Productivity Commission Submission - Regulatory Burden on the Science Services Industry

Duncan Jones – Feb 26, 2010

Scope of Submission: *ANZSIC 6910, 6999, 9422 & 9429*

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

If this growth in business red tape is not stopped, reversed and reduced, the competitive edge of much of Australia's technology-based service SMEs will be significantly damaged.

Using case studies from our science services member companies, we will attempt to highlight the more egregious examples of regulatory burden and inefficiency in our industry and try to quantify their monetary impact

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SCIENCE INDUSTRY AUSTRALIA INC. (SIA)
SUBMISSION TO THE
PRODUCTIVITY COMMISSION (PC) INQUIRY INTO
ANNUAL REVIEW OF REGULATORY BURDEN ON BUSINESS:
BUSINESS AND CONSUMER SERVICES

1. Introduction

In the fourth year of review the PC will focus on those regulations that mainly impact on the whole or any part of business and consumer service industries. In broad terms, this includes financial and insurance services, accommodation and food services, hiring, real estate, professional and personal services, arts and recreation, and repair and maintenance services.

An issues paper was released on 3 December 2009. The terms of reference for this inquiry are, but not limited to:

1. What regulations impacting on business and consumer services is SIA concerned about?
2. How could underlying regulatory objectives be met in a more cost effective or less distortionary manner?
3. What recommendations should come out of the Commission's review?

2. Science Industry Australia, Inc. (SIA) – the science industry peak body

Science Industry Australia Inc is the peak body for the Australian science industry. Its members are responsible for more than 75% the science industry's exports and >90% of science-related imports of scientific goods, apparatus and services.

3. The Science industry and the Australian economy

In February 2004, the Australian Government announced an Action Agenda for the science industry. The Department of Industry, Tourism and Resources and the Department of Education, Science and Training collaborated jointly with Science Industry Australia Inc to develop the Science Industry Action Agenda (SIAA).

In launching the Science Industry Action Agenda (SIAA) and its report 'Measure by Measure' on 31 August 2005, the then Australian Federal Industry Minister, Ian Macfarlane said:

> 'Australia's science industry punches well above its weight. It is outperforming many other sectors in its commitment to innovation, exporting and workplace excellence. And it is the kind of industry that Australia needs more of if we are to maintain our international competitiveness'.

After the discontinuance of Action Agendas by the current Federal Government in March 2008, SIA developed their Science Industry Strategic Plan (SISP) from the work undertaken and planned during the SIAA process.

To achieve its 10-year vision to 2015 of being export oriented and recognised world wide for its quality, innovation and commercialisation of leading edge technologies, the priorities of the SISP are to:

- commercialise more Australian innovation;
- grow exports;
- improve quality;
- progress regulation reform;
- attract and retain a skilled and flexible workforce; and
- improve the industry's internal and external linkages.

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.

Australia's science industry comprises manufacturers and importer/distributors of scientific equipment, laboratory and technical service companies and the scientific research community.

Measurement matters. Australia's science industry is a key enabler of many other industries. Its equipment and laboratory services provide for the measurement and identification of very low quantities of substances to ensure the quality of our food, water, air, environment, health and many other aspects of our daily lives. Its products and services are used by industries such as agri-food; resources; environmental monitoring; manufacturing; medical and health care; research and development and education.

Australia's domestic market for scientific equipment and laboratory-related services is estimated to be $11.78 billion in 2009/10. Australia's market represents an estimated 2 per cent of the global market, compared with Australia's gross domestic product (GDP) being around 1 per cent of global GDP. Australia's production of science services is estimated to be one-half of its production of science goods and services. Employment, including researchers and laboratory and technology service providers, is approximately 47 000.

Science services production was $7.45 billion, of which exports are $303 million, and employment is 39 000. Australia's publicly-funded researchers also provided significant services to the industry.

Manufacturing production is $1.38 billion, exports $1.27 billion, imports $3.31 billion and employment 8 000. Australia's scientific product manufacturers produce $110 million of the $3.31 billion domestic market for scientific products.

Over 70% of science industry manufacturing occurs within Victoria generally, and in Melbourne's eastern and south eastern suburbs, specifically.

Australia's science industry is outperforming many other industries in terms of its growth, innovation, exports and workplace excellence.

The industry is growing at an annual rate of 11 per cent. Its laboratory and technical services companies invest 5.9 per cent of their turnover in R&D. Its manufacturers invest 7.9 per cent of their turnover in R&D, which is 10 times Australia's manufacturing industry average. This is consistent with high performing manufacturers and technical service companies in Canada and United Kingdom. The larger science manufacturing companies export up to 97 per cent of their production. Almost 50 per cent of the industry's workforce has a university degree, and the industry spends more than 5 per cent of its turnover on training.

