



National Industrial Chemicals Notification and Assessment Scheme Proposal for Regulatory Reform of Industrial Nanomaterials

Public Discussion Paper – October 2009

Have Your Say Questionnaire

All submissions will be placed on the NICNAS's website. For submissions made by individuals, all personal details other than your name will be removed from your submission before it is published on the NICNAS website. Confidential material contained within submissions should be clearly marked. Reasons for a claim to confidentiality must be included in the submission coversheet. Where possible confidential material will be redacted from information published on the NICNAS website.

1. What is the significance and/or consequence of this working definition for 'industrial nanomaterials'?

It is unclear what the term 'typically' implies. Does it mean that 1-100nm is the range that will trigger regulatory action or does it imply that NICNAS will pursue a definition of nanomaterials based on functionality (as recommended by the UK Royal Commission on Environmental Pollution)? At the moment this is unclear and this ambiguity needs to be removed to avoid confusion, potential loopholes and ongoing debate. In defining what counts as a nanomaterial, it does not make sense to impose an arbitrary upper limit on the nanoscale. Definition and regulatory testing be based on function; that is, if particles of 500 nm are found to demonstrate the unique properties associated with the nanoscale, they should not be excluded from definitions of nanomaterials simply because they exceed a 100 nm limit. Until testing capable of adequately documenting functional properties is available, a broad and inclusive definition (beyond the typical 1-100) would allow for a greater margin of safety.

2. How do you think the proposal to limit access to exemptions for nano-forms of new chemicals will contribute to protecting health and the environment?

It is very important that nanoforms of new chemicals not be permitted a low volume or low concentration exemption and I am pleased to read that NICNAS is suggesting this amendment.

3. Describe any ways in which you think self-assessment by an independent third party could be used to effectively achieve the same results?

4. If in R&D, what, if any, practical issues arise from the proposed administrative amendment for annual reporting of R&D exemptions? Would it require a significant increase in reporting? If so – how much?
5. What are your views on the impact of the proposal to regulate nano-forms of new chemicals with the above changes to the permit and certificate categories? Can you identify additional advantages or disadvantages?

This system places quite a deal of emphasis on the concept of 'no unreasonable risk', however, no details are provided on how what a 'reasonable' level of risk actually is will be decided, including according to who and what criteria this will be done. I would suggest that the role of public engagement processes be considered here since what is a reasonable or acceptable level of risk is clearly not something that can be objectively determined. Additionally, the benefits that such nanomaterials and their products are claimed to generate should also be made clear and a part of the assessment process. It is impossible to assess what a reasonable level of risk is without simultaneously discussing the social need that the product aims to meet and its relative importance.

6. What are your views on a system that is sufficiently flexible to amend permit conditions where new data indicates a new risk profile?
Clearly a flexible system able to quickly adjust to new information is needed for nanomaterials. Practically, however, it is important to consider the degree and type of information that would be required to trigger action. For example, will one study published in a peer reviewed journal be considered enough to change a material's risk profile? What will be the criteria used for judging the quality of knowledge and new data? What will count as sufficient evidence to indicate a new risk profile?
7. What are your views on the impact of the proposal for mandatory once-off, use specific reporting for nano-forms of 'existing chemicals'? Can you identify additional advantages or disadvantages?

That the program is mandatory is crucial. However, there is still a large degree of uncertainty regarding the appropriate methods for characterising, understanding and documenting relevant properties of nanomaterials. The current inability to adequately detect, characterise and measure relevant aspects of nanomaterials is not, however, a reason to implement a voluntary scheme to allow industry time to prepare for a mandatory scheme. Rather, it is a reason to immediately implement a mandatory scheme so as to encourage industry to more rapidly develop the capacity to provide the information required for safety assessment. The approach of 'No data, no market' (as being pursued in Europe) must be adopted from the outset.

8. Explain how you think the potential burden of once-off, use specific reporting could or could not balance community expectations in relation to health and environmental standards?

Community expectations for health and environmental standards are that products are not just reported but actually assessed for their safety. Therefore to meet community expectations, reporting should be followed up with comprehensive safety assessment.

9. What are your views on making the information gathered through streams 1A and 1B publicly available?

This is absolutely essential.

10. What are the advantages and disadvantages of the introduction of a system that required a mandatory notification and assessment program for all nano-forms of existing chemicals? What are the reasons for this answer?

11. What are current issues that affect the feasibility of such a program?

The feasibility of such a program will suffer significantly if a traditional model of risk assessment is proposed for the assessment process. Given the gaping chasms of scientific information on the risks relating to nanomaterials, it is simply not possible to rely on risk assessment as a sufficient tool. The program should therefore seriously consider alternative approaches to assessment that give enhanced weight to social priorities and values and to identifying and negotiating uncertainties (in addition to risks). This could include processes such as multicriteria mapping, real time technology assessment and pedigree assessment. All of these are better equipt to transparently handle issues of uncertainty and integrate the inevitable social dimension directly into the assessment process. Feasibility of a mandatory notification and assessment program requires innovation in regulatory processes that can match the technological innovation at hand. The pursuit of a traditional risk assessment model is in no way sufficient to handle the novel regulatory challenges involved for nanomaterials.

12. What are your views on making the information gathered from assessments of nano-forms of existing chemicals publicly available?

This is absolutely essential. I would, however, suggest that the information should not just be made publicly available, but that the assessment processes themselves should actually actively work to include public engagement processes, for example through the use of extended peer review techniques.

13. How might an integrated approach provide for more effective regulation of industrial nanomaterials compared to the package of options proposed in sections 3a and 3b?

What you should know about nano

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1. Introduction: what is nano?

We are constantly told that ‘nano’ science and technology are going to revolutionise our lives—but what does this really mean? This paper explores the question by giving a sweeping overview of issues surrounding the development of nanoscale sciences and technologies, with a soft spotlight cast over Australian policy. Specifically, the topics addressed include:

- 1) what ‘nano’ is
- 2) its presence in consumer products
- 3) the grand visions for its future
- 4) the stories about its past
- 5) the question of potential risks and the answer of real uncertainties
- 6) the social and ethical questions at stake
- 7) the Australian regulatory context.

In providing this overview, the paper aims to introduce and engage its audience in the experiment that is nanoscale sciences and technologies, particularly from the perspectives of consumer and environmental protection and occupational health and safety. By concluding with recommendations for policy, it aims to create a setting in which there can be an open debate over our collective involvement in this experiment and a broad-based public negotiation of appropriate controls.

The term ‘nano’ refers to the scale length of one billionth (10^{-9}); that is, one ‘nanometre’ (nm) is equivalent to a billionth of a metre. To give a sense of this incredibly small size, a sheet of paper is around 100,000 nm thick. The term ‘nano’ is increasingly being used to refer to a field of science and technology that works at the level of atoms and small molecules and currently encompasses a whole range of different sciences (chemistry, biology, physics, engineering, information technology) and technologies across various sectors (energy, electronics, agriculture, communications, cosmetics, textiles, medicine). This extensive diversity means that the field is often referred to in the plural as nanosciences and nanotechnologies or as nanoscale sciences and technologies (nanoST).

The fact that ‘nano’ effectively refers only to a unit of measure is an important reason why a number of extremely different projects and products are collected under the label of nanoST. Consider, for example, the diversity that a concept like ‘metre science and technology’ would include—all the science and technology that takes place within a certain range of metres, a very diverse and broad field indeed. However, what binds the incredible diversity of nanoST together and separates it out as something unique is that, at the nanoscale, materials can express different properties from those expressed at larger scales. Properties such as colour, conductivity and reactivity, for example, can all change. An example of this is the way in which nano-sized particles of gold appear red and are reactive rather than inert.

The expression of novel properties at the nanoscale is typically explained by three features: the presence of quantum effects, the increase in surface area to volume ratio and/or the potential for alternative molecular structures. Quantum effects are the peculiar phenomena that manifest at the atomic level and are not adequately explained by classical (Newtonian) physics. For example, at the quantum level, matter behaves like both a wave and a particle and is said to occupy a kind of ‘superposition’ as both simultaneously until observation fixes it as one or the other. An increase in surface area to volume ratio occurs whenever an object is divided into smaller pieces (that is, more surfaces are created while the volume stays the same). The incredibly small size of nanoscale

objects means that the majority of atoms or molecules become located on surfaces and because surfaces represent potential interfaces, this often enhances reactivity.

Novel properties can also occur because atomic configurations can be altered at the nanoscale. For example, both graphite and diamond are made of carbon atoms but these materials have very different physical properties because of the way in which the atoms are arranged (in a sheet form for graphite and in a tetrahedral shape for diamond). One of the early areas of significant development in nanoST has been the discovery of, and ability to fabricate, different atomic structures for carbon, including soccer-ball-like shapes (fullerenes) and cylindrical tubes (carbon nanotubes). Carbon nanotubes are both stronger and lighter than steel and can have very high conductivity, a good example therefore of how restructuring atoms at the nanoscale can create materials with novel properties. In many definitions, nanoST are seen as not just working on a nanoscale but actively investigating and utilising the novel properties in effect there.

A definition of 'the nanoscale' as 1-100 nm is increasingly becoming standardised because this is the range within which novel properties are considered most likely to occur. However, using this range to define nanoST remains controversial and its appropriateness is subject to ongoing debate, chiefly because some of the unique properties of nanoscale objects can be observed at sizes larger than 100 nm.¹ How 'nanoscale sciences and technologies' are defined (including the range used) is highly significant as it has the potential to affect research funding and regulatory requirements across a whole range of sectors.

Applications of nanoST can be 'nanoscale' in one, two or three dimensions. For example, very thin films and surface coatings might be nanoscale in one dimension (height). Nanowires and nanotubes can be nanoscale in two dimensions (height and width but not length), while nanoparticles and quantum dots are usually nanoscale in all three dimensions. In applications, nanomaterials (materials that are nanoscale in one, two or three dimensions) may also be 'free' or 'fixed'. Free nanomaterials are those that are free to move around, often appearing in the form of powders, liquids and solutions for example. Fixed nanomaterials, on the other hand, are those that have been set in a solid matrix or embedded into larger composite materials.

When talking about nanoST, many people choose to emphasise that nano-sized particles and processes exist in nature. For example, nano-sized particles can be produced by volcanic eruptions while processes performed inside a cell occur on the nanoscale. Since 'the nanoscale' simply refers to a particular level of material reality, we should not be surprised that we find nanoscale products and processes in nature. What is perhaps surprising is the way in which people take very different approaches to interpreting what this means. For example, some interpret it to mean that nanoST are 'natural' and therefore harmless. Others suggest that it provides a 'proof of principle' for what nanoST hope to achieve. Still others claim it means nanoST will be best advanced by using the nanoscale 'tools' already developed in nature.

People describe and interpret the relationship between nature and nanotechnology in a range of different ways and all have significant implications for what type of research is pursued and

¹ For example, Friends of the Earth Australia has consistently called for an extension of the definition up to 300 nm. See G Miller and R Senjen, *Out of the Laboratory and on to our plates: Nanotechnology in food & agriculture*, a report prepared for Friends of the Earth Australia, Friends of the Earth Europe and Friends of the Earth United States and supported by Friends of the Earth Germany, March 2008. Available at: http://nano.foe.org.au/filestore2/download/219/nano_food_report.pdf (last accessed 29.07.09).

The Standing Committee on State Development of the NSW Parliament Legislative Council also recently suggested that the definition be extended to 300 nm in its report *Nanotechnology in NSW*, Report No. 33, 2008. Available at:

[http://www.parliament.nsw.gov.au/Prod/parlment/committee.nsf/0/35d2e3e37498a908ca2574f1000301bb/\\$FILE/Final%20Report%20Oct](http://www.parliament.nsw.gov.au/Prod/parlment/committee.nsf/0/35d2e3e37498a908ca2574f1000301bb/$FILE/Final%20Report%20Oct).

supported.² While this is certainly an issue worthy of further reflection and research, in this paper the term 'nanotechnologies' will be used specifically to refer to the novel materials and processes that result from nanoscale manipulation, design and engineering conducted with human intent.

