By Diana Bowman
POSTDOCTORAL RESEARCH FELLOW, FACULTY OF LAW, MONASH UNIVERSITY

Rules for nano

Nanotechnology is the subject of science fiction, media hype and loads of promise. To some commentators, this heterogeneous family of technologies will provide solutions for curing cancer, feeding the poor and generating cheap, environmentally friendly energy. To others it will revolutionise military capabilities, lead to new classes of 'nano-weapons', exacerbate current economic divides, and result in a myriad of unintended and unpredicted consequences. As with earlier technologies, the truth will probably lie somewhere in-between.

There is little doubt that this tiny technology will be of increasing importance to traditional industry sectors. Nanotechnologies exploit the novel physico-chemical properties of matter that exist at the nanoscale. In Australia, innovative companies, including Starpharma, CAP-XX, Micronisers, and Advanced Nanotechnology, have already cemented their positions as global leaders in the development and commercialisation of nanotechnology-based products and applications. Their current applications include nano-pharmaceuticals, supercapacitors, nano-scale powders for sunscreens, cosmetics, and industrial chemicals. Many more applications and products are likely just around the corner.

Former Industry Minister, Ian Macfarlane, suggested that nano-enabled products and applications may be worth up to $50 billion annually to the Australian economy. To assist in realising this goal, a four year, $21.5 million, National Nanotechnology Strategy (NNS) was initiated in 2007. Its broad objective was to equip Australia with the necessary knowledge and skills to balance the anticipated economic and societal benefits against potential risks. In doing so, it acknowledged the need to invest in these areas, while realising that the current regulatory paradigm may not be adequate for all dimensions of the technology. Such concerns and policy directions have been recognised around the world.

Public sector spending on nanotechnology R&D continues unabated. This includes research into human and environmental health and safety and the regulatory challenges posed by nanotechnologies, within jurisdictions such as the EU and the US. Yet recent reforms to Australia's NNS have meant that the current Strategy will cease after two years, saving some $12 million to the Australian Government's budget. Perhaps in the broader context of Australia's innovation policy, and the present Cutler Review (see 'Innovation at the crossroad', R&D Review, February 2008), this change is not so surprising. Looking forward though, Australia's innovation policy faces real challenges identifying and lowering unnecessary barriers to innovation, whilst encouraging a role for nanotechnology as part of Australia's future global competitiveness.

In terms of our future, some current regulatory frameworks may need to be revised or strengthened. Why? Because the novel properties that make nanotechnology so attractive to industry and consumers also bring new challenges. Scientific studies suggest that some engineered nanoparticles appear to exhibit greater toxicity than their larger scale equivalents. Other studies indicate that the current risk assessment methodologies – which primarily rely on mass metrics for evaluating safety – may not be appropriate for evaluating the hazards of engineered nanoparticles, potentially resulting in an underestimation of their potential risks.

Nanotechnology-based applications and products continue to be regulated in Australia through conventional regulatory regimes. For the most part, these regimes treat nanotechnology-based products as being equivalent to their non-nano counterparts. A commercially available cosmetic product that is subsequently reformulated to contain, for example, nano-scale aluminium oxide (alumina) particles in preference to larger particles would be considered by the regulatory regime to be equivalent to the traditional cosmetic product. A risk assessment of the nanoscale alumina by the relevant regulatory agency would therefore be unlikely as the alumina nanoparticles will be considered to be a 'prior existing chemical' and not 'new.' Despite their novel properties, and potentially different risk profiles, it would appear in this case that the nanoparticles fail to trigger regulatory oversight. So the sensible thing to do here is for the regulator agencies, scientists and industry to proceed with a degree of caution..

Is this a concern from a public health point of view? At this stage, scientists and regulators simply do not know and are unlikely to know for some time. For this reason, a number of leading commentators have called on government to introduce nano-specific amendments to current regulatory frameworks. These advocates want engineered nanoparticles be considered as 'new' and subject to risk assessment regimes even when larger-scale counterparts have already been approved. Others have called for more extensive reforms. Some civil society groups have called for a moratorium on the use of engineered nanoparticles in applications such as food, food products and cosmetics. A moratorium is however highly unlikely. For one thing it is probably logistically impossible. But importantly, too, many uses of nanotechnologies are likely to be benign. As such it is important that we do not therefore overreact and undermine public confidence in the existing regulatory arrangements. A needless public backlash against the technology would be both damaging for industry as well as society more generally, given the potential and wide-ranging benefits offered by nanotechnologies.

So what might we conclude overall? Nanotechnologies are destined to play a significant role in driving Australian innovation forward. But without doubt greater scientific and regulatory certainty is required. And herein lays the challenge: regulating unknown risks and balancing these against the public interest without compromising the development of a promising technology. While the Cutler Review may not in itself be able to address these concerns in the short term, the Review will play a crucial role in laying the foundations for innovation policy more generally. In doing so, the Review represents a tremendous opportunity to advance Australia's scientific future, in which nanotechnology will undoubtedly play a central role. Regulation will of course be a facet of the governance solution. But it will only be one part of a multi-dimensional approach needed to ensure the successful development and commercialisation of this promising technology.

Nanotechnologies are destined to play a significant role in driving Australian innovation forward. But without doubt greater scientific and regulatory certainty is required.