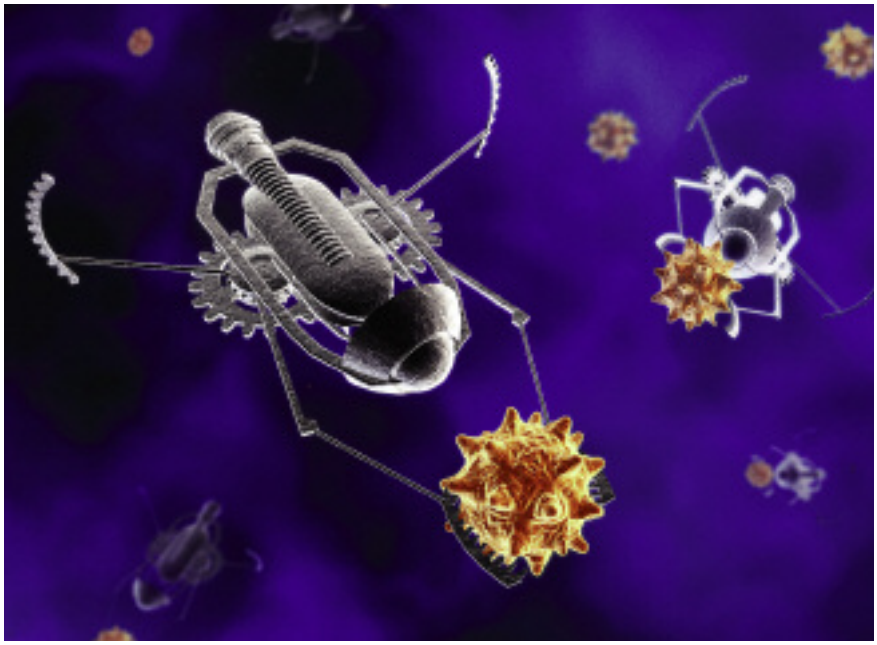

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NANOTECH SAFETY: Who Is Responsible?

Sarah Belfield warns that regulation of nanotechnology products is being shared by a number of agencies, potentially leading to a lack of ethical and legal clarity.

Like other countries hosting nanotechnology research sectors and manufacturers, Australia has some regulatory and ethical spring cleaning ahead, plus a research shopping list to prepare.

When asked to identify the single most important thing Australia's legislators needed to do in the next 12 months in the nanotechnology realm, Dr Thomas Faunce of the Australian National University said they needed to assist research into the safety and cost-effectiveness of nanomedicine.

Faunce and his colleagues say that nanomedicine, which is a rapidly expanding area of research, could influence how we detect and analyse disease, deliver drugs and perform reconstructive, neurological and cardiac surgery. According to Faunce, most major pharmaceutical companies are working on nanotechnology-related research and development.

But Faunce, from the ANU's College of Law and Medical School, said cost-effectiveness evaluations – where nanomedicine is compared with existing therapeutics – were often overlooked in regulatory discussions even though it was one of Australia's genuine regulatory strengths as a result of the expertise built up through the Pharmaceutical Benefits Advisory Committee.

On the safety front, he said the value of lifetime animal studies for drug safety had been called into question by "the recent harm to healthy volunteers in a stage 1 trial in the UK". In March, the experimental drug TGN1412 put six British trial volunteers into critical hospital care, one of whom remained in hospital until late June. "Studies of nanomedicine may be even more unpredictable," Faunce said.

Faunce was the lead author of a debate paper examining policy challenges stemming from the recent Senate inquiry into workplace exposure to toxic dust. The inquiry's scope included nanoparticles.

Faunce's paper said that the worldwide problem of workplace-related disease from toxic dusts did not have as much to do with the creation of standards as with implementing them. However, standards seemed absent for the use of nanomaterials in medicine, with "currently no effective methods to measure and assess exposure risks to nanoparticles in patients or healthcare workers. Nanoparticle exposure limits do not exist and manufacturers currently have no obligation to publish details of the safety checks imposed on their nanoproducts."

