SCIENCE INDUSTRY AUSTRALIA
SUBMISSION TO THE
PRODUCTIVITY COMMISSION REVIEW OF
REGULATORY BURDENS AFFECTING MANUFACTURING AND
DISTRIBUTIVE TRADES

Introduction

The Productivity Commission is asked to conduct ongoing annual reviews of the burdens on business arising from the stock of Government regulation. Following consultation with business, government agencies and community groups, the Commission is to report on those areas in which the regulatory burden on business should be removed or significantly reduced as a matter of priority and options for doing so.

The Commission is to review all Australian Government regulation cyclically every five years.

Australia's science industry

Science Industry Australia Inc is the peak body for the Australian science industry. Its members are responsible for more than half the science industry's exports and a significant proportion of science-related imports.

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.

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 was estimated to be $6 billion in 2002/03. 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, was approximately 47 000.

Science 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. Manufacturing production was $930 million, exports $670 million, imports $2820 million and employment 8 000. Australia’s scientific product manufacturers produce $260 million of the $3 billion domestic market for scientific products. The rest of the domestic market is serviced by the specialist importers and distributors of scientific consumables, equipment and instrumentation. Over 98% of these importer and distributor companies supply product into 3 or more states in Australia.

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 10 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 in Canada and United Kingdom. The larger science manufacturing companies export up to 95 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.

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 and distributor companies were cited

General regulations not specific to the industry included

- Import Regulations
- Electrical Conformance (C Tick)
- Workchoices/Forward with fairness
- 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 eg 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.

Why does NICNAS require the data, and what does the Government do with the data?

The Government requires the MSDS to be submitted in hard copy, as no electronic submission system is available.
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.

With regards AQIS permits, 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, multiply that by each supplier (20-50) in a distributor business and this becomes significant in terms of fees, as well as administration to keep them all current and keep the customs agent current. 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.

There are inconsistent requirements for environmental site licenses for waste management. For example, laboratory analysis facilities in WA and NSW require licenses for waste storage and generation while identical facilities in QLD and SA do not. This is due to the definition of a waste under Environmental Protection Legislation as well as differences in interpretation of the regulations by each State Regulator.

Action imperatives

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 their customers.

NICNAS requires companies to pay a relatively large annual fee of $381 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 $381 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: 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

Recommendation: AQIS permit renewals for continuing importation of the same product from the same supplier be extended from 2 years to 5 years

Case study #3 indicates the absurdity of the requirements to report and pay quarterly for the importation of precharged equipment containing small amounts (grams)of envirnomnetally 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: Importers with a history of low importation amounts of ozone depleting gases be allowed to report and pay on an annual basis

Case study # 4 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 that: a) A national guideline be developed that details the restriction on access to scheduled poisons that 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 States adopt without alteration.

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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 5,000 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 not-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 $381[1] which is about 4% 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 28 September 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/Publications/NICNAS_Handbook/Appendices072007.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 in excess of 100 grams.
What is to be done with this data? Why is it required? The chemicals are sold into laboratory environments where they are used by professionally or technically trained scientists, chemists and other laboratory personnel.
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 specific purpose of the considered National Repository now escapes us, but we seem to recall that it was not to diminish the legal responsibility of the supplier of a chemical from the availability and provision of a MSDS in approved format as is still the case.
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 ($)
A. Unit cost of original MSDS preparation :		$100	
D. No. of compounds under A	600		
G. No of occurrences pa of A	100		
			$6,000,000
Amortise over 5 years		Cost per annum $ 1,200,000	

Servicing market needs

B. Unit cost of issuing MSDS on request or to a new customer			$150
C. Unit cost of issuing updated R & S MSDS			$20
E. No. of compounds under B	600		
F. No. of compounds under C	600		
H. No of occurrences pa of B	40,000	100companies	$60,000,000
I. No of occurrences pa of C	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. 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 # 4. 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 labelling 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.