Herron, William

From: O'Bryen, Gail
Sent: Thursday, 4 September 2008 10:29 AM
To: Mackay, Ruth
Cc: Wunsch, John; Noble, David; Falkenberg, Dianne; Ham, Samson; Lamb, Elizabeth; Milne, Gary; Probyn, Glenn; Rowe, Maree
Subject: Minute on nanotechnology - to read before Glenn presents his EC paper today?
Importance: High
Attachments: Nanotechnology and the ACCC minute 8-08.doc; Media release DIISR 7-08.pdf; Principles talking Points 9 July 2008 FINAL.doc

Hi Ruth

As I have mentioned, PSC has been keeping a voluntary watching brief on the emerging safety issues with nanotechnology since 2005 when it first started gaining popular attention. When PSC had David Noble placed here on a graduate rotation, it enabled him to work with Glenn to consolidate our knowledge to date, conduct some further research and analysis and compile the attached brief. David has written an excellent information minute outlining the latest state of play in nanotech and its relevance to the ACCC.

* Please note that Glenn's EC paper on standards reviews mentions nanotech as an emerging issue and just might be the subject of a question at today's meeting.

Due to our maintaining a watching brief to date, Glenn has acted as the ACCC's liaison officer in dealings with the Office of nanotechnology so far. However, as you would appreciate, this issue fits more with PSP and I would like to discuss handing it over to John. We have collected a substantial bank of material that we can pass on. The next steps will be to determine what action the ACCC needs to take to manage emerging factors. Glenn will be able to discuss this in further detail (and if necessary we may also be able to prevail on David who's now in Comms Branch in Melbourne).

Many thanks to Glenn and David for their work on this to date.

Please let me know when you're ready to discuss.

Gail

Gail O'Bryen
Director, Product Safety Compliance
Australian Competition and Consumer Commission
www.accc.gov.au
Phone: 03 9290 1912
Fax: 03 9290 6901

AUSTRALIAN COMPETITION & CONSUMER COMMISSION
MINUTE

DRAFT

OFFICE: **Melbourne**
TRACKIT No:
FILE REF.:
DATE: 12 August 2008

TO: **Ruth Mackay**
C.C: Gail O'Bryen, John Wunsch, Glenn Probyn

FROM: David Noble

SUBJECT: **NEW TECHNOLOGIES – NANOTECHNOLOGY AND THE ACCC**

PURPOSE

1. To advise you of:
   - the applications and types of products to use nanotechnology
   - the issues surrounding nanotechnology for the ACCC
   - the Monash Report

BACKGROUND

2. Nanotechnology can best be described as a catch-all description of activities at the level of atoms and molecules that have applications in the real world. A nanometre is a billionth of a metre, that is, about one ten-thousandth the width of a human hair. In basic terms, nanotechnology is the engineering of devices and materials at the atomic or molecular scale. It is widely accepted internationally by governments, industry, scientists and academics that nanotechnology will increasingly impact on the way we live our lives.

3. It has been estimated that nanotechnology could be worth up to $50 billion a year to the Australian economy,[1] with the Australian public and private sectors currently spending $100 million per annum on nanotechnology R&D.[2]

---

[1] I. Macfarlane, *Media Release: Report into the Technology of the Small – Nanotech*, 12 September 2006 Canberra: Minister for Industry, Tourism and Resources.
[2] Invest Australia, *Australian Nanotechnology – Capability and Commercial Potential*, 2005. Canberra: Australian Government.

Applications and Products

4. The applications of nanotechnology are extremely wide and varied. Research programmes engaged in the design and development of advanced materials and the processes and systems used to manufacture them exist within a number of Australian universities, CSIRO and industry. Advanced materials of interest include fibre and polymer composites with superior performance characteristics; biologically derived biopolymers for use in food production; smart materials capable of self-monitoring faults such as cracking; and alloys and composites using the lighter metals.