2. Nano consumer goods: they're everywhere

While still largely an emerging field, nanoST are already entering our daily lives through a range of consumer goods and, at the time of writing, over 800 consumer products have been identified as containing nanomaterials. This figure comes from the most comprehensive inventory currently available for nano-consumer products, produced and maintained online by the Project on Emerging Nanotechnologies, a partnership between the Woodrow Wilson Center for Scholars and Pew Charitable Trusts.³

As demonstrated by this inventory, nanomaterials can be found in a very diverse range of consumer products, including but not limited to: cosmetics, sunscreens, clothing, sports equipment, food, food packaging, nutritional supplements, toys, electronics, household appliances, kitchen utensils, cleaning products, paint, surface coatings and automotive accessories. The inventory lists nano silver and carbon as the most commonly-used materials (with titanium, zinc, silica and gold also in use) and the category of 'health and fitness' as containing the most products (particularly in items of personal care, cosmetics and clothing). Products listed as originating from Australia include sunscreens, surface coatings and kitchen appliances, although this does not indicate the full range of nano-consumer products currently available for sale in Australia.

Products such as household appliances, toys, food packaging and kitchen utensils predominantly make use of the antimicrobial properties of nanoparticles of silver. Sunscreens tend to include nanoparticles of zinc oxide or titanium dioxide that allow the liquid to be transparent. Sports equipment typically employs carbon nanotubes and their novel properties of additional strength and reduced weight while clothing, car accessories, cleaners and coatings exploit the ability of nanostructured surfaces to repel dirt and water. The use of nanomaterials in food, cosmetics and nutritional supplements is currently most often in the form of nanoscale particles or capsules to protect active ingredients and deliver substances directly into cells.

Identifying nanomaterials in consumer products is currently incredibly difficult because of the ongoing debate about the exact definition and boundaries of what constitutes nanoST. Related to this challenge, there are currently no labelling requirements in this field, which means that some products containing nanomaterials are marketed as such while others are not, with manufacturers disagreeing as to whether the 'nano tag' is likely to be beneficial or detrimental to product sales now and in the future. Some products also employ the nano-marketing tag when there is arguably no use of nanomaterials involved at all (Apple's ipod nano is perhaps the most widely-cited example of this, although some aspects of its electronics may indeed qualify as nanoST). All of these factors hinder accurate identification of consumer goods containing nanomaterials and make it difficult to ensure that nanomaterials are visible/traceable throughout production, consumption and disposal systems.

3. Future visions and socio-technical imaginaries

While current applications may appear rather superficial and modest (tennis rackets that don't break, socks that don't smell and shirts that don't stain), nanoST are surrounded by some very grand visions, some of which relate simply to the ability of nanoST to revolutionise a range of different industries by enabling the creation of new materials, processes of production and commercial

² F Wickson, 'Narratives of nature and nanotechnology', *Nature Nanotechnology*, 3:6, 2008, pp.313–316.

³ Available at: <http://www.nanotechproject.org/inventories/>.

applications. One of the more extravagant applications commonly used to popularise and promote nanoST is that of building an elevator into space utilising the unique properties of carbon nanotubes.⁴ On another level however, the grandest vision for nanoST relates to a very powerful, indeed mythical, quest for control of matter at its most fundamental level, which suggests that through mastering how to work with individual atoms and molecules, we will ultimately be able to construct 'anything we want, atom by atom' (mediated through instrumentation and software programs, of course). The ability to manipulate the 'building blocks' of matter will open up limitless potential according to this reductionist vision.

Among scientists actively working with nanoST, this grand vision of control is a source of debate about what is possible at the nanoscale, most famously captured in an open exchange of views between scientists K. Eric Drexler and Richard Smalley.⁵ In the Drexler-Smalley debate, there is a conflict between what can be understood as a chemist's versus an engineer's approach to nanoST.⁶ Adopting an engineering position, Drexler has argued for the possibility of 'molecular manufacturing' using devices he calls 'molecular assemblers'. According to him, a molecular assembler could build almost anything through guiding reactive molecules with atomic-level precision. Smalley, however, has argued that Drexler's vision for the miniaturisation of industrial styles of manufacturing is not possible due to a range of physical and chemical constraints at the nanoscale, including what he has referred to as the problems of 'fat' and 'sticky' fingers. The first is a problem of space caused by the fact that there is not enough 'room' to have nanoscale machines manipulating nanoscale objects (fat fingers). The second relates to problems associated with molecular forces of attraction due to the fact that it would not be possible to control what the molecules would react with (sticky fingers). Without getting into the extensive technical details of the argumentation on both sides, this debate can be understood as being about what is and is not possible on the nanoscale and therefore what approaches are most likely to be successful. According to the engineering approach, you can build anything you want by manipulating and arranging component parts in a desired way and you just need the tools to do this. According to the chemist's position, however, what you can do is limited by pre-existing forces, dispositions and abilities for interaction but enormous potential exists for utilising and mimicking the self-organising capabilities of chemical and biological systems.

Drexler is often scorned by scientists, not just for promoting a particular vision of nanoST that is considered technically questionable, but also because of a very dystopian vision he has articulated, known as the 'grey goo' scenario.⁷ According to this vision, molecular assemblers could have the ability to assemble copies of themselves and thereby become self-replicating. Assemblers (often referred to in popular culture as 'nanobots') could then run out-of-control and consume all of the world's resources in an endless process of self-replication, leaving the earth as nothing more than 'grey goo'. Drexler sees potential social and technical solutions to any problems of self-replication and established the Foresight Institute⁸ to help society prepare for nanotechnological advance. In an article in *Wired Magazine*, computer scientist Bill Joy took a different position, however, and famously argued that the risks associated with self-replication in fields such as biotechnology and

⁴ For example, see P L Barry, 'The Next Giant Leap', Science@NASA, 27 July 2005. Available at: http://science.nasa.gov/headlines/y2005/27jul_nanotech.htm (last accessed 29.07.09).

⁵ While this debate can be seen as taking place in numerous arenas between the years 2001–2005 (when Richard Smalley lost his battle with cancer), it is the published exchange in 2003 that is often cited as representative of the competing positions. See K E Drexler and R E Smalley, 'Nanotechnology', *Chemical and Engineering News* 81:48, 2003, pp. 37–42.

⁶ See B Bensuade-Vincent, 'Two Cultures of Nanotechnology?' *HYLE* 10:2, 2004, pp. 65–82 and A Ferrari, 'The Nano Control-Freak: Multifaceted strategies for taming nature', in *Nano meets Macro: Social perspectives on nanoscale sciences and technologies*, K. Kjølberg and F Wickson (eds), Pan Stanford Publishing, Singapore (2009).

⁷ See K E Drexler, *Engines of Creation: The coming era of nanotechnology*, Anchor Books, New York, 1986.

⁸ See the Foresight Institute website at <http://www.foresight.org/> (last accessed 15.07.09).

nanotechnology are so great as to warrant our not pursuing their further development.⁹ A similar dystopian vision of nanoscale machines running out of control has been presented in the popular science fiction novel *Prey* by Michael Crichton.¹⁰

Another vision of the future that has a particularly strong presence is the convergence of nanoST with other fields of research. An important articulation of this vision is that from Mihail Roco and William Bainbridge. Their report, *Converging technologies for improved human performance: nanotechnology, biotechnology, information technology and cognitive science*,¹¹ was supported by the US National Science Foundation and lays out a vision for the future in which the convergence of these fields creates the potential to alter radically human physical traits and mental performance—a situation the authors describe as representing a ‘new renaissance in science and technology’. This vision includes advances such as direct interfaces between brains and machines, bodies more resistant to ageing, wearable health and environmental sensors and effective exploitation of resources on Mars. The European response to this vision, presented in the report *Converging technologies: shaping the future of European societies*,¹² extended what was converging to include social sciences. Here, convergence was seen as directed not towards the goal of human enhancement but towards the achievement of publicly negotiated social and ethical goals. The contrast between these two reports demonstrates the importance of cultural differences in future visions for nanoST, most notably Europe’s generally more precautionary, socially inclusive approach to new technologies.¹³

One of the most influential future visions driving nanoST is advanced by the US National Science Foundation, which predicts that nanoST will become a (US) trillion dollar annual market between 2011 and 2016.¹⁴ This prediction has attracted a host of criticism for both its lack of precision in defining nanoST and its lack of accuracy (seen by different actors as either an under- or over-estimation).¹⁵ Despite these criticisms, the high-level performative impact of this vision (that is, its role in bringing about what it purports to describe), is arguably demonstrated by the multitude of references to it in academia, industry and politics as well as in the ever-growing allocation of funding that has followed the prediction.

Perhaps the most important question is not whether any of these particular future possibilities are likely but rather the role that both utopian and dystopian visions play in shaping social and political support for nanoST. All of these visions are science fictions—fictitious stories of imagined futures for science and technology. What is important to realise is that these fictional visions for our future (or what can be called our ‘socio-technical imaginaries’) play a crucial role in prioritising and driving forward particular fields of scientific research and technological development. Recognising the role of

⁹ B Joy, ‘Why the Future Doesn’t Need Us’, *Wired Magazine* 8:4, 2000, pp.1–11. Available at: http://www.wired.com/wired/archive/8.04/joy.html?pg=9&topic=&topic_set= (last accessed 15.07.09).

¹⁰ M Crichton, *Prey*, New York, HarperCollins Publishers, 2002.

¹¹ M C Roco and W S Bainbridge (eds), *Converging technologies for improved human performance: nanotechnology, biotechnology, information technology and cognitive science*, National Science Foundation, Arlington Va, 2002. Available at: http://www.wtec.org/ConvergingTechnologies/1/NBIC_report.pdf (last accessed 15.07.09).

¹² A Nordmann (ed), *Converging Technologies: Shaping the future of European societies*, European Commission, Brussels, 2004. Available at: http://www.ntnu.no/2020/final_report_en.pdf (last accessed 15.07.09).

¹³ K Kjølborg, G C Delgado-Ramos, F Wickson and R Strand, ‘Models of governance for converging technologies’, *Technology Analysis and Strategic Management* 20:1, 2004, pp. 83–97.

¹⁴ M C Roco and W S Bainbridge (eds), *Societal Implications of Nanoscience and Nanotechnology*, Kluwer Academic Publishers, Boston and Dordrecht, Netherlands, 2001. Available at: <http://www.wtec.org/loyola/nano/societalimpact/nanosi.pdf> (last accessed 23.07.09).

¹⁵ See for example M Berger, ‘Debunking the trillion dollar nanotechnology market size hype’ *Nanowerk*, 2007. Available at: <http://www.nanowerk.com/spotlight/spotid=1792.php> (last accessed 23.07.09).

future visions and socio-technical imaginaries allows us to reflect on how these differ across communities and cultures and how we should manage these differences in decision-making.

4. The history of nanoST: a sexy new science

The history of how and why nanoST have emerged as the ‘sexiest’ new area of research and development can be told in a number of ways. The standard story that has developed in the field is as follows.¹⁶ In 1959, physicist Richard Feynman made a speech at the American Physical Society entitled ‘There is plenty of room at the bottom’,¹⁷ in which he suggested that the laws of physics did not, in principle, prohibit the idea of manipulating and controlling matter at the atomic level. The speech contained a rich description of various possibilities, including writing and reading information on the atomic scale (with biology cited as an inspirational example of what is possible), as well as the technical possibility of creating new materials with novel properties through precise atomic placement. In this way, many refer to Feynman as the conceptual father of nanoST. However, it is open for debate as to whether this inspirational role had an active influence on later nanoST developments or has simply been retroactively prescribed.¹⁸

The next step in the standard history of nanoST was the development of necessary instrumentation. In 1982, Heinrich Rohrer and Gerd Binnig received a patent for their invention of a scanning tunnelling microscope (STM), for which they won a Nobel Prize in 1986. This was the first in a series of probe-style microscopes that have enabled scientists to ‘see’ the nanoscale. The term ‘see’ is presented in inverted commas here because the nanoscale is smaller than the wavelength of light, so that these microscopes do not provide optical images of nano phenomena as such. Instead, they use an incredibly fine-tipped probe to scan a nanoscale surface and measure differential current flows. This data is then fed into software programs and translated into a range of visual forms (from two-dimensional line graphs to far more evocative three-dimensional, richly coloured, peak and valley landscapes).¹⁹ Importantly, these microscopes have also enabled atomic-level manipulation. The ability to use the tip to move atoms around was dramatically demonstrated in 1990 when the company logo for IBM was spelled out in individual xenon atoms.²⁰ This image was called ‘The Beginning’ by its creators and is widely viewed as the first demonstration of an ability to position individual atoms with precision.