The science industry is well integrated with global supply chains. Its scientific instruments, clinical diagnostics and laboratory services are globally recognised as the best available and used extensively in by the world's best companies. Its larger science manufacturing companies export up to 97 per cent of their production. Australian science industry manufacturers that compete globally

include Aim Lab, GBC Scientific Equipment Pty Ltd, Leica Biosystems, Rofin, Photron, Aqua Diagnostics, Ecotech, Invetech, SGE Analytical Science and Agilent/Varian.

Australia's laboratory and technical services companies provide a range of laboratory-related services that involve measurement, analysis and diagnosis. Companies that provide product maintenance and service are also included in this industry segment. The main types of services sold by laboratory and technical services companies are environmental and chemical analysis, technical services, and pathology/diagnostic services, and materials characterisation. The main customers of laboratory and technical services companies are environment, engineering, mining and healthcare (pathology testing and medical/health).

Significant Australian companies with international operations engaged in providing laboratory and technical services include Amdel Pty Ltd, ALS Laboratory Group, Healthscope (Gribbles Group) and Sonic Healthcare Ltd.

This knowledge-intensive global industry relies heavily on its investment in research and development and innovation more generally to provide a continuous supply of high value-added world-competitive products, processes and services. This investment must continue for the industry to remain globally competitive.

Innovation services, such as research and development (R&D) from universities and publicly funded research agencies (PFRAs), necessarily support the industry's sustainable competitive advantage. A current underpinning research direction is the development of 'lab on a chip' measurement devices that will take a low-volume high-value production to high-volume low-cost with the potential to spawn a new industry in Australia. Supporting the emergence of this technology are global security issues and the need to have cheap, mobile devices that can check for all types of contaminants.

With the growth in off-shoring of low technology manufacturing, Australia's science industry technology services offer significant potential to generate growth and prosperity of Australia during all economic cycles of Australia's resources industry. Laboratory and technology services either bundled with scientific equipment or as scientific services in their own right, are a growing component of science exports.

The SISP priorities of particular relevance to this inquiry are commercialising more Australian innovation, growing exports, progressing regulation reform, and attracting and retaining a skilled and flexible workforce. The impediments and policy developments necessary for Australia to realise greater opportunities for its science industry laboratory and technology services are multifarious and multi-faceted, many of which fall outside the scope of this inquiry.

4. Industry Impost of Regulation in Australia

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.

As has been noted in a recent international comparative review[1] there is universal acknowledgement of the difficulty of determining true compliance costs. Australia is no exception. What is known, however, is that service SMEs bear a relatively higher burden of costs than larger businesses. As an

[1] Regulatory Burdens of Small Business: A Literature Review (2002) Chittenden F, Kauser S, Poutziouris P. Manchester Business School

example, service SMEs with up to 20 employees were reported to incur direct costs that are at least 35% higher than for the largest firm.

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 Commonwealth, state/territory and local government regulations) becomes large and a majority contributor to the total economic cost of regulation.

Any steps that could be taken to develop and implement a consistent regulatory costing regime that could be applied across Australia's three levels of regulatory authorities would be an excellent starting point for implementing regulatory reform. For a country with a relatively small population, as an industry we often have to suffer with differing legislation upon the same topic in all 9 of Australia's jurisdictions. This is where COAG is so important (q.v.)

Within the Commonwealth, regulation setting is currently guided by two documents, 'Best Practice Regulation Handbook' produced by the Office of Best Practice Regulation (OBPR) and '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). In addition, some Commonwealth Government agencies have produced supplementary interpretative guides, for example 'A Best Practice Framework for considering Business Regulation' produced by the Department of Industry Tourism and Resources in 2002.

Unfortunately the OBPR handbook is somewhat dated (being based as it is on the Office of Regulation Review's "A Guide to Regulation (1998)") and does 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. OBPR, or another appropriate agency, needs to grasp the nettle and provides some strong guidance in this area.
- The guidance stops at the implementation phase, whereas the operational aspects of regulatory programs, e.g. the day-to-day ***interpretation*** of regulations, is probably the largest area of angst (and therefore economic 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 are parallel deficiencies within the COAG document which also attempts, but fails, to be a panacea for all national regulation /standard setting. The case study below (see section 8) 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.