5. Nanotechnology is producing new products in the areas such as *nanobiotechnology and biomaterial* in the human medical device market with the development of detection and analysis and drug delivery products; in *energy and environment* with more efficient means of energy storage, for example obtaining greater battery efficiencies and improved insulation materials to conserve energy; in *electronics and photonics* where nanotechnology is allowing for significant downsizing of electronic components and products and the integration of electronic and optical technology; in *quantum computing* with the aim of constructing a device which will form the fundamental building block of a silicon-based quantum computer.

6. Arguably the most significant area of nanotechnology development with implications for product safety is the area of *materials*. Particles and coatings nanotechnology is translating into a wide variety of product applications. These include extremely hard, antibacterial, antiviral and smooth coatings for industrial tools; enhanced paints and glass; prosthetics; membranes in energy production and storage and pollution control; and cosmetic applications.

Current and Emerging Products

7. There are a wide variety of products that utilise nanotechnology available on the Australian market, but these are currently more prevalent in overseas markets, such as North America, Japan, and Europe, than Australia. These products can range from high strength/low weight sporting equipment, to textiles (eg. stain-resistant clothing), to cosmetics, to coatings used in construction (including self-cleaning windscreens), to a gamut of 'anti-bacterial' products that utilise nanosilver (including toothpaste, soft toys, fridges and keyboards). Food packaging that warns of contaiminated food and matter to rebuild bones and nerves have also been touted.

8. According to the International Risk Governance Council,[3] products such as micro-electronics and high strength materials represent the first generation of nanotechnology products, with '**passive nanostructures**'. Whilst further research is required to understand the risks associated with these products, they may not 'present consumer or society with excessive novelty.'

[3] IRGC, Policy Brief: Nanotechnology Risk Governance, 2007.

9. Other generations of products currently emerging and under development include **'Active'** and **'more complex'** nanostructures and nanosystems. Currently, these include products that change state during operation, such as drug delivery systems, but looking further ahead may include products with synthesis and assembly techniques, including advanced therapeutic implants or applications of nano-size machines. Applications of these technologies are likely, according to the IRGC, to result in genuinely new products, and could have significantly greater societal impacts and potentially raise greater concerns.

Possible Hazards

10. The assessment of the potential hazards associated with the applications of nanotechnology is currently underway. Numerous research groups (in government, industry and universities) are conducting studies into the health, safety and environmental impacts of nanotechnology. These include *in vitro* (outside living organisms, i.e. test tube) and *in vivo* (within living organisms, i.e. animal testing) testing of the toxicity of nanomaterials.

11. Some recent health related issues include:

- ***Sunscreens containing Nanoparticles of Titanium Dioxide and Zinc Dioxide***
  In January 2006, the TGA published a review of the scientific literature on the safety of nanoparticulate titanium dioxide or zinc oxide in sunscreens. They found that whilst there was evidence that these nanoparticles may damage cells, this would only be a concern if the nanoparticles penetrated into viable skin cells. The TGA concluded, however, that 'the weight of current evidence is that they remain on the surface of the skin and in the outer dead layer (stratum corneum) of the skin.'

- ***Cosmetics***
  Similarly to sunscreens, nanotechnology has numerous applications in cosmetics including light-diffusion, moisturising and other therapeutic benefits.

  Note: NICNAS are planning to undertake a review of the current state of nanomaterials in cosmetics in 2008-09 (NICNAS have requested this information remain confidential).

- ***Carbon Nanotubes***
  Different varieties of carbon nanotubes have many applications from strengthening steel to assisting in targeted drug delivery. Two 2008 studies published in the *Journal of Toxicological Sciences* and *Nature Nanotechnology* have found that some multi-walled carbon nanotubes can induce a response similar to that induced by certain asbestos fibres. This response may develop into the disease mesothelioma. These studies do not address whether humans may be exposed to multi-walled carbon nanotubes but point to a potential for them to cause injury to humans.

