REGULATION TASKFORCE SUBMISSION FROM THE SCIENCE INDUSTRY ACTION AGENDA (SIAA)

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1. Preface

The Business Council of Australia in a report earlier this year 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 tapes is not stopped, reversed and reduced, the competitive of much of Australia's technology-based SMEs will be significantly damaged. Science Industry Australia and the Science Industry Action Agenda (SIA / SIAA) wholeheartedly agree with this statement.

2. Science industry and the Australian economy

Measurement matters. The science industry's equipment and laboratory services measure the quality of our water, food and air, our health and many other aspects of our daily lives. Australia's science industry comprises manufacturers and importer/distributors of scientific equipment, laboratory and technical service companies and researchers.
It is outperforming many other industries in terms of its growth, innovation, exports and workplace excellence.
Australia's domestic market for scientific equipment and laboratory-related services was estimated to be $6 billion in 2002/03. Employment, including researchers and technology service providers, was approximately 47 000.

Manufacturing production was $930 million, exports $670 million, imports $2820 million and employment 8000. Services production was $3070 million, of which exports were $110 million, and employment was 39 000.Australia's publicly-funded researchers also provided significant services to the industry. Australia's scientific products manufacturers produce $260 million of the $3 billion domestic market for scientific products.

Late August and early September saw the launch by the Hon Ian Macfarlane MP, Minister for Industry, Tourism and Resources and the Hon Gary Nairn MP, Parliamentary Secretary to the Prime Minister in Sydney and Melbourne respectively of the Science Industry Action Agenda three year implementation phase.

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

The plan's priorities are broadly to commercialise more Australian innovation, grow exports, improve quality, ***progress regulation harmonisation***, attract and retain a skilled and flexible workforce, and improve the industry's internal and external linkages.

Mr Macfarlane said "Australia's science industry has developed the Action Agenda to help unlock the creativity needed for its continued high growth and development in the 21st century with the support of the Australian Government."

3. An Introduction – The Science Industry Action Agenda Regulatory Reform

The Science Industry Action Agenda (SIAA) "Measure by Measure" report included the following key recommendation:

"Progress the harmonization of regulations and standards relevant to the science industry across Australian, State and Territory governments, and align them with relevant international standards"

The challenges and imposts to the science industry are epitomized by the plethora of regulatory agencies and associated regulatory requirements, including:

Chemicals: Drug Precursors, Labelling & transport, Poisons scheduling, refrigerant licensing, Materials Safety Data Sheets, Licensing, etc.
Other: Electromagnetic Compliance, Radiation Compliance, In Vitro Diagnostics, etc.

A Regulatory and Workplace Practices Working Group which reports to the Implementation Group of the SIAA has been established to progress the above recommendation. It will work with parallel organizations, State and Commonwealth Agencies and Authorities to progress its agenda.

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, ie 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 SMEs bear a relatively higher burden of costs than larger businesses. As an example, SMEs with up to 20 employees were reported to incur direct costs that are at least 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 (eg, 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.

Within the Commonwealth, regulation setting is currently guided by two documents, 'A Guide to Regulation – Second Edition: December 1998' produced by the Office of Regulation Review (ORR) 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.

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

Unfortunately the ORR guide is somewhat dated 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. ORR, 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 operation aspects of regulatory programs, eg 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 (ie 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, ie 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. Changing Dynamics of International Reforms

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/SIAA support 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, eg 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 case study #xx 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 ORR'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 ORR 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, ie 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, ie 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 level 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 more than $150.
2) Permit to import Radioactive Isotopes – issued by the Australian Radiation Protection and Nuclear Safety Agency every Year at a cost of $1200.
3) Australian Register of Therapeutic Goods Listing of Medical Device – issued by the Therapeutic Goods Administration at a cost of $550.00 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

The Science Industry Action Agenda (and other Action Agendas) seek 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.

9. Action Imperatives

The SIA/SIAA believe 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:

- Elaboration of a standardised cost model within the Commonwealth and state / territory regulatory frameworks
- Updating of the ORR guide
- Updating and expansion of the COAG principles and guidelines (including stronger buy-in by the states / territories)
- Adoption of the three stage 'Dutch Model'
- Adoption of the UK 'One in, One out' approach
- Cultural change in regulators at all levels
- Adoption of a stronger regulatory governance framework within regulatory agencies
- Adoption of a stronger risk analysis / risk management framework within the RIS process
- Rationalisation of regulators where possible
- Strengthening of the oversight of regulation setting

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