5. Regulations impacting on the science industry, their impacts and costs

From a recent survey of SIA members, the following regulations or compliance agencies affecting the science industry manufacturers, distributor and technical/professional service companies were cited

General regulations not specific to our industry but affecting our industry include:

- Import Regulations
- Electrical Conformance (C Tick)
- Fair Work Australia
- OHS Regulations different in each state
- Varying licensing conditions for environmental management across the country
- Payroll Tax regulation is different in every state
- Workcover regulation requirements are different in every state
- Equal Opportunity for Women in the Workplace Act 1999, requiring employers with 100 or more employees to report annually on the steps being taken in the workplace to ensure equal opportunity for women
- Immigration Policy (use of overseas labour)

Regulations more specific to the industry

- Quarantine (AQIS) permits
- TGA regulations
- NICAS registration
- Poisons Code
- Ozone Protection - Pre-Charged Equipment
- Regulations governing Chemical handling and storage
- Duplication of Federal & State regulatory authorities e.g. AQIS permit to import radioactive research products plus individual licences for each State that the products are sold into as well as annual reporting to various State authorities
- ARPANSA requirements for permits to import radioactive substances for items of low radioactivity that would not require a licence to use
- MSDS
- Environmental management for laboratories

Case studies for examples are provided in the Attachment

Case studies # 1 and 2 demonstrate the cost to business of the Government requiring importers and users of chemicals to submit Material Safety Data Sheets (MSDS) to the Department of Health and Ageing's (DHA) National Industrial Chemicals Notification and Assessment Scheme (NICNAS).

Case study # 1 estimates that industry incurs a regulatory compliance cost $1.6 million per annum. This estimate is based on 100 typical science industry companies each importing an average of 600 chemical entities in laboratory quantities.

The MSDS requirement appears to be an inappropriate method for managing any risk associated with the chemicals in question and the quantities of chemicals involved.

Case study # 2 extends Case study # 1 and estimates that the same 100 companies incur a regulatory compliance cost of $71.2 million per annum due to the duplicated effort arising from them issuing and updating MSDS for an average of 600 chemical entities in laboratory quantities that they sell.

Case Study # 3 shows both the inflexibility of the AQIS process for issuing 2 year permits as well as the extremely high cost to SMEs of renewing AQIS permits every two years.

A 2 year permit results in re-applying for the same permit for the same products from the same company every 2 years, is duplication. Cost for each permit, varies between $ 80 - $ 200 (not including labour/time costs, opportunity costs), multiply that by each overseas supplier (20-50) in a supply business and this becomes significant in terms of fees, as well as administration to ensure the permits are current and the customs/import clearance has the correct and current paperwork to expedite product supply. Delays in product delivery can occur also if customs is not happy with the paperwork and sometimes the goods which often need to be stored cold or have a short shelf life become unsaleable, adding to further cost for the importer and delays in provision of critical science services.

Recommendations I

The following areas identified from the above have the potential to deliver the greatest productivity gains for the science industry. Most of the gains come from the time saved in employing people to interact with the numerous government bodies to ensure their permits and licences are current so the business is able to supply the service provider.

NICNAS requires companies to pay a relatively large annual fee of $711 for very small quantities of Tier 1 chemicals. DHA sets the annual fee according to the monetary value of the chemical in question. In this instance, the annual fee is $711 for each incidence of chemicals valued at between $1 and $499,000. The NICNAS fee is aimed at recovering costs associated with the implementation of the *Industrial Chemicals Act 1989*.

Science industry importers and distributors supply small to medium amounts of high purity chemicals. The chemical transactions often involve less than 1 gram of material. However, these quantities are regulated in the same or similar ways as bulk chemicals are regulated elsewhere in the chemicals and plastics industry.

The threshold boundaries are too broad for companies importing very small quantities of chemicals.

Recommendation 1: Regulatory authorities should use a standardised approach to risk analysis as per AS4360:2004

AQIS permits for importation from the same supplier of the same product are required to be renewed every 2 years. Increasing this time frame to 5 years would save significant compliance costs.

AQIS requires that all products from each of a distributor's suppliers to be been assessed and considered as either not applicable (non biological), excluded from import, or approved for import under the supplier's current AQIS permit.

The same permit also contains a 'Declaration Requirements' clause which imposes an additional and unnecessary burden of paperwork for every inbound shipment under the current permit.

Therefore this results in the importer/distributor being required to provide a manufacturer's declaration on company letterhead stating that the products in the consignment are deemed as non-biological or of minimal biological risk (as per the definition from AQIS and stated as a condition of the AQIS biological import permit); and/or a shipment declaration or minimum biological Risk Letter from the importer/distributor stating the same. These letters usually require reference to the incoming consignment Air Way Bill number and catalogue product numbers and descriptions of goods (also page numbers in catalogue 'if applicable') which come from different sources.