  In response to these studies, the UK Environment Agency (EA) published advice on the classification and disposal of waste containing unbound (i.e. not fixed within a matrix and capable of being inhaled) high aspect ratio carbon nanotubes (CNT). Such

waste, according to EA, should be considered hazardous, and should be managed and disposed of according to the appropriate guidelines.

- *Nanosilver*

Nanosilver is used for its antibacterial properties in many products from socks, to paints, toothpaste, and fridges. Macro-scale silver is known to have a fairly low toxicity to humans, although continued consumption of significant levels over time will often lead to a condition known as argyria.[4] Research continues, however, as to the effects of nano-scale silver on humans and animals.

The release of nanosilver into the environment is of particular concern to researchers. In larger concentrations, silver is a pollutant and the United States Environmental Protection Agency (EPA) places strict regulations on the amount of silver that can be released into the environment. Because of its antibacterial properties there is a concern about the harm that nanosilver may cause to fish, other aquatic organisms and waterway ecosystems as a whole.

AUSTRALIAN GOVERNMENT ACTION

Regulatory Agencies

12. The regulation of products including nanomaterials is shared across agencies with industry specific jurisdictions in Australia.

Therapeutic Goods Administration (TGA):
Pharmaceuticals/Therapeutics

National Industrial Chemicals Notification and Assessment Scheme (NICNAS):
Chemicals for industrial and cosmetic use

Food Standards Australia and New Zealand (FSANZ):
Food products and packaging

Australian Pesticides and Veterinary Medicines Authority (APVMA):
Chemicals for use in agriculture or veterinary medicine

Australian Competition and Consumer Commission (ACCC):
Consumer products including cosmetic labelling

13. Other departments and agencies also have regulatory powers in regards to nanomaterials, such as the Australian Quarantine and Inspection Service/Customs (importation), DoTARS (transportation), Australian Safety and Competition Council

[4] This condition permanently turns the skin a grey or blue colour and may contribute to other more serious health effects.

(occupational health and safety), the Office of the Gene Technology Regulator (genetically modified organisms) and the Department of Environment, Heritage and the Arts (environmental issues). Some agencies have responsibilities for environmental protection as well as health safety, such as NICNAS.

14. There are also numerous state and territory authorities with responsibility for regulation and enforcement, particularly in the area of environment and OH&S issues.

ACCC Regulatory Capabilities

15. The ACCC is responsible for developing and enforcing mandatory standards or bans for products where a significant risk to consumer safety has been identified.

16. The TPA provides broad powers to regulate over a wide range of products, however, the application of these powers requires an ability to **identify and assess hazards** posed by the application of nanotechnology in products.

17. As the ACCC currently has limited ability to determine risks that nanotechnology may pose, the ACCC would need to employ the services of other government agencies/test laboratories to identify hazards (these may include the National Measurements Institute, NICNAS or the CSIRO). Close relationships with standards organisations, research bodies and other regulatory agencies is essential for assisting with the identification of these risks. International monitoring is also an important element in this process.

18. Note: Standards Australia has not published any voluntary standards relating to nanotechnology at present, but it is currently engaging with the ISO's technical committee on nanotechnology, ISO/TC 229, and the International Electrotechnical Commission (IEC) in the development international standards.

The National Nanotechnology Strategy and HSE Working Group

19. The Australian Office of Nanotechnology (AON), based at the Department of Innovation Industry Science and Research, coordinates the implementation of the Government's National Nanotechnology Strategy (NNS), which commenced in July 2007. Due to budget cut backs, the NNS will cease in June 2009.

20. AON's current role is to:
    - ensure whole of government approach to nanotechnology issues. AON chairs an interdepartmental committee to consider cross portfolio issues – the Health Safety and Environment Working Group (HSE)
    - work with State and Territory Governments to encourage cooperation and coordination of nanotechnology policies and industry development activities
    - undertake initiatives to develop an understanding of the economic and social impacts of nanotechnology and to support its uptake in Australia. Works with the Investment Promotion Division of the DIISR and industry groups to promotes Australian nanotechnology capability internationally
    - report annually to the Government on the implementation of the NNS and nanotechnology development in Australia more generally.