Around the same time as these scientific advances were being made, Drexler was spelling out his vision of the technical possibility of molecular manufacturing. His work is widely credited with powerfully popularising the potential of nanotechnology (for both benefit and harm as highlighted above) just as the science appeared on the brink of major breakthroughs. Following these advances in instrumentation and popularisation, the potential of nanoST was recognised, supported and dramatically boosted by the establishment of the US National Nanotechnology Initiative (NNI) in 2001. The creation of this program, and the specific and significant funding for ‘nanotechnology’ it

¹⁶ For an interpretation of this standard history as referring to general trends rather than specific events, see H Fogelberg, ‘Historical Context of the US National Nanotechnology Initiative’, in *Nano meets Macro: Social perspectives on nanoscale sciences and technologies*, K. Kjølberg and F. Wickson (eds), Pan Stanford Publishing, Singapore (2009).

¹⁷ R Feynman, ‘There is plenty of room at the bottom’, speech at the annual meeting of the American Physical Society at the California Institute of Technology (Caltech), 1959. Available at: <http://www.zyvex.com/nanotech/feynman.html> (last accessed 15.07.09).

¹⁸ See for example, C Toumey, ‘Apostolic Succession’, *Engineering and Science* 1:2, 2005, pp. 16–23 and C Toumey, ‘Reading Feynman into Nanotechnology: A text for a new science’, *Techné* 12:3, 2008, pp. 133–168.

¹⁹ All imaging of the nanoscale requires some degree of imagining. This imag(in)ing process raises particularly interesting questions about the boundary between science and art and the ethics of image presentation.

²⁰ The iconic image of this logo can be viewed at <http://www.almaden.ibm.com/vis/stm/images/stm10.jpg> (last accessed 15.07.09).

generated, dramatically helped advance nanoST, not only in the US but globally as other countries were inspired/intimidated into following suit and developing their own nanotechnology initiatives.²¹

Nanotechnology first became a funding priority for the Australian Research Council in 2002.²² It was the subject of a working group report from the Prime Minister's Science, Engineering and Innovation Council (PMSEIC) in 2005,²³ which was followed up by the launch of a National Nanotechnology Strategy in Australia in 2007. The global cascade of national programs for nanoST that has followed the NNI has created the strong perception that there is currently a 'race' to avoid missing out on a new frontier field of research with enormous commercial potential.

In contrast to this standard history, some may argue that what chemists have been doing for 100 years or more is manipulating matter on the nanoscale and creating new materials with novel properties. A similar argument may be made for materials science. These fields did not, however, refer to their work as 'nanoST'. According to this position, nanoST are primarily a political construct created by the NNI and the funding it made available and not, therefore, a new field of research and development at all but simply a new term that scientists can use to re-label their research and apply for new pots of funding. While others will argue that new instrumentation has indeed created new capabilities, they may still see an important question in why nanoST are now being given political priority. This prioritisation could be due to grand future visions of ultimate control or technological revolution, but it could also be seen as driven by a perceived ability to sustain economic growth through exploring, exploiting and colonising a 'new frontier'.²⁴ In this story, we see the driver of the knowledge economy and the idea that nanoST have become a sexy 'new' field of R&D because of the perceived economic potential of drilling down to the foundations of matter and mining the potential that lies there.

What is important to realise in these stories of the history of nanoST is the way in which scientific, economic and political factors combine and are arguably co-responsible for driving the field forward.

5. Potential risks and real uncertainties

In the last five years, there has been a dramatic growth of interest in the potential health and environmental impacts of nanoST, arguably because it cannot be assumed that 'novel properties' will only be novel for the good, and also because considering new technologies critically in terms of 'risks' has become a characteristic feature of modern industrialised societies.²⁵ The answer to the question, 'What are the risks of nanoST?' remains hotly contested, with the level of knowledge described as 'rudimentary'²⁶ and the level of uncertainty 'extreme'.²⁷ The so-called 'gaps' in knowledge stretch out

²¹ M C Roco, 'Government Nanotechnology Funding: An International Outlook', *National Science Foundation*, 2003. Available at: <http://www.nano.gov/html/res/IntlFundingRoco.htm> (last accessed 23.07.09).

²² D Bowman and G Hodge, 'Nanotechnology products in Australia: chemicals, cosmetics and regulatory character', in G Hodge, D Bowman and K Ludlow (eds), *New Global Frontiers in Regulation: The age of nanotechnology*, Edward Elgar Press, Cheltenham, 2007, pp. 239–264.

²³ PMSEIC (Prime Minister's Science, Engineering and Innovation Council), *Nanotechnology: Enabling technologies for Australia's innovative industries*, report presented at the 13th meeting of PSEIC, 11 March 2005. Available at: http://www.dest.gov.au/NR/rdonlyres/1E1B501A-727A-4153-85EF-134B2DAF0925/4112/nanotechnology_pmseic110305.pdf (last accessed 30.07.09).

²⁴ For a more detailed description of frontier and space exploration analogies in nanoST, see A Nordmann, 'Nanotechnology's Worldview: New Space for Old Cosmologies', *IEEE Technology and Society Magazine* Winter 2004, pp. 48–54.

²⁵ See U Beck, *Risk Society: Towards a New Modernity*, SAGE Publications, London, 1986.

²⁶ J M Balbus, A D Maynard, V L Colvin, V Castranova, G P Daston, R A Denison, K L Dreher, P L Goering, A M Goldberg, K M Kulinowski, N A Monteiro-Riviere, G Oberdörster, G S Omenn, K E Pinkerton, K S Ramos, K M Rest, J B Sass, E K Silbergeld and B A Wong, 'Meeting Report: Hazard Assessment for Nanoparticles—Report from an interdisciplinary workshop', *Environmental Health Perspectives* 115:11, 2007, pp. 1654–1659.

to resemble something more like gaping chasms. Research is, however, starting to emerge on this topic and some of the key findings and future challenges will be summarised here. On this topic, the first point to note is that while research in the nascent field of nanotoxicology remains shrouded in uncertainty, it certainly indicates the *potential* for harm from certain applications. Currently, most concern is focused on free nanoparticles and carbon nanotubes.²⁸

5.1 Could carbon nanotubes be the new asbestos?

Carbon nanotubes share a general structural similarity to asbestos in that both are small, needle-like fibres. A pressing question has therefore been, 'Could nanotubes pose similar risks to asbestos?' The answer emerging from early scientific research appears to be 'Yes'. In the research currently available, carbon nanotubes have been shown to cause inflammation and granulomas (scar-like lesions),^{29,30,31,32,33,34,35} the same bodily response that results from exposure to asbestos and precedes the development of cancers such as mesothelioma. It has been demonstrated that carbon nanotubes also have the potential for skin-cell toxicity through dermal exposure³⁶ and genotoxicity (toxicity at a molecular level) that includes an ability to damage DNA.^{37,38}

Carbon nanotubes can be single-walled or multi-walled, come in a range of different sizes, tend to agglomerate, and can contain different amounts of residues from metal catalysts used during their production. All of these factors have the potential to impact their observed toxicity and therefore not all

²⁷ M Kandlikar, G Ramachandran, A Maynard and B Murdock, 'Health risk assessment for nanoparticles: A case for using expert judgement', *Journal of Nanoparticle Research* 9, 2007, pp.137–156.

²⁸ Some people use the term 'nanoparticles' to include nanotubes but, taking the approach described earlier, this paper uses the term 'nanoparticle' to refer to an object that is nanoscale in three dimensions. Nanotubes can be nanoscale in only two dimensions (for example, when they are longer than 100 nm). Some actors have also narrowed the focus of concern to insoluble or bio-persistent nanomaterials, although the value of this is still contested.

²⁹ C A Poland, R Duffin, I Kinloch, A Maynard, W A H Wallace, A Seaton, V Stone, S Brown, W MacNee and K Donaldson, 'Carbon nanotubes introduced into the abdominal cavity of mice show asbestos-like pathogenicity in a pilot study', *Nature Nanotechnology* 3, 2008, pp. 423–428.

³⁰ J Muller, F Huaux, N Moreau, P Misson, J-F Heilier, M Delos, M Arras, A Fonseca, J B Nagy and D Lison, 'Respiratory toxicity of multi-wall carbon nanotubes', *Toxicology and Applied Pharmacology* 207, 2005, pp. 221–231.

³¹ A A Shedova, E R Kisin, R Mercer, A R Murray, J L Johnson, A I Potapovich, Y Y Tyurina, O Gorelik, S Arepalli, D Schwegler-Berry, A F Hubbs, J Antonini, D E Evans, B-K Ku, D Ramsey, A Maynard, V E Kagan, V Castranova and P Baron, 'Unusual inflammatory and fibrogenic pulmonary responses to single-walled carbon nanotubes in mice', *American Journal of Physiology—Lung Cellular and Molecular Physiology* 289, 2005, pp. L698–L708.

³² A Takagi, A Hirose, T Nishimura, N Fukumori, A Ogata, N Ohasi, S Kitajima and J Kanno, 'Respiratory toxicity of multi-wall carbon nanotubes', *The Journal of Toxicological Sciences* 33:1, 2008, pp. 105–116

³³ D B Warheit, B R Laurence, K L Reed, D H Roach, G A M Reynolds and T R Webb, 'Comparative Pulmonary Toxicity Assessment of Single-wall Carbon Nanotubes in Rats', *Toxicological Sciences* 77, 2004, pp. 117–125.

³⁴ L Ma-Hock, S Treumann, V Strauss, S Brill, F Luizi, M Mertler, W Wiench, A O Gamer, B van Ravenzwaay and R Landsiedel, 'Inhalation toxicity of multi-wall carbon nanotubes in rats exposed for three months', *Toxicological Sciences*, 2009 (advanced online access). Available at: <http://toxsci.oxfordjournals.org/cgi/content/abstract/kfp146> (last accessed 20.07.09)

³⁵ C-W Lam, J T James, R McCluskey and R L Hunter, 'Pulmonary Toxicity of Single-Wall Carbon Nanotubes in Mice 7 and 90 Days After Intratracheal Instillation', *Toxicological Sciences* 77, 2004, pp. 126–134.

³⁶ A Shedova, V Castranova, E Kisin, D Schwegler-Berry, A Murray, V Gandelsman, A Maynard and P Baron, 'Exposure to Carbon Nanotube Material: Assessment of Nanotube Cytotoxicity using Human Keratinocyte Cells', *Journal of Toxicology and Environmental Health* 66:20, 2003, pp. 1909–1926.

³⁷ L Zhu, D W Chang, L Dai, and Y Hong, 'DNA Damage Induced by Multiwalled Carbon Nanotubes in Mouse Embryonic Stem Cells', *Nano Letters* 7:12, 2007, pp. 3592–3597.

³⁸ Balbus et al.

types of carbon nanotubes will pose the same type or degree of risk. The studies cited above have been conducted with different:

- types of carbon nanotubes (single-walled, multi-walled)
- lengths of nanotubes (short, long)
- preparations of nanotubes (single tubes, tangled agglomerates, ground pieces)
- test systems (for example, cell cultures, mice, rats)
- exposure methods (inhalation, injection, dermal deposition).

However, all of these studies indicate the potential for harm in varying degrees. It could, of course, be argued that these findings result from flaws in the scientific process (for example, they are actually the product of contamination or the use of an inappropriate method) or that they are contradicted by results from other studies. Openness to this type of contestation is usual in science. The high level of uncertainty and lack of standardised testing procedures for nanotoxicology do, however, significantly extend the space for varying interpretations. It has, for instance, been suggested that these studies may not individually hold up in a court of law as demonstrating evidence that 'the inhalation of carbon nanotubes causes mesothelioma'.³⁹ However, it is important to note that all of the cited studies have been assessed for their quality through peer-review processes and been deemed worthy of publication in top-ranking academic journals. Many in the scientific community interpret the totality of the findings as indicating an emerging pattern of potential for carbon nanotubes to cause harm.

