Case studies

Case Study #1: A Proposal for a New Regulatory Framework for *In Vitro* Diagnostic Devices

The Therapeutic Goods Administration (TGA) issued a discussion paper entitled 'A Proposal for a New Regulatory Framework for *In Vitro* Diagnostic Devices' in 2003. The new framework will be underpinned by the Therapeutic Goods Act 1989 (the TGA Act).

The rationale for the new framework, ie to establish quality, safety and performance requirements for *in vitro* diagnostic devices (IVDs), is to be commended. Not only does it provide assurance to all Australians that diagnostic testing is carried out using appropriate materials, it also harmonises with similar approaches that have been implemented in the EU and Canada.

The IVD proposal was developed by the National Coordinating Committee on Therapeutic Goods *In Vitro* Diagnostic Devices Working Group. Membership of this working group included relevant professional societies (eg Royal College of Pathologists of Australia), industry groups (Medical industry Association of Australia) and government representatives.

There was no direct involvement by Science Industry Australia, the industry group representing manufacturers/importers/distributors (predominantly SMEs) of generic scientific equipment[1], laboratory consumables[2] and laboratory reagents[3].

These three categories of materials are routine laboratory tools that are found in university and government research laboratories, in analytical laboratories (food, environment, mining, etc) and in school science laboratories. Under the proposed legislation, a significant number of scientific equipment will be Class 1 IVD items. Other consumable items might fall into this category.

Therefore, the IVD legislation, in its proposed form, "captures" a relatively large number of science-based SMEs (perhaps 200 of the ~ 500) that previously fell outside the TGA net and that have had no experience with the TGA listing/registration processes.

It appears that the prime driver for the all-inclusive nature of the proposed legislation is simply that, ie to be all inclusive. TGA have assessed Class 1 IVDs as having no public health risk. The imposition of regulation, in the form of the IVD legislation, when there is no public health risk and no obvious market failure, is contrary to all "rules" underpinning good regulatory practice.

There also appears to be elements of international harmonisation. This goal is laudable but when there is a basic question mark over the appropriateness of the international framework then question should be asked and alternative approaches should be canvassed.

The estimated cost of drawing the 500 science-based SMEs into the TGA net through need for adherence to Class 1 requirements can be summarised as:

Direct costs per company (annual fee)	$500
Indirect costs per company (paperwork)	$2,500
Opportunity costs (loss of strategic time)	$5,000
Total cost per company	**$8,000**
No. of SMEs impacted	~200

[1] Examples of such equipment include centrifuges, automatic pipettes and chromatography instruments
[2] Examples include disposable plastic collection vessels, other plasticware and glassware.
[3] Examples include buffers used to calibrate pH meters, chemicals and biochemicals (enzymes)

Total cost to science-based SMEs	**$1,600,000**

Case Study #2: Framework for ozone protection

The *Ozone Protection and Synthetic Greenhouse Gas Management Act 1989* (the Ozone Act), administered by the Department of Environment and Heritage (DEH), controls the manufacture, import and export of range of ozone depleting substances (ODS) and synthetic greenhouse gases (SGG) in Australia.

The import, export and manufacture of these "controlled substances", and the import and manufacture of certain products containing or designed to contain some of these substances, is prohibited in Australia unless the correct licence or exemption is held. The cost of a pre-charged equipment licence is a flat $3,000 for two years (1 January 2006 to 31 December 2007), immaterial of the number of importations, the volume of importations or their frequency.

Therefore a small science-based company that conducts infrequent imports of a refrigerated laboratory cooler as a necessary component of a larger specialised piece of scientific equipment would be liable for the $3,000. There is no discrimination based on level (value, quantity or frequency) of imports—a regular importer of thousands of a commodity items, such as a domestic refrigerator, would also be subject to the same $3,000 licence fee. There is case for a graduated fee, possibly based on volume of items, rather than the current “one-size-fits-all” fee.

Holders of licences are required to provide quarterly reports covering items such as the quantities of ozone depleting substances imported, exported or manufactured. The reports are used to generate an activity fee based on the quantity of substance imported; this is payable at the end of each quarter. As an example, the activity fees are $165 per metric tonne of hydrofluorocarbons (HFCs) and much higher for hydrochloroflurocarbons (HCFCs) which have a higher ozone depleting ability.

As most scientific equipment importers or manufacturers are SMEs, the amount of controlled substances listed on the quarterly reports is invariably quite small and therefore results in even smaller levy (tax) payments. As an example, one medium sized scientific company imported 0.0000 kg, 1.1850 kg, 0.0400 kg and 0.0000 kg for the four quarters starting October-December 2004 and ending July-September 2005. The levies payable were $0.00, $0.20, $0.01 and $0.00, respectively, a total of $0.21.

Apart from the cost to the company of raising cheques for $0.20 and $0.01 (there is no threshold payment exemption under the Ozone Act), the notion of a bureaucrat processing the paperwork relating to such minor amounts is beyond comprehension. Again, there is clearly a case for an alternative approach, based on reporting/payment thresholds and/or less regular reporting when the amount of controlled substances is below a reasonable risk-assessed level.

On top of the above, there is also a requirement for all licensees to be current members of a Product Stewardship Scheme. There appears to be a market failure in this area as the only available scheme is conducted by Refrigerant Reclaim Australia Limited (RRA). The cost of membership is $100 (plus GST) per annum if the contributor imports 100 kilograms or less during a calendar year; most scientific SMEs would fall into this category. There is an associated annual (by 31 March) reporting/payment deadline.

According to RRA’s website (see http://www.refrigerantreclaim.com.au/program_perform.html) the amount of controlled substances reclaimed is approximately 15,000 kilograms per month (or 180,000 kilograms per annum) and trending upwards. Considering that most scientific SMEs import/handle relatively low amounts of controlled substances, of the order of several kilograms per annum (less than 0.005% of RRA’s turnover), there is an argument for a threshold exemption based on materiality.

At such low levels, the issue of free-rider is negligible compared to the relative impost on the science industry. In addition, any “load” that the science industry imposes on controlled substances is subject to fees collected through mainstream refrigeration companies who carry out maintenance on refrigerated scientific equipment. One could mount an argument that double charging was occurring.

The estimated annual cost of complying with the Ozone Act can be summarised as:

DEH-related costs	Direct costs per company (annualised licence fee)	$1,500
	Direct costs per company (levies)	$20
	Indirect costs per company (paperwork)	$2,500
	Opportunity costs (loss of strategic time)	$5,000
	Total DEH costs per company per annum	**$9,020**
RRA-related costs	Direct costs per company (annual fee)	$100
	Indirect costs per company (paperwork)	$500
	Opportunity costs (loss of strategic time)	$1,000
	Total RRA costs per company per annum	**$1,600**
	Total cost per company per annum	**$10,620**
	No. of SMEs impacted	~100
	Total cost to science-based SMEs	**$1,062,000**