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Parliament House

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## SCIENCE INDUSTRY ACTION AGENDA

Submission to

House of Representatives Standing Committee on  
Legal and Constitutional Affairs

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## **Background**

In February 2005, the House of Representatives Standing Committee on Legal and Constitutional Affairs called for submissions to inquire and report on the lack of harmonisation in Australia's legal system, and between the legal systems of Australia and New Zealand. There was particular reference to the differences that have an impact on trade and commerce. In conducting the inquiry, the Committee will focus on ways of reducing costs and duplication. Particular areas the Committee may examine to determine if more efficient uniform approaches can be developed, include, but are not limited to:

- Statute of limitations;
- Legal procedures;
- Partnership laws;
- Service of legal proceedings;
- Evidence law;
- Standards of products; and
- Legal obstacles to greater federal/state and Australia/New Zealand cooperation.

The Committee will examine Federal and State legal regimes within Australia and the comparative position of relevant Australian and New Zealand laws. Within these contexts the Committee will focus on the following issues:

1. What are the existing differences among the various jurisdictions that impact adversely on trade and commerce?
2. The extent to which greater harmonisation is desirable and achievable; and
3. The means by which greater harmonisation might be achieved, for example, the development of new models for better cooperation between jurisdictions, particularly given the difficulties inherent in the models used to date.

## **Introduction**

The Science Industry Action Agenda is pleased to present the House of Representatives Standing Committee on Legal and Constitutional Affairs with its submission to the inquiry harmonisation of legal systems.

The Science Industry Action Agenda (SIAA) is a collaboration between leaders from the Australian science industry, the Department of Industry, Tourism and Resources and the Department of Education Science and Training to develop a strategic plan for the industry. The

action agenda process is aimed at identifying impediments to the industry's growth and defining and implementing long-term strategies to overcome these impediments.

A key priority in the Science Industry Action Agenda's nine recommendations is to progress the harmonisation of regulations and standards relevant to the science industry across Australia's nine jurisdictions and their alignment with relevant international standards.

### **What is the Australian science industry?**

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 of physical, chemical and biological phenomena.

The industry comprises manufacturers of high value added scientific and laboratory equipment and clinical diagnostic equipment, analytical laboratories, importer/distributors and R&D organisations.

Australia's domestic market for science industry products and services was estimated to be \$6 billion (2002/03), of which imports were \$2.8 billion and domestic sales were \$3.2 billion. Employment was approximately 47 000. In addition, scientific research was valued at around \$3 billion with an estimated employment of 22 500. Exports of science industry products and services in the same period accounted for an estimated \$780 million.

In Australia, this industry is outperforming most others in terms of its commitment to innovation and exporting.

The industry's manufacturers invest 7.9 percent of their total annual sales in research and development, which is ten times higher than the manufacturing industry's average. Complementing this is the industry's highly educated workforce with over 50 percent of its staff having at least a bachelor degree. By comparison, the manufacturing industry's average is 13 percent.

The industry is growing at more than 10 percent per annum, which is more than twice the national average, and it expects this pattern of growth to continue in the medium term. Its small to medium-sized enterprises, large enterprises and multinational corporations have world recognised strengths in providing instruments and services that can measure very low concentrations of substances and identify microscopic components present in minute quantities of matter. In some instances, Australian scientific products have significant global market shares.

Its larger companies are exporting up to 90 percent of their production. The industry's principal overseas markets for its products are US, EU and Japan, while laboratory and technical service companies export mainly to Asia, EU and the Americas. These traditional markets and the emerging markets of China, South East Asia and South America present new opportunities for future growth.

## **Industry issues**

The Australian science industry relies heavily on international trade, and it recognises that a strong regulatory framework that can operate seamlessly with international regulations and standards is essential to preserving public trust and for trade in the industry's products and services.

However, Australia has a complex regulatory regime. Its nine jurisdictions (eight States and Territories and the Commonwealth) each have their own regulations and standards that are administered by many different regulatory bodies. The Commonwealth alone has around 60 Government departments and agencies, and 40 national standard-setting bodies and Ministerial Councils that have power to prepare or administer regulations. Another layer of complexity is added by international markets having regulations and standards different from domestic ones. These compliance costs are exacerbated by companies having to remain current with the continuously changing regulatory environment.

It is a costly process for the industry to remain compliant with all the regulations and standards under this administrative framework. This reduces the industry's international competitiveness and is a significant impediment to the efficient operation of the market. The costs associated with such compliance are ultimately borne by the community.

As the industry has an international focus, it believes that Australia should be a single, united market rather than one that is fragmented into nine smaller markets.

