OUTCOMES OF ROUNDTABLE OF HEALTH PORTFOLIO REGULATORS ON 6 OCTOBER 2010

Introduction

Nanotechnology is a rapidly expanding field, with the potential to provide advances in healthcare applications such as diagnostics, therapeutics and preventive medicine. For some time, health portfolio regulatory agencies have been aware of the possible future uses of nanotechnology and potential health and safety aspects of the technology.

The current regulatory framework relating to nanotechnology involves a number of health portfolio regulatory agencies, including the Therapeutic Goods Administration (TGA), the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and Food Standards Australia New Zealand (FSANZ), and, to a lesser extent, the Office of Gene Technology Regulator (OGTR).

A roundtable of health portfolio regulators, chaired by Deputy Secretary Ms Murnane, was held on 6 October 2010. Roundtable participants included representatives from each of the regulatory agencies, the Chief Medical Officer and representatives from Regulatory Policy and Governance Division and the Office of Health Protection (see Attachment A).

The roundtable discussed current and emerging regulatory policy issues relating to nanotechnology. Individual agencies presented the issues in their areas of responsibility and discussed the broader regulatory implications.

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Background

In 2007, the previous government introduced the National Nanotechnology Strategy (NNS). Until June 2009, the Department of Innovation, Industry, Science and Research (DIISR) funded activities under the NNS to ensure that Australia's regulatory frameworks could satisfactorily cover nanotechnology-based materials, products and applications. Over 2007-08 and 2008-09, the Department received some funding through DIISR to:

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- coordinate Health portfolio advice on any action necessary to address regulatory issues identified in *A Review of Possible Impacts of Nanotechnology on Australia's Regulatory Framework* – conducted by the Centre for Regulatory Studies at Monash University (the Monash Report);
- monitor developments in nanotechnology and develop policy advice on health implications of nanotechnology; and
- provide effective coordination of portfolio agencies and departmental input to the National Nanotechnology Strategy development and implementation.

DIISR also provided funding of $1.42m to NICNAS, TGA and FSANZ over those two financial years. This funding contributed to NICNAS activities to address regulatory issues identified in the Monash Report, international engagement and regulatory and technical capacity building. This funding was used to xxx.

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In May 2009, the current government discontinued the NNS and announced a four-year National Enabling Technologies Strategy (NETS) to provide a framework for the responsible development of enabling technologies including nanotechnology. In 2009-10, NICNAS received $120,000 NETS funding through DIISR that contributed to NICNAS's development of amendments to its new chemicals program for nanomaterials, stakeholder outreach and communication activities and international engagement and FSANZ received some NETS funding through DIISR of around $100,000 each to xxx. However, no NETS funding was provided through DIISR to either the Department or to TGA. [NB. Need to check with NICNAS and FSANZ if further funding was provided in FY 2010-11 bids for funding sought – NICNAS awaits DIISR decision on funding for 2010-11.]

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In early 2010, a NICNAS staff member attended a *Workshop on the Human and Environmental Risk Assessment of Nanomaterials 2010* in Canada, that focused on industrial nanomaterials. The report back to the Department highlighted a number of developments in nanotechnology that might benefit health portfolio regulators to consider, including that:

- evaluation and regulation of nanomaterials may need to continue to be on a case by case basis as no general rules can be applied as yet for management other than the use of precaution; and
- international harmonisation in regulatory approaches for nanomaterials may benefit Australian regulatory programs by facilitating cooperation, reducing duplication of effort and protecting human health and the environment.

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Regulatory approaches of health portfolio regulatory agencies:

National Industrial Chemicals Notification and Assessment Scheme

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is the Australian government agency responsible for the risk assessment of new and existing industrial chemicals, including those industrial chemicals incorporating nanotechnologies.

In response to the Monash Report, NICNAS undertook a review of its regulatory framework. NICNAS established a Nanotechnology Advisory Group to consider the regulatory implications of industial nanomaterials and advise NICNAS on measures it can take to address these implications. This Group is made up of industry and community representatives and technical experts.

NICNAS also developed a strategy and on-going reform programs to ensure effective management of future challenges arising from the application of nanoscale materials as industrial chemicals. NICNAS strategy involves modification of its regulatory framework to address potential risks that may be associated with nanomaterials. Key principles underpinning the strategy include:

- utilizing the existing NICNAS framework with some modifications;
- enabling the use of the best available scientific information;
- providing for the review of decisions as the science matures and new information becomes available;
- using a ''precautionary' approach when scientific evidence is insufficient or uncertain;
- evaluating risks pre-market on a case by case basis; and
- developing the Strategy in consultation with all stakeholders.

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Proposed amendments, to the regulatory framework that have already been subject to public consultation include:

- A working definition of nano-forms of industrial chemicals.
- Administrative changes to notification and assessment of nano-forms of new chemicals (ie chemicals not listed on the national inventory). These will inform future decisions on any regulatory/legislative changes.
- Exploration of options for regulating nano-forms of existing chemicals (ie chemicals listed on the national inventory) including information gathering to ascertain extent of use and notification and assessment options.