Due to this extra, unnecessary work, temperature sensitive goods (for example) and products urgently needed for medical research and provision of other science services are quite often delayed in transit and sitting unnecessarily in quarantine often for periods up to an extra week or more. In many instances, especially with mainstream freight companies such as FedEx, the goods cannot be appropriately handled/stored at required temperatures and have perished before delivery and cannot subsequently be used.

All this could be alleviated by the establishment of a Nationally based "registered AQIS Importer" scheme to help ensure that this example of egregious duplication of paperwork and waste of time and money is avoided.

Recommendation 2a: AQIS permit renewals for continuing importation of the same product from the same supplier be extended from 2 years to 5 years.
Recommendation 2b: Any issued permits when amended to reflect changed conditions, be given an expiry date calculated from the date of Permit amendment, not the initial expiry date being carried forward.
Recommendation 2c: Establish a nationally recognised 'Registered AQIS Importer Number" to facilitate and streamline importation paperwork for approved and reputable commercial importers. Such importers would be subject to biannual audits to ensure compliance.

Case study # 4 indicates the absurdity of the requirements to report and pay quarterly for the importation of precharged equipment containing small amounts (grams)of environmentally unfriendly gases for companies. Such time and effort to pay small amounts ($0.01) each quarter could well to be taken out to an annual process without affecting the intent of the legislation

Recommendation 3: Importers with a history of low importation amounts of ozone depleting gases be allowed to report and pay on an annual basis

Case study # 5 highlights the impact of State Governments varying the national guidelines for regulation.

This leads to inconsistencies across jurisdictional boundaries in the regulation of scheduled poisons and listed drug precursors. The company in question, Merck Pty Limited, is an international company with a manufacturing and import business in Victoria. Merck Pty Limited distributes its goods Australia-wide. The compliance cost to Merck Pty Limited is estimated to be $12,500 per annum. This can be extrapolated to the conservative estimate of 100 companies in science industry affected by these different regulations.

To improve the control of scheduled poisons and listed drug precursors, **it is recommended (#4)** that:
a) A national guideline be developed that details the restriction on access to scheduled poisons that individual States adopt without alteration.
b) A national guideline be developed that details the actions required to be taken prior to the sales of listed drug precursors that individual States adopt without alteration.

How could underlying regulatory objectives be met in a more cost effective or less distortionary manner?

Many governments are implementing new strategies and new forms of regulatory and non-regulatory instruments to reduce the compliance costs of achieving public policies. These reform strategies and instruments should, when properly implemented, reduce regulatory costs and achieve improved policy outcomes. SIA supports the overall thrust of a number of recent international strategies designed to decrease the overall economic burden of regulations. These include:

Reduction of current (and future) compliance costs. The so-called 'Dutch Model' has been invoked by several economies as an appropriate means to drive a reduction in the economic cost of regulation. The approach has three components:

- measurement of the burden using a standardised approach;
- political commitment to a reduction target; and
- an organisational structure that provides incentives to achieve that target.

Simplification of regulation. This could be through:

- deregulation (removing regulations);
- horizontal consolidation of existing regulations to improve transparency and understanding; and
- vertical rationalisation to replace a variety of sector specific regulations with an over-arching regulation.

A 'One in, One out' approach to new regulation. This assumes that, with few exceptions, the total number of regulations under one agency stays constant, or actually decreases over time. This approach forces individual regulators to prioritise between proposed regulations, and simplifying and removing existing regulations.

Cultural change. This is required of regulations both at the stage of developing regulations, particularly with a 'One in, One out' approach, and at the implementation (compliance/enforcement) stage. It is the experience of SIA members that 'over zealous' black and white implementation of regulations is a major component of the angst and therefore opportunity cost of most regulations. Regulators need to become more aware of, and responsive to, the impact of the detail of their regulations at the SME level.

Regulatory governance. The shift away from the process of regulation to higher concepts such as effectiveness, timeliness, cost-efficiency, transparency and accountability is occurring across developed economies including Australia. This process is to be commended and should be expedited as it should bring many of the reforms necessary to relieve cost-of-compliance concerns across the Science Industry within Australia.

Risk analysis. 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.

Rationalisation of regulators. 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 agencies are involved in regulating the importation of certain goods (see point **7.** [below]). Not only does this result in the need for multiple fees, there is time-consuming replication of information. A 'one stop shop' for all regulators (thematic or otherwise), or at least, a single form/point of contact can be justified as a means of decreasing the economic cost of compliance.

