PRODUCTIVITY COMMISSION STUDY INTO CHEMICALS AND PLASTICS REGULATION SUPPLEMENTARY SUBMISSION FROM THE SCIENCE INDUSTRY ACTION AGENDA

PREPARED BY:

SCIENCE INDUSTRY ACTION AGENDA SECRETARIAT

– SCIENCE INDUSTRY AUSTRALIA INC &

– AUSTRALASIAN LABORATORY MANAGERS ASSOCIATION

This supplementary submission provides five case studies that amplify the themes in Science Industry Australia's (SIA) initial submission (no. 51) lodged with the Productivity Commission's (PC) Study into Chemicals and Plastics Regulation on 2 November 2007. The Attachment provides the case studies.

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.

Theme 1 and the accompanying recommendation in SIA's initial submission cover the issue described in Case studies 1 and 2, and propose a standardised approach reduce compliance costs, namely:

> Recommendation 1: The role of the Office of Best Practice Regulation should be expanded to ensure that federal/state/territory/local government regulation should be standardised in terms of wording and implementation in the broadest sense (timing, and approach to compliance).

Case study # 3 provides evidence from Eppendorf South Pacific Pty Ltd on the cost it incurs from complying with regulation controlling very small quantities of silicon grease and reagent grade water that it imports for laboratory uses.

The issue is that 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*.

As described under Theme 2 in SIA's initial submission, the science industry includes suppliers and users of 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.

As the recommendation for Theme 2 in SIA's initial submission states:

> Recommendation 2: Regulatory authorities should use a standardised approach to risk analysis as per AS4360:2004.

The second issue highlighted in Case study # 3 is the pressing need for governments to consult with industry during the making and amendment of regulations. This issue is captured under Themes 3 and 4 and the accompanying recommendations in SIA's initial submission, namely rationalising the number of regulators to improve the quality of regulation making, and reducing the economic cost of compliance.

> Recommendation 3: 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 4: 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.

The third issue in Case study # 3 deals with the compliance cost to companies of regulating ozone depleting chemicals. Appendix 2, and Theme 2 and the accompanying recommendation in SIA's initial submission describe the issue and propose a risk management approach as described above.

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.

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.

Theme 1 and the accompanying recommendation in SIA's initial submission cover the issue and propose a standardised approach reduce compliance costs, as described above.

Case study # 5 is similar to Case study # 4 and highlights the impact of multi-jurisdictional regulations on the laboratory company, ALS Laboratory Group.

Theme 1 and the accompanying recommendation in SIA's initial submission cover the issue and propose a standardised approach reduce compliance costs, as described above.

Prepared by: Dr Terry Spencer
Chair
Regulatory Working Group
Science Industry Action Agenda; and

Duncan Jones
Executive Director
Science Industry Australia Inc.

Contacts: PO Box 337 Hawthorn VIC 3122
Ph: 03 9872 5111
Fax: 02 9872 5566
Mobile: 0408 096 111
Email: sia@scienceindustry.com.au
Web: www.scienceindustry.com.au

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 suppliers 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 on R&D undertaken in Australia.

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.

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.

[1] See http://www.nicnas.gov.au/Publications/NICNAS_Handbook/Appendices072007.pdf

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 processes. 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-based SMEs	$1,600,000

See Case study # 3 for the impact on a small enterprise.

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		No. of companies	Cost ($)
A. Unit cost of original MSDS preparation :	$100		
D. No. of compounds under A	600	100	$ 6,000,000
G. No of occurrences pa of A			
Amortise over 5 years	5	Cost per annum	$ 1,200,000
Servicing market needs		**No. of companies**	**Cost ($)**
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	100	$60,000,000
I. No of occurrences pa of C	5,000	100	$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.

See Case study # 3 for the impact on a small enterprise.

Case study # 3. The impact of Australian Government regulations on an importer / distributor of chemicals in 'scientific' quantities

Q1 – Company name: Eppendorf South Pacific Pty. Ltd.

Q2 – What is the core business of your organisation?
Importer/distributor of scientific instruments and consumables; sales of calibration and repair services; provider of technical support.

1) What industry do you consider your company to be in? *Science industry*

Q3 – What particular regulatory issues are of particular concern to your company? Give examples.

- NICNAS: we are required to pay an annual fee to the Department of Health and Ageing for the NICNAS that aims to recover costs associated with the implementation of the Industrial Chemicals Act 1989. The threshold for Tier 1 is $1 to $499,000, attracting a fee of $381.00. In principle, we believe the band is too broad as we import very small quantities of silicon grease and reagent grade water, only.
- Ozone Protection - Pre-charged equipment: we are required 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.
- Consultation by government with companies in the making of regulation: of course, Eppendorf South Pacific would always like to be consulted about regulations that will affect our business and industry.

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.

1) What industry do you consider your company to be in?
   Chemicals industry and science industry

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;
- Consultation by STATE government with companies in the making of regulation.

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. Ridiculous.

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?

a) 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.

Case study # 5. The impact of multi-jurisdictional regulations a national laboratory company

Q1 – Company name: ALS Laboratory Group

Q2 – What is the core business of your organisation?

Broad range of sophisticated state-of-the-art analytical services including physical, inorganic, organic, bacteriological and toxicological analyses for mining and minerals exploration, environmental monitoring, equipment maintenance, commodity analysis and certification, including food, pharmaceutical testing and certification, coal testing services.

1) What industry do you consider your company to be in?

Laboratory operation providing chemical, food and other technical services industry.

Science industry.

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.
- Diagnostic test kits.
- Consultation by government with companies in the making of regulation.
- Denying the importation of small amounts of laboratory chemicals for analytical purposes based on UN regulations and providing no portal for advising end users.
- Various State based requirements differ in each state.
- DIAZALD is an example of a ban costing ALS business.
- Varying regulations in each state on precursors (although we understand there has been agreement between the states to align the regulations)

Q6 – What agency administers them?

a) Federal Government regulations (e.g. AQIS, Customs, workplace relations)
b) State government regulations (e.g. OH&S, chemical/biological safety)
c) Local government regulations (e.g. environmental discharges, planning approvals)