

PRODUCTIVITY COMMISSION STUDY ON REGULATION OF CHEMICALS AND  
PLASTICS IN AUSTRALIA  
SUBMISSION FROM  
THE SCIENCE INDUSTRY ACTION AGENDA (SIAA)

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### Introduction

The Business Council of Australia in a 2005 report stated that new laws and regulations were increasing at 10 per cent a year - approximately three times as fast as Australia's rate of economic growth.

Information that Science Industry Australia (SIA) has collected through a recent survey of its members supports this contention. In fact, according to this survey, the increase in the regulation of chemicals has been exponential over the past several years; the rate is currently beyond 10 per cent per year.

This is not good news for those, predominantly high technology, SMEs that need to manage the plethora of new regulatory offerings that are coming from all levels of government. SIA believes that if this growth in business red tape is not stopped, reversed and reduced, the competitive strengths of much of Australia's technology-based SMEs will be significantly and possibly irretrievably, damaged.

SIA welcomes the opportunity to provide informed comment and suggestions relating to the Productivity Commissions *Study on Regulation of Chemicals and Plastics in Australia* as summarised in the associated issues paper dated September 2007 (the "Issues Paper").

SIA provided input in late 2005 to the Australian Government's Regulation Taskforce which was charged with a similar, but broader, undertaking. We note that some of the matters we raised in that submission have been recommended for action.

We are also aware of the recent COAG discussions and agreements to act on regulatory burdens as summarised and recommended in the February 2006 COAG background paper: *COAG National Competition Policy Review*.

SIA believes these initiatives are a necessary first step required to address, and hopefully minimise, the negative aspects of the increasing regulatory impost on Australian business activities in order to maintain the economic, environmental and social wellbeing of Australians.

### Science industry and the Australian economy

Measurement matters. The science industry's<sup>1</sup> chemicals, equipment and laboratory services are integral to modern society. They are required to measure the quality of our water, food and air, our health and many other aspects of our daily lives. Australia's science industry comprises manufacturers and importer/distributors of chemicals, scientific equipment, laboratory and technical service companies and researchers. It is outperforming many other

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<sup>1</sup> The science industry is defined as "research and development, design, production, sale and distribution of laboratory-related goods, services and intellectual capital used for measurement, analysis and diagnosis"

industries in terms of its growth, innovation, exports and workplace excellence. It is also an employer of highly skilled personnel.

Australia's domestic market for scientific equipment and laboratory-related services was estimated to be \$6 billion in 2002/03. Employment, including researchers and technology service providers, was approximately 47 000.

Manufacturing production was \$930 million, exports \$670 million, imports \$2820 million and employment 8 000. Services production was \$3070 million, of which exports were \$110 million, and employment was 39 000. Australia's publicly-funded researchers also provided significant services to the industry. Australia's scientific product manufacturers produce \$260 million of the \$3 billion domestic market for scientific products.

The report "Measure by Measure" released on 31 August 2005 is a blueprint for expansion of an industry made up of many thousands of manufacturers, distributors, laboratory service providers and, most importantly, Australia's scientific research community.

The industry's priorities, as espoused in the Science Industry Action Agenda (SIAA) report *Measure by Measure*<sup>2</sup> is a blueprint for expansion of an industry made up of many thousands of manufacturers, distributors, laboratory service providers and, most importantly, Australia's scientific research community. These priorities are:

- to commercialise more Australian innovation,
- to grow exports,
- to improve quality,
- to *progress regulation reform*<sup>3</sup>;
- to attract and retain a skilled and flexible workforce; and
- to improve the industry's internal and external linkages.

#### Addressing the Issues

While acknowledging that regulating access to, and the use of, chemicals is necessary to protect the public and preserve society the SIA believes there are more efficient means of achieving these high level goals in ways that are beneficial to all parties. As a first suggestion the SIA sees that any regulatory reform relating to chemicals and plastics can be addressed under three main themes. These themes are:

- standardisation;
- appropriate risk assessment;
- minimisation of duplication; and
- balanced regulation

This submission will elaborate on these themes through reference to the Issues Paper, reference to other reports on regulation and through case studies.

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<sup>2</sup> Endorsed by Federal Cabinet and released by the Minister for Industry on 31 August 2005

<sup>3</sup> The wording in the SIAA report *Measure by Measure* is "Progress the harmonization of regulations and standards relevant to the science industry across Australian, State and Territory governments, and align them with relevant international standards"

- standardised legislation
- a single date of implementation
- standardised compliance procedures
- a commitment through the COAG process for standardised chemicals legislation across the nation

#### Theme Number 1 - Standardisation

Regulation, or more precisely the development of regulation, is guided differently across the COAG partners. One common thread is the 'Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial and Standard-Setting Bodies - amended 2004' produced by the Council of Australian Governments (COAG).