The harmonisation of other regulations and standards has been progressing within Australia and internationally to address this impediment to industry growth. For example:

- The Australian Building Codes Board was created to oversee the harmonisation of building codes, regulations and standards across all jurisdictions.
- The Australian Chemicals and Plastics Industry Action Agenda in 2001 made a number of recommendations to Government aimed at reducing compliance costs. Since then a strong partnership between industry and Government has produced good results in reforming the

regulation of chemicals. Central to the progress achieved was the leadership provided by Government. The then Parliamentary Secretary to the Minister for Health and Ageing, the Hon Trish Worth MP, coordinated the Australian Government's work with industry across all relevant regulatory bodies.

This led to the introduction of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and the substantially improved regulatory regime introduced by the *Industrial Chemicals (Notification and Assessment) Amendment (Low Regulatory Concern Chemicals) Act 2004*. The reforms in the act are focused on achieving regulatory efficiency and positive incentives to drive improvements in the safe and sustainable use of chemicals in Australia. They reflect a balance between developing actions to reduce the regulatory burden with actions to strengthen compliance, transparency and access to chemical safety information.

- A significant degree of harmonisation has been achieved to date in weights and measures from the adoption by all states (WA will enact legislation soon) of Uniform Trade Measurement Legislation (UTML). However, since agreement to adopt UTML in 1990, it has taken 15 years for all jurisdictions to adopt this legislation.
- The Globally Harmonised System of Classification and Labelling of Chemicals (GHS) is an initiative of the United Nations Economic Commission for Europe. The provisions for implementation of the GHS allow the uniform development of national policies, while remaining flexible enough to accommodate any special requirements that might have to be met. Furthermore, the GHS is intended to create user-friendly approach, to facilitate the work of enforcement bodies and to reduce the administrative burden.

The science industry's particular concerns regarding Australia's regulatory framework are:

- The inconsistent administration of certain regulations relevant to the industry;
- The lack of consultation by governments in their formulation and implementation of regulations and national codes of practice;
- The alignment of Australian regulations and standards with relevant international ones; and
- Industry awareness of product certification regulations and standards.

The science industry considers that the process for formulating and implementing regulations, standards and national codes of practice is often inconsistent amongst the various jurisdictions. The regulations and standards at issue are certain poisons on schedules 4 and 7, drugs and explosives precursors, in vitro diagnostics, weights and measures and electrical safety. The industry is seeking the introduction of a harmonised national code of practice that

Commonwealth, State and Territory Governments use for packaging and labeling of hazardous substances – poisons, precursors for drugs and explosives and therapeutic substances.

In regard to weights and measures, the National Measurement Institute, the Weighing Industry Association of Australia and other have been working to progress the harmonisation of Australia's national measurement system. However, further progress is needed for Australian firms to gain greater benefits from a fully uniform, national trade measurement system. Under the UTMS agreement all jurisdictions must agree to any amendment and then these are enacted according to jurisdiction's legislative priorities. As a result, at any one time, there can be variations between jurisdictions. Jurisdictions have different interpretations of the core trade measurement legislation, different administration and enforcement legislation and different arrangements for cost recovery. Firms that operate across Australia's internal borders have to meet the requirements of more than one jurisdiction. The lack of uniformity in administration also means that Australia cannot negotiate as a single unit with overseas countries in this regard. The Standing Committee of Senior Officials on Consumer Affairs (SCOCA) is to commission a study into national arrangements for trade measurement, and the report is expected in about four months.

In regard to electrical safety, the science industry shares its concern about compliance with electrical safety regulations and standards with Australia's electrical industry, as many scientific items are electrical in nature. Electrical safety compliance in Australia is regulated by the individual States and Territories rather than being coordinated at the national level. This situation has led to some potentially unsafe electrical products entering into the Australian market.

The electrical industry's peak body, Australian Electrical and Electronic Manufacturers Association (AEEMA), has suggested that the State and Territory legislation be superseded by Australian legislation that is complementary to Part 5A of the *Trade Practices Act* (1974). AEEMA has also suggested that a National Electricity Safety Regulator be created and overseen by a Ministerial Council.

The Australian science industry has found that the various regulatory bodies in the different jurisdictions have not consulted the industry satisfactorily during their formulation of regulations, standards and codes of practice. Also, the process in each jurisdiction is different for each issue. The science industry is seeking a common and more inclusive process for the development of the reporting and monitoring requirements on hazardous substances.

The Australian science industry is seeking the alignment of Australian regulations and standards with relevant international ones such as CE Mark, UL certification, US Food and Drug

Administration and the quality standards ISO and American Stand Test Method. In particular, the industry considers that Australian regulations and standards should be aligned with those of Australia's major export markets.

In a regulatory environment that is under constant change, small and medium sized enterprises (SMEs) are particularly challenged to remain compliant with the regulations. To facilitate this, the industry considers that it is essential for SMEs to have readily available access to accurate domestic and international information on product certification regulations and standards through, for example, a dedicated website.

### **Conclusion**

The science industry places great importance on the need for greater harmonisation of Australia's regulations and standards that relate to the trade and commerce of scientific goods and services to improve the international performance of the industry.

The action agenda secretariat and representative of the industry would be happy to further expand on these issues to the committee.