Faunce added that incomplete nanomedicine safety and toxicity profiles may create knock-on effects for other medical standards processes, such as marketing approvals by the Australian Therapeutic Goods Administration, cost-effectiveness evaluations by the Pharmaceutical Benefits Advisory Committee and Medical Services Advisory Committee, and the horizon-scanning program of the Health Policy Advisory Committee on Technology.

Faunce and his colleagues said that carrying out the nano-related policy recommendations in the Senate inquiry's final toxic dust report was "a matter of national urgency" given the "burgeoning" nanotech research already happening in Australia.

In the report, inquiry committee chair Senator Claire Moore said that the high surface area and very small size of nanoparticles meant that traditional worker safety regulations on exposure standards, risk assessments and measurement methods and equipment will need modifying. Moore also said that the Senate committee believed

Australia's regulatory set-up needed to be flexible to accommodate nanoparticles, and needed to include ways for all federal regulatory agencies to address regulatory developments overseas.

The committee recommended that a working party on nanotechnology regulation be established and that representatives from the Therapeutic Goods Administration, the National Chemicals Notification and Assessment Scheme and the Australian Safety and Compensation Council be involved to consider the impact of the emerging field of nanotechnology on the regulatory set-up. Work would include judging whether existing regulations were appropriate, how gaps and uncertainties could be addressed, and whether a need existed to establish a permanent nanotech regulatory body.

The working party was to consult widely and report back publicly on these and other regulatory questions by March 2007.

Regulations in Need of Polishing or Renovating?

ANU academic Judith Jones, an environmental law lecturer with expertise in regulatory design, said that her ideal picture of how nanotech-related laws or regulation should be handled involved case-by-case science-based analysis of environmental and heath risks.

Her scenario included the monitoring of research activity alongside the products themselves. She said precautionary principles, public consultation, and social and ethical assessments would be features too. She said it was "now recognised by many academic writers that ideal risk analysis processes would effectively incorporate both science and values in a transparent manner".

Judith Jones says that clarity about Australia's regulatory set-up is important for public confidence in nanotechnology.

"From a regulatory design perspective one important question is whether adaptation of a pre-existing regime can effectively achieve this." Jones said that if pre-existing regulations were used to steer nanotechnology risk analyses, then the transparency of established regulatory processes would dictate how transparent nano-related decision-making was. Any nano-specific laws added on would be another factor.

She said "the emergence of clarity" about Australia's regulatory set-up was important for public confidence – in the science of nanotechnology as well as its regulation. This need for clarity applied whether Australia adapted current regulations to suit nanotechnology or created a separate regulatory regime.

According to Diana Bowman and Graeme Hodge of Monash University's Centre for Regulatory Studies, Australia has been taking the same approach as other countries hosting nanotechnology research sectors – nano-related regulation was being farmed out among existing decentralised regulators. In a joint paper in press at the time of writing, Bowman and Hodge cited a 2004 survey by the public policy centre Meridian Institute and the US National Science Foundation showing that most of the 25 countries examined had not yet enacted nano-specific guidelines or legislation.

However, a government-commissioned report, *Options for a National Nanotechnology Strategy*, which was publicly released by the the National Nanotechnology Strategy Taskforce in September, concluded that there is "currently no case for establishing any new, nanotechnology-specific regulations, but rather, existing regulations may need some adjustment". This was despite their recommendation that issues such as whole-of-government coordination, nano-measurement standards, international cooperation and impacts on health/safety/environment should be addressed immediately.

The Taskforce also recommended that any proposed changes to existing health, safety and environmental regulations should not add unnecessary regulatory burdens to industry.

The Taskforce report was commissioned by federal Industry Minister Ian Macfarlane. Of the nine members of the nanotechnology reference group set up to advise the Taskforce, only Simon Longstaff of the St James Ethics Centre was independent of business or scientific interests.

Despite the report's conclusions, the future responsibilities of decentralised regulators remains unclear. Bowman and Hodge believe that each regulator's

" there probably are areas in nanotech where we should seriously consider at least perhaps slowing things down a bit, and pouring money into research to find out whether there are problems".

set of regulations, codes of practice and guidance material will need revising as the size of the nanotechnology industry increases and commercial activity matures.