In order to understand the extent that any potential for harm will actually manifest, we need to understand the extent to which workers, consumers, and the environment will be exposed. If we are to believe the optimists, that nanoST will have a revolutionary impact touching upon every aspect of our lives we might reasonably expect exposures to nanoST to be high. The appearance of nanotechnologies across an already vast range of sectors also indicates the potential for multiple sources of exposure. There is currently, however, extremely limited information available on levels of exposure to carbon nanotubes and what is available suggests that workers in nanotechnology industries and R&D facilities are exposed, to some degree, through both inhalation and dermal deposition.^{40,41} This information says nothing about public and environmental exposures, nor does it take into account the expected increase in future levels of exposure as use becomes more widespread. In studies of toxicity and exposure, it is crucial to take into account the incredible persistence of carbon nanotubes, which represent one of the most biologically non-degradable man-made materials currently available.⁴² This makes it important to consider full life cycles and the likelihood of extended time delays between exposure and effect. Carbon nanotubes represent one of the 'boom areas' of nanoST, with a predicted global market of over US\$800 million by 2011.⁴³

Challenges to understanding the risks posed by carbon nanotubes relate not only to the limited information available but also to a deep-level debate about the paradigms, methods and approaches that are most appropriate for testing. For example, in studies designed and conducted according to a

³⁹ J C Monica Jnr and J C Monica, 'A Nano-Mesothelioma False Alarm', *Nanotechnology Law and Business* 5:3, 2008, pp. 319–333.

⁴⁰ An important exception being A Maynard, P A Baron, M Foley, A A Shedova, E R Kisin and V Castranova, 'Exposure to carbon nanotube material: Aerosol release during the handling of unrefined single-walled carbon nanotube material', *Journal of Toxicology and Environmental Health* 67:1, 2004, pp. 87–107.

⁴¹ E Bergamaschi, 'Occupational exposure to nanomaterials: present knowledge and future development', *Nanotoxicology*, 3:3, 25 June 2009, pp. 194–201 (advance access).

⁴² Lam et al.

⁴³ BCC Research, *Carbon Nanotubes: Technologies and Commercial Prospects*, BCC Report, March 2007. Available at: <http://www.bccresearch.com/report/NAN024C.html> (last accessed 21.07.09).

fibre-toxicology paradigm, long nanotubes appear most pathogenic. However, if tested according to the methods and approaches most relevant for particles, short nanotubes may also demonstrate significant toxicity.⁴⁴ While therefore relevant for nanotubes, the latter paradigm is largely being applied to understand the toxicity of nanoparticles.

5.2 Engineered nanoparticles in biological systems

There is general consensus within the scientific community that understanding the toxicity of engineered nanoparticles⁴⁵ cannot be derived from our understanding of their bulk counterparts.^{46,47,48,49} Nanoparticles of materials such as titanium dioxide, zinc oxide and silver are, in fact, likely to be more toxic than the bulk counterparts we have previously experienced on micro- and macro-scales. In the first instance, this is because the same novel properties that make the nanoscale useful for technological application can also result in novel toxicological potential. In particular, as smaller particles have a larger surface area and surfaces are generally more reactive, nanoscale particles can interact with biological systems in ways that differ from their bulk counterparts. Additionally, because engineered nanoparticles are so small, they have the ability to penetrate cell membranes, enter the blood stream and lymphatic system, and move throughout the body, including into the heart, nervous system, bone marrow, brain and potentially, a foetus.^{50,51,52,53,54} Engineered nanoparticles also have the ability to act as vectors, able not only to bind and carry other chemicals and pollutants with them as they move throughout biological systems, but also to enhance their toxicity and biological availability.⁵⁵ This has been referred to as the 'Trojan horse' effect.^{56,57} All of these features have resulted in calls for nanoscale materials, and particularly

⁴⁴ Poland et al.

⁴⁵ The term 'engineered nanoparticles' is used here to indicate that the focus in this section is not on naturally occurring nanoscale particles but on those purposefully engineered and manufactured by humans. We can certainly learn from our experience with 'natural' nanoscale particles (for example, that they often have the potential to create harm) and from the methods developed for studying them (for example, research on ultrafine particles), but it is also important to note that the purposeful generation of nanoparticles is creating a range of novel materials and that the unique characteristics of these need to be researched to understand their (eco)toxicological potential.

⁴⁶ K Donaldson, R Aitken, L Tran, V Stone, R Duffin, G Forrest and A Alexander, 'Carbon Nanotubes: A review of their properties in relation to pulmonary toxicology and workplace safety', *Toxicological Sciences* 92:1, 2006, pp. 5–22.

⁴⁷ G Oberdörster, E Oberdörster and J Oberdörster, 'Nanotoxicology: An emerging discipline evolving from studies of ultra fine particles', *Environmental Health Perspectives* 113:7, 2005, pp. 824–839.

⁴⁸ SCENIHR, 'The appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies', opinion adopted during the 7th plenary meeting, 28–29 September 2005, European Commission, Health & Consumer Protection Directorate General, 2006. Available at: http://ec.europa.eu/health/ph_risk/committees/04_scenih/ docs/scenih_r_o_003b.pdf (last accessed 21.07.09).

⁴⁹ R Owen and R Handy, 'Formulating the problems for environmental risk assessment of nanomaterials', *Environmental Science and Technology*, 15 August 2007, pp. 5582–5588.

⁵⁰ Oberdörster et al., 'Nanotoxicology'.

⁵¹ E Oberdörster, 'Manufactured nanomaterials (fullerenes, C60) induce oxidative stress in the brain of juvenile largemouth bass', *Environmental Health Perspectives* 112:10, 2004, pp. 1058–1062.

⁵² P L Lockman, J M Koziara, R J Mumper and D D Allen, 'Nanoparticle Surface Charges Alter Blood-Brain Barrier Integrity and Permeability', *Journal of Drug Targeting* 12:9–10, 2004, pp. 635–641.

⁵³ Oberdörster et al., 'Nanotoxicology'.

⁵⁴ SCENIHR.

⁵⁵ A Baun, S N Sørensen, R F Rasmussen, N B Hartmann and C B Koch, 'Toxicity and bioaccumulation of xenobiotic organic compounds in the presence of aqueous suspensions of aggregates of nano-C60', *Aquatic Toxicology* 86, 2008, pp. 379–387.

⁵⁶ Royal Commission on Environmental Pollution, *Novel Materials in the Environment: The case of nanotechnology*, The Stationery Office, Norwich, 2008.

engineered nanoparticles, to be treated and evaluated as new substances in toxicity testing and regulation.

One of the primary concerns about nanoscale materials is that current regulatory systems and approaches to defining safety limits may not be adequate to take into account the unique properties of the nanoscale. For example, safety limits for particles in the air (for example, in workplace environments) are generally based on mass concentrations per volume while those for fibres are typically based on the number of certain-sized fibres present. These approaches to understanding safety limits do not take into account the characteristics of surface area and surface chemistry that have been suggested as particularly relevant for nanoparticle toxicity.⁵⁸ They also do not account for the way in which the standard method of counting fibres would not be able to detect single nanotubes or those that have bundled in a way that reduces their overall length.⁵⁹ This means that not only is more information on toxicology and exposure for both humans and the environment required, but there is also an urgent need to develop further methods for detection and measurement and to assess whether current approaches to setting safety limits are adequate for the unique properties of nanomaterials.

5.3 The substantial challenges of nanotoxicology

The complexity of scientifically assessing the impact of nanomaterials on humans and the environment should not be underestimated. As suggested above, we cannot extrapolate an understanding of nanomaterial toxicity from our experience with the same material in bulk form. The most important factors for understanding toxicity are also not necessarily the traditional dose metrics of mass or number, but rather characteristics such as surface area, surface charge, length, shape, agglomeration state and solubility. These features differ for different nanomaterials as well as for different forms or 'species' of the same nanomaterial. Additionally, all of the above characteristics, important for understanding potential toxicity, can be altered through interaction with environmental factors such as pH, salinity, water hardness and the presence of organic matter.^{60,61} This means that the relevant properties can change throughout the life cycle of a product.^{62,63}

While free nanoparticles and nanotubes may be an appropriate focus of concern, it is also important to note that some fixed nanoparticles may become free during the wear and degradation of products through their life cycle.^{64,65} Not only does the variety of product types suggest the possibility of multiple exposure pathways to nanomaterials (including ingestion, inhalation, injection and dermal exposure),⁶⁶ it may also be relevant to consider different routes at different stages throughout a product's life cycle.⁶⁷ In addition, the mobility of nanoparticles means they may translocate to parts of an organism's body that may not be indicated as relevant by the initial route of exposure. Different

⁵⁷ R D Handy and R Owen, 'The ecotoxicology of nanoparticles and nanomaterials: current status, knowledge gaps, challenges and future needs', *Ecotoxicology* 17, 2008, pp. 315–325.

⁵⁸ G Oberdorster, A Maynard, K Donaldson, V Castranova, J Fitzpatrick, K Ausman, J Carter, B Karn, W Kreyling, D Lai, N Olin, S Monteiro-Riviere, D Warheit and H Yang, 'Principles for characterizing the potential human health effects from exposure to nanomaterials: elements of a screening strategy', *Particle and Fibre Toxicology* 2:8, 2005, pp. 1–35.

⁵⁹ Donaldson et al.

⁶⁰ Handy and Owen.

⁶¹ Royal Commission on Environmental Pollution.

⁶² Royal Commission on Environmental Pollution.

⁶³ Balbus et al.

⁶⁴ Owen and Handy.

⁶⁵ SCENIHR.

⁶⁶ Oberdörster et al., 'Principles for characterizing the potential human health effects'.

⁶⁷ Bergamaschi.

species have very different susceptibilities to nanomaterials so tests done with a single species are insufficient for understanding environmental risks.⁶⁸ Furthermore, understanding ecological risk as well as human exposure requires an awareness of the fate and behaviour of nanomaterials in the environment (for example, their movements through soil, air, water and the various organisms of an ecosystem). Adding to this complex picture is the fact that testing should ideally be done not just on acute effects, but also on the potential for chronic effects, multitrophic effects (through the food chain), bioaccumulation, and sublethal impacts such as behavioural change and reduced immunity and/or reproductive fitness.⁶⁹

This means that in order to ‘scientifically assess the risks’ posed by nanomaterials to human health and the environment so as to ‘ensure safety’, we need research that:

- documents the various physico-chemical characteristics of each nanomaterial throughout the different stages of a product’s life cycle
- considers multiple routes of organism exposure
- tests various species of organisms (including micro-organisms)
- examines various body parts of exposed organisms (including cell components)
- reflects on potential movements through complex ecosystems
- uses an extended timeframe
- is sensitive to a range of different possible impacts beyond acute toxicity and death.

To make matters significantly more difficult, there is widespread recognition that for nanomaterials we have not yet developed the appropriate methods and instrumentation necessary to perform the required testing.⁷⁰ This extends to the very fundamental level of lacking appropriate ways to detect, measure, characterise and therefore monitor nanoparticles in a range of different mediums,⁷¹⁻⁷²⁻⁷³⁻⁷⁴ so that not only is there acutely limited research on the toxicity of nanomaterials, there is also an inability to achieve this in the short term. In fact, it has been suggested that toxicity testing on just the nanomaterials currently commercially available would take decades to complete and require the investment of over US\$1 billion.^{75,76} The extended time lag that subsequently exists between commercialisation of nanomaterials and knowledge of their potential health and environmental impacts has led some environmental organisations^{77,78} and politicians^{79,80} to call for a moratorium on

⁶⁸ Royal Commission on Environmental Pollution.

⁶⁹ Owen and Handy.

⁷⁰ K D Grieger, S Hansen and A Baun, ‘The known unknowns of nanomaterials: Describing and characterising uncertainty within environmental, health and safety risks’, *Nanotoxicology*, 2009 (advance access), pp. 1–12. Available at: <http://www.informaworld.com/smpp/content~db=all~content=a912823263> (last accessed 21.07.09)

⁷¹ SCENIHR.