21. The ACCC is a member of the HSE. Glenn Probyn has been the primary contact to date.

22. The HSE is responsible for:
    - analysing the impact of nanotechnology on regulatory frameworks
    - coordinating the assessment of existing regulations with all relevant agencies
    - liaising with research bodies on areas of potential scientific and policy research (where appropriate)
    - working with the Public Awareness and Engagement Program of the National Nanotechnology Strategy on the provision of balanced and factual information.

23. The HSE meets on an 'as required' basis and provides updates on news and department work plans via email and an extranet.

24. The HSE work group consists of all the relevant national regulatory agencies as listed in point 12, as well as other groups such as:
    - CSIRO
    - Australian Research Council (ARC)
    - Defence Science and Technology Organisation (DSTO)
    - National Health and Medical Research Council (NHMRC)
    - National Measurements Institute (NMI)

25. The following federal departments are also represented on the HSE:
    - Dept. of Health and Ageing
    - Dept. of Agriculture, Fisheries and Forestry
    - Dept. of Foreign Affairs and Trade
    - Dept. of Education, Employment and Workplace Relations
    - Dept. of Transport and Regional Services
    - Dept. of Environment, Heritage and the Arts
    - Dept. of Defence
    - Dept. of Innovation, Industry, Science and Research

MONASH REPORT

26. The 'Review of Possible Impacts of Nanotechnology on Australia's Regulatory Framework' (known as the Monash report) was commissioned by the Office of Nanotechnology and completed by Monash University's Centre for Regulatory Studies. It was submitted to the government in September 2007 and released publicly on 11 July 2008.

27. The report highlighted the degree to which the health, safety and environmental concerns raised by a range of nanotechnology applications would be covered by the current regulatory regimes, and identified, for a range of nano technologies, the existence of some potential regulatory gaps.

28. It is important to note that the framework of the TPA and the ACCC's role in product safety were not assessed by this report, as these were not included in the DIISR's

Request For Tender. The frameworks covered in the report were primarily those from the Health and Environment portfolios, and also included the frameworks for importation and transport. The report, however, did identify the TPA as a 'potentially relevant regime.'

29. The Monash report found that while Australia's regulatory regime is well placed to respond to the impact of nanotechnology, there are certain aspects of the regulatory system that will potentially need amending in the future, which will require a long-term effort across multiple government agencies.

30. More specifically, the report identified potential regulatory gaps concerning six 'regulatory triggers' for nanomaterials. These were:
    a) Triggers on the Basis of Name – 'New' or 'Existing' Substances or Products? (e.g. 'new' chemicals may require assessment for the Australian Inventory of Chemical Substances)
    b) Triggers on the Basis of Weight or Volume
    c) Triggers Requiring Knowledge of Presence or Implications of Presence of NMs
    d) Triggers Reliant on Risk Assessment Protocols or Conventional Techniques
    e) Research and Development Exemptions
    f) Triggers Reliant on International Documents

31. The report, however, does not offer solutions as to how to address these regulatory gaps but asserts that the next phase in regulatory action on nanomaterials will be 'to firm up on metrology and risk assessment protocols,' as well as for regulators to 'improve their understanding of NMs and adjust regulatory arrangements in the light of this understanding.'

32. In terms of imported consumer products that may fall under ACCC jurisdiction, these are likely to first come under the jurisdiction of Customs and AQIS. The Monash report found, however, that under their current regimes these bodies may not be able to take action against products that contain nanomaterials. AQIS's evaluation/risk assessment focuses on the prevention of spread of disease or pests, and not the toxicity or ecotoxicology of nanomaterials. Customs only focuses on classes of goods that are subject to conditional importation.

33. The government response to the Monash report was articulated in a media release on 11 July 2008 by the Minister of Innovation, Industry, Science and Research Senator Carr. The government accepts the findings of the report.