NICNAS is taking action on the regulation of nanoforms of new industrial chemicals through administrative changes that will be introduced in January 2011. The NICNAS legislation allows for pre-market assessment of new chemicals, hence administrative adjustments will enable all nano-forms of new chemicals to be reviewed pre-market and on a case-by-case basis. The regulation of nanoforms of existing chemicals is more complex. The current framework for conventional existing chemicals, that also applies to their nano-forms, only permits post market risk assessment of these substances. Therefore, legislative change will be required to give NICNAS the power to undertake pre-market risk assessment of nano-forms of existing chemicals.

NICNAS is also strengthening its technical capability and tools and benchmarking its risk assessment methodologies for nanomaterials. It is in the process of determining a position on health hazards of six nanomaterials - silver, fullerenes, zinc oxide and titanium dioxide, carbon nanotubes and cerium oxide.

The case-by case, premarket approach to risk assessment taken by NICNAS is due to the uncertainty surrounding the health and environmental impacts of nanomaterials, the uncertainty around the applicability of current risk assessment protocols and the highly variable level of understanding and knowledge across the industry. Recent research indicates the potential for certain nanomaterials to cause adverse health effects , eg carbon nanotubes demonstrating cancer causing potential in experimental animals. For these reasons, the administrative amendments proposed for new chemicals will disallow the use of current industry self assessment provisions for nanomaterials (applicable to certain new chemical exemptions and industry self-assessment certificate categories).

NICNAS is continuing its well-established communication and consultation with stakeholders and experts and intends to increase publicly available communication products. Its proposals and regulatory approach are supported by its Nanotechnology Advisory Group and have strong overall stakeholder support. These are also consistent with international approaches such as in Canada, the United States and the European Union. NICNAS is actively engaged in the Working Party on Manufactured Nanomatrials within the Organisation for Economic Cooperation and Development (OECD), the lead international body for industrial chemicals matters.

Therapeutic Goods Administration

The Therapeutic Goods Administration (TGA) carries out a range of assessment and monitoring activities to ensure the quality and safety of therapeutic goods available in Australia. Prior to approval for marketing in Australia, the sponsor of a therapeutic good must make an application with supporting data to provide substantive scientific evidence

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demonstrating the quality, safety and efficacy of that product. Once approved, the product is included in the Australian Register of Therapeutic Goods (ARTG).

Under this process, the TGA regulates therapeutic products as separate and distinct goods with each good assessed and regulated individually. Novel nanotechnology applications, such as new medicine delivery or tissue targeting systems are subject to the same comprehensive safety assessment as applies to conventional prescription medicines. The ARTG currently includes nano-particle based products such as sunscreens (zinc and titanium oxide), nano-sized drugs, drug delivery substances, diagnostics, carriers and devices such as nanosilver dressings.

TGA does not currently have a specific communication strategy on nanotechnology.

There have been concerns raised in the media about safety of nanoparticles in sunscreens, calling for sunscreen labels to declare the presence of nanoparticles. TGA has assessed these studies and determined that there is no indication of increased risk to the health and safety of people posed by nanoparticles in sunscreens. Sunscreens with sun protection factor (SPF) greater than 15 come under the TGA's responsibility while those with SPF 15 or less come under NICNAS.

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A key industry lobby group, ACCORD, has requested that TGA and Australian Competition and Consumer Commission adopt labelling requirements that mirror the European Union (EU) Cosmetic Directive. ACCORD want a single labelling regime in both Europe and Australia and there is likely to be a huge consumer demand. Currently, therapeutic goods product labels in Australia must list active ingredient but not size. Any regulatory policy changes would have implications for all therapeutic goods in Australia and possible flow-on effects to other sectors and industries.

Comment [1]: It is not a Directive anymore – it is now in EU regulations

Food Standards Australia New Zealand

Food Standards Australia New Zealand (FSANZ) is the independent statutory authority responsible for developing food standards, including those relating to new food technologies. All food supplied in Australia must comply with the *Australia New Zealand Food Standards Code* (the Code) and be safe for human consumption. This involves a rigorous premarket safety assessment which uses the best available scientific evidence as it applies to Australian circumstances.

Since 2006, FSANZ has been active in researching the potential use of nanotechnologies in food and developing a strategy to adapt its regulatory framework, as necessary. In December 2008, FSANZ amended its Application Handbook to take account of potential applications of nanotechnologies. Information about particle characteristics must be provided in applications and this will trigger specific consideration in a mandatory risk assessment of any potential hazards posed by nanoscale materials. FSANZ will not recommend approval of any food substance or food packaging unless sufficient data is available and safety can be established.

FSANZ is further reviewing the food regulatory framework to assess whether it can adequately manage any future risks posed by nanotechnologies. The review will identify any gaps in regulation or risk assessment and communication with a view to recommending necessary action to address any gaps.