⁷² EFSA, ‘The Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety’, scientific opinion of the Scientific Committee, *The EFSA Journal* 958, 2009, pp. 1–39. Available at: http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/sc_op_ej958_nano_en.pdf?ssbinary=true (last accessed 21.07.09).

⁷³ Grieger et al.

⁷⁴ Balbus et al.

⁷⁵ Royal Commission on Environmental Pollution.

⁷⁶ J-W Choi, G Ramachandran and M Kandlikar, ‘The impact of toxicity testing costs on nanomaterial regulation’, *Environmental Science and Technology* 43:9, 2009, pp. 3030–3034.

⁷⁷ ETC Group, ‘Nanotechnology’, 2009. Available at: <http://www.etcgroup.org/en/issues/nanotechnology.html> (last accessed 22.07.09).

commercialisation, and significant scientific organisations to recommend that environmental release should be avoided as much as possible.⁸¹

The situation is such that we cannot rely on our knowledge of bulk materials for understanding related nanomaterials.

- Toxicological specificities arguably require that they be assessed on a case-by-case basis, but this is practically impossible.⁸²
- We need physico-chemical characterisation for nanomaterials throughout their life cycles, but good methods for this are not currently available.⁸³
- There is a critical need for information on exposure levels, but new methods and equipment are required with the ability to adequately detect and measure nanoparticles.⁸⁴
- Mass and number alone are insufficient as dose metrics but alternative factors such as surface area and surface chemistry have not been incorporated into safety assessment regulations.
- Further research is urgently needed, but there is a lack of standardised testing procedures and reference materials that would enable coordinated development and comparison across studies.

Notwithstanding these contradictions and knowledge needs, the funding currently available for eco/toxicology research on nanomaterials is extremely limited, despite regular statements on its clear importance.⁸⁵ Funding for health and environmental research is often in combination with that available for ethical, legal and social aspects and, in total, both are typically only awarded at around three to five per cent of the budgets available for nanoST development.

The traditional decision-making tool of 'scientific risk assessment' is crippled by the profound lack of information on nanotoxicology. The vast seas of uncertainty and the decades required to conduct the necessary research mean that the idea of regulation and decision-making through an 'evidence-based' assessment of risks should be recognised as not currently possible.^{86,87} There is therefore a need to move away from a sole focus on 'scientific risk assessment' as a decision-making tool and towards the exploration of approaches that enable a deliberative negotiation of uncertainty. This is *not* to suggest that risk assessment based on the best available nanotoxicology research should not be carried out to help inform decision-making—just that this is not sufficient. The extreme uncertainties

⁷⁸ Friends of the Earth Australia, *Nanomaterials, sunscreens and cosmetics: Small ingredients, big risks*, 2006. Available at: <http://nano.foe.org.au/node/100> (last accessed 22.07.09).

⁷⁹ 'Call for a moratorium on nanotechnology', *Sydney Morning Herald*, 17 March 2007, Available at: <http://www.smh.com.au/news/National/Call-for-moratorium-on-nanotechnology/2007/03/17/1174080202836.html> (last accessed 22.07.09).

⁸⁰ C Lucas, 'We must not be blinded by science', *The Guardian*, 12 June 2003. Available at: <http://www.guardian.co.uk/politics/2003/jun/12/nanotechnology.science> (last accessed 22.07.09).

⁸¹ Royal Society & the Royal Academy of Engineering, *Nanoscience and nanotechnologies: opportunities and uncertainties*, London, Royal Society, 2004. Available at: <http://www.nanotec.org.uk/finalReport.htm> (last accessed 21.07.09).

⁸² N J Walker and J R Bucher, 'A 21st Century Paradigm for Evaluating the Health Hazards of Nanoscale Materials?' *Toxicological Sciences* 110:2, 2009, pp. 251–254.

⁸³ SCENIHR.

⁸⁴ SCENIHR.

⁸⁵ 'The same old story', editorial, *Nature Nanotechnology* 3:12, 2008, pp. 699–700.

⁸⁶ Bergamaschi.

⁸⁷ Royal Commission on Environmental Pollution.

involved in nanoST make it vital to recognise the importance of social and ethical aspects, including the crucial role played by visions, values and beliefs.

6. Social and ethical aspects: who's leading this revolution?

Negotiating situations of uncertainty involves making choices without complete knowledge, which means that these choices cannot help but be influenced by values, beliefs, assumptions and world views.⁸⁸ For science and technology, this includes the choices we make about what research to fund, how that research is conducted, how the results of such research are interpreted, and what actions are taken on the basis of those interpretations. In the model of risk analysis that usually informs decision-making on science and technology, the role of values is generally recognised only in the last stage when choosing what actions to take given the scientific assessment of risk provided. It is, however, important to realise that values permeate all stages, including that of conducting scientific research. For example, in eco/toxicology research on nanoST, scientists have to make a range of choices that cannot help but be based on values, beliefs and assumptions and include:

- what nanotechnology to study (for example, which nanoparticle is considered most relevant, interesting or important)
- what test subject to use (for example, on what organism or part of an organism to test effects)
- what test system, methods, tools or paradigm to use (for example, what dose metric to focus on—mass of particles, number of particles or surface area of particles)
- what route of exposure to examine (for example, choosing how test subjects will be exposed)
- what endpoints to observe (for example, whether to observe deaths, lesions, white blood cell counts, protein activity levels and so on)
- how to interpret the results (for example, to what extent they are related to the nanoparticle under study, impurities/contaminants in the test sample, the specificities of the organism involved, limitations of the method and so on).

Within the scientific community, these choices are part of the natural progression of knowledge, always with the general aim of developing (through alternative studies and approaches) a consensus around the most appropriate and useful methods for studying the phenomenon at hand. When scientific consensus develops around such issues, research approaches become normalised and standardised, shaping future research efforts, making results from different studies easy to compare, reducing contestation around how particular studies should be interpreted, and thereby gradually building a body of accepted knowledge. For nanotoxicology, however, no such consensus or standardisation currently exists and, in many instances, the methods and instruments for conducting research still need to be developed. The enormous uncertainties involved mean that scientists make inevitable choices in generating their knowledge and that all of these choices remain open to legitimate debate through alternative framing and interpretation.

Within the scientific community, this is not a problem. In fact, it is arguably the normal thing to expect from a field in the early stages of development. However, when science is used to inform political decision-making or public understanding, recognising uncertainty and the importance of different choices and assumptions becomes paramount. It has been suggested that when the stakes are high, values in dispute, and decisions urgent (as is indeed the case for nanoST), a new type of science for

⁸⁸ Royal Commission on Environmental Pollution.

policy is needed—a ‘post-normal science’,^{89,90} which acknowledges the uncertainties involved and opens up for a process of ‘extended peer review’ in which assessment of quality occurs through exposure to alternative framings and interpretations and a deliberative process of negotiation. This process should occur not just across different disciplines of science, but also among various stakeholders and members of the public. A broad-based deliberative process allows the strength and quality of any evidence for decision-making to be tested by exploring how it could be differentially framed and/or interpreted and what degree of support different choices and assumptions attract within different communities.

As indicated above, values permeate various stages of scientific and technological development. While deliberative interrogation of ‘end-of-pipe’ science for policy is particularly important for nanoST, so are deliberative negotiations around the allocation of funding and the socio-technical trajectories developed as a result. This is particularly important for nanoST because public-sector investment has been primarily responsible for stimulating the development and institutionalisation of the field.^{91,92}

Some of the fundamental beliefs supporting the currently permissive position on nanotechnology commercialisation (despite the lack of comprehensive toxicological research) include:

- economic growth is the highest good
- all innovation contributes to economic growth and is thereby good
- ‘progress’ is equivalent to technological advance
- technological fixes to any future problems will be possible.

These may hold true for some people, but legitimate alternatives to these beliefs clearly exist and in pluralistic democratic societies should rightfully be subject to open negotiation and debate. Some people will hold an optimistic position and want nanoST to advance as rapidly as possible so that economic benefits can be gained. Others will advocate a more tentative approach, wanting to apply the best available risk-assessment tools so harm can hopefully be minimised. Still others may adopt the position that rapid technological advance coupled with inadequate risk assessment has created a host of health and environmental crises and that the uncertainties surrounding nanoST mean that we should proceed with extreme caution and ensure that any advance offers significant social benefit. Differences such as these reflect inconsistencies across world views and, while these may mean that we will not all be able to agree all the time, there is also no reason that one position should dominate in democratic societies without open public debate and negotiation.

If nanoST truly represent a revolutionary new field with the potential to ‘impact every aspect of our daily lives’, we would certainly be wise to stop and ask *not just about the potential risks* but also about some of the broader social and ethical questions at stake. Questions such as:

- What are the underlying assumptions and visions driving nanoST forward?
- Do we support these assumptions and visions?
- How might applications change our society and communities in practice?

⁸⁹ S O Funtowicz and J R Ravetz, ‘Science for the post-normal age’, *Futures* 25:7, 1993, pp. 739–755.

⁹⁰ S O Funtowicz and J R Ravetz, ‘Uncertainty, complexity and post-normal science’, *Environmental Toxicology and Chemistry* 13:12, 1994, pp. 1881–1885.

⁹¹ B R Bürgi, ‘Societal implications of nanoscience and nanotechnology in developing countries’, *Current Science* 90:5, 2006, pp. 645–658.

⁹² J Schummer, ‘The global institutionalisation of nanotechnology research: A bibliometric approach to the assessment of science policy’, *Scientometrics* 70:3, 2007, pp. 669–692.

- How might they impact fundamental concepts such as human/nature relations?
- Who will be the winners and who will be the losers?
- How might ethical values of justice and fairness be applied?
- Can we choose to pursue certain aspects and not others?
- Who or what is controlling where the field is going?
- How should we control it?
- Can we steer nanoST in sustainable or socially beneficial directions?
- How can nanoST contribute to our concept of ‘the good life’?
- What exactly is it that we want to prioritise and invest our time and money in?

Academic research on all these questions is emerging,^{93,94} and ELSA research (research on Ethical, Legal and Social Aspects)⁹⁵ is increasingly being recognised as an important accompaniment to investment in frontier fields of science and technology. Everyone, however, is able to engage in reflections and deliberations on these issues. Indeed, arguing for and facilitating this is what much of the academic literature on social and ethical dimensions of nanoST is currently about.⁹⁶

For nanoST, the concept of ‘upstream public engagement’^{97,98} has gained increasing academic currency and political importance. It has been suggested that controversies over genetically-modified organisms (GMOs) were a result of public engagement in technological development coming too late;⁹⁹ that the technological trajectories of genetic engineering were fixed through years of financial investment and product development without public input on what was actually desirable and acceptable. With nanoST, however, there appears to be a unique opportunity to have broad-based public involvement at an early stage of development. Upstream public engagement aims to open up the future trajectories of nanoST for discussion, debate and community choice.

Upstream engagement involves dialogue between various stakeholders and citizens to generate not only more informed citizens, but also scientists sensitive to the social and ethical aspects of their work and, importantly, inputs for policymaking on public opinion, priorities and preferences. Although moving ideals of public engagement into realities of practice raises a range of challenges and competing demands,¹⁰⁰ a host of different experimental approaches to achieving this are currently underway in the case of nanoST. The UK has been particularly active in funding public engagement activities¹⁰¹ and one recently completed exercise involved stakeholders working with the Engineering

⁹³ K Kjølberg and F Wickson, ‘Social and Ethical Interactions with Nanotechnology: Mapping the early literature’, *NanoEthics* 1, 2007, pp. 89–104.

⁹⁴ K Kjølberg and F Wickson, *Nano meets Macro: Social perspectives on nanoscale sciences and technologies*, Pan Stanford Publishing, Singapore, (2009).

⁹⁵ Also sometimes referred to as ELSI (Ethical, Legal and Social Implications/Impacts) research.

⁹⁶ Kjølberg and Wickson, ‘Social and Ethical Interactions with Nanotechnology’.