There are acknowledge deficiencies within the COAG document which attempts, but fails, to be a panacea for all national regulation / standard setting. The case study below (see Appendix 1) provides an example where there has been national (i.e. Commonwealth / state / territory) agreement to a particular course of action (in this case controlling access to drug precursors) yet individual states / territories have generated their own parochial lists of candidate chemicals.

This type of 'national' variation should be managed through the COAG process, i.e. a tightening of the COAG principle and guidelines document, in order to minimize the economic burden of businesses that operate nationally. Other comments on COAG involvement in the regulatory process can be found below.

Within the federal sphere the recent creation of the Office of Best Practice Regulation (OBPR) located within the Productivity Commission is a laudable attempt to ensure that the regulation process is appropriate. Most state/territories have a similar body. Unfortunately the 'rules' under which these bodies operate are at best harmonised and at worst at variance to each other. They also have no role in ensuring that regulation is appropriate at the micro level (where it tends to hit hardest, i.e. the fine print and/or local implementation) or in ensuring that COAG-endorsed regulation is standardised both in terms of wording and in terms of implementation dates. Industry could possibly 'live' with the current level of regulation if relevant federal/state/territory regulations were standardised.

***Recommendation: The role of the Office of Best Practice Regulation should be expanded to ensure that federal/state/territory/local regulation is standardised in terms of wording and implementation in its broadest sense (timing, approach to compliance)***

COAG has produced and recently amended (2004) a document entitled "*Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard-Setting Bodies*". This document provides guidance for the two major levels of government to develop regulations that are appropriate, taking into account economic, environmental, health and safety concerns, and minimise inconsistencies across state/territory boundaries.

Although the intent of this document is relatively clear, i.e. standardisation of regulations across Australia, adherence during both development of regulations and their implementation/enforcement can be variable.

There is usually inter-governmental consultation and therefore standardisation on what are deemed to be major regulatory changes – an example of relevance to the science industry is the controls on the use of ammonium nitrate, a potential agent of terror. However, the detailed changes to the relevant state/territory regulations, such as requirements for labelling, paperwork trails, reporting, monitoring and implementation dates, are far from standardised. In some cases other minor changes are laid on top of previous minor divergences to create larger divergences, thus increasing the burden on industry to maintain up-to-date and compliant with (each) state/territory requirements.

This scenario of high-level adherence to standardisation and low level divergence is common, if not universal in some areas of regulation. Similarly, states/territories invariably invoke different enforcement/compliance regimes, often at the whim of regional offices or even individual officers. It is obvious that the concept of one-country-one-standard does not percolate much below the high level regulatory decision makers. The chain of accountability for regulatory reform and standardisation needs to be lengthened to include lower levels within regulatory agencies, accompanied by a relevant awareness campaign for relevant regulators and enforcement officers.

#### Theme Number 2 - Appropriate Risk Assessment

In addition to the COAG approach, governments across Australia, including New South Wales, have produced guidance/principles documents primarily concerned with the implementation of regulation. Unfortunately these are of varying utility and quality as most are somewhat dated and do not reflect international best practice. For example: reference is not made to appropriate/relevant best practice risk analysis/risk management/risk assessment methodologies. This is unfortunate, as the risk assessment process should be the prime decision point for the implementation or otherwise of regulation and the type/level of regulation implemented; the fact that risk can never be zero and therefore the notion that some risk has to be accepted is not explicitly stated. Instead the default appears to be that any risk requires regulation. Regulators need to grasp the nettle and provide some strong guidance in this area. The guidance stops at the implementation phase, whereas the operation aspects of regulatory programs, e.g. the day-to-day interpretation of regulations, is probably the largest area of angst (and therefore cost) of many SMEs. Although the ultimate solution to this problem requires a cultural change within regulatory agencies there is a corresponding need for elaboration of guiding principles.

There have been a number of major developments in the application of risk analysis and its components (risk assessment, risk management, risk communication) in the past ten years. This includes:

- an internationally accepted standard developed by Standards Australia (AS4360:2004);
- the wider application of qualitative risk assessment tools where quantitative data is difficult to obtain or cannot be generated;
- the acknowledgement by government and industry of the need to communicate risk in a timely and open fashion in order to counter wrong or misguided perceptions; and, importantly
- the use of risk assessment across ALL aspects of the regulatory process, e.g. design of enforcement programs, setting of thresholds, etc.