In order to keep abreast of developments and deal with future issues, FSANZ has established a dedicated unit that proactively gathers information on nanotechnology from all available scientific sources. FSANZ also has established comprehensive networks and contacts for exchange of information on the use of nanotechnology in food and food products both within Australia and internationally. Like NICNAS, FSANZ is a member of the Health, Safety and Environment Working Group managed by DIISR and liaises with agencies through the Food and Agriculture Organization and the World Health Organization and food safety liaison forums. Its approach around this issue is robust and comprehensive and based on international best practice. FSANZ has a extensive consultation built into its regulatory processes.

There are currently no applications for use of nanotechnology in food or food packaging in Australia. However, there are two applications each for use of nanotechnology in food packaging in the United States and Canada. FSANZ advises that there is no evidence that nanoparticles in food packaging transfer into the food.

FSANZ is of the view that the food industry is not keen to use nanotechnology in food or food packaging. However, the development of technologies more generally means that the issues raised by applications are becoming more complex i.e. changing nutritional profiles of foods. Almost 50 GM food applications have been approved, to date.

Office of Gene Technology Regulator

Gene technology regulation under the *Gene Technology Act 2000* (the Act) is set up to provide a complementary role in regulation, working together with TGA, FSANZ and NICNAS. The Gene Technology Regulator (the Regulator) applies a case by case assessment. If necessary, he will ask for further information.

As gene technology regulation is still relatively new and this is a contentious area, the consultative mechanisms are open, transparent and very extensive. Expert advice and public input is sought at a number of stages and there are many avenues for obtaining information. The Regulator has approved some GM food crops and GM cotton with possible trials of GM wheat and possibly barley coming along in the near future.

To date there have not been any applications to the Regulator involving nanotechnology and GM. While there may be some crossover between nanotechnology and GM. The Office of the Gene Technology Regulator is not aware of any research in this area.

Other agencies

Department of Health and Ageing

The Chief Medical Officer highlighted that we need to understand more about the artificial distinction between nano, macro and solution and that we need to be better informed about the distribution in the body of each of these. Toxicology can inform us as to whether there is something special about a nanoform of a substance such as absorption and distribution in the body. There needs to be a sound scientific basis for evaluation of risks.

National Health and Medical Research Council
The National Health and Medical research Council (NHMRC) currently funds 15 projects which involve nanotechnology. They look at nanotechnology from the perspective of the potential benefits. These projects all relate to nanotechnology enabling the more effective delivery of medicine or a device by closer targeting.

NHMRC have no regulatory role in relation to nanotechnology except in terms of its Ethics Committee.

Issues needing further discussion

Principles for nanotechnology regulation
The roundtable discussed the value of utilising the principles put forward by NICNAS more broadly to other regulatory schemes, including:

- We do not want to act to deter innovation but we do want to ensure safety.
- We should utilise a 'proportionate' approach to manage potential risks (including the degree of uncertainty) to humans and environment i.e. the approach should be appropriate to the risk and degree of uncertainty
- We should, as much as possible, have a consistent approach to regulation, within the parameters of individual regulatory frameworks, in terms of degree and rigour and take international best practice into account.
- We need to balance the potential risks of nanotechnology and regulation against the benefits, such as new cancer treatments.

Labelling

- Labelling of products containing nanomaterials is a highly contentious and controversial issue.
- As nanomaterials are naturally found in the environment, a sensible basis for labelling needs to be found.
- Issus that need to be considered include:
  - a whole of government approach;
  - a consistent definition of nano-materials and products;
  - legislative amendments and a regulatory impact assessment;
  - consultation with industry and possibly a transition period to allow industry to make necessary changes;
  - consideration of the broader implications for introducing labelling requirements; and
  - benefits to labelling to support control of a new technology at the consumer end.

Definitions

- There was some discussion of issues relating to defining 'nanomaterials' or 'nanoproducts' and how these might be utilised in regulation. For example, while nano-

therapeutic goods and devices may fit within the size range, these may not necessarily be of concern.

Lack of data/evidence and tools to support regulation

- There is still a lack of data/evidence and the tools available to support good decisions about regulation. The rules around the information required are still being developed and are therefore unclear and highly variable across industry (this is also true overseas).
- Techniques to identify and test for nanomaterials are also still under development.

Outcomes of the meeting

The key message from the meeting is that Australia does have a robust regulatory framework which can deal with emerging technology including nanotechnology.

The roundtable participants agreed to:

- further consider a portfolio view of the 'proportionate' approach consistent with the level of risk (incorporating the degree of uncertainty) to protect human health and the environment while allowing innovation and industry advancement;
- continue talking and sharing information and building common understanding and support continuities across portfolio; and
- monitor international developments in nanotechnology applicable to individual regulatory frameworks and their regulation in order to be prepared to respond to future activity in this area and to align, where possible, to international best practice relating to relevant regulation of emerging technologies.

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