⁹⁷ J Wilsdon, ‘Paddling Upstream: New Currents in European Technology Assessment’, in *The Future of Technology Assessment*, M. Rodemeyer, D. Sarewitz and J. Wilsdon (eds), Woodrow Wilson International Center for Scholars, Washington DC, 2005, pp. 22–29.

⁹⁸ P Macnaghten, M Kearnes and B Wynne, ‘Nanotechnology, Governance, and Public Deliberation: What Role for the Social Sciences?’ *Science Communication* 27:2, 2005, pp. 1–24.

⁹⁹ See for example, J Wilsdon and R Willis, *See-through Science: Why public engagement needs to move upstream*, Demos, London, 2004.

¹⁰⁰ A Delgado, K Kjølberg and F Wickson, ‘Public Engagement Coming of Age: From theory to practice in STS encounters with nanotechnology’, *Public Understanding of Science*, (in revision 2009).

¹⁰¹ For example, see K Gavelin, R Wilson and R Doubleday, *Democratic technologies? The final report of the Nanotechnology Engagement Group*, Involve, London, 2007.

and Physical Sciences Research Council (EPSRC) to help set priority fields for medical nanoST funding. There has also been some support for practices of ‘midstream’ engagement, particularly in the US,^{102,103} between social and natural scientists in laboratories (as well as in education and training), with the aim being to sponsor enhanced reflection on social and ethical aspects of research, often so as to open up for potential modulation of technological trajectories. Australia has conducted a small number of public engagement exercises on nanotechnology; however, these have been far fewer than in either the US or the UK, and have generally adopted the very narrow, academically scorned position that the purpose of engagement is to educate the public and achieve acceptance of nanotechnologies.¹⁰⁴

Underlying all questions of science policy and governance is the extent to which we believe citizens and social institutions have control over the trajectories of science and technology. If we believe that technology determines its own path of development and also, subsequently, our dominant social structures and cultural beliefs (technological determinism), there is of course little we can do except try and minimise the impact of any negative consequences that may arise. If, however, we believe that social, political and economic factors (such as funding bodies, legal constraints, regulatory institutions, patterns of consumption and cultural values) play a role in determining what science and technology is pursued, arguably we have the power to take a more active role and guide science and technology in directions that seem most beneficial and desirable according to our social goals and ethical frameworks. This entails a shift from ‘risk governance’ to ‘innovation governance’.¹⁰⁵

The current (usually implicit) default position is that what is socially beneficial and desirable is increased economic growth; therefore, as long as nanoST promote this, the field should be supported and encouraged (with the market ultimately taking care of what will be developed or not). Other approaches that place more emphasis on social goals and ethical priorities are, however, starting to emerge for nanoST. For example, in addition to sponsoring a range of public engagement exercises, the European Commission has recently released a code of conduct for nanoST research,¹⁰⁶ which suggests that ‘responsible’ nano-research should not only involve maximum creativity and planning for innovation, it should also be conducted in line with the precautionary principle, contribute to the achievement of a sustainable society and the Millennium Development Goals, be transparent and comprehensible to all, and involve participation from all stakeholders during decision-making. In consultation with stakeholders, the Commission also identified particular areas of restriction for nanoST research, including a prohibition on human enhancement research and a selective moratorium on developing products involving intrusion into the human body (for example, food and cosmetics) until more studies on long-term safety are available. This means that in thinking about what research fields should be prioritised and given public funding, the European Commission is advocating a more active role in steering developments in socially desirable and publicly negotiated directions. Of course, the extent to which a voluntary scheme can be successful in achieving the stated goals remains questionable.

¹⁰² E Fisher, R L Mahajan and C Mitcham, ‘Midstream Modulation of Technology: Governance from Within’, *Bulletin of Science, Technology and Society* 26:6, 2006, pp. 485–496.

¹⁰³ R Doubleday and A Viseu, ‘Questioning Interdisciplinarity: What roles for laboratory based social science?’ in *Nano meets Macro: Social perspectives on nanoscale sciences and technologies*, K Kjølberg and F Wickson (eds), Pan Stanford Publishing, Singapore, (2009).

¹⁰⁴ R Kyle and S Dodds, ‘Avoiding Empty Rhetoric: Engaging publics in debates about nanotechnologies’, *Science and Engineering Ethics* 15, 2008, pp. 81–96.

¹⁰⁵ U Felt and B Wynne, *Taking European Knowledge Society Seriously*, report of the Expert Group on Science and Governance to the Science, Economy and Society Directorate, Directorate-General for Research, European Commission, Luxembourg, 2007.

¹⁰⁶ European Commission, *Recommendation on a code of conduct for responsible nanosciences and nanotechnologies research*, European Commission, Brussels, 2008. Available at: http://ec.europa.eu/nanotechnology/pdf/nanocode-rec_pe0894c_en.pdf (last accessed 23.07.09).

7. Who's in charge? Are things under control?

7.1 The regulatory context in Australia

Because nanoST fall across so many disciplines and applications exist across so many industries and sectors, there has not yet been (and is unlikely to be) a single specific regulatory regime for nanoST in Australia. Rather, products containing nanomaterials fall under the authority of a range of existing regulatory bodies, including Food Standards Australia New Zealand (FSANZ), the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) (which includes cosmetics), the Therapeutic Goods Administration (TGA) (also covering sunscreens), and the Australian Pesticides and Veterinary Medicines Authority (APVMA). National standards for aspects such as occupational health and safety are set by the Australian Safety and Compensation Council (ASCC). Other relevant agencies include the Australian Quarantine and Inspection Service (AQIS), Australian Customs and Border Protection Service and the Department of the Environment, Water, Heritage and the Arts (DEWHA), as well as the various state bodies relating to health standards, transport and the environment.

While these different regulatory bodies could be seen to cover all potential products containing nanomaterials, it is not clear that they are all necessarily appropriately sensitive to the unique properties of materials engineered at this scale. Rather than aiming to provide a comprehensive review of the adequacy of Australia's regulatory matrix for nanomaterials,¹⁰⁷ this section will highlight some of the most significant current limits using illustrative examples from three fields for which the potential for public controversy exists—cosmetics, sunscreens and food products. The potential for controversy around these fields is demonstrated by their being the focus of campaigns of non-governmental organisations¹⁰⁸ and their selection for a kind of voluntary moratorium by the European Commission.

Nanoscale ingredients used in cosmetics manufactured or imported into Australia need to be assessed for safety under NICNAS only if they are considered to be 'new' chemicals (that is, not listed as an existing chemical on the Australian Inventory of Chemical Substances (AICS)). This raises the serious, and as yet unanswered, question of whether nanoscale materials represent 'new' substances. Similarly, while FSANZ has a standard specifically for 'novel foods', the extent to which nanomaterials are considered 'novel' remains unclear. As highlighted in the sections above, there is certainly scientific consensus that knowledge of the properties of nanoscale materials cannot be derived from experience with their bulk counterparts. Therefore, they should arguably be treated as 'new' substances for toxicity and safety testing.

Within NICNAS however, manufacturers or importers can apply for a 'low volume permit' (if less than 100 kg a year) and thereby bypass the assessment process even when the nanomaterials are seen as 'new' substances. As also highlighted above, within the scientific community volume is not considered to be the most important metric for understanding the toxicity of nanomaterials. A similar problem arises in FSANZ's approach to regulating food contaminants. It is possible that

¹⁰⁷ A task already performed by others, see K Ludlow, D Bowman and G Hodge, *A Review of Possible Impacts of Nanotechnology on Australia's Regulatory Framework: Final Report*, Monash Centre for Regulatory Studies, Faculty of Law, Monash University and Institute for Environmental and Energy Law, Faculty of Law, KU Leuven, 2007. Available at: <http://www.innovation.gov.au/Industry/Nanotechnology/Documents/MonashReport2008.pdf> (last accessed 24.07.09).

¹⁰⁸ Such as that driven by the Friends of the Earth Australia Nanotechnology Project, which has had widespread international impact and attention. See <http://nano.foe.org.au/> (last accessed 25.07.09).

nanomaterials used in food packaging could migrate into food products¹⁰⁹ and, while they may then be regulated as contaminants by FSANZ, a weight threshold, which may not be the most appropriate metric for nanomaterials, is applied to trigger regulatory action. Neither does the TGA distinguish ingredients in medicines on the basis of size, which means that safety testing and labelling of the inclusion of nanoscale particles in products such as sunscreens are not currently required. With regard to the labelling of ingredients in cosmetics, it is also not required to indicate the size of any material. While materials that are 'likely to cause bodily harm' are expressly forbidden by current food standards, one of the problems with applying this approach to nanomaterials is that the scientific evidence is not yet available to know whether they would be 'likely' to cause harm or not.

For all of these regulatory bodies, problems with the current lack of methods to characterise, detect and measure nanomaterials is a serious inhibitor towards ensuring the protection of health and safety. There is an urgent need to develop physico-chemical characterisation of various nanomaterials and to recognise and account for the relevance of new metrics for nanomaterial toxicity. It is worth noting here that NICNAS has issued two calls for the voluntary submission of information on the use of nanomaterials in Australia.¹¹⁰ The first was made in 2006 and was specifically focused on market uses of nanomaterials (over a threshold of 100 g a year), while the latter one (closed in January 2009) was extended to include uses in research. The purpose of these calls was to try and establish what and how nanomaterials are being used in Australia, in what volume they are being used and what is known about physico-chemical and toxicological properties. While this effort at information gathering is commendable, a major problem with the approach taken by NICNAS is not only that it was a voluntary call and therefore received a limited response, but also that it did *not* request information as such on the properties, merely an indication of whether this information was known or not (a yes/no question). This means that as a result of these calls, NICNAS has not gathered any actual information on the physico-chemical or toxicological properties of nanomaterials.

The extent to which nanomaterials should be considered 'new' substances requires urgent clarification across all regulatory regimes.¹¹¹ Ongoing debates about the definition of the nanoscale, particularly what counts as the upper range, will have a significant impact on regulatory schemes hoping to adjust to nanomaterials by acknowledging them as something 'new'. For example, the nanomaterials being used in many cosmetics can be 200 nm, 300 nm or 500 nm in size and the extent to which these materials express the unique properties characteristic of the nanoscale, thereby requiring incorporation into definitions and regulatory regimes, remains unclear. There is clearly a need for both a coordinated approach to defining nanomaterials (nationally and internationally) and a concentrated effort to develop new standards, characterisation methods, and toxicological research if the regulation of nanoST is to be effective in protecting public and environmental health.

An effort towards standardisation of terminology and testing procedures is currently underway in international organisations such as the Organisation for Economic Cooperation and Development (OECD) and the International Organization for Standardization (ISO), and Australia should continue

¹⁰⁹ K Tiedeae, A B A Boxallae, S P Tearb, J Lewis, J David and M Hassellov, 'Detection and characterization of engineered nanoparticles in food and the environment', *Food Additives and Contaminants* 25:7, 2008, pp. 795–821.

¹¹⁰ Note that this call for information was limited to the field of industrial chemicals for which NICNAS is responsible and therefore did not capture or relate to information used in other fields such as therapeutic goods, foods, agricultural chemicals and so on.

¹¹¹ In some cases (for example NICNAS and TGA), advisory groups and task forces have been established to consider any unique challenges nanoST may pose to the regulatory body's system. For some of these groups, the question of whether nanomaterials constitute something 'new' or 'novel' is being considered. The outcomes of these considerations are, however, currently unknown, as is whether any response will be coordinated across different bodies.

its commitment to participating in these processes.¹¹² Australia has also begun its own effort towards coordination around nanoST policy. While a National Nanotechnology Strategy began in 2007 and was implemented by the specifically created Australian Office of Nanotechnology, this strategy came to an (early) end in June 2009.¹¹³ It is now to be replaced by the National Enabling Technologies Strategy (NETS), which has been granted \$38.2 million in funding for four years and is meant to apply to 'biotechnology, nanotechnology and other technologies as they emerge'. While this approach should be commended for recognising the unique challenges posed by emerging technologies and attempting to provide a coordinated and flexible approach to managing these, its definition of what counts as an 'enabling technology' currently appears so broad as to be meaningless. Enabling technologies are defined as 'new technologies or new uses for technologies that enable new things to be done or things to be done better'.¹¹⁴ Surely this applies to all technologies? Articulating more specifically what this strategy is meant to cover within its limited budget and timeframe is arguably a worthwhile step forward.