In many cases there is no threshold level for regulatory compliance and/or it is ignored during any risk assessment process leading to the development of regulation. Thus our industry, which in general includes suppliers and users of small to medium amounts of high purity chemicals (often less than one gram), is regulated to the same or similar extent as a bulk supplier<sup>4</sup> of tonnes of chemicals. This is not good regulatory practice. A case study is provided at Appendix 2.

***Recommendation: regulatory authorities should used a standardised approach to risk analysis as per AS4360:2004 to communicate clearly to industry guidance that includes the implementation phase***

### Theme Number 3 - Duplication

The challenges and imposts to the science industry are epitomized by the plethora of regulatory agencies and associated regulatory requirements. This is acknowledged within the Issues Paper. As an example, chemicals are subject to requirements at federal/state/territory/local government levels through legislation relating to drug precursors, labelling & transport, poisons scheduling, refrigerant licensing, Materials Safety Data Sheets, OH&S, radiation, anti-terrorism, trade measurement, business licensing, etc, etc.

The issues paper produced as a component of this review alludes to the need for coordination within and across jurisdictions. We totally support this concept which is an extension of our position that regulation should be standardised across Australian governments.

The economic cost of complying with regulations is a key determinant of national competitiveness and the investment environment for businesses. These costs can be direct, such as capital and operating costs. They can also be indirect, i.e. opportunity costs, where the principal(s) of the businesses are taken away from their strategic roles of driving innovation, securing investment and increasing productivity. The SIA has used the phrase the 'buggery factor' to describe the impost of non-core activities such as micro-regulation.

The SIA also notes that the schematic chart reproduced in the Issues Paper and indeed the Issues paper itself is silent on the role that regulators play at the border.

It is the experience of SIA members that one of the major regulatory imposts occur in complying with regulations that control the entry of chemicals including processed biological materials such as antibodies) into the country. The relevant agencies are:

the Australian Quarantine and Inspection Service (AQIS);  
the Australian Customs Service (ACS); and  
the Department of Health and Ageing (through NICNAS and TGA)

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<sup>4</sup> Such suppliers are usually represented by Plastics and Chemicals Industry Association (PACIA), although there is some cross membership

The roles of these agencies (and their sub-agencies) need to be taken into account when developing recommendations related to the Issues Paper.

As an outcome of the 2005 Hampton Review, "Reducing administrative burdens: effective inspection and enforcement", the UK government has moved to reduce 31 regulators to seven thematic bodies. There are similar opportunities available within the Australian context where, for example, up to five federal agencies are involved in regulating the importation of certain goods. This is without including the federal support and state/territory lead and support agencies that may be involved<sup>5</sup>. Not only does this result in the need for multiple fees, there is time-consuming replication of form filling, reporting, etc. A 'one stop shop' for all regulators (federal or state), or at least, a single form/point of contact can be justified as a means of decreasing the economic cost of compliance.

***Recommendation: A 'one stop shop' for all regulators (federal or state), or at least, a single form/point of contact can be justified as a means of decreasing the economic cost of compliance.***

#### Theme Number 4 - Balanced Regulation

The SIA believes that regulation should be balanced to the risk that is being managed. This is consistent with the comments made above concerning the use of an appropriate risk assessment framework.

Unfortunately regulators when they are developing their approach to regulation tend to use a fairly coarse sieve in addressing the impact of regulation. For example, the New South Wales Government has endorsed the use of Regulatory Impact Statements (RIS) to support introduction of new regulation (or changed regulation) only when the change is significant<sup>6</sup>. There is also a tendency for the RIS to amortise the cost over a large segment of a given industry when the impact is narrower.

This means that the total regulatory impost can increase without appropriate review through a series of non-significant changes over a given period of time. This is akin to the apocryphal frog in water scenario, i.e. a slow increase in the regulatory impost, to a non-sustainable level, occurs without raising concerns. The historical level of regulation should be taken into consideration when determining if additional change requires a RIS.

As has been noted in a recent international comparative review<sup>7</sup> there is universal acknowledgement of the difficulty of determining true compliance costs. Australia is no exception. What is known, however, is that SMEs bear a relatively higher burden of costs than larger businesses. As an example, SMEs with up to 20 employees were reported to incur direct costs that are at least

<sup>5</sup> Ref: Table I from the Issues Paper for Industrial chemicals that may be imported and that may have a biological component.

<sup>6</sup> See [http://www.cabinet.nsw.gov.au/\\_data/assets/pdf\\_file/0015/8340/Webpage\\_-\\_Government\\_Response\\_to\\_IPART\\_17-74\\_-\\_230807.pdf](http://www.cabinet.nsw.gov.au/_data/assets/pdf_file/0015/8340/Webpage_-_Government_Response_to_IPART_17-74_-_230807.pdf)

<sup>7</sup> Regulatory Burdens of Small Business: A Literature Review (2002) Chittenden F, Kauser S, Poutziouris P. Manchester Business School

35% higher than for the largest firm. A recent report<sup>8</sup> commissioned by the National Farmers Federation confirms this finding. This report found that the total expense of regulatory compliance for the average farm (effectively a SME) equates to approximately 14% of the net farm profit!

