less than half a day and is certainly less complex than the TGA Listing Application, for which the TGA fee is $400. NICNAS should be required to justify their $2600 fee for this evaluation. In addition, if companies wish to continue importing the same ingredient after the three-year permit has expired, they must submit another application and another $2600 fee – even if the details remain exactly the same. We contend that fees should be substantially reduced if there are no changes in the application.

International harmonisation of chemical inventories would largely eliminate the need to have "new" substances reviewed for listing on the AICS. A notification without review should be sufficient provided the chemical can be used elsewhere.

In addition, the TGA should apply adequate risk assessment processes to determine the level of risk it should accept for certain products. This does not occur consistently at present.

For instance, antibacterial hand soaps using a specific active ingredient for domestic use have been available in most countries for more than 25 years, yet the TGA insist that any products utilising this “new” substance and making antibacterial claims must be registered – subsequently requiring full efficacy, toxicity and pharmacological data for the application to be successful.

One ACSMA member company has spent a considerable amount of time and money in attempting to register such a hand soap. Lengthy discussions with the TGA and regulatory consultants revealed that the soap would be required to pass the TGA Antiseptic Test Option D. However, the company discovered that this was an inappropriate test for soaps because of gel formulation.

Much time and money was spent with consulting laboratories in attempts to devise a suitable test.

The eventual outcome was that after having spent about $20,000, the member company decided not to make any therapeutic claims and sell the product as a cosmetic. In this situation, the public exposure is exactly the same as it would have been if the product was sold as a therapeutic good.