It seems clear at least that the NETS is specifically meant to apply to nanotechnologies. Although the details of how this strategy will impact the regulation, control and funding of nanoST remain to be seen, some commentary and criticism can be offered on its initial framing, particularly on the predominant role given to 'evidence-based policy' and the limited role awarded to public engagement processes. In line with the 'Australian Government Approach to the Responsible Management of Nanotechnology',¹¹⁵ NETS advocates a commitment to 'evidence-based policy', but as described in detail above, one of the key problems facing nanoST policy is precisely the lack of a comprehensive evidence base.

Research on important factors such as risks to human health and the environment is scarce and incomplete. While indicative of potential for harm, the extensive uncertainties mean that any 'evidence' available on nanoST remains open to different interpretations from competing interests and beliefs. For example, is there 'evidence' that carbon nanotubes are harmful to human health? How should the available knowledge be interpreted? Should the commercial use of carbon nanotubes be banned or should we wait until further information is available? If we postpone policy action until incontrovertible evidence of harm becomes available, this could well be too late to avoid damage. Additionally, even though there may be no evidence of physical harm, it may be that societies wish to avoid particular applications or fields of development based on ethical grounds, on social values or on preferences for particular forms of social organisation. Of course, policymaking should always be 'evidence-supported', but to suggest that for nanoST we are in a situation where policy can be 'evidence-based' is naïve at best and actively misleading at worst.

While the dearth of information and 'evidence' for nanoST means that greater attention should be paid to uncertainty and the role of social values, goals and visions in decision-making, this does not appear to be the case in the NETS where the role for public engagement seems marginalised. In the NETS discussion paper,¹¹⁶ the Public Awareness and Community Engagement Program is

¹¹² It is worth noting that the standards and terminologies developed by the ISO are not freely available. For example, its current document outlining definitions for nanomaterials costs 56 Swiss francs, creating a serious barrier for widespread communication, uptake and standardisation in terminology.

¹¹³ The National Nanotechnology Strategy was originally created as a four-year program.

¹¹⁴ Australian Government Department of Innovation, Industry, Science and Research, *National Enabling Technologies Strategy*, Discussion Paper, 2009. Available at: <http://www.innovation.gov.au/Industry/Nanotechnology/Documents/NETSDiscussionpaper.pdf> (last accessed 24.07.09).

¹¹⁵ Australian Government Department of Innovation, Industry, Science and Research, *Australian Government Approach to the Responsible Management of Nanotechnology*, 2008. Available at: <http://www.innovation.gov.au/Industry/Nanotechnology/Documents/ObjectivesPaper.pdf> (last accessed 27.07.09)

¹¹⁶ Australian Government Department of Innovation, Industry, Science and Research, *National Enabling Technologies Strategy*.

described as having ‘a clearly defined goal of providing balanced and factual information to support evidence-based policy and regulatory practice and to increase community awareness and understanding of nanotechnology’. This seems to indicate that the role of public engagement is to educate the community about nanoST, ‘maximize trust’, and thereby enhance acceptance. If so, Australia is adopting a heavily criticised, ‘deficit model’ understanding of public relations to emerging technologies.¹¹⁷ While it is suggested that there will be ‘two-way communications’, there is no indication that this will involve public engagement influencing policymaking. Indeed, in the fact sheet on the NETS,¹¹⁸ it is clearly stated that the strategy will aim to encourage ‘greater community engagement in debates about the development and use of enabling technologies’ and *not* greater community engagement in *policymaking* about the development and use of nanoST.

The separation between decision-making and public engagement in the NETS vision is perhaps most clearly indicated by the proposal that its implementation will be achieved through two different sections within the Department of Innovation, Industry, Science and Research—the Enabling Technologies Policy Section and the Enabling Technologies Public Awareness Section. Here again we see an emphasis on public education over genuine public engagement and a strict separation between the public and policymaking. Interestingly, this contradicts the government’s own vision of responsible management of nanotechnology, in which it is specifically stated that public awareness and engagement should not only inform the community but also ‘contribute to policy development’.¹¹⁹ The disappearance of this particular emphasis and phrase in the early information on NETS is ominous and should be strictly monitored throughout its further development and implementation.

7.2 International comparisons

Both Canada and the US have taken steps towards recognising nanomaterials as ‘new’ substances for regulatory and safety-testing purposes. In the United States Environmental Protection Agency (*Toxic Substances Control Act of 1976*) and in Environment Canada (*New Substances Notification Regulations*), nanomaterials are now recognised as ‘new’ substances if they possess a different molecular arrangement from what appears on the list of existing substances. This means, for example, that for regulatory purposes, carbon nanotubes will be recognised as ‘new’ and different from graphite or carbon black. This position does *not*, nevertheless, recognise that some nanomaterials exhibit novel properties that are not related to changes in molecular structure. For example, nanoparticles of silver are *not* recognised as a new material according to these rules. However, both bodies also have the ability to request new information on ‘existing’ chemicals through their ‘significant new use’ and ‘significant new activity’ provisions.¹²⁰

¹¹⁷ The deficit model understanding is that public resistance to new technologies stems from a lack of knowledge (or, increasingly, a lack of trust in science and decision-makers); therefore, to overcome any potential resistance, the public needs to be educated and informed. This position fails to acknowledge the legitimacy of public concerns or to recognise the way in which concerns may extend beyond issues of physical risk that are often the focus of decision-making discourse. For example, in the debate over GMOs, it has been shown that much of the demonstrated public concern did not stem from a lack of knowledge (in fact the more people learned, the more they tended to be concerned) or from concerns about physical risk, but rather related to social issues such as enhanced corporate control over the food chain and ethical questions around developments such as transgenic manipulation. For more on the deficit model in Australian science policy, see R Schibeci, J Harwood and H Dietrich, ‘Community Involvement in Biotechnology Policy? The Australian Experience’, *Science Communication* 27:3, 2006, pp. 429–445.

¹¹⁸ Australian Government Department of Innovation, Industry, Science and Research, ‘National Enabling Technologies Strategy Fact Sheet’, 2009. Available at: <http://www.innovation.gov.au/Section/AboutDIISR/FactSheets/Pages/NationalEnablingTechnologiesStrategyFactSheet.aspx> (last accessed 27.07.09).

¹¹⁹ Australian Government Department of Innovation, Industry, Science and Research, *Australian Government Approach to the Responsible Management of Nanotechnology*, 2008.

¹²⁰ The following report provides a good international summary of different regulatory systems: J Pelley and M Saner, *International Approaches to the Regulatory Governance of Nanotechnology*, Regulation Papers,

The European Parliament has also recently moved to recognise the novelty of certain nanomaterials. According to the recast of its Cosmetics Directive (Council Directive 76/768/EEC) legislation, a nanomaterial is defined as ‘an insoluble or bio-persistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm’.¹²¹ For these materials, it is suggested that a nano-specific safety assessment procedure is required.¹²² Following this action on cosmetics, the European Parliament is also currently in the process of amending its legislation on novel foods, suggesting that where these foods are produced with the aid of nanotechnology, they should not be accepted for market until the method of production has been approved and adequate safety assessment performed.¹²³ Since methods for such a safety assessment are currently lacking, this may be viewed as an effective moratorium on nanomaterials in food in the European Union (EU) if the amendment is passed into legislation.¹²⁴ Also of interest in this proposed amendment is the statement that ‘all ingredients present in the form of nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word ‘nano’ in brackets’. This indicates recognition that nanomaterials are new/different materials, not only for safety assessment but also for labelling purposes.

Europe can also be seen as having taken the lead in investigating the challenges and limitations of traditional risk assessment approaches for nanoST. It has commissioned scientific opinions on this topic from the Scientific Committee on Consumer Products,¹²⁵ the Scientific Committee on Emerging and Newly Identified Health Risks,¹²⁶ and the Scientific Committee of the European Food Safety Authority.¹²⁷ The reports of all three of these scientific committees have highlighted the substantial uncertainties involved, the lack of information in key areas, and the need to generate both new information and new methods of testing in order for risk assessment to be possible. Consistent with its commitment to transparency and public engagement, the European Commission has undertaken a public consultation on the adequacy of these reports and the topics that they cover before its scientific hearing held in Brussels in September 2009.¹²⁸

For information gathering on engineered nanomaterials, the UK has had voluntary reporting schemes in place since 2006¹²⁹ and the US since 2008.¹³⁰ These efforts have, however, been widely criticised because of the limited participation they have experienced, potentially due to the lack of perceived

Carleton University, 2009. Available at:

http://www.carleton.ca/regulation/publications/Nanotechnology_Regulation_Paper_April2009.pdf (last accessed 30.07.09).

¹²¹ European Parliament, *Cosmetic products (repeal. ‘Cosmetics Directive’ 76/768/EEC). Recast*, 2008. Available at: <http://www.europarl.europa.eu/oeil/file.jsp?id=5598862> (last accessed 30.07.09).

¹²² Note that for this amendment, political agreement has been reached but the final decision from the Council is still pending.

¹²³ See European Parliament, *Novel foods (repeal. Regulation (EC) No 258/97*, 2008. Available at: <http://www.europarl.europa.eu/oeil/file.jsp?id=5583302> (last accessed 30.07.09).

¹²⁴ Pelley and Saner.

¹²⁵ European Commission, Health & Consumer Protection Directorate-General, Scientific Committee on Consumer Products, *Opinion on Safety of Nanomaterials in Cosmetic Products*, adopted by the SCCP after the public consultation on the 14th plenary of 18 December, 2007. Available at: http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_123.pdf (last accessed 30.07.09).

¹²⁶ SCENIHR.

¹²⁷ EFSA.

¹²⁸ For more information on the hearing and the public submissions, see European Commission, ‘Scientific Hearing on Risk Assessment of Nanotechnologies’, 2009. Available at: http://ec.europa.eu/health/ph_risk/committees/04_scenih/scenih_cons_10_en.htm (last accessed 30.07.09).

¹²⁹ See Department for Environment, Food and Rural Affairs, ‘Nanotechnologies—policy activities’, 2009. Available at: <http://www.defra.gov.uk/ENVIRONMENT/nanotech/policy/> (last accessed 30.07.09).

¹³⁰ Environmental Protection Authority, ‘Nanoscale Materials Stewardship Program’, 2009. Available at: <http://www.epa.gov/oppt/nano/stewardship.htm> (last accessed 30.07.09).

incentives to become involved. Recently, both Canada and France have proposed mandatory reporting for nanomaterials, not only on levels of use but also on physico-chemical characteristics and available toxicological research. While both of these proposals were promoted in early 2009, firm policy requirements for mandatory reporting remain under development.

It is interesting (and worrying) to note that in a recent report comparing regulatory governance of nanotechnology in the US, Canada, the UK, Australia and Europe,¹³¹ Australia was *not* described as setting 'best practice' standards in *any* of the following areas:

- coordination of regulatory governance
- flexible and adaptive approaches to regulatory development
- sophisticated information gathering; a comprehensive life-cycle approach to risk management
- the weighing of risks against benefits
- an accountable and transparent approach.

There are clearly opportunities for improvement in Australia's approach to the regulatory governance of nanoST.

8. Recommendations: what should be done

While nanoST could be like asbestos, it may also be useful to think of them as being like plastic. For example, there exists an incredible potential to create useful new materials, which will in turn create new industries, transform old industries, and become widespread across a range of different sectors. To match the unique beneficial properties, however, there are also likely to be unexpected negative properties with problems arising throughout product life cycles (for example, pollution, accumulation, persistence, and unexpected health and environmental impacts). To ask whether or not we want plastic does not make sense; we want some applications and not others. We want to avoid toxic varieties. We want knowledge of impacts and appropriate safety controls. We want recycling abilities and facilities. We want those applications that substantially improve our lives and not those that degrade the environment and damage our health.