    The message is that 'while Australia's regulatory regime is well placed to respond to the impact of nanotechnology there are certain aspects of the regulatory system that will potentially need amending in the future, which will require a long-term effort across multiple Government agencies.'

34. AON identifies the report as a working document for the National Nanotechnology Strategy. Individual agencies referred to in the report will be reporting to their Ministers on the implications for their agency. The Minister for Competition Policy and Consumer Affairs is unlikely to be briefed by another department.

35. AON will be coordinating a report to the Government on the full range of government activities related to nanotechnology, which will include activities in response to the issues raised in this report.

INTERNATIONAL ACTION

Voluntary Standards Development

36. The International Organisation for Standardisation (ISO) is involved in developing international standards relating to nanotechnology. Technical committee ISO/TC 229 for Nanotechnologies was created in 2005 and is currently developing nanotechnology related standards.

37. No standards have been completed as yet. Standards Australia is participating in the work being undertaken by ISO/TC 229

38. The British Standards Institute (BSI) has published 10 temporary standards relating to nanotechnology, particularly in regards to terminology and OH&S issues. These have been created through a consultative process with industry but have not gained the full consensus of a technical committee. These standards will be superseded by those being developed by ISO/TC 229.

39. ASTM International in the United States is also developing standards relating to nanotechnology. Its E56 Committee on Nanotechnology has published 6 standards to date, including standards on various test methodologies and one on OH&S issues.

International Regulations

40. The US Consumer Product Safety Commission released a statement in 2005 as to their policy on regulating products using nanomaterials. It assessed that potential health and safety risks from nanomaterials would be covered through the Consumer Product Safety Act's provisions against hazardous products, or the Federal Hazardous Substances Act's regulations on hazardous substances. The CPSC acknowledged that the relevant legislation required no pre-market registration or approval, and therefore evaluation of a product would normally take place once it had been distributed in commerce. The reporting obligations on suppliers to notify the CPSC when they obtain information as to an issue with a product were also noted

41. The US EPA and the Food and Drug Administration also have jurisdiction of some products utilising nanotechnology. The EPA has successfully prosecuted some companies under pesticide regulations for making anti-bacterial claims for nanosilver products. In May 2008, the International Centre for Technology Assessment (ICTA), along with groups like Friends of the Earth and Greenpeace, filed legal petitions against the FDA and the EPA, calling for further regulatory action over nanotechnology products.

42. The CPSC, EPA and FDA are all participants in the US Government's National Nanotechnology Initiative (NNI), a federal nanoscale science, engineering, and

technology research and development program founded in 2000/2001 which coordinates US policy on nanotechnology. There is currently an Amendment to the NNI before the US Senate that aims to toughen the NNI by increasing its commitment to environmental health and safety research.

43. The Canadian federal Minister of Health commissioned a report from the Council of Canadian Academies into the knowledge of health and environmental risks of nanotechnology which could inform regulatory activity. The report, released in July 2008, concluded that there is too little known to assess the overall human and environmental risks posed by the introduction of nanoproducts into society. The panel, however, did not identify any evidence that nanoproducts already present in the market in Canada presented risks that could not be addressed through available risk management strategies. Health Canada is the government department responsible for health and product safety regulation in Canada.

44. In Europe, the European Commission published a report in June 2008 on the 'Regulatory Aspects of Nanotechnology'. The report found that for general consumer products, measures in place such as the General Product Safety Directive and market surveillance powers of member states ensured an ability to regulate nanomaterial in products. Companies are also required to notify government if they have reason to believe that their product is dangerous. Further legislation, however, may be required for cosmetic products.

45. Some issues with the implementation of current regulation were identified, including the need establish test and risk assessment methods. Specific labelling requirements for use of nanomaterials in products may also be required to help inform consumers, the report found.

International Coordination

46. International organisations such as the OECD Working Party on Manufactured Nanomaterials, WHO and the UN Food and Agriculture Organisation, are developing international policy on this issue.