This has relevance within the Australian Science Industry as the major proportion of companies are SMEs. When the lower critical mass of senior managers in such SMEs is taken into account, the opportunity costs associated with undertaking compliance and associated activities (e.g., keeping abreast of changes across federal, state/territory and local government regulations) becomes relatively large and a majority contributor to the total economic cost of governance for a given business.

***Recommendation: Regulatory Impact Statements must be used in all cases of drafting new or substantially revised legislation. The cost of regulatory compliance on the end user must be accurately determined***

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<sup>8</sup> Sandy McEachern, John Francis, David Lee Holmes Hackett (2007) The Cost of Bureaucratic Red Tape in Agriculture (see <http://www.nff.org.au/get/2440791874.pdf>)

### Lack of Standardisation

In the early 1990's the Plastics & Chemical Industry Association (PACIA) and the Scientific Suppliers Association of Australia (SSAA - now SIA), together with the NSW Police Service, developed a Code of Practice to protect against the diversion of chemicals into the illicit production of drugs. The adoption of this code by the Science Industry and the Chemical Industry dramatically reduced the supply of drug precursor chemicals to clandestine laboratories.

The Code includes three categories of chemicals, with Category 1 chemicals only being sold to account customers and only after an End User Declaration (with detailed ID provided) was provided by the buyer. The Code is updated every few years after input from stakeholders.

Over the last few years, each jurisdiction across Australia, has seen fit to add or subtract compounds at their pleasure to these categories. Some of these changes are now embodied in legislation, some in regulation and some still to be legislated.

In summary, we see a failure in adoption and adherence to COAG principles as being present in this and similar types of instances.

Lack of conformance to COAG principles results in:  
Inefficient regulatory systems imposing inappropriate costs  
Complexity and inflexibility impeding innovation and growth  
Inconsistencies and overlapping responsibilities between agencies and across jurisdictions  
Complexity and inconsistencies undermine industry compliance

We believe the variances from COAG principles goes to the lack of training, awareness and appropriate regulatory impact analysis being undertaken with legislative drafting by Attorneys General departments in the States and Territories.



## Thresholds

The *Ozone Protection and Synthetic Greenhouse Gas Management Act 1989* (the ozone Act), administered by the Department of Environment and Water Resources, controls the manufacture, import and export of range of ozone depleting substances and synthetic greenhouse gases in Australia.

The import, export and manufacture of these "controlled substances", and the import and manufacture of certain products containing or designed to contain some of these substances, is prohibited in Australia unless the correct licence or exemption is held. The cost of a pre-charged equipment licence is a flat \$3,000 for two years (1 January 2006 to 31 December 2007), immaterial of the number of importations, the volume of importations or their frequency.

A small science-based company that conducts infrequent imports of a refrigerated laboratory cooler as a necessary component of a larger specialised piece of scientific equipment is liable for the \$3,000 bi-annual licence fee. There is no discrimination based on level (value, quantity or frequency) of imports—a regular importer of thousands of a commodity items, such as a domestic refrigerator, would also be subject to the same \$3,000 licence fee. There is case for a graduated fee, possibly based on volume of items, rather than the current "one-size-fits-all" fee.

Holders of licences are required to provide quarterly reports covering items such as the quantities of ozone depleting substances imported, exported or manufactured. The reports are used to generate an activity fee based on the quantity of substance imported; this is payable at the end of each quarter. As an example, the activity fees are \$165 per metric tonne of hydrofluorocarbons and much higher for hydrochlorofluorocarbons which have a higher ozone depleting ability.

As most scientific equipment importers or manufacturers are SMEs, the amount of controlled substances listed on the quarterly reports is invariably quite small and therefore results in even smaller levy (tax) payments. As an example, one medium sized scientific company importing limited numbers of specialized instruments has been invoiced for an average of \$0.01 (one cent) per three months over the past three years.

Apart from the cost to the company of raising a cheque for \$0.01 (there is no threshold payment exemption under the ozone Act), the notion of a bureaucrat processing the paperwork relating to such minor amounts is beyond comprehension. Again, there is clearly a case for an alternative approach, based on reporting/payment thresholds and/or less regular reporting when the amount of controlled substances is below a reasonable risk-assessed level.

At such low levels, the issue of free-rider is negligible compared to the relative impost on the science industry.