While nanoST pose many unique challenges that make them substantially different from plastic (for instance, their 'invisible' size), there is value in making this analogy. NanoST are incredibly diverse and, in the future, it is likely that there will be a greater differentiation in the discussion of different spheres of development and types of applications. Some fields of development will be desirable while others may be best left alone; perhaps the whole quest for molecular-level manipulation could be abandoned as a 'dead end' for progressing social goals and values. What is required now is greater social inclusion in policymaking on nanoST development so that we can decide exactly what is desirable and what controls we should have in place.

¹³¹ Pelley and Saner.

The 11-point plan for action

1. Recognise nanomaterials as new materials for the purposes of regulation and safety assessment and use a broad definition based on functional characteristics.

In defining what counts as nanoST, it does not make sense to impose an arbitrary upper limit on the nanoscale. Definition and regulatory testing should be based on function;¹³² that is, if particles of 500 nm are found to demonstrate the unique properties associated with the nanoscale, they should not be excluded from definitions of nanomaterials simply because they exceed a 100 nm limit. Until testing capable of adequately documenting functional properties is available, a broad and inclusive definition of nanoST would allow for a greater margin of safety.

2. Supplement work on measurement standardisation with enhanced development of characterisation research.

Through NETS, Australia is indicating a clear commitment to further research and the development of measurement standards for nanoST, which should be complemented by a similar commitment to characterisation research so that the relevant properties of nanomaterials in commercial use (such as their size, shape, surface chemistry, solubility, agglomeration state and so on) can be documented and compared. Public and private actors developing and employing nanomaterials across all sectors should have a mandatory responsibility to contribute towards knowledge generation by providing information on the characteristics of the material they are working with. This information should be held and maintained in an open-access database.

3. Adjust metrics for safety testing and regulatory assessment to include the characteristics relevant for nanomaterials.

Traditional metrics (such as mass and volume) used for setting safety limits and triggering regulation assessment and action are not always the most appropriate for nanomaterials. There is a need to understand and implement new metrics for defining nanomaterial safety, including consideration of the currently identified important characteristics of surface area, surface chemistry, size, shape, solubility and agglomeration state.

4. Commit to the development of a pragmatically tiered eco/toxicology research program for the life cycle of nanoST commercial products.

The development of comprehensive eco/toxicology research on nanomaterials is a daunting task. There is therefore a real need not only to support the expansion of this field with significant financial investment, but also to create a coordinated and tiered approach to testing. This will involve setting priorities for the particular nanomaterials to study, the characteristics for documentation, the organisms/systems of most interest, approved test methods, relevant endpoints, and appropriate reference materials. Ideally, the priorities for testing will focus not only on the toxicological potential of different nanomaterials in commercial use, but will also pay particular attention to life-cycle assessments and studies on the mobility and movement of nanomaterials through biological systems (for example, through soil, air, water, organisms).

¹³² This is a point also supported by the Royal Commission on Environmental Pollution.

Developing the relevant tiers of priorities for the knowledge-building process will require a trans-disciplinary approach.¹³³

5. Require that the ingredient lists of consumer products indicate when components have been engineered on the nanoscale.

It is important to note that this is not the same as suggesting a particular 'nano' label for all consumer products. The diversity of nanoST, in combination with the specificity of toxicology, ensures that a single, general 'nano' label would not be meaningful for consumer products. But when we see fit to list a product's ingredients (such as in cosmetics or food, for example), it is fair to indicate when these have been engineered on the nanoscale,¹³⁴ which could be as simple as having '(nano)' follow the relevant ingredient in the list. This is important because of the unique properties that manifest on the nanoscale and the necessary status of nanomaterials as 'new' materials. This would not represent a warning label as such; rather, it would present factual information about the ingredients used with the benefit of allowing people to make their own choices and judgements about any potential risks involved. This approach to labelling would not only enable consumer choice for interested parties, it would also be enormously beneficial for future tracing, monitoring and surveillance of potential effects.

6. Shift from a discourse of 'assessing risk' to one of 'negotiating uncertainty'.

There needs to be innovation in traditional approaches to regulation to respond to the innovation in science and technology. For nanoST, there are clear, well-recognised deficiencies in knowledge that make uncontested risk assessment impossible. All information will inevitably be interpreted differently according to particular values, beliefs and assumptions and it is therefore critical that we acknowledge and face the quantitative and qualitative uncertainties involved in decision-making on nanoST.¹³⁵ This requires recognising the crucial role of values in research and development and engaging in cross-disciplinary, multi-stakeholder deliberation over the quality of evidence in science as a basis for policy.¹³⁶ It also requires recognising that science is not the only relevant source of knowledge and expertise.

An approach to decision-making focused on the negotiation of uncertainty also includes explicit consideration of broader social and ethical criteria. Existing methods for approaching such considerations include multi-criteria mapping,¹³⁷ real-time technology assessment,¹³⁸ constructive

¹³³ F Wickson, A L Carew and A W Russell, 'Transdisciplinary Research: characteristics, quandaries and quality', *Futures* 38, 2006, pp. 1046-1059.

¹³⁴ It is worth noting here that in its recent report on nanotechnology in NSW, the NSW Parliament, Legislative Council, Standing Committee on State Development recommended a mandatory labelling scheme for engineered nanomaterials in the workplace.

¹³⁵ For a description of different types of uncertainties affecting science for policy see F Wickson, 'From Risk to Uncertainty in the Regulation of GMOs: Social Theory and Australian Practice', *New Genetics and Society* 26:3, 2008, pp. 325-339.

As these specifically apply to nanoST, see F Wickson, F Gillund and A I Myhr, 'Treating Nanoparticles with Precaution: Recognising qualitative uncertainty in scientific risk assessment', in K Kjølberg and F Wickson, (eds), *Nano meets Macro: Social perspectives on nanoscale sciences and technologies*, Pan Stanford, Singapore (2009).

¹³⁶ For how to do this, see examples of pedigree assessment such as that described in F Wickson, 'Reliability Rating and Reflective Questioning: A case study of extended review on Australia's risk assessment of Bt Cotton', *Journal of Risk Research* 12:6, 2009, pp.749-770.

¹³⁷ See for example, University of Sussex, 'Multicriteria Mapping', 2009. Available at: <http://www.multicriteria-mapping.org/> (last accessed 27.07.09).

¹³⁸ See for example D Guston and D Sarewitz, 'Real-time Technology Assessment', *Technology and Society* 24:1-2, 2002, pp. 93-109.

technology assessment,¹³⁹ and exercises in upstream public engagement.¹⁴⁰ The aim of these approaches need not necessarily be to reach a single consensus answer on what should be done. Rather, they can focus on articulating a range of alternative policy options, describing how they are differentially weighted by people and communities according to various beliefs, assumptions, visions of the good life and so forth. They can also focus on how characteristics such as flexibility, reversibility and resilience might be sponsored by pursuing a range of different options, thereby avoiding situations of single trajectory lock-in. As a decision-aiding tool, the availability of a portfolio of possible policy options weighted according to different underlying values does not dictate the superiority of one particular decision. Rather, it showcases a range of alternatives that are available for policymakers and enhances transparency around the decisions that they ultimately take.

7. Support public engagement not just in debate but also in decision-making.

While the Australian Government appears to have acknowledged the importance of socially-inclusive policy in its objectives for responsible management of nanoST, it seems to be failing to implement this in practice through the NETS. There is a need to see the role for public engagement as creating not just informed public debate, but also socially and ethically sensitive policies. It is also important to realise that advocating enhanced public engagement in decision-making does not refer merely to ‘end-of-pipe’ regulatory decision-making but also to more ‘upstream’ decisions, including the allocation of public funding. This means that public engagement in decision-making should not only be about the governance of risks but also about the governance of innovation and include participation in the prioritisation of fields for research funding.

8. Carry out health surveillance and environmental monitoring of high potential exposures.

Until more is known about the toxicology of nanomaterials, it would seem prudent to take the indicators of potential for harm seriously and to monitor human and environmental health in areas with potentially high-exposure levels. This would include health surveillance procedures for workers involved in manufacturing and processing and for researchers regularly handling free nanomaterials. For environmental monitoring, it would be useful to develop information on background levels and to monitor exposure and effects in areas such as sewerage treatment plants and the air around manufacturing facilities. Currently, such monitoring efforts are challenged by limitations in the methods available for detection and measurement, thus it is important that developments in these fields occur as soon as possible.

9. Adopt a precautionary approach to decision-making that allows for and negotiates selective moratoria in areas where concerns exist, knowledge is lacking, and social benefit is marginal.

As a response to the uncertainties involved and the early indications of potential for harm, it seems reasonable that precaution should be applied in some cases, requiring a policy stance that is open to the notion of selective moratoria on the commercial release of particular classes of nano-products until more information on health and environmental impacts can be generated. This will be particularly relevant for those cases where the potential for harm has been demonstrated, significant uncertainties remain, and social benefits appear marginal. For example, while transparent sunscreens are pleasant, it may be that large sections of the community, if consulted, would suggest that more research should be conducted on the potential

¹³⁹ See for example Schot and Rip.

¹⁴⁰ See for example Gavelin et al.

health effects of nanoparticles for this benefit to really outweigh the potential risk. Additionally, while nanoparticles of silver are becoming widespread in products such as washing machines, socks and refrigerators due to their antibacterial properties, the value of and need for this use may be considered questionable in comparison to the risks of enhancing antibiotic resistance in bacteria we don't like and destroying the communities of those we remain dependent on. A responsible approach to the management of nanoST would allow for selective moratoria in certain fields and the ability to negotiate these among a broad cross-section of the community.

10. Encourage interdisciplinary education and training for future scientists.

A long-term approach to science and technology governance necessarily includes a focus on education. NanoST comprise a field that clearly has the potential to benefit from enhanced interaction and learning across different scientific disciplines. For example, nanotoxicology will be most effective where its scientists are able to comprehend the physics of atomic forces, combine this with knowledge on the chemistry of molecule interactions, and then situate this knowledge within the biology and ecology of living systems. However, this recommendation for enhanced interdisciplinary education and training is also meant to emphasise the importance of interaction between natural and social sciences. At various levels of education (bachelor, masters, PhD), future scientists should be exposed to courses in social science subjects such as philosophy of science, research ethics, and science communication¹⁴¹ to help build a greater appreciation of the role of science in society, improve capacity for social and ethical reflection, and enhance skills in public communication. All of these are arguably required to achieve responsible scientific and technological advances in the long term.

11. Conduct a parliamentary inquiry into nanoST that includes the question of what 'evidence-based policy' means for emerging/enabling technologies.

Australia has adopted the position that emerging (or what it has labelled 'enabling') technologies such as nanoST will be met by 'evidence-based' policy. This position requires enriching. There needs to be a serious (re-)exploration of what 'evidence' means in the context of emerging technologies and a clearer recognition that 'evidence' in the form of scientific knowledge is substantially lacking in this field and that its development will take both time and commitment. This is particularly the case for knowledge on the human-health and environmental impacts of nanoST.

Until more knowledge is generated, regulation through the traditional processes of risk analysis is simply not possible. There needs therefore to be a serious engagement with the challenges of negotiating uncertainty, which will require investing in more research, subjecting to deliberative quality assessment through 'extended peer review' any evidence used to support policy, and approaching social and ethical dimensions through socially-inclusive policy. NanoST is emerging under conditions of high uncertainty and competing values. Any claim that the urgent decisions required can simply be 'evidence-based' manifestly hides the values, beliefs and assumptions actually involved. Science and technology play an enormous role in the everyday lives of citizens and there is therefore no reason that the shape of their development should be excluded from democratic processes.

¹⁴¹ As is done in other parts of the world, for example compulsorily in Norway.

Conclusion

NanoST are surrounded by some very grand visions for the future—fictional futures that motivate and inspire us as well as frighten and repel us. Of course, none of our visions can materialise unless we prioritise, invest in, commit to, and pursue them. Money and hope is currently pouring into nanoST and the consequent outcomes are rapidly entering our lives; the experiment in nanoST has already begun and we are all involved. The question is, do we want to be and if so, how do we want to be? How will we approach the ripples of interaction throughout larger social and biological systems? What vision of the future are we actually pursuing? What values and assumptions are driving nanoST forward and to what extent do these match commonly-held social goals and ethical beliefs? We are all a part of this collective experiment, so we should all have our say in the role that we want nanoscale sciences and technologies to play in our lives.

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