Improved regulatory oversight. The OBPR's role is to promote the Australian Government's objective of effective and efficient legislation and regulations. The prime instrument it uses is the review of the Regulatory Impact Statements produced by Commonwealth Government regulators. Taken together with other related functions these are fairly blunt instruments compared to international best practice. The role and functions of OBPR needs to be either strengthened or strengthened and transposed into another body in order to become best practice.. The UK approach provides some guidance here where one agency is now involved in developing standardised guidance for regulatory bodies whereas a separate agency has responsibility for ensuring compliance with these standards, i.e. a separation of powers.

6. Role of the Council of Australian Governments

COAG has elaborated 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 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.

We believe further minimisation of inter-governmental differences in current regulations, and developing and ensuring compliance with regulations, should be one matter to be addressed by a high level COAG working party. The Canadians, who have similar inter-governmental issues to those in Australia, acknowledged the crucial role that inter-governmental standardisation plays in driving regulatory reform in their 2004 report "Smart Regulation". One recommendation coming from this

report was the establishment of an inter-governmental working group on regulatory reform in order to drive the standardisation/harmonisation process. We understand this working group is well advanced.

7. A Case Study to Illustrate Commonwealth Challenges

A small Importer of Diagnostic Test kits is required to have four different permits from four different agencies for the importation of a single kit for the detection of Testosterone in blood samples for children suffering from precocious puberty.

These permits cover the following:

1) Importation of Biological material – issued by AQIS every 2 years specifically for a Product line at a cost of $150 plus assessment fees ranging between $40 & $320
2) Permit to import Radioactive Isotopes – issued by the Australian Radiation Protection and Nuclear Safety Agency every Year at a cost of $1500.
3) Australian Register of Therapeutic Goods Listing of Medical Device – issued by the Therapeutic Goods Administration at a cost of $550 per annum
4) Permit to import anabolic steroids – issued by Department of Heath and Aging – this covers only a period of 2½ months and is for a single importation of a kit containing less than 1 microgram of testosterone – less than 1/5000 of a medically significant amount……

The total sale value of this product is around $50 000 per annum.

Comment & Observations on the above

i. Anabolic steroids should have different permit system based on adequate risk assessment protocols which also has threshold values that allow permit free importation.
ii. Involvement of four regulatory agencies in this instance is farcical
iii. There is some merit in a threshold value of Iodine 125 (the radioisotope used in the test kits) being included in regulations.

8. A Case Study to Illustrate State Challenges

In the early 90'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. So much so that the criminals diverted their attention to sourcing pseudoephedrine compounds from pharmacies by way of cold tablets.

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 has been updated every few years after input from stakeholders.

Over the last few years, each jurisdiction 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.

Both PACIA and the SIA serve on the National Working Group on the Diversion of Precursor Chemicals (NWGDPC) which meets quarterly under the patronage of the Attorney General's department. PACIA serve on the IGCD Scheduling Working Party on Controlled Substances (IGCDSWGCS). A copy of their paper of the 12July 2005 is attached as a separate file.

At the October2005 9th National Chemical Diversion Congress in Darwin, PACIA and the SIA made pleas for a return to 1997 COAG principles and guidelines. We were successful in having the Congress accept the following resolution:

- Task one of the two multi-stakeholder committees established under the Ministerial Council on Drugs Strategy to develop a workable, cost effective national model regulation focused on preventing diversion of chemical precursors
- Industry, government and law enforcers could work in partnership to:
    - develop a national model regulation in full compliance with COAG Principles, subject to public comment and RIS processes, and
    - support consistent implementation and promote high level compliance with all obligations
- Chemical Industry fully supports the Federal Government commitment to "promote a consistent and coordinated national approach to policy development and implementation in relation to all drugs issues"

We are able to provide an electronic copy of the PACIA presentation to the Congress. (Slides 18 to 26 show the variances in the combined Categories 1 and 2).

Maybe we will make progress via NWGDPC. Without model regulation, we are not convinced that we will make adequate progress in this forum. Even with model legislation/regulation, we see variances between States in many areas including Weights & Measure Trade regulation.

We understand that State regulation falls outside the Terms of Reference of the Regulation Taskforce. However, we see a failure in adoption and adherence to COAG principles as being present in this and similar types of instances.

Comment & Observations on the above

SIA seeks a commitment to COAG principles, improved governance & accountability, efficient and cost-effective regulation with national uniformity.

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.