Eventually, advances in nano-related applications would mean that nanotechnology's potential to strain a conventional regulatory set-up "will increase commensurately", they said. "Bolt-on" nano-related legislation might work as a short-term fix, but in the longer term the convergence of nanotech, biotech and information technology may prompt "more proactive" regulation, such as a more centralised set-up.

Bowman and Hodge warned that if a government remained passive during such a convergence of scientific arenas, the risk was that "a blurring of [regulator] jurisdictions will occur along with a resulting lack of ethical, policy and legal clarity".

Ethical Self-Examination

Professor John Weckert, professorial fellow with the Centre for Applied Philosophy and Public Ethics at Charles Sturt University, said that the term "convergence" often included cognitive science, artificial intelligence or neuroscience. This was because "once you get down to that scale the differences tend not to matter, and all these different [scientific] areas merge".

He thought nanotechnology "is forcing us to re-examine some big-picture issues". For instance, do we want to or should we get involved in human enhancements? "Now that's down the track a bit, but it is one of those big-picture issues which I think is always lurking in the background when we talk about nanotech."

Weckert is also editor-in-chief for the new academic journal *Nanoethics*, the first issue of which is scheduled for March. Weckert said the aim was to examine nano-related ethical and social issues in a philosophically rigorous way that was also clearly based on science.

"There's so much hype around in the nanotech area and in all of these convergent technology areas, really, that there needs to be some forum for actually looking at these things in a sensible, rigorous way so that they get examined properly," he said.

Weckert has found that Australian scientists seemed "surprisingly keen" to discuss ethical and social nano-related matters. "Now one can be a bit cynical, because one of the issues that comes up regularly is that the nanotech or nanoscience community doesn't want to have the same problems as there were with [genetically modified] food and so on. That makes it look a bit as if they are using people like me to give a good ethical front to the whole thing.

"But I'm not too skeptical. Most of the scientists I talk to do seem to be genuinely interested in these areas. So I'm fairly optimistic about more co-operation."

When asked what he thought about a moratorium on nanotechnology research, Weckert gave a brief chuckle: "I guess I try and have a bit both ways. It does seem to me that just stopping research can create in itself big problems... [But] I think that there probably are areas in nanotech where we should seriously consider at least perhaps slowing things down a bit, and pouring money into research to find out whether there are problems."

Sarah Belfield is a freelance science writer.

Regulator Calls for Data from Nanotech Importers and Manufacturers

In a step towards setting a clearer picture of nanomaterials in Australia, the industrial chemicals regulator NICNAS made its first call in February for voluntary information from companies. NICNAS, the National Chemicals Notification and Assessment Scheme, asked for details on which nanomaterials would be imported or manufactured in Australia in 2005 and 2006, and what amounts were involved. "This information will assist in understanding which nanomaterials are available on the market or close to commercialisation, and in focusing our efforts to ensure the adequacy of the regulatory scheme," the regulator said in its *Chemical Gazette*.

The information that companies supply will go towards the regulator's upcoming report on the extent and scope of the use of nanomaterials in industrial, cosmetic and personal care products in Australia. The call for information did not cover agricultural chemicals, veterinary chemicals, food, food additives or nanomaterials used only as therapeutic goods, such as sunscreens.

Deborah Willcocks, team leader of rapid risk assessment at NICNAS, told *Australasian Science* that she hoped a draft of the report would be ready by the end of September. "That is probably being very optimistic," she said, adding that the drafting process meant ensuring all data being publicly reported was in a non-confidential form. One example might be the slight broadening of nanomaterial categories so that individual products wouldn't be easily identifiable.

Willcocks said that despite the widespread discussion of nano-product availability, "our gut feeling is [there's] not as many as people think". She said the information NICNAS was gathering would help a great deal in obtaining "a fairly good idea of what is out there".

An inventory of consumer nano-products kept by the Project on Emerging Nanotechnologies tallied up conservatively in mid-July to around 275 products across 15 countries, according to project director David Rejeski. The project is co-supported by the non-partisan Woodrow Wilson International Center for Scholars in the United States.