    The ISO is engaging in broad international consultation in the development of standards.

FUTURE ACTIONS

47. **Monash Report**: The Monash Report did not include the TPA regulatory framework as part of its Review but the findings of the report will assist the ACCC in identifying some product safety issues that emerging nanotechnologies may pose

48. The ACCC needs to work closely with our colleagues in research, standards and regulatory agencies, both domestically and internationally, to help identify any possible risks with products that utilise nanotechnology, and develop appropriate regulations as needed.

49. **Media Enquiries**: A government-agreed talking-points document has been released by AON regarding how government is handling nanotechnology. The ACCC Media Unit is aware of the issue and has a copy of this document. Attached is a copy of the media talking points and the DIISR Minister's media release of 11/7/08 which lists key regulatory issues.

50. **Product Safety Compliance**: PSC has kept a watching brief to date and maintains regular contact with the HSE to monitor nanotechnology issues.

David Noble

MEDIA RELEASE

SENATOR KIM CARR

Minister for Innovation, Industry, Science and Research

Friday 11 July 2008

SHAPING UP TO THE NANOTECHNOLOGY CHALLENGE

Australia's regulatory systems are well placed to respond to the introduction of nanotechnology products. Two documents released today identify areas for further work and the way the Government will address emerging nanotechnology issues.

Senator Kim Carr, Minister for Innovation, Industry, Science and Research said: "Nanotechnology is developing very quickly on a global scale. Governments, industry and research need to be flexible and active to keep pace with these developments. We need a long-term effort across multiple Government agencies and we are committed to that.

"In the interests of open government we are today publishing two documents on the regulation and application of this emerging technology."

A Review of Possible Impacts of Nanotechnology on Australia's Regulatory Framework, was independently conducted by the Centre for Regulatory Studies at Monash University. The review found that whilst there is no immediate need for major changes to the regulatory regime, there are many areas which potentially will need amending.

"At the same time I am issuing the *Australian Government Approach to the Responsible Management of Nanotechnology*," Senator Carr said.

This document identifies three guiding objectives for nanotechnology management:

- protect the health and safety of humans and the environment;
- foster informed community debate, and
- achieve economic and social benefits from the responsible adoption of nanotechnology.

"The Government is committed to capturing the benefits of nanotechnology, while addressing any potential health, safety and environmental risks," Senator Carr said.

Copies of both documents are available at: www.nanotechnology.gov.au

Media contact: Catriona Jackson, Minister's Office, 0417 142 238
Media contact: Craig Cormick, Department, 0418 963 914

Key regulatory issues

The Monash Report, *Review of Possible Impacts of Nanotechnology on Australia's Regulatory Frameworks*, identified six regulatory triggers which may need addressing in the regulatory framework. These are:

1. 'New' or 'Existing' substances or Products?
The most significant potential gap concerns the uncertainty as to whether new nanoforms of conventional products will be considered as 'different' to traditional products.

2. Weight or volume
Many regulatory triggers currently exist on the basis of a threshold weight or volume. For nanomaterials such thresholds may not be meaningful.

3. Knowledge of presence or implications of presence of nanomaterials
In some instances appropriate regulation requires particular knowledge of either the presence of nanomaterials and/or the risks posed by nanomaterials.

4. Risk assessment protocols or conventional techniques
Australia's current regulatory regimes often rely on risk assessment protocols as a means of ensuring human or environmental safety of products or applications. However it is uncertain whether the current risk assessment methodologies being employed by various regulatory agencies are suitable for goods that contain nanomaterials.

5. Research and Development exemptions
There are some gaps relevant to research and development, which although not unique to nanomaterials may apply when there are regulatory exemptions for R&D purposes that are based on weight thresholds.

6. International documents
Many of our regulatory frameworks refer to international documents or documents sourced outside regulators. If these documents themselves do not adequately address health, safety and environment concerns raised by nanomaterials, this may lead to a further potential regulatory gap.