Recommendations II

SIA believes that the overall economic cost of regulation within Australia can only be lowered through a package of initiatives and that this package should reflect current international initiatives and best practice. There does not need to be a reinvention of the wheel, simply an adaptation of the UK and Canadian approaches to the Australian situation. These should include the following recommendations:

Recommendation 5: Elaboration of a standardised cost model within the Commonwealth and state / territory regulatory frameworks

Recommendation 6: Updating of the OBPR handbook

Recommendation 7: Updating and expansion of the COAG principles and guidelines (including stronger buy-in by the states / territories)

Recommendation 9: Adoption of the UK 'One in, One out' approach

Recommendation 10: Adoption of a stronger regulatory governance framework within regulatory agencies

Recommendation 11: Adoption of a stronger risk analysis / risk management framework within the Regulatory Impact Assessment process.

Recommendation 12: Rationalisation of regulators where possible

Recommendation 13: Strengthening of the oversight of regulation setting

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Attachment

Case studies

Case study #1. Australian Inventory of Chemical Substances

Introduction

The majority of laboratory and research chemicals used in Australia's 7,500 laboratories are produced overseas. The needs of these laboratories are primarily serviced through about 100 local importers with significant amounts being ordered direct from overseas catalogue houses or manufacturers. Some catalogues list as many as 50,000 chemicals, with most used for research purposes.

Australian Inventory of Chemical Substances

The Australian Inventory of Chemical Substances (AICS), the legal device that distinguishes new from existing chemicals, is administered by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) within the Department of Health and Aging. There are 38,000 chemicals on the register which is established under the auspices of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the NICNAS Act).

Definition of industrial chemicals

Along with bulk chemicals that are used in manufacturing processes, laboratory chemicals are defined under the NICNAS Act as industrial chemicals. For all intents and purposes laboratory (industrial) chemicals that are used in a controlled environment by highly trained professionals are subject to the same regulatory framework that over-the-counter industrial chemicals (for example pool chemicals). The only exemption is related to the amount of chemical (see below).

Registration

It is obvious from the tier structure used by NICNAS to register introducers of industrial chemicals that the intent of the NICNAS Act is to control, in the broadest sense, high volume chemicals. The lowest tier available in the three tier NICNAS registration system is for chemicals which have a value below $500,000.

The other tiers are $500,000 to $5,000,000 and greater than $5,000,000. The implications of this high threshold can be seen in the following non-hypothetical situation. A supplier introduces 100 kilograms of a laboratory-only chemical valued at $100 per kilogram, total value $10,000. The annual registration fee is $711[1] which is about 7% of the value of the introduced chemical. ***The lack of a lower threshold for laboratory chemicals is a significant cost for the importer and distributor.***

Reporting annually

Low volume chemicals, chemicals for which controlled use permits have been issued, and chemicals for which exemption certificates have been issued are just three of the categories of industrial chemicals which are required to be reported to NICNAS by August 31 each year. The NICNAS web-based reporting system, which was proposed as a means of minimizing the regulatory burden, is still not operational. Until this system is operational, suppliers are required to use a labour-intensive hardcopy 'intent to report' statement.

1 See http://www.nicnas.gov.au/Industry/New_Chemicals/Fees_and_Charges/Fees_Charges_2009_10_PDF.pdf

Research and development exemption

This exemption is available to introducers of new chemicals that are introduced solely for the purpose of research, development or analysis, at a total quantity of not more than 100 kilograms in a period of 12 months.

Reporting requirements

Chemicals introduced at a total quantity of < 100 grams do not need to be reported. Introducers using this exemption category to introduce chemicals at quantities greater than 100 grams are still required to report the following information about the chemical.

- **Chemical Name**
  The preferred chemical name is the CAS Approved Name however other naming conventions will be accepted.

- **CAS number**
  If available.

- **Quantity**
  The quantity of the chemical introduced in the previous registration year in kilograms. Introducers also have the option of reporting quantities in bands of ≤ 10 kilograms or 10 to 100 kilograms.

  Additionally, for chemicals introduced at a total quantity of 100 grams to 10 kilograms, suppliers can opt to provide only the total number of chemicals introduced at this level (i.e. no chemical details) and provide more information to NICNAS via an auditing process. Note that it is the entity introducing the chemical into Australia that is required to report. An entity does not need to report on chemicals sourced from an Australian supplier.

Implications for industry

The volume of work required to meet this reporting requirement is substantial. Larger suppliers might import as many as 5,000 – 10,000 compounds that are not on the AICS, but have previously been exempt under the research, development or analysis clause. Smaller importers might import 1,000 or more compounds that have annual sales volumes less than 100 grams.

What is to be done with this data? Why is it required?

The chemicals are used in laboratory environments where they are used by professionally or technically trained scientists, chemists and other laboratory personnel to deliver scientific based services by way of analyses and reporting..

The occupational health and safety risk used to justify the required level of reporting appears to be extremely small. By law, approved Material Safety Data Sheets (MSDS) are required to be made available for customers as well as for importers' staff use. This requirement is an effective way in which the minimal risk can be managed.

Financial imposts on industry

The estimated cost of complying with the NICNAS reporting requirements can be summarised as:

Indirect costs per company of the paperwork – assuming 600 chemical entities per company	$6,000
Opportunity costs (loss of strategic time)	$10,000
Total cost per company	**$16,000**
No. of SMEs impacted 100	
Total cost to science-industry companies	**$1,600,000**

Case study # 2. Material Safety Data Sheets

Material Safety Data Sheets (MSDS) provide information to allow for the safe handling of substances used at work. Under the National Model Regulations for the Control of Workplace Hazardous Substances that have been adopted under state and territory legislation, manufacturers and importers of any chemical that is a hazardous substance are obliged to produce a MSDS for the substance, and to make it freely available to employees, as well as customers, handling the substance. The provision of MSDS with the first delivery of a chemical or when there is a change to the MSDS, has been prescribed by dangerous goods legislation in State and Territories legislation for at least 10 years.

When the Australian Inventory of Chemical Substances (AICS) legislation was being prepared in the 1990s, it was envisaged that a national repository for MSDS would be established to support the AICS initiative.

Suppliers / manufacturers were to be expected to provide copies of their MSDS to the National Repository.

The AICS contains 38,000 industrial chemicals, each of which is supported by a MSDS. The majority of these chemicals are 'pure' compounds and not mixtures or proprietary chemicals. They have a unique identifier in a Chemical Abstract Service (CAS) Number.

It is likely that 80% of shipment value is attributed to around 20% of chemical compounds, i.e. about 600 to 1,000 compounds. Some hundreds of suppliers exist who regularly are required to issue and/or update MSDS for these compounds to tens of thousands of users of these products. Whilst these compounds have perhaps the easiest MSDS to produce, it still is a massive time and dollar cost to the economy.

To demonstrate the economic impact on industry of this huge duplication of effort, consider the following example.

Assume, on the very conservative basis 100 companies regularly supplying MSDS on the more common compounds – conservatively estimated to be on average 600 in number:

Initial products

	Cost ($)
Unit cost of original MSDS preparation :	$100
No. of compounds	600
No. of companies	100
	$6,000,000

Amortise over 5 years Cost per annum $ 1,200,000

Servicing market needs

Unit cost of issuing MSDS on request or to a new customer[1]			$150
Unit cost of issuing updated Requested & Sent MSDS[2]			$20
[1]No. of chemical entities			600
[2]No. of chemical entities			600
[1]No. of occurrences p.a.	40,000	100companies	$60,000,000
[2]No. of occurrences p.a.	5,000	100 companies	$10,000,000

Cost per annum $70,000,000

Cost of duplicated effort per annum $71,200,000

We also acknowledge that there are local companies offering MSDS preparation services for industry. We also point out that MSDS content, use and regulation is moving to greater global harmonisation.

Case Study # 3: AQIS Permit Applications-Millennium Science

Nov 2008 - AQIS Permit BioAnnual Renewal Application for Various Suppliers (total of x10)/All Countries, including information/suppliers previously on x2 separate import permits for Millennium Science.

- This took one month to process (incl. several communication hours) after all website catalogue references and product information sheets/MSDS's/Certificates of Origin were supplied as requested
- Cost $ 1,035 with expiry date of 2 years (Nov 2010)

April 2009 – Application to AQIS for Amendment to current import permit for Various Suppliers (x2 additional)/All Countries, including update of Supplier contact details, online catalogue references and any additional information required/requested for assessment of particular products.

- This took 16 days to process at a cost of $370 and although a new permit number was issued, the permit expiry date *remained as Nov 2010*.

Oct 2009 - Application to AQIS for Amendment to current import permit for Various Suppliers (x3 additional and x1 removed)/All Countries, including update of Supplier contact details, online catalogue references and any additional information required/requested for assessment of particular products.

- This took 23 days to process at a cost of $550 and several communication hours, and again - although a new permit number was issued, the permit expiry date *remained as Nov 2010!*

Jan 2010 – Application to AQIS for another Amendment to current import permit for Various Suppliers (total of x15, incl. x1 new supplier due to change of distribution agency) and including additional kits with same components as other catalogue products previously assessed and approved for current permit, but one or two additional components required for assessment and approval to ensure compliance to the rules!

- This took 24 days to process at a cost of $230, with multiple email communications between AQIS, Millennium Science Personnel and Suppliers and several hours on various days facilitating this evaluation process.
- This considerably delayed medical research projects and the initialization of business, with customers wanting to order and receive their products in a timely manner.
- And again - although a new permit number was issued, *the permit expiry date remained as Nov 2010!*

Note: Apparently AQIS cannot refer back to previous assessment documents and each amendment/additional product requested for assessment requires all the same information as provided previously but with current dated documentation from the supplier/manufacturer. However, the same permit document, with original assessment date (Nov 2009), is actually re-issued but with a new permit number reference at the top! And within the permit it states on page 4 – point 5, that "Amendments and additions to the catalogue or product list may be imported using this import permit providing that the products comply with all conditions of the permit (i.e. Minimum risk biological or products not requiring an import permit)

Case study # 4. Eppendorf South Pacific

Ozone Protection - Pre-Charged Equipment: there is a requirement to submit quarterly returns to the Department of Environment and Heritage detailing the quantity (grams) of ozone depleting refrigerants imported during the previous quarter. The only instruments applicable for Eppendorf are centrifuges. As we import only several instruments per year for demonstration purposes, due to our business model which means we sell through dealers who import directly from Germany, we often have nothing to declare. When we do have gases to declare they typically result in a payment of $0.01. The time and resource involved for such a low quantity and value seems wasteful. Whilst symbolic, perhaps a more efficient process would be to require annual submissions from suppliers with a history of very low import quantities of these environmentally unfriendly gases.

Case study # 5 The impact of State Governments varying national guidelines for regulation leading to inconsistencies across jurisdictional boundaries

Q1 – Company name: **Merck Pty Limited**

Q2 – What is the core business of your organisation?
Manufacturer and importer / distributor of laboratory products serving the scientific market with analytical reagents, test kits and equipment, and specialty fine chemicals of high purity and pearl lustre pigments.

Q3 – What particular regulatory issues are of particular concern to your company?
• Packaging and labeling of hazardous substances e.g. certain poisons on schedules 4 and 7; ozone depleting substances, drugs precursors;
• Transport and storage of hazardous substances;

Q4 – What ranking would you give them?
1) Variation in interpretation of guidelines produced by the Commonwealth that see, when implemented by the states, variation in regard to requirements to be met across state boundaries. Examples of this are
a. Poisons scheduling controls within each state and territory
b. Controls on the sale of precursor chemicals, legislated in some states, not in others. Also the lists of chemicals are not consistent.

Q5 – What legislation / regulations apply to the issues of concern – please specify?

a. The scheduling of poisons is set in the 'Standard for the Uniform Scheduling of Drugs and Poisons' produced by the National Drugs and Poisons Schedule Committee. Implementation on restriction of access to the different schedules is then implemented, differently by the various states through the (Victorian) Department of Human Services or equivalent. What I cannot sell to a Victorian customer without a licence I can happily sell to a customer without restriction interstate.

b. We actively co-operate with the Victorian Police in all occasions of sale of drug precursors across all states. Victoria then notifies other states. We do this voluntarily as there is no legal requirement to do so. We are aware that some others suppliers do not bother or provide on an ad hoc basis. In some of the other states it is mandatory to notify. We use the PACIA/SSA code of practice for our list of chemicals, other states have legislated a different list. We cannot keep up – but nor is there a legal obligation to do so.

Q6 – What agency administers them?

In both occasions above the problem lies with State government implementation of the regulations (e.g. OH&S, chemical/biological safety).

Q7 – What administrative procedures are a concern?

In both occasions above the problem lies with State government implementation of the restrictions on access to the products detailed. For example:
a) If we sell a Schedule 7 poison to a Victorian customer, we must ensure that the product is listed on their licence. If the customer is in NSW we do not need to check anything at all. Additionally, we are not familiar with what the requirements are in the various states even if we voluntarily decided to comply.
b) We are happy to assist with restricting the supply of precursors. But voluntary is not working. We need mandatory notification, following the same guidelines in all states based on the same list of restricted chemicals.

Q8 – What duplication / inconsistencies exist within and across jurisdictions – please specify?
As detailed above.

Q9 – What are the estimated costs of complying with each of these areas of concern?

a) From our point of view – none. We have no legal requirement to comply. Morally I am uncomfortable.
b) I think that drugs is so topical at the moment that the Government has a good grasp on the cost involved in dealing with this problem. It can be looked at from the cost of ensuring compliance through the various Police forces, the cost on our medical system, the impact on society.
Our costs at estimate run to $50 per order. We would have approximately an order per day.

Q10 – What would you like changed?

c) A national guideline written that details the restriction on access to scheduled poisons that is adopted without alteration by the states.
d) A national guideline written that details the actions required to be taken prior to the sales of listed drug precursors that is adopted